Supportive Care in Cancer (2019) 27:3499–3507
https://doi.org/10.1007/s00520-019-4637-3

ORIGINAL ARTICLE

Tri-country translation, cultural adaptation, and validity confirmation of the Scored Patient-Generated Subjective Global Assessment

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Received: 3 August 2018 / Accepted: 7 January 2019 / Published online: 25 January 2019

Abstract

Purpose The Scored Patient-Generated Subjective Global Assessment (PG-SGA) is the only malnutrition (risk) assessment tool that combines patient-generated measures with professional-generated (medical) factors. We aimed to apply international standards to produce a high quality, validated, translation and cultural adaptation of the original PG-SGA for the Austrian, German, and Swiss setting.

Methods Analogue to methodology used for the Dutch, Portuguese, and Thai versions of PG-SGA, the ten steps of the International Society for Pharmacoeconomics and Outcomes Research's principles of good practice for translation and cultural adaptation were followed. Comprehensibility and difficulty of the translation were assessed in 103 patients and 104 healthcare professionals recruited from all three German-speaking countries. Content validity of the translation was assessed among healthcare professionals (HCP). Item and scale indices were calculated for content validity (I-CVI; S-CVI), comprehensibility (I-CI; S-CI), and difficulty (I-DI; S-DI).

Results Patients' perceived comprehensibility and difficulty of the PG-SGA fell within the range considered to be excellent (S-CI = 0.90, S-DI = 0.90), HCP-perceived content validity (S-CVI = 0.90) was also excellent, while HCP-perceived comprehensibility fell within the high range of acceptable (S-CI = 0.87). The professional component of the PG-SGA was perceived as below acceptable (S-DI = 0.72) with the physical exam being rated the most difficult (I-DI=0.29-0.75).

Conclusions The systematic approach resulted in a high-quality validation of the German language version of the PG-SGA, that is internationally comparable, comprehensible, easy to complete, and considered relevant for use in Austria, Germany and Switzerland.

Keywords PG-SGA · Disease-related malnutrition · Screening · Nutritional Assessment · Validation

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Introduction

Disease-related malnutrition (DRM) is a multifaceted process which can develop as a consequence of the complex interplay of disease and nutrition-related factors. These factors include, but are not limited to, nutrient losses and/or nutritional deficiencies resulting from malabsorption, increased energy requirements, side effects from medications and medical treatments, and metabolic factors associated with a disease state. Furthermore, it is important to consider the possible role of a combination of internal and external factors that may also affect nutrient intake, such as social and psychological factors, age, and dental health [1–4]. The effect of DRM on clinical outcomes and healthcare resources has been well documented [5–7]. For patients, DRM can impact directly quality of life and disease prognosis [8–10]. The European Society for Clinical Nutrition and Metabolism (ESPEN) therefore recommends that subjects at risk of malnutrition are identified by validated screening tools and should be assessed and treated accordingly [1].

Various screening tools have been developed, validated, and established to identify patients at risk for malnutrition. Among these tools, the Scored Patient-Generated Subjective Global Assessment (PG-SGA) is, to our knowledge, the only malnutrition risk assessment tool that utilizes a combination of patient-reported measures and professionally assessed medical factors. The PG-SGA includes items related to nutrient balance; body shape, size, and composition; function; inflammatory activity; and imbalance in fluid status to categorize nutrition risk and nutritional deficit/loss, covering the full breadth of the conceptual ESPEN malnutrition definition [11, 12]. The PG-SGA was developed and validated as a modification of the Subjective Global Assessment (SGA) and has been widely used internationally since its introduction in the late 1990s. The PG-SGA utilizes global categories to evaluate the patient's nutritional status. In addition, the PG-SGA generates a numerical score to triage for nutritional interventions [12]. Currently, no validated German language version of the PG-SGA is available. Multiple working groups in various countries worldwide are working together to ensure accurate and consistent translations and cultural adaptations of the PG-SGA for various cultural settings. In this study, we aimed to systematically translate and culturally adapt the original English PG-SGA for the Austrian, German, and Swiss setting, including content and linguistic validity in both patients and healthcare professionals.

Methods and statistical analysis

Methods

The entire process of translation, cultural adaptation, and content and linguistic validation was conducted between December 2015 and September 2017, and was carried out with permission from and in close cooperation with the key developer and copyright holder of the PG-SGA, an international expert on translation and cultural adaptation of the PG-SGA and key country representatives in Germany, Austria, and Switzerland. The medical ethics committee of the University of Munich and cantonal ethics committee Zurich ruled that no permission was needed to perform the study.

To assure that the internal and external validity of the English PG-SGA can be preserved in a translation, linguistic and cultural aspects must also be considered and evaluated and integrated into the process [13, 14]. Therefore, the translation and cultural adaptation process was performed according to the ten steps of the International Society for Pharmacoeconomics and Outcomes Research's (ISPOR's) principles of good practice for the translation and cultural adaptation process for patient-reported outcome measures [14]. Furthermore, with the aim of ensuring consistency among international translations and cultural adaptations of the PG-SGA, the methods utilized for the translation and cultural adaptation, as well as the methods utilized for the calculation and presentation of the results, were carefully chosen and implemented in agreement with those used in the Dutch project [15]. Sealy et al. gave a detailed overview of the 10 required steps for the translation and cultural adaptation process. Key components of this process are that both multiple independent forward translations and independent back translations are performed. Moreover, the translations performed are conceptual translations rather than literal translations [14]. The wordings of the target language are chosen to optimally suit in the target setting, which may culturally differ from the setting for which the original instrument was used. This is followed by a cognitive debriefing and exploration of content validity. For our study, step 1 (preparation phase) was carried out by the developer of the PG-SGA and the international expert on translation and cultural adaptation of the PG-SGA. Step 2 (forward translation) was carried out by two native German speakers. Step 3 (reconciliation) was carried out by the full team, which included the project manager, key developer, and international expert. Step 4 (back translation) was performed by two native English speakers in Germany. Step 5 (back translation review) was performed by the full team, after which the forward translation was harmonized (step 6). Subsequently, key country representatives from the German-speaking countries/regions of Austria, Germany, and Switzerland were identified to carry out step 7 (cognitive debriefing), which also included exploration of content validity, i.e., relevance, and step 8 (review of cognitive debriefing results and finalization).

For the cognitive debriefing, patients from Austria, Germany, and Switzerland evaluated comprehensibility and difficulty of the patient component, and healthcare professionals from these three countries evaluated comprehensibility and difficulty of the professional component of the PG-SGA,

as well as content validity of the full PG-SGA. The tri-country approach was consciously chosen in order to assure content validity throughout the different German-speaking regions by including a diverse range of dialects. This goal was further supported through the fact that the questionnaire was distributed to and completed by participants throughout Germany. This method ensured that the cognitive debriefing and content validity results would apply to all German-speaking regions/countries, despite differences in linguistic cadences.

Inpatient and outpatient patients were recruited by the key country representatives in all three countries. Native speakers ≥8 years or higher not 8 years of age who had no previous experience with the PG-SGA before participating and who were willing and able to provide demographic information were asked to rate comprehensibility and difficulty of the first four boxes of the PG-SGA. The questionnaire contained 36 four-point scales addressing comprehensibility, six addressing difficulty, four open-ended questions asking for feedback on the German wordings, and four questions addressing demographics.

In parallel, a variety of professionals (nurses, dietitians, nutritionists, doctors, physiotherapists, and students of nutrition) spread across the three countries were asked to provide demographic information and to complete a questionnaire consisting of 38 four-point scales on comprehensibility and 35 on difficulty of the professional component of the PG-SGA (i.e., the Worksheets), and 75 four-point scales on content validity of the full PG-SGA. In addition, eight open-ended questions were posed to ask for feedback on the German wordings of the professional component of the PG-SGA and six questions on demographics of the respondents. These professionals were recruited by word of mouth, professional networks including email lists and social media, and requests at seminars and conferences. For both groups, patients and healthcare professionals, we collected data on demographics. Afterwards, all results were collected, the data was entered into SPSS version 24 for statistical analysis, and a professional data scientist assisted to ensure accuracy of data input and the resulting calculated indices.

Statistical analysis

Content validity, also referred to as perceived relevance, of the full PG-SGA is reflected by the scale content validity index (S-CVI), as perceived by healthcare professionals. The higher the S-CVI, the more a consensus about the nature of the construct can be assumed. The S-CVI was adapted for this study, to quantify the concepts of comprehensibility and difficulty analogue to methodology used in the pilot testing of the Dutch PG-SGA [15]. To this purpose, indices for item comprehensibility (I-CI) and item difficulty (I-DI) were calculated and averaged into a scale comprehensibility index (S-CI) and scale difficulty index (S-DI). A four-point scale (1 = very irrelevant/very unclear/very difficult, 2 = irrelevant/unclear/difficult, 3 = relevant/clear/easy, 4 = very relevant/very clear/very easy) was chosen to have a neutral and ambivalent midpoint and to represent the results of each item. The points from 0 to 1 were calculated by dividing the number of respondents who considered the item to be "comprehensible and not difficult" (i.e., scores 3 or 4 for each construct) by the total number of respondents.

The total S-CI and S-DI scores of the patient-generated component of the PG-SGA were calculated by averaging I-CI scores and I-DI scores of boxes 1 to 4. The S-CI and S-DI of the professional component of the PG-SGA were calculated by averaging I-CI scores and I-DI scores of Worksheets 1 to 5. The scale indices S-CI and S-DI reflect respectively overall comprehensibility and difficulty as perceived by patients for the patient-generated component and as perceived by professionals for the professional component of the PG-SGA. S-CVI was calculated for both the patient-generated and the professional component of the PG-SGA. Cutoff values for the evaluation of validity were defined in agreement with the values listed in previously published standards applied to the translation and cultural adaptation of the PG-SGA [15]. These values were defined as follows: an item index score (I-CVI, I-CI or I-DI) > 0.78 was considered excellent, and item index scores < 0.78 requires further analysis of the item. A scale index score (S-CVI, S-CI, or S-DI) of 0.80 to 0.89 was considered acceptable, and a scale index score of ≥ 0.90 was considered excellent [15]. Patients and healthcare professionals' non-response to items was excluded from the results, and only completed questionnaires were considered.

Results

The first six steps of the ISPOR process resulted in the prefinal version of the German version of the PG-SGA, which was then evaluated for comprehensibility, difficulty, and content validity between January and September 2017. Documentation and details on each of the steps of the ISPOR process are available upon request from the last author.

In total, 103 patients from different regions of Germany and Switzerland completed the questionnaire on comprehensibility and difficulty of the patient-generated component of the PG-SGA. In parallel, 104 German, Austrian, and Swiss healthcare professionals completed the questionnaire developed for the professionals. The sample consisted of 10 nutritionists, 34 registered dietitians, 18 physiotherapists, 14 physicians, 17 nurses, and two students, as shown in Table 1. Nine participants categorized their professions as other but worked in a healthcare setting. None had previous experience with the PG-SGA. Due to persistent and clear communication with the

Table 1 Overview of professionals who completed the questionnaire on content validity of the full PG-SGA and comprehensibility and difficulty of the professional component of the PG-SGA

	Germany	Austria	Switzerland	Total
Nutritionist	3	6	1	10
Dietitians	23	4	7	34
Physiotherapist	0	0	18	18
Doctor	3	0	11	14
Nurse	9	0	8	17
Student	1	1	0	2
Other	0	3	6	9
	39	14	51	104

participants, item response rate for both professionals and patients was maintained at 100%.

The indices for comprehensibility and difficulty (as perceived by patients) and content validity (as perceived by professionals) for the patient-generated component of the German language version of the PG-SGA are presented in Table 2. For the patient-generated component, scale index on content validity/relevance fell into the predefined excellent range (S-CVI = 0.90), with individual item scores ranging from 0.89 to 0.98. Likewise, for comprehensibility and difficulty, patient's perception fell within the excellent range (S-CI = 0.96 and S-DI = 0.91 respectively). Here, individual item scores ranged from 0.88 to 1.00 for I-CI and 0.86–0.95 for I-DI.

Table 3 presents the results of the evaluation of the professional component of the PG-SGA. Like the patient-generated component, scores given by the professionals on content validity of the professional component fell into the predefined excellent range (S-CVI = 0.90). However, for the professional component, individual item scores ranged from I-CVI = 0.64 to I-CVI = 0.98. All scores for individual items that fell below the predefined cutoff of 0.80 for acceptability came from Worksheet 4—physical exam. Results of the professionals' perceived comprehensibility fell into the acceptable range (S-CI = 0.87). Individual item scores for comprehensibility ranged from 0.63 to 0.98. Results for difficulty fell slightly below the acceptable range (S-DI = 0.72), and here, individual item scores ranged from 0.29 to 0.97. For difficulty, the item scores that fell below the cutoff for acceptability were again from Worksheet 4, and a single item, i.e., the heading "metabolic demand" from Worksheet 2 (I-DI = 0.70).

Content validity of the overall PG-SGA was perceived sufficient for the assessment of malnutrition on scale level (S-CVI = 0.90).

In consideration of the individual item scores and in response to the comments given by the respondents, the key country members, the developer of the PG-SGA, and the international expert on translation and cultural adaptation of the PG-SGA consulted together and agreed to a few tweaks to the pre-final version of the German PG-SGA. These included three spelling and grammar improvements and four linguistic changes that were not considered significant.

Subsequently, the German language PG-SGA was finalized (version 18-006 v03.26.18) and published at www.pt-global.org on 26 March 2018. Based on additional suggestions from users of the PG-SGA, the German PG-SGA was further improved one more time. These improvements included three minor spelling and grammar improvements and minor linguistic fine tuning. For example, the Latin terminology, in addition to the German terms for muscles, were added to Worksheet 2. The first and last authors can provide details of these changes upon request. The second final version (18-006 v05.10.18) was published in www.pt-global.org on 10 May 2018. This final version of the German PG-SGA is presented in Fig. 1a (patient component, i.e., boxes) and Fig. 1b (professional component, i.e., worksheets).

Discussion

Overall, the results from the translation and cultural adaptation of the PG-SGA to the Austrian, German, and Swiss settings represent a successful validation, indicating that the German PG-SGA is comprehensible, easy to use, and relevant for use by patients and professionals in these countries.

Overall, the results of the cognitive debriefing in our study are comparable with those in the Dutch and Thai studies. In the current study, patients gave lower scores on perceived comprehensibility of the patient component of the German PG-SGA (S-CI = 0.90) than the Dutch and Thai patients (both S-CI = 0.99). However, scores for perceived difficulty (S-CI = 0.96) were similar to the Dutch and Thai (S-DI = 0.96 and 0.95 respectively). This could be due to the nature of the tri-country area that was covered in our study. The tri-country approach meant that the German-speaking collective was made up of heterogeneous regions and dialects. It is also of interest that the professionals in our study gave higher scores on perceived comprehensibility and difficulty of the professional component of the German PG-SGA than the Dutch professionals (S-CI = 0.81 and S-DI = 0.55), but lower than the Thai professionals (S-CI = 0.92 and S-DI = 0.79) [15, 16].

Similar to findings in the Dutch and Thai studies, scores falling below the acceptable range stemmed from the professional component of the questionnaire. These lower scores were mainly related to perceived difficulty, despite the fact that the professionals' scores on comprehensibility indicated that they understood linguistically what was being asked. The lower scores on perceived difficulty can be explained by the lack of experience and prior knowledge of the instrument or the PG-SGA among these professionals. In fact, ten healthcare

Table 2 Indices for content validity, comprehensibility, and difficulty for the patient-generated component of the German Patient-Generated Subjective Global Assessment as perceived by professionals and cancer patients in Germany, Switzerland, and Austria

	Professionals content validity/relevance $N = 104$	Patients comprehensibility $N = 103$	Patients difficulty $N = 103$
Item	I-CVI	I-CI	I-DI
Box 1. Weight			
1a I currently weigh about___ kg	0.98	1.00	0.94
1b I am about ___ cm tall	0.96	1.00	
1c One month ago, I weighed about___ kg	0.92	0.98	
1d Six months ago I weighed about___ kg	0.94	0.98	
1e Weight—decreased, not changed, increased	0.90	0.92	0.93
Box 2. Food intake			
2a. As compared to my normal intake, I would rate my food intake during the past month as	0.97	0.95	0.92
2a1 Unchanged, more than usual, less than usual	0.89	0.95	
2b. I am now taking	0.97	0.98	0.86
2b1 Normal food- but less than normal amount	0.93	0.94	
2b2 Little solid food	0.89	0.97	
2b3 Only liquids	0.89	0.88	
2b4 Only nutritional supplements	0.89	0.88	
2b5 Very little of anything	0.89	0.93	
2b6 Only tube feedings or only nutrition by vein	0.93	0.97	
Box 3. Symptoms			
3a. I have had the following problems that have kept me from eating enough during the past 2 weeks	0.94	0.99	0.95
3a1 No problems eating	0.93	0.96	
3a2 No appetite. Just did not feel like eating	0.99	0.95	
3a3 Nausea	0.96	0.97	
3a4 Constipation	0.96	0.97	
3a5 Mouth sores	0.94	0.94	
3a6 Things taste funny or have no taste	0.92	0.96	
3a7 Problems swallowing	0.96	0.96	
3a8 Pain, where?	0.96	0.98	
3a9 Other	0.92	0.97	
3a10 Vomiting	0.98	0.97	
3a11 Diarrhea	0.93	0.97	
3a12 Dry mouth	0.94	1.00	
3a13 Smells bother me	0.89	0.96	
3a14 Feel full quickly	0.94	0.98	
3a15 Fatigue	0.91	0.98	
Box 4. Activities and function			
4a. Over the past month. I would generally rate my activity as	0.98	0.93	0.89
4a1 Normal with no limitations	0.96	0.99	
4a2 Not my normal self, but able to be up and about with fairly normal activities	0.91	0.80	
4a3 Not feeling up to most things, but in bed or chair less than half the day	0.92	0.93	
4a4 Able to do little activity and spend most of the day in bed or chair	0.92	0.96	
4a5 Pretty much bedridden, rarely out of bed	0.93	0.98	
Scales indices patient-generated component	S-CVI (= 0.90)	S-CI (= 0.96)	S-DI (= 0.91)

Table 3 Indices for content validity, comprehensibility, and difficulty for the professional component of the German Patient-Generated Subjective Global Assessment as perceived by professionals in Germany, Switzerland, and Austria

	Professionals content validity/relevance $N = 104$	Professionals comprehensibility $N = 103$	Professionals difficulty $N = 103$
Item	I-CVI	I-CI	I-DI
Scoring weight (Wt) loss	0.98	0.91	0.89
Worksheet 2. Disease and its relation to nutritional requirements	0.98	0.98	0.97
2a. Cancer	0.95	0.96	0.91
2b. AIDS	0.91	0.95	0.95
2c. Pulmonary or cardiac cachexia	0.95	0.92	0.89
2d. Chronic renal insufficiency	0.94	0.98	0.95
2e. Presence of decubitus, open wound or fistula	0.90	0.96	0.96
2f. Presence of trauma	0.87	0.89	0.88
2g. Age greater than 65	0.90	0.98	0.97
2h. All relevant diagnoses	0.87	0.93	0.83
2i. Primary disease staging (circle if known or appropriate) I, II, III, IV, other	0.85	0.82	0.79
Worksheet 3. Metabolic demand	0.85	0.71	0.70
3a. Fever	0.88	0.94	0.84
3b. Fever duration	0.84	0.90	0.80
3c. Corticosteroids	0.84	0.89	0.80
Worksheet 4. Physical exam	0.90	0.68	0.47
4a. Temples (temporalis muscles)	0.77	0.83	0.53
4b. Clavicles	0.76	0.81	0.50
4c. Shoulders (deltoids)	0.77	0.81	0.51
4d. Interosseous muscles	0.68	0.63	0.29
4e. Scapula (latissimus dorsi. Trapezius. deltoids)	0.74	0.76	0.51
4f. Thigh (quadriceps)	0.80	0.87	0.56
4g. Calf (gastrocnemius)	0.79	0.86	0.56
4h. Global muscle status rating	0.92	0.85	0.55
4i. Orbital fat pads	0.76	0.78	0.48
4j. Triceps skin fold	0.84	0.85	0.56
4k. Fat overlying lower ribs	0.77	0.81	0.52
4l. Global fat deficit rating	0.90	0.88	0.52
4m. Ankle edema	0.89	0.88	0.75
4n. Sacral edema	0.74	0.83	0.60
4o. Ascites	0.88	0.88	0.58
4p. Global fluid status rating	0.93	0.89	0.62
Worksheet 5. Global Assessment Categories Stage A: well nourished; Stage B: moderate/suspected malnutrition; Stage C: severely malnourished	0.96	0.91	0.88
Nutritional triage recommendations: Additive score	0.94	0.81	0.74
Triage: 0–1, no intervention required at this time. Re-assessment on routine and regular basis during treatment	0.95	0.94	0.86
Triage: 2–3, patient and family education by dietitian, nurse, or other clinician with pharmacologic intervention as indicated by symptom survey (box 3) and lab values as appropriate	0.94	0.90	0.86
Triage: 4–8, requires intervention by dietitian. in conjunction with nurse or physician as indicated by symptoms (box 3)	0.96	0.90	0.86
Triage: ≥ 9, indicates a critical need for improved symptom management and/or nutrient intervention options	0.97	0.88	0.86
	S-CVI (= 0.90)	S-CI (= 0.87)	S-DI (= 0.72)

a

Scored Patient-Generated Subjective Global Assessment (PG-SGA) (Patientenbezogenes Ernährungsassessment)

Krankengeschichte: Die Kästchen 1–4 sind vom Patienten auszufüllen.

(Kästchen 1–4 werden auch als Kurzform [Short Form] des PG-SGA bezeichnet [PG-SGA SF])

Patientenkennung

1. Gewicht *(siehe Arbeitsblatt 1)*

Zusammenfassung meines derzeitigen und kürzlichen Gewichts:

Ich wiege derzeit etwa _____ kg.
Ich bin etwa _____ cm groß.

Vor einem Monat habe ich etwa _____ kg gewogen.
Vor sechs Monaten habe ich etwa _____ kg gewogen.

In den vergangenen zwei Wochen hat sich mein Gewicht:

☐ verringert (1) ☐ nicht verändert (0) ☐ erhöht (0)

Kästchen 1 ☐

2. Nahrungsaufnahme: Im Vergleich zu meiner normalen Nahrungsaufnahme würde ich diese im vergangenen Monat wie folgt bewerten:

☐ unverändert (0)
☐ mehr als gewöhnlich (0)
☐ weniger als gewöhnlich (1)

Derzeit nehme ich folgende Nahrung auf:

☐ normale Nahrung, aber kleinere Mengen als normal (1)
☐ kleine Mengen fester Nahrung (2)
☐ nur Flüssigkost (3)
☐ nur Trinknahrung/Astronautennahrung (3)
☐ sehr wenig Nahrung irgendeiner Art (4)
☐ nur Sondennahrung oder nur künstliche Ernährung über die Vene (parenteral) (0)

Kästchen 2 ☐

3. Symptome: Bei mir traten die folgenden Probleme auf, die mich in den vergangenen zwei Wochen davon abgehalten haben, ausreichend zu essen (alles Zutreffende ankreuzen):

☐ keine Probleme mit dem Essen (0)
☐ kein Appetit, mir war einfach nicht nach Essen (3)
☐ Übelkeit (1)
☐ Verstopfung (1)
☐ Schmerzen im Mund (2)
☐ Dinge schmecken komisch oder haben keinen Geschmack (1)
☐ Probleme mit dem Schlucken (2)
☐ Schmerzen – wo? (3) _____
☐ Sonstiges (1)** _____
☐ Erbrechen (3)
☐ Durchfall (3)
☐ trockener Mund (1)
☐ Gerüche stören mich (1)
☐ fühle mich schnell satt (1)
☐ Müdigkeit (1)

**Beispiele: Depression, Geldsorgen oder Zahnprobleme

Kästchen 3 ☐

4. Aktivitäts- und Funktionsniveau: Mein Aktivitätsniveau in den letzten vier Wochen würde ich allgemein wie folgt bewerten:

☐ normal ohne Einschränkungen (0)
☐ nicht wie gewohnt, aber ich war auf den Beinen und konnte Aktivitäten wie üblich nachgehen (1)
☐ fühlte mich den meisten Dingen nicht gewachsen, aber verbrachte weniger als den halben Tag im Bett oder Sessel (2)
☐ konnte nur wenig aktiv sein und verbrachte die meiste Zeit des Tages im Bett oder im Sessel (3)
☐ größtenteils bettlägerig, nur selten außerhalb des Bettes (3)

Kästchen 4 ☐

Der Rest dieses Bewertungsbogens ist von Ihrem Arzt, Ihrer Pflegekraft, Ihrem Diätassistenten* oder Therapeuten auszufüllen. Vielen Dank.

E-Mail: faithotterymdphd@aol.com oder info@pt-global.org

**** oder Ökotrophologen, Diätologen, Ernährungsberatern***

Addierter Score der Kästchen 1–4 ☐ **A**

Fig. 1 German language version of the Scored Patient-Generated Subjective Global Assessment (PG-SGA)

professionals reported in the open-ended questions section that they lacked the experience and training regarding the physical examination. These results underscore the previously identified need to train professionals on the necessity and interpretation of physical exams in the context of malnutrition assessment. The fact that professionals necessitate training on the implementation of Worksheets 2–5 is further underscored by two more of our results. First, the individual item from Worksheet 3, with the heading "metabolic demand,", scored slightly below the acceptable range for both comprehensibility and difficulty (0.71 and 0.70). However, the individual items 3a–3c which defined the term "metabolic demand" all scored within the acceptable to the excellent range (0.80–0.94) (see Worksheet 3). As no comments were given about this inconsistency in the open-ended questions section and as the relevance and content validity score for this item fell within the acceptable range, it was not deemed necessary to revise this heading. However, it does indicate that professionals may not understand the relevance of metabolic demand for the assessment of malnutrition. Second, in the open-ended questions sections, eight professionals added a comment that they wanted to add a sublist defining item 2i from Worksheet 2, which refers to the primary disease staging. Here, difficulty fell slightly below the acceptable range for the individual item (I-DI = 0.79) while the individual content relevance/validity and comprehensibility score fell into the acceptable range (I-CVI = 0.85 and I-CI = 0.82 respectively). This result reflects that some professionals may not be properly educated on tumor staging.

Implications for research and practice

When a previously validated research tool is translated into another language and used in a different cultural setting, it is essential that a systematic translation and cultural adaptation process is followed in order to maintain the original purpose and intention. This ensures that the scientific data collected by the tool are consistent and reliable throughout different

b

Scored Patient-Generated Subjective Global Assessment (PG-SGA)

Arbeitsblatt 1 – Bewertung des Gewichtsverlusts

Sofern verfügbar, sind zur Score-Bestimmung die Gewichtsdaten eines Monats zu verwenden. Die Gewichtsdaten über 6 Monate sind nur zu verwenden, falls keine Gewichtsdaten eines Monats vorliegen. Verwenden Sie die nachfolgenden Punkte, um die Gewichtsveränderung zu bewerten, und fügen Sie einen Extrapunkt hinzu, falls der Patient in den vergangenen 2 Wochen Gewicht verloren hat. Tragen Sie den Gesamtpunktescore in Kästchen 1 des PG-SGA ein.

Gewichtsverlust in 1 Monat	Punkte	Gewichtsverlust in 6 Monaten
10 % oder mehr	4	20 % oder mehr
5–9,9 %	3	10–19,9 %
3–4,9 %	2	6–9,9 %
2–2,9 %	1	2–5,9 %
0–1,9 %	0	0–1,9 %

Numerischer Score von Arbeitsblatt 1 ☐

Addierter Score der Kästchen 1–4 (siehe Seite 1) ☐ **A**

5. Arbeitsblatt 2 – Krankheit und deren Zusammenhang mit den Ernährungsanforderungen:

Der Score wird berechnet, indem 1 Punkt für jede der folgenden Erkrankungen hinzuaddiert wird:

☐ Krebs ☐ Vorliegen eines Dekubitus, einer offenen Wunde oder Fistel
☐ AIDS ☐ Vorliegen eines Traumas
☐ Pulmonale oder kardiale Kachexie ☐ Alter über 65
☐ Chronische Niereninsuffizienz

Sonstige relevante Diagnosen (bitte angeben) _____

Stadium der Grunderkrankung (einkreisen, sofern bekannt oder zutreffend) I II III IV Sonstiges ____

Numerischer Score von Arbeitsblatt 2 ☐ **B**

6. Arbeitsblatt 3 – Stoffwechselbedarf

Der Score für die Stoffwechselbelastung wird durch eine Reihe von Variablen ermittelt, die bekanntermaßen den Protein- und Kalorienbedarf erhöhen. **Hinweis:** Fieberintensität oder -dauer bewerten, je nachdem, was den höheren Wert ergibt. Der Score wird addiert, so dass ein Patient mit einem Fieber von 38,8 °C (3 Punkte), das < 72 Std. (1 Punkt) andauert, und der eine Langzeitbehandlung mit 10 mg Prednison (2 Punkte) erhält, für diesen Abschnitt einen addierten Score von 5 Punkten aufweisen würde.

Belastung	keine (0)	gering (1)	mäßig (2)	hoch (3)
Fieber	kein Fieber	> 37,2 und < 38,3	≥ 38,3 und < 38,8	≥ 38,8 °C
Dauer des Fiebers	kein Fieber	< 72 Stunden	72 Stunden	> 72 Stunden
Kortikosteroide	keine Kortikosteroide	niedrige Dosis (< 10 mg Prednison-Äquivalente/Tag)	mittlere Dosis (≥ 10 mg und < 30 mg Prednison-Äquivalente/Tag)	hohe Dosis (≥ 30 mg Prednison-Äquivalente/Tag)

Numerischer Score von Arbeitsblatt 3 ☐ **C**

7. Arbeitsblatt 4 – Körperliche Untersuchung

Die Untersuchung umfasst eine subjektive Beurteilung von 3 Aspekten der Körperzusammensetzung: Fett, Muskeln und Flüssigkeit. Da dies subjektiv ist, wird für jeden Aspekt der Untersuchung der Grad bewertet. Ein Muskeldefizit/-verlust wirkt sich stärker auf den Score aus als ein Fettdefizit/-verlust. Definition der Kategorien: 0 = keine Abweichung, 1+ = leicht, 2+ = mäßig, 3+ = schwer. Die Bewertung in diesen Kategorien wird *nicht* addiert, sondern zur klinischen Einschätzung des Defizitgrades (bzw. des Vorhandenseins überschüssiger Flüssigkeit) verwendet.

Muskelstatus					Fettpolster				
Schläfen (m. temporalis)	0	1+	2+	3+	Orbitale Fettpolster	0	1+	2+	3+
Schlüsselbein (m. pectoralis major und m. deltoideus)	0	1+	2+	3+	Trizeps-Hautfalte	0	1+	2+	3+
					Fettschicht über den unteren Rippen	0	1+	2+	3+
Schultern (m. deltoideus)	0	1+	2+	3+	**Gesamtbewertung des Fettdefizits**	**0**	**1+**	**2+**	**3+**
Zwischenknochenmuskeln (m. interosseus)	0	1+	2+	3+	**Flüssigkeitsstatus**				
Schulterblatt (m. latissimus dorsi, m. trapezius, m. deltoiudeus)	0	1+	2+	3+	Knöchelödem	0	1+	2+	3+
					Sakralödem	0	1+	2+	3+
Oberschenkel (m. quadriceps)	0	1+	2+	3+	Aszites	0	1+	2+	3+
Wade (m. gastrocnemius)	0	1+	2+	3+	**Gesamtbewertung des Flüssigkeitsstatus**	**0**	**1+**	**2+**	**3+**
Gesamtbewertung des Muskelstatus	**0**	**1+**	**2+**	**3+**					

Der Score für die körperliche Untersuchung wird durch die allgemeine, subjektive Bewertung des Gesamtkörperdefizits bestimmt.

Kein Defizit	Score = 0 Punkte	**Denken Sie daran, dass ein Muskeldefizit/-verlust in höherem Maße zu berücksichtigen ist als ein Fettverlust oder eine Flüssigkeitsansammlung.**
Geringes Defizit	Score = 1 Punkt	
Mäßiges Defizit	Score = 2 Punkte	
Schweres Defizit	Score = 3 Punkte	

Numerischer Score für Arbeitsblatt 4 ☐ **D**

PG-SGA-Gesamtscore (Gesamter numerischer Score von A+B+C+D) ☐

Unterschrift des Arztes Dr. _____ Sonstiges_____ Datum _____

Kategorie-Gesamtbewertung anhand des PG-SGA (Stadium A, Stadium B oder Stadium C) ☐

Arbeitsblatt 5 – PG-SGA-Kategorien zur Allgemeinbeurteilung

	Stadium A	Stadium B	Stadium C
Kategorie	**guter Ernährungszustand**	**Mäßige/Verdacht auf Mangelernährung**	**Schwere Mangelernährung**
Gewicht	Kein Gewichtsverlust **ODER** kürzliche nicht-flüssigkeitsbedingte Gewichtszunahme	≤ 5 % χαμένα τα τελευταία 1 Monat (≤ 10 % in 6 Monaten) **ODER** progressiver Gewichtsverlust	> 5 % Verlust in 1 Monat (> 10 % in 6 Monaten) **ODER** progressiver Gewichtsverlust
Nahrungsaufnahme	Kein Defizit **ODER** kürzlich aufgetretene signifikante Verbesserung	Eindeutig geringere Nahrungsaufnahme	Schweres Defizit bei der Nahrungsaufnahme
Symptome mit Einfluss auf Nahrungsaufnahme (Nutrition Impact Symptoms, NIS)	Keine **ODER** kürzlich aufgetretene signifikante Verbesserung, die eine ausreichende Nahrungsaufnahme zulässt	Vorliegen von Symptomen mit Einfluss auf Nahrungsaufnahme (Kästchen 3 des PG-SGA)	Vorliegen von Symptomen mit Einfluss auf Nahrungsaufnahme (Kästchen 3 des PG-SGA)
Funktionsfähigkeit	Kein Defizit **ODER** kürzlich aufgetretene signifikante Verbesserung	Mäßiges Funktionsdefizit **ODER** kürzlich aufgetretene Verschlechterung	Schweres Funktionsdefizit **ODER** kürzlich aufgetretene signifikante Verschlechterung
Körperliche Untersuchung	Kein Defizit **ODER** chronisches Defizit, aber mit kürzlich aufgetretener klinischer Verbesserung	Nachweis eines geringen bis mäßigen Verlusts der Muskelmasse und/oder des Muskeltonus bei Palpation und/oder Verlust des subkutanen Fettgewebes	Offensichtliche Anzeichen einer Mangelernährung (z. B. schwerer Muskel- oder Fettverlust bzw. mögliches Ödem)

Ernährungsbezogene Triage-Empfehlungen: Der addierte Score wird verwendet, um die speziellen Ernährungsinterventionen zu definieren, einschließlich Patienten- und Familienunterweisung, Symptombehandlung einschließlich pharmakologischer Intervention und entsprechende Ernährungsintervention (Triage in Bezug auf Nahrung, Trinknahrung, enterale oder parenterale Ernährung).

Zur Erstlinien-Ernährungsintervention gehört ein optimales Symptom-Management.

Triage auf Grundlage des PG-SGA-Scores

0–1	Keine Intervention zu diesem Zeitpunkt erforderlich. Routinemäßige und regelmäßige Neueinschätzung während des Behandlungsverlaufs
2–3	Aufklärung von Patient und Familie durch einen Diätassistenten, eine Pflegekraft oder einen Arzt hinsichtlich pharmakologischer Intervention, wie im Symptomfragebogen angegeben (Kästchen 3) und ggf. gemäß den Laborwerten
4-8	Erfordert Intervention durch einen Diätassistenten in Verbindung mit einer Pflegekraft oder einem Arzt, abhängig von den Symptomen (Kästchen 3)
≥ 9	Zeigt einen kritischen Bedarf für eine verbesserte symptomatische Behandlung und/oder für Ernährungsinterventionen an

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Fig. 1 (continued)

countries and settings. Our results mirror the methods followed by Sealy et al. for the translation and cultural adaptation of the PG-SGA to the Dutch setting, which has become the standard methodology for the development of all future language versions of the PG-SGA worldwide [15]. This method produces not only a culturally valid translation of the PG-SGA but also safeguards cultural equivalence [14]. The results for the German translation and cultural adaption indicate that the resulting German version of the PG-SGA maintained purpose, meaning, and format. Furthermore, the acceptable values for content validity reflect that the German version presented in this paper is ready for use in a clinical setting and in future studies conducted in the German language throughout Germany, Austria, and Switzerland. Our results have produced a high quality and validated version of the tool that is, to our knowledge, the only internationally validated tool for collecting patient-reported data focusing on nutrition status and including the metabolic demand, a physical exam, and nutrition impact symptoms. Now, the PG-SGA can be easily implemented in the German language, and results will be reliable and consistent with international data derived from validated versions of the PG-SGA.

Nevertheless, before implementing the full PG-SGA in clinical practice, training of professionals is recommended. Previous research in the Netherlands and Portugal has shown that a full day of both theoretical and practical training improves perceived comprehensibility and difficulty by enhanced skills and knowledge in applying the PG-SGA [17, 18].

Although a large geographical and dialect range extending from northern to southern Germany and into Switzerland was covered by our participants, our study was limited by the low number of participants from Austria. Unfortunately, our efforts to recruit Austrian patients were not fruitful and the number of Austrian professionals ($n = 14$) fell below our target of 50 per country. Nevertheless, the total number of patients ($n = 103$) and professionals ($n = 104$) that participated in the cognitive debriefing remains well above the total number of participants as recommended by ISPOR (i.e., $n = 5$ to 8) for the testing of the translation and cultural adaptation. In fact, the number of participants in both our professional and patient

groups is significantly higher than those reported by Sealy et al. in the Netherlands (six patients and eight professionals) and Nitichai et al. in Thailand (50 patients and 50 professionals) [15, 16].

Conclusion

The systematic approach employing ISPOR principles utilized for the translation and cultural adaptation of the PG-SGA resulted in a German language version of the PG-SGA that is comprehensible, easy to complete, and considered relevant for use in Austria, Germany, and Switzerland, while safeguarding the purpose, meaning, and format of the original English PG-SGA.

Acknowledgments The authors would like to thank everyone who supported this study, be it in recruiting patients and professionals, spreading the word, or doing "busy work" like filing the completed questionnaires. In particular, we would like to thank Diana Schweizer, Caroline Kiss, Ursula Lukas, Carmen Lautner, the dietitian association in Germany and thier oncology specialists group. Furthermore, we would like to thank Roche, for providing funding for the completion of steps 1-6 (translation and back translation). Roche was not involved for the completion of steps 7-10.

Compliance with ethical standards

Conflict of interest F. O is co-creator PG-SGA and co-founder PG-SGA/Pt-Global Platform. She was co-developer of the PG-SGA-based Pt-Global app/web tool. H. J.-W. was co-developer of the PG-SGA-based Pt-Global app/web tool. All other authors have no conflict of interest to declare. All authors have full control of all primary data and agree to allow the journal to review their data if requested.

References

1. Cederholm T, Bosaeus I, Barazzoni R, Bauer J, Van Gossum A, Klek S et al (2015) Diagnostic criteria for malnutrition - an ESPEN consensus statement. Clin Nutr 34(3):335–340. https://doi.org/10.1016/j.clnu.2015.03.001
2. Cederholm T, Jensen GL (2017) To create a consensus on malnutrition diagnostic criteria: a report from the Global Leadership Initiative On Malnutrition (GLIM) meeting at the ESPEN congress 2016. Clin Nutr 36(1):7–10. https://doi.org/10.1016/j.clnu.2016.12.001
3. Poulia KA, Klek S, Doundoulakis I, Bouras E, Karayiannis D, Baschali A, Passakiotou M, Chourdakis M (2017) The two most popular malnutrition screening tools in the light of the new ESPEN consensus definition of the diagnostic criteria for malnutrition. Clin Nutr 36(4):1130–1135. https://doi.org/10.1016/j.clnu.2016.07.014
4. Barker LA, Gout BS, Crowe TC (2011) Hospital malnutrition: prevalence, identification and impact on patients and the healthcare system. Int J Environ Res Public Health 8(2):514–527. https://doi.org/10.3390/ijerph8020514
5. Lim SL, Ong KC, Chan YH, Loke WC, Ferguson M, Daniels L (2012) Malnutrition and its impact on cost of hospitalization, length of stay, readmission and 3-year mortality. Clin Nutr 31(3):345–350. https://doi.org/10.1016/j.clnu.2011.11.001
6. Navarro DA, Boaz M, Krause I, Elis A, Chernov K, Giabra M, Levy M, Giboreau A, Kosak S, Mouhieddine M, Singer P (2015) Improved meal presentation increases food intake and decreases readmission rate in hospitalized patients. Clin Nutr 35:1153–1158. https://doi.org/10.1016/j.clnu.2015.09.012.
7. Löser C (2010) Malnutrition in hospital: the clinical and economic implications. Dtsch Arztebl Int 107(51–52):911–917. https://doi.org/10.3238/arztebl.2010.0911.
8. Escamilla DM, Jarrett P (2016) The impact of weight loss on patients with cancer. Nurs Times 112(11):20–22
9. Marin Caro MM, Laviano A, Pichard C (2007) Impact of nutrition on quality of life during cancer. Curr Opin Clin Nutr Metab Care 10(4):480–487. https://doi.org/10.1097/MCO.0b013e3281e2c983
10. Ravasco P, Monteiro Grillo I, Camilo M (2007) Cancer wasting and quality of life react to early individualized nutritional counselling! Clin Nutr 26(1):7–15. https://doi.org/10.1016/j.clnu.2006.10.005
11. Ottery FD (1996) Definition of standardized nutritional assessment and interventional pathways in oncology. Nutrition 12(1 Suppl): S15–S19
12. Jager-Wittenaar H, Ottery FD (2017) Assessing nutritional status in cancer: role of the Patient-Generated Subjective Global Assessment. Curr Opin Clin Nutr Metab Care. 20(5):322–329. https://doi.org/10.1097/MCO.0000000000000389
13. Beaton DE, Bombardier C, Guillemin F, Ferraz MB (2000) Guidelines for the process of cross-cultural adaptation of self-report measures. Spine 25(24):3186–3191
14. Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, Erikson P (2005) Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. Value Health 8(2):94–104. https://doi.org/10.1111/j.1524-4733.2005.04054.x
15. Sealy MJ, Hass U, Ottery FD, van der Schans CP, Roodenburg JLN, Translation J-WH (2017) Cultural adaptation of the Scored Patient-Generated Subjective Global Assesment: an interdisciplinary nutritional instrument appropriate for Dutch cancer patients. Cancer Nurs 41:450–462. https://doi.org/10.1097/NCC.0000000000000505.
16. Nitichai N, Angkatavanich J, Somlaw N, Sirichindakul B, Chittawatanarat K, Voravud N, Jager-Wittenaar H, Ottery FD (2017) MON-P187: translation and cross-cultural adaptation of the Scored Patient-Generated Subjective Global Assessment (PG-SGA) to the Thai setting. Clin Nutr 36:S247. https://doi.org/10.1016/S0261-5614(17)30900-7
17. Sealy MJ, Ottery FD, van der Schans CP, Roodenburg JLN, Jager-Wittenaar H (2018) Evaluation of change in dietitians' perceived comprehensibility and difficulty of the Patient-Generated Subjective Global Assessment (PG-SGA) after a single training in the use of the instrument. J Hum Nutr Diet 31(1):58–66. https://doi.org/10.1111/jhn.12491
18. Pinto P, Pinho JP, Vigáio A, Ottery FD, Jager-Wittenaar H (2016) MON-LB258: does training improve perceived comprehensibility, difficulty and content validity of the Portuguese scored PG-SGA? Clin Nutr 35:S247–S2S8. https://doi.org/10.1016/S0261-5614(16)30892-5.