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## Medical care for older people – what evidence do we need?

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In Germany today, reaching a very old age is no longer an exception. About 4.5 million people (5.4 percent of the population) are 80 years of age and older, and their numbers continue to grow. In recent decades, the over 85-year-olds have been the group with the fastest and greatest gain in life span and many positive developments for this growing population group have been recorded. The increasing life expectancy and the improved health of older people over a longer period are also attributable to therapeutic and preventive measures, in addition to other factors. Sick old people, however, may possibly have entirely different medical needs than younger people; this is not sufficiently reflected in the German healthcare system.

The high standard in medicine, not only in relation to medical care, but also in research of diseases and the development of therapies, focuses typically on middle-aged patients with a single disease. Accordingly, knowledge gained from the treatment of middle-aged people is frequently also applied for older patients – although they differ both physically and mentally from younger people in terms of their medical care priorities and personal circumstances. This does not comply with good scientific practice, and often leads not only to inappropriate care, but may occasionally also actually endanger the concerned patients.

Older people, who frequently suffer from multiple chronic disorders, take many medications at the same time, each of which focuses on one individual ailment. This polypharmaceutical treatment does not at times correspond to the health targets of older patients and may even pose a considerable health risk. There is a lack of external evidence on how to improve treatment for multimorbid older and very old people. There is also a lack of guidelines that indicate the current knowledge gaps and risks. At the same time, important medications are often not offered. Therefore, research to provide specific scientific evidence specifically for older people is absolutely essential. New treatment objectives come to the fore and determine the indication for pharmacotherapeutic, surgical and other interventions: In younger patients cure, restoration of working ability or long-term prognoses determine the course of action. In older patients, these priorities are often replaced by independence, quality of life despite complaints, and the relief of symptoms.

The pressure for a quick and effective change to the healthcare situation of older people is growing continuously in line with the rapid demographic change. Physicians, therapists and carers alike must adjust to old and very old people in their daily work – particularly in hospital care. This also applies to basic, advanced and continuing staff training and the cooperation with other health care providers. At all points in the medical care chain, from the lack of scientific evidence to the implementation in practical care, the focus must be on older people and their specific needs.

#### Who is an “old” or “geriatric” patient?

In Germany in 2007 and in the EU in 2008, geriatric specialist associations formulated a definition: According to this, it is not the chronological age, but a condition that characterises “old” or “geriatric” patients. These are defined as people of higher age, either suffering from several concurrent illnesses, or who are physiologically particularly prone to illness, which can result in complications and secondary diseases and the risk of chronicity and an increased risk of losing autonomy.

Empirically, particularly people over 80 years of age are currently receiving geriatric health care. In clinical studies however, the age limit is usually drawn at 65 or even younger.

#### What is “old” from the point of view of ageing research?

Based on the different and characteristic experiences gained during the course of life, ageing researcher Paul Baltes has defined the terms “First age” for childhood and adolescence, “Second age” for the middle years of adult life and “third” and “fourth age” for the last third of life. Even though these terms are not unanimously accepted as standard (for example, people in the “fourth age” represent a very diverse group), they are helpful in differentiating the still frequently used terms “the aged” or “the elderly”. The emergence of a “third or young age” (about 60 to 80/85 years, partly even older) as a phase comparatively low in illness and disability can be considered a success. This phase must be differentiated from a “fourth age” (from about 80/85 years, also referred to as “very old”, as more than half of the contemporaries have died), which is even today not short and certainly will not be in the future, and in which the risks of illness accumulate, multi-morbidity (multiple illnesses) becomes standard and normal everyday functions are highly endangered by numerous simultaneous changes (e.g. loss of cognitive, motoric and sensory skills). Findings based on research and pertaining to the course of cognitive ability, the need for nursing care and to well-being even suggest the definition of a future “fifth age”. However, these chronologically focussed divisions of the phases of ageing can be criticised, for instance by arguing that the differences between individuals are extremely high and increase continually with age. In other words: there are considerable overlaps between the various phases of ageing, and a significant number of the over 85-year-olds are well within the range of the 65 to 84-years-olds (and vice versa) in terms of health, functional and cognitive parameters.

Ultimately, a comprehensive and highly differentiated view of old people that gives equal consideration to their strengths and vulnerabilities must be communicated at an early stage to medical students and students and trainees of all other professional groups dealing with older people.

## Approaches to evidence-based medical care

First of all, it must be pointed out that there is no such thing as “the old patient”: no group of patients is as inter-individually different as that of the elderly. For that reason, in medical care particular attention must be paid to individual differences such as gender, socio-economic, ethnic-cultural and biographical backgrounds.

Relatives and the close environment are often extremely burdened with providing support for sick and/or functionally impaired older people and are therefore in need of particular attention and support (structural, psychosocial and financial) within the framework of regular care.

Changes in biological processes as well as in functional and social needs in older people have been intensively researched. Nevertheless, there are only few studies for the group of old and very old patients that meet the standards of evidence-based medicine (EBM). This has several reasons, one of the most significant of which is the fact that the established procedures of scientific knowledge acquisition and standardisation in the medical field do not correspond with the characteristics and health targets of older people. Science-based principles for evidence-based geriatric healthcare have to a large extent not yet been determined. This is why doctors and other health care professionals are not sufficiently prepared for their task of treating old and very old patients. An improvement in data availability and the health care situation is thus an absolute requirement.

Randomised, controlled studies should also be specifically conducted on elderly and very old people. Furthermore, other study methods are also available, which should be increasingly promoted and performed, as they are better able to demonstrate the needs and requirements of old people with regard to medical care: pragmatic studies that include the realities of the patients’ lives, multiple-component interventions (complex interventions) as well as observational studies. The research subject should not (only) be the efficacy of a medicinal product, but an overall health care algorithm. The co-existence of risks should be examined and, if possible, individually presented in absolute figures. As these types of studies have not been sufficiently undertaken by the industry to date, more public funds need to be provided for this purpose.

Clinical studies on medicinal products to be prescribed for people above 65 and especially for those above 80 years of age must represent this age group sufficiently and carry out an age-related assessment. Here, age-specific characteristics, in particular frailty, should be taken into consideration in the inclusion and exclusion criteria and in the analysis and interpretation. The marketing authorisation for medicinal products should be subject to carrying out studies on old and very old patients, similar to the procedure usual for children (Paediatric Regulation of the EU).

In addition to conventional indicators of efficacy tests (such as cure, relief and survival), important functional and other objectives should be tested, in particular activities of daily living, participation and quality of life. Maintaining the functions of everyday life and hence also the quality of life is the pre-

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<sup>1</sup> By the term “evidence-based” medical care, we mean the decision for diagnostic and therapeutic measures based on current scientific knowledge, professional expertise and the values and preferences of those affected. This refers to individual and population-based decisions.

dominant aim for old and very old people. Hearing, seeing and mobility play a crucial role in their participation.

Methodological complexities are an important reason for the exclusion of old people from controlled studies. The emphasis has to be on patient-oriented study objectives, but also on challenges in terms of study design and evaluation (e.g. number of cases, missing data). The corresponding further development of methodological knowledge is therefore imperative. This requires the combination of geriatric-gerontological, biostatistical and information-related expertise. Ethical and legal aspects, such as the ability of the study participants to give their consent, also require particular consideration in research involving older people. Therefore, expertise on the medical treatment of such patients should be represented in research ethics commissions. In addition, information and consent documents within the framework of geriatric health care and studies must also be adjusted to the needs of old and very old people.

The investigation of interventions in the case of multi-morbidity must take top priority. As the parallel intake of medications is unavoidable, the interaction of active substances must be examined and validated. In addition, studies dealing with the reduction of polypharmacy are necessary, in particular with regard to the discontinuation of medicines.

Behavioural and technical interventions play an increasingly important role in maintaining independence and delaying the necessity of moving into a nursing home. Research in geriatric medicine should therefore also focus on the linking with such interventions. The benefits of auxiliary appliances, technology and adapted living space have hardly been examined. There is a lack of studies involving larger numbers of cases and representative participant groups including control groups, but also studies on the ethics of application. This also applies to

telemedicine, the most frequently investigated field at the moment.

Evidence-based patient information as a prerequisite for the participation of patients in medical decision-making processes must also be available in geriatric care and must be adjusted to the prerequisites of older people. It is necessary to determine therapy expectations and preferences in groups of older people with different socio-economic and cultural backgrounds as well as in various care settings. Better knowledge assists the planning of clinical studies by taking adequate consideration of patient-relevant health targets.

There has as yet been hardly any diagnostic research in accordance with EBM standards in general and for all age groups. The demand remains for manufacturers not only to have to present proof of safety, but also of patient-specific benefit.

The treatment requirements of older patients are currently not identified at all, or not early enough. This often leads to expensive over-use, under-use, and misuse of health care services. Therefore, a geriatric assessment should take place in the emergency room, the patient's condition permitting. This is of particular significance when deciding whether the patient should be admitted to the geriatric ward or to a specialist one. The assessment should then be continued on the respective ward and be completed within the first 72 hours.

Transfer management and the flow of information between care settings, e.g. hospital and GP, need to be urgently optimised in such a way as to reduce losses of information to the detriment of the patients. The aim should be for a standardised and coordinated information management system of primary and secondary care service providers and facilities in order to improve intra- and inter-sectoral communication and consequently also improve care, and to gain scientific knowledge from the data collected.

Health care service providers must communicate with nursing home residents regarding their health targets and the organisation of their last stage of life, and negotiate these issues together. Returning to the home environment after being in a nursing home should be made easier, and should also be an important target factor in research projects.

Basic geriatric knowledge should be compulsory for all medical disciplines and health service professions; such teaching should begin at undergraduate level and be intensified in the post-graduate period. Multi-professional competence and EBM concepts play a significant role in basic, advanced and continuing professional training. Embedding them in such a way as to incorporate them in the standard repertoire of medical staff should be an important training objective.

It is essential to intensify and further develop methodological training in order to meet the challenges of medical research and health research for elderly people. In Germany there is a great deficit in this field. A first step would be to set up corresponding specialist professorships.

Finally, the aim must be to dispel negative impressions of old age in geriatric health care – for example through cross-disciplinary offers of advanced and continuing training in geriatric medicine.

In its expert reports from 2000 and 2009, the German Council of Experts on Developments in Health Care (SVR Gesundheit) has already explicitly pointed out that the “adequate care of elderly patients with chronic and multiple ailments” is one of the most pressing tasks in the health system. Despite, or perhaps even because of the precarious junior physician situation in medicine – and especially in geriatric medicine – it is urgently necessary to launch a geriatric health care campaign.

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