UNIVERSITÄTSKLINIKUM HAMBURG-EPPENDORF

Psychosoziales Zentrum

Institut und Poliklinik für Allgemeinmedizin

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Quality of Care for Patients with Multimorbidity

Dissertation

zur Erlangung des Doktorgrades Dr. rer. biol. hum.

an der Medizinischen Fakultät der Universität Hamburg.

vorgelegt von

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aus Leipzig

Hamburg 2023

Angenommen von der

Medizinischen Fakultät der Universität Hamburg am: 08.06.2023

Veröffentlicht mit Genehmigung der

Medizinischen Fakultät der Universität Hamburg.

Prüfungsausschuss, der Vorsitzende: Prof. Dr. Martin Scherer

Prüfungsausschuss, zweite Gutachterin: PD Dr. Christine Blome

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List of Publications

The thesis is based on the following publications:

(1) **Schulze, J.**, Glassen, K., Pohontsch, N. J., Blozik, E., Eißing, T., Breckner, A., Rakebrandt, A., Schäfer, I., Szecsenyi, J.; Scherer, M., Lühmann, D. (2022). Measuring the quality of care for older adults with multimorbidity: Results of the MULTIqual project. *The Gerontologist, 62*(8), 1136-1145. https://doi.org/10.1093/geront/gnac013

(2) Pohontsch, N. J., **Schulze, J.**, Höflich, C., Glassen, K., Breckner, A., Szecsenyi, J., Lühmann, D., Scherer, M. (2021). Quality of care for people with multimorbidity: A focus group study with patients and their relatives. *BMJ Open, 11*(6), e047025. https://doi.org/10.1136/bmjopen-2020-047025

(3) **Schulze, J.,** Breckner, A., Duncan, P., Scherer, M., Pohontsch, N. J., & Lühmann, D. (2022). Adaptation and validation of a German version of the Multimorbidity Treatment Burden Questionnaire. *Health and Quality of Life Outcomes, 20*(1), 90. https://doi.org/10.1186/s12955-022-01993-z

Synopsis

Multimorbidity, the simultaneous presence of multiple chronic conditions in one person, is becoming a growing concern for healthcare systems worldwide. This phenomenon leads to increased difficulty in managing and treating patients, ultimately resulting in higher healthcare costs and reduced health outcomes. To combat these challenges, healthcare providers and researchers must seek a better understanding of the specific experiences and needs of people with multimorbidity and use targeted interventions to improve care. The introduction of quality measures helps to identify areas for improvement, track progress over time and ensure accountability for the delivery of quality care.

This thesis presents three studies that aim to gain insight into the quality of care and experiences of patients with multimorbidity through the development of measurement tools and frameworks. The first chapter explores the significance of multimorbidity and the impact of its growing prevalence on healthcare systems. It also examines methodological considerations for the generation of scientific evidence in this area and the applicability of existing measures for evaluating care in multimorbidity. The synopsis outlines the research questions that were derived from the current gaps in the literature and provides an overview of the methodology and results of the three individual studies. The overall findings are then discussed in relation to previous research, highlighting their strengths and limitations and drawing implications for research and clinical practice.

Background

As a result of demographic ageing and changes in lifestyle and environmental risk factors, chronic diseases are on the rise (Münzel et al., 2021; Sly et al., 2016; van Oostrom et al., 2016). Meanwhile, advanced medical technologies and medicines are enabling people to better manage their chronic conditions and prolong their lives (Cutler & McClellan, 2001; National Center for Health Statistics, 2017; Pefoyo et al., 2015; Rosland et al., 2019). Epidemiological studies suggest that the prevalence of multimorbidity is increasing at an even faster pace than the prevalence of single conditions (Paez, Zhao, & Hwang, 2009; Pefoyo et al., 2015; Steffler et al., 2021; Uijen & van de Lisdonk, Eloy H, 2008). Patients with multimorbidity now account for over half of all consultations in general practice (Cassell et al., 2018; Salisbury, Johnson, Purdy, Valderas, & Montgomery, 2011) and see 60% more different physicians, thereby incurring higher healthcare costs (Olm et al., 2021; van den Bussche et al., 2016). This elevated healthcare utilisation is putting a strain on systems designed to treat single conditions (Fortin, Soubhi, Hudon, Bayliss, & van den Akker, 2007).

Managing Multimorbidity within the Healthcare System

Fragmentation and insufficient collaboration across disciplines and sectors are among the most challenging issues for healthcare providers in the management of patients with multimorbidity (Søndergaard et al., 2015). Uncoordinated treatment plans can result in harmful regimens due to potential interactions of disease-specific treatment recommendations (Boyd et al., 2005). Given the complex treatment decisions faced by these patients, there is a growing recognition of the imperative of a patient-centred generalist approach to care that addresses patient preferences and prioritises treatment accordingly (Boyd & Lucas, 2014; Moffat & Mercer, 2015). Effective care for this population requires relational continuity, care coordination, medication management, and self-management support (Gruneir et al., 2016; Smith, Wallace, Clyne, Boland, & Fortin, 2021). Primary care, with its core pillars of first-contact care, continuity, comprehensiveness and coordination according to Barbara Starfield (1998), presents an ideal setting for responding effectively to the demands of multimorbidity. Providing primary care for patients with multimorbidity is more than the sum of its parts; it involves a collaborative effort that focuses on the patient as a whole, including their values, goals, medical and personal history, and their overall health. Despite awareness of the need to shift away from disease-centric care (Tinetti & Fried, 2004), the trend towards greater specialisation continues (Luijks, Lagro-Janssen, & van Weel, 2016), reinforcing silos within the healthcare system.

The lack of reliable evidence is another major barrier to meeting the care needs of this patient group (Damarell, Morgan, & Tieman, 2020). Less than 20 years ago, the call for clinical practice guidelines for multimorbidity brought this issue to the forefront of healthcare research (Boyd et al., 2005; Starfield, 2006). While numerous descriptive studies have investigated the prevalence, clusters and consequences of multimorbidity, it is only recently that patients with multimorbidity have been included in clinical trials (Johnston, Crilly, Black, Prescott, & Mercer, 2019; Smith et al., 2021). Traditionally, the presence of multiple health conditions has been considered a criterion for exclusion from clinical trials because of potential treatment interactions and the difficulty of attributing effects to treatment, among other reasons (Weiss et al., 2014). The mismatch between the population for which treatments have been tested and those receiving them further complicates care for those patients. Another methodological obstacle for clinical research is the absence of a universally accepted operationalisation of multimorbidity.

Definition and Operationalisation of Multimorbidity

The distinction between comorbidity and multimorbidity is pivotal to the understanding of this concept. Feinstein first introduced comorbidity as 'any distinct additional entity that has existed or may occur during the clinical course of a patient who has the index disease under study' (1970). Unlike multimorbidity, the focus here lies with one specific disease and thus predominantly with specialised care (Harrison et al., 2021). A common definition of multimorbidity by van den Akker et al. (1996) refers to the 'co-occurrence of multiple

chronic or acute diseases and medical conditions within one person'. However, studies indicate that between 52% and 74% of the primary care population would fall into this category (Excoffier, Herzig, N'Goran, Déruaz-Luyet, & Haller, 2018; Hauswaldt, Schmalstieg-Bahr, & Himmel, 2022), increasing the probability of including patients who are not significantly impacted by their conditions or do not require ongoing treatment.

In response to this problem, Ho et al. (2022) conducted a Delphi panel to reach international consensus on an operationalisation of multimorbidity. The panel agreed that conditions should be included in a measure of multimorbidity if they meet a least one of the following criteria: 'currently active; permanent in their effects; requiring current treatment, care, or therapy; requiring surveillance; or relapsing-remitting conditions requiring ongoing care'. Based on these criteria, they propose a list of conditions to always or usually include in this measure given their impact on mortality, quality of life, frailty, mental health and treatment burden, all of which were considered to be the most relevant health outcomes. The concept of 'complex multimorbidity' encompasses patients with a higher level of care needs, but there is no universally accepted definition of this term (Ho et al., 2022). Suggested definitions are the simultaneous presence of four or more conditions (Kingston et al., 2018), three or more chronic conditions affecting three or more different body systems (Harrison, Henderson, Miller, & Britt, 2016), or multiple chronic conditions with concomitant functional limitations and/or geriatric syndromes (Warner et al., 2017).

Navigating Clinical Complexity: The Role of Clinical Practice Guidelines and Quality Metrics

Greater clinical complexity is associated with an increased risk of quality deficits due to diagnostic uncertainty and interactions between diseases and treatments. This additional layer makes it more difficult to diagnose and treat patients effectively, which can lead to potential misdiagnosis, reduced treatment efficacy and adverse treatment effects. Moreover, the care-related workload faced by multimorbid patients may contribute to decreased treatment adherence (van Merode, van de Ven, & van den Akker, 2018). Discordant conditions, with unrelated pathophysiological profiles and treatment approaches, add to the complexity of care, whereas concordant conditions, with a shared pathophysiological profile and treatment approach, allow for synergistic management (Boyd & Fortin, 2010; Piette & Kerr, 2006). Zulman et al. (2014) argue that clinical complexity, together with the inadequate use of disease-specific clinical guidelines and quality metrics, can negatively affect the quality of care. Establishing clinical practice guidelines for multimorbidity has the potential to improve care by providing evidence-based recommendations and preventing harm to patients (Guerra-Farfan et al., 2022). However, without systematic assessment of the current state of healthcare, it remains difficult to evaluate new quality initiatives and translate them into standard care. Clinical trials often compare interventions with 'usual care', yet we have limited understanding of what this actually means. The application of standardised quality measures offers valuable information about opportunities for improvement, problems within healthcare systems and pathways, and patients' needs and experiences.

The Evolution of Quality Management in Healthcare

The use of quality metrics in healthcare has a long history, with early examples dating back to the 19th century when vital statistics were collected to identify patterns of morbidity and mortality (Harolds, 2015). In the 1950s, the US-American physicist William E. Deming developed comprehensive quality management programmes for the Japanese automobile industry (Colton, 2000; Dahlgaard, Reyes, Chen, & Dahlgaard-Park, 2019), which were later adapted for non-industrial sectors and informed Avedis Donebedian's seminal work on the quality of healthcare (1988). Donebedian's three dimensions of quality – outcome, structure and process – are still regarded the standard today (Marjoua & Bozic, 2012; Raffle & Muir Gray, 2007). Other changes in healthcare have also shaped the modern conception of quality, including the gradual shift from a hierarchically organised patient-provider relationship to shared decision-making and patient-centred care, the growing importance of evidence-based medicine, and greater demands for transparency (Abraham, 2015). In 1992, the Social Insurance Code (Federal Republic of Germany) made quality management a mandatory part of medical practice in Germany. As part of these efforts, the Federal Joint Committee (2005) issued a directive outlining the components of the required quality management, such as systematic analysis and optimisation of care processes and outcomes, documentation of quality and patient involvement. Since then, quality metrics have been widely used in Germany to assess and evaluate the quality of inpatient care, with the aim of enhancing the quality of treatments and services and ensuring patient safety (Mansky, Völzke, & Nimptsch, 2015).

The United Kingdom has relied on quality indicators, primarily derived from standard documentation data, since 2004 to monitor primary care and and guide pay-for-performance models within the Quality and Outcomes Framework (Roland, 2004). In contrast, the lack of interoperable outpatient documentation systems in Germany hinders the adoption of benchmarking procedures (Pohlmann et al., 2020). Consequently, quality indicators remain optional for practitioners in this sector and are rather used to evaluate new models of care or as reference points in quality circles. The Institute for Applied Quality Improvement and Research in Health Care (aQua), in partnership with the statutory health insurance Allgemeine Ortskrankenkasse (AOK), introduced quality indicator systems for ambulatory care (QISA volumes) to support the implementation of evidence-based quality management (Szecsenyi, Stock, & Chenot, 2009).

Strengths and Limitations of Quality Indicators: A Fine Line between Simplification and Complexity

Quality is seen as an ongoing process oriented towards a vision of optimal care, rather than an endpoint (Abraham, 2015). This concept of quality, which cannot be measured in its entirety, is quantified through indicators that assign numerical values to specific quality criteria for relevant aspects of care (Birkner & Gramsch, 2008). By putting the pieces together, like a jigsaw puzzle, a more comprehensive picture of the overall quality of care can be obtained. The strengths of quality indicators make them one of the most valuable assessment tools in healthcare. Still, the downside to this reductive approach is that it leaves the interpretation

and communication of the results to the users. Adopting quality indicators without taking thoroughly considering potential biases and developing action plans can result in an oversimplification of the complexity of care.

Following Donebedian's dimensions of quality (1988), indicators can be categorised into structures (e.g. organisational structures, professional training or access to services), outcomes (e.g. patient safety and changes in health outcomes) and processes (e.g. interpersonal aspects of care, technical skills and service delivery processes). Outcome indicators reflect patient benefit more directly, but are subject to random and individual factors, particularly in the presence of multimorbidity (Abel et al., 2018). Therefore, analysis of outcome quality requires large comparison groups and risk adjustment for confounding factors. Process indicators, on the other hand, are less susceptible to external influences and can be better targeted by service providers. Structural indicators tend to be more complex to implement, often requiring reorganisation of operational procedures, but they provide clear guidance for health policy makers and healthcare providers. Nevertheless, the effects of procedural and structural changes on actual health outcomes are limited and difficult to demonstrate empirically (Salzer, Nixon, Schut, Karver, & Bickman, 1997).

Challenges of Quality Measurement for Multimorbidity

Few efforts have been made to create and validate metrics that are specific to or robust in the presence of multimorbidity (Valderas et al., 2019). In addition, the development of quality indicators specifically for multimorbidity is fraught with several methodological problems. Previous research shows that quality of care seems to increase with the number of diagnoses when measured with disease-oriented indicators, especially for concordant conditions (Piette & Kerr, 2006; Ricci-Cabello et al., 2015a; Ricci-Cabello, Violán, Foguet-Boreu, Mounce, & Valderas, 2015b). In contrast, patient safety and patient-centred indicators appear to be negatively associated with the number and severity of conditions (Panagioti et al., 2015; Ricci-Cabello et al., 2015b). Much of the literature has focused on the management of specific combinations of an index condition with common comorbidities (Pillay, Dennis, & Harris, 2014), but for patients with multimorbidity, these measures may prioritise the treatment or consequences of one condition over others, creating false incentives (Bayliss et al., 2016). Although some researchers have argued for the use of tailored quality measures based on individual health profiles and clinical complexity, such as interaction matrices for combinations of comorbidities (Gassmann et al., 2017; Guthrie, Payne, Alderson, McMurdo, & Mercer, 2012; Muth et al., 2014; Zulman et al., 2014), this approach presents significant challenges when applied to patients with multiple conditions and syndromes that cannot be attributed to a single underlying disease. Extensive adjustment procedures to account for clinical complexity can increase the appropriateness of quality indicators at the expense of their usability. Furthermore, it is uncertain how such parameters should be compared across patients and healthcare organisations. These challenges raise questions about the feasibility of tailoring quality measures in primary care.

Instead, generic measures relevant to patients with multimorbidity and empirical knowledge of patients' preferences and experiences of care are required to assess quality of care. Patient participation is gaining momentum for its role in improving the legitimacy and acceptability of these tools, but it is not yet part of the standard methodology (Kötter, Schaefer, Scherer, & Blozik, 2013). As perceptions of what constitutes high-quality care often differ between healthcare professionals and patients (Baudendistel et al., 2015), both perspectives need to be considered when developing quality metrics (Herzberg et al., 2016).

Treatment Burden in Patients with Multimorbidity

Identifying and addressing treatment burden is a critical aspect in providing quality care to patients with multimorbidity (National Institute for Health and Care Excellence, 2016). Treatment burden, or the workload and impact on daily life associated with managing health conditions, is a concern for many patients with multimorbidity, who may have complex treatment regimens and may be seen by multiple healthcare professionals (Alsadah, van Merode, Alshammari, & Kleijnen, 2020; Boyd et al., 2005). Early evidence suggests that patients overwhelmed by this burden may be at greater risk of reduced health and adherence, with potential implications for patient safety (Boyd et al., 2014; Schreiner et al., 2020). Several factors contribute to treatment burden, including the number and complexity of conditions and treatments, the ability of patients to cope with these demands, and structural determinants such as access to services, fragmentation and insurance coverage (Rosbach & Andersen, 2017; Sheehan et al., 2019). Mair et al. (2009) were the first to advocate minimally disruptive medicine as an approach to chronic care that aims to minimise the burden on patients whilst ensuring high-quality care. This involves evaluating the depth of this burden and implementing strategies such as streamlining treatment schedules, coordinating care among multiple healthcare professionals, and engaging patients in shared decision-making to balance this workload. Moreover, low-quality care can increase the treatment burden through ineffective or unnecessarily complex, potentially harmful treatments that place greater demands on patients. Healthcare providers need reliable tools that allow them to assess the burden of treatment on patients in order to identify those who struggle to manage their care and to pinpoint areas that may be causing difficulties. Such patient-reported tools offer a valuable perspective that can be utilised not only in clinical practice, but also in health services research (Eton et al., 2020).

Research to develop an instrument to measure patients' experience of treatment burden has been conducted in several countries, such as the US, the UK, France, Denmark and China (Boyd et al., 2014; Dou, Huang, Duncan, & Guo, 2020; Duncan et al., 2018; Eton et al., 2017; Eton et al., 2020; Pedersen et al., 2022; Tran et al., 2012; Tran et al., 2012), but no such instrument is currently available for Germany. Given the distinct structure of the healthcare system, it is crucial to adapt existing instruments to make them suitable for this context. In a review of different tools for measuring the treatment burden of patients with multimorbidity, we found that many of them require a considerable amount of time to administer, which creates additional burden for patients. The

Multimorbidity Treatment Burden Questionnaire (MTBQ) was identified as a more viable option for research and quality management purposes because of its brevity and user-friendly format (Sheehan et al., 2019).

Aims and Research Questions

While the topic of multimorbidity has garnered attention in recent years due to its widespread prevalence and impact on patient outcomes, current research in this field reveals a considerable gap in the understanding of the quality of care provided to people with multimorbidity. In particular, there is a lack of evidence-based interventions and tools for ensuring and monitoring the quality of care for this population. The objective of this work is to bridge this gap by advancing our knowledge of the quality of care for multimorbidity and developing methods for measuring the quality of care for multimorbidity in the German healthcare system. Within the scope of this thesis, a mixed-methods approach was employed to address the following research questions:

(1) *Which indicators can be used to assess the quality of care in multimorbidity? (Study 1)*

The aim of the first study was to develop quality indicators and a measurement framework for the management of patients aged 65 years and older with multimorbidity in primary care based on empirical evidence and expert consensus.

(2) *Which aspects of quality of care are relevant to multimorbidity from the patients' perspective? (Study 2)*

This study examined the subjective experiences and views of patients with multimorbidity and their (informal) carers on the quality of care using focus groups. We sought to identify important aspects of quality of care that could inform the development of quality indicators as outlined in the first publication.

(3) *How can treatment burden be measured in patients with multimorbidity? (Study 3)*

The goal of this study was to create a German version of the Multimorbidity Treatment Burden Questionnaire (MTBQ) through translation and cultural adaptation, and to determine its validity in a sample of patients with multimorbidity.

Methods

This synopsis comprises three studies carried out as part of the third-party funded project 'Development and Validation of Quality Indicators for Multimorbidity' (MULTIqual). The research design of the framework study is described first, followed by the methods of each individual publication.

Framework: The MULTIqual Research Project

The MULTIqual project, funded by the Innovation Fund of the Federal Joint Committee (grant no. 01VSF16058), started in July 2017 and ended in December 2020. Led by Professor Martin Scherer of the Department of General Practice and Primary Care at the University Medical Center Hamburg-Eppendorf, the project was conducted in partnership with the Department of General Practice and Health Services Research at the University Hospital of Heidelberg. Its objective was to develop and validate quality indicators for multimorbidity.

The project was divided into three work packages. The first included a systematic literature review of quality indicators and guidelines for multimorbidity, as well as a qualitative study of the experiences and treatment priorities of patients with multiple chronic conditions and their informal carers. The second work package involved a two-stage consensus-building process with an independent expert panel using the nominal group technique. In the third step, a cross-sectional study was conducted to test the developed quality measures and evaluate their measurement properties. Ethics approval was obtained from Ethics Committee of the Hamburg Medical Association, the Clinical Ethics Committee Heidelberg and the Medical Association of Baden-Württemberg. The study was compliant with the Declaration of Helsinki and all patients gave written informed consent before participating. The project was registered in the German Clinical Trials Register (DRKS00015718) prior to data collection.

Methods of Study 1: Measuring the Quality of Care for Older Adults with Multimorbidity

In this study, we used a mixed-methods approach to develop quality indicators for multimorbidity for the German healthcare system drawing on evidence from the literature and a formalised expert consensus. In a systematic literature review, we identified available quality indicators and guideline recommendations for the care of patients with multimorbidity. The focus group data yielded additional quality indicators, which are presented in more detail in *Study 2*. An independent, multidisciplinary expert panel then rated, revised and consented on a set of indicators via nominal group technique (McMillan, King, & Tully, 2016).

Systematic Literature Review and Development of Quality Indicators

We performed a systematic literature review to identify existing guidelines, quality indicators and quality standards for the care of patients with multimorbidity. We searched electronic databases for combinations of descriptors and manually checked the reference lists of all relevant publications. Clinical setting and operationalisation of multimorbidity were not specified. Publications that were limited to medication management or specific index diseases were excluded. The minimum methodological requirement was the use of a systematic research design in the development of recommendations or quality metrics. Eligible references in English or German were independently reviewed by two researchers. A third reviewer was consulted in order to reach consensus on the inclusion of references. All recommendations and quality indicators related to the management of patients with multimorbidity were extracted from the relevant references.

Based on the findings from the literature and the focus groups (see *Study 2*), we designed candidate quality indicators using standardised indicator sheets. Following the recommendations, we specified the numerator (the quality criterion to be measured) and denominator (the target population) of the quality indicators and defined inclusion and exclusion criteria (Agency for Healthcare Research and Quality, 2011). In a best-evidence synthesis (Slavin, 1995), we derived indicators from recommendations supported by the strongest level of evidence and opted for recommendations with lower levels of evidence for relevant quality aspects for which evidence was sparse. The indicator sheets indicated the sources and levels of evidence and served as the basis for the subsequent evaluation by the expert panel.

Formal Consensus Process

We recruited experts from the fields of general practice, nursing, social medicine, social work, physical therapy, pharmacology, health economics and health services researchers as well as patient representatives to form an independent panel. They were selected from across Germany for their clinical or methodological expertise and had to disclose conflicts of interest to minimise potential bias. In preparation, we trained the participants to facilitate their understanding of the methodology and objectives of the study. The panelists then evaluated candidate indicators in an online survey according to the QUALIFY criteria (Reiter et al., 2008) and made suggestions for improvement. In the second stage, they discussed the outcomes of the rating, revised candidate indicators and voted on their inclusion or exclusion in the final set at an in-person meeting.

Measurement Framework

Using the results of the previous steps, we constructed a measurement framework for assessing the quality of care in multimorbidity. This framework guided the selection of the final indicators to ensure that the key components of quality of care were addressed. For this purpose, all recommendations from the literature and

the focus groups were grouped into domains of care (Agency for Healthcare Research and Quality, 2014). In order to highlight the links between the domains, they were assigned to the levels at which the interventions affect healthcare provision. The work of Taplin et al. (2012) on the multilevel influences on the care continuum, from the patient level to the national policy level, provided the foundation for our model. It outlines the dynamic relationship between patient health outcomes and contextual influences on the quality of care, organised within a hierarchical ecological system.

Methods of Study 2: Quality of Care for People with Multimorbidity - A Focus Group Study with Patients and their Relatives

In the second study, a qualitative research design with focus group methodology was used to explore what aspects of quality of care are relevant from the perspective of patients with multimorbidity and their informal carers. These informed the development of quality indicators for *Study 1*.

Recruitment and Data Collection

General practices in the greater Hamburg and Heidelberg areas recruited patients aged 65 years or older with at least three chronic conditions among their active clientele. Patients were excluded if they were not proficient in German or unable to give informed consent. Eligible patients received a written invitation with information about the study and were asked to invite their family members, partners or friends who provide care for them, to a focus group for carers.

Focus groups were hosted at the study centres in Hamburg and Heidelberg. Participants gave their informed consent for data recording and analysis. Standardised questionnaires were used to collect sociodemographic information. Separate guideline-based focus groups were conducted for patients and carers. The guidelines, which were analogous for both groups, were designed in recognition of the multifaceted nature of the concept of quality, which is often understood and interpreted differently by lay people and experts (Sofaer & Firminger, 2005). We therefore approached the subject of quality through questions about positive and negative experiences of care, specific care needs related to multimorbidity, and visions of ideal primary care. At the end, all gathered aspects of quality of care were ranked on a Likert scale from 1 (not important) to 4 (very important), and participants were asked to give reasons for their assessment. The focus groups, each led by two moderators, lasted approximately two hours and were digitally recorded and minuted by a trained research assistant. The digital recordings were transcribed verbatim, and all personally identifiable information was pseudonymised.

Data Analysis

The transcripts were analysed in MAXQDA 11 software following Kuckartz' approach to qualitative content analysis (2012). Deductive categories were derived from the literature-based indicator set. Inductive categories were created to code any new aspects of quality of care that emerged from the transcripts. Coding was carried out in two rounds, with researchers regularly discussing and comparing their coding decisions. The results were then shared with other working groups to ascertain intersubjective comprehensibility of data interpretation (Steinke, 2010).

Methods of Study 3: Adaptation and Validation of a German Version of the Multimorbidity Treatment Burden Questionnaire

The process of translating and adapting a patient-reported instrument to measure the burden of treatment, the MTBQ, for use in Germany involved multiple steps. First, the questionnaire was translated from English into German using a forward-backward translation approach (International Test Commission, 2017). Cognitive interviews and pilot tests were then conducted to assess comprehension, acceptance and content validity of the German version from the patients' perspective. Finally, the psychometric properties of the German MTBQ were determined in the cross-sectional sample of the MULTIqual project, which included primary care patients aged 65 years and older with three or more chronic conditions.

The Multimorbidity Treatment Burden Questionnaire

The original questionnaire covers important aspects of treatment burden that are relevant to patients in the German healthcare system as well, such as medical appointments, medication intake, self-care, financial strain and seeking social support and has been validated in a large sample (n=1,524) of primary care patients with multimorbidity in the UK (Duncan et al., 2018). It consists of ten items, with three optional questions that may not be applicable to all target populations. Responses are given on a 5-point Likert scale, and the global score is calculated as the mean score multiplied by 25, resulting in a range of 0 to 100. This score can be used to categorise treatment burden into four groups: no burden (global score = 0), low burden (< 10), medium burden (10–22), and high burden (≥ 22). The initial psychometric evaluation showed satisfactory internal consistency and strong positive correlations with self-reported disease burden and moderate negative correlations with quality of life and self-rated health status, indicating good construct validity. Regression analysis revealed significant associations between changes in MTBQ scores over time and changes in health-related quality of life and patient assessment of chronic care at nine-month follow-up, which suggests good responsiveness.

Translation, Cognitive Interviews and Pilot Test

To adapt the full 13-item MTBQ, two translators independently translated the English questionnaire into German. These translations were then combined into a single version, followed by back-translations by two independent translators. Both versions were checked for discrepancies and examined for cross-cultural validity (Hambleton & Zenisky, 2010) before agreeing on a final German translation. In semi-structured cognitive interviews, we asked primary care patients aged 65 years and older with multimorbidity to verbalise their thoughts and probed for insights into the cognitive process involved in answering the questions. Interviews were recorded and transcribed verbatim, and qualitative analysis was conducted to identify any misunderstandings of the questions and whether responses reflected the intended meaning (Willis & Artino, 2013). Additionally, we conducted a pilot test with adults receiving chronic care to establish feasibility and detect problems that might arise during test administration.

Assessment of Psychometric Properties

We recruited patients from general practices in the greater Hamburg and Heidelberg areas. The GPs screened their client base for a minimum age of 65 years and the presence of three or more conditions out of a list of the most common chronic conditions associated with symptom burden and requiring active medical treatment (Breckner et al., 2022). Patients were excluded if they had severe cognitive impairment, communication difficulties such as limited German language skills, or were in a terminal stage of disease. Eligible patients were invited by their GP to take part in the study, and written informed consent was obtained by research staff after explaining the purpose and procedures of the study. Data collection included sociodemographic characteristics, healthcare utilisation and quality indicator data. Further patient-reported experiences and outcome measures were collected using the Medication Adherence Rating Scale (Mahler et al., 2010), the Patient Activation Measure 13-item version (Brenk-Franz et al., 2013), the 14-item version of the Social Support Questionnaire (Fydrich, Sommer, Tydecks, & Brähler, 2009) and the EQ-5D-5L for measuring health-related quality of life and self-rated health (The EuroQol Group, 1990).

We applied the original thresholds for categorising the global score into four levels of treatment burden for comparison between the UK, Chinese, and Danish versions. We calculated item properties in SPSS 25.0 and computed McDonald's omega as a reliability coefficient utilising the MBESS package for R (Rosseel, 2012). We also performed exploratory factor analyses using scree plots, parallel analysis of eigenvalues, and Velicer's minimum average partial test with R package EFA (O'Connor, 2021). Goodness of fit was examined with Root Mean Square Error of Approximation (RMSEA), Standardised Root Mean Square Residual (SRMR) and Comparative Fit Index (CFI), with values closer to zero indicating better support for the proposed model. Construct validity was established by analysing the relationship between MTBQ scores and number of long-

term conditions, medication adherence, patient activation, perceived social support, health-related quality of life and self-rated health using Mann-Whitney *U* tests. The significance level was set to $\alpha = 0.05$.

Results

The following section summarises the findings of the separate studies. The findings are interrelated, as the focus group conducted in the second study provided crucial input for the development of the quality indicators in the first study.

Results of Study 1: Measuring the quality of care for older adults with multimorbidity

The results of the study produced 51 candidate quality indicators for the care of patients with multimorbidity, with 47 of these indicators drawn from the available literature and four additional indicators generated through focus group discussions. These were used to create a measurement framework encompassing patient factors, patient-provider communication, and context and organisational structures. A final set of 25 indicators was then selected by the expert panel.

Systematic Literature Review and Development of Quality Indicators

The search algorithm yielded a total of 14,225 hits and, after removing duplicates, titles and abstracts of 5,793 references were screened for eligibility. Out of these, 178 publications were reviewed in full and eight were included in the final synthesis. We identified three guidelines, one from the UK National Institute for Health and Care Excellence (2016), one from the German College of General Practitioners and Family Physicians (2017) and one from the American Geriatrics Society Expert Panel on the Care of Older Adults with Multimorbidity (2012). Another two references were categorised as guiding framework (Muth et al., 2014; Palmer et al., 2018), and three references were related to quality measures (National Institute for Health and Care Excellence, 2017; National Quality Forum, 2012; Working Group on Health Outcomes for Older Persons with Multiple Chronic Conditions, 2012). From these references we obtained 81 guideline recommendations and six quality indicators with some thematic overlap, addressing 47 different quality criteria. In addition, four quality criteria were derived from the focus groups in *Study 2*. Drawing on these findings, we created 51 candidate quality indicators.

Measurement framework

The quality criteria extracted from the previous findings were mapped to 13 domains of care, which were then assigned to three levels of care. The criteria covered three layers of the Multilevel Model (Taplin et al., 2012), the patient level, the direct communication between provider and patient, and the organisational level. This resulted in a conceptual framework of quality of health care for older adults with multimorbidity, as depicted in *Figure 1*.

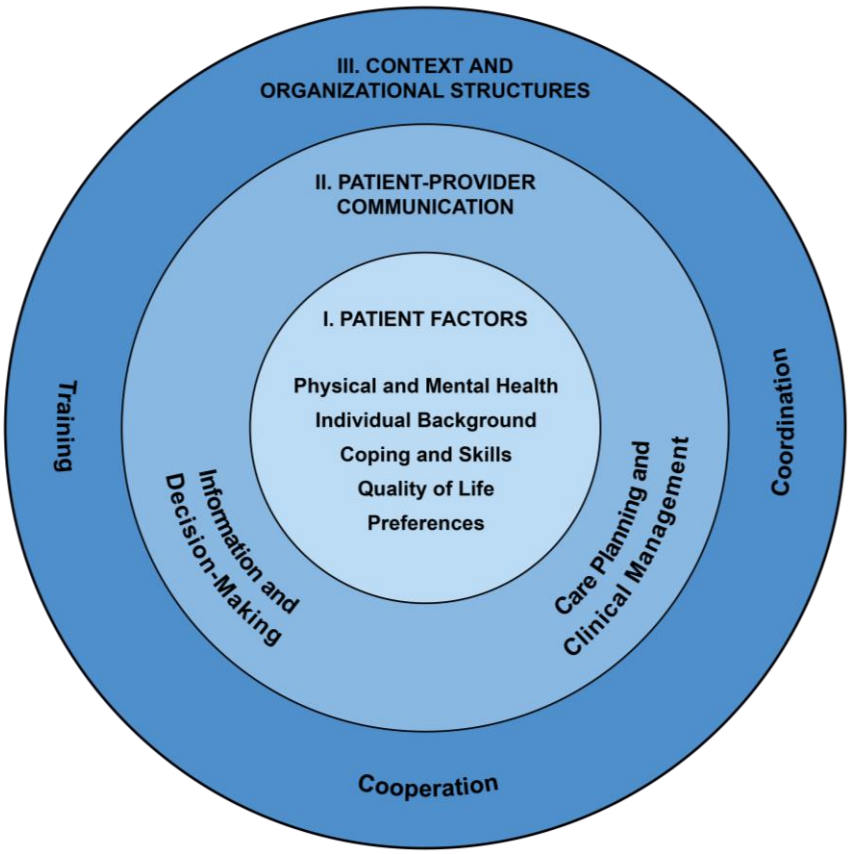

Figure 1 Conceptual framework of quality of health care for older adults with multimorbidity.
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Formal Consensus Process

The consensus process involved a panel of 23 experts, four of whom were unable to participate in the second phase. In the initial assessment, 23 indicators received a positive rating, 22 received a mixed rating and six received a poor rating. Weaknesses in the underlying evidence and insufficient support for a link between target indicator values and better outcomes were the main reasons for poor ratings. In the second stage, the panel dropped five indicators that had previously received positive ratings because they were considered duplicative or less clear in their operationalisation than other indicators. The final set consisted of 25 quality indicators, which are outlined in *Table 1*, together with their corresponding domains of care within the framework.

Table 1 Overview of accepted quality indicators within the measurement framework

Target level of health care	Care Domains	Quality Indicator	Numerator	Denominator
Patient factors	Physical and mental health	Screening for depression	No of pts whose risk of depression was assessed using screening questions	No of pts (65+) with ≥ 3 cc without prior diagnosis of depression
		Proactive pain assessment	No of pts who were asked about the presence of pain	No of pts (65+) with ≥ 3 cc
		Identification of patients with multimorbidity	Number of patients for whom the presence of multimorbidity was identified and labelled in their file	No of pts (65+) with ≥ 3 cc
	Individual background	Addressing financial support needs	No of pts who were asked about their need for financial support	No of pts (65+) with ≥ 3 cc
		Involving partners, family and caregivers	No of pts that had a discussion whether and to what extent partners, family and caregivers should be involved in important decisions	No of pts (65+) with ≥ 3 cc
	Coping and skills	Patient education/ self-management	No of pts who were offered participation in a patient training or support group or given a written self-management plan	No of pts (65+) with ≥ 3 cc
		Monitoring adherence to treatment	No of pts whose adherence to treatment was assessed	No of pts (65+) with ≥ 3 cc
	Quality of life	Quality of life assessment	No of pts that had a discussion about their subjective quality of life	No of pts (65+) with ≥ 3 cc
		Assessment of symptom burden	No of pts whose symptom burden was assessed using validated measurement tools	No of pts (65+) with ≥ 3 cc
		Assessment of biopsychosocial support needs	No of pts whose biopsychosocial support needs were assessed and documented according to ICF	No of pts (65+) with ≥ 3 cc
	Preferences	Eliciting patient preferences	No of pts whose priorities, goals and values were discussed and documented	No of pts (65+) with ≥ 3 cc
Patient-provider communication	Information and decision-making	Information about medication	No of pts who were informed about their medication (indication, effect, intake)	No of pts (65+) with ≥ 3 cc receiving pharmacological treatment
		Information about potential benefits and harms of treatment options	No of pts who were informed about potential benefits and risks of treatment options prior to treatment decisions	No of pts (65+) with ≥ 3 cc
		Shared decision making	No of pts who state that they are involved in treatment decisions to the extent they wish	No of pts (65+) with ≥ 3 cc

Target level of health care	Care Domains	Quality Indicator	Numerator	Denominator
		Mutual agreement on treatment goals	No of pts with whom treatment goals were established	No of pts (65+) with ≥ 3 cc
	Care planning and clinical management	Written treatment plan	No of pts with a written treatment plan	No of pts (65+) with ≥ 3 cc
		Medication review	No of pts that received a review of their medication	No of pts (65+) with ≥ 3 cc with long-term medication
		Regular updates of medication plan	No of pts whose medication plan was checked for updates in the last three months	No of pts (65+) with ≥ 3 cc with ≥3 long-term medications
		Documentation of adverse drug reactions	No of included practices/units where the identification and documentation of adverse drug reactions follows a standardized procedure	No of included practices/units
		Monitoring of pain management	No of pts with chronic pain whose pain management was monitored and adjusted if necessary	No of pts (65+) with ≥ 3 cc
		Assessment of treatment burden	No of pts that had a discussion of their treatment burden	No of pts (65+) with ≥ 3 cc
Context and organisational structures	Coordination	Assigning responsibility for coordination of care	No of pts with whom it was agreed and recorded which health care provider is responsible for the overall coordination of care	No of pts (65+) with ≥ 3 cc
	Cooperation	Comprehensive care documentation	No of pts for whom reports from all health care providers involved are accessible to the care coordinator	No of pts (65+) with ≥ 3 cc
	Training	Training programs addressing the management of pts with multimorbidity	No of practices/units where a) at least one physician and b) at least one member of the non-physician staff has participated in training programs for multimorbidity	No of included practices/units

Abbreviations No = number; pts = patients; cc = chronic conditions; ICF = International Classification of Functioning, Disability and Health.

Table adapted from Schulze et al., 2022. Copyright by the authors.

Results of Study 2: Quality of Care for People with Multimorbidity - A Focus Group Study with Patients and their Relatives

For this study, we conducted eight focus groups with patients and three focus groups with family members. The sample consisted of 47 patients, aged 65 to 84 years, and nine family members, aged 49 to 78 years. Among the patient sample, 61.7% of participants were women, compared with 33.3% women among the family members. The majority of the quality indicators previously identified in the literature were supported by the results of the focus groups. Four novel aspects of quality emerged from the data, which are described in more detail below.

Patient education/self-management: Participants placed great importance on the availability of training opportunities and strategies for self-management. Those who had received training reported using these skills to help manage their conditions on a daily basis.

Regular updates of medication plan: Many patients had been provided with a medication plan, as required by law in Germany, and considered its accuracy a critical quality aspect, especially when taking multiple medications or receiving prescriptions from different providers. Some patients always carried a copy of their medication plan with them, in case of emergencies.

GP-coordinated care: In the focus groups, participants valued the role of GPs in coordinating or guiding their care. This includes, for example, making targeted referrals to their network specialists, maintaining a comprehensive medical record that contains reports from other healthcare providers and planning preventive measures.

Regular check-ups: Participants expressed support for regular screenings and appointments for health check-ups, often provided as part of disease management programmes, for their potential to identify and prevent health deterioration at an early stage.

These quality aspects were used to create four new indicators, which were subsequently evaluated by the expert panel. Two of the indicators, regular check-ups and GP-coordinated care, were not endorsed by the panel due to the possibility that other health professionals, such as care managers, could also play a coordinating role, and that a rigid schedule of check-ups would not adequately address the diverse needs of patients with multiple conditions and therefore might incentivise overutilisation. However, the indicators for *'Regular updates of medication plan'* and *'Patient education/self-management'* were accepted and retained in the indicator set (see *Study 1*).

Results of Study 3: Adaptation and Validation of a German Version of the Multimorbidity Treatment Burden Questionnaire

This section outlines the results of the translation, cognitive interviews, pilot test and assessment of psychometric properties of the German MTBQ.

Translation, Cognitive Interviews and Pilot Test

The review of forward and backward translation and findings from the cognitive interviews highlighted inconsistencies in the adaptation of the optional item '*Getting help from community services*'. The different structures of the healthcare systems do not allow for an appropriate adaptation, which led to the exclusion of this item. Additionally, the cognitive interviews revealed that respondents had difficulty distinguishing between the two options '*does not apply*' and '*not difficult*'. For this reason, we added a more detailed test instruction. No other modifications were deemed necessary at this stage of the study. With an average time to complete the test of 4 minutes, the burden on participants was low.

Assessment of Psychometric Properties

Among the 1,243 eligible patients invited to the cross-sectional MULTIqual study, 362 (29.1%) agreed to participate. In total, 344 participants completed the minimum requirement of 50% of the MTBQ questions and were therefore included in the statistical analysis. The sample was on average 77.5 years old and included slightly more women (55.2%) than men. Participants had a median of 10 chronic conditions.

Table 2 displays descriptive statistics for each item and the global score. Scores were positively skewed, indicating a potential floor effect. Item 9 ('*Getting health care in the evenings and at weekends*') was removed in accordance with the guidelines in the original MTBQ test instructions, as it applied to less than 60% of the study population. Contrary to the original questionnaire, item 3 ('*Paying for prescriptions, over the counter medication or equipment*') was retained as it was relevant to the majority of participants. Item 13 ('*Having to rely on help from family and friends*') represented the greatest burden for patients. Categorisation of MTBQ global scores indicated that 25.6% of participants experienced no treatment burden, 39.0% experienced low treatment burden, 28.2% experienced medium treatment burden and 7.3% experienced high treatment burden. Global scores were significantly higher for women than for men ($Mdn_1 = 6.82$, $Mdn_2 = 4.55$; $U = 11729$, $p = .001$) and for patients with anxiety or depression ($Mdn_1 = 9.10$, $Mdn_2 = 4.55$; $U = 3172$, $p = .024$). The data were suitable for exploratory factor analysis according to the Kaiser-Meyer-Olkin measure of sampling adequacy (0.755).

Table 2 Descriptive analysis of MTBQ items and global score (N = 344)

No.	Items	Applicability (in %)	Mean score	Standard deviation
1	Taking lots of medications	86.3	.39	.89
2	Remembering how and when to take medication	94.8	.14	.49
3	Paying for prescriptions, over the counter medication or equipment	90.1	.33	.73
4	Collecting prescription medication	87.2	.18	.70
5	Monitoring your medical conditions (eg, checking your blood pressure or blood sugar, monitoring your symptoms, etc)	90.7	.10	.45
6	Arranging appointments with health professionals	95.1	.23	.71
7	Seeing lots of different health professionals	93.6	.44	.92
8	Attending appointments with health professionals (eg, getting time off work, arranging transport, etc)	87.5	.24	.77
9	*Getting health care in the evenings and at weekends**	46.8	.15	.57
11	Obtaining clear and up-to-date information about your condition	94.7	.17	.58
12	Making recommended lifestyle changes (eg, diet and exercise)	93.0	.59	.87
13	Having to rely on help from family and friends	70.8	.61	1.02
	Global MTBQ score	100	7.86	9.55

Notes * *Item 9 optional*. Item 10 not applicable in the German healthcare system.

The scree plot, parallel eigenvalue analysis and Velicer's minimum average partial test all pointed towards a single-factor solution, although this accounted for only 21.20% of total variance. Results on the model fit were inconclusive with robust *CFI* = .845, robust *RMSEA* = .073 and *SRMR* = .072. At ω_t = .71, the internal reliability was found to be adequate. The data analysis revealed significant negative correlations between treatment burden and factors such as health-related quality of life, self-rated health, social support, patient activation, and adherence to medication regimen. There was also a positive correlation between treatment burden and the number of comorbidities. These patterns in the data supported prior hypotheses about construct validity.

Discussion

The present research lays the groundwork for the systematic assessment of the quality of care for patients with multimorbidity in the German health care system by providing standardised measurement instruments. The two main outcomes were (1) a set of quality indicators and a measurement framework for

multimorbidity (*Studies 1 and 2*), and (2) a German instrument to measure treatment burden (*Study 3*). The process of developing the quality indicators involved a systematic literature review, focus groups with patients, and nominal group technique with experts from a variety of professional and stakeholder groups. This resulted in a set of 25 quality indicators and a conceptual framework representing three core layers of multilevel influences on the quality of care. The identified indicators can be utilised in healthcare practices for quality management purposes and may serve as a basis for the implementation of treatment standards for multimorbidity. The German MTBQ, obtained through a combination of qualitative and quantitative research methods, demonstrated good validity. The potential use of the MTBQ as a measure in future clinical trials and its effectiveness in clinical practice require further investigation.

Relationship between Quality of Care and Patient Outcomes

The indicators proposed in this thesis aim to promote comprehensive, patient-centred communication and consider the patient's overall situation, including treatments, personal goals, well-being and individual circumstances. For instance, the set of indicators includes process measures that focus on eliciting patient priorities, assessing treatment burden and conducting medication reviews. A study by Tinetti et al. (2019), albeit with methodological limitations, found that care aligned with patient preferences led to lower treatment burden and fewer unwanted interventions. This suggests that high-quality care, as measured by the proposed indicators, may also contribute to a reduction in treatment burden and costs. Furthermore, researchers need to re-evaluate whether patient-centred outcomes should be given a higher priority in interventional studies than in the past (Sasseville, Chouinard, & Fortin, 2021). Dowrick (2018) asserts that patient-centred care should be seen as an 'end in itself', as long as interventions do not compromise patient safety. However, the idea that there is a direct link between patient-centred care and improved health outcomes has been challenged by the findings of large randomised-controlled clinical trials (Fortin, Stewart, Almirall, & Beaupré, 2022; Smith et al., 2021). While the provision of high-quality primary care is crucial, it alone cannot fully address the intricate nature of multimorbidity. A multilevel strategy comprising public health and healthcare policy is necessary to drive substantial advancements in patient outcomes.

Multilevel Influences on the Quality of Care in Multimorbidity

In the past, efforts to improve healthcare have been directed primarily at optimising individual aspects of the care process, resulting mainly in technological progress. Yet this proved insufficient to significantly transform the quality of care, thus confirming the need for a comprehensive approach that takes into account the individual, provider and organisational levels. In light of this, we adopted the model

of multilevel influences on the cancer care continuum by Taplin et al. (2012) as the basis for our quality measurement framework for multimorbidity. The model was selected because it encompasses the entire healthcare continuum, including prevention and end-of-life care, and factors in contextual influences and changes in national policies. The model is exemplified in cancer, but its principles apply equally to multimorbidity.

The original multilevel model identifies family and social support as a target for quality management. However, it is widely recognised that multimorbid older people are often carers themselves rather than receiving support, e.g. as spousal carers. To reflect this, family and social support were included in the patient parameters in our measurement framework, acknowledging that their availability depends on the individual circumstances of each patient. In addition, greater emphasis has been placed on the patient-provider interaction, which Taplin et al. describe as an interface of care.

The traditional approach of evaluating healthcare by structural and outcome metrics such as service availability, mortality and costs offers little information about the actual quality of care delivered to patients. To fill this gap, the new set of indicators has been created to guide quality improvements at all levels of healthcare delivery that can be targeted by providers. Measuring treatment burden also helps to detect barriers that negatively affect patients' experience of care and contribute to lower quality of care. (Gaspar & Miranda, 2022). The literature points to organisational and delivery aspects of healthcare, rather than patient- or treatment-specific factors, as significant contributors to treatment burden (Hu et al., 2022). Tran et al. (2014) observed higher financial burden in the US and Australia, which is consistent with qualitative research identifying this as a common concern for patients from these countries. Conversely, in the UK, the study found that the burden of treatment was impacted by the relationship between patients and healthcare providers, which may be due to pay-for-performance initiatives incentivising biomedical targets at the expense of patient-centeredness and continuity of care. The newly developed standardised measurement tools will facilitate the evaluation of factors that influence quality of care and enable the design of multilevel interventions by mapping these factors to different levels of the conceptual model.

The Vital Role of Healthcare Policy in Quality Care

The use of quality indicators in internal quality management alone is not enough to achieve sustainable progress in the quality of care. As outlined above, the definition of high-quality care in the context of multimorbidity should be translated into healthcare policy as well. The results of the focus groups show that patients value an approach from their GP that considers both the medical and psychosocial aspects of their health. Allocating sufficient time for communication in primary care might help GPs to

foster strong relationships with patients and their families, to engage in shared decision-making, and to tailor treatment plans to individual needs. Patients also stress the importance of their GP coordinating their care, including keeping track of specialist visits and monitoring treatments and their effects. In Germany, with its combination of fee-for-service and per-case payment for outpatient services, primary care representatives criticise inadequate remuneration for communication-based interventions and the limited time available to address complex problems during consultations (German Association of General Practitioners; German College of General Practitioners and Family Physicians, 2018; Lühmann et al., 2016). Likewise, reimbursement for tasks such as updating medication plans is low, and multidimensional assessments are budgeted on a per-patient basis (Fricke & van den Bergh, 2016; Korzilius & Osterloh, 2018; National Association of Statutory Health Insurance Physicians, 2023). Practices operate on a mixed calculation with some patients being more profitable than others, and this imbalance may be exacerbated by the predicted increase in multimorbidity. The number of specialists in Germany surpassed the number of GPs in 2005, raising concerns about filling GP vacancies in the near future (Robert Bosch Foundation, 2021; Statista, 2014). To attract young medical professionals to general practice, working conditions must be better aligned with the realities of caring for complex patients: There is a need for care models that make room for communication and coordination in day-to-day practice, which could lead to higher satisfaction for both patients and providers.

Strengths and Limitations

Quality indicators are useful tools for assessing the quality of health care, but they are limited by the fact that they focus on the measurable aspects of quality and neglect others that are equally relevant but difficult to quantify (Nothacker et al., 2021). On one hand, due to practical challenges in quantifying coordination and collaboration between different providers, the indicator set only partially addresses these aspects. Both the indicator set and the MTBQ do not properly account for the diffusion of responsibility between providers that is common in the German healthcare system. The gatekeeping role of the GP is voluntary and tied to certain care subcontracts, such as GP-coordinated care ('Hausarztzentrierte Versorgung'). With free choice of healthcare providers and unrestricted access to specialist services, patients can receive treatment without their GP being aware of it. This can lead to greater treatment burden and higher probability of important information being lost or not properly shared between providers (Penm, MacKinnon, Strakowski, Ying, & Doty, 2017). It is therefore important to interpret the outcomes of these measures with caution and to consider the contributing factors carefully before drawing conclusions about individual services provided to patients. On the other hand, the current set of indicators has several strengths. One key advantage is its focus on process and communication parameters that promote patient-

centred care. This guarantees that patients, regardless of their individual combination of health conditions, can benefit from the implementation of the quality standards measured by the indicators. In contrast, research into the impact of large pay-for-performance initiatives, such as the Quality and Outcomes Framework, suggests that they create an undue focus on certain disease-specific outcomes and diagnostics (Gillam, Siriwardena, & Steel, 2012; Tran et al., 2014).

Another limitation of this work is the selection of an older demographic of patients aged 65 and over. This raises questions about the generalisability of these findings to a younger population, and whether high-quality care would mean the same for them. Research indicates that the burden of treatment is significantly higher in younger patients with multimorbidity (Duncan et al., 2018; Pedersen et al., 2018), and the present measurement tools may not fully capture these challenges. For example, balancing care-related workload with other demands, such as work and family responsibilities, may pose bigger difficulties for young and middle-aged adults (Smith et al., 2021). The scaling of the MTBQ and its pronounced floor effects make it more responsive to improvements in care for high burden patients, and thus potentially more suitable for this particular age group. Furthermore, the operationalisation of multimorbidity as three chronic conditions, although based on the German guideline for multimorbidity (German College of General Practitioners and Family Physicians, 2017) and user-friendly, is controversial in the scientific community, as a simple count of diagnoses may not adequately reflect clinical complexity.

Current indicator and test development manuals lack clear instructions for patient involvement. Even though their participation is recognised as the gold standard in the development of guidelines and performance measures, it is not sufficiently translated into research practice (Domecq et al., 2014; Kötter et al., 2013; Rashid, Thomas, Shaw, & Leng, 2017). We aimed to address this by making a conscious effort to seek input from patients at several stages of the process. Successful patient participation requires adequate support and empowerment to enable them to contribute meaningfully to the project. Especially the complex methodological background of quality indicators requires a comprehensive introduction to the topic. To collaborate effectively with patient partners in the indicator development, we supplied handbooks with easy-to-understand material on quality indicators and selected evaluation criteria that could be assessed by lay people without expert medical knowledge. We also used qualitative methods such as focus groups and cognitive interviews to gain a deeper understanding of patients' perspectives. Assessment of face validity, although often neglected in research, is essential as it sheds light on the perception of the measurement tool by its intended respondents and users and problems with its application (Scott et al., 2020). It can also enhance usage and response rates, because participants are more likely to engage with an instrument that they clearly understand and perceive as relevant (Willis & Artino, 2013).

Implications for Clinical Practice and Directions for Future Research

These studies have taken a noteworthy approach in incorporating the perspectives of older adults with multimorbidity throughout the process. Nevertheless, it is important to extend the focus to younger adults and to examine any unaddressed quality aspects in order to assess the validity of the instruments for this population. Given the growing importance of patient participation in health care research, methodological guidelines must prioritise transparent reporting of their involvement (Domecq et al., 2014; Kötter et al., 2013; Kötter, Blozik, & Scherer, 2012).

Currently, the slow progress of digitization and the variety of documentation systems in healthcare practices in Germany (Nohl-Deryk, Brinkmann, Gerlach, Schreyögg, & Achelrod, 2018) make it challenging to derive process indicators from standard documentation data or electronic health records. For this reason, the indicator set is best suited for internal quality management and health services research. The recently published QISA volume on multimorbidity provides guidance on the collection of indicator data to support these efforts (Glassen et al., 2022). However, before these quality indicators can be utilised to assess standard care on a broader level, they need to be subjected to further clinimetric validation. As a first step, the MULTIqual project carried out a cross-sectional study to validate a core indicator set (Schäfer et al., manuscript submitted for publication). If advances in care render existing indicators obsolete or require new indicators, the set will have to be updated accordingly. Longitudinal studies are needed to assess whether their implementation in clinical practice leads to long-term improvements in patient outcomes and reductions in overuse and underuse.

The first German instrument to measure treatment burden was developed as a result of this work. The availability of the MTBQ in a number of languages makes it a useful tool for comparative research between countries, and it is currently being administered for this purpose in the EU-funded trial 'Evaluation of a patient-centred biopsychosocial blended collaborative care pathway for the treatment of multimorbid elderly patients' (Herrmann-Lingen et al., 2022). The use of this questionnaire will facilitate empirical exploration of the relationship between treatment burden, patients' social support systems and health services (May et al., 2014). The link between elevated levels of treatment burden and adverse health outcomes has been postulated in many theoretical models (e.g. in the 'cumulative complexity model' by Shippee, Shah, May, Mair, & Montori, 2012), but remains understudied. The MTBQ can be used in future observational and interventional studies to gain a better understanding of this relationship. It should also be evaluated as a screening tool to identify burdened patients and as a basis for shared decision-making in clinical practice.

Conclusion

The research presented in this thesis makes significant contributions to the field of multimorbidity and healthcare quality assessment. The development of quality indicators, a measurement framework as well as a German instrument for measuring treatment burden, offer a much-needed systematic approach to evaluating the care of patients with multimorbidity. While the focus on older adults was a warranted step given their high prevalence, future studies should also consider the perspectives of younger adults. The quality indicators are mainly applicable to internal quality management and health services research but require further validation before they can be utilised on a larger scale. The MTBQ may prove to be a viable tool for analysing the determinants and consequences of treatment burden in subsequent studies. Going forward, these findings strengthen the case for patient-centred care and a primary care system that allows sufficient time for communication and coordination to ensure high-quality care. The implementation of the instruments developed within this thesis will provide valuable information for healthcare providers and policy makers seeking to optimise the care of patients with multimorbidity.

Summary

Multimorbidity, the presence of multiple chronic conditions in one person, is a major challenge for healthcare systems worldwide. Fragmentation and lack of reliable evidence are among the main obstacles for healthcare providers, making the care of patients with multimorbidity vulnerable to quality deficits. As overburdened patients are more likely to be less compliant and have a poorer experience of care, treatment burden is an important aspect of quality of care for this patient group. Inadequate application of clinical guidelines and quality metrics designed for single conditions can adversely affect the quality of care. Standardised quality measures that take account of multimorbidity are needed to assess the current state of health care. So far, however, there are none available for Germany. This thesis comprises three studies designed to gain insight into the quality of care for patients with multimorbidity and their experience of care. The research employed a mixed-methods approach and addressed the following objectives: (1) developing quality indicators and a measurement framework for the management of multimorbidity, (2) exploring patients' perspectives on the quality of care through focus groups; and (3) creating a German version of the Multimorbidity Treatment Burden Questionnaire (MTBQ) and determining its validity.

The development of the quality indicator set was informed by a systematic literature review of guidelines and quality metrics, which resulted in the identification of 81 recommendations and six relevant metrics. The results of the focus group supported most of the quality aspects found in the literature, and four new ones emerged. These were used to create new quality indicators, which were then assessed by an independent multidisciplinary expert panel. In a two-stage nominal group consensus process, the panel selected a set of 25 indicators. A conceptual framework was developed to visualise and organise quality measurement for multimorbidity covering three layers of multilevel influences on quality of care. Another main outcome is the German adaptation of the MTBQ, a brief tool to assess treatment burden in patients with multimorbidity. A robust and well-established methodology was utilised for translation and minor changes were made to the obtained version in order to ensure cross-cultural validity. The analysis showed robust face validity, acceptable reliability, a single-factor structure and good construct validity.

These findings present the first standardised instruments to assess the quality of care for multimorbidity in the German health care system. The importance of including the patient perspective in quality assessment is underlined by the involvement of patients at multiple stages of the research process. Further empirical validation is needed before the indicators can be used to evaluate standard care. The MTBQ holds potential as an outcome measure in future clinical trials, and its effectiveness as a tool in clinical practice should be examined in the future. Both instruments offer a promising solution to the limitations of disease-specific measures of quality of care that fail to address the complexity of multimorbidity.

Zusammenfassung

Multimorbidität, das gleichzeitige Vorliegen mehrerer chronischer Erkrankungen, ist eine der größten Herausforderungen für Gesundheitssysteme weltweit. Zu den Hauptproblemen für die Leistungserbringer gehören die Fragmentierung und der Mangel an belastbarer Evidenz, was die Versorgung von Menschen mit Multimorbidität anfällig für Qualitätsdefizite macht. Die mit der Behandlung verbundene Belastung ist ein entscheidender Aspekt der Versorgungsqualität, da überforderte Patienten mit größerer Wahrscheinlichkeit negative Behandlungserfahrungen machen und eine geringere Therapieadhärenz aufweisen. Die Anwendung krankheitsspezifischer Leitlinien und Qualitätsindikatoren kann sich nachteilig auf die Versorgungsqualität bei Multimorbidität auswirken. Um den Ist-Zustand der Versorgung beurteilen zu können, werden standardisierte Instrumente benötigt, die bisher für Deutschland nicht zur Verfügung stehen. Die vorliegende Arbeit umfasst drei Teilstudien, die einen Einblick in die Versorgungsqualität multimorbider Patienten und deren Versorgungserfahrungen geben sollen. Im Rahmen eines Mixed-Methods-Ansatzes wurden folgende Zielstellungen verfolgt: (1) Entwicklung von Qualitätsindikatoren und eines Rahmenmodells zur Versorgungsqualität bei Multimorbidität, (2) Untersuchung der Patientenperspektive auf die Versorgungsqualität mittels Fokusgruppen und (3) Adaption und Validierung einer deutschen Version des Multimorbidity Treatment Burden Questionnaire (MTBQ).

Die Entwicklung der Qualitätsindikatoren erfolgte auf Basis einer systematischen Literaturrecherche zu Leitlinien und Qualitätsmaßen, bei der 81 Empfehlungen und sechs relevante Maße identifiziert wurden. Die Ergebnisse der Fokusgruppen bestätigten den Großteil der in der Literatur gefundenen Qualitätsaspekte und brachten vier zusätzliche Aspekte hervor. Anhand der Ergebnisse wurden neue Qualitätsindikatoren abgeleitet, die anschließend von einem unabhängigen, multidisziplinären Expertenpanel bewertet wurden. In einem zweistufigen nominalen Gruppenprozess konsentierte das Panel ein Set von 25 Indikatoren. Darauf aufbauend wurde ein konzeptioneller Rahmen entwickelt, der die Elemente der Versorgungsqualität bei Multimorbidität strukturiert und visualisiert. Ein weiteres zentrales Produkt ist die deutsche Version des MTBQ, eines Kurzfragebogens zur Erfassung der Belastung durch die Behandlung multimorbider Patienten. Bei der Übersetzung wurde auf eine etablierte Methodik zurückgegriffen und geringfügige Änderungen vorgenommen, um die kulturübergreifende Validität zu gewährleisten. Die Ergebnisse weisen auf eine hohe Augenscheinvalidität, eine akzeptable Reliabilität, eine einfaktorielle Struktur und eine gute Konstruktvalidität hin.

Mit den vorgestellten Ergebnissen liegen erstmals standardisierte Messinstrumente zur Beurteilung der Versorgungsqualität bei Multimorbidität im deutschen Gesundheitswesen vor. Die Einbeziehung der Patientenperspektive in den gesamten Forschungsprozess spiegelt deren Relevanz für die Definition von

Versorgungsqualität wider. Bevor die Indikatoren jedoch zur Evaluation der Regelversorgung eingesetzt werden können, ist eine empirische Validierung erforderlich. Der MTBQ könnte in zukünftigen klinischen Studien als Endpunkt verwendet werden, und seine Wirksamkeit als Instrument in der klinischen Praxis sollte untersucht werden. Die neu entwickelten Messinstrumente stellen eine vielversprechende Alternative zur bisherigen krankheitsbezogenen Qualitätsmessung dar, die der Komplexität von Multimorbidität nicht hinreichend gerecht wird.

List of Abbreviations

AOK ..... Allgemeine Ortskrankenkasse

aQua ..... Institut für Angewandte Qualitätsförderung und Forschung im Gesundheitswesen

CFI ..... Comparative Fit Index

ICF ..... International Classification of Functioning, Disability and Health

Mdn ..... Median

MTBQ ..... Multimorbidity Treatment Burden Questionnaire

MULTIqual ..... Development and Validation of Quality Indicators for Multimorbidity

QISA ..... Quality Indicator Systems for Ambulatory Care

RMSEA ..... Root Mean Square Error of Approximation

SRMR ..... Standardised Root Mean Square Residual

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Study 1: Measuring the Quality of Care for Older Adults with Multimorbidity

THE GERONTOLOGICAL SOCIETY OF AMERICA®

The Gerontologist
cite as: *Gerontologist*, 2022, Vol. 62, No. 8, 1135–1146
https://doi.org/10.1093/geront/gnac013
Advance Access publication January 28, 2022

OXFORD

Research Article

Measuring the Quality of Care for Older Adults With Multimorbidity: Results of the MULTIqual Project

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Received: August 20, 2021; Editorial Decision Date: January 4, 2022

Decision Editor: Barbara J. Bowers, PhD, RN, FAAN, FGSA

Abstract

Background and Objectives: Providing health care for older adults with multimorbidity is often complex, challenging, and prone to fragmentation. Although clinical decision making should take into account treatment interactions, individual burden, and resources, current approaches to assessing quality of care mostly rely on indicators for single conditions. The aim of this project was to develop a set of generic quality indicators for the management of patients aged 65 and older with multimorbidity that can be used in both health care research and clinical practice.
Research Design and Methods: Based on the findings of a systematic literature review and eight focus groups with patients with multimorbidity and their family members, we developed candidate indicators. Identified aspects of quality were mapped to core domains of health care to obtain a guiding framework for quality-of-care assessment. Using nominal group technique, indicators were rated by a multidisciplinary expert panel (n = 23) following standardized criteria.
Results: We derived 47 candidate quality indicators from the literature and 4 additional indicators from the results of the focus groups. The expert panel selected a set of 25 indicators, which can be assigned to the levels of patient factors, patient–provider communication, and context and organizational structures of the conceptual framework.
Discussion and Implications: We developed a comprehensive indicator set for the management of multimorbidity that can help to highlight areas with potential for improving the quality of care and support application of multimorbidity guidelines. Furthermore, this study may serve as a blueprint for participatory designs in the development of quality indicators.

Keywords: Chronic care, Comorbidity, Patient-centered care, Primary care, Quality standard

With demographic aging and the rise of chronic conditions, caring for patients with multimorbidity has become a significant challenge across all health care settings (Afshar et al., 2015; Kingston et al., 2018; Uijen & van de Lisdonk, 2008). In contrast to comorbidity, which is the combination of an index condition of primary interest with additional conditions (Feinstein, 1970), multimorbidity refers to the joint presence of multiple, potentially interacting chronic health conditions, "where one is not necessarily more central than the others" (Boyd & Fortin, 2010). Multimorbidity is linked to increased health care utilization and costs (Bähler et al., 2015; Glynn et al., 2011), and patients

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frequently report functional limitations, psychological distress, and reduced quality of life (Fortin et al., 2006; Jindai et al., 2016; Williams & Egede, 2016). In primary care practices, patients with multiple chronic conditions account for more than half of all consultations (Cassell et al., 2018). Although multimorbidity is the rule rather than the exception in older adults (Salive, 2013; Violan et al., 2014), traditional clinical practice guidelines often focus on the management of single diseases with little consideration of comorbidities (Hughes et al., 2013; Tinetti et al., 2004). Primary care providers consider the inadequacy of disease-oriented guidelines and disintegration of care as major obstacles in providing optimal care for persons with multimorbidity (Sinnott et al., 2013). Uncoordinated and fragmented care increases the risk of greater treatment burden, polypharmacy, poor adherence, and can lead to potentially harmful treatment interactions, especially in the presence of discordant conditions with competing health care requirements (Lorgunpai et al., 2014; Wallace et al., 2015).

To date, there is no consensus on the metrics that best reflect the quality of health care delivered to patients with multimorbidity. Recent studies have targeted the question of which outcome measures are most relevant to address the impact of health care interventions for adults with multimorbidity (Hurst et al., 2020; Smith et al., 2018). Quality of care for people with multimorbidity is often evaluated by aggregating performance measures for single conditions (Valderas et al., 2019). However, previous research suggests that this strategy might lead to worse results in quality assessment when discordant conditions are present (Ricci-Cabello et al., 2015). Ferris et al. (2017) identified the application of condition-specific performance measures as an important risk factor for fragmented and burdensome care. Implementing generic quality metrics that correspond to patients' priorities offers an opportunity to improve health care substantially. Quality indicators reflect processes, structures, and outcomes sensitive to quality improvement and may provide a quantitative basis for the assessment of clinical performance (Mainz, 2003). There is consensus that for older adults with multimorbidity the focus of quality assessment should be directed at primary care, as this setting is best suited to meet the needs of this patient group for comprehensive and patient-centered care as well as continuity and coordination (Moffat & Mercer, 2015; World Health Organization & United Nations Children's Fund, 2018). In Germany, the first point of contact for older adults with chronic conditions is usually the general practitioner (GP). However, there is no legally binding gatekeeper system. Rather, the GP's coordinating and gatekeeping role is based on trust and a long-standing relationship with the patient. This, in turn, can only endure if conditions and their consequences for everyday life are addressed in a way that is aligned with patient preferences.

The aim of our study was to identify indicators and guideline recommendations (as a basis for indicators) with relevance to multimorbidity care in Germany and amend these findings with quality aspects meaningful to patients with multimorbidity. Our study proposes a conceptual framework for quality of care and a set of quality indicators for the management of older adults (aged 65 and older) with multimorbidity in primary care based on a systematic consensus approach. Although the importance of patient involvement in indicator development is well appreciated, a gold standard on effective engagement strategies is still lacking (Kötter et al., 2013). To ensure the representation of quality aspects relevant to the target group, patients were involved at multiple stages of the process.

Method

The MULTIqual project implemented a mixed-methods approach to combine the best available evidence on the effectiveness of interventions with clinical expertise on the management of patients with multimorbidity. We derived candidate quality indicators based on a systematic literature review. To inform the decision-making process and amend the literature-based indicator set, focus groups with patients affected by multimorbidity and their family members were conducted. We convened a multidisciplinary expert panel that further refined and selected a preliminary indicator set via nominal group technique (McMillan et al., 2016). In addition, we developed a conceptual model that defines core components of health care delivery for this target group. The methodology and results of indicator development are reported following the standards for guideline-based performance measures established by the Guidelines International Network (GIN) Performance Measures Working Group (Nothacker et al., 2016).

Systematic Literature Review

A systematic literature review was performed to identify existing references on clinical guidance and quality metrics for multimorbidity care in the electronic databases PubMed, CINAHL, CareLit, Cochrane Library, PsycInfo, Livivo, and GeroLit over a period of 10 years (from 2007 to September 2017) as well as GIN and National Guideline Clearinghouse databases. The full search strategy is provided in Supplementary Table 1. We also searched via OpenGrey, HSRProj, and ICTRP databases to identify ongoing or unpublished research and conducted a manual search based on the reference lists of all publications selected for the final review. References were included if they reported a methodologically rigorous development process. Publications limited to the management of polypharmacy or specific index conditions with respect to comorbidities were excluded. We did not define any restrictions regarding clinical settings or operationalization of multimorbidity. Based on title and abstract screening, papers were selected for full-text reading if they were available in English or German. Eligible references were reviewed for inclusion by two researchers independently (J. Schulze, T. Eißing) and discussed with a third reviewer (D. Lühmann) in order to reach a consensus.

The methodological quality of references providing clinical guidance was assessed using the AGREE II instrument (AGREE Next Steps Consortium, 2014). We extracted all recommendations and quality metrics directed at the clinical management of people with multimorbidity and made suggestions for candidate quality indicators. Taking into consideration that high-quality evidence in the field of health care for patients with multimorbidity is scarce (Smith et al., 2021), we chose to follow the best evidence approach. Wherever possible, quality indicators were derived based on the recommendation with the highest possible level of evidence. In cases where sources with lower levels of evidence provided aspects not yet covered, these recommendations were extracted as well.

Focus Groups

We invited randomly selected GPs from the northern and southern regions of Germany (Hamburg and Heidelberg and surroundings) to support the study by recruiting patients aged 65 and older with three or more chronic conditions from their practice. Patients were encouraged to invite family members to participate in the study as well. We convened eight focus groups with patients with multimorbidity and three focus groups with patients' family members in December 2018 and January 2019. Informed written consent was obtained from all participants prior to the beginning of the focus groups. Discussions in the focus groups followed a semistructured format.

Due to its complexity and multifaceted nature, the term "quality" is often understood differently by laypersons. Therefore, we did not address this term directly in the focus group guide, but approached it indirectly by asking questions about positive and negative experiences with care (Sofaer & Firminger, 2005), changes in health care needs when living with multiple conditions, and suggestions for quality improvement. Digital recordings were transcribed verbatim. In line with Sandelowski (2000), we used a descriptive qualitative methodology to uncover important issues for patients and relatives. We followed Kuckartz's (2012) approach to qualitative content analysis to analyze the collected data in a systematic but flexible way. As part of the coding process, we developed inductive and deductive codes using MAXQDA software: Emerging quality aspects were matched to the previously identified literature-based indicators (deductive codes). The working group derived new quality indicators when aspects of relevance to patients or family members were not represented in the literature (inductive codes). Each category was described in a code memo to help allocation of text passages to categories (an example is given in Supplementary Table 2). Further details can be found in a separate publication (Pohontsch et al., 2021).

Expert Panel

An independent interdisciplinary expert panel was convened to comment, rate, and select candidate quality indicators via nominal group technique that included an online rating and a face-to-face meeting. To reflect the broad range of possible care constellations and care pathways in multimorbidity, the panel included the most central stakeholders from a variety of clinical fields (general practice, geriatrics, nursing, social work, physical therapy, and pharmacology), health economy as well as researchers with methodological expertise in quality and health services research and patient representatives. Candidates were invited based on their clinical or methodological expertise. We contacted patient organizations to recruit patient representatives with lived experience of chronic conditions who were able to participate as advocates for the interests of people with multimorbidity. To minimize bias, we ensured a gender-balanced representation within the panel, recruited experts from different regions of Germany, and reviewed conflicts of interest disclosed by all potential panel members.

Prior to the first stage of the consensus process, participants received a handbook containing basic information on the purpose of the study as well as information on terminology and methodology of indicator development. Challenges related to indicator development in the field of multimorbidity, methodological questions, and the role of the experts were explained and discussed in preparatory video conferences with up to 10 panel members each. An online rating was conducted from November 2018 to January 2019 via EFS Survey (Questback). Panel members were encouraged to comment on the candidate indicators to clarify descriptions and data sources. Rating criteria (Table 1)

Table 1. Rating Criteria for Candidate Quality Indicators

Category	Key statement	Response format
Significance	"The indicator covers essential aspects of quality of life, morbidity, or mortality, or relevant care processes or structures."	Four-level Likert scale: 1 = strongly disagree
Clarity of definition	"The indicator is defined clearly and unambiguously."	2 = disagree
Possibility to influence the indicator manifestation	"The indicator refers to aspects of care that are under the practitioner's control."	3 = agree 4 = strongly agree
Strength of evidence	"The existence of the measured structure/process leads to a better result" or "The measured outcome is associated with a higher quality of care."	
Potential risks/undesirable effects	"Does the indicator create potential misincentives?"	Dichotomous (Yes/No)

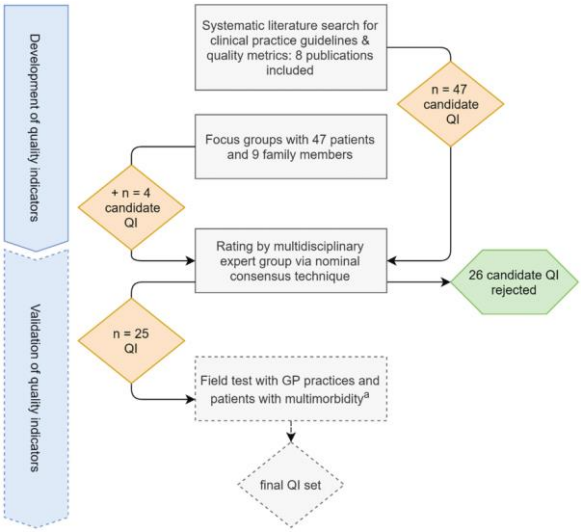

Figure 1. Flowchart of indicator development and number of resulting quality indicators (QIs). [a]Further details to be published separately (Schulze et al., 2022).

were based on the QUALIFY tool (Reiter et al., 2008) following the German National Disease Management Guidelines manual on quality indicators (Altenhofen et al., 2009).

The results of the first stage of the consensus process were analyzed by assessing the proportion of "agree" and "strongly agree" votes for the dimensions significance, strength of evidence, possibility to influence the indicator manifestation, and clarity of definition. Consistent with established methods for guideline and indicator development in Germany (Schorr et al., 2017), an agreement of at least 75% in all categories was regarded as the general acceptance of an indicator. Less than 75% agreement in more than two of the four categories suggested rejection. Mixed ratings of indicators were deemed inconclusive and consequently assigned to open discussion. Votes on potential risks and undesirable effects were evaluated separately and furthermore, the panel was asked for free-text comments for indicator improvement. The results of the first stage were then made available to the panel in aggregated form. The second stage took place in February 2019 as an in-person meeting with all panel members for discussion, refinement where necessary, and selection of the preliminary set of quality indicators via open voting.

Measurement Framework

Based on our findings, we inductively derived a conceptual framework to capture the most vital aspects of quality of care for this target group. In a first step, all extracted recommendations from the literature and focus groups were categorized into different domains of care (Agency for Healthcare Research and Quality [AHRQ], 2014). In a second step, these care domains were mapped onto the levels of interventions that affect health care delivery

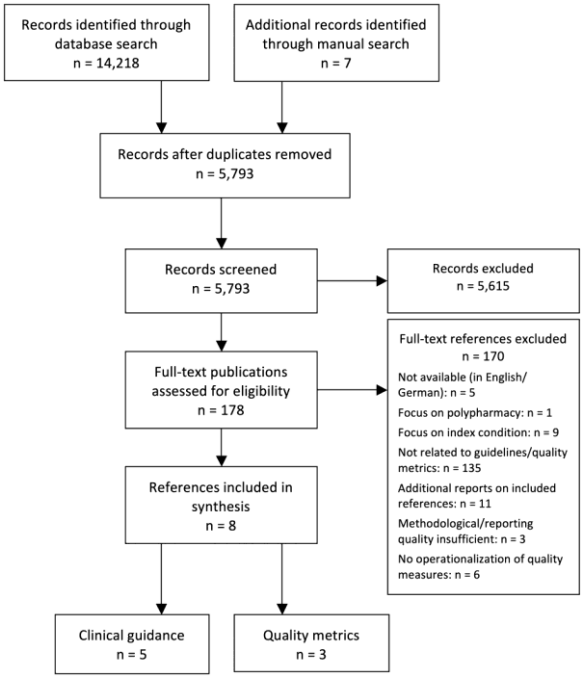

Figure 2. Flowchart of systematic literature review.

(Taplin et al., 2012) to illustrate the relationships between the targeted aspects of care. Discrepancies were discussed within the working group until consensus was reached.

Results

Figure 1 illustrates the results of the different methodological approaches.

Literature Review

About 14,218 references were identified through database searching and seven additional papers through hand searching. After removal of duplicates, titles and abstracts of 5,793 hits were screened and 178 papers were retained for full-text review (Figure 2). In total, three guidelines and two guidance papers as well as three references on quality metrics were included in the final review. Table 2 lists all included documents.

Results of the quality appraisal were overall positive for two of the three guidelines (see Supplementary Figure 1 for AGREE II ratings). We extracted 81 recommendations and six performance measures from the literature. We did not derive quality indicators based on recommendations that were not applicable to the German health care system or addressed rather specific aspects of care, for example, detailed requirements for the assessment of frailty. All recommendations were translated into quality indicators by defining numerators, denominators, and data sources. To provide users with a

Table 2. Characteristics of Included References

Reference	Country of origin	Document type	Target population	Target setting	Target audience
National Institute for Health and Care Excellence (NICE), 2016	UK	Guideline	Adults with two or more long-term health conditions, not including people with only mental and not physical health problems	Primary and secondary care	Patients, health care professionals (primarily GPs, geriatricians, specialists)
German College of General Practitioners and Family Physicians, 2017	Germany	Guideline	Adults with three or more chronic conditions	Primary care	Patients, primary care practitioners
American Geriatrics Society Expert Panel on the Care of Older Adults with Multimorbidity, 2012	USA	Guiding principles	Older adults with multiple chronic conditions	Primary and secondary care	Clinicians, researchers, public health professionals, payers, policymakers, interested public
Muth et al., 2014	North America and Europe	Guiding principles	Patients with multiple chronic conditions	Decision making in primary care	Family physicians, primary care researchers, medical education, training services
Palmer et al., 2018	EU	Health care framework	Patients with multiple chronic diseases or conditions	European health care systems	National policymakers, providers
NICE, 2017	UK	Quality standard	Adults with two or more long-term health conditions	Primary and secondary care	Providers, health care practitioners, commissioners, adults with multimorbidity
National Quality Forum, 2012	USA	Guiding principles and high-priority domains for quality measurement	Adults with two or more conditions that collectively have an adverse effect on health status, function, or quality of life and that require complex health care management, decision making, or coordination	Various health care settings	Providers, health professionals, purchasers, health plans, consumers, researchers
Working Group on Health Outcomes for Older Persons with Multiple Chronic Conditions, 2012	USA	Standard health outcome measures	Older adults with multiple chronic conditions	Various health care and residential settings	Clinical researchers, policymakers, practitioners

systematic but easy-to-perform computation, we chose to operationalize multimorbidity as the presence of three or more chronic conditions. Previous studies propose using the more selective threshold of ≥3 conditions to identify patients with multimorbidity (Lee et al., 2021; van den Bussche et al., 2011), as the often-used criterion of ≥2 conditions (Johnston et al., 2019) results in prevalence rates of 75%–99% in primary care for this age group (Cassell et al., 2018; Fortin et al., 2005). There was a substantial overlap within care domains, resulting in a list of 47 candidate quality indicators. For example, both the National Institute for Health and Care Excellence (NICE) guideline (2016) and quality standards (2017) suggest reviewing medications for risks and benefits, as well as potential interactions, to determine whether any should be discontinued or changed. The DEGAM guideline (2017) points out that a higher number of different medications increases the risk of drug interactions, adverse effects, and nonadherence.

Focus Groups

A total of 47 patients and nine family members (spouses and adult children) took part in the focus groups. A large proportion of literature-based quality indicators were supported by the aspects suggested in the focus groups. For instance, the aspect of reviewing medication was also raised in the focus groups: "Especially in the case of multiple chronic conditions, I find it extremely important that the GP explains to me that the drugs are compatible, that there is no interaction or that it is possible that they will cancel each other out or even worsen the condition, as in the case of my mother […]" (focus group with family members, cited from Pohontsch et al., 2021). Four additional quality aspects emerged from the discussions and were added to the list of candidate indicators: offer self-management support and education, regular updates of medication plans, periodic checkups, and GP-coordinated care. Participants considered information on education and self-management strategies to be highly relevant to quality of care. In the focus groups, participants emphasized the value of up-to-date medication plans for patient safety, especially when there are many medications or multiple prescribing physicians. They advocated for GPs to take on a coordinating role, including targeted referrals to a network of specialized treatment providers. Participants shared their preference for regular screenings and checkups to detect potential health deterioration at an early stage. These findings were presented to the expert panel and evaluated, discussed, further operationalized, and selected in the nominal group process (Pohontsch et al., 2021).

Expert Panel

The expert panel consisted of 23 experts (as listed in the Acknowledgments section), with a drop out of n = 4 in the second stage due to time constraints. After the first stage, 23 indicators met the criteria for general acceptance, whereas 22 showed mixed ratings and six were rejected. In these cases, rejection was due to concerns about the evidence base and the link between indicator scores and better outcomes. The working group assessed all free-text comments for relevance and applicability: Some comments were incorporated into indicator descriptions, reference periods, or data collection. Relevant comments that could not be applied directly were assigned to open discussion. Out of the indicators with mixed ratings, seven were accepted (after refinements) in the second stage of the consensus process. However, after discussion, the panel decided to drop five indicators with positive ratings in the first round because of overlaps with other indicators that were found to be more appropriate and clearer in operationalization. Rejected candidate indicators are listed in Supplementary Table 3. Ultimately, 25 quality indicators were included in the final set. The indicator on reviewing medication, for example, obtained over 90% agreement in all categories and was retained in the final set by consensus. Table 3 provides an overview of the accepted indicators.

Measurement Framework

Resulting from this iterative process, we developed a conceptual framework for quality-of-care assessment in older adults with multimorbidity (Figure 3). For this purpose, we derived 13 care domains from included references and focus group data, such as training or decision making. Identified care domains were then categorized into three target levels: (a) patient factors, (b) patient–provider communication, and (c) context and organizational structures. By using this model as a guiding framework, we wanted to ensure that the final indicator set covered the core components of quality of care. The proposed framework can be used to illustrate and structure quality measurement for this target group, indicating for which areas of interest quality metrics are available.

Discussion

Here we presented the first thoroughly developed indicator set for multimorbidity for use in the German health care system. Through systematic literature review, eight relevant publications were identified, and 81 recommendations and six quality metrics were extracted and operationalized for quality measurement. Four additional quality indicators were derived based on the findings from 11 focus groups. The resulting 51 candidate quality indicators were evaluated by an independent multidisciplinary expert panel that selected a set of 25 quality indicators via a two-stage nominal group technique. Based on the obtained results, we developed a measurement framework that conceptualizes and structures quality measurement for older adults with multimorbidity.

When reviewing the scientific literature, we encountered significant challenges related to the lack of high-quality

Table 3. Description of Quality Indicators Accepted by Expert Panel

Quality indicator	Numerator	Denominator	Data source
Screening for depression	No. of patients whose risk of depression was assessed using screening questions	No of patients (65+) with ≥3 cc without a prior diagnosis of depression	GP survey/medical records
Proactive pain assessment	No. of patients who were asked about the presence of pain	No. of patients (65+) with ≥3 cc	GP survey/medical records
Monitoring of pain management	No. of patients with chronic pain whose pain management was monitored and adjusted if necessary	No. of patients (65+) with ≥3 cc	GP survey/medical records
Addressing financial support needs	No. of patients who were asked about their need for financial support	No. of patients (65+) with ≥3 cc	GP survey/medical records
Quality of life assessment	No. of patients who had a discussion about their subjective quality of life	No. of patients (65+) with ≥3 cc	GP survey/medical records
Assessment of symptom burden	No. of patients whose symptom burden was assessed using validated measurement tools	No. of patients (65+) with ≥3 cc	GP survey/medical records
Assessment of biopsychosocial support needs	No. of patients whose biopsychosocial support needs were assessed and documented according to ICF	No. of patients (65+) with ≥3 cc	GP survey/medical records
Eliciting patient preferences	No. of patients whose priorities, goals, and values were discussed and documented	No. of patients (65+) with ≥3 cc	GP survey/medical records
Involving partners, family, and caregivers	No. of patients who had a discussion whether and to what extent partners, family, and caregivers should be involved in important decisions	No. of patients (65+) with ≥3 cc	GP survey/medical records
Patient education/self-management	No. of patients who were offered participation in a patient training or support group or given a written self-management plan	No. of patients (65+) with ≥3 cc	Patient survey
Identification of patients with multimorbidity	No. of patients for whom the presence of multimorbidity was identified and labeled in their file	No. of patients (65+) with ≥3 cc	GP survey/medical records
Information about medication	No. of patients who were informed about their medication (indication, effect, intake)	No. of patients (65+) with ≥3 cc receiving pharmacological treatment	GP survey/medical records
Information about potential benefits and harms of treatment options	No. of patients who were informed about potential benefits and risks of treatment options prior to treatment decisions	No. of patients (65+) with ≥3 cc	GP survey/medical records
Shared decision making	No. of patients who state that they are involved in treatment decisions to the extent they wish	No. of patients (65+) with ≥3 cc	Patient survey
Mutual agreement on treatment goals	No. of patients with whom treatment goals were established	No. of patients (65+) with ≥3 cc	GP survey/medical records
Written treatment plan	No. of patients with a written treatment plan	No. of patients (65+) with ≥3 cc	GP survey/medical records
Medication review	No. of patients who received a review of their medication	No. of patients (65+) with ≥3 cc with long-term medication	GP survey/medical records
Regular updates of medication plan	No. of patients whose medication plan was checked for updates in the last 3 months	No. of patients (65+) with ≥3 cc with ≥3 long-term medications	GP survey/medical records
Monitoring adherence to treatment	No. of patients whose adherence to treatment was assessed	No. of patients (65+) with ≥3 cc	GP survey/medical records
Assessment of treatment burden	No. of patients who had a discussion of their treatment burden	No. of patients (65+) with ≥3 cc	GP survey/medical records
Assigning responsibility for coordination of care	No. of patients with whom it was agreed and recorded which health care provider is responsible for the overall coordination of care	No. of patients (65+) with ≥3 cc	GP survey/medical records
Comprehensive care documentation	No. of patients for whom reports from all health care providers involved are accessible to the care coordinator	No. of patients (65+) with ≥3 cc	GP survey/medical records
Documentation of adverse drug reactions	No. of included practices/units where the identification and documentation of adverse drug reactions follow a standardized procedure	No. of included practices/units	Practice survey
Training programs addressing the management of patients with multimorbidity	No. of practices/units where (a) at least one physician and (b) at least one member of the nonphysician staff have participated in training programs for multimorbidity	No. of included practices/units	Practice survey

Note: No. of patients = number of patients; cc = chronic conditions; GP = general practitioner; ICF = International Classification of Functioning, Disability, and Health.

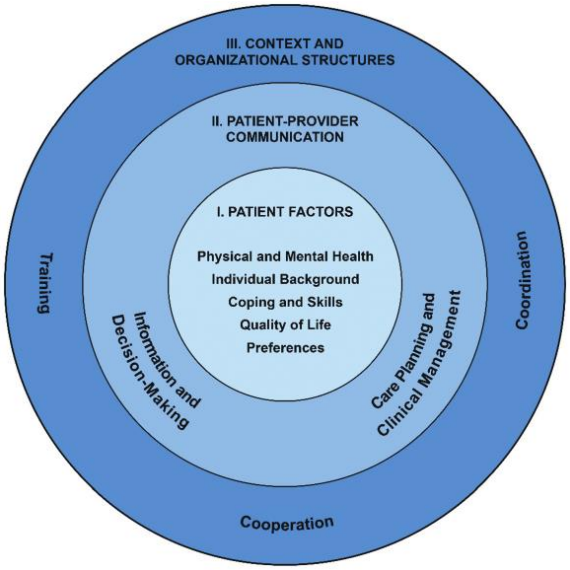

Figure 3. Conceptual framework of quality of health care for older adults with multimorbidity. *Note:* A guiding framework for categorizing quality indicators in relation to domains of care and different levels of influences that affect health care, adapted from Taplin et al. (2012).

evidence in this area (Smith et al., 2021). In our set, only a few indicators are based on the results of randomized controlled trials, whereas the majority is supported by lower levels of evidence. We addressed this limitation by integrating perspectives of patients, practitioners, and researchers to supplement systematic evidence with clinical expertise and lived experience and achieve greater acceptance among these user groups. In combining different approaches for patient involvement, we demonstrated the feasibility of a multilevel approach to patient involvement. Using focus groups, we were able to capture additional quality aspects not reflected in previous research. This project demonstrates how qualitative studies of patients' and carers' views on care pathways and (unmet) care needs can enrich traditional processes of indicator development. Another major strength of our study is the diversity of professional backgrounds within the expert panel. However, panel members were invited to participate based on their expertise and were not appointed as official representatives of stakeholder organizations.

The indicator set has only limited applicability to routine quality assessment. Because most recommendations in multimorbidity guidelines refer to communication and decision-making processes between providers and patients, the indicators address a broad spectrum of "soft" factors not captured in routine data. The lack of standardization of clinical documentation in ambulatory care poses an additional challenge for both research and quality management. Data collection requirements vary widely for medical practices, with more than 140 different practice management systems currently in use (National Association of Statutory Health Insurance Physicians, 2020). Nonetheless, our findings offer directions for future implementation in electronic documentation systems and can be adopted once documentation standards have been picked up. In addition, patient-reported experience data can be integrated into patient surveys, which are already a part of the legally required quality management for practices in Germany (Federal Joint Committee [GBA], 2020).

A distinct feature of our indicator set in comparison to condition-specific quality measures is the particular focus on processes of care. As older patients with multimorbidity are a heterogeneous target group, standardized health outcomes are difficult to compare. While adverse events, health-related quality of life, and functioning have previously been established as relevant quality domains (Valderas et al., 2019), studies have shown associations between those variables and different patterns of multimorbidity (Marengoni et al., 2020; Panagioti et al., 2015; Sum et al., 2019). Outcome parameters may be influenced by several factors beyond the control of practitioners, and some aspects of health care aspects will only show their impact on health outcomes within a longer time frame. In comparison, process indicators are more sensitive to changes in care (Mant, 2001) and less prone to differences in casemix (AHRQ, 2015).

Our findings are in many ways consistent with the NICE quality standards for multimorbidity (2017). Both sets took a generic approach to define quality of care in multimorbidity and share their mutual goal to describe measures sensitive to quality improvement, which applies to care processes as well as structures and outcomes. Vital aspects of patient-centered clinical management are reflected within both sets: defining responsibility for care coordination, discussing priorities and goals, and reviewing medication as well as other treatments. We also found similarities between the quality dimensions obtained in our study and an integrated model of patient-centeredness recently adapted for this target group (Kivelitz et al., 2021). Moreover, our framework aligns quality measurement with an approach to personalized clinical management based on patient preferences and shared decision making. Another person-centered measurement framework for people with multimorbidity was developed by the National Quality Forum (NQF, 2012). Unlike our project, their objective was to provide guidance for public reporting and performance-based payment programs. Therefore, the NQF framework also includes different providers and types of care that are not relevant to the user perspective of our project. A shared feature is that patient preferences are at the centerpiece of both conceptual frameworks. Likewise, the included aspects of quality relevant to primary care show great similarities. Two aspects missing from our set are advance care planning and health literacy. Both were covered in candidate indicators but were ultimately dropped in the second stage of the consensus process. During the discussion, it became clear that although both aspects were considered relevant, there was a lack of clarity in

operationalization and insufficient evidence to apply these indicators to the entire target group. It remained unclear which minimum requirements should be placed upon these processes and their documentation in order to provide a reliable operationalization. Outcomes such as advance health care directives in place were not considered equally relevant for all patients of the target group. Similarly, there was no majority on how to assess health literacy without imposing disproportionate burden on primary care practices. These considerations highlight the importance of further research in those areas and corresponding updates to the indicator set. A universally accepted approach to conceptualizing and operationalizing multimorbidity is still lacking (Johnston et al., 2019). Although our operationalization of multimorbidity as the presence of at least three chronic conditions clearly brings advantages in terms of practicality, there is reasonable doubt that the number of diagnoses can be regarded as a reliable unit of information. Application of these indicators in a primary care sample could yield further insights into effective identification of multimorbidity.

While developing indicators is essential to identify and control aspects relevant for quality improvement, their clinical utility strongly depends on their feasibility and their capability to indicate differences across providers (Campbell et al., 2002). As a next step, we conduct a field test in a sample of 35 GP practices and 350 older patients with multimorbidity to assess clinimetric properties of the indicators. Continued evaluation and refinement will be essential to adjust metrics across care settings and to determine which measures add value to clinical practice (AHRQ, 2011).

Conclusions and Implications

This study described the development of a comprehensive set of 25 indicators to assess health care quality for multimorbidity. We adopted an innovative approach, bringing together an established methodology for indicator development and active patient involvement. With these quality indicators, we aim to provide health professionals, researchers, policymakers, and educators in the field of aging with a building block for managing multimorbidity in the face of changing demographics. The indicator set can be used for quality monitoring in primary care as well as health care research and will be proposed as an additive element for the German multimorbidity guideline. The indicators are an alternative to the inadequate combination of disease-focused quality metrics and can be used to promote patient-centered care for this target group. They will help to elicit approaches to quality improvement and advance standardization of care delivery. Nevertheless, their implementation should be continuously evaluated in order to promote dynamic maintenance and adaptation of the indicators.

Supplementary Material

Supplementary data are available at *The Gerontologist* online.

Funding

The MULTIqual project was supported by the Innovation Fund of the Federal Joint Committee (G-BA; grant no. 01VSF16058). The funding body had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Conflict of Interest

M. Scherer, D. Lühmann, and I. Schäfer authored the DEGAM guideline on multimorbidity but did not take part in its quality assessment or data extraction. All other authors declare that they have no competing interests.

Acknowledgments

We thank all expert panel members for their most valuable input and contribution to the project: Dr. Dominik Ahlquist, Prof. Dr. Katrin Balzer, Prof. Dr. Andreas Büscher, Martin Beyer, Dr. Tobias Braun, Dr. Klaus Döbler, Udo Ehrmann, Dr. Peter Engeser, Dr. Johannes Falk, Dr. Markus Follmann, Annette Hans, Joachim Kolb, Dr. Detlef Niemann, Johannes Petereit, Stefanie Restle, Anne von Reumont, Dr. Christa Scheidt-Nave, Andrea Schreiter, PD Dr. Hanna Seidling, Marianne Simon, Prof. Dr. Petra Thürmann, Dr. Gerald Willms, and Gaby Winter. We are grateful to all patients and their family members who supported this project. We also thank Prof. Dr. Frank-Peters Klimm and Prof. Dr. Hendrik van den Bussche for their feedback on candidate quality indicators.

Ethics Approval and Consent to Participate: Ethics approval was obtained from Ethics Committee of the Hamburg Medical Association on September 10, 2018 (file no. PV5846), Clinical Ethics Committee Heidelberg on December 19, 2018 (file no. S-665/2018), and Medical Association of Baden-Wuerttemberg on November 13, 2018 (file no. B-F-2018-096). All study participants gave written informed consent prior to their participation in the study.

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Supplementary materials:

Available from gnac013_suppl_supplementary_material.docx (live.com)

Additional file 1: Search strategy for the systematic literature search

Additional file 2: Quality appraisal of included guidelines using AGREE I

Additional file 3: Example of inductive coding procedure - excerpt from the coding manual

Additional file 4: Quality indicators rejected by the expert panel

Study 2: Quality of Care for People with Multimorbidity - A Focus Group Study with Patients and their Relatives

Open access Original research

BMJ Open

Quality of care for people with multimorbidity: a focus group study with patients and their relatives

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To cite: Pohontsch NJ, Schulze J, Hoeflich C, *et al*. Quality of care for people with multimorbidity: a focus group study with patients and their relatives. *BMJ Open* 2021;**11**:e047025. doi:10.1136/bmjopen-2020-047025

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-047025).

Received 16 November 2020
Accepted 12 May 2021

Check for updates

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ABSTRACT

Background Prevalence of people with multimorbidity rises. Multimorbidity constitutes a challenge to the healthcare system, and treatment of patients with multimorbidity is prone to high-quality variations. Currently, no set of quality indicators (QIs) exists to assess quality of care, let alone incorporating the patient perspective. We therefore aim to identify aspects of quality of care relevant to the patients' perspective and match them to a literature-based set of QIs.

Methods We conducted eight focus groups with patients with multimorbidity and three focus groups with patients' relatives using a semistructured guide. Data were analysed using Kuckartz's qualitative content analysis. We derived deductive categories from the literature, added inductive categories (new quality aspects) and translated them into QI.

Results We created four new QIs based on the quality aspects relevant to patients/relatives. Two QIs (patient education/self-management, regular updates of medication plans) were consented by an expert panel, while two others were not (periodical check-ups, general practitioner-coordinated care). Half of the literature-based QIs, for example, assessment of biopsychosocial support needs, were supported by participants' accounts, while more technical domains regarding assessment and treatment regimens were not addressed in the focus groups.

Conclusion We show that focus groups with patients and relatives adding relevant aspects in QI development should be incorporated by default in QI development processes and constitute a reasonable addition to traditional QI development. Our QI set constitutes a framework for assessing the quality of care in the German healthcare system. It will facilitate implementation of treatment standards and increase the use of existing guidelines, hereby helping to reduce overuse, underuse and misuse of healthcare resources in the treatment of patients with multimorbidity.

Trial registration number German clinical trials registry (DRKS00015718), Pre-Results.

Strengths and limitations of this study

- ► Affected patients and their relatives (who often function as informal caregiver) were interviewed in the focus groups.
- ► Focus group participants from two differently structured regions in Germany representing a wide spectrum of combinations of different diseases were queried.
- ► Focus groups with patients and their relatives (asking about positive and negative experiences with care) seem to be an effective tool to identify quality aspects relevant to quality indicator development.

INTRODUCTION

Our society is ageing and higher life expectancy is associated with higher rates of chronic diseases. Care for patients with multimorbidity is likely to evolve into one of our most prominent challenges in the future.[1 2] Multimorbidity is strongly linked to functional limitations, lower quality of life and increase in healthcare utilisation, costs and higher mortality.[3 4] Care for patients with multimorbidity is very complex[5] and therefore prone to deficits in quality and major (unintended) interindividual differences regarding the impact of illness and carer performance.[6–9] Multimorbidity creates many challenges to general practitioners (GPs) and affected patients alike, for example, (too) short consultation times, polypharmacy, increased healthcare utilisation, high treatment burden and self-management requirements as well as psychological distress.[10 11] Several decades of research and discussion have provided us with suggestions for management approaches in primary care to better address the needs of this patient group, inter alia, the Chronic Care Model[12 13] and the meta-algorithm[14] for treating patients with multimorbidity.

Generic standards for high quality of care are hard to define due to the infinite number of possible (combinations of) medical problems in patients with multimorbidity. Evidence-based standards relevant to patients with multimorbidity are urgently

needed, because single-disease clinical guidelines are for several reasons often inadequate for this patient population.[10] As long as the current state of healthcare cannot be mapped systematically, for example, by using a set of quality indicators (QIs) specific for multimorbidity, it remains impossible to compare the effects of interventions and healthcare models to optimise quality or to identify sectors, regions or healthcare providers needing improvement.

In Germany, the first point of contact in the healthcare system for people who fall ill is usually a GP. GPs are usually licensed to provide care on the basis of contracts with the statutory health insurance (SHI) and are members of the corresponding association of SHI doctors. The SHI covers about 90% of Germany's residents and is complemented by a private health insurance system. German GPs have usually completed 5 years of further training to be allowed to call themselves specialists in general practice/primary care. Patients are free to consult any GP unless they choose to enrol themselves in a GP contract ('Hausarztzentrierte Versorgung'). The contractually defined GP-coordinated care further strengthens the role of the GPs as guides and coordinators for the healthcare of their patients.[15] GPs refer patients to outpatient specialists or hospitals when further or specialised care is needed. There are more than 100 different types of patient record management software[16] and usually the patient records of different doctors are not linked, which means that their communication and coordination often rely on (referral/discharge) letters and patients' reports.

Taking the patients' perspective into consideration is even more relevant when dealing with patients with multimorbidity. Every decision made concerning risks and benefits of treatments and interventions has to be weighed against individual impairments, comorbidities and gain in subjective quality of life.[14] Prioritisation must take the whole range of biopsychosocial complexities into account and follow principles of patient-centred clinical management and decision-making. Views on high-quality healthcare often differ between patients and their healthcare providers.[17 18] For example, quality of care seems to be higher when process or intermediate outcome indicators are measured and lower when patient-reported experiences of care are reviewed.[18] Therefore, patients[19] can and must be involved in guideline and QI development.[20–23] Studies show that this is not often the case[21] even though approaches to patient involvement in QI development, for example, focus groups, exist and are considered to be of high value.[20]

The MULTIqual Project aims for the development of a QI set which can be used to evaluate the current state of healthcare provided for patients with multimorbidity and to promote the implementation of treatment standards for future care. We conducted focus groups with patients with multimorbidity and their relatives to validate and amend a literature-based and expert consensus-based set of QIs by qualitatively surveying their views on healthcare quality.

METHODS

The MULTIqual Project is a multicentre mixed-methods project comprising a systematic literature review, focus groups, a two-stage expert consensus process, and a quantitative survey with patients with multimorbidity and GPs. Following the Consolidated criteria for Reporting Qualitative research,[24] this paper presents the results of focus groups with patients with multimorbidity and their relatives conducted in Hamburg and Heidelberg and of the expert consensus on the qualitatively derived QIs. The details of the systematic literature review, expert panel, consensus process and QI development process are not directly relevant to the work presented here, but can support the understanding of the whole project. A summary of the process can be found in online supplemental file 1. An extensive description will be presented elsewhere (manuscript in preparation).

Participant selection and recruitment

We randomly selected the GPs from the register of SHI-accredited doctors of the city districts or within a radius of 25 km around the two study centres, respectively. We invited the selected GPs to participate in our study and informed them in detail about the project if they were interested. Participating GPs were asked to recruit patients aged 65 years and above with three or more chronic conditions who attended the practice at least once in the last 3 months. Patients with multimorbidity willing to participate were asked to invite close relatives to take part in the study as well. Exclusion criteria were insufficient knowledge of the German language and inability to give informed consent. Patients received an invitation containing study information, a response sheet and a reply envelope. Participants received an allowance of €30 plus a reimbursement of travel expenses. Participants gave written informed consent for the focus groups to be recorded, transcribed and the data being published anonymously.

Focus group guide

Guide development was based on the literature review (eg,[25]) and the research questions outlined above. As lay persons mostly relate to implicit experiential knowledge when defining quality criteria (eg,[26 27]), we chose to question our focus group participants about their own positive and negative experiences with primary healthcare, changes in their healthcare needs and experiences due to multimorbidity, and their vision of ideal primary care for people like them (see online supplemental file 2 for 'patients' focus group guide'). With patients' relatives, the same topics were discussed in respect of the associated patient with multimorbidity (see online supplemental file 3 for 'relatives' focus group guide').

Data collection

Either JS, CH, AB or KG had spoken to the participants on the phone, but had no other relationship with them. In December 2018 and January 2019, we conducted

eight focus groups with patients with multimorbidity (city A=3, city B=5) and three focus groups with patients' relatives (A=1, B=2) using the semistructured guides described above. Two moderators facilitated the focus groups (NJP, JS, KG, AB, CH and TKl, respectively) which lasted about 2 hours. Discussions were digitally recorded and transcribed verbatim by a trained research assistant following designated transcription rules. Accuracy of the transcripts was checked by the respective moderators. In order to protect the focus group participants' identity, names and other identifying details were changed during transcription.

Data analysis

Data were analysed using the qualitative content analysis approach described by Kuckartz,[28] following a realistic paradigm.[29] Coders (NJP, CH and JS) read all transcripts to familiarise themselves with the data. Transcripts were broken down into fragments adopting different sizes ranging from part of a sentence to one or more paragraphs in relation to the segment length needed to understand the content and context of the relevant accounts. We created deductive codes representing the aspects of quality described in the literature-based QI set and selected by the expert panel and inductive codes when new aspects of quality emerged from the data (see below). We then subjected all transcripts to a second round of coding by a different coder. Coding was carried out with constant discussions between the three coders about the coded text passages and assigned codes. To ensure intersubjective reproducibility and comprehensibility,[30] the results were presented to and discussed with the interdisciplinary workgroup 'qualitative methods' and the coauthors DL (postdoctorate, MD) and MS (professor, MD). Data were managed using MAXQDA V.11 (Verbi).

Identification of additional patient-relevant quality aspects and expert rating of deduced QI

We aimed to supplement the preliminary QI set extracted from a systematic literature review by QI based on patient-relevant quality aspects derived from the focus group data. A multidisciplinary research team (NJP, CH, KG, AB and JS) allocated subjectively important quality aspects from patients' and their relatives' views to the preliminary set of QIs based on the literature review and identified important additional quality aspects where needed. Afterwards, the research team transformed the additionally identified quality aspects into QI (including description, numerator, denominator, exclusion criteria, etc). These QIs were presented by NJP to an expert panel during an in-person meeting. The expert panel consisted of representatives of primary care, nursing, practice management, quality research methodology, social work, physical therapy, geriatrics, clinical pharmacology, social medicine and patient representatives. The in-person meeting took place on 1 February 2019. During the meeting, NJP presented the focus group material-based new QI to the expert panel. After a rating of relevance, strength of evidence and their potential for undesirable effects, the expert panel voted for keeping or rejecting the QI deduced from the focus group material via nominal group technique.

Patient and public involvement

Patients were involved in the recruitment of focus group participants (viz. their relatives). Patient representatives and representatives of relevant fields (see above) were involved in the rating and selection of QI. Apart from that, there was no patient or public involvement in the study.

Researcher characteristics

Researchers' characteristics, beliefs and assumption influence qualitative research and data interpretation. NJP (♀): post-doc psychologist, experienced qualitative researcher (patient involvement in QI development, healthcare research focusing on general practice); JS (♀): psychologist/junior scientist; CH (♀): medical student; AB (♀): junior scientist, M A Health Information Management; DL (♀), KG (♀), JSz (♂), MS (♂): medical professionals, experienced post-doc researchers in the field of general practice and QI development.

RESULTS

Participants' characteristics

We included 29 female and 18 male patients aged 65–84 years as well as three female and six male relatives (five spouses/four children) aged 49–78 years in five patient groups, and three relatives groups, respectively. Nine registered volunteers did not take part, with n=3 due to acute health problems and n=6 due to organisational difficulties.

Focus group-based additional quality aspects included into the QI set after the expert panel rating

Two focus group-based quality aspects were finally supported by the expert panel and included in the QI set.

Patient education/self-management

Patients consider it very helpful to be informed about their diseases and possible (self-)treatment and management strategies (for example, nutrition counselling). Daily disease management can be supported by specific information on self-management strategies, training in disease-related competencies (for example, measuring the INR (International Normalized Ratio) value), addressing coping strategies and provision of knowledge for the patient.

> I took part in a course in [city] and have been monitoring my 'Quick' [prothrombin time] myself for over 20 years and I have a book and also keep a record. And I always took it with me to the hospitals and the doctors were amazed that they could see exactly how I did it and how I tested my 'Quick'. […] And I always write it down and then I

dose the medication myself. No, I am still grateful to the doctor for giving me the tip that I can do the course how to measure my 'Quick' on my own […]. (city B, patient focus group A, paragraph 162–166)

Regular updates of medication plan

Patients report to have been provided with medication plans and consider it very important for them to be up to date especially when taking a high number of different medications or when medication is prescribed by specialists. Some patients always have copies of their medication plan at hand in case of an emergency and it would be considered helpful if this plan was accessible electronically on the health insurance card.

This is also from the GP, right? It's a medication plan. So you know when to take it and so on. One should know that. But also that you can show it, if someone asks: 'What are you taking?' Oh god, yes, what am I taking? What's it called again? It just changed again, hasn't it? Well, I know it, but it's also good for the other doctors if they have something printed and to be able to see exactly what she needs, what she takes, how often and when […]. So, it is very pleasant when GPs do something like that. Gives you a certain amount of security. (city A, patient focus group B, paragraph 251–253)

Focus group-based additional quality aspects not included into the QI set after the expert panel rating

Two other indicators were not supported by the expert panel and not included in the final QI set.

Regular check-ups

Patients with chronic diseases see a need for regular check-ups as it would allow for early detection of health deterioration and they know these procedures from the disease management programmes, for example, for diabetes or chronic obstructive pulmonary disease (COPD). They value the regular contact with the GP at fixed appointments.

[…] if you take these medications regularly and then say: "We'll have a general check-up once every two years" – I think that's not enough. I think it should be every year. The status should be checked once in a while, if I'm taking these pills regularly. (city A, patient focus group C, paragraph 97)

GP-coordinated care

Patients appreciate the GPs to coordinate their care which involves, for example, writing referral letters for specialist visits (and the GP receiving medical reports), having a network of specialists at hand, planning preventive measures, and keeping track of medications and their interactions and side effects. Patients who describe their relationship with their GP as trusting want all information on their healthcare to converge at their GPs' practice.

[…] when the diagnoses are made and the GPs know what's going on, then they should actually act as a control center and have the possibility to coordinate everything. (city A, patient focus group A, paragraph 264)

That's a given in our practice. He always wants to give you referrals because he wants to have doctor's letters. Otherwise he says he doesn't have an overview. And I think that's very, very good. (city B, relatives' focus group A, paragraph 66)

Literature-based quality aspects supported by focus groups

Table 1 gives an overview of quality aspects identified in the literature review and supported by both focus groups and expert consensus and shows supporting quotes from the focus groups. Descriptions of categories shown in table 1 follow below.

Assessment of biopsychosocial support needs

Patients expressed a need for the GP to have a holistic view on the patient's health problems and needs. They underlined the importance of not only seeing and treating physical symptoms, but also the overall picture of medical and psychosocial aspects of the patient's situation. They consider it important for the GP to have at least basic information on the patient's background and personal history. Sometimes house calls can be necessary for a realistic judgement on biopsychosocial support needs, for example, for elderly people with beginning dementia.

Involving partners, family and caregivers

Relatives of people with multimorbidity often appreciate the GPs' willingness to communicate with them and support them in the process of giving care. Support and advice are often desperately needed by informal caregivers of persons with multimorbidity, especially if dementia is an issue. GP's awareness of informal caregivers' problems and concerns is important and could, for example, be addressed by offering consultation hours for relatives and other informal caregivers.

Shared decision-making and mutual agreement on treatment goals

Shared decision-making to find a customised treatment approach for individual patients is highly appreciated by the focus group participants. Communicating, informing and deciding on treatment regimens and goals on a par with the patient are seen as essential for increasing adherence and patient satisfaction. Patients value the freedom to set their own priorities and make decisions based on their values and preferences concerning their health and healthcare behaviour. They appreciate their GPs

Table 1 Quality aspects identified in the literature and supported by focus groups and expert panel ratings

Patient-related factors	Assessment of biopsychosocial support needs	"So for me, I would like to see myself not only as a body, or only as organs, but as a complex human being. That's very important for me,(…)this union of body, mind and soul." (city B, patient focus group A, paragraph 70) "This is certainly an aspect that the doctors should(…)actually take a closer look at again: What is the situation at home? Does the person need support? Do we have to organize something?" (city B, relatives' focus group A, paragraph 91)
	Involving partners, family and caregivers	"Perhaps this could be discussed in a phone call with relatives, so that I am informed about the current situation, what is pending or how the medication maybe, yes, what I have to pay attention to as a caring relative and, as I said, if this is okay for my mother, as I know that she is not informed at all." (city B, relatives' focus group A, paragraph 174)
Physician–patient interaction	Shared decision-making and mutual agreement on treatment goals	"A doctor's sole decision: (.) "Do this or that" - if the patient doesn't agree, it is pointless (…). He won't do it anyway. (…) And that's why I think that those issues really need to be discussed together. And determined together what is possible for the patient. Not everything is possible." (city A, patient focus group A, paragraph 468) "(…)we discussed it(…)at eye level in a VERY thorough conversation, so that we decided on the therapy regimen together, which I follow, and use take control of the disease." (city A, patient focus group A, paragraph 21)
	Information about medication and potential benefits and harms of treatment	"It's important to me(…)that I get information in an(…)understandable way about what is going on with me and how this could be treated." (city A, relatives' focus group A, paragraph 357) "And then that in some cases he may explain the disease. Not the disease, but the measures, that's the way I wanted to put it. But then we come back to the time factor again. But in some cases, as I said, it is done this way. So that you get a little more time and get information about what is actually going on and what you can do about it. Or against it." (city B, relatives' focus group B, paragraph 98) "But it's just that when I get pills and it says this and that and you don't even know what it's for.(…)" (city B, patient focus group C, paragraph 43)
	Medication review and documentation of adverse drug reactions	"Especially in the case of multiple chronic diseases, I find it extremely important that the general practitioner explains to me that the drugs are compatible, that there is no interaction or that it is possible that they will cancel each other out or even worsen the condition, as in the case of my mother(…)" (city B, relatives' focus group A, paragraph 69) "I also consider close monitoring of drug effects and side effects important. Because there are side effects that one does not even register, which develop so insidiously. So it's a good thing that experts with their backgrounds check for possible side effects and say: "Watch this, something is happening to you, that doesn't fit in or it's a side effect". Because I only read the package insert when I really have something and suspect a side effect. I do not read them in advance. Because then you don't take the drug." (city A, relatives' focus group A, paragraph 357)
	Written treatment plan	"I packed a little something from my management. I don't know if you know anything like that, here is a blood sugar diary for people on insulin. This is from the diabetes clinic. It contains all my data, every record, both blood sugar levels and blood pressure and then the insulin dose. And I also check my weight and write it down here, so I always keep everything together. And I take this to my general practitioner as well as to the other doctors, for example, to the eye specialist. And I think that's good." (city A, patient focus group A, paragraph 167–168)

Continued

Table 1 Continued

Context and organisational structures	Comprehensive care documentation	"I think(…)to keep an overview of the attending specialists is actually very important. Because(…)when I go to the eye specialist or ear, nose and throat specialist, and the GP doesn't even know this, and usually doesn't get a medical report from them either, then he is actually missing out(…)on important information. I could have glaucoma, or whatever. And he doesn't even know about it and he doesn't even know what kind of medication you might have to take.(…)" (city A, patient focus group A, paragraph 466)
	Training programmes addressing management of patients with multimorbidity	"Whereby I have to say with my GP's joint practice, you can't complain. So there are two [employees], I think, they are still trained nurses. That's how long they've been at it. They are REALLY competent. And I'd say they already have a certain diagnostic instinct. They can tell when someone comes in with swollen eyes, whether it's just a flu-like infection or a real flu, that he should perhaps be isolated." (city A, relatives' focus group A, paragraph 108) "Well, of course we have the problem that we have more and more elderly people who are sick, and have multiple diseases. And we have fewer and fewer GPs. So, I think it would be a very good care model if we had, for example, registered physicians who specialize in geriatrics. I think it would be a good care model if we had general medical training, with additional specialization, for example, in mental health. I would prefer geriatrics and that these doctors with such training, who also have many, many or mostly older patients, are given more time. That perhaps, there are also these reference numbers, what they can charge. Because, we have to get there, because there are more and more elderly people, that they would get the possibility, the aspect of time and if it is only five min. Five minutes is a lot per patient. But that is of course an idle wish(…)" (city B, patient focus group A, paragraph 85)

supporting them in this approach and the autonomy this respect gives them.

Information about medication and potential benefits and harms of treatment

Our focus group participants did not differentiate clearly between information and advice on their diagnosis, disease or condition and risks, medications (for example, indication, dosage and interactions), or non-pharmacological treatments and their benefits and potential side effects. They emphasise the importance of detailed and comprehensible information on all these aspects. Either way, some stated not to be interested in very detailed descriptions of potential risks and side effects. The amount of information given must be tailored to the patient's needs even though these consultations might need more time than usually budgeted.

Medication review and documentation of adverse drug reactions

Medication reviews are highly acclaimed by the focus group participants. Patients and their relatives wish for the GP to check for interactions regularly especially with medication prescribed by others and over-the-counter drugs. They expressed criticism of the high numbers of prescribed drugs and low engagement of health professionals to actively inquire about drug-related problems and to search for highly tolerable medications. Patients focus less on the thorough documentation of adverse drugs reactions than on their monitoring and handling. They wish for the GP to detect signs of adverse effects and monitor them, for example, through regular follow-ups.

Written treatment plan

Focus group participants recognise the value of written treatment schedules that include overviews on scheduled healthcare appointments plus instructions, for example, whether they have to appear with an empty stomach for bloodwork. They emphasised the advantages of automated recalls systems. Another focus was on recorded treatment protocols, for example, keeping a blood pressure journal or a diabetes log book containing measured values and other relevant parameters. Patients proposed using digital solutions for facilitating care coordination between different providers.

Comprehensive care documentation

The vast majority of the focus group participants consider comprehensive care documentation as a vital part of high-quality care, emphasising importance of the exchange of information on diagnostic testing or examination results and prescribed medication, giving the GP the opportunity to coordinate care and consult the specialist about the patient's treatments. Patients report that the responsibility for this exchange is often in the patients' hand, being the ones to take care of specialists' letters being issued to the GP. Under the premise of data security, patients would support a digital exchange of doctor's letters, but sometimes doubt the 'digital competencies' especially of the older generation of physicians.

Table 2 Literature-based quality aspects not supported by focus groups

Patient-related factors	Screening for depression
	Proactive pain assessment
	Monitoring of pain management
	Addressing financial support needs
	Quality of life assessment
	Assessment of symptom burden
	Establishing patient preferences
Physician–patient interaction	Identification of patients with multimorbidity
	Assessment of treatment burden
	Monitoring adherence to treatment
Context and organisational structures	Assigning responsibility for coordination of care

Training programmes addressing management of patients with multimorbidity

Patients put emphasis on the competencies of the practice team. For medical assistants this means, for example, being experienced in taking blood samples or administering vaccinations or injectable medications. Another aspect is the ability to triage patients according to the severity and urgency of their treatment needs. GPs should engage in continuous medical education, be up to date on actual research results and technological advances. Participants valued additional training in the field of geriatrics or psychology and proposed regular supervision and peer consultation for complex problems in multimorbid patients.

Literature-based quality aspects not supported by focus groups

Table 2 gives an overview of quality aspects identified in the literature review and supported by the expert panel but not accounted for in focus groups. As this paper focuses on the focus group result, these quality aspects are described extensively elsewhere (manuscript in preparation).

DISCUSSION

Main results

By asking patients with multimorbidity and their relatives in focus groups about their experiences with primary healthcare, we were able to identify important quality aspects from their point of view and derived four new patient-relevant QIs to date not represented in guidelines or the literature on quality of care in multimorbidity. Out of these, two QIs concerning regular updates of written medication plans and patient education and fostering self-management were supported by the expert panel. On the other hand, regular check-ups and GP-coordinated care were not supported by the expert panel. Half of the literature-based QI, for example, assessment of biopsychosocial support needs, establishing patient preferences and shared decision-making, were supported by participants' accounts, while more technical domains regarding assessment and treatment regimens were not covered in the focus groups.

Strength and limitations

To obtain a comprehensive picture of aspects of quality of care from the affected persons' point of view, we asked not only patients with multimorbidity, but also their relatives (often informal caregivers) in separate groups. Focus group participants were recruited in two very differently structured regions of northern and southern Germany and represent a wide spectrum of combinations of different diseases. We therefore assume that our results might be cautiously generalisable to patients with multimorbidity in primary care all over Germany. However, the experiences reported by patients with multimorbidity and their relatives in the focus groups may to some extent be specific to the German healthcare system. In other countries, such as the UK, for example, medication reviews and the provision of medication information are the responsibility of pharmacists. Our results should not be transferred to other countries without cautious reflection, as the organisation of healthcare systems and the implementation of (primary) care differ between Germany and other countries.

Reflecting and evaluating own experiences are dependent on representation of different perspectives, lived experiences and group interaction, and must be fragmentary, as participants were lay persons regarding healthcare (quality). Therefore, it did not seem feasible to ask the participants to propose QI. Instead, we focused on positive and negative experiences with primary care and derived patient-relevant QI indirectly. As many accounts can be matched to QI derived from the literature and half of the newly developed QIs were supported by expert consensus, this methodology seems to be plausible and practicable.

Although the questions focused on experiences regarding the related patients with multimorbidity, the results from focus groups with relatives show that for some participants it was difficult to focus on their role as (caregiving) relative. Many participants referred to their own healthcare experiences being affected by multiple conditions themselves, which reflects the spectrum of issues and challenges in the field as the prevalence of multimorbidity increases in older age.[31]

Discussion of results and comparison with existing literature

The complexities of managing multimorbidity are widely known[10] and there is a growing amount of literature on interventions for improving outcomes in patients with

multimorbidity.[11 32] Different approaches to tackle the challenges of caring for patients with multimorbidity were discussed, from the Chronic Care Model,[13] a systematic collection and review of interventions[32] and quality standards[33] to a German meta-algorithm,[14] but a QI set involving the perspective of affected patients and their (potential) informal caregivers is still missing.

Since 2016, patients enrolled in SHI in Germany have a right to be provided with a recorded medication plan if they are prescribed at least three different long-term medications, which is very much appreciated by persons with multimorbidity in our study and elsewhere.[34] If patients consent, these data can be saved to the electronic health card or record to allow for a standardised digital exchange of this information of these data between providers.[35 36] Despite preferring a written medication plan and stating the problem of insufficient communication between prescribing physicians, participants of our focus groups judged this incorporation ambivalently as they saw problems concerning data safety and confidentiality[37] as well as (older) GPs' digital literacy.

Patients with multimorbidity wish for patient education, fostering of self-management and periodical check-ups might arise from their experiences with patient education and regular control of, for example, blood values, respiratory function and blood pressure during the structured disease management programmes (DMPs, eg,[38]) that many patients with diabetes, COPD or heart failure take part in. DMPs for single diseases and lone-standing self-management interventions for patients with multimorbidity have shown to be helpful (eg,[39 40]), which supports the patient-education QI (see also[19]). While a recent systematic review supports the importance of monitoring treatment effects and clinical parameters,[11] this is no plea for generalised periodical check-ups without a definite indication.

The proposition of a GP-coordinated care was not supported by the expert panel as this care model is not yet sufficiently embedded within routine care in Germany,[41] although §73 SGB V[42] makes way for general practitioner-centred primary care (coordination) since 2003, which is also highlighted in the policy paper of the German College of General Practitioners and Family Physicians from 2012.[43]

Literature-based QIs validated by the focus group focus mostly on aspects that address interpersonal communication, holistic treatment approaches and processes that allow patients to make their own choices based on comprehensive information. This aligns our findings with the wide scientific consensus that the treatment of patients with multimorbidity should be informed by a patient-centred approach.[19 44–46] The majority of the quality statements proposed by the National Institute for Health and Care Excellence[33] align with the indicators resulting from our study (eg, 'assessing values, priorities and goals', 'care coordination' and 'reviewing medicines and other treatments'). All measurement frameworks seem to have one thing in common: taking shared decision-making into account as central aspect of patient-centred care.[47]

An explanation for the lack of support for the QI dealing with screening and assessment issues in the focus groups might be due to the participants' perspective as individuals and end users of care structures and processes. Qualitative methods are mostly able to elicit patients' personal experiences with and views on healthcare (processes) and lay persons are seldom confronted with meta-level issues directed at groups of patients and not individual patients.

Other projects aiming for the development of quality frameworks in multimorbidity predominantly focused on outcome measurement.[48–50] Scientific evidence on generic health outcome measures to assess quality of care for patients with multimorbidity is still lacking. In the light of individual goals and priorities of patients with multimorbidity, it proves difficult to define outcome indicators suitable for all. Keeping that in mind, our QI set addressing mainly care processes and covering a broad range of care domains is evidence based and seems to be very adequate for the evaluation of quality of care for patients with multimorbidity.

Future research

Primary care patients (≥65 years) and their GPs will be questioned using standardised patient-reported outcome measures (related to the identified QI) and other instruments (measuring behaviour described in the identified QI) to study validity and applicability of the developed set of QIs. The definite set of QIs will be determined based on the study results.

Practical implications

The QI set finally developed in the MULTIqual Study can be used as a framework for assessing the quality of care in the German healthcare system. It will facilitate implementation of treatment standards, increase the use of existing guidelines,[14 51] and help to reduce overuse, underuse and misuse of healthcare resources. The QI set will serve as a reference framework for future evaluations of complex interventions and care models for patients with multimorbidity.

CONCLUSION

Our study has demonstrated that focus groups with patients and their relatives adding important aspects in QI development should be incorporated by default in QI development processes and constitute a reasonable addition to traditional QI development.[19 20] Future challenges lie in the adoption of these quality criteria as practical and valid standardised measures and their implementation in primary care.

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Acknowledgements We would like to thank all patients and their relatives for their time and effort invested in participating in the focus groups, the experts for participating in the expert panel, Tabea Eissing for her contributions to the

development of the focus group guides and Thomas Kloppe for co-moderating one of the focus groups.

Contributors MS, DL and JSz—acquisition of funding for and conception, design and supervision of the study. AB, KG, NJP and JSc—moderation of focus groups. AB, KG, CH, NJP and JSc—data analysis and interpretation. NJP—drafting of the manuscript. AB, KG, CH, DL, JSc, JSz and MS—critical revision of former versions and final approval of the manuscript.

Funding This work was supported by the Innovation Fund of the Federal Joint Committee (G-BA; grant no. 01VSF16058).

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Ethics approval was obtained from the Ethics Committee of the Hamburg Medical Association, (10 September 2018, PV5846), from the Clinical Ethics Committee Heidelberg (19 December 2018, S-665/2018) and the Medical Association of Baden-Wuerttemberg (13 November, B-F-2018-096).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. The data generated and analysed during the current study are not publicly available due to the study's assurances to participants that the full raw focus group data would not be shared publicly, and that all attempts would be made to maintain confidentiality. We named the people who are responsible for data analysis to the focus group participants in the written consent and they did not agree with the sharing of the full raw data.

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Supplementary materials:

Additional file 1: Literature review and rating/consensus process

bmjopen-2020-047025supp001_data_supplement.pdf

Additional file 2: Guideline for focus groups with patients

bmjopen-2020-047025supp002_data_supplement.pdf

Additional file 3: Guideline for focus groups with relatives

bmjopen-2020-047025supp003_data_supplement.pdf

Study 3: Adaptation and Validation of a German Version of the Multimorbidity Treatment Burden Questionnaire

Schulze *et al.*
Health and Quality of Life Outcomes (2022) 20:90
https://doi.org/10.1186/s12955-022-01993-z

Health and Quality of Life Outcomes

RESEARCH Open Access

Adaptation and validation of a German version of the Multimorbidity Treatment Burden Questionnaire

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Abstract

Background: Patients with multiple long-term conditions often face a variety of challenges arising from the requirements of their health care. Knowledge of perceived treatment burden is crucial for optimizing treatment. In this study, we aimed to create a German version of the Multimorbidity Treatment Burden Questionnaire (MTBQ) and to evaluate its validity.

Methods: The steps to translate the MTBQ included forward/back translation, cognitive interviews ($n=6$) and a pilot test ($n=7$). Psychometric properties of the scale were assessed in a cross-sectional survey with primary care patients aged 65 and older with at least 3 long-term conditions ($n=344$). We examined the distribution of responses, dimensionality, internal reliability and construct validity.

Results: Cognitive interviewing and piloting led to minor modifications and showed overall good face validity and acceptability. As expected, we observed a positively skewed response distribution for all items. Reliability was acceptable with McDonald's omega = 0.71. Factor analysis suggested one common factor while model fit indices were inconclusive. Predefined hypotheses regarding the construct validity were supported by negative associations between treatment burden and health-related quality of life, self-rated health, social support, patient activation and medication adherence, and positive associations between treatment burden and number of comorbidities. Treatment burden was found to be higher in female participants ($Mdn_1=6.82$, $Mdn_2=4.55$; $U=11{,}729$, $p=0.001$) and participants with mental health diagnoses ($Mdn_1=9.10$, $Mdn_2=4.55$; $U=3172$, $p=0.024$).

Conclusions: The German MTBQ exhibited good psychometric properties and can be used to assess the perceived treatment burden of patients with multimorbidity.

Keywords: Primary care, Comorbidity, Quality of life, Patient-reported outcome, Patient-centred care, Adherence

Background

More and more elderly people are affected by multiple health problems and face a significant burden in managing these conditions [1, 2]. Patients with multimorbidity are often seen by multiple primary and secondary healthcare professionals, each advising different treatment, including long-term medications and recommendations for diet and exercise. There is a growing body of literature recognizing the critical role of treatment burden in chronic care [3]. This concept describes the workload of health care-related tasks and its impact on patients' daily lives and their well-being [4]. There is a positive correlation between treatment burden and the number

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of conditions [5, 6], especially in discordant conditions with different pathophysiologic profiles and/or treatment strategies. Tran et al. [7] found that about 40% of people with long-term conditions do not feel able to sustain the present efforts for their care in the future. Although patients with a poor overall health status spend more than 3.5 h per week on health-related self-care, clinicians tend to overlook their workload [8].

Boyd et al. [9] demonstrated in their classic example of a hypothetical 79-year-old woman with diabetes, chronic obstructive pulmonary disease (COPD), osteoporosis, hypertension and osteoarthritis how following single clinical practice guidelines can lead to a complex and contradictory treatment regimen with 19 daily doses of medication and 14 non-pharmacological recommendations. The authors concluded that for patients with complex care needs, individual treatment burden, potential risks and benefits should be taken into account in a shared decision-making process. Shippee et al. [10] used the *Cumulative Complexity Model* to illustrate that overburdening and non-adherence occur when patients' treatment-related workload is greater than their capacity to cope with these demands. A recent systematic review outlines that treatment burden is determined not only by health care-related workload and individual abilities and resources, but also by context factors such as health care structures [11]. For example, in countries with universal health coverage (such as Germany or the UK), individual financial resources are less likely to have a significant impact on treatment burden [12]. Eton et al. [13] further distinguish three components of perceived treatment burden: care-related tasks, strategies for facilitating treatment burden such as seeking support from family or friends, and factors that increase burden, such as problems with medication, financial challenges, or a lack of information. In their *Guideline for Clinical Assessment and Management of Multimorbidity,* the National Institute for Health and Care Excellence recommends monitoring treatment burden and taking action to reduce it where indicated, with the ultimate goal to improve quality of life [14]. In clinical practice, this can be an opportunity to initiate an open dialogue about patients' preferences and challenges in managing their conditions [15], as well as a first step towards shared-decision making. Similarly, it could help to identify those at risk of being overburdened and resulting non-adherence. However, no instrument is yet available for use in German language.

Several patient-reported instruments for the assessment of treatment burden in patients with multimorbidity have recently been developed for the English-speaking population [16–19]. When assessing these instruments, we found the Multimorbidity Treatment Burden Questionnaire (MTBQ) to be most appropriate for the target population of older adults with multiple chronic conditions and diverse educational backgrounds. Whereas other instruments were longer and more difficult to understand or focused only on specific aspects of treatment burden, the MTBQ stood out for its brevity, intelligibility, and participatory and theoretically informed development [19]. The original MTBQ was tested in a large sample (n = 1,524) of older adults with multimorbidity (defined as the presence of three or more long-term conditions) recruited from general practices in England and Scotland as part of the 3D Study [20]. The MTBQ demonstrated good construct validity, internal consistency and responsiveness. The questionnaire has previously been translated into Danish [5, 21] and Chinese [22]. Its items address aspects of treatment burden that are also relevant to patients navigating the German health care system: Scheduling medical appointments, obtaining prescriptions, challenges related to medication intake, self-management and necessary lifestyle changes, financial aspects and the impact of treatments on personal relationships.

In this study, our objective was to (a) translate and cross-culturally adapt a German version of the MTBQ, (b) validate the adapted version in a sample of older adults with multimorbidity and (c) analyse the relationship between treatment burden scores and sociodemographic characteristics as well as other patient-reported health measures.

Materials and methods

Following the *Guidelines for Translating and Adapting Tests* by the International Test Commission [23], we used a multiple step translation process and conducted cognitive interviews as well as a pilot test. Psychometric properties of the questionnaire were determined in a sub-study of the MULTIqual project [24], which included a sample of 346 older adults (65 years and older) with three or more long-term conditions.

Description of the multimorbidity treatment burden questionnaire

The MTBQ is an easy-to-understand questionnaire on the perceived difficulty of health care tasks and their impact on everyday life. The original questionnaire consists of ten items and includes three optional questions (items 3, 9, and 10) that were not applicable in the UK study sample but may be relevant in other populations. The MTBQ was developed based on a literature review and discussions with a patient and public involvement group. In addition, cognitive interviews were conducted to examine content validity. Responses are given on a 5-point Likert scale, with values ranging from 0 (*not*

difficult or *does not apply*) to 4 (*extremely difficult*). The global score is computed as the mean score multiplied by 25, resulting in a global score between 0 and 100. The global score can be computed if a person has answered at least 50% of the questions. Four treatment burden groups were categorized in the UK sample: no treatment burden (score 0) and the tertiles low (< 10), medium (10–22) and high treatment burden (≥ 22).

A previous psychometric study of the original MTBQ found positively skewed scores with floor effects for all items. Exploratory factor analysis yielded a one-factor solution with a Cronbach's Alpha of 0.83 suggesting high internal consistency. Analysis of construct validity revealed a strong positive association with self-reported disease burden ($r_s = 0.43$, $p < 0.001$), and moderate negative associations with quality of life ($r_s = -0.36$, $p < 0.001$) and self-rated health ($r_s = -0.36$, $p < 0.001$). Moreover, higher treatment burden scores were significantly associated with a higher number of comorbidities ($r_s = -0.31$, $p < 0.001$. Regression analysis showed significant associations of changes in MTBQ scores with changes in measures of health-related quality of life and patient's assessment of chronic care at nine-month follow-up, suggesting good responsiveness [19].

Translation

Two translators with in-depth knowledge of the target language, health care system and culture (a researcher with experience in test development and a cultural scientist) carried out the forward translation of the full 13-item version of the MTBQ independently. The two versions were then reconciled into one by both translators. This was followed by two independent backward translations by a psychologist and a professional interpreter. All translators speak German as their mother tongue. The translations were reviewed using the checklist by Hambleton and Zenisky [25] in order to reach consensus on a final version. To ensure cross-cultural validity, ambiguities concerning the different healthcare systems were resolved by consulting the translator group and the author of the original questionnaire.

Cognitive interviews and pilot test

Applying verbal probing and think-aloud technique, we conducted semi-structured cognitive interviews. The aim was to assess the underlying cognitive mechanisms in item processing according to Tourangeau et al. [26]: comprehension, information retrieval, judgement and response behaviour. At first, patients were asked to verbalize their thoughts when answering the questions. Following this, a series of probe questions was administered to elicit further information on the cognitive process [27]. Interviews were digitally recorded and transcribed verbatim. Analysis of the cognitive protocol was performed question by question to identify difficulties that could potentially lead to responses that did not reflect the intended meaning of the item. The coding corresponded to the categories outlined above. Cognitive interviews were conducted among six patients aged 65 and over with three or more long-term conditions recruited from two GP practices. In addition, we carried out a pilot test in order to determine feasibility and to identify potential problems with test administration. Five researchers piloted the questionnaire in a sample of seven persons living with (multiple) long-term conditions.

Study setting and data collection

We recruited patients (aged 65 and over) with multimorbidity from GP practices as part of the cross-sectional MULTIqual study on quality of care for older patients with multimorbidity [24, 28]. GP practices in North and South Germany (Hamburg and Heidelberg and surroundings) were randomly selected, stratified by region, and invited to take part in the study. Participating GPs screened their regular practice clientele for the presence of at least three long-term conditions out of a pre-defined list of diagnoses that were found to be associated with high disease burden and lower subjective health status. We excluded patients without sufficient German language skills or ability to give informed consent, patients living in nursing homes and patients in palliative care. Out of 1,243 eligible patients from 35 GP practices, 346 patients agreed to participate (response rate: 27.9%). Following written informed consent, standardized interviews were carried out in their homes or in the GP practice. We collected data on sociodemographic characteristics, health care utilization, course of treatment and medication. Other patient-reported health outcomes were assessed with validated instruments: Medication adherence via MARS-D [29], patient activation via PAM 13-D [30], health-related quality of life and self-rated health via EQ-5D-5L [31], and perceived social support via F-SozU K-14 [32]. Recruitment and data collection took place from April 2019 to March 2020.

Statistical analysis

We used descriptive statistics in SPSS 25.0 to assess item properties. Assuming a congeneric model with varying means and variances of true values, we calculated McDonald's omega as reliability coefficient using the *MBESS* package for R [33], with scores above 0.70 considered sufficient given the length and purpose of the instrument [34]. We conducted an exploratory factor analysis to assess the dimensionality of the questionnaire. Underlying factors were extracted according results of scree plot, parallel analysis of eigenvalues and Velicer's

minimum average partial test with the R package *EFA. dimensions* [35]. Confirmatory factor analysis was computed using R package *lavaan* [36]. Goodness of fit was examined using the following indices: Robust root mean square error of approximation (RMSEA) with values below 0.05 indicating good model fit and values between 0.05 and 0.08 indicating acceptable model fit; standardized root mean square residual (SRMR) with values below 0.05 indicating good model fit and values between 0.05 and 0.10 indicating acceptable model fit; and comparative fit index (CFI) with values below 0.90 indicating poor model fit [37].

In examining construct validity, we used bivariate correlation analyses to assess the relationship between MTBQ scores and related measures. We hypothesized a positive correlation with number of long-term conditions and negative correlations with medication adherence, patient activation, health-related quality of life and self-rated health, as previously established for several self-report treatment burden questionnaires [6, 18, 19, 38]. Furthermore, we expected lower levels of social support to be associated with greater treatment burden. Unfortunately, there was no comparator scale available to assess concurrent validity. Mann–Whitney U tests were used to analyse the associations between participant characteristics and treatment burden scores. We expected higher treatment burden scores for female respondents and respondents with mental health conditions, as similar results were previously reported for the UK version [19].

Results

Translation, cognitive interviews and pilot test

Discrepancies between forward and backward translation as well as the final review highlighted problems in the adaptation of optional item 10: *"Getting help from community services"*. Due to the different organization of the health care systems, there is no analogous service structure in Germany. Although an item was created to determine treatment burden pertaining to services such as physiotherapy and mobile nursing service, cognitive interviews revealed that respondents already included these services under item 6: *"Arranging appointments with health professionals"*. Accordingly, the adaptation led to ambiguities and queries and therefore, we decided to exclude item 10. All other items were found to be applicable to the German health care system.

Furthermore, respondents reported that it was difficult to distinguish between the response categories *"does not apply"* and *"not difficult"*, as the German translations are commonly used for similar purposes. For this reason, we added an instruction to further distinguish between both options*: "It is also possible that some of the aspects do not play a role in your care and do not apply to your situation"*. Cognitive interviews showed that this addition was sufficient to enable a clearer distinction between the two responses. Interviewed patients listed a wide range of health care providers for answering questions 6 to 8, indicating a comprehensive understanding of these items. Likewise, a number of monitoring behaviours were specified for item 5. Respondents did not describe any further aspects of treatment burden not covered by the questionnaire, so that we assume no limitations to the face validity of the German adaptation. The results of the cognitive interviews are presented in more detail in Additional file 1. In the pilot test, it took about 4 min to answer the questionnaire, indicating little burden for respondents. There were no suggestions for any further changes.

Statistical analysis

Out of the initial sample of 346 patients who participated in the main study, 344 patients responded to at least half of the MTBQ questions, which allowed inclusion in the statistical analysis. Table 1 illustrates the characteristics of the participants. The mean age was 77.5 years with a range from 65 to 97. The sample included slightly more female (55.2%) than male participants. The majority (56.4%) had less than ten years of school education which equates to CASMIN (Comparative Analysis of Social Mobility in Industrial Nations classification of education) grade 1 [39]. On average, participants reported 9.8 long-term conditions.

Item properties

Proportion of missing data was less than 1% for each item (see Table 2). We observed floor effects for all items, with positively skewed distributions (Skewness = 2.02, Kurtosis = 4.72). Following the instruction of the original questionnaire, all items with more than 40% *"does not apply"* responses were excluded from the statistical analysis, which led to the removal of item 9. However, in contrast to the original questionnaire, we retained item 3, as this applied to most respondents. The mean score was multiplied by 25 to obtain the global MTBQ score. Descriptive statistics are provided in Table 3. For the purpose of comparison, we retained the original thresholds for categorizing the global score into four levels of treatment burden as applied to the UK, Chinese, and Danish versions. As a result, 25.6% of the study population showed no treatment burden, 39.0% low treatment burden, 28.2% medium treatment burden, and 7.3% high treatment burden (see Table 1). Mann–Whitney U tests showed that global MTBQ scores were significantly higher in female ($Mdn_1 = 6.82$) than in male participants ($Mdn_2 = 4.55$; $U = 11{,}729$, $p = 0.001$) and higher for persons with

Table 1 Characteristics of the study sample

Characteristics	Patient sample ($N = 344$)
Age: mean ± SD	77.5 ± 7.1
Gender	
Female	190 (55.2%)
Male	154 (44.8%)
Marital status	
Married	189 (54.9%)
Widowed	99 (28.8%)
Divorced	33 (9.6%)
Single	23 (6.7%)
Education level (via CASMIN [39])	
Primary	193 (56.4%)
Secondary	95 (27.8%)
Tertiary	54 (15.8%)
Country of birth	
Germany	319 (92.7%)
Other	25 (7.3%)
Nursing care dependency	
Yes	78 (22.7%)
No	266 (77.3%)
Total number of comorbidities: mean ± SD	9.8 ± 4.5
Total number of long-term medications: mean ± SD	6.0 ± 3.2
Comorbidities	
Chronic low back pain	196 (57.0%)
Urinary incontinence	136 (39.5%)
Diabetes	119 (34.6%)
Coronary heart disease	71 (20.6%)
COPD	71 (20.6%)
Heart failure	61 (17.7%)
Depression	51 (14.8%)
Asthma	50 (14.5%)
Chronic kidney disease	41 (11.9%)
Stroke/Transient ischaemic attack	31 (9.0%)
Anxiety disorder	27 (7.8%)
Parkinson's disease	5 (1.5%)
Treatment burden level (as assessed via MTBQ global score)	
No burden (0)	88 (25.6%)
Low burden (< 10)	134 (39.0%)
Medium burden (11–22)	97 (28.2%)
High burden (≥ 22)	25 (7.3%)

anxiety or depression ($Mdn_1 = 9.10$, $Mdn_2 = 4.55$; $U = 3172$, $p = 0.024$).

Dimensionality and reliability

The Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy (0.755) indicated that the data was suitable for exploratory factor analysis. Although Kaiser Guttman criterion determined a four-factor solution, the scree plot (see Additional file 2) and both parallel analysis of eigenvalues and Velicer's Minimum Average Partial test (MAP) suggested one common factor, which explained 21.20% of total variance. Model indices for the confirmatory factor analysis showed acceptable to slightly less than good model fit: $\chi^2 = 86.917$ (44), $p = 0.000$, Robust CFI = 0.845, RMSEA = 0.073, SRMR = 0.072. Internal reliability was satisfactory with $\omega_t = 0.71$.

Construct validity

We found a positive association between the global MTBQ score and patient-reported number of comorbidities ($r_s = 0.409$, $p < 0.001$). There was an association between greater burden and lower health-related quality of life ($r_s = -0.351$, $p < 0.001$) and self-rated health ($r_s = -0.335$, $p < 0.001$). We found negative associations for social support ($r_s = -0.308$, $p < 0.001$), patient activation ($r_s = -0.457$, $p < 0.001$) and medication adherence ($r_s = -0.222$, $p < 0.001$) as well. Our results (see Table 3) support all our hypotheses on construct validity, with coefficients comparable to the results shown for the UK version of the MTBQ.

Discussion

In this study, we developed a German tool to measure treatment burden in patients with multimorbidity. We used a thorough and well-established methodology to translate and adapt a German version of the MTBQ. The questionnaire contains 11 core items and one optional item that was not applicable to our study population but may be relevant for other settings. Cognitive interviewing and piloting led to smaller adaptations and demonstrated overall good content validity. Statistical analysis was performed within a cross-sectional design. Validity analysis yielded significant associations to related constructs as hypothesized, similar to the results reported for other instruments assessing treatment burden [19, 40]. While factor analysis indicated a single-factor solution, the proportion of explained variance and model fit were only satisfactory. The UK version showed one-dimensionality, whereas other psychometric studies suggested alternative three-factor solutions for the Chinese and Danish versions [21, 22]. Due to these differences, we assume that the underlying construct is a formative model rather than a reflective model and therefore dimensionality is less relevant for this instrument [41]. The difference between formative and reflective models in psychometric validation mainly relates to the internal structure of the patient-reported outcome measure. In a reflective model, one latent variable manifests itself in all indicators, i.e., in the items of a (sub-) scale, so that the items are expected to be positively correlated. In a formative model, on the

Table 2 Distribution of responses ($N = 344$)

Items	*n*	Not difficult (in %)	A little difficult (in %)	Quite difficult (in %)	Very difficult (in %)	Extremely difficult (in %)	Does not apply (in %)
1. Taking lots of medications	342	65.2	10.2	5.8	2.6	2.3	13.7
2. Remembering how and when to take medication	344	84.3	8.7	0.9	0.0	0.9	5.2
3. Paying for prescriptions, over the counter medication or equipment	342	68.1	14.3	5.0	1.8	0.9	9.9
4. Collecting prescription medication	344	78.8	4.4	1.2	0.6	2.3	12.8
5. Monitoring your medical conditions (eg, checking your blood pressure or blood sugar, monitoring your symptoms, etc.)	344	84.0	4.1	1.7	0.6	0.3	9.3
6. Arranging appointments with health professionals	344	82.0	7.3	2.9	1.5	1.5	4.9
7. Seeing lots of different health professionals	343	69.1	12.2	6.1	4.4	1.7	6.4
8. Attending appointments with health professionals (eg, getting time off work, arranging transport, etc.)	344	76.2	4.1	2.9	2.9	1.5	12.5
9. Getting health care in the evenings and at weekends	344	36.6	4.7	2.6	1.7	1.2	53.2
11. Obtaining clear and up-to-date information about your condition	341	84.5	5.6	2.9	1.2	0.6	5.3
12. Making recommended lifestyle changes (eg, diet and exercise)	343	52.8	26.5	8.7	4.4	0.6	7.0
13. Having to rely on help from family and friends	342	36.8	16.7	8.8	6.4	2.0	29.2

Item 9 was excluded from the analysis, as it was not applicable for most participants. This item may be relevant to different populations and is therefore retained as an optional question for use in other appropriate settings. (Optional) item 10 of the English version was excluded from the German MTBQ due to lack of transferability to the German health care system

Table 3 Descriptive statistics of health measures and correlation to global MTBQ scores

	N	Mean	Range	Std. Deviation	Spearman rank correlation to global MTBQ score (r_s)	*p*
German MTBQ: Treatment burden	344	7.81	0.00–52.27	9.46	–	–
PAM-13: Patient activation	341	76.10	22.60–100.00	16.43	− 0.457	< 0.001
MARS-D: Medication adherence	335	24.01	8.00–25.00	1.87	− 0.222	< 0.001
F-SozU K14: Perceived social support	327	4.36	1.57–5.00	0.67	− 0.308	< 0.001
EQ-5D-5L utility score: Health-related QoL	336	0.75	− 0.14–1.00	0.23	− 0.351	< 0.001
EQ VAS: Self-rated health	338	63.05	0–100	20.65	− 0.335	< 0.001

QoL quality of life, *VAS* visual analogue scale

other hand, the measured items constitute the latent variable, with no presumption of inter-item correlation [42]. Regarding the construct of treatment burden, our empirical results support theoretical assumptions: The manifestation of treatment burden is influenced by relatively stable individual factors such as diseases, resources and coping strategies, while it varies as a function of the workload resulting from treatment regimens and also the organisational requirements of health care systems. While this finding suggests limited utility of factor analysis, it also underscores the importance of cross-cultural adaptation and qualitative pretesting. The distinct floor effects of the scale are similarly reported for other instruments on treatment burden [16, 43], in some cases even to a greater extent [18].Nevertheless, in patients with low burden, the responsiveness to improvement may be limited.

In our sample, patients scored lower on average for treatment burden than in the UK sample of Duncan et al. [19]. These differences could be explained by the dense medical care structure in the regions of our study centres and the older age of our participants. Previous studies found that treatment burden tends to be greater in younger patients [19, 40, 44]. One possible explanation may be that younger people not only experience stronger life demands and requirements regarding to their social roles but also have different expectations of their general functioning. The longer patients live with long-term conditions, the more likely they are to adjust to everyday treatment requirements, such as taking medication regularly or monitoring symptoms.

We were surprised to see that item 3 on financial burden was relevant to most of our participants, in contrast to the original UK sample. In outpatient care in

Germany, out-of-pocket costs of statutory health insurance only apply to co-payments for medication, supportive therapies and medical aids. For patients with long-term conditions, there is a burden limit of 1% of their income. Even so, not all patients use this exemption or are even aware of this possibility. On average, the highest scores were obtained for item 12 (*"Making recommended lifestyle changes"*) and item 13 (*"Having to rely on help from family and friends"*). These findings corroborate the relevance of intervention studies to target these aspects of care.

One major advantage in our study is that the sample represents the most prominent target group of multimorbidity research. On the other hand, the sample restrictions might pose a limitation to the generalizability of these findings to younger patients and patients with fewer comorbidities. Moreover, it should be noted that our data collection is confronted with a possible self-selection bias: those who already perceive a greater burden and feel overwhelmed might be less likely to respond to a study invitation. Due to the cross-sectional design, we were not able to establish the predictive value of the German MTBQ and to explore the possible effect of overburden on non-adherence. One psychometric property we did not examine was test–retest reliability, which should be addressed in the future. Despite our promising results, additional research is required to determine the responsiveness of the German MTBQ in longitudinal designs and the clinical utility of this tool in primary care settings. Future studies will be needed to confirm and advance the threshold values for categorizing MTBQ scores into four levels of treatment burden, ideally based on a clinical anchor [21]. Further work is required to shed light on the impact of life demands, social roles, coping behaviour and resources on treatment burden to allow a better understanding of our findings.

Conclusions

The German MTBQ is a brief and concise patient reported outcome measure to examine perceived treatment burden in patients with multimorbidity. It demonstrated good psychometric properties and is the first valid instrument to assess treatment burden in patients with multiple long-term conditions in Germany. Since cross-culturally adapted and validated versions of the MTBQ are available in several languages, it could also be used in international research studies. With its short administration time, the MTBQ may be suitable to detect people experiencing high burden in clinical practice, although its use in as a clinical tool has not yet been validated. Implementing the MTBQ as a clinical tool has the potential to inform shared decision-making and elicit areas where patients need additional support.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12955-022-01993-z.

Additional file 1. Results of cognitive interviews.

Additional file 2 Exploratory factor analysis: Scree plot for German MTBQ.

Acknowledgements
We are grateful to all patients and GPs who supported this project. We would also like to thank the whole MULTIqual study group for their most valuable contribution.

Author contributions
JS and MS contributed to the design and implementation of the study. AB, JS and NP collected the data. DL and MS supervised the project. PD provided expertise on the original questionnaire. JS performed data analysis and drafted the manuscript. All authors critically revised the draft and approved submission of the final version.

Funding
Open Access funding enabled and organized by Projekt DEAL. This study was part of the MULTIqual project supported by the Innovation Fund of the Federal Joint Committee (G-BA; Grant No. 01VSF16058). The funding body had no role in study design, data collection and analysis, decision to publish or preparation of the manuscript.

Availability of data and materials
The analysed dataset is available from the corresponding author on reasonable request. The MTBQ can be requested from: https://www.bristol.ac.uk/primaryhealthcare/resources/mtbq/

Declarations

Ethics approval and consent to participate
Ethics approval was obtained from Ethics Committee of the Hamburg Medical Association on 10th September 2018 (file no. PV5846), Clinical Ethics Committee Heidelberg on 19th December 2018 (file no. S-665/2018) and Medical Association of Baden-Wuerttemberg on 13th November (file no. B-F-2018-096). All study participants gave written informed consent prior to their participation in the study.

Consent for publication
Not applicable.

Competing interests
Polly Duncan developed and validated the Multimorbidity Treatment Burden Questionnaire. She is also an investigator for an industry-university collaboration study between the University of Bristol and Pfizer investigating the burden of lower respiratory tract infection and community acquired pneumonia in primary care. The other authors declare that they have no competing interests.

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Received: 5 October 2021 Accepted: 17 May 2022
Published online: 03 June 2022

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Supplementary materials:

Additional file 1: Results of cognitive interviews

12955_2022_1993_MOESM1_ESM.pdf (springer.com)

Additional file 2: Exploratory factor analysis: Scree plot for German MTBQ

12955_2022_1993_MOESM2_ESM.pdf (springer.com)

Declaration of Own Contributions to the Publications

(1) **Schulze, J.**, Glassen, K., Pohontsch, N. J., Blozik, E., Eißing, T., Breckner, A., Rakebrandt, A., Schäfer, I., Szecsenyi, J.; Scherer, M., Lühmann, D. (2022). Measuring the quality of care for older adults with multimorbidity: Results of the MULTIqual project. *The Gerontologist, 62*(8), 1136-1145. https://doi.org/10.1093/geront/gnac013

Contributions by the author:

- Performed the systematic literature review (together with TE and DL)
- Developed candidate quality indicators (together with TE, NJP and DL)
- Recruited members of the expert panel (together with KG, DL and NJP)
- Evaluated the results of the consensus process (together with DL, MS, NJP, KG, AB, AR and IS)
- Drafted the first manuscript
- Revised the manuscript during the peer-review process (together with DL, NJP and MS)

(2) Pohontsch, N. J., **Schulze, J.**, Höflich, C., Glassen, K., Breckner, A., Szecsenyi, J., Lühmann, D., Scherer, M. (2021). Quality of care for people with multimorbidity: A focus group study with patients and their relatives. *BMJ Open, 11*(6), e047025. https://doi.org/10.1136/bmjopen-2020-047025

Contributions by the author:

- Recruited participants (together with AB and CH)
- Conducted focus groups (together with NJP, KG and AB)
- Contributed to data analysis and interpretation (together with NJP, CH, KG and AB)
- Critically revised the first draft, contributed parts of the written material
- Assisted in the revision of the manuscript during the peer-review process

(3) **Schulze, J.,** Breckner, A., Duncan, P., Scherer, M., Pohontsch, N. J., & Lühmann, D. (2022). Adaptation and validation of a German version of the Multimorbidity Treatment Burden Questionnaire. *Health and Quality of Life Outcomes, 20*(1), 90. https://doi.org/10.1186/s12955-022-01993-z

Contributions by the author:

- Contributed to the design of the study
- Coordinated the translation of the questionnaire
- Recruited participants (together with AB)
- Conducted all semi-structured interviews
- Conducted 18% of the standardized interviews
- Analysed the data
- Drafted the first manuscript
- Revised the manuscript during the peer-review process (together with DL, NJP and PD)

Acknowledgements

I would like to thank everyone who has supported and contributed to this thesis.

First and foremost, I must thank my supervisor, Prof Martin Scherer, for encouraging me to pursue this topic for my PhD and providing me with the necessary resources to conduct this research. I would like to express my gratitude to the members of my thesis committee, PD Dr Christine Blome and Prof Dr Bernd Löwe, for generously giving their time, expertise and feedback to improve my thesis.

I am deeply grateful to Dr Dagmar Lühmann for her invaluable guidance at all stages of this project. Special thanks to Dr Nadine Pohontsch, who introduced me to qualitative research methods and was a great support during this time. I would also like to thank all my friends and colleagues at the Department of General Practice and Primary Care for their help and advice.

This thesis would not have been possible without the contributions of the expert panel members, GPs, patients and their families who gave their time and energy to this study. They all have my sincere gratitude.

Finally, I would like to thank my husband for his unwavering love and patience and for bearing with me through the ups and downs of this journey.

Curriculum Vitae

Not disclosed for privacy reasons

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