

# Developing, Implementing, and Validating a Social Toxicity Assessment Tool of Cancer

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**PURPOSE** The social impact of cancer on patients and their family is well known. Yet, unlike with physical and financial toxicities, no validated tools are available to measure this impact. This study aimed at developing, validating, and implementing a novel social toxicity assessment tool for patients with cancer diagnosis (STAT-C).

**METHODS** Questions were generated through multiple steps including focus groups of patients, their families, and oncology care professionals. These steps along with relevant literature resulted in the development of an initial 20-item questionnaire. Content validity and relevance of the tool were assessed using Content Validity Index for individual items and Content Validity Index for the entire scale. Following expert examination, the constructed STAT-C tool consisted of 14 items grouped into three domains—social relations, social activities, and economic impact. Based on the total possible score for the survey in 150 patients for all the items, three levels of a socioeconomic toxicity were determined—severe social toxicity, mild social toxicity, and no social toxicity.

**RESULTS** The 14 items were marked as relevant, and the Content Validity Index for individual items ranged between 0.80 and 1.00. An overall average Content Validity Index for the entire scale of 0.87 showed high content validity of the constructed tool. Exploratory factor analysis revealed retention of 13 items of the constructed STAT-C Tool, which loaded across three factors that mapped groupings into measures of *social relations*, *social activities*, and economic impact domains.

**CONCLUSION** Our study revealed that STAT-C is a valid, reliable tool, and well captures and measures unique and pertinent social toxicity constructs for Arabic-speaking patients. The tool should enable oncology professionals to deliver better patient-centered care as a component of a comprehensive approach.

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## INTRODUCTION

The WHO long considered quality of life (QoL) as part of individuals' perceptions of their position in life in the context of the culture and value systems where they live and in relation to their goals, expectations, standards, and concerns.<sup>1</sup> However, the diagnosis of cancer is associated with negative impacts on different aspects of patients' lives including physical, emotional, financial, and social consequences.<sup>2-4</sup> Patients with cancer experience many physical symptoms related to the disease and the treatment. It has been shown that health-related hindrance is a significant problem for adolescents with cancer, particularly those who are experiencing pain, and is associated with poorer health-related QoL and depressive symptoms.<sup>5</sup> Older people with cancer exhibit changes in social, psychologic, and physical well-being over time, including deterioration in physical functioning, depressive symptoms, and role functioning.<sup>6</sup> The treatment of cancer is usually demanding and may be protracted,

putting major demands on patients and their family to keep up with appointments, financial responsibilities, and daily living needs.<sup>7,8</sup>

Furthermore, patients experience psychologic disorders including depression, stress, anxiety, and others.<sup>2,3</sup> Taking care of patients with cancer is demanding for family members and caregivers, exposing them to emotional, physical, and financial challenges. Social isolation and difficulty in maintaining normal social relationships by patients and their caregivers were reported previously.<sup>2,3,9</sup> Caregivers' and family members' ability to reveal and share emotional states and dealing with disintegration have been shown to improve psychosocial function in families affected by cancer.<sup>10</sup>

All the above may reflect on the patient's social life and relations with his family members, friends, coworkers, and others. Many of the negative physical, family, and financial problems associated with cancer are

## ASSOCIATED CONTENT

### Data Supplement

Author affiliations and support information (if applicable) appear at the end of this article.

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## CONTEXT

### Key Objective

To develop and validate a social toxicity assessment tool for Arabic-speaking patients with cancer (STAT-C).

### Knowledge Generated

A tool of 13 items was developed and validated in patients with cancer that cover three types of measures of social relations, social activities, and economic impact domains. The tool assesses the impact of cancer on relations with family members and social circles and the impact on various social and leisure activities. Based on the score, three categories of social toxicity were defined: *severe social toxicity* (score:  $-26$  to  $-9.3$ ), *mild social toxicity* ( $-9.2$  to  $7.5$ ), and *no social toxicity* ( $7.6$  to  $24$ ).

### Relevance

STAT-C will help oncology providers determine the severity of social toxicity experienced by their patients so that they can be addressed appropriately.

intertwined. For instance, pain management among patients with cancer is more frequently associated with financial burden and negatively affects work life and domestic life and family relationships.<sup>11</sup>

Generally, evidence shows that although the use of QoL tools in patients with cancer may improve the patient-physician communication and hence, care management, such instruments are not widely used in clinical practice and in many cases are used for specific cancer types and for the assessment of specific consequences.<sup>12</sup>

Although the impact of cancer diagnosis on the social life of patients is well known, yet, unlike physical and financial toxicity, there is dearth of available validated tools to assess the severity of the social toxicity of cancer on affected patients in Saudi Arabia and the region. The scanty evidence in the country indicates that exotic QoL tools do not dovetail well with the important functional and symptom domains of patients with cancer, underscoring the need for a better local, national, and regional holistic assessment tool.<sup>13</sup>

The purpose of our study was to develop, validate, and implement an encompassing multidimensional tool to assess the social toxicity of cancer on affected patients in terms of social relations, social activities, and economic impact.

## METHODS

### Tool Development

**Item generation phase.** The initial process of questionnaire design started with reviewing the literature areas such as family interactions, interactions with friends, participation in social activities, and financial concerns. Items were also generated inductively by interviewing experts in the topic ( $N = 10$ ; oncologists, social workers, other health care workers from the department of oncology, and research personnel), conducting two focus groups among health care workers (10 physicians, and nine health educators and nurses), two focus groups among patients with cancer and survivors (nine women and six men), and two focus

groups among family members of patients with cancer (five women and six men). Twenty items were generated to reflect two major dimensions of toxicity of the cancer experience: social and financial. The instrument was designed in Likert scale type (strongly disagree, disagree, do not know, agree, and strongly agree) that were scored from  $-2$  to  $2$ , respectively.

**Validity and reliability phase.** The preliminary constructed list of 20 items (in Arabic language) to be included in the questionnaire was submitted for a review and feedback from a group of eight oncology staff who were chosen as experts in social welfare of patient. The Content Validity Index for individual items and the Content Validity Index for the entire scale were assessed. Moreover, face validity was conducted among 24 patients with cancer to address whether the questions were clear, comprehended, and manageable by patients with cancer. The first 10 patients were interviewed by a research coordinator and were asked for feedback about each individual question and the remaining 14 patients were texted the questions requesting their feedback on them digitally to simulate the method that will be used to disseminate the tool.

An exploratory factor analysis (principal components analysis) was conducted followed by an orthogonal (varimax) factor rotation to prove the construct validity. In addition, an oblique (promax) factor rotation was conducted as a robustness check. The purpose of these steps was to identify domains in the constructed tool and items to retain that most clearly represent the content of every domain. Sample adequacy for extraction of the factors was assessed with the Kaiser-Meyer-Olkin (KMO) and Bartlett's tests. Additionally, interitem correlations among the variables were examined.

Construct validity was accomplished by assessing the correlation with similar constructs extracted from the Arabic WHOQOL.<sup>1</sup> Eleven questions from WHOQOL were related to patients' satisfactions with the support they are receiving from their family, friends, and others, and how satisfied they

were with their financial situation and living place. None of the WHOQOL questions was used in the final tool.

A value of Cronbach's alpha of at least .70 was considered acceptable for internal consistency. Test and retest reliability as a measure of consistency was conducted as an additional step of confirmation of reliability of the tool and significant agreement between the two administrations. Test-retest reliability was conducted on 14 patients by asking them to respond to the constructed tool twice within 1-week interval.

The survey was developed using SurveyMonkey. The final tool was then administered to patients with cancer treated at our institution via text messages (Data Supplement). The study was approved by Institutional Review Board at King Abdullah International Medical Research Center, Ministry on National Guards Health Affairs (RC19/077/R).

## RESULTS

### Descriptive Statistics

Sample characteristics are shown in [Table 1](#).

### Content Validity

Of the initial 20-item version of the instrument that was distributed to the experts, six items were removed because of lack of relevance as judged by experts and low Content Validity Index scores. Fourteen items were marked as relevant, and the Content Validity Index for individual items ranged between 0.80 and 1.00. An overall average Content Validity Index for the entire scale of 0.87 showed high content validity of the constructed tool. After inquiring from the experts for their opinion about the relevance, clarity, and comprehensiveness of the suggested questions, a final draft of 14 items of the instrument was set.

**TABLE 1.** Characteristics of Patients (N = 157)

Characteristic	No. (%)
Age, years, mean (range)	50.7 (8-89)
< 50	76 (48.41)
≥ 50	81 (51.59)
Sex	
Yes	64 (40.76)
No	93 (59.24)
Metastatic cancer	
Yes	115 (73.25)
No	42 (26.75)
Currently on treatment	
Yes	53 (33.76)
No	104 (66.24)
Treatment type	
Surgery	26 (16.56)
Chemotherapy	65 (41.40)
Radiation	75 (47.77)

### Face Validity

To evaluate this validity, 24 participating patients with cancer in the pilot study rated the questions based on appearance, comprehension, and acceptability by the target population. Approximately 95% of the participants in this phase of the validation process rated the selected questions as adequate for the criteria of rating.

### Factor Analysis

Although we grouped the 14 items into three domains (social relations, social activities, and economic impact), no predetermined structure was assumed. Hence, we conducted factor analysis to explore, reduce the individual items, and simplify data.

The ability to conduct factor analysis was assessed with the collected data. The KMO Measure Kaiser Meyer was 0.76, which is superior to the proposed 0.6, and Bartlett's test of sphericity was significant (chi-square = 665.622,  $P < .001$ ). All the 14 items in the tool showed an interitem correlation of at least 0.3 ([Table 2](#)).

Initially, the exploratory factor analysis of the questionnaire identified two factors based on an eigenvalue of  $\geq 1$ , which cumulatively accounted for 83.7% of the variation in the data.

As a result, these factors were retained based on Kaiser Criterion.<sup>14</sup> Kaiser's rule assumes that to retain a factor that explains less variance than a single original variable is not psychometrically reasonable.<sup>15</sup>

As depicted in [Table 3](#), the unrotated factor loadings indicate that Factor 1 moderately correlates with measures of social relations domains except for the relationship with parents. Items in the social activities also load moderately on factor 2. In addition, parents, siblings, and friends load on factor 3.

In the factor rotation, three factors are retained. However, many of the items of the constructed Social Toxicity Assessment Tool of Cancer (STAT-C) Tool loaded across the three factors, making it difficult to see how they group, hence the need for factor rotation.

However, when the factors are rotated, we see a clearer pattern where measures of social relations domains load on factor 1, showing a moderate correlation. At the same time, we see those measures of social activities and economic impact domains load on factor 2 ([Table 4](#)). This is true as the loadings  $< 0.3$  were suppressed, leaving a clearer picture than the unrotated case. The loadings suggest that the social relations items split into correlating the factors. Children, members, spouse, and divorce with factor 1; caregiver with factor 2; and parents, siblings, and friends with factor 3. The social activity items (weddings and leisure) and finance and economic items (standard of living, savings, and finances) load on and are correlated with factor 2. Job loss did not load on any of the underlying factors. There is no measure difference when the rotation is

**TABLE 2.** Eigenvalues and the Proportion of Variations Explained by Each Factor

Factor	Eigenvalue	Difference	Proportion	Cumulative
1	3.042	1.532	0.559	0.559
2	1.510	0.623	0.278	0.837
3	0.888	0.479	0.163	1.000
4	0.408	0.023	0.075	1.075
5	0.386	0.221	0.071	1.146
6	0.165	0.147	0.030	1.176
7	0.017	0.021	0.003	1.179
8	-0.003	0.067	-0.001	1.179
9	-0.070	0.022	-0.013	1.166
10	-0.092	0.025	-0.017	1.149
11	-0.118	0.010	-0.022	1.127
12	-0.128	0.134	-0.024	1.104
13	-0.262	0.042	-0.048	1.056
14	-0.303	—	-0.056	1.000

done orthogonally or obliquely as often revealed in the literature.<sup>14</sup>

Regarding the commonality of the items in the STAT-C Tool with all the underlying factors, the results suggest that extracted factors explain more of the variance of some *social activity* items such as relations with a spouse and divorce. The extracted factors also relatively explain more of the variance of participation in weddings as leisure.

The Arabic version appears to have loaded on 13 items, although the distribution varied across the three domains of the constructed STAT-C questionnaire. Social relations domain (consisting of eight questions) related to relationship with parents, spouse, children, siblings, friends,

members of a congregation, and caregiver; social activities domain (consisting of two questions) measures participation in social events and leisure; and economic impact domain (consisting of three questions) related to standard of living, savings, and finances. The total possible score for each patient for the remaining 13 items in the tool varied between -26 and +24 (range = 50). Dividing the range by three levels of a socioeconomic toxicity yielded the length of each level, which effectively defined the categories as *severe social toxicity* (score: -26 to -9.3), *mild social toxicity* (-9.2 to 7.5), and *no social toxicity* (7.6 to 24).

**Convergent Validity**

Questions retrieved from the Arabic version of WHOQOL measuring concepts related to happiness with relationships with family members, satisfactions with personal relationships, receiving support from social encounters, receiving support from family members, and receiving support from friends were cumulatively correlated with the social relationships domain of the constructed tool. The results of the convergent validity analysis showed a significant positive correlation between the social relationships domain and the questions related to the satisfactions and happiness with social relationships from the WHOQOL ( $r = 0.3142$ ;  $P = .0001$ ). Scores of variables from WHOQOL related to finances and scores of variables related to leisure activity correlated significantly with scores from economic impact domain and social activities domain from the newly developed tool ( $r = 0.50$ ;  $P < .001$  and  $r = 0.42$ ;  $P < .001$ ; respectively). Further analysis indicated that the severe social toxicity in STAT-C tool has significant moderate correlation with some of the social relationship items in the WHOQOL (Table 4).

**Internal Consistency and Test-Retest Reliability**

The internal consistency by Cronbach’s alpha was calculated for each domain of the developed tool. All identified domains showed favorable internal stability. The internal consistency results for the instrument showed a Cronbach’s coefficient alpha value of 0.78 for social relationships, 0.81 for social activities, and 0.77 for economic impact. Test-retest reliability of 82% was detected between the two instrument administrations of the tool (Cohen’s Kappa of 0.66;  $P < .003$ ).

**DISCUSSION**

The importance of QoL issues among long-term cancer survivors has long been examined in the literature.<sup>16-19</sup> There are various scales to assess various aspects of patients well-beings such as QoL, psychologic health, physical symptoms and adverse events, and financial toxicity<sup>20,21</sup>; along with the need of holistically assessing patients’ needs, the demand for reporting both the psycho and social components of the disease experience is constantly growing.<sup>20</sup> In particular, numerous psychologic tools were previously commonly used in oncology containing dimensions with social content items from social or

**TABLE 3.** Rotated Factor Loadings and Unique Variances

Variable	Orthogonally (varimax) Rotated Factor Loadings			Obliquely (Promax) Rotated Factor Loadings		
	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2	Factor 3
	Relations with parents			0.536		
Relations with siblings			0.555			0.593
Relations with friends	0.358		0.579			0.595
Relations with children	0.551			0.552		
Relations with members	0.378			0.302		
Relations with spouse	0.888			0.875		
Participation in weddings	0.735			0.764		
Participation in leisure		0.588			0.573	
Standards of living	0.594			0.643		
Status of savings		0.370			0.328	
Impact on finances		0.570			0.584	
Changes with caregiver		0.423			0.451	
Got divorced	0.798			0.853		
Experienced job loss						

**TABLE 4.** Correction of Toxicity Levels in STAT-C and Social Relations Items in the WHOQOL

Questions	STAT-C SST	STAT-C MST	STAT-C LST
Are you able to work?	0.142	-0.003	-0.064
	0.078	0.973	0.428
How satisfied are you with the support you get from your friends?	0.218 <sup>a</sup>	0.023	-0.128
	0.006	0.771	0.111
Do you feel happy about your relationship with your family members?	0.431 <sup>a</sup>	-0.123	-0.073
	< 0.001	0.128	0.368
How satisfied are you with your personal relationships?	0.376 <sup>a</sup>	-0.051	-0.123
	< 0.001	0.527	0.126
How satisfied are you with the support you get from your family?	0.303 <sup>a</sup>	-0.086	-0.051
	< 0.001	0.286	0.528
How satisfied are you with the support you get from your friends?	0.472 <sup>a</sup>	-0.082	-0.135
	< 0.001	0.307	0.093
How satisfied are you with your financial situation?	0.231 <sup>a</sup>	0.028	-0.140
	0.004	0.730	0.084

Abbreviations: LST, low social toxicity; MST, mild social toxicity; SST, severe social toxicity; STAT-C, Social Toxicity Assessment Tool of Cancer.

<sup>a</sup>Significant at 5% level.

functioning role (eg, EORTC QoL Core 30),<sup>22</sup> to social support (eg, Psychological Screen for Cancer),<sup>23</sup> to partner relationships (eg, Brief Cancer Related Worry Inventory),<sup>24</sup> to relatives (eg, Functional Assessment of Cancer Therapy—General Measure),<sup>25</sup> and to social dysfunction (eg, General Health Questionnaire).<sup>26</sup>

Unlike physical and financial toxicities, there is a dearth of validated tools to measure social impact of cancer in Saudi Arabia and the region, which is why our study attempted to develop, validate, and implement a novel STAT-C for Arab-speaking patients with cancer. In fact, one study in the country that used the European QoL tools showed patients scored low on the important functional and symptom domains.<sup>13</sup>

The results suggest that the social relations domain of our constructed STAT-C Tool has a convergent validity with questions retrieved from the Arabic version of WHOQOL, which measured satisfactions and happiness. The WHOQOL captures happiness with relationships with family members, satisfactions with personal relationships, receiving support from social encounters, receiving support from family members, and receiving support from friends.<sup>27</sup> The WHOQOL tool is cross-culturally applicable and, among other things, can be used to assess aspects of spirituality, religiousness, and personal beliefs.<sup>1</sup> In specific cancer types, the WHO Quality of Life Tool Brief (WHOQOL-BREF) has been shown to have satisfactory psychometric properties in patients with advanced-stage lung cancer.<sup>28</sup>

These items cumulatively appeared to be correlated with the social relations domain of the constructed tool. Our results also suggest that all identified domains showed favorable internal consistency and stability. This is consistent with

studies in the Gulf region, which showed that the Arabic version of the WHOQOL-BREF demonstrated good psychometric properties, with high internal consistency reliability.<sup>29</sup>

Our factor exploratory analysis initially indicated that many of the items of the constructed STAT-C Tool load on across the three factors, making it difficult to see how they group. However, a further analysis of factor rotations revealed a clearer pattern and groupings into measures of social relations, social activities, and economic impact domains. The rotations analysis also rendered some items in the STAT-C Tool such as job loss redundant, which suggests that they can as well be removed altogether. Consistent with the literature, there was no measure difference when the rotation is done orthogonally or obliquely.<sup>14</sup> In fact, the literature suggests that allowing for factors that are correlated with one another is especially applicable in psychometric research, since attitudes, opinions, and intellectual abilities tend to be correlated, and since it would be unrealistic in many situations to assume otherwise.<sup>30</sup>

Our analysis revealed that save for some social activity items such as relations with a spouse and divorce and participation in weddings as leisure, the extracted factors moderately explained most of the items in the STAT-C Tool. As a rule of thumb, items that are highly correlated will share a lot of variance and that values closer to one suggest that extracted factors explain more of the variance of an individual item.<sup>31</sup> That said, the mixed result in the commonality of the items in our constructed tool is not surprising. The common factors can be overidentified or underidentified in analysis when the selected items over-represent or under-represent the domain of interest in the variable selection.<sup>32,33</sup>



Finally, KMO Test indicated sampling adequacy of the data captured in Arabic version and is suited for exploratory factor analysis. This is consistent with statistical cutoff suggestions as espoused in the factor analysis literature.<sup>24</sup>

We find the contribution of STAT-C in its uniqueness in focusing on the social toxicity of cancer and especially social relations and activity. The tool is expected to help in quantifying a complex domain of patient life, which will enable care providers, clinicians, and support staff understand the magnitude of impact and seek the appropriate interventions. Understanding this aspect of patient needs will enable the team to provide a better integrated approach to care. The tool is also expected to enable future researchers to measure the impact of various interventions and compare and correlate between the social toxicity and various aspects of patients' health and well-being and understand better various health behaviors and choices made by patients. Patients with cancer and caregivers may suffer from social isolation and change in their social activities, which may be related to the toll of cancer on the body and emotion or related to its negative impact on productivity and financial status. As shown in the literature, cancer can have negative impact on the lives of siblings, caregivers, and family in general. Family caregivers of palliative care patients face a high burden of depressive

symptoms.<sup>34</sup> The literature shows that a chronic illness can have a potentially life-threatening outcome on siblings as they have the potential to perceive threatened or actual losses as a result of their brother's or sister's illness.<sup>35</sup> At the same time, siblings are shown to report lower psychosocial and physical functioning when they perceived their parents provided them with less affection than their affected brother or sister, affecting family relations.<sup>36</sup>

The development of STAT-C tool in Saudi population may, however, be limited, especially in its applicability to other populations for language barriers and differences in cultural, societal, and social factors. Therefore, translating and validating the tool in different populations is required. The challenge comes from the unpredictability and the huge variations in many variables that affect the patient's life throughout the disease trajectory. Therefore, the questions of when to apply the tool and how often to repeat require study. Furthermore, the interventions needed in response of the assessment should be individualized.

In conclusion, STAT-C is a valid and reliable tool in assessing the social toxicity of cancer that should enable the oncology team to understand the needs of patients. The tool is expected to enhance patient-centered care as a component of a holistic approach.

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## AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated unless

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