



Cross-cultural adaptation of the PROFFIT Instrument to measure financial toxicity in people living with cancer within a UK population

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ABSTRACT

Background: This study aimed to develop a British version of the Patient Reported Outcomes for Fighting Financial Toxicity of Cancer (PROFFIT): originally designed to measure financial toxicity in cancer for an Italian universal healthcare system. The instrument was carefully evaluated for crosscultural equivalence, face validity and practicality.

Methods: A systematic approach to cross-cultural adaptation was used, including forward translation, synthesis, backward translation, consolidation of translations with an expert committee, and cognitive interviews. As part of the cognitive interview process, 18 cancer patients completed a structured interview of 60–90 min in length. **Results:** The translated and modified PROFFIT questionnaire demonstrated good psycho-linguistic properties, including high compliance (only one item was revised for clarity), high retrieval from memory, high decision-making processes, and high response processes.

Conclusion: PROFFIT has been found to be functional and adaptable in a new social environment. The tool may be useful for tailoring interventions to address and measure financial hardships within the cancer population, which appear to be a current challenge for public health.

Policy summary: Even in universal healthcare systems, financial toxicity due to the increase in out-of-pocket expenses poses a significant problem. The FT phenomenon warrants proper attention in the United Kingdom since it may negatively impact financial well-being, quality of life, psychosocial health, and treatment adherence.

1. Introduction

Financial Toxicity (FT) refers to the objective and subjective financial burdens that patients face and the third party payer, such as the government or insurance system. However, the term FT is used inconsistently across healthcare literature and different healthcare systems, and there is no uniform definition used consistently across the healthcare community. The US National Cancer Institute (NCI) defines FT as “Problems a patient has related to the cost of medical care. Not having health insurance or having a lot of costs for medical care not covered by health insurance can cause financial problems and may lead to debt and

bankruptcy. FT can also affect a patient's quality of life and access to medical care” [1]. A study which examined financial insolvency as a risk factor for early mortality in cancer patients in the USA demonstrated an adjusted hazard ratio of 1.79 (95% CI, 1.64–1.96) for mortality among patients with cancer who filed for bankruptcy versus those who did not [2].

While the NCI definition provides a simplified view of FT and is focused on insurance-based direct costs that patients suffer, FT can have many other aspects. For example, cancer treatment can be costly, which impacts payers [3,4]. Due to the increasing co-payments in the US, cancer patients are more likely to declare bankruptcy than the general

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population [5]. Financial difficulties are associated with lower patient satisfaction [6], lower compliance [7], lower quality of life (QoL) [8], and lower survival [9,10].

To address the problem of financial difficulties, specific tools are needed. The US healthcare system recently introduced the COST (Comprehensive Score for Financial Toxicity) instrument, which measures financial distress based on patient-reported outcomes (PRO) [11]. However, this questionnaire might not be as sensitive in health systems that do not require co-payments for anticancer medications such as the United Kingdom (UK).

Italy has a health care system similar to the UK which does not impose co-payments for anticancer medications. Within Italy financial difficulties have been demonstrated to negatively affect cancer patients' quality of life (QoL) and life expectancy during anticancer treatment [12]. An Italian study analysed the relevance of financial difficulties in the Italian public health care system using a pooled analysis of 16 trials involving 3670 patients [12]. This study analysed the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30, a widely used patient-reported outcome measure. Question 28 of this questionnaire is specific for assessing the financial impact for patients.

"Have you experienced financial difficulties as a result of your physical condition or medical treatment?"

Responses were measured on a 4 point Likert scale, ranging from 'not at all' to 'very much' [12]. The burden of financial impact reported by 26% of patients at baseline was associated with a worse QoL after treatment (OR 1.35, 95%CI: 1.08–1.70, $p = 0.009$). It found that 616 patients (22.5% of respondents) gave progressively worse responses to question 28, indicating that they had developed FT during treatment. For these patients there was a statistically significant increase in the risk of death when the landmark time of 4.5 months was used. (HR 1.20; 95% CI: 1.05–1.37, $p = 0.007$) [12].

Within the UK neither of the major health-related organisations (National Institute of Clinical Excellence, National Health Service, Cancer Research UK) have any published definitions for FT. However, the topic of FT within the UK setting is becoming more pertinent, with a UK-based patient cancer charity publishing a survey focused on the costs of living and linking health-related outcomes with rising patient costs [13].

A recent study in the North-West of England examined the answers to question 28 of the EORTC QLQ-C30 to evaluate financial burden and toxicity, finding that young age, tumour type, and geographical region were associated with poorer socio-economic status. [14].

There was a financial burden reported by 38% of patients, as well as a financial toxicity reported by 20%. A multiple regression analysis revealed that young age, tumour type, and geographical region were associated with poorer socio-economic status measured by an index of multiple deprivation (IMD).

As a result of the Italian study, an instrument called PROFFIT (Patient Reported Outcomes for Fighting Financial Toxicity of Cancer) was developed to describe and understand the determinants and effects of cancer-related FT in Italy [15]. This was based on the methodology devised by the Patient Reported Outcomes Content Validity Good Research Practices Task Force of the International Society for Pharmacoeconomics and Outcome Research (ISPOR) [16,17]. As of March 2020, the instrument has been internally validated and is available for use [18]. A further assessment of the external validity and responsiveness is being conducted in Italy (NCT03473379) and a validated English translation has been recently produced [15].

We consider the topic of FT to be an emerging issue within the UK and quantifying FT requires the use of a validated tool or instrument.

At the time of writing there was no published literature or reports on the use of PROFFIT in English speaking countries. However, linguistic translation alone is insufficient to apply the PROFFIT questionnaire to the UK population and maintain the validity of the original instrument. Therefore, cross-cultural adaptation of PROFFIT was

undertaken to evaluate its acceptability and internal consistency in a sample of British respondents. The primary objective of this study was to adapt the original version of PROFFIT for use with a UK population and examine its acceptability and internal consistency among a sample of UK respondents.

2. Methods

2.1. The instrument

The PROFFIT (Patient Reported Outcomes for Fighting Financial Toxicity) comprises of 16 items and is the first instrument developed for assessing FT of cancer in a country with a fully public health care system [15]. It consists of the "outcome" of FT (i.e. the consequences for the patient's life and disease) and other specific items referred to as "determinants" (i.e. the causes of FT such as delays in treatment, transportation problems, bureaucracy, etc.). The Cronbach alpha coefficient for the PROFFIT scale was 0.87 and the item-total correlation coefficients ranged from 0.53 to 0.74. Test-retest analysis revealed a good internal validity of the 16 items retained in the final questionnaire [15]. The Italian version of the PROFFIT was linguistically adapted to English following the first four steps described by Guillemin et al. [19] and Beaton et al. [20], intended for questionnaires of self-report health status measures. This preliminary version was published for a purely linguistic purpose to get the content more intelligible to the academic public. This version was the result of the following methodological steps:

Step 1 - Forward translation: Two certified translators with English as their native language translated the questionnaire into English. Consequently, two English versions of the questionnaire were prepared, labelled T1 and T2.

Step 2 - Synthesis: The two translators discussed their work and agreed on a common Italian translation (T12). The translators discussed the differences between the two versions and resolved them by consensus.

Step 3- Back translation: two certified translators (native Italian speakers) independently translated the questionnaire into Italian, thereby producing two back translations of the questionnaire.

Step 4 - Harmonization: A committee was formed, consisting of the two translators, two physicians and one psychologist, and a methodologist-medical statistician. Back translations were compared with the original version for semantic, idiomatic, experiential, and contextual equivalence, to identify discrepancies.

The PROFFIT instrument is described in Riva et al., 2021 [15] and detailed below in Table 1.

2.2. The cultural adaptation

The current paper describes the cultural adaptation process of an instrument in the UK. According to literature, it is highly recommended to conduct additional testing after the translation and adaptation process to ensure that the new version can demonstrate the required measurement properties for the intended population [20]. For this purpose, a cognitive debriefing analysis was planned. To achieve this goal, we gathered data from a sample of 15 patients from different areas of Manchester. The eligibility criteria included adults (>18 years) with a confirmed diagnosis of solid cancer or hematological malignancy through histopathology or cytology, who received medical treatment (chemotherapy, target agents, immunotherapy, hormonal treatment, radiotherapy, or a combination of these) in the past 3 months. To ensure that the qualitative analysis could capture the diversity of patients, we performed stratification in each area based on geographic location (urban, sub-urban), proportions of both genders, age groups, educational levels, and socioeconomic backgrounds. The examination of the PROFFIT was conducted during a private consultation with the examiner that lasted between 60 min and 90 min.

Table 1

Final PROFFIT instrument Item type Italian version English translation (for comprehension and only) number Outcome items (FT-scale).

Item type and number	Italian version	English translation (for comprehension and only)
Outcome items (FT-scale)		
1.	Sono in grado di sostenere le mie spese mensili senza difficoltà (ad esempio per electricity, affitto, elettricità, telefono...)	I can afford my monthly expenses difficulty (for example rent, phone...)
2.	La mia malattia ha ridotto le mie disponibilità economiche	My illness has reduced my financial resources
3.	Sono preoccupato dei problemi economici che potrei avere in futuro a causa della malattia	I am concerned by the economic problems I may have in the future due to my illness
4.	La mia condizione economica incide possibilità sulle mie possibilità di curarmi	My economic situation affects the of receiving medical care
5.	Ho ridotto le spese per attività ricreative come vacanze, ristoranti o spettacoli per affrontare le spese della mia malattia	I have reduced my spending on leisure activities such as holidays, restaurants or entertainment in order to cope with expenses related to my illness
6.	Ho ridotto le spese per acquisti essenziali (ad esempio il cibo) per affrontare le spese per la mia malattia	I have reduced spending on essential goods (for example food) in order to cope with expenses related to my illness
7.	Sono preoccupata/o di non riuscire a work lavorare a causa della mia malattia	I am worried that I will not be able to due to my illness
Determinant items (single items)		
8.	Il Servizio Sanitario Nazionale copre tutti i costi sanitari associati alla mia	The National Health Service covers all health costs related to my illness malattia
9.	Ho sostenuto spese per una o più visite medical private per la mia malattia	I have paid for one or more private examinations for my illness
10.	Ho sostenuto spese per farmaci supplementari o integratori per la mia	I have paid for additional medicines or supplements related to my illness malattia
11.	Devo sostenere spese per cure integrative a mio carico (es. fisioterapia,psychotherapy, psicoterapia, cure odontoiatriche)	I have to pay for additional treatment myself (for example physiotherapy, dental care)
12.	Il centro di cura è lontano dalla mia abitazione	The treatment centre is a long way from where I live
13.	Ho dovuto sostenere rilevanti costi di trasporto per curarmi	I have spent a considerable amount of money on travel for treatment
14.	Il personale sanitario (cioè medici, infermieri, etc.) ha agevolato il percorso di cura	Medical staff (that is doctors, nurses etc.) have been helpful throughout my medical care
15.	Il personale ospedaliero amministrativo (cioè centro di prenotazione, segreterie, have etc.) ha agevolato il percorso di cura	Staff in hospital administration (that is for booking appointments, secretaries, etc.) have been helpful throughout my medical care
16.	C'è stata comunicazione tra i medici e strutture sanitarie che mi seguono	Medical staff and medical facilities I le attended communicated with each other

Figure taken from Riva et al., (2022) BMJ Open

2.3. The cognitive interview

The most general model is described by Willis [21], which consists of the following classical processes adopted for the purpose of this study: 1 - comprehension of the question (what does the respondent believe it is asking?), 2 - retrieval of relevant information from memory (what types of information must the respondent recall to answer the question?), 3-decision processes (does the respondent devote sufficient mental effort to answer the question accurately and thoughtfully?) and 4-response processes (did the options scale make sense to you?). The

sociodemographic, clinical, and quantitative data were all described using SPSS Version 26.

3. Results

Eighteen adults participated in the evaluation of the item, completing cross-cultural adaption (see Table 2). There were seven males (39%) and eleven females (61%). The median age was 58 years (range 36–83). The highest level of education was high school for 11 (61%), National Vocational Qualification level or higher education equivalent for three (17%) and higher degree for four (22%). In terms of employment; two were on long term sick leave or disabled, eight were retired, one was self-employed and one unemployed, where one were working as an employee.

Each interview consisted of two standard parts: the administration of the instruments and the cognitive interview. All four stages of the cognitive interview were strictly adhered to in accordance with the literature.

Regarding the "comprehension of the question," minimal discrepancies were noted between the two back translations and the original version of the instrument, indicating that the T1/2 (synthesis of the 2 forward translations) was substantially accurate. However, two questions showed translational discrepancies. For Question 4 ("I am concerned about the economic financial problems I may have in the future due to my illness") and Question 5 ("My economic financial situation affects the possibility of receiving medical care"), the word "economic" was deemed unsuitable, and "financial" was deemed more appropriate for the British context. The final decision was based on the term that allowed for the best balance between medical and informal wording. The language was kept informal and simple to follow the English version, with slight modifications made to suit the British style.

During the "retrieval of relevant information from memory" phase, patients reflected on each item related to their treatment experiences. All patients related to all items without difficulty. For "decision

Table 2
Socio-demographics information.

Criteria	n	%
Gender		
Male	7	39%
Female	11	61%
Age		
Median (range)	58 (36 – 83)	
High Education Level Attained		
Highschool	11	61%
NVQ/College	17	17%
Degree	4	22
Socioeconomic Background		
Working as an employee	6	33
Self-employed	1	5.5
Unemployed	1	5.5
Long term sick/Disabled	2	11
Retired	8	61.1
Living with a Dependent		
No	16	88
Yes	2	11
Living with family members with cancer or chronic disease		
No	18	100
Yes	0	0
Time (years) from initial diagnosis		
Less than a year	6	33.3
1–4 years	6	33.3
5 years or above	5	27
Last Ongoing Cancer Treatment		
Trial	5	27
Immunotherapy	2	11
Surgery	1	5.5
Chemotherapy	5	27
Chemotherapy/Radiotherapy	2	11

processes," the average response time to each question was a few seconds to less than a minute, indicating no issues in understanding the content. Regarding "response processes," the answer option scale was considered clear and easy to assign a proper answer based on individual experiences. However, one respondent suggested alternative response terms: "Not true at all," "Partially true," "Mostly/Mainly true," "Entirely/Completely true."

After discussion among the authors, we found little agreement among patients in response to Question 16. We rephrased the question to improve clarity and retained it to facilitate the applicability of the questionnaire to the original version, improving its external validity. Table 3 describes the final version of the UK PROFFIT questionnaire.

4. Discussion

Using a systematic, standard process, we were able to translate and culturally adapt the validated Italian version of the PROFFIT questionnaire into English for UK contexts, ensuring semantic and conceptual equivalence between the translated version and the original tool.[22] An analysis of the instrument was undertaken using the established cognitive interview method, based on the previous process of forward and back translation for the development of the pre-final version.

As a result of the evaluation phase, no major problems were identified. Approximately 80% of examinees rated the clarity of wording and appropriateness of content as high for 16 items, while one item was rephrased to suggest that the current instrument could detect a specific health outcome in a clear area of a patient's life This final version is supported by a good completion of item response and a collection of individual experiences that confirm its utility and the need to study this area in the United Kingdom.

An analysis of differences in gender, education, and socioeconomic background was conducted using the PROFFIT instrument as part of the development paper in order to collect multiple experiences from a heterogeneous group of patients. In all user groups, PROFFIT UK shows a high level of functionality, usability, and utility.

Therefore, we believe the PROFFIT questionnaire UK version can be used as a tool within the UK healthcare system for assessing FT toxicity., The validity of pre-specified theoretical assumptions within the UK context should be verified before any health intervention can be developed [23,24]. This project aims to progress to the second stage which will involve using this instrument in larger cohort of patients across multiple UK centres to begin generating data to support external validation of this tool within a UK based population.

Overall, these results indicate that the cross-cultural adaptation of the questionnaire was a successful process. There was good linguistic acceptability of the UK version of PROFFIT. Our results were comparable to those obtained with the original version of the PROFFIT questionnaire, with the exception of some aspects of construct validity that differed, suggesting cultural contexts rather than a decrease in the validity of the instrument after translation.

The main limitation of this study is that we have focused on the cross-cultural translation without administering the instrument to a sample of patients. We recognise the sample size is small however we do not believe this to be a major limitation as this has followed the methodology for undertaking a study of this nature and the sample population is a heterogenous sample reflecting a good level of saturation [25].

By using the UK version, researchers can measure FT in English-speaking countries and compare it with data from other countries. Additionally, a better understanding of attitudes towards FT, in addition to determining determinants and outcomes, will facilitate the development of public education campaigns to increase awareness of FT and reduce the burden of patients and their caregivers.

Further analysis of the validated version.

Although the primary objective for this was to undertake validation of the instrument for a UK population there was an opportunity to collect qualitative experiences from patients during their cognitive interviews.

Table 3
The UK PROFFIT questionnaire.

1-I can afford my monthly expenses without difficulty (eg, rent, electricity, phone...)
2-My illness has reduced my financial resources
3-I am concerned by the financial problems I may have in the future due to my illness
4-My financial situation affects the possibility of receiving medical care
5-I have reduced my spending on leisure activities such as holidays, restaurants or entertainment in order to cope with expenses related to my illness
6-I have reduced my spending on essential goods (eg, food) in order to cope with expenses related to my illness
7-I am worried that I will not be able to work due to my illness
8-The National Health Service covers all health costs related to my illness
9-I have paid for one or more private medical examinations for my illness
10-I have paid for additional medicines or supplements related to my illness
11-I have to pay for additional treatment myself (eg, physiotherapy, psychotherapy, dental care)
12-The treatment centre is a long way from where I live
13-I have spent a considerable amount of money on travel for treatment
14-Medical staff (ie, doctors, nurses, etc) have been helpful throughout my medical care
15-Staff in hospital administration (ie, for booking appointments, secretaries, etc) have been helpful throughout my medical care
16-Healthcare staff communicated well with each other in relation to my care
For each item, four response options are available
I do not agree at all (1)
I agree partially (2)
I agree substantially (3)
I very much agree (4)

Several respondents gave accounts of treatment related FT issues such as travel related expenses and a significant increase in personal financial difficulties as a result of their treatment. One subject discussed in detail the fact their treatment/diagnosis meant they had to take significant sick leave from work. Within the UK statutory sick pay is £ 99.35 per week [26]. In 2022 the average UK household budget is around £ 726.75 a week based on an average of 2.4 people per household [27]. This meant that the subject had to subsidise the deficit with financial savings.

Author contributions

AP conducted the interviews, made the analyses and drafted the manuscript. SR conceived the study, made the analyses and drafted the manuscript. NF, NC, DA and FP were involved in the conception of the manuscript, the drafting and/or critically reviewing of the manuscript and have approved the final version for publication.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Alkesh Patel reports financial support was provided by National Institute of Health Research (NIHR).

Data Availability

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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