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Establishing patient-centered nutrition screening for German speaking oncology patients

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Abbreviations

Abbreviation	**Meaning**
ESPEN	European Society for Clinical Nutrition and Metabolism
HCP	Health care professionals
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
NRS-2002	Nutrition Risk Screening 2002
MNA-SF	Mini Nutritional Assessment (Short Form) Revised
MUST	Malnutrition Universal Screening Tool
PCC	Patient-centered care
PG-SGA	Patient Generated Subjective Global Assessment
PG-SGA SF	Patient Generated Subjective Global Assessment Short Form
SGA	Subjective Global Assessment

Publication List

1. Erickson N, Storck LJ, Kolm A, Norman K, Fey T, Schiffler V, Ottery FD, Jager-Wittenaar H. Tri-country translation, cultural adaptation, and validity confirmation of the Scored Patient-Generated Subjective Global Assessment. Support Care Cancer. 2019 Sep;27(9):3499-3507. doi: 10.1007/s00520-019-4637-3. Epub 2019 Jan 25. PMID: 30684046.

2. Erickson N, Schinkoethe T, Eckhardt C, Storck L, Joos A, Liu L, Ballmer PE, Mumm F, Fey T, Heinemann V. Patient-reported outcome measures obtained via E-Health tools ease the assessment burden and encourage patient participation in cancer care (PaCC Study). Support Care Cancer. 2021 Dec;29(12):7715-7724. doi: 10.1007/s00520-021-06351-1. Epub 2021 Jun 22. PMID: 34159428; PMCID: PMC8549920.

1. Detailed description of author's contribution to each publication

1.1. Contribution to publication 1

The doctoral candidate independently did background research to determine the most appropriate methods to perform a valid translation and cultural adaption of the internationally recognized nutrition screening tool, the Patient Generated Subjective Global Assessment. She then assembled an international team of researchers and professionals in 5 separate countries (Austria, Germany, the Netherlands, Switzerland, and the United States of America) to coordinate the study. As the preparation and reconciliation of the translation had already been initiated, she obtained the appropriate permissions and documents and took over the process starting with the completion of the harmonization of the forward and back translations. Thereafter, she managed the entire cognitive debriefing and content validity in coordination with key representatives in Germany, Austria and Switzerland. She also managed, and participated in, the recruiting process in Germany. The doctoral candidate then independently performed the statistical analysis, drafted the manuscript, selected an appropriate journal to disseminate the results and managed the entire submission and publication process as corresponding author. Her supervisor, Prof. Dr. med. Volker Heinemann and co-supervisor Dr. rer. nat. Theres Fey provided feedback and guidance throughout the entire process. The last author, Prof. Harriët Jager-Wittenaar, who leads the international validation and cultural adaptation worldwide for this screening tool, also provided advice and resources as required.

1.2. Contribution to publication 2

The doctoral candidate conceptualized and coordinated the entire study from beginning to end. She worked closely with the cooperation partner, CANKADO, to ensure the E-health tool was programmed according to specifications. She actively led, and participated in, recruiting suitable participants from the German site. Throughout the study she managed all coordination with CANKADO and the participating centers. As lead investigator, she was responsible for the interpretation of the data and the statistical analysis in consultation with a statistician. She independently prepared the manuscript, acted as corresponding author during the submission process, and created the figures and tables published in the paper in accordance to the journal specifications. During the review process she responded to, and implemented, all suggestions for changes to the manuscript. Her supervisor Prof. Dr. med. Volker Heinemann and co-supervisor Dr. rer. nat. Theres Fey provided advice and guidance throughout the duration of the study.

2. Introduction

2.1. Patient-centered care and its importance in oncology

Modern medical care has begun to shift focus from the traditional disease-focused, clinician-centric care model to a system which empowers, and enables patients to participate in shared decision making. This concept is embodied in the term, “patient-centered care” (PCC) (1-3). Although exact definition and terminology varies in the literature, there seems to be a consensus that PCC describes a form of medicine in which a partnership is established between patients, their caregivers, and all members of the multidisciplinary team in order to ensure that patient preferences, needs, and values are taken into account when making medical decisions (2-9).

Historians and scientists have traced the roots of the concept of PCC back to Florence Nigtingale who was credited with acknowledging the patient’s view as an essential part of communication when providing medical care (10, 11). Other scientists argue, however, that the idea is embodied in the Hippocratic oath (3, 12). Nevertheless, it was not until 1969, that the term “patient-centered medicine” was first credited to Balint (1). Since then, the concept has been built upon, extended, and discussed extensively in the literature. Although there are many definitions of PCC, the following core conceptual principles seem to remain consistent throughout the literature (5, 6, 9, 13-18):

1. *The whole patient:* Also referred to as the biopsychosocial perspective, this dimension takes on a holistic view of the patient and includes the biological, spiritual, and psycho-social aspects. It embodies the idea that the disease itself can both have an effect on, and be affected by, these aspects. Therefore, this principle embodies the idea that the provision of medical care is not complete, nor as effective, unless the patient and disease are also considered within this framework (7, 9, 18).

2. *Individualized care:* This principle describes the need to consider the unique needs, perspectives, history, contextual setting, and health concerns of every patient. Medical care should then be customized in order to best meet a patient’s particular needs and preferences at any point in the care continuum. The concept of individualized care also takes into account the unique way each patient may experience and cope with the illness and treatment (7, 9, 13, 18).

3. *Respectful clinician-patient relationship:* This concept embodies the idea that individuals have a right to be recognized and respected as competent partners in the decision-

making process. This goal cannot be achieved without the acknowledgement of the patient's perspectives and choices. The importance of the reciprocal nature of this relationship is stressed by an established mutual understanding and underscored by guidance, education and communication. Essential characteristics required for clinicians to be effective partners in care include not only medical competency, but also empathy, honesty, the ability to self-reflect and the respectful consideration of the patient's viewpoint (8, 9, 18).

4. *Empowerment:* This principle has received significant attention in the literature in recent years (2, 15, 16, 19, 20). It embodies the idea that participation in shared decision-making is facilitated by activating the individual's resources and providing patients and their caregivers with the appropriate education and tools. It includes the need to actively support the patient's ability to self-manage and ensure that tailored information enables them to become a knowledgeable partner in the management of their healthcare (7, 13, 15, 21). Notably, empowerment can only be achieved when a patient is able to obtain the right information at any particular step along the care continuum. Additionally, all information, educational programs and health promotion interventions should be carefully tailored and provided in a manner that the particular individual is able to understand. This principle is supported by effective communication on behalf of the health care professionals (HCP) (2, 13-16).

PCC is particularly important when patients are faced with a devastating diagnosis and/or a chronic disease. The latest data from the German Centre for Cancer Registry Data at the Robert Koch Institute reveals that in the year 2017, a little less than half a million citizens were diagnosed with cancer (22). After being diagnosed, each of these individuals then must learn to navigate an often-fragmented medical system. They are simultaneously faced with complex treatment options and are forced to weigh potential risks and benefits. Decisions have to be made that are appropriate to each individual's needs and particular situation. These challenges are then compounded with the emotional, social, physical, and, at times, financial repercussions of the disease and the diagnosis itself (2-4).

In order to address and alleviate these challenges, in 2011, the Institute of Medicine's National Cancer Policy Forum held a multidisciplinary workshop together with patient advocates, government representatives and industry partners with the aim of developing recommendations for PCC throughout the cancer care pathway. At this workshop, tools, resources, policy options and models for placing patients at the center of treatment planning while promoting a partnership between the patient and HCP were discussed (2). In 2014, PCC was then the first of six interconnected components listed by the Institute of

Medicine as essential for the delivery of high-quality cancer care (18). In 2015, the German Medical Association (Bundesärztekammer) included similar recommendations in their quality criteria for any disease-oriented certified center (23). All recommendations included a greater use of patient support services, including nutrition care.

2.2 Nutrition care and its relationship to patient-centered care

Nutrition care is by nature patient-centered. High quality evidence-based medical nutrition care is ensured through the use of the internationally recognized four-step workflow model known as the nutrition care process (NCP) (24). This model was adopted by the Academy of Nutrition and Dietetics in 2003 and is based on critical thinking, shared decision-making, and etiology-based care. It was originally designed to establish a global standard for provision of high-quality nutrition care through the consistent delivery of evidence-based, individually tailored nutrition care to diverse populations, regardless of delivery settings (24, 25). The NCP model was translated and adapted in Germany in 2015, where it is referred to as the German-nutrition care process (G-NCP) (26). The process model is recommended by the European Society for Clinical Nutrition and Metabolism (ESPEN) guidelines on nutrition in cancer patients and in their consensus statement for diagnostic criteria for malnutrition (27-29). In 2020, the German Cancer Society added the requirement that nutrition care is provided using the NCP (or an equivalent model) to the certification criteria for the certification of visceral oncology centers (30).

Figure 1 illustrates how the core concepts of PCC listed in 2.1 coincide with those represented in the NCP model. Certain concepts central to PCC were already reflected in the original NCP model, which always placed the individual in the center. Furthermore, the words, ”collaboration” and “communication” are placed in the part of the model representing the core competencies, qualities and attributes that nutrition professionals embody, demonstrating the basis of a respectful patient-clinician relationship (31, 32). Both models consider how education and jointly determined goals enable the patient to move toward the desired outcome. Furthermore, the framing ring of the NCP model was designed to represent how socio-economic factors, setting, and the system itself influences how patient’s receive and implement nutrition information. This same context is reflected in the PCC principle that the provision of medical care can only be effective when contextual settings and the biopsychosocial perspective are also considered. In 2017, the NCP model was redesigned to further highlight another core concept of PCC reflected in nutrition care. In this step, the word “interaction” was placed within the core of the model in order to underscore the central role patients play in nutrition-related treatment decisions and the provision of individualized treatment strategies (31).

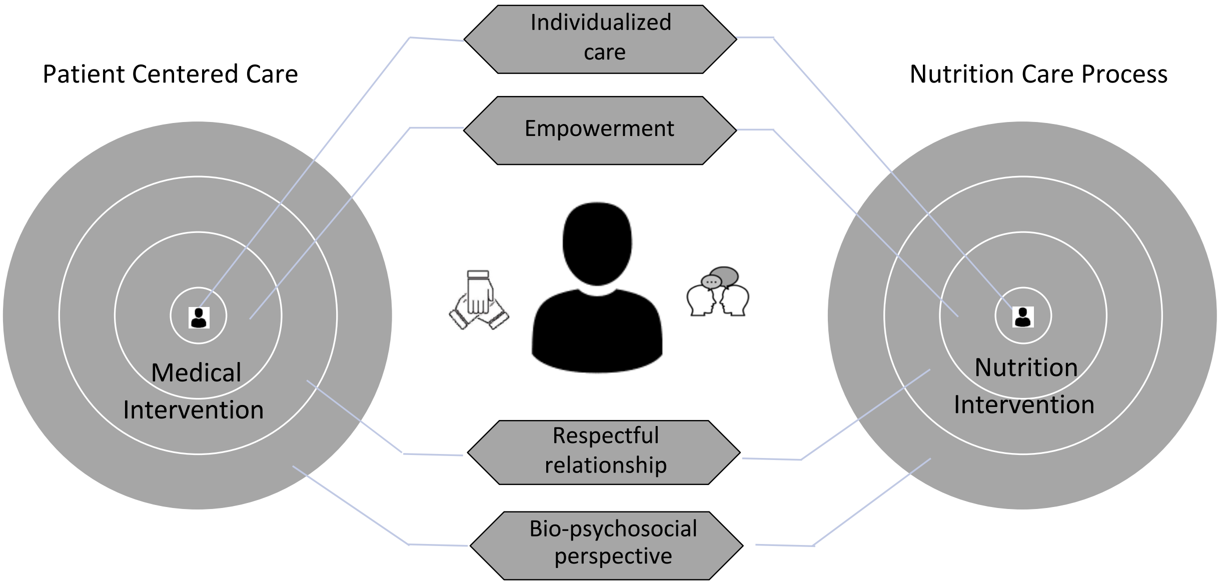

Figure 1: Overlap of the core concepts of patient-centered care with the core concepts of the nutrition care process (18, 31)

Key:
🤝 depicts collaboration and interaction
💬 depicts communication
👤 represents the patient

2.3 Nutrition screening in oncology

The NCP model begins with nutrition screening, which then flows into the nutrition assessment. Representing the first step of nutrition care, one of the goals of nutrition screening is to increase awareness of malnutrition and allow early recognition and treat-ment referral for patients. Nutrition status has consistently been shown to have negative effects on a patient’s quality of life, daily function, and overall well-being and is therefore an important aspect of PCC (31-33). Clinically, nutrition status has consistently been shown to affect treatment outcomes including progression free survival and overall survival of different patient populations with cancer (27, 28, 31, 33-36).

Nutrition screening is designed to quickly and easily identify patients who may benefit from a nutrition intervention. Screening is generally carried out by a nurse, dietitian, or any other medical profession who is a member of the interdisciplinary team. The importance of the nutrition screening and assessment step for cancer patients is stressed in both national and international guidelines (29, 33, 37). These guidelines consistently state that nutrition screening should begin with the diagnosis of cancer and be repeated at regularly intervals throughout the care continuum. Furthermore, the ESPEN guidelines specify that ≥80% of all cancer patient should be screened for malnutrition.

In practice, nutrition screening can be implemented using one of the various validated nutrition screening tools. Table 1 shows an overview of the screening tools recommended in the national and international guidelines for oncology patients (28, 29, 33, 38).

Table 1: Overview of Screening tools recommended in the guidelines for oncology patients

Validated Tool	Abbreviation	Setting	Designed to be completed by
Nutrition Risk Screening 2002 (39)	NRS-2002	Clinical	Health Care Professionals
Malnutrition Universal Screening Tool (40)	MUST	Outpatient, Clinical	Health Care Professionals
Mini Nutritional Assessment (Short Form) Revised (41, 42)	MNA-SF	Geriatrics, Long-term care, Outpatient, Clinical	Health Care Professionals
Subjective Global Assessment (43)	SGA	Geriatrics, Long-term care, Outpatient, Clinical	Health Care Professionals
Patient-Generated Subjective Global Assessment (44)	PG-SGA	Geriatrics, Long-term care, Outpatient, Clinical	Patient (*Short Form*) *Or* Patient followed by Health Care Professional *(Long Form)*

2.4 Patient-centered nutrition screening in oncology

In order to truly achieve a comprehensive PCC approach, it is important that all aspects of medical care provided to oncology patients, including nutrition care, are provided in a manner that encourages patient participation and shared decision making. However, as table 1 has made apparent, nutrition screening is currently based largely on screening tools, which are completed only by HCP (45, 46). This not only places the screening burden onto a busy professional, it also requires time that could be spent focusing on other aspects of care or in dialogue with the patient. Therefore, it is important to find and establish a model for nutrition screening in daily practice that not only supports PCC, but also has the potential to provide efficient nutrition screening during daily care.

The two publications that make up this dissertation aim to provide a basis for patient-centered nutrition screening in the German language and establish its utilization in practice. The only validated screening tool currently recommended by oncology guidelines, which is designed to be completed (in part) by the patient, is the Patient-Generated Subjective Global Assessment (PG-SGA). Faith Ottery and colleagues first developed the PG-SGA specifically for oncology patients in 1996 in the United States of America (44). The PG-SGA has subsequently been validated in various international settings not only for oncology patients, but also for other patient populations at risk for malnutrition (47-51).

Notably, the PG-SGA was developed with the specific intention of harnessing a patient-centric approach to streamline clinical care. The core conceptual basis considers both anabolic and catabolic factors that not only have therapeutic implications, but also directly affect a patient’s nutrition requirements and functional status (44, 47). The short form (PG-SGA-SF), which is designed to be completed by the patient without assistance, is made up of four sections that are referred to as boxes (See Figure 1a in Section 5. Publication 1 on page 25). Each section focuses on a different aspect of the nutrition status. This first part collects anthropometric data and includes a weight history recall going back six months. Section two considers current nutrition intake in amount and delivery method. The third section makes up the core of the total score and considers 14 specific symptoms that are known to interfere with energy intake. The last section consists of a patient-reported adaptation of the Karnofsky performance status and considers how functional status is related to nutrition status. The PG-SGA in its full form is then completed by the HCP and considers comorbidities and components of metabolic stress such as the presence of fever and administration of corticosteroids. It further assesses physical aspects of catabolic wasting such subcutaneous fat and muscle loss. The numerical score provided by the PG-SGA-SF is validated as a stand-alone screening tool that provides clear scored-based guidelines as to the appropriate medical nutrition therapy required (47, 52-55). The longer version is useful for collecting data for studies and/or providing valuable parts of the nutrition assessment (47, 56).

The aim of the first publication was to provide a German language version of the PG-SGA. This was achieved through a systematic translation, followed by a cultural and linguistic adaptation of the original validated PG-SGA while preserving conceptual, semantic and operational equivalence. The methods utilized to carry out this study were carefully chosen. The goal was to simultaneously fulfill the principles of good practice for translation and cultural adaptation as set by the International Society for Pharmacoeconomics and Outcomes Research, while ensuring that the German language version is comparable to existing translations and can thus be used as an international benchmarking tool (57). The process consisted of a series of forward and back translations performed by native speakers. Thereafter, it was culturally and linguistically adapted to be utilized in all three German-speaking countries in Europe in consultation with representatives from each area. Finally, internal and external validity was tested among a collective of both HCP and patients scattered across the three different countries and regions. In order to achieve this, not only the methods used in the validation process, but also the calculation and presentation of the results were performed in concordance with the original version and existing translations from the Netherlands, Portugal (58, 59). Since the publication of the German results in 2019, further translations following the same steps and presented in the same manner have been published from Thailand, Greece, Norway, Iran and Japan (60-64). As all translations and cultural adaptations of the PG-SGA also preserve the layout, the potential for using and interpreting the screening tool in clinical practice despite linguistics barriers presents a way to break down barriers to patient-centered care. Furthermore, the fact that nations across the world are also using the screening tools enables international comparisons (47).

The second publication aimed to assess the utility, accuracy, and acceptance of the use of the newly translated and validated German version of the PG-SGA in clinical practice. In order to achieve these goals, the screening tool was first programmed into an E-health platform called CANKDO, a Class I medical device, which is designed to be used in both clinical trials and/or in routine care. The use of the E-health platform was chosen because after programming the tool into the system, the total score could be automatically calculated. With a dashboard system, the identification of patients in need of a nutrition intervention could be done rapidly and the appropriate care could be initiated. The study was conducted among patients undergoing therapy for stomach, pancreas and colorectal cancer in Germany and Switzerland.

In this study acceptability and difficulty of completing the PG-SGA using the E-health platform was evaluated with the use of five-point Likert scales. Results were analyzed with respect to the effect of age and gender using the Wilcoxon-Tests. The accuracy of patient-reported data regarding height and weight was depicted through Bland and Altman plots. The evolution of the patient-reported weight history was visualized according to cancer type using a linear regression model. The accuracy of the PG-SGA as a screening tool, and potential psycho-social effects of a declining nutrition status were both evaluated using the Chi-Squared Test of Independence. Finally, the number of patients who requested supportive care after completing the screening was tracked and analyzed. The results of this exploratory study support the accuracy of patient-reported nutrition screening and indicated that patient-generated screening with the E-health platform could potentially encourage patient participation.

The publications presented in this dissertation lay the groundwork for establishing patient participation in nutrition screening. The first one provides a validated and accurate patient-generated nutrition screening tool in the German language and the second publication demonstrates one method in which this tool could be easily integrated into routine care. Furthermore, the exploration of the acceptance of E-health platforms provides a basis for further research regarding the potential such tools may have to encourage patient-centered care. While the design of the second study does not examine the effect of patient participation in nutrition care on clinical outcomes such as the nutrition status or quality of life, this candidate has recently begun a randomized controlled trial designed to encourage patient participation in nutrition care using the screening tool and same E-health platform as a basis.

3. Abstract

Patient-centered care (PCC) has become part of the foundation for the delivery of high-quality medical care. PCC can only be delivered through empowering and enabling patients to participate in shared decision making, while simultaneously acknowledging and accounting for the patient's individual situation. PCC is particularly important in the field of oncology. Cancer patients often have to deal with the emotional, social, and physical repercussions of the disease, while simultaneously navigating the complex medical system.

Among cancer patients, nutrition status has consistently been shown to affect clinical outcomes, quality of life, and functional and emotional well-being. The consideration of nutrition status is thus an essential part of PCC. While nutrition care is, by nature, patient centered, nutrition screening in Germany currently begins with a clinician-generated tool. This means there is an opportunity to change this process to encourage patient participation while optimizing the efficiency of care and allowing for the prioritization of patient-reported concerns.

Therefore, the aim of this dissertation was to establish a patient-centered nutrition screening tool in the German language (Publication 1) and to implement and analyze a manner in which it could be easily implemented into daily practice (Publication 2).

4. Zusammenfassung

Patientenzentrierung gehört mittlerweile zu der Grundlage einer hochwertigen medizinischen Versorgung und beinhaltet unter anderem die Befähigung der Patienten zur gemeinsamen Entscheidungsfindung. Gleichzeitig sollen die individuelle Situation, Bedürfnisse und Präferenzen des Patienten berücksichtigt werden. Im Bereich Onkologie kommt der Patientenzentrierung eine besondere Bedeutung zu. Krebspatienten müssen sich oft mit den emotionalen, sozialen und körperlichen Auswirkungen der Krankheit auseinandersetzen, während sie gleichzeitig durch das komplexe medizinische System navigieren müssen.

Die Berücksichtigung des Ernährungsstatus von Krebspatienten ist ein wesentlicher Bestandteil der Patientenzentrierung, da dieser den klinischen Verlauf, die Lebensqualität, sowie das funktionelle und emotionale Wohlbefinden beeinflussen kann. Während die Ernährungsinterventionen von Natur aus patientenzentriert sind, beginnt der Prozess mit dem Ernährungsscreening, welches in Deutschland aktuell von medizinischem Personal

durchgeführt wird. Daher bietet sich die Möglichkeit Chance, diesen Prozess zu ändern, um die Beteiligung der Patienten zu fördern und somit den Screening-Prozess patientenzentriert zu gestalten. Gleichzeitig könnte dadurch die Effizienz der Versorgung optimiert und die Priorisierung von patientenberichteten Anliegen ermöglicht werden.

Das Ziel dieser Dissertation war es, ein patientenzentriertes Ernährungsscreening-Tool in deutscher Sprache zu etablieren (Publikation 1) und eine einfache Anwendungsmethode in die tägliche Praxis zu implementieren und analysieren (Publikation 2).

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