

## **A cross-sectional study to develop and describe psychometric characteristics of a patient-reported instrument (PROFFIT) for measuring financial toxicity of cancer within a public healthcare system**

### **Appendix**

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## Scoring procedure

Responses to PROFFIT items are coded in four categories of agreement with the statement of each item, scoring from 1 to 4:

1 - I do not agree at all, 2 - I agree partially, 3 - I agree substantially, 4 - I very much agree.

PROFFIT results are reported as a FT-score (including items #1 to #7) and nine separate items for FT determinants. All the scores are normalised to 0-100%, where 100 indicates the highest toxicity.

For **calculation of the FT-score**, including items #1 to #7, the following steps should be followed:

- Reverse the score for Item #1 according to the following formula

$$X_{1-reverse} = 5 - X_1$$

where  $X_1$  is the response given to item #1.

- Calculate the FT-score according to the following formula

$$\frac{X_{1-reverse} + X_2 + X_3 + X_4 + X_5 + X_6 + X_7 - Y}{3 \times Y} \times 100$$

where  $X$  is the response given for each item and  $Y$  is the number of items with valid response; if  $Y$  is 3 or less the score should be considered missing. At least 4 valid responses are needed to calculate the FT-score.

## Examples of calculation of FT score

Item: response	Intermediate	Final FT score
Example 1		
#1: I very much agree (4) #2: I agree partially (2) #3: I agree substantially (3) #4: I do not agree at all (1) #5: I agree partially (2) #6: I agree substantially (3) #7: I do not agree at all (1)	$X_{1-reverse} = 5 - 4 = 1$	$\frac{1 + 2 + 3 + 1 + 2 + 3 + 1 - 7}{3 \times 7} \times 100 = 38$
Example 2.		
#1: I do not agree at all (1) #2: I very much agree (4) #3: I agree substantially (3) #4: I agree substantially (3) #5: I do not agree at all (1) #6: I agree partially (2) #7: MISSING	$X_{1-reverse} = 5 - 1 = 4$	$\frac{4 + 4 + 3 + 3 + 1 + 2 - 6}{3 \times 6} \times 100 = 61$

For calculation of the score for items #8, #14, #15 and #16 use the following formula

$$\frac{4 - X_j}{3} \times 100$$

where X is the response given and j is the item (8, 14, 15, or 16).

For calculation of the score for items #9, #10, #11, #12, #13 use the following formula

$$\frac{X_j - 1}{3} \times 100$$

where X is the response given and j is the item (9, 10, 11, 12 or 13).

### Examples of calculation of single determinants scores

Item: response	Final single score
Example 3.	
#8: I do not agree at all (1)	$\frac{4-1}{3} \times 100 = 100$
#14: I agree substantially (3)	$\frac{4-3}{3} \times 100 = 33$
Example 4.	
#9: I very much agree (4)	$\frac{4-1}{3} \times 100 = 100$
#13: I agree partially (2)	$\frac{2-1}{3} \times 100 = 33$

Table S1. List of items in the pre-final instrument

<i>Item ID in the pre-final instrument</i>	<i>Item ID in the final instrument</i>	<i>Item</i>
Q1		Ho rapidamente trovato la struttura dove curarmi
Q2		Il tempo necessario per la diagnosi è stato breve
Q5		Ho sentito molto il peso della burocrazia (ad esempio per prenotare visite o per usufruire di benefici assistenziali, previdenziali e lavorativi)
Q26	10	Ho sostenuto spese per farmaci supplementari o integratori per la mia malattia
Q27	9	Ho sostenuto spese per una o più visite private per la mia malattia
Q28	11	Devo sostenere spese per cure integrative a mio carico (es. fisioterapia, psicoterapia, cure odontoiatriche)
Q49	8	Il Servizio Sanitario Nazionale copre tutti i costi sanitari associati alla mia malattia
Q68	1	Sono in grado di sostenere le mie spese mensili senza difficoltà (ad esempio per affitto, elettricità, telefono...)
Q76	3	Sono preoccupata/o dei problemi economici che potrei avere in futuro a causa della malattia
Q85	2	La mia malattia ha ridotto le mie disponibilità economiche
Q86	4	La mia condizione economica incide sulle mie possibilità di curarmi
Q90		I miei problemi economici mi preoccupano
Q95		La mia famiglia ha dovuto sostenere i costi di trasporto, vitto e alloggio per curarmi in una città diversa da quella in cui vivo
Q99	7	Sono preoccupata/o di non riuscire a lavorare a causa della malattia
Q102		Ho perso molti giorni lavorativi a causa della mia malattia
Q103		Non riesco a guadagnare come prima per via della mia malattia
Q106		Ho dovuto smettere di lavorare a causa della mia malattia
Q107		Ho ridotto le ore al lavoro a causa della mia malattia
Q111	14	Il personale sanitario (cioè medici, infermieri, etc.) ha agevolato il percorso di cura
Q112	15	Il personale ospedaliero amministrativo (cioè centro di prenotazione, segreterie, etc.) ha agevolato il percorso di cura
Q113	16	C'è stata comunicazione tra i medici e le strutture sanitarie che mi seguono
Q114		Il medico di famiglia ha agevolato il percorso di cura
Q121	5	Ho ridotto le spese per attività ricreative come vacanze, ristoranti o spettacoli per affrontare le spese della mia malattia
Q122	6	Ho ridotto le spese per acquisti essenziali (ad esempio il cibo) per affrontare le spese per la mia malattia
Q138		I servizi di trasporto per raggiungere l'ospedale (mezzi pubblici, parcheggi) sono scarsi
Q139		Ho dovuto sostenere i costi di trasporto, vitto e alloggio per curarmi in una città diversa da quella in cui vivo
Q140	13	Ho dovuto sostenere rilevanti costi di trasporto per curarmi
Q141	12	Il centro di cura è lontano dalla mia abitazione
Q151		È stato facile ottenere le agevolazioni economiche a cui ho diritto (ad esempio esenzione dal ticket, assegni o pensioni di invalidità)
Q156		So che la mia malattia mi dà diritto ad agevolazioni economiche (ad esempio esenzione dal ticket, assegni o pensioni di invalidità)

## Questionnaire development

The first step of the analysis was estimating the between-item correlation matrix. Because of the ordinal nature of the items the pairwise Spearman rank correlation coefficients ( $r_s$ ) were used.

We ascertained that there were about a third (68/184, 37%) of missing responses for the five job items from patients, who declared themselves retired or jobless (i.e. househusbands, housewives or individuals in search of employment); thus we decided to estimate two separate bivariate correlation matrices, one limited to job items, where only the 116 cases without missing information were used (**Table S2a below**), and one for all the other items, where the complete sample of 184 cases was used (**Table S2b below**). For every pair, whose  $r_s > 0.65$ , the item with the greater score in the previously published importance analysis was retained.

At the end of this preliminary analysis, six items (Q103, Q106, Q107, Q90, Q95, Q139) were excluded, because  $r_s$  was greater than 0.65, leading to 9 outcome and 15 determinant items for subsequent analyses. Out of the five job items, two were retained, one outcome (Q99) and one determinant (Q102).



Table S2. Spearman correlation coefficients between items

Table S2a. Job items

	Q99	Q102	Q103	Q106	Q107
Q99	1				
Q102	0,63	1			
Q103	0,72	0,66	1		
Q106	0,55	0,50	0,60	1	
Q107	0,56	0,67	0,67	0,78	1

Table S2b. All other items

	Q1	Q2	Q5	Q26	Q27	Q28	Q49	Q68	Q76	Q85	Q86	Q90	Q95	Q111	Q112	Q113	Q114	Q121	Q122	Q138	Q139	Q140	Q141	Q151	Q156
Q1	1																								
Q2	0,29	1																							
Q5	-0,08	-0,05	1																						
Q26	-0,18	-0,13	0,22	1																					
Q27	-0,16	-0,04	0,33	0,30	1																				
Q28	-0,07	-0,03	0,40	0,36	0,40	1																			
Q49	0,18	0,15	-0,23	-0,46	-0,27	-0,41	1																		
Q68	0,09	0,15	-0,03	-0,25	-0,09	-0,13	0,34	1																	
Q76	-0,22	-0,10	0,21	0,41	0,29	0,29	-0,32	-0,45	1																
Q85	-0,18	-0,04	0,27	0,46	0,31	0,37	-0,41	-0,41	0,65	1															
Q86	-0,24	-0,11	0,27	0,40	0,39	0,34	-0,46	-0,44	0,56	0,57	1														
Q90	-0,21	-0,15	0,16	0,34	0,22	0,26	-0,29	-0,53	0,71	0,67	0,70	1													
Q95	-0,23	-0,10	0,19	0,25	0,29	0,30	-0,23	-0,12	0,20	0,33	0,28	0,21	1												
Q111	0,35	0,25	-0,26	-0,26	-0,30	-0,29	0,38	0,14	-0,11	-0,17	-0,31	-0,13	-0,17	1											
Q112	0,25	0,10	-0,12	-0,20	-0,15	-0,16	0,41	0,10	-0,17	-0,18	-0,31	-0,14	-0,10	0,53	1										
Q113	0,21	0,13	-0,20	-0,05	-0,45	-0,22	0,22	0,00	-0,11	-0,07	-0,22	-0,15	-0,11	0,43	0,33	1									
Q114	0,15	0,09	-0,23	-0,10	-0,17	-0,24	0,12	0,25	-0,24	-0,12	-0,24	-0,24	0,02	0,37	0,38	0,28	1								
Q121	-0,21	-0,15	0,12	0,31	0,36	0,28	-0,21	-0,41	0,57	0,59	0,48	0,62	0,28	-0,06	-0,09	-0,17	-0,10	1							
Q122	-0,08	-0,09	0,09	0,36	0,25	0,31	-0,37	-0,47	0,48	0,49	0,64	0,66	0,33	-0,15	-0,17	-0,15	-0,10	0,57	1						
Q138	-0,08	-0,05	0,28	0,25	0,22	0,27	-0,30	-0,17	0,24	0,34	0,31	0,31	0,08	-0,24	-0,23	-0,03	-0,15	0,18	0,34	1					
Q139	-0,23	-0,02	0,18	0,28	0,33	0,36	-0,25	-0,19	0,26	0,36	0,34	0,23	0,69	-0,14	-0,10	-0,07	-0,02	0,30	0,42	0,15	1				
Q140	-0,17	-0,04	0,27	0,30	0,33	0,29	-0,27	-0,21	0,28	0,41	0,33	0,31	0,59	-0,20	-0,10	-0,02	-0,04	0,38	0,45	0,27	0,66	1			
Q141	-0,14	0,02	0,16	0,09	0,11	0,10	-0,02	-0,08	0,11	0,18	0,12	0,12	0,34	-0,04	0,04	0,05	-0,13	0,10	0,18	0,11	0,45	0,55	1		
Q151	0,10	0,11	-0,15	-0,21	-0,15	-0,11	0,27	0,24	-0,20	-0,29	-0,29	-0,24	-0,09	0,18	0,20	0,17	0,20	-0,22	-0,21	-0,10	-0,18	-0,18	-0,07	1	
Q156	0,15	0,27	-0,02	-0,14	-0,03	-0,07	0,33	0,39	-0,18	-0,22	-0,32	-0,25	-0,07	0,22	0,23	0,20	0,18	-0,15	-0,32	-0,22	-0,13	-0,08	0,01	0,35	1

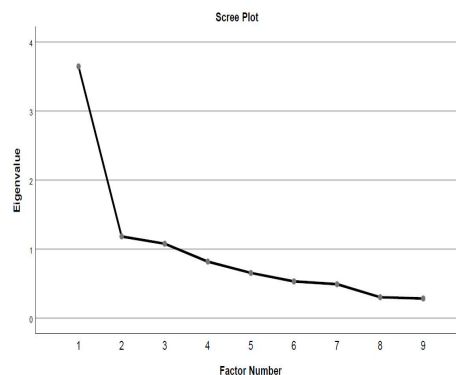
## Exploratory Factor Analysis (EFA)

### EFA on Outcome

EFA on the 9-outcome correlation matrix was performed by Principal Axis Factor (PAF) extraction option of SPSS, with VARIMAX rotation, in the sample of 116 subjects with complete information, because of the presence of the job item Q99.

The items considered at the start were Q5, Q68, Q76, Q85, Q86, Q99, Q121, Q122, Q151. In the initial factor solution, three factors met the Kaiser criterion of eigenvalue >1 and accounted for 66% of the variance, the first axis alone explaining 41% of the total variance (see Table and scree plot below).

Factor	Total	% of variance	Cumulative %
1	3.645	40.501	40.501
2	1.185	13.163	53.665
3	1.079	11.986	65.651
4	0.819	9.105	74.756
5	0.656	7.286	82.042
6	0.533	5.927	87.969
7	0.492	5.470	93.439
8	0.304	3.383	96.821
9	0.286	3.179	100.000



Communalities and unrotated factor loadings are reported in the table below.

	Communalities		Factor		
	Initial	Extraction	1	2	3
<b>Q5</b>	0.133	0.31	0.261	0.203	-0.448
<b>Q68</b>	0.233	0.266	-0.452	0.248	-0.020
<b>Q76</b>	0.574	0.653	0.793	0.152	-0.027
<b>Q85</b>	0.605	0.729	0.819	0.238	0.034
<b>Q86</b>	0.510	0.677	0.723	-0.305	-0.248
<b>Q99</b>	0.248	0.344	0.424	0.387	0.119
<b>Q121</b>	0.471	0.593	0.704	0.118	0.290
<b>Q122</b>	0.437	0.623	0.630	-0.458	0.131
<b>Q151</b>	0.089	0.116	-0.265	-0.018	0.214

The item Q151 shows communality <0.20, Child 2006), and factor loadings <0.3 (Field, 2013) with all three factors, and was removed from further analyses.

Analogously at the next step the item Q5 was removed (communality = 0.072).

Eventually, seven items were retained with two factors meeting the Kaiser criterion of eigenvalue >1.

Communalities and factor loadings after Varimax rotation in the reduced sample of 116 patients are reported below. Many items cross loaded on both axes, that seemed both expression of financial burden: after rotation, the first one was more correlated with items mirroring an actual severe burden (Q68, Q86, Q122), while the second one appeared more correlated with worries about the future.

	Communalities		Factor	
	Initial	Extraction	1	2
<b>Q68</b>	0.222	0.269	-0.498	-0.145
<b>Q76</b>	0.570	0.648	0.468	0.655
<b>Q85</b>	0.600	0.737	0.413	0.753
<b>Q86</b>	0.491	0.588	0.719	0.266
<b>Q99</b>	0.247	0.356	0.012	0.596
<b>Q121</b>	0.470	0.510	0.397	0.594
<b>Q122</b>	0.426	0.566	0.735	0.159

The previous interpretation might imply that some correlation between axes would be expected. Thus, the oblique Promax rotation was applied. The same seven-item final solution was found with two factors meeting the Kaiser criterion of eigenvalue >1, and findings were reinforced. The factor loadings with Promax rotation are reported below.

	Factor	
	1	2
<b>Q68</b>	-0.549	0.047
<b>Q76</b>	0.248	0.616
<b>Q85</b>	0.129	0.766
<b>Q86</b>	0.764	0.004
<b>Q99</b>	-0.292	0.753
<b>Q121</b>	0.191	0.571
<b>Q122</b>	0.839	-0.140

The same analysis was repeated in the whole sample, replacing the missing information on the Q99 job in the 68 cases with the average score of the other items. We did that, according to the protocol, for both increasing the power of the analysis and as a sensitivity analysis of findings in the restricted sample. We chose to input the average score rather than the minimum score (that would sound *I am not worried at all that I will not be able to work due to my illness*) because it could be true for retired people (at least in the Italian population), but not for younger people without job. We think, indeed, that imputing the minimum score would definitely bias the score toward the null, while imputing the average could possibly only slightly overestimate the financial issues. Further, this choice is consistent with the calculus of the score, where the missing items are not considered in the denominator. This question will be further dealt with in the next validation steps. In the full sample similar and stronger results were found: items Q151 and Q5 were removed because of low communalities (both <0.10). With the eventual 7-item analysis only the first axis met the Kaiser criterion of eigenvalue >1. Communalities and factor loadings in the complete sample are reported below. With one factor extracted no rotation was needed.

	Communalities		Factor 1
	Initial	Extraction	
<b>Q68</b>	0.309	0.309	-0.556
<b>Q76</b>	0.555	0.622	0.788
<b>Q85</b>	0.582	0.647	0.805
<b>Q86</b>	0.534	0.547	0.739
<b>Q99</b>	0.318	0.273	0.522
<b>Q121</b>	0.494	0.537	0.733
<b>Q122</b>	0.506	0.485	0.697

Therefore, the PROFFIT FT-score includes 7 outcome items.

## EFA on Determinants

EFA on the 15-outcome correlation matrix was performed by Principal Axis Factor (PAF) extraction option of SPSS, with VARIMAX rotation, in the sample of 116 subjects with complete information, because of the presence of the job item Q102.

The items considered at the start were Q1, Q2, Q26, Q27, Q28, Q49, Q102, Q111, Q112, Q113, Q114, Q138, Q140, Q141, Q156. In principle, the 15 determinants could be expression of three categories: (i) direct medical expenses (Q26, Q27, Q28, Q49), (ii) indirect costs due to travelling needs for medical care (Q138, Q140, Q141), (iii) indirect costs due to bureaucracy (Q1, Q2, Q111, Q112, Q113, Q114, Q156), plus a single job item (Q102).

In the initial factor solution, five factors met the Kaiser criterion of eigenvalue >1 and accounted for 62% of the variance (Table below), but the first axis explained only the 26% of the total variance.

Factor	Total	% of variance	Cumulative %
1	3.869	25.793	25.793
2	1.851	12.341	38.133
3	1.403	9.356	47.490
4	1.135	7.567	55.057
5	1.041	6.943	62.000
6	0.975	6.502	68.503
7	0.825	5.501	74.004
8	0.766	5.104	79.107
9	0.664	4.425	83.532
10	0.583	3.885	87.417
11	0.554	3.696	91.113
12	0.416	2.774	93.887
13	0.364	2.426	96.313
14	0.326	2.171	98.484
15	0.227	1.516	100.000

The job item Q102 had the smallest communality (0.183) and was removed. All the other items had complete responses, thus it seemed meaningless to continue in the restricted sample, and the subsequent analysis was only performed in the complete sample, where all of the responses were available.

The initial factor solution with 14 items in the full sample is reported below. Almost nothing changed: five factors met the Kaiser criterion of eigenvalue >1 and accounted for 63% of the variance, and the first axis explained only the 26% of the total variance.

Factor	Total	% of variance	Cumulative %
1	3.571	25.508	25.508
2	1.712	12.232	37.740
3	1.290	9.211	46.951
4	1.223	8.733	55.684
5	1.078	7.703	63.387
6	0.869	6.207	69.594
7	0.776	5.543	75.136
8	0.735	5.253	80.389
9	0.649	4.635	85.023
10	0.554	3.954	88.978
11	0.451	3.219	92.197
12	0.413	2.949	95.146
13	0.373	2.662	97.808
14	0.307	2.192	100.000

At the next steps items Q1, Q2, Q156, Q138 and Q114 were removed in turn because of small communalities, leading to the final solution with nine items and four factors retained. Communalities and factor loadings in the complete sample are reported below.

	Communalities		Factor			
	Initial	Extraction	1	2	3	4
Q26	0.305	0.425	0.628	-0.113	0.124	0.050
Q27	0.374	0.597	0.350	0.010	0.183	0.664
Q28	0.335	0.453	0.604	-0.048	0.137	0.259
Q49	0.393	0.576	-0.660	0.372	-0.012	-0.045
Q111	0.369	0.487	-0.210	0.592	-0.081	-0.294
Q112	0.333	0.610	-0.144	0.765	0.039	-0.049
Q113	0.319	0.556	0.001	0.332	0.059	-0.665
Q140	0.426	0.741	0.283	-0.069	0.803	0.105
Q141	0.316	0.449	0.009	0.033	0.669	0.005

Seemingly the first axis is related to direct medical expenses, the second axis to health bureaucracy items and the third axis to travelling costs, but some cross load on the factors is present.

Therefore we decided to retain the nine determinant items as single items in the final questionnaire.

## Convergent validity

We said above that the PROFFIT FT-score includes 7 outcome items. In the table below correlation between each item and the total score of the scale, removing that item from the sum (convergent validity), is reported. Correlations are quite good, all  $r_s$  being greater than 0.5 in the full sample.

Table S3. Spearman correlation coefficients between each item and total score\*

Item number	Full sample (N=184)	Restricted sample (N=116)
1	0.5325	0.5243
2	0.7360	0.7267
3	0.7251	0.7158
4	0.6646	0.6559
5	0.6887	0.6765
6	0.6712	0.6626
7	0.5537	0.3684

\*calculated removing each item from the sum

## Repeatability

Agreement between repeated measurements was assessed by intra-class correlation coefficient (ICC) and weighted Cohen's Kappa coefficient. Scores were stable enough over time, with ICCs ranging from 0.56 and 0.79. ICC was equal to 0.81 for the FT-score.

Table S4. Test-retest results

	ICC	Weighted K	Agreement %
<b>Outcome items</b>			
Item 1	0.70	0.70	95.7
Item 2	0.68	0.68	93.7
Item 3	0.56	0.56	90.7
Item 4	0.64	0.64	93.2
Item 5	0.65	0.65	91.0
Item 6	0.65	0.65	93.9
Item 7	0.79	0.81	94.4
<b>FT-score</b>	<b>0.81</b>	<b>0.82</b>	<b>97.4</b>
<b>Determinant items</b>			
Item 8	0.61	0.61	94.4
Item 9	0.72	0.72	94.2
Item 10	0.65	0.65	93.0
Item 11	0.61	0.62	92.4
Item 12	0.79	0.79	96.6
Item 13	0.78	0.78	92.2
Item 14	0.53	0.52	96.5
Item 15	0.59	0.58	95.0
Item 16	0.61	0.61	93.9



Table S5. Association of FT score with baseline characteristics of patients

	Median	(IQR)	P (Mann-Whitney)
<b>All patients</b>	38.1	(23.8-57.1)	
<b>Region of the hospital</b>			<b>0.005</b>
North	<b>28.6</b>	<b>(14.3-47.6)</b>	
Center	<b>33.3</b>	<b>(23.8-61.9)</b>	
South	<b>42.9</b>	<b>(23.8-57.1)</b>	
Islands	<b>52.4</b>	<b>(33.3-57.1)</b>	
<b>Gender</b>			0.932
Female	38.1	(23.8-57.1)	
Male	33.3	(23.8-52.4)	
<b>Age category</b>			<b>0.005</b>
≤65	<b>42.9</b>	<b>(23.8-57.1)</b>	
>65	<b>26.2</b>	<b>(14.3-47.6)</b>	
<b>Education level</b>			<b>0.018</b>
Elementary/Middle school	<b>42.9</b>	<b>(23.8-57.1)</b>	
High school/degree	<b>33.3</b>	<b>(19.0-50.0)</b>	
<b>Cohabitant/Married</b>			0.298
No	33.3	(23.8-52.4)	
Yes	38.1	(23.8-57.1)	
<b>With dependent family members</b>			0.060
No	33.3	(19.0-52.4)	
Yes	42.9	(28.6-57.1)	
<b>Family members with cancer or chronic disease</b>			<b>0.017</b>
No	<b>31.0</b>	<b>(19.0-52.4)</b>	
Yes	<b>42.9</b>	<b>(23.8-57.1)</b>	
<b>Working status</b>			0.531
Not working	33.3	(19.0-52.4)	
Working	38.1	(23.8-57.1)	
<b>Site of treatment</b>			0.134
Within the region of residency	38.1	(23.8-57.1)	
Outside the region of residency	28.6	(19.0-42.9)	
<b>Time (years) from initial diagnosis</b>			0.920
≤1	38.1	(23.8-57.1)	
1-5	33.3	(23.8-52.4)	
≥5	33.3	(19.0-61.9)	
<b>Previous surgery</b>			0.175
No	42.9	(23.8-61.9)	
Yes	33.3	(23.8-52.4)	
<b>Last/ongoing anticancer treatment at registration</b>			0.546
Chemotherapy	38.1	(23.8-57.1)	
Target-based agents	40.5	(23.8-52.4)	
Immunotherapy	28.6	(9.5-47.6)	
Hormonal therapy	38.1	(33.3-42.9)	
Radiotherapy	28.6	(28.6-28.6)	