## **CORVINUS UNIVERSITY OF BUDAPEST**

## FINANCIAL TOXICITY AND HEALTH-RELATED QUALITY OF LIFE IN INDONESIAN PATIENTS WITH CANCER

DISSERTATION BOOKLET

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Budapest, 2025

### 1. Research background and justification

The primary objective of this dissertation is to investigate financial toxicity, health-related quality of life, and well-being, and their associations in patients with cancer in Indonesia.

Financial toxicity refers to the negative financial impact of cancer care and diagnosis on the well-being of patients.<sup>1-3</sup> This construct has gained increasing relevance due to the rising prevalence of cancer and its substantial global disease burden.

There are two main forms of financial toxicity: objective and subjective. Objective financial toxicity refers to quantifiable economic burdens, such as out-of-pocket healthcare expenses. Subjective financial toxicity, on the other hand, is the perceived distress that patients experience due to financial hardship. Measuring the subjective form requires the use of patient-reported outcome measures.

Health-related quality of life (HRQoL) reflects how a person's health status affects their ability to lead a fulfilling life, encompassing physical, psychological, and social functioning.<sup>4,5</sup> Over the past few decades, HRQoL has gained importance in clinical trials, patient care, and healthcare economic evaluations. In oncology, HRQoL is a critical health outcome, as it is closely associated with prognosis and survivorship.<sup>6-9</sup>

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Patients experiencing financial toxicity are more likely to struggle with treatment adherence or encounter barriers to receiving necessary care. Mitigating financial toxicity (or improving financial well-being) may lead to better HRQoL, potentially enhancing increasing chances of survivorship. This suggests a link between financial toxicity and HRQoL.

This dissertation presents five published, peer-reviewed scientific journal articles, each contributing to the overall aim:

- Chapter II: A systematic literature review on the association between financial toxicity and HRQoL.
- Chapter III: A qualitative study exploring financial toxicity experiences among patients with cancer
- Chapter IV: A psychometric validation of a measure for subjective financial toxicity
- Chapter V: A psychometric validation of multiple HRQoL and well-being measures
- Chapter VI: A quantitative study examining the associations between financial toxicity, HRQoL and well-being

Data for Chapters III-VI were collected from patients with cancer in Indonesia, while Chapters IV-VI specifically used data from a single-center study on breast cancer.

## 2. Research methodology

#### 2.1. Systematic literature review and meta-analysis

A systematic review and meta-analysis were conducted to synthesize publications on financial toxicity and HRQoL, following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.<sup>10</sup> Four electronic journal databases were searched: PubMed, Web of Science, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and APA PsycInfo. The search strategy was developed using a set of keywords related to cancer, financial toxicity, and HRQoL.

Inclusion criteria for studies were as follows: published in English, original research articles with primary data collection, included adult cancer patients or survivors of any type, assessed financial toxicity using the Comprehensive Score for Financial Toxicity (FACIT-COST), and measured HRQoL, using any standardized and validated measure.

Key findings, sample, and study characteristics of were extracted. Two critical appraisal tools were used to assess the methodological quality of the included studies: Appraisal Tool for Cross-Sectional Studies (AXIS) and the Critical Appraisal Skills

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Program (CASP) Cohort Study checklist. Extracted data were qualitatively synthesized.

In addition, a meta-analysis was conducted to integrate findings from good-quality studies that used the Functional Assessment Cancer Therapy (FACT) instrument family. The metaanalysis pooled correlation coefficients between FACIT-COST and FACT scores. A random-effects model with a restricted maximum likelihood estimator was used to account for heterogeneity, as indicated by the I-squared statistic.<sup>11-14</sup> Publication bias was assessed using Egger's regression test.<sup>15</sup> Correlation coefficients were interpreted as very weak (<0.2), weak (0.20-0.39), moderate (0.40-0.59), strong (0.60-0.79), or very strong ( $\geq$ 0.8)

#### 2.2. Qualitative interpretive phenomenological analysis

To explore the lived experiences of financial toxicity among cancer patients, semi-structured, in-depth phenomenological interviews were conducted with eight patients in Indonesia. Eligibility criteria included: aged 23 years or older, fluent in Indonesian, diagnosed with any type of cancer at least five years before the study, possessed health insurance at the time of diagnosis, actively undergoing treatment, and provided informed consent. The interview guide included questions like: "what burdens did you experience due to cancer?", "did your cancer disrupt your finances?", and "were there any financial adjustments that you had to make?"

Interpretive phenomenological analysis was used to analyze the qualitative data.<sup>16,17</sup> All interviews were transcribed verbatim and thoroughly familiarized. Initial exploratory notes were coded inductively. Potential themes were refined iteratively. Any discrepancies in theme development were resolved through a consensus process led by the author. The final synthesized themes were ultimately interconnected and reflective of patients' experiences.

## 2.3. Psychometric assessment of patient-reported outcome measures

A longitudinal data collection was conducted from September 2023 to March 2024 at a primary referral public hospital in Bandung, Indonesia. Eligible participants were female patients aged 18 years or older, diagnosed with any type and stage of breast cancer, undergoing active treatment, cognitively able to complete the survey, fluent in Indonesian, and consented to participate. A total of 300 patients were recruited at baseline and categorized into two groups: Group 1, undergoing an active treatment cycle (followed up in the next cycle), and Group 2, in their final treatment cycle (followed up during their post-treatment visit). Patients self-completed a paper-and-pencil questionnaire, which included official Indonesian versions of the following outcome measures: EQ Health and Wellbeing (EQ-HWB), EQ-5D-5L, FACIT-COST, Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS), and Functional Assessment of Cancer Therapy – General (FACT-G). Additional questions covered sociodemographic characteristics, caregiver usage, symptoms experienced in the past week, a five-point general health scale, and financial coping strategies. A seven-point Global Rating of Change (GRC) scale was included in the follow-up questionnaire to assess changes in patients' health status.

Clinical data, including stage and type of breast cancer, disease duration, metastasis status, comorbidities, and current treatment, were provided by oncology department nurses.

#### 2.3.1. Measurement properties of the FACIT-COST

The analytical framework included the following assessments, which followed previous FACIT-COST validation studies:<sup>18-20</sup>

- Distributional characteristics: response distribution of the items was reported. Ceiling or floor effects at the instrument level was defined as 15% or more patients scoring the highest or lowest possible total score.
- 2. Structural validity: principal component analysis (PCA) using the parallel analysis technique and oblique Promax rotation

method determined the number of factors.<sup>21,22</sup> A confirmatory factor analysis (CFA) tested the PCA-proposed model, with parameters estimated using the diagonally weighted least squares method. Model fit was evaluated using the root mean square error of approximation (RMSEA), standard root mean square residual (SRMR), comparative fit index (CFI), and Tucker-Lewis Index (TLI), with good fit indicated by RMSEA <0.06, SRMR <0.08, and CFI and TLI both >0.95.<sup>23</sup>

- Internal consistency reliability: Cronbach's alpha and McDonald's omega values were calculated to assess internal consistency of the items,<sup>24,25</sup> as well as for each factor identified in PCA.<sup>26,27</sup>
- 4. Known-group validity: FACIT-COST total scores were compared using the Mann-Whitney or Kruskal-Wallis test across subgroups defined by age, education level, residential setting (urban/rural), income level, employment status, metastasis status, number of symptoms, and financial coping strategies.
- 5. Test-retest reliability: Gwet's AC2 coefficient was used to assess item-level reliability,<sup>28,29</sup> and intraclass correlation coefficient (ICC) for the instrument-level reliability. Analysis was performed on patients with unchanged responses at follow-up based on FACIT-COST item 12 (global summary item which was not used to compute the total score). ICC values of 0.0-0.39, 0.40-0.59, 0.60-0.74, and 0.75-1.0 were

interpreted as poor, fair, good, and excellent test-retest reliability.

6. Responsiveness: standardized response mean (SRM), and standardized effect size (SES) were estimated to assess responsiveness. Patients were categorized improved, worsened, or unchanged, based on their responses to FACIT-COST item 12 at follow-up. SRM and SES values were interpreted as small (<0.50), moderate (0.50-0.79), or large (≥0.80).</p>

#### 2.3.2. Measurement properties of the EQ-HWB and EQ-HWB-S

The measurement properties of EQ-HWB, and EQ-HWB-S were assessed and compared against EQ-5D-5L, FACT-G, FACT Eight Dimension (FACT-8D), WEMWBS, and Short WEMWBS (SWEMWBS). Prior methodological frameworks for testing the psychometric performance of preference-accompanied measures were followed.<sup>30-33</sup>

- Distributional characteristics: ceiling and floor effects were assessed at the item level using a 70% threshold,<sup>31,34</sup> and at the instrument level using a 15% threshold.<sup>35</sup>
- 2. Convergent and divergent validity: Spearman's rank-order correlations were used to examine associations between individual items or instrument scores across different

measures. Absolute correlation coefficients were interpreted as none (r=0.00-0.09), weak (r=0.10-0.29), moderate (r=0.30-0.49), or strong (r=0.50 and above).

- Known-group validity: Student's t test or analysis of variance was used to compare mean differences across known-groups based on cancer stage, EQ VAS score (≥80), number of comorbidities, number of symptoms, and general health status. Effect sizes were calculated using Cohen's d or etasquared (η<sup>2</sup>) and interpreted as trivial (d=0–0.19, η²<0.01), small (d=0.20–0.49, η²=0.01–0.05), moderate (d=0.50–0.79, η²=0.06–0.13), or large (d≥0.80, η²≥0.14).
- 4. Test-retest reliability: Gwet's AC2 coefficient was used for item-level reliability,<sup>28</sup> while ICC with two-way mixed effects model with absolute agreement was calculated for the instrument-level reliability. This analysis conducted on Group 1 patients who reported no change in health status on the GRC scale. ICC values of 0.0-0.39, 0.40-0.59, 0.60-0.74, and 0.75-1.0 were interpreted as poor, fair, good, and excellent testretest reliability.
- 5. Responsiveness: SRM was calculated to assess responsiveness. The analysis was performed on Group 2 patients, classified as unchanged, worsened, or improved based on the GRC scale. SRM values were interpreted as small (<0.50), moderate (0.50-0.79), or large ( $\geq$ 0.80).

#### 2.4. Multivariate linear and logistic regression analysis

The associations between financial toxicity, HRQoL, and well-being were explored using correlation and regression analyses. Subjective financial toxicity was measured using the FACIT-COST total score, while objective financial toxicity was assessed based on the number of financial coping strategies used (i.e., withdrawing savings or pension, selling assets, incurring debt, or closing business). FACIT-COST scores of  $\leq 17.5$  indicated high subjective financial toxicity. HRQoL and well-being were measured using EQ-5D-5L and EQ-HWB, respectively. Baseline data, as described in Section 2.3 of this booklet, was used.

- Correlations analysis: Spearman's rank-order correlation examined the associations between FACIT-COST total score and selected items of EQ-5D-5L and EQ-HWB. Pearson's correlation was used for associations at the instrument level. Absolute correlation coefficients were interpreted as none (r=0.00-0.09), weak (r=0.10-0.29), moderate (r=0.30-0.49), or strong (r=0.50 and above).
- Covariate adjustment: a forward stepwise procedure was used to identify key socio-demographic and clinical variables were for covariate adjustment. Variables with p≥0.05 in bivariate analyses with the dependent variable were excluded. Retained covariates included disease duration, metastasis status,

chemotherapy treatment, number of comorbidities, and number of symptoms.

- Logistic model: multivariate ordinal logistic regression models were used to examine the associations between financial toxicity and items of EQ-5D-5L and EQ-HWB items, adjusting for the selected covariates. Odds ratios were calculated to quantify the associations.
- 4. Linear models: multivariate linear regression models were used to examine the predictive value of financial toxicity for EQ-5D-5L, EQ VAS, EQ-HWB, and EQ-HWB-S scores. Three models were constructed incrementally, with both subjective and objective financial toxicity as predictors: i) no covariates, ii) adjusted for socio-demographic covariates, and iii) adjusted for both socio-demographic and clinical covariates. Robust standard errors were used to address heteroskedasticity, as detected using the Breusch-Pagan test. No significant multicollinearity was confirmed by computing variance inflation factors. R-squared values were used to compare the predictive power of financial toxicity across different outcomes.

## 3. Main findings of the dissertation

#### 3.1. Systematic literature review on financial toxicity and HRQoL

- Thirty-one studies were included in the systematic review with a combined sample of 13,481 patients and survivors with more than 25 types of cancer.
- Nineteen different standardized HRQoL instruments were identified, with FACT-G being the most common, followed by EORTC QLQ-C30, and EQ-5D.
- Thirty studies reported that higher financial toxicity was significantly associated with worse HRQoL.
- Ten HRQoL domains found to be correlated with FACIT-COST: physical health, social health, mental health, daily functioning, global health, fatigue, physical functioning, pain, cognitive functioning, and sleep.
- The meta-analysis pooled ten studies and indicated a moderate correlation between financial toxicity and overall HRQoL scores measured by FACT instruments (r=0.49, 95% confidence interval: 0.44-0.54).

# **3.2.** Qualitative interpretive phenomenological analysis of financial toxicity experiences

- Two main themes were derived. The first theme, 'the experienced financial burden', explained the factors that influence the occurrence of financial toxicity, with three sub-themes: underinsurance, out-of-pocket non-healthcare cancerrelated costs, and negative income effect from employment disruption.
- The second theme, 'the financial coping strategies', explained how the patients adjusted their financial conditions in coping with the financial toxicity experience, with four sub-themes: reallocating household budget, seeking family support, rationalizing treatment decisions, and topping up insurance for family members.

#### 3.3. Psychometric validation of the FACIT-COST

- No patients reported best or worst possible FACIT-COST total scores.
- Two-factor structure with a good model fit was suggested for the Indonesian version of FACIT-COST (v2). Internal consistency reliability of the factors was adequate.
- The FACIT-COST significantly discriminated across knowngroups defined by age, education, residential setting, income, employment, metastasis status, number of symptoms, and financial coping strategies.

- FACIT-COST showed excellent instrument-level test-retest reliability and satisfactory responsiveness.

## **3.4.** Psychometric validation of the EQ-HWB, EQ-HWB-S, EQ-5D-5L, FACT-G, FACT-8D, WEMWBS, and SWEMWBS

- EQ-HWB-S index had a lower ceiling than EQ-5D-5L and SWEMWBS, but not the FACT-8D.
- EQ-HWB-S index value correlated strongly with EQ-5D-5L and FACT-8D index values, while EQ-HWB correlated strongly with FACT-G and moderately with WEMWBS.
- EQ-HWB and EQ-HWB-S significantly discriminated with large effect sizes across known-groups defined by EQ VAS grouping, number of symptoms, and general health.
- EQ-HWB and EQ-HWB-S showed excellent instrument-level test-retest reliability and acceptable responsiveness.
- Overall, the EQ-HWB and EQ-HWB-S performed comparably to the widely validated EQ-5D-5L and FACT-G/FACT-8D.

## **3.5.** Associations between financial toxicity, HRQoL and wellbeing

- Overall, 21% patients experienced high subjective financial toxicity, and 51% reported any objective financial toxicity.

- Higher subjective financial toxicity was associated with more problems in EQ-5D-5L pain/discomfort, anxiety/depression, EQ-HWB-S exhaustion, anxiety, sadness/depression, pain, and EQ-HWB frustration, discomfort items. It was also associated with lower EQ-5D-5L index values, EQ VAS scores, EQ-HWB-S index values, and higher EQ-HWB LSS. Meanwhile, higher objective financial toxicity was associated with more problems in the EQ-HWB-S exhaustion.
- Higher subjective financial toxicity was associated with worse HRQoL and well-being. Financial toxicity was a stronger predictor of well-being than HRQoL, explaining 46.3% and 31.2% of the variances, respectively.

### 4. Theoretical contributions

The dissertation makes several novel contributions to financial toxicity research. It includes the first systematic review and meta-analysis on the association between subjective financial toxicity, measured using FACIT-COST, and HRQoL in patients and survivors of cancer, the first qualitative study on financial toxicity in Indonesia, and the first psychometric validation of FACIT-COST in breast cancer.

In HRQoL and well-being measurement, this dissertation validates the EQ-HWB and EQ-HWB-S in breast cancer and provides initial evidence on the measurement properties of their Indonesian versions. In addition, it presents early findings on the test-retest reliability and responsiveness of these measures, along with comparative evidence on EQ-HWB and FACT-G, as well as EQ-HWB-S, FACT-8D, and SWEMWBS. Lastly, it is also the first to explore the relationship between financial toxicity (both subjective and objective), HRQoL, and well-being in breast cancer.

Overall, this dissertation provides mixed-methods evidence highlighting financial toxicity as an important and relevant construct and outcome of cancer. Furthermore, it addresses a significant gap in the literature by presenting evidence from the Indonesian context, a middle-income and non-English-speaking country.

## **5.** Publications of the author

- <u>Pangestu S</u>, Purba FD, Setyowibowo H, Mukuria C, Rencz F. Associations between financial toxicity, health-related quality of life, and well-being in Indonesian patients with breast cancer. *Qual Life Res* (Q1). 2025; online ahead of print. doi: 10.1007/s11136-025-03925-y
- <u>Pangestu S</u>, Purba FD, Setyowibowo H, Azhar Y, Mukuria C, Rencz F. The Psychometric Properties of the EQ-HWB and EQ-HWB-S in Patients With Breast Cancer: A Comparative Analysis With EQ-5D-5L, FACT-8D, and SWEMWBS. *Value Health* (D1). doi: 10.1016/j.jval.2024.12.003
- <u>Pangestu S</u>, Purba FD, Setyowibowo H, Mukuria C, Rencz F. Validity, test-retest reliability, and responsiveness of the Indonesian version of FACIT-COST measure for subjective financial toxicity. *Health Qual Life Outcomes* (Q1). 2024;22(1):89. doi:10.1186/s12955-024-02303-5
- <u>Pangestu S</u>, Harjanti EP, Pertiwi IH, Rencz F, Nurdiyanto FA. Financial Toxicity Experiences of Patients With Cancer in Indonesia: An Interpretive Phenomenological Analysis. *Value Health Reg Issues* (Q1). 2024;41:25-31. doi: 10.1016/j.vhri.2023.11.007
- <u>Pangestu S</u>, Rencz F. Comprehensive Score for Financial Toxicity and Health-Related Quality of Life in Patients With Cancer and Survivors: A Systematic Review and Meta-Analysis. *Value Health* (D1). 2023;26(2):300-316. doi: 10.1016/j.jval.2022.07.017

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