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Financial toxicity questionnaire (FIT): development and validation of the italian version (FITALY) in head and neck cancer patients undergoing multimodal curative treatment

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Abstract

Background Financial toxicity from cancer treatments is rising as an important patient-reported outcome. Its relevance was first assessed in the context of privately financed healthcare system, where the financial hardship caused by out-of-pocket payments negatively affects survival, while fewer evidence exists on its role in countries where care is financed by the public health care system. Head and Neck Cancer (HNC) patients face an increased risk for financial toxicity due to multimodal treatment and relevant out of pocket costs. The aim of this study was to develop and validate an Italian version of the Canadian Financial Index of Toxicity (FIT) questionnaire, defined FITALY.

Methods FIT questionnaire was translated through a forward-backward process by two investigators independently, and the process was reviewed by a certified medical scientific English native speaker. Once reached consensus upon Italian translation, two Health Economics experts were consulted to adapt the questionnaire to Italian socio-economic context. The FITALY questionnaire v1.0 hereby developed was anonymously administered to two consecutive groups of 30 patients who had received curative, multimodal treatment for HNC cancer at ASST Spedali Civili of Brescia, Italy. A cognitive debriefing form was simultaneously administered to ask patients to exclude recurring and redundant items and include new relevant items.

Results The 14-item FITALY questionnaire provides a global evaluation of financial toxicity ranging from 0 to 100. The questionnaire is divided into 4 domains: financial burden (6 items), exploring the objective financial toxicity burden; financial distress (2 items), which refers to the psychological distress related to financial toxicity; out-of-pocket costs (4

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items), which focus on medical expenses paid by the patient; and loss of productivity (2 items), that investigates the disease impact on both patient's and caregiver's job activity.

Conclusions Starting from the Canadian 9-item FIT questionnaire, we developed and validated the Italian 14-item FITALY questionnaire. Prospective application to a cohort of Italian HNC patients is ongoing.

Keywords Financial toxicity, Head and neck cancer, Questionnaire development and validation, Supportive care, Patient financial burden

Introduction

Head and Neck Cancer (HNC) represents the fifth most common cancer worldwide [1]. Due to a locally advanced presentation at diagnosis in most cases, the therapeutic approach encompasses a multimodal treatment including surgical procedures, radiation therapy, and systemic treatments [2]. The intricate and diverse nature of these interventions places a considerable distress on patients, impacting their quality of life, emotional well-being, and financial stability [3]. The financial challenges associated with cancer care, also known as "financial toxicity", represent an emerging issue that can compromise treatment adherence, lead to delayed care-seeking in case of toxicities, and ultimately affect survival outcomes [4–6]. Financial toxicity prominence was certified with a survey on patients undergoing active cancer treatments presented at ASCO 2018: on average, patients were more worried about the financial effect of their disease and of the treatments administered than about the risk of dying from cancer [7]. Up to 40% of patients experience financial toxicity during their treatment [8]. In countries with a private healthcare system, or were out-of-pocket (OOP) payments are the norm, financial toxicity has been identified as a relevant patient-reported outcome (PRO) [9], but its relevance was also proven in countries with social insurance [10–12] or universal healthcare [13–15]. Most recent randomized controlled trials started taking into consideration financial toxicity as a relevant PRO, albeit such assessment lacks generalizability to real-world settings due to the use of QoL questionnaires which are not validated to evaluate financial difficulties and the fact that drugs are provided by study sponsor for free, while financial toxicity occurs in real-life settings when patients must pay for the drugs and other medical expenses [16]. Moreover, financial toxicity largely depends upon the Healthcare system (universalistic versus private) and socio-economic peculiarities of the single country, so that universal tools for its assessment are unrealistic.

Among all cancer patients, HNC patients face heightened sensitivity to financial toxicity due to social issues, substantial disease burden, treatment-related toxicities requiring support and leading to inability to work and subsequent income loss, and the frequent need for multimodal treatments [17]. Few validated questionnaires have been developed to investigate financial toxicity, with some limitations in terms of financial toxicity domains coverage and the health care finance system of the countries considered [18]. Among those questionnaires, the Canadian FIT questionnaire emerges as being specific for HNC patients living in a universal healthcare system country [13]. However, adaptation of the FIT questionnaire to every single country is paramount to have a tool able to depict precisely financial toxicity in that given nation.

To shed light on the financial toxicity endured by Italian HNC patients, we developed and validated an Italian version of the FIT questionnaire, which we have named "FITALY".

Materials and methods

Questionnaire development procedure included translation and adaption to Italian context. The translation process consisted of a forward-backward Italian translation, performed by two Italian-native speaking research team members (CC and DS). First, they independently translated the FIT questionnaire into Italian and then reached consensus upon a unique translation (Supplementary S1). Subsequently, the Italian questionnaire was translated back into American English, and once again a unique translation was agreed by the two different team members (LL and DM). The entire forward-backward translation process was then reviewed by a certified medical scientific English native speaker, who also evaluated the similarity of the original and back-translated English versions of the questionnaire.

Italian context adaption was performed by two experts in the field of Health Economics (RL and RM), with the aim to make the questionnaire items suitable to Italian health and social care system.

Questionnaire validation process was carried out by administering the provisional questionnaire (v 1.0, Supplementary S2) and a Cognitive Debriefing (CD) form (Supplementary, S5) to 60 patients who already received a multimodal curative treatment for HNC (defined as at least two treatments received between surgery, radiotherapy, and systemic treatment), regardless of their disease status at the time of questionnaire administration. According to literature, 30 patients are considered a minimum sample size to allow questionnaire validation, while for questionnaire development it has been

shown that when the variables-to-factors ratio exceeds 6, the minimum sample size begins to stabilize regardless of the number of items. Therefore, applying a variables-to-factors ratio of 6 to the 10-item provisional v1.0 questionnaire, 60 patients were required for the validation process. The choice of two-step validation on 30 patients was made in order to collect suggestions by patients about potential new items and validate those items through the administration to the second group of patients [19, 20].

Patients were consecutively enrolled at the Medical Oncology Unit and the ENT Department of the ASST Spedali Civili of Brescia. Salivary glands, nasopharyngeal, and sinonasal primaries were allowed, while skin and thyroid cancers were excluded. The choice of including only patients who had already been treated was aimed at depicting real-life patients own insights and experience with financial toxicity during curative treatment rather than their worries and expectations before treatment start.

CD questioned the patients about the ease of understanding the questionnaire, the presence of items that were superfluous or deemed as repetitive, and the possibility of including additional items suggested by the patients themselves according to their personal experience, with the aim of investigating fields not explored by the original questionnaire. The cut-off for applying the changing suggested by patients through the CD form was set at ≥ 10% disagreement rate for each item.

The final version of the FITALY questionnaire underwent a backward American English translation, with the process then being reviewed by a certified medical scientific English native speaker.

The study was approved by the Ethical Committee of ASST Spedali Civili of Brescia (NP 5560).

Results

The translation process led to an Italian version of the FIT questionnaire, consisting of 9 items. Health Economics experts adapted the questionnaire to the Italian peculiarities checking the appropriateness of items wording and including 1 item about the possibility for patients to use personal savings to address financial toxicity (item 6 in the final version of the FITALY questionnaire). The 10-item questionnaire hereby developed was defined FITALY v1.0 (Supplementary S2) and underwent the validation process. In detail, between December 2022 and January 2023 the FITALY v1.0 questionnaire and the CD form were administered to two groups of 30 consecutive outpatients each. The first round of the validation process led to: modify 3 items (in the final version, items 4, 13, and 14); eliminate item 2; and include 4 new items concerning about out-of-pocket costs upon patients' suggestion (in the final version, items 8, 9, 10–11, and 12). The so-developed 13-item FITALY questionnaire v2.0 (Supplementary S3) then underwent the second round of the validation process, being administered along with the CD to 30 HNC patients different from the ones of the first round. A significant disagreement was observed only for the newly introduced items: one item was modified according to patients' comments (in the final version, item 9) and one was split into 2 items (in the final version, items 10 and 11) (Supplementary S4). The entire process of questionnaire development and validation is graphically described in Fig. 1.

The 14 items of the final version of the FITALY questionnaire (Fig. 2) were divided into four subdomains, to integrate the inner subdivision of the FIT questionnaire: financial burden ("financial stress" in the FIT questionnaire), which analyzes the objective burden of financial toxicity faced by the patient (items 3, 4, 5, 6, 7, and 12); financial distress ("financial strain" in the FIT questionnaire), which focuses on the psychological distress felt by the patient and correlated to financial toxicity (items 1 and 2); out-of-pocket cost (not existing in the FIT questionnaire), which focuses on the costs not covered by the universal health care system and therefore paid by the patients (items 8, 9, 10, and 11); and loss of productivity (equal to the subdomain present in the FIT questionnaire), which investigates the impact on patient's and caregiver's working capability. This internal division allows to calculate 5 scores: one for each of the three subdomains and a global score (Fig. 3). Each score can be calculated by multiplying by 100 the average value of responses to items defining a given domain/subdomain.

The final version of the FITALY questionnaire was finally backward translated to American English, in order to make this tool accessible to further language validation works in other countries with a universal health care system (Supplementary S4).

Discussion

The process of backward-forward translation of the FIT questionnaire, Italian adaptation by two Health Economics experts, and validation, based on patients' opinion collected throughout a two-round cognitive debriefing procedure, has led to develop a 14-item questionnaire specific for Italian HNC patients undergoing curative treatment, with a specific focus on out-of-pocket costs in a universal health care system and patient's psychological distress related to financial toxicity.

Understanding the financial toxicity of cancer patients is becoming paramount for healthcare practitioners and the healthcare system. Several studies have outlined the association between cancer and financial hardship regardless of healthcare finance models, leading to consider financial toxicity as a relevant PRO that should be kept into consideration in each patient undergoing

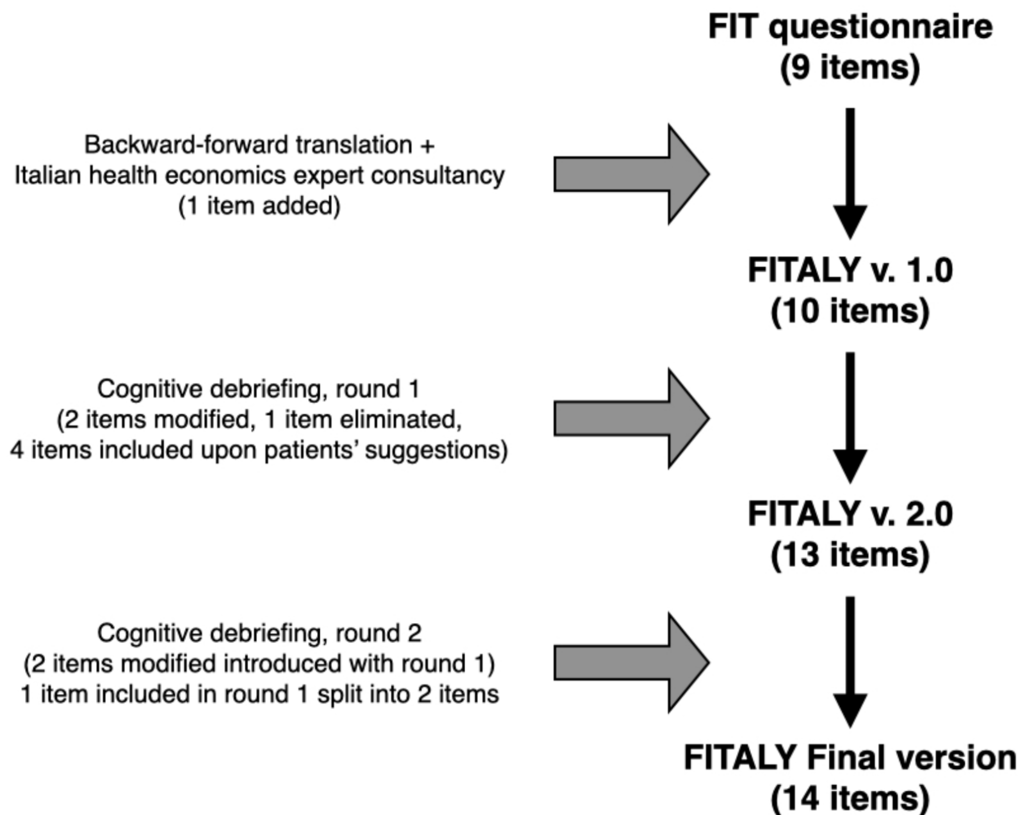

Fig. 1 The process pursued to develop and validate the 14-item FITALY questionnaire starting from the canadian 9-item FIT questionnaire

cancer treatments. Moreover, this aspect could not only impact on patients' quality of life after treatment, but also on the quality of treatments themselves, meaning that patients could choose to not pursue the best treatment options due to economical constraints, with a detrimental effect on oncological outcomes. In order to tackle this issue, defining its real scope and identifying the tools most useful for patients to overcome it, several questionnaires have been developed – even if most of them focus on privately financed health care countries and do not properly assess the financial distress of the patients [18]. The administration of such questionnaires has led to identify HNC patients as a target population at risk for financial hardship. In a retrospective analysis of cancer surveyors from the Medical Expenditure Panel Survey dataset, HNC patients (489 patients) compared to patients with other cancers (16,282 patients) reported higher median annual medical expenses ($8,384 vs. $5,978; difference $2,406, 95% CI: $795-$4,017) and higher relative OOP expenses (3.93% vs. 3.07%; difference 0.86%, 95% CI: 0.06-1.66%) [4]. In a prospective survey based on the administration of COST questionnaire to HNC patients in follow-up at an academic US cancer center, patients with lower COST scores reported greater privations, such as decreasing spending on food and clothing (54%), using savings (43%), and borrowing money (13%) in order to pay for treatment, and were significatively more likely to make medical sacrifices such as not taking all prescribed/recommended nutritional supplements, supportive medications, and pain medications, skipping clinic visits, and refusing recommended tests when compared to non-HNC cancer patients [21]. Another prospective survey was conducted in Leipzig University Hospital, administering a slightly modified version of the questionnaire by Mehlis et al. [22] to 209 HNC survivors in the aftercare setting [12]. About 60% of patients reported a significant financial burden as a consequence of OOP costs, esteemed to be on average 1,716€ per year, and/or income loss, with mean monthly income loss of 620€ [12]. Advanced TNM stage, T3 or T4 category, and larynx/hypopharynx site were statistically significant predictors of higher financial burden [OR 2.908

1. Nell'ultimo anno, sei stato soddisfatto della situazione finanziaria del tuo nucleo famigliare?
   - Molto soddisfatto *(0.00)*
   - Abbastanza soddisfatto *(0.25)*
   - Nella norma *(0.50)*
   - Abbastanza insoddisfatto *(0.75)*
   - Molto insoddisfatto *(1.00)*
2. Come percepisci la situazione finanziaria del tuo nucleo famigliare rispetto ad altre persone della tua stessa età?
   - Molto migliore *(0.00)*
   - Abbastanza migliore *(0.25)*
   - Uguale (0.50)
   - Abbastanza peggiore *(0.75)*
   - Molto peggiore *(1.00)*
3. Nell'ultimo anno, sei stato in grado di sostenere le spese quotidiane necessarie a comprarti il cibo?
   - Sempre *(0.00)*
   - Quasi sempre *(0.33)*
   - Qualche volta *(0.67)*
   - Mai (1.00)
4. Nell'ultimo anno, sei stato in grado di sostenere le spese quotidiane necessarie a mantenere la tua casa? Nello specifico, sei sempre stato in regola con i tempi di pagamento delle bollette (ad esempio, quelle per il condominio, l'acqua, il gas o l'elettricità; non considerare le bollette telefoniche)?
   - Sempre *(0.00)*
   - Qualche volta no *(0.33)*
   - Quasi mai *(0.67)*
   - Mai *(1.00)*
5. Nell'ultimo anno, sei stato in grado di sostenere le spese mediche correlate a patologia?
   - Sempre *(0.00)*
   - Quasi sempre *(0.33)*
   - Qualche volta *(0.67)*
   - Mai *(1.00)*
6. Nell'ultimo anno, sei stato costretto ad attingere ai tuoi risparmi per sostener spese mediche correlate alla tua patologia?
   - No *(0.00)*
   - Sì *(1.00)*
7. Durante l'anno appena trascorso, sei stato costretto a richiedere denaro in p tua famiglia, ai tuoi amici o a istituti di credito/banche per sostenere le spese correlate alla tua patologia?
   - No *(0.00)*
   - Sì *(1.00)*
8. Quanto hanno inciso sulla tua condizione economica le spese per trasferime l'alloggio per poter effettuare le cure correlate alla tua patologia?
   - Per nulla *(0.00)*
   - Poco *(0.33)*
   - Abbastanza *(0.67)*
   - Molto *(1.00)*
9. Quanto hanno inciso sulla tua condizione economica le spese per visite (es. fisioterapia, psicoterapia, logopedia, nutrizionista, cure odontoiatriche) ed es medici (es. esami radiologici, esami del sangue) correlati alla tua patologia?
   - Per nulla *(0.00)*
   - Poco *(0.33)*
   - Abbastanza *(0.67)*
   - Molto *(1.00)*
10. Quanto hanno inciso sulla tua condizione economica le spese per farmaci o medicazioni per sintomi legati alla tua patologia o per effetti collaterali del trattamento?
    - Per nulla *(0.00)*
    - Poco *(0.33)*
    - Abbastanza *(0.67)*
    - Molto *(1.00)*
11. Quanto hanno inciso sulla tua condizione economica le spese per ottenere assistenza domiciliare (infermiere a domicilio, fisioterapia, assistenza alla persona, ...)?
    - Per nulla *(0.00)*
    - Poco *(0.33)*
    - Abbastanza *(0.67)*
    - Molto *(1.00)*
12. Nell'ultimo anno, il tuo reddito si è ridotto a causa della malattia e/o del trattamento?
    - No *(0.00)*
    - Sì, di una quota inferiore al 20% *(0.33)*
    - Sì, di una quota tra 20% e 50% *(0.67)*
    - Sì, di una quota superiore al 50% *(1.00)*
13. Hai abbandonato in modo definitivo la tua occupazione lavorativa a causa della malattia e/o del trattamento?
    - No *(0.00)*
    - Sì *(1.00)*
14. Qualcuno dei tuoi familiari ha abbandonato in modo definitivo la sua occupazione lavorativa per aiutarti nei tuoi bisogni o per assisterti a causa della malattia e/o del trattamento?
    - No *(0.00)*
    - Sì *(1.00)*

Fig. 2 The final version of the FITALY questionnaire, composed of 14 items

$$FITALY\ Global\ Score = \frac{Q1 + Q2 + Q3\ \ldots + Q14}{14} \times 100$$

$$Financial\ Distress\ Score = \frac{Q1 + Q2}{2} \times 100$$

$$Financial\ Burden\ Score = \frac{Q3 + Q4 + Q5 + Q6 + Q7 + Q12}{6} \times 100$$

$$Out\ of\ Pocket\ Score = \frac{Q8 + Q9 + Q10 + Q11}{4} \times 100$$

$$Lost\ Productivity\ Score = \frac{Q13 + Q14}{2} \times 100$$

Fig. 3 Formulas for calculating FITALY global score, financial burden score, financial distress score, out of pocket score, and loss of productivity score

(1.539–5.493); p-value 0.0008] [12]. A recent systematic review of published studies measuring financial toxicity in HNC patients confirms the relevance of financial toxicity in HNC patients but highlights high discrepancies for what concerns the magnitude of patients' hardship considering heterogeneity in definitions and tools of measurement along with different countries healthcare systems – thus limiting the chance to produce solid

evidence [23]. Even fewer evidence is reported about the strategies to tackle financial toxicity [23]. A possible solution model comes from the results of a single institution, retrospective analysis of a cohort of American HNC patients treated with radiotherapy, where from a specific date a financial counsellor was offered to patients: those who did not receive financial counseling showed a significantly worsening of financial difficulty after treatment (based on EORTC QLQ-C30), while no relevant difference was seen in patients who received financial counseling [24]. A recent published ESMO Expert Consensus on the screening and management of financial toxicity in cancer patients state that financial counselling by a dedicated professional (i.e., a social worker) should be offered to all patients starting a treatment with curative or palliative intent, as well as to cancer survivors, tailoring the frequency according to factors such as cancer stage, risk of cancer recurrence and potential for late complications, including secondary cancers [25].

Moving our focus to the Italian picture, a survey led by the Italian Federation of Volunteer Associations in Oncology (FAVO) in 2018 showed that Italian health care system covers 74% of healthcare expenses, with an average annual OOP expense for each cancer patient estimated to be €1,841 [26]. A pooled analysis of the results of the administration of EORTC QOL C30 questionnaire item 28 in 3,670 Italian patients from 16 prospective, multicenter trials in lung, breast and ovarian cancer showed that financial burden at baseline was not associated with the risks of death (HR 0.94, 95% CI: 0.85–1.04, p 0.23) and severe toxicity (OR 0.90, 95% CI: 0.76–1.06, p 0.19), but was predictive of worse global QOL response (OR 1.35, 95% CI: 1.08–1.70, p 0.009) [27]. Financial toxicity developed during treatment was significantly associated with an increased risk of death (HR 1.20, 95% CI: 1.05–1.37, p 0.007) [27].

In view of the great variability of Health systems and country-specific socio-economic and cultural peculiarities, it is paramount to have a dedicated tool for each single context. In Italy, the first questionnaire developed to assess financial toxicity was the 16-item PROFFIT questionnaire (Patient-Reported Outcome for Fighting FInancial Toxicity), which was validated on Italian patients affected by solid or hematological malignancies who were receiving or had received within the previous 3 months whatever type of medical anticancer treatment (including radiotherapy, chemotherapy, and other systemic treatments) [28]. However, we found crucial to develop a new specific tool for HNC patients for several reasons: (a) the special characteristics of HNC patients, whose socio-economic status is often lower compared to those with other types of cancer, and therefore with higher risk for financial toxicity; (b) the peculiarity of the acute side effects of their multimodal treatments, with an impact on functions as eating, drinking, swallowing, breathing; (c) the impact of long-term treatment-related sequelae (i.e., xerostomia, dysphagia, tracheotomy, etc.), which are associated to increased OOP medicaments and need for at home support, and may affect the ability to work; (d) the need of pointing at the psychological distress felt by the patients, that is instead overlooked by the PROFFIT questionnaire. In light of the above, FITALY questionnaire may represent a precious tool for prospective trials investigating financial toxicity in HNC patients in Italy. However, it should be mentioned that FITALY questionnaire has been developed and at least until now validated in HNC patients undergoing multimodal curative treatment. Therefore, further validation is required and highly encouraged in the recurrent/metastatic and palliative setting, as well as in long survivors HNC patients, in order to tackle this issue in all HNC patients potentially exposed to financial toxicity.

Conclusions

Starting from the Canadian FIT questionnaire, we developed and validated the FITALY questionnaire, which provides a new tool to investigate financial toxicity in Italian HNC patients. A prospective, observational, multicenter study based on this questionnaire is currently ongoing to investigate the impact of financial toxicity on oncological outcomes and quality of life in Italian HNC patients.

Abbreviations

HNC	Head and neck cancer
FIT	Financial index of toxicity
OOP	Out-of-pocket
PRO	Patient-reported outcome
QoL	Quality of life
CD	Cognitive debriefing
FAVO	Italian federation of volunteer associations in oncology
PROFFIT	Patient-reported outcome for fighting financial toxicity

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12885-024-13230-5.

Supplementary Material 1: **Supplementary S1**: Forward-backward Italian translation of the FIT Questionnaire.

Supplementary Material 2: **Supplementary S2**: FITALY questionnaire v1.0. The modifications from the translated FIT questionnaire are underlined. English translation of this provisional version of the questionnaire is provided below.

Supplementary Material 3: **Supplementary S3**: FITALY questionnaire v2.0. The modifications from FITALY questionnaire v1.0 are underlined. English translation of this provisional version of the questionnaire is provided below.

Supplementary Material 4: **Supplementary S4**: FITALY questionnaire Final Version. The modifications from FITALY questionnaire v2.0 are underlined. English translation of the final version of the questionnaire is provided below.

Supplementary Material 3: **Supplementary S3**: The Cognitive Debriefing (CD) form used during the validation process. English translation of the form is provided below.

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Author contributions
DS and CC (conception, design of the work, data acquisition and analysis, manuscript writing, manuscript revision, graphic content), LL (conception, design of the work, manuscript revision), DM (conception, design of the work, manuscript revision), RL (conception, design of the work, manuscript revision), RM (design of the work), SC (design of the work, data analysis), AD (conception), CP (data management and acquisition), AA (manuscript revision), SG (manuscript revision), CR (design of the work, manuscript revision), AB (manuscript revision, mentorship), CP (manuscript revision, mentorship), PB (conception, design of the work, mentorship, manuscript revision).

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Data availability
Questionnaires and CD forms paper are available from the corresponding author on reasonable request. No dataset was created since no patient data has been collected during this phase of the study.

Declarations

Ethics approval and consent to participate
The study was approved by the Ethical Committee of ASST Spedali Civili of Brescia (NP 5560). According to this approval, informed Consent Form was not required for the procedure of questionnaire development and validation since patients participated anonymously and no patient data was collected. Patients were asked to provide personal insights and experience with financial toxicity, and to evaluate the intelligibility and the completeness of the questions and answers of the questionnaire.

Consent for publication
No/Not applicable (this manuscript does not report data generation or analysis).

Competing interests
The authors declare no competing interests.

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