Development of Subjective Financial Distress Questionnaire (SFDQ) for Measuring Financial Toxicity Among Cancer Patients Undergoing Radiation Therapy

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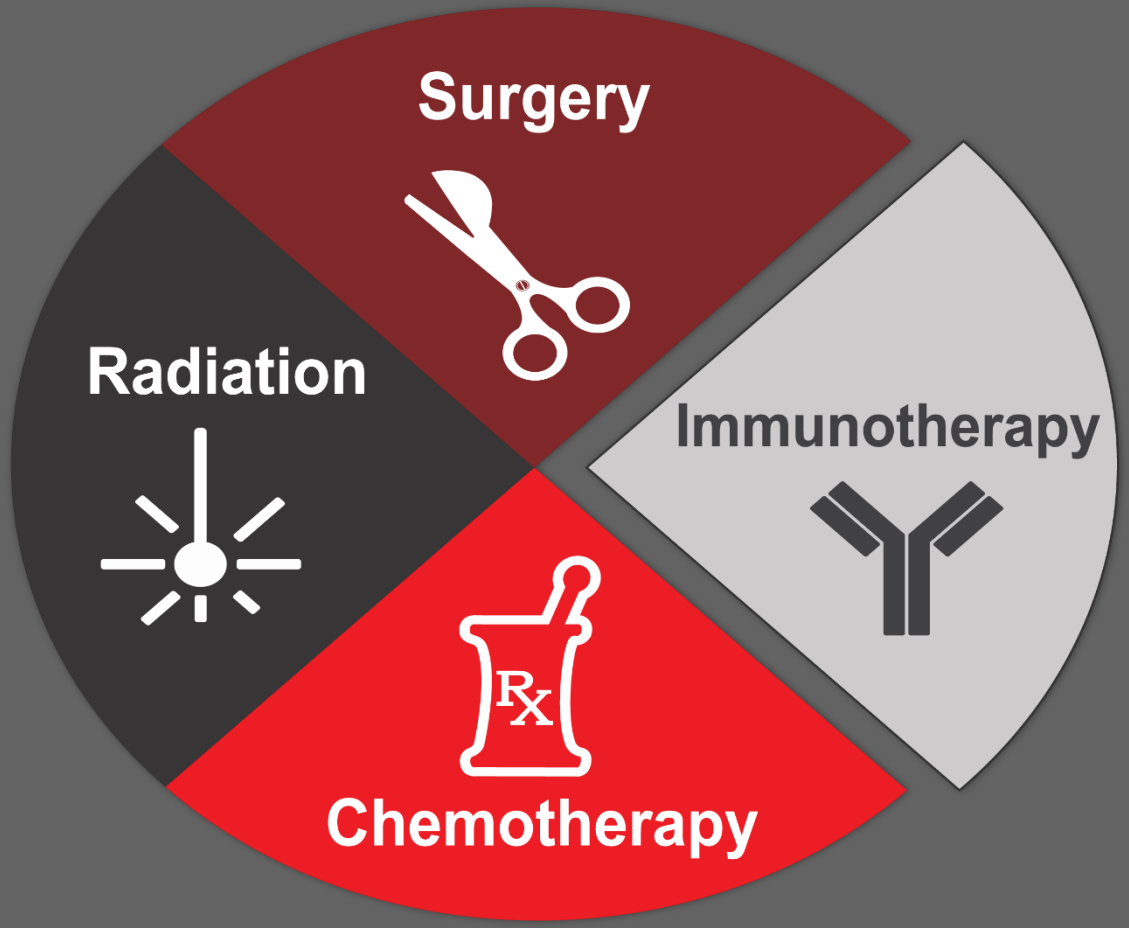
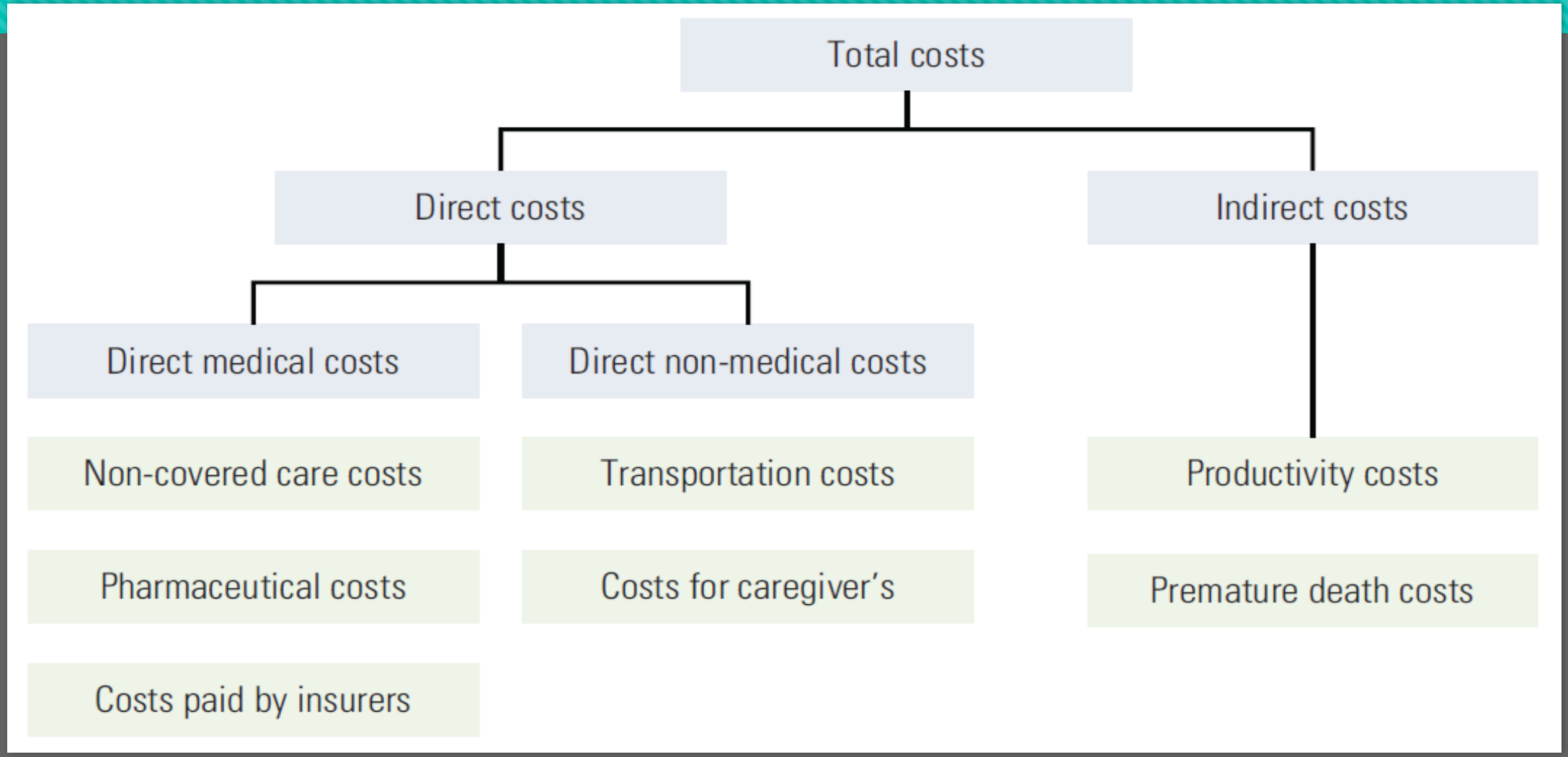
Burden of Cancer: GLOBOCAN 2020 Estimates

- Globally the burden of cancer is increasing at an alarming rate
- GLOBOCAN-2020 reported that worldwide cancer burden is estimated to have escalated to **19.3 million** new cancer cases and **9·9 million** cancer deaths in 2020
- GLOBOCAN 2020 has estimated over **1.3 million** new cancer cases and **0·85 million** cancer deaths in India in 2020.
- The results of GLOBOCAN 2020 are available at (http://gco.iarc.fr/).

Modalities of Treatment for Cancer



Direct & Indirect Costs of Cancer Treatment



Being Diagnosed with Cancer

Emotional Stress

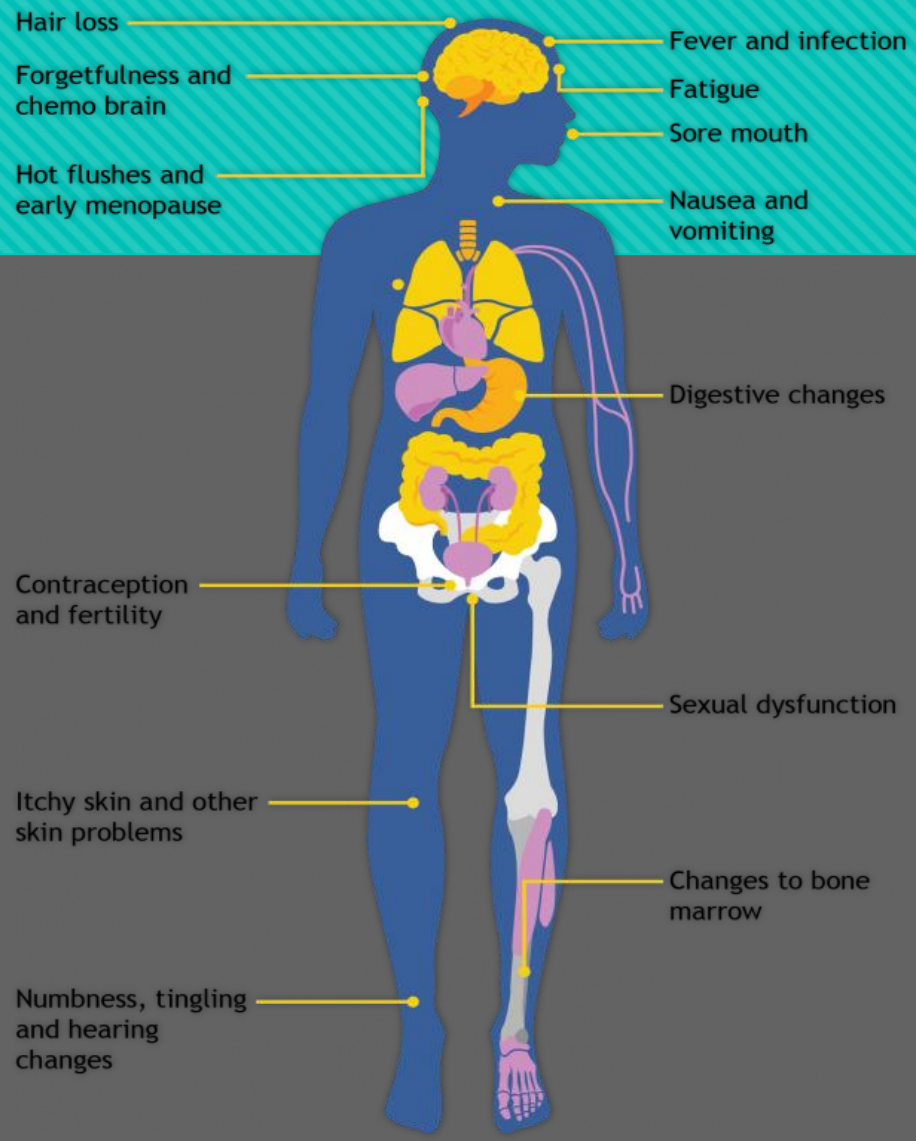
Financial Stress

Mental Stress

Physical Stress

Side Effects of Cancer Treatment

- The Side Effects of Cancer Treatment are many & well documented.
- As treatment become more complex and expensive, another toxic reaction has to be dealt with: **"Financial Toxicity"**
- Several terms have been used to describe the financial consequences of managing cancer, such as financial burden, ***financial toxicity***, financial hardship, and financial stress/distress.



Financial Toxicity

- The **Adverse Effects** of financial hardships experienced by cancer patients because of cancer care is termed as **Financial Toxicity**
- Financial toxicity has been defined as **'a potential consequence of subjective financial distress experienced by patients due to cancer related direct and indirect out-of-pocket (OOP) treatment expenditures'**
- Financial toxicity is analogous to physical toxicity among cancer patients

Financial Toxicity & Implications

- Researchers have linked Financial Toxicity with several clinically relevant outcomes including:
- ✓ Health-related quality of life (HRQOL)
- ✓ Early mortality
- ✓ Treatment compliance
- ✓ Medication non-adherence
- ✓ Forgoing treatment
- ✓ Greater risk for bankruptcy

Financial Toxicity & Implications on Clinical Outcomes

- **Delgado et al. (2015)** reported association of financial distress with anxiety, depression and poor quality poor life among advanced cancer patients.
- More than **30%** of the patients rated financial distress as more severe than physical distress, social/family distress and emotional distress.
- **Barbaret et al. (2017)** reported **51%** of the cancer patients suffered financial distress and greater financial burden is negatively associated with quality of life.
- **Kale et al. (2016)** reported that Cancer-related financial burden was associated with **lower health-related quality of life**, **increased risk of depressed mood**, and a higher frequency of worrying about cancer recurrence.

Financial Toxicity Quality of Life

- **Ramsey et al. (2016)** reported that severe financial distress as manifested by personal bankruptcy might be a **significant risk factor for mortality.**
- **Linda et al. (2012)** reported that depression was raised **three folds** in those patients reporting financial burden.
- **Ramsey et al. (2013)** reported that patients with cancer are **2.65** times more likely to declare bankruptcy than those without cancer.
- **Chino et al. (2014)** has reported a **poor overall patient satisfaction** in cancer patients with financial distress.

Financial Toxicity & Medication Non-Adherence

Zullig et al. (2013) reported 45% cost related medication nonadherence

- ✓ 27% did not fill their prescription
- ✓ 5% filled partial prescription
- ✓ 22% took less medication
- ✓ 4% took medication prescribed for another person

Cheryl et al. (2017) in a Systematic Review reported that

- ✓ **47-49%** of cancer survivors experienced some form of financial distress
- ✓ **4-45%** of survivors did not adhere to the recommended prescription medication due to cost

Financial Toxicity: Indian Scenario

Financial toxicity in cancer care in India: a systematic review

Jeffrey Mathew Boby, Senthil Rajappa, Aju Mathew

Although financial toxicity is widely acknowledged to be a potential consequence of costly cancer treatment, little is known about its prevalence and outcome among the Indian population. In this study, we systematically reviewed the prevalence, determinants, and consequences of financial toxicity among patients with cancer in India. 22 studies were included in the systematic review. The determinants of financial toxicity include household income, type of health-care facility used, stage of disease, area of residence, age at the time of diagnosis, recurrent cancer, educational status, insurance coverage, and treatment modality. Financial toxicity was associated with poor quality of life, accumulation of debts, premature entry into the labour market, and non-compliance with therapy. Our findings emphasise the need for urgent strategies to mitigate financial toxicity among patients with cancer in India, especially in the most deprived sections of society. The qualitative evidence synthesised in this systematic review could provide a basis for the development of such interventions to reduce financial toxicity among patients with cancer.

Lancet Oncol 2021; 22: e541–49

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Methods for measuring financial toxicity

- **Objective assessment**

Measuring actual Out of Pocket (OOP) expenses during cancer treatment

- **Subjective assessment**

Understanding the consequence of cost concerns on individual patient (Patient's perspective)

- Three instruments have been developed specifically for measuring financial toxicity:

1) The Comprehensive Score for Financial Toxicity (COST)
2) Financial Index of Toxicity (FIT),
3) Breast Cancer Finances Survey Inventory (BCFS)
4) In-Charge Financial Distress/ Financial Wellbeing Scale (IFDFW)
5) Socioeconomic Wellbeing Scale (SWBS)

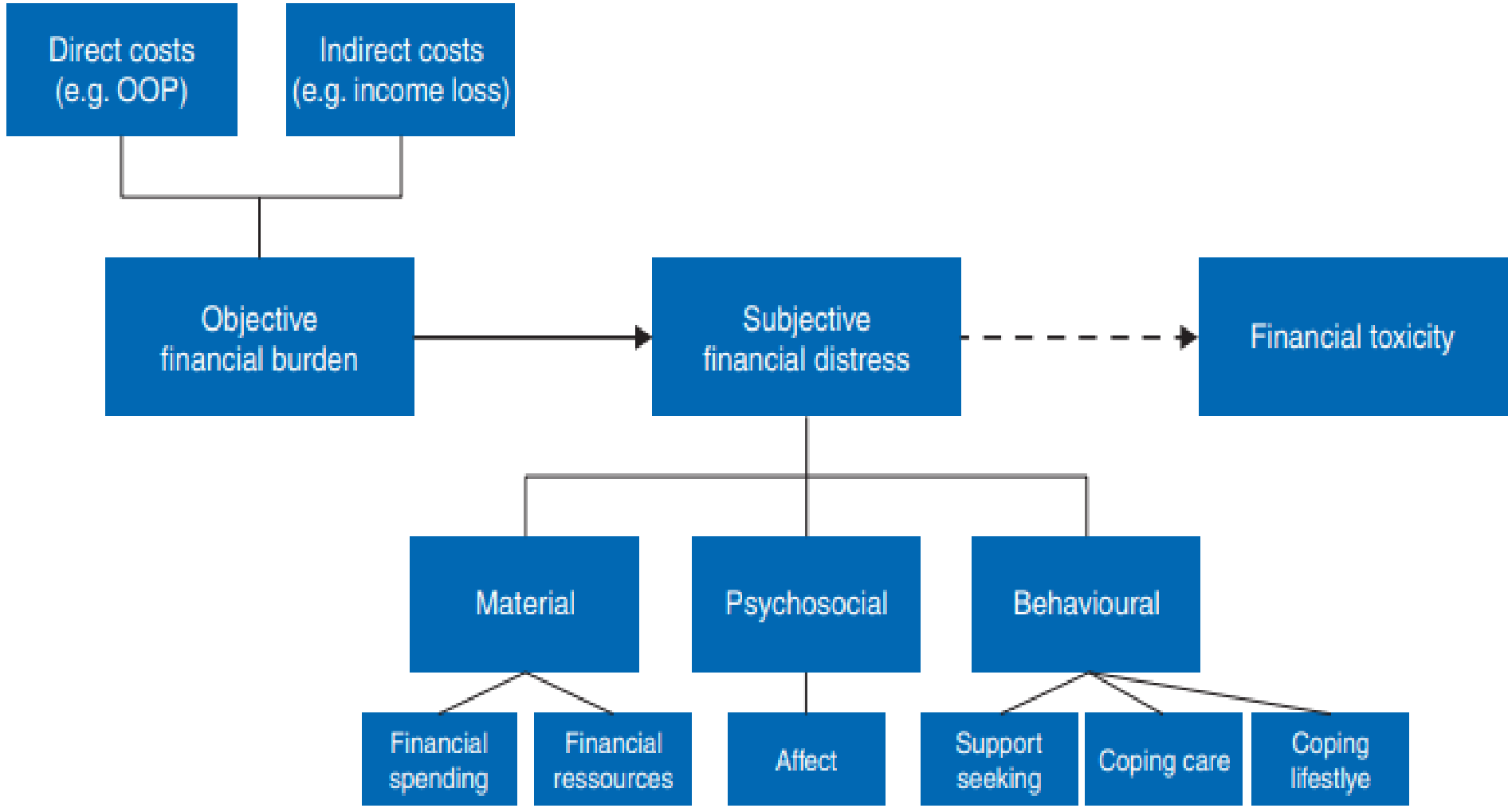
OBJECTIVE

Development and Validation of a reliable instrument for measuring financial toxicity among radiation oncology patients

Ethical Consideration

- This is a **Cross-Sectional** patient reported outcome study being conducted at Mahaveer Cancer Sansthan and Research Centre (MCSRC), Patna
- This study was approved **(Reference No. RMRI/EC/41/2020)** by Ethics Committee ICMR-Rajendra Memorial Research Institute of Medical Sciences (RMRIS), Agamkaun, Patna
- An informed consent was taken from each patient before participating in this study

Framework of Financial Toxicity



Limitations of current scales

- Three instruments including have been developed for assessment of financial toxicity among cancer patients
  - ✓ Financial Index of Toxicity (FIT),
  - ✓ Comprehensive Score for financial Toxicity (COST)
  - ✓ Breast Cancer Finances Survey Inventory (BCFS)

METHODOLOGY

Step-1: Item Generation for Scale Development

- ✓ Review of Literature
- ✓ Patient Perspectives
- ✓ Expert Opinion

Step-2: Patient enrolment and Data Collection

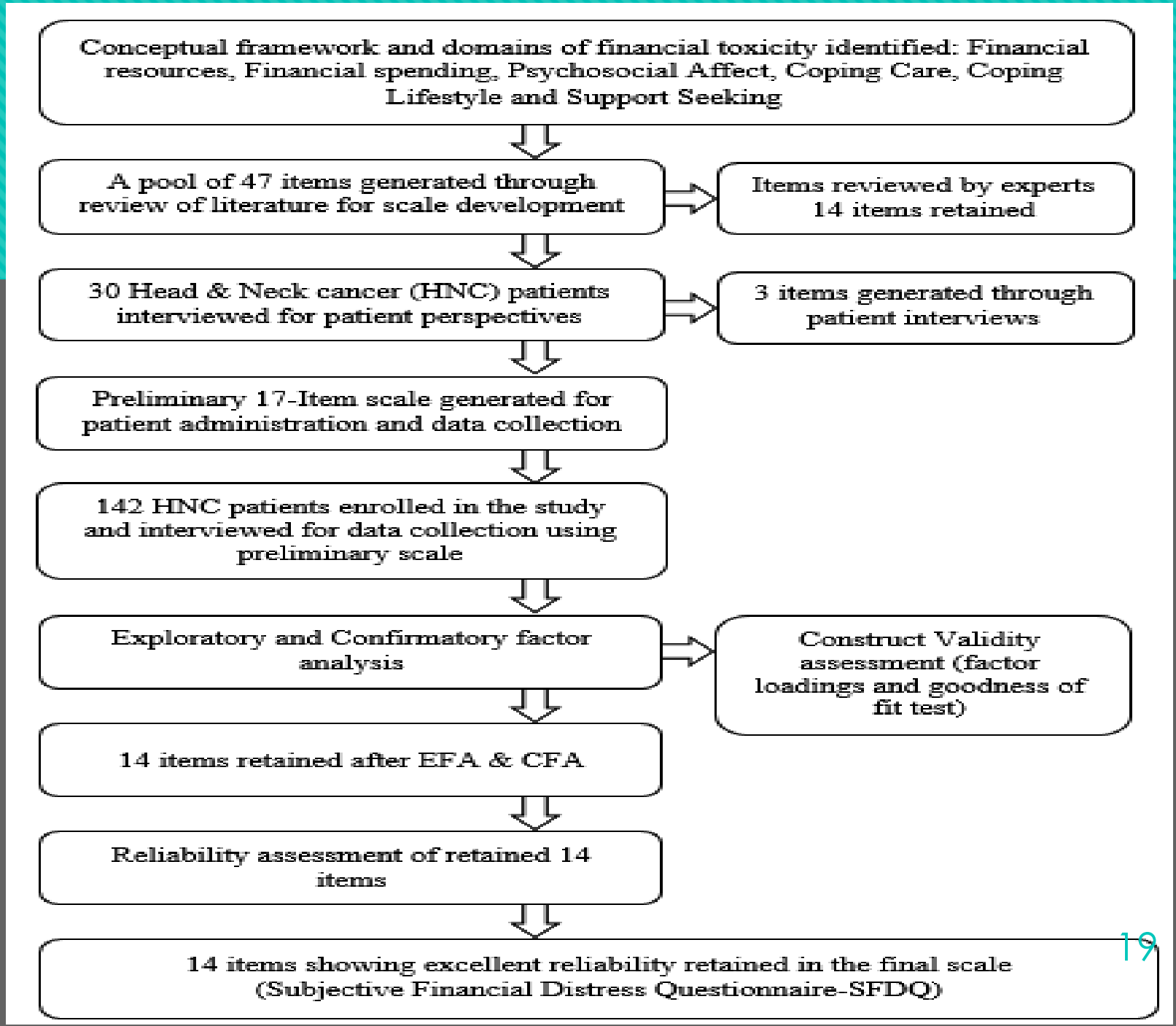
Step-3: Validity Analysis

- ✓ Exploratory factor analysis (EFA)
- ✓ Confirmatory factor analysis (CFA)

Step-4: Reliability Analysis

- ✓ Cronbach's a coefficient

Flowchart Depicting Scale Developmental Process



METHODOLOGY

Inclusion Criteria

1) Patients having completed radiation therapy either as stand-alone or part of multimodal treatment regimen
2) Patients of any gender and ≥18years of age
3) Patients willing to participate in the study

Exclusion Criteria

1) Patients not able to give consent or withdraw from the study
2) Patients with missing or incomplete data

Sample Size

- The most common guideline for suitable sample size in EFA is the ratio of sample size to the number of variables (participant to item ratio)
- Hair et al. recommends a minimum 5:1 participant to item ratio, and 10:1 as more acceptable sample size
- A sample size of 150 was considered appropriate for this study
- The participant to item ratio for this analysis was approximately 9:1 (where sample size was 150 and the number of variables included was 17)

Preliminary Scale Development

- Based on extensive literature search, expert opinion and patient participation,
- A preliminary 17-item scale was developed measuring six domains of financial toxicity including;
  - ✓ Financial resources & Financial spending
  - ✓ Psychosocial Affect
  - ✓ Coping care & Coping lifestyle
  - ✓ Support Seeking
- The construct validity indicating the extent to which the individual items in the scale reflect and measure the corresponding domain/factor of financial toxicity was evaluated by EFA and CFA.

Socio-Demographic & Clinical Characteristics (N=142)

Characteristics	N (%)	Characteristics	N (%)
Gender		Current employment Status	
Male	122 (85.9)	Stopped Working	99 (69.7)
Female	20 (14.1)	No Change in Work	26 (18.3)
Age Group		Reduction in Work	17 (12.0)
18-59	97 (68.3)	Primary Cancer Site	
≥60	45 (31.7)	Oral Cavity	92 (64.8)
Residence		Larynx	12 (8.5)
Rural	140 (98.6)	Oropharynx	12 (8.5)
Urban	2 (1.4)	Hypopharynx	9 (6.3)
Marital Status		Salivary Glands	6 (4.2)
Married	135 (95.1)	Paranasal Sinus	3 (2.1)
Unmarried	6 (4.2)	Thyroid	2 (1.4)
Others	1 (0.7)	Others	6 (4.2)
Education Level		Disease Extent	
Not Educated	72 (50.7)	Metastatic	7 (4.9)
Primary level	44 (31.0)	Non-Metastatic	133 (93.7)
Secondary Level	15 (10.6)	Treatment Modality	
Graduate and above	11 (7.8)	RT	17 (12.0)
Occupation		RT+S	59 (41.5)
Employed	13 (9.2)	RT+CT	44 (31.0)
Unemployed	17 (12.0)	RT+CT+S	22 (15.5)
Labour Work	37 (26.1)	Treatment Intent	
Farming	25 (17.6)	Definitive	129 (90.8)
Homemaker	16 (11.3)	Palliative	13 (9.2)
Others	34 (23.9)	Time Since RT	
Annual Household Income		less than 1 month	26 (18.3)
less than 50000	56 (39.4)	1-6 months	35 (24.6)
50000-100000	51 (35.9)	6-12 months	23 (16.2)
100000-150000	17 (12.0)	12-18 months	11 (7.7)
150000-200000	6 (4.2)	18-24 months	18 (12.7)
>200000	12 (8.5)	>24 months	29 (20.4)
Health Insurance			
Yes	5 (3.5)		
No	137 (96.5)		

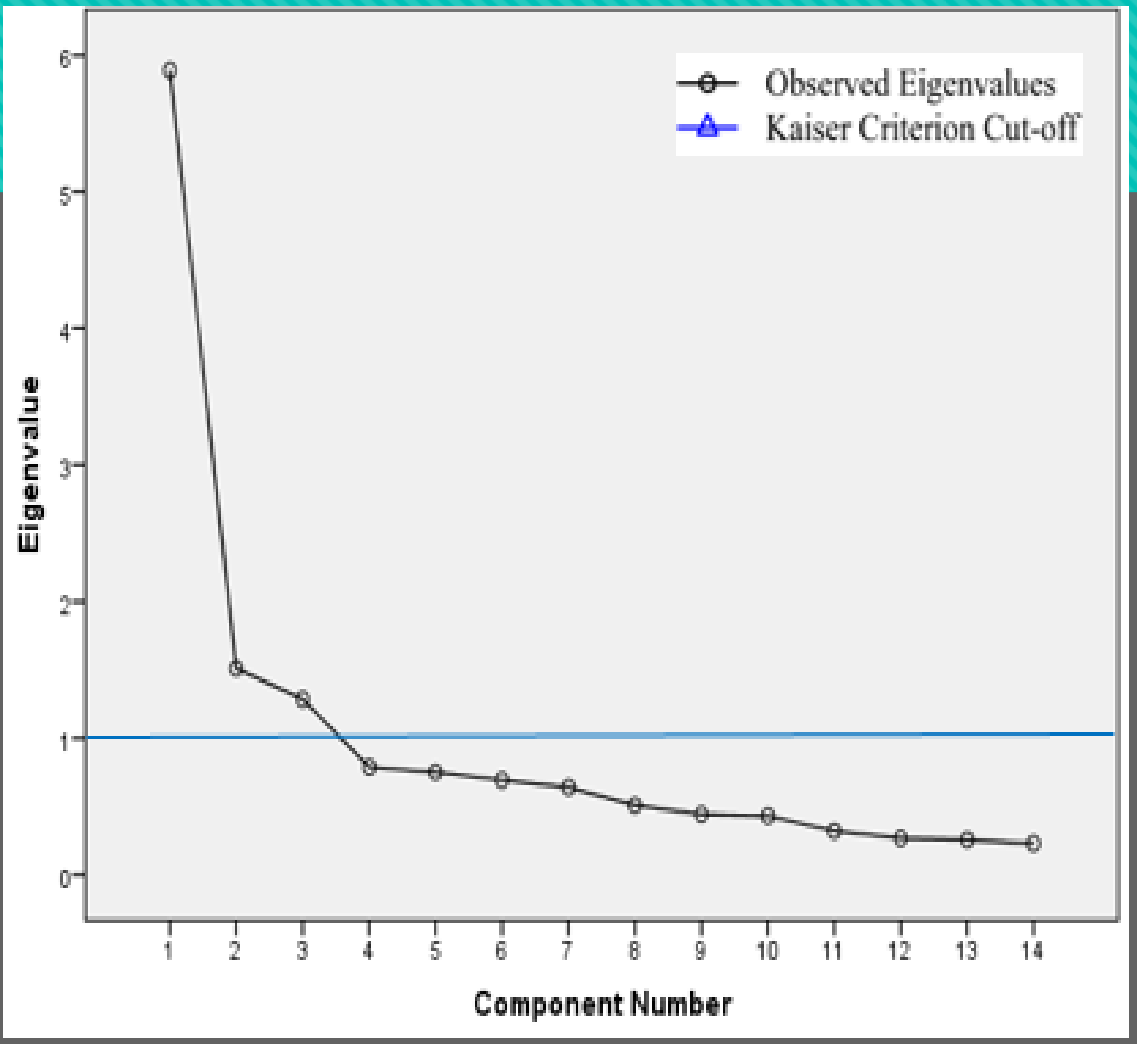
Exploratory Factor Analysis (EFA)

KMO and Bartlett's Test (*N*=142)		
Kaiser-Meyer-Olkin Measure of sampling adequacy		0.888
Bartlett's Test of Sphericity	Approx. χ^2	888.538
	df	91
	Sig. (*p*)	.000**

*p-value significance level <0.001

Exploratory Factor Analysis (EFA)

- EFA was performed on preliminary 17-item instrument
- Three items (Item 3, 4 and 5) were removed due to factor loadings <0.5 and cross-loadings
- After removing three items, 14-items loaded onto **three factors** explaining 62.0% of the total variance in EFA
- **Factor-1** comprising of 10-items was classified as "Financial and Psychosocial affect domain".
- **Factor-2** comprising of 2-items was classified as "Coping behaviour domain".
- **Factor-3** comprising of 2-items was classified as "Support seeking domain".



Item Factor loadings in rotated component matrix

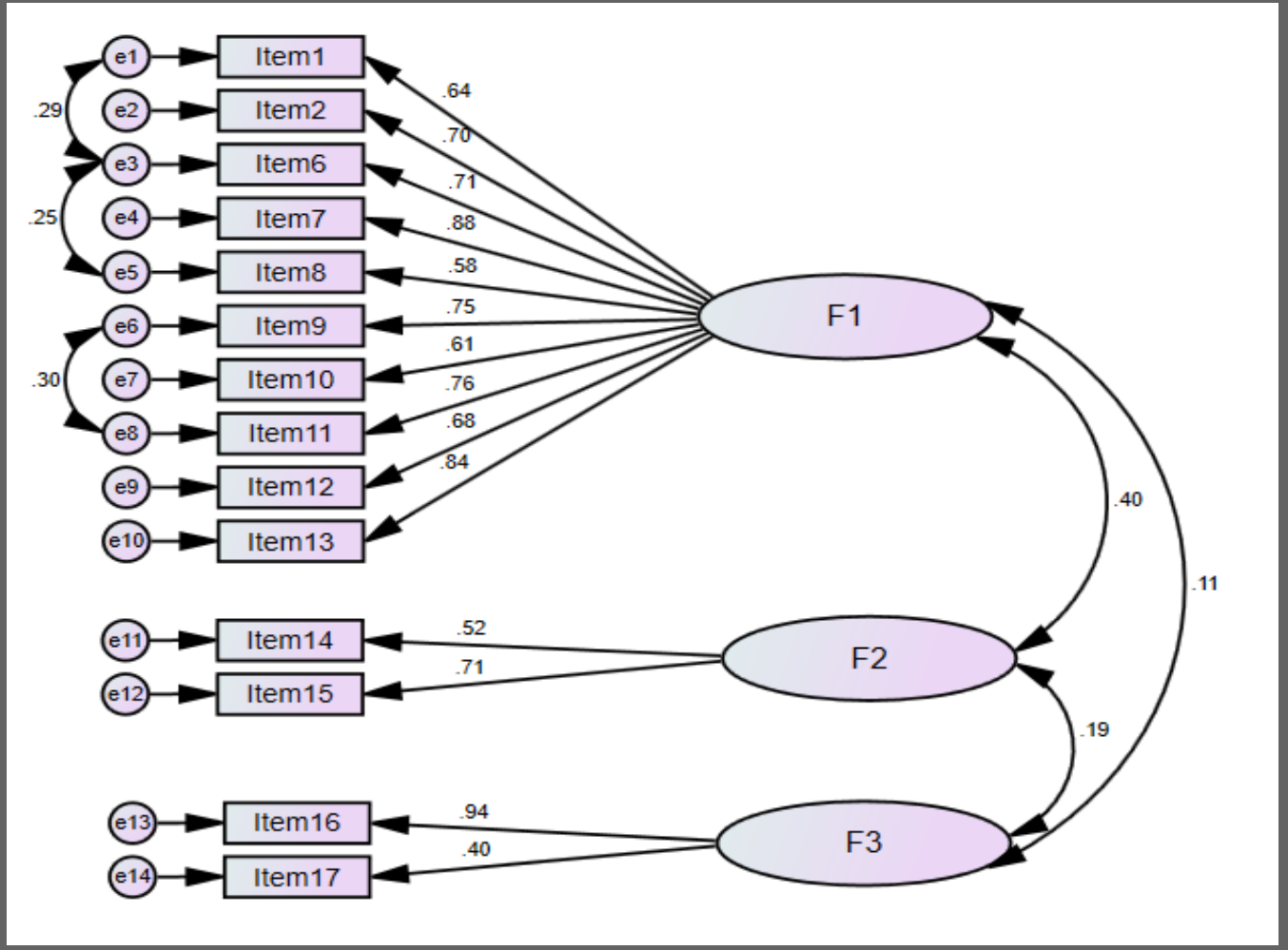
Items	Factors		
	F1	F2	F3
Item1	.685		
Item2	.733		
Item6	.746		
Item7	.859		
Item8	.605		
Item9	.794		
Item10	.633		
Item11	.813		
Item12	.753		
Item13	.817		
Item14		.827	
Item15		.765	
Item16			.775
Item17			.836

Eigenvalues and percentage of total variance explained in EFA

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	5.889	42.068	42.068	5.889	42.068	42.068	5.626	40.188	40.188
2	1.510	10.787	52.854	1.510	10.787	52.854	1.557	11.122	51.310
3	1.285	9.177	62.032	1.285	9.177	62.032	1.501	10.722	62.032
4	.788	5.626	67.658						
5	.750	5.356	73.014						
6	.691	4.935	77.949						
7	.639	4.568	82.517						
8	.508	3.625	86.142						
9	.442	3.154	89.296						
10	.430	3.073	92.369						
11	.319	2.282	94.651						
12	.266	1.899	96.550						
13	.256	1.825	98.375						
14	.228	1.625	100.000						

Confirmatory Factor Analysis (CFA)

CFA of 14-items retained in EFA was performed to determine whether the factors F1, F2, and F3 adequately describe the data



Confirmatory Factor Analysis (EFA)

- The results of CFA showed that χ^2 test was not significant (P >0.01) suggesting that the CFA model adequately fits the data indicating a good model fit.
- The values of other model fit indices including RMSEA = 0.056, SRMR = 0.012, GFI = 0.92, CFI = 0.98 and TLI = 0.97 are all indicative of a good model fit.
- The results of EFA and CFA support excellent construct validity of 14-item SFDQ for assessment of financial toxicity.

Reliability Analysis

- ✓ The reliability/ internal consistency of final 14-item scale was assessed using the Cronbach's a coefficient.
- ✓ The Cronbach's a for the final scale was 0.87 (~0.9) indicating excellent reliability
- ✓ The Cronbach's a coefficient of all the individual 14 items was ≥0.85 (range 0.853-0.88).
- ✓ No increase in Cronbach's a values was observed if any of the individual items were deleted from the scale.

Reliability Analysis

Cronbach's α, if any individual item was deleted

Items	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
Item1	14.13	21.464	.649	.857
Item2	14.41	20.697	.622	.856
Item6	14.30	20.510	.697	.853
Item7	14.65	18.201	.803	.844
Item8	14.32	21.651	.558	.861
Item9	15.11	20.469	.684	.853
Item10	14.61	20.794	.558	.860
Item11	14.13	21.246	.708	.855
Item12	14.09	21.786	.598	.860
Item13	14.72	19.651	.768	.847
Item14	15.46	22.576	.248	.877
Item15	15.44	22.135	.322	.874
Item16	15.08	23.581	.167	.876
Item17	15.08	24.058	.058	.880

CONCLUSION

- With the extensive literature search, expert opinion and patient participation, **Subjective Financial Distress Questionnaire (SFDQ)** for measuring financial toxicity among radiation oncology patients was developed.
- SFDQ showed excellent construct validity and reliability.
- SFDQ captures and integrates all the relevant domains of subjective financial distress.
- However, the provisional SFDQ instrument warrants further larger sample studies to improve the generalizability of this instrument.

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Thank You!


Q&A