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BMJ Open Laying the foundation for a core set of the International Classification of Functioning, Disability and Health for community-dwelling adults aged 75 years and above in general practice: a study protocol

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ABSTRACT

Introduction With the medical focus on disease, the problem of overdiagnosis inevitably increases with ageing. Considering the functional health of patients might help to discriminate between necessary and unnecessary medicine. The International Classification of Functioning, Disability and Health (ICF) is an internationally recognised tool for describing functional health. However, it is too detailed to be used in primary care practices. Consequently, the aim of this study is to identify relevant codes for an ICF core set for community-dwelling older adults (75 years and above) in primary care.

Methods and analysis The study will follow the methodology proposed by the ICF Research Branch to identify relevant concepts from different perspectives: (1) Research perspective: A systematic review of studies focusing on functional health in old age will be conducted in different databases. Relevant concepts will be extracted from the publications. (2) Patients' perspective: Relevant areas of functioning and disability will be identified conducting qualitative interviews and focus groups with community-dwelling older persons. The interviews will be transcribed verbatim and analysed using the documentary method of interpretation. (3) Experts' perspective: An online survey with open-ended questions will be conducted. Answers will be analysed using the qualitative content analysis of Mayring. (4) Clinical perspective: A cross-sectional empirical study will be performed to assess the health status of communitydwelling older adults using the extended ICF checklist and other measurement tools. Relevant concepts identified in each study will be linked to ICF categories resulting in four preliminary core sets.

Ethics and dissemination Ethical approval for the study was obtained (90 17B). All participants will provide written informed consent. Data will be pseudonymised for analysis. Results will be disseminated by conference presentations and journal publications.

Trial registration number Projektdatenbank Versorgungsforschung Deutschland: VfD_17_003833,

Strengths and limitations of this study

- A strength lies in incorporating views from researchers, community-dwelling older adults, experts and the clinic. Thus, the study will provide comprehensive insights in the functioning of adults aged 75 years and above.
- Another strength is that the study will be conducted by a multidisciplinary team of researchers having expertise in the fields of geriatrics, primary care medicine, psychology, sociology and health sciences.
- A weakness might be that participants for the qualitative study and the empirical study will be recruited in Franconia (State of Bavaria, Germany). While the resulting International Classification of Functioning, Disability and Health core set might be appropriate for most industrialised Western countries, it might not be entirely applicable to community-dwelling older adults from other world regions with different socioeconomic and cultural backgrounds.

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INTRODUCTION

With growing age, incidence and prevalence of chronic conditions and acute health problems increase. At the same time, evidence indicates that self-perceived health in old age has been improving and the prevalence of disability, often measured as limitations in activities of daily living, has been falling in recent years.^{1 2} What might seem contradictory can be explained by different developments: Medical progress in the last decades allows for an earlier detection and treatment

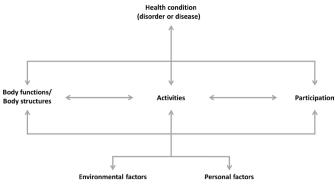


Figure 1 The framework of the International Classification of Functioning, Disability and Health (WHO, 2001).

of diseases. On the one hand, this might have led to a reduction of disabilities by mitigating the progression of disease. On the other hand, this might have increased the incidence of milder forms of diseases that do not yet have any implications for self-perceived health, but pose an increased risk to develop a certain condition. Also improvements made in rehabilitative medicine and assistive technologies as well as changes in the social perception of disability might have had a positive influence on self-perceived health.^{1 2} As the psychiatrist and medical anthropologist Arthur Kleinman wrote in 1988, there is an essential difference between the patients' subjective feeling of being unwell (illness) and the concept a doctor applies to it in form of a diagnosis (disease). This indicates that the diagnoses given are a rather vague indicator for the physical, mental and social health status of an individual. Other, more patient-focused approaches are needed for the medical decision-making process, the allocation of resources and the direction of medical attention to the areas of patients' greatest needs. Medicine, which is traditionally focusing on combating disease without considering the patients' needs and resources might, especially in older persons, lead to unnecessary medical interventions. Examples are unnecessary surgical operations and use of medication. By labelling asymptomatic persons as patients, medical overuse might do physical and psychological harm to the patients. Salient examples are screening programmes for prostate cancer labelling a great number of patients as having cancer who if undetected would never have lived to see any problem. ^{5 6} Although the full extent is not clear yet, the literature shows that medical overuse leads to a waste of limited resources and increased healthcare costs.⁷⁸ Especially for older, multimorbid patients leaving out medical interventions with little or no effects for functional health becomes mandatory. 910 A rational choice of the most effective interventions is required. Focusing on the functional health of the individual patient might help to discriminate between necessary and unnecessary medicine.

The International Classification of Functioning, Disability and Health (ICF), first published by WHO in 2001, is a worldwide approved tool for describing functional health.¹¹ In contrast to the International

Classification of Disease, which is used to classify the doctors' view (ie, the diagnoses), the ICF was developed to classify the patients' view, taking into account body functions and structures, and activities, participation, personal factors and environmental factors (see figure 1). The interaction between these components is dynamic and always bidirectional.

However, containing 1.424 categories to describe one patient, the ICF is far too detailed to be used in daily practice. Thus, especially in rehabilitation medicine, ICF core sets have been developed. 12-14 Core sets are short versions of the ICF, containing only the most relevant categories for certain health problems or a certain group of patients. ICF core sets exist for musculoskeletal, cardiopulmonary, neurological and other diseases such as breast cancer, hand conditions and sleep disorders. With more and more ICF core sets being developed, the ICF Research Branch proposed a methodology to standardise the development process and to improve the quality of the resulting core sets. 15 This process is scientifically based and integrates evidence from different perspectives (research, target group, experts and clinical assessments). To this date, an ICF core set for geriatric patients in primary care, which has been developed following this methodology, does not exist. A core set for geriatric patients in early postacute rehabilitation already exists since 2005. 12 As primary care and rehabilitation patients may vary, this core set is not necessarily applicable to geriatric patients in primary care. For this reason, two core sets, one for primary care and one for geriatric patients, have been developed in the Netherlands recently. 16 17 However, neither development process had followed the proposed methodology of the ICF Research Branch, leaving out either the perspective of community-dwelling older persons or of the researchers. Therefore, an ICF core set based on comprehensively captured information on ageing adults is needed in order to provide physicians with an appropriate tool for assessing the functional health of older patients and to better balance medical interventions according to their patients' needs. The objective of this paper is to describe the development process of the ICF core set for community-dwelling older adults in primary care. The process will follow the proposed methodology for ICF core set development¹⁵ in order to answer the following question: What are relevant ICF categories (body functions and structures, activities, participation and environmental factors) of community-dwelling persons aged 75 years and above in primary care?

METHODS AND ANALYSIS

The development of an ICF core set is a stepwise process, consisting of three phases: a preparatory phase, a consensus conference and a validation and testing phase (see figure 2).¹⁵ In this study, only the preparatory phase including four preparatory studies is performed. The aim of the preparatory studies is to gather information on functional health in community-dwelling older persons from different perspectives.

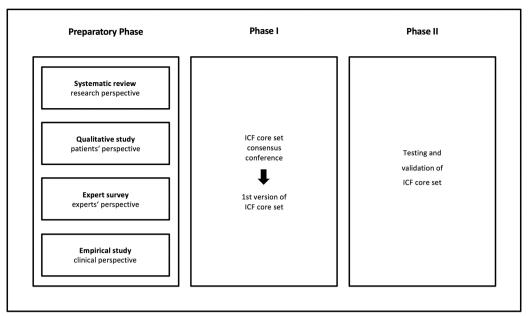


Figure 2 Process of ICF core set development (Selb et al). 15 ICF, International Classification of Functioning.

Systematic literature review

Methods

To cover the research perspective, a systematic literature review will be conducted.

Inclusion and exclusion criteria *Population*

Publications of studies focusing on community-dwelling independent persons aged 75 years and above shall be identified through online searches in established databases. As the core set is meant to be used in primary care practices in Germany, only studies conducted in highly developed countries with a similar socioeconomic and cultural background will be considered. Consequently, studies conducted in the European Union, in the states of the European Free Trade Association, in the USA, Australia and New Zealand and published between 2007 and 2017 in peer-reviewed journals in English or German will be searched. Since the aim is to get an unbiased overview of relevant categories of abilities and disabilities of community-dwelling older adults in general, studies with participants from only one specific ethnic group or suffering from only one specific health condition will be excluded. Studies in which participants were recruited in a hospital or in a rehabilitation centre will be excluded as well, because the core set is meant to be used in primary care practices.

Intervention

Not applicable.

Control

Not applicable.

Outcomes

The primary outcomes are all instruments and concepts referring to functional health as defined by the ICF (activities, participation, environmental factors and body functions/body structures).

Study design

As suggested in the ICF core set development guideline, randomised controlled trials, clinical controlled trials, cross-sectional studies, observational studies and qualitative studies will be included. Study protocols, case studies, economic evaluation studies, conference papers, psychometric studies, prevention studies, studies of phase-II clinical trials, studies exclusively showing laboratory parameters, animal experiments, letters, comments and editorials will be excluded, as those publications usually do not include relevant information on functional health. Furthermore, systematic reviews and meta-analyses will not be included in this review, but might be used for reference tracking in case an insufficient number of articles will be identified by the search.

Data collection

A computerised search will be conducted in five major databases in the fields of medicine and psychology: PubMed, Scopus, EMBASE, PsycINFO and CINHAL. Search terms referring to old age will be used along with terms referring to independent living as well as with terms referring to the four ICF components (activities, participation, environmental factors and body functions/body structures). The search terms will include subject headings of the respective database (eg, Medical Subjects Headings (MeSH) terms in PubMed) as well as free-text words. Additionally, terms referring to language (English and German) and a time frame for the publication year (2007–2017) will be included.

Data analysis

The publications found in all databases will be exported to a systematic review software (Covidence). Two

investigators will independently perform a title and abstract screening based on predefined inclusion and exclusion criteria. In a next step, the full texts will be screened based on predefined inclusion and exclusion criteria to identify publications for data extraction. As the purpose of this review is not to assess the effects of particular interventions or to give treatment recommendations, but to systematically identify relevant concepts of functional health, a quality assessment of the studies is not needed. However, only studies, which were published in peer-reviewed scientific journals and thus have already undergone a quality control, will be included in this review. Following the full-text screening, data of interest, including study population, study design, instruments and outcome variables will be extracted in duplicate by two independent researchers. Concepts will be identified and linked to ICF categories using established linking rules. 18 A frequency analysis will be performed. All ICF categories identified in at least 5% of the publications will be included as possible candidates for a core set.¹⁵ This will result in a list of relevant ICF categories from the research perspective. In case of an overwhelming number of publications being identified for full-text screening, a random sample will be drawn to ensure manageability. 15 This procedure has already been applied in the development process of other ICF core sets. 19-22 The data analysis is expected to be finished by October 2018.

Qualitative study

Methods

To gather data on the perspective of community-dwelling older persons, qualitative interviews and focus groups will be conducted.

Study population

As the number of health-related problems increases in old age, the population of interest will be community-dwelling adults aged 75 years and above. Persons with higher grades of dementia will be excluded as they are expected not to be able to fulfil the study requirements. In Germany, nursing care needs are determined based on five care-grades based on physical, mental and psychological disabilities to establish eligibility for benefits from the long-term care insurance. It ranges from care-grade 1 (little impairment of independence) to care-grade 5 (hardship cases). It was decided that only persons with a care-grade 1 will be included as persons with higher grades are expected to be too impaired to live independently. Also, persons living in nursing homes will be excluded as the core set is meant to be used in primary care practices only. As the core set is meant to be used in primary care practices, participants will be recruited by 77 primary care practices in Franconia (so-called 'Forschungspraxen Franken'), which are part of the Preventing Overdiagnosis in Primary Care (PRO PRICARE) research network. Convenience sampling will be applied. Based on the results of other ICF core set development studies²³ 24 as well as recommendations

for adequate sample sizes in qualitative studies,²⁵ about 20–25 interviews will be conducted to achieve richness of data while still being able to undertake in-depth, meaningful analysis.

Data collection

Persons, who indicate their interest in the study, will be contacted via telephone to collect data on sociodemographic and health-related variables to ensure eligibility. Eligible persons, who sign the informed consent, will be handed out a digital camera to take pictures of their activities of daily living. These pictures will serve as a basis for in-depth semistructured interviews to explore and understand which aspects of functioning are important to older adults. Additionally, the participants will be invited to focus groups to stimulate discussion between the participants and produce further relevant concepts. ²⁶ The interviews and focus groups will be conducted at a time and place convenient to the participants. Each study participant will receive €75 as a representation allowance.

Data analysis

The interviews and focus groups will be audio recorded and transcribed verbatim. During the transcription process data will be pseudonymised. As the interviews and pictures need to be assignable, data will only be anonymised once the analysis is completed. The transcripts will be analysed based on the approach of the documentary method of interpretation to identify concepts of functioning relevant to the participants.²⁷ In contrast to other, more superficial, methods (eg. qualitative content analysis of Mayring), this methodology allows an in-depth analysis of the transcripts. This is important as the topic of the interview is a rather sensitive one. According to this methodology the transcript will be divided into units according to the topics being discussed (topical structuring) after an initial read-through of the transcript.²⁷ In the next step, the researchers will reformulate what has been said by the participants (formulating interpretation), before bringing up their own interpretations (reflecting interpretation).²⁷ Concepts will be extracted from each unit. Each unit can contain more than one concept. Finally, the identified concepts will be linked to ICF categories following established linking rules. 18 Based on other ICF core set development studies, two strategies will be followed to enhance accuracy of the data analysis. 23 24 28 29

Multiple coding: The first interview will be analysed and linked to ICF categories by four researchers to achieve agreement concerning the implementation of the analysis method and the linking rules. If agreement cannot be reached, another person from the research team will be consulted.

Peer review: All subsequent interviews as well as the focus groups will be analysed by just one researcher. A random sample of the transcribed text and the identified concepts of the first researcher will be analysed and linked to ICF categories by a second researcher.

This will result in a list of relevant ICF categories from the perspective of community-dwelling older persons. The data analysis is expected to be finished by July 2019.

Expert survey

Methods

In order to capture the experts' perspective, an online survey will be performed.

Study population

The experts of interest are health professionals, for example, general practitioners, geriatricians or nurses with at least 2 years of experience in caring for community-dwelling older persons in an ambulatory setting. Experts will be recruited by the 'Forschungspraxen Franken' (PRO PRICARE research network) and other existing networks of the respective project partners.

Data collection

A random sample of experts, stratified for specialty, will be invited to take part in an online survey. Experts will be asked open-ended questions regarding functioning in old age to identify concepts they consider most relevant. The questions being asked will be based on the recommendations given in the methodology of ICF Research Branch. Questions will start with 'If you think about ...' and will target opinions, for example, about bodies and minds of individuals, daily life as well as environment and living conditions. In addition, sociodemographic information and information about the experts' experience in the field will be recorded.

Data analysis

Data analysis will be performed using the qualitative content analysis of Mayring. Following the inductive category development, the data are worked through until relevant text passages for answering the research question are identified. Categories are deduced from these relevant text passages. During the further analysis process, existing categories are revised, reduced or extended. Identified categories will be linked to ICF categories using established linking rules. This will result in a list of relevant ICF categories from the perspective of experts in the provision of ambulatory care for community-dwelling older persons. The analysis is planned to be finished by October 2019.

Empirical study

Methods

For covering the clinical perspective, an empirical study with a cross-sectional study design will be carried out.

Study population

The study population will include the participants of the qualitative study. Additionally, participants will be recruited by the primary care practices, other contacts or city departments. At least 50 older adults will be assessed.

Data collection

A trained study nurse will assess the health status based on the ICF checklist V.2.1a. ³¹ The ICF checklist consists of ICF categories representing the most frequently experienced problems in clinical practice. A qualifier, ranging from 0 to 4, will be assigned to each category, with 0 representing no impairment (in the sections 'body functions' and 'body structures'), no difficulties (in the section 'activities and participation') or no barrier/no facilitator (in the section 'environmental factors') and 4 representing complete impairment, complete difficulties or complete barriers/ facilitators. The ICF checklist will be extended by four categories contained in the geriatric core set16 and another 11 categories contained in the core set for patients in geriatric postacute rehabilitation facilities³² that are not already part of the ICF checklist. The participants will also be asked to grade the importance of the categories of the section 'activities and participation'. Additionally, the following measurement tools will be included: The Erlangen Test of Activities of Daily Living in Persons with Mild Dementia or Mild Cognitive Impairment is a performance test used to assess Instrumental Activities of Daily Living (IADLs) and can also be used for persons with no cognitive impairment.³³ Its development was theoretically driven by the ICF domain 'activity and participation'. The total possible score is 30 points with higher values indicating greater competence in the mastery of IADLs. The Geriatric Depression Scale Short Form-15 is a self-report measure of depression in older adults.³⁴ Scores range from 0 to 15. A score of 0–4 is considered to be within the normal range, a score of 5–9 indicates mild depression and a score of 10 or more indicates moderate to severe depression. 35 The Montreal Cognitive Assessment is a brief performance test to screen for mild cognitive impairment.³⁶ Scores range from 0 to 30 points, with higher scores indicating better cognitive performance. The 12-Item Short-Form Health Survey is a commonly used self-administered questionnaire to measure physical and mental health-related quality of life.³⁷ It has two summary measures: the Physical Component Summary score and the Mental Component Summary score. Higher scores represent better health-related quality of life. The Timed Up and Go Test is one of the most popular performance tests used to evaluate overall functional mobility of older persons.³⁸ A person is timed when rising from a chair, walking 3 m and turning to return to sit down on the chair. Hand grip strength is measured using the Lafayette hydraulic hand dynamometer (Model J00105). The 12-Item WHO Disability Assessment Schedule V.2.0 (WHODAS V.2.0) 39 40 is a self-report questionnaire grounded in the conceptual framework of the ICF measuring overall functioning. It assesses the activity limitations and participation restrictions experienced by an individual. Higher scores indicate more functional limitations.

Data analysis

The qualifiers of the ICF categories resulting from this assessment will be analysed using descriptive statistics.

The result will be a list of relevant ICF categories representing the most common problems of functional health in old age from the clinical perspective. Furthermore, it will be possible to analyse which parts of the section 'activities and participation' are the most important ones for each participant and compare it to the level of functioning rated to the qualifiers and assessed with the other measurement tools. This is of high relevance for the general practitioner in light of necessary and unnecessary medical interventions. The analysis is planned to be finished by January 2020.

This study will result in four preliminary core sets listing relevant ICF categories from different perspectives. In a possible follow-up project, these four preliminary core sets can then be combined to one comprehensive ICF core set.

Patient and public involvement

Patients or public were not involved in the development of the research question or in the design of the study. Neither were the outcome measures informed by patients' priorities, experience or preferences. Patients are recruited by primary care practices as well as different organisations for the elderly. Patients were not involved in the recruitment or in the conduct of the study, but were interviewed as part of the study. It is planned to organise a meeting with all participants at the end of the study to inform them about the results.

ETHICS AND DISSEMINATION

The participants will be enrolled after signing an informed consent.

In detail, the participants of the qualitative and the empirical multicentre study will receive an information sheet outlining the content and the course of the study as well as data protection regulations. Furthermore, they will be informed orally about these issues. For the expert survey, all potential participants will receive appropriate information on the study. Informed consent will be indicated by a check box on the online survey form. All participants have the right to refuse answers to any question. The audio-recorded interviews and focus groups will be pseudonymised during the transcription process. Once the data analysis is finished, data will be anonymised. Audio files, transcripts and data from the online survey will be stored in a password-protected computer. Only the research team will have access to the data. All hard copy data will be kept in a locked cabinet within the responsible institute. Following the recommendation of the German Research Foundation, data will be stored for 10 years before being erased irretrievably.⁴¹

Results from this study will be published in peer-reviewed scientific journals, following reporting guidelines, and presented at scientific conferences. Information allowing for the identification of individual participants will not be published in any way.

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Contributors JT: project administration and conduct of the systematic review and the qualitative study, partaking empirical study and experts' survey, writing original draft. SB: project administration and conduct of the empirical study, partaking systematic review, qualitative study and empirical study, review and editing of the draft, SG: project administration and conduct of the experts' survey, partaking systematic review, qualitative study and experts' survey, review and editing of the draft. SH: partaking systematic review, review and editing of the draft. TK: study design, supervision in all four studies, review and editing of the draft. EF: study design, supervision in all four studies, partaking systematic review, review and editing of the draft. EG: study design, supervision in all four studies, review and editing of the draft. SHu: study design, supervision, provision of support and important suggestions for the overall project, review and editing of the draft. SHo: supervision in all four studies, provision of support and important suggestions for the overall project, review and editing of the draft. All authors have read and approved the final version of the manuscript. SHu and SHo contributed equally to this work.

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Competing interests None declared.

Patient consent Not required.

Ethics approval This study was approved by the institutional review board (Ethikkommission der Friedrich-Alexander-Universität Erlangen-Nürnberg, Erlangen, Germany; Ethics Committee of the University of Erlangen-Nuremberg: Number 90_17 B).

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