



The FACT-8D, a multi-attribute utility instrument (MAUI) derived from the FACT-G

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Background: The FACT-G is widely used to assess health-related quality of life (HRQoL) in oncology. It has proved valid and useful as a HRQOL profile measure, but requires a preference-based scoring algorithm to calculate quality adjusted life years (QALYs) for cost-utility analysis (CUA). While previous mapping studies (e.g., from FACT-G to EQ-5D-5L) provide algorithms to estimate utility weights from FACT-G data, these are vulnerable to the limitations of the samples from which they are derived, and vulnerable to potential insensitivity of the MAUI they map to.

Aim: to develop a preference-based MAUI derived from the FACT-G.

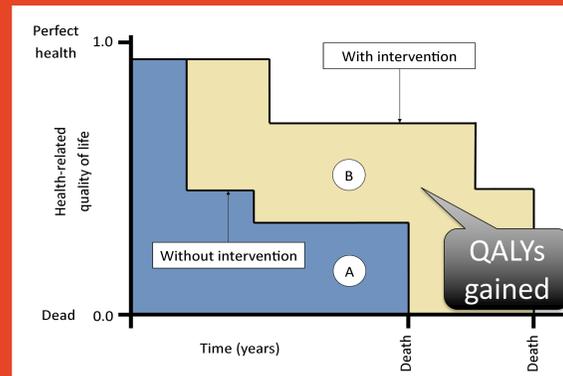


Diagram illustrating the use of quality-adjusted life years (QALYs) by Chris Sampson https://en.wikipedia.org/wiki/Quality-adjusted_life_year

STAGE 1: Developing the health state classification system (HSCS)

AIM: Reduce the 27 items of the FACT-G to a smaller number, amenable to preference-based valuation techniques, and covering the key HRQoL dimensions.

METHODS:

- Secondary analysis of 17 datasets pooled:
 - n = 6,912 patients
 - Primary cancer sites: breast, colorectal, genito-urinary, gynaecological, head and neck, leukaemia, liver/bile/pancreas, lung, lymphoma, melanoma, oesophagus/stomach, prostate, sarcoma, testicular
 - Cancer stages: 61% locoregional, 39% metastatic

Analysis focused on individual items to determine which best represented a particular domain / which could be excluded due to poor psychometric performance or redundancy:

- Distribution of each item's responses
- Confirmatory factor analysis
- Rasch analysis of items within domains
- Sensitivity to clinically defined groups (early vs late stage cancer)
- Responsiveness over time (where more than one observation available)

- Patient survey regarding relative importance of items within domains (n=82)

- Review by investigators to determine final items and wording.

RESULTS: The HSCS contains eight HRQOL dimensions: nausea, pain, fatigue, sleep, work, worry health will get worse, sadness, and support from family/friends.

Stage 1 Output: FACT-8D HSCS

FACT-8D Dimensions	FACT-G item
Pain	GP4
Fatigue (lack of energy)	GP1
Nausea	GP2
Problems sleeping*	GF5
Problems doing work (including work at home)*	GF1
Problems with support from my family and/or friends*	GS2, GS3
Sadness	GE1
Worry my health will get worse	GE6

* The wording of 3 items was modified to standardise response direction and response options, due to DCE responder concerns.

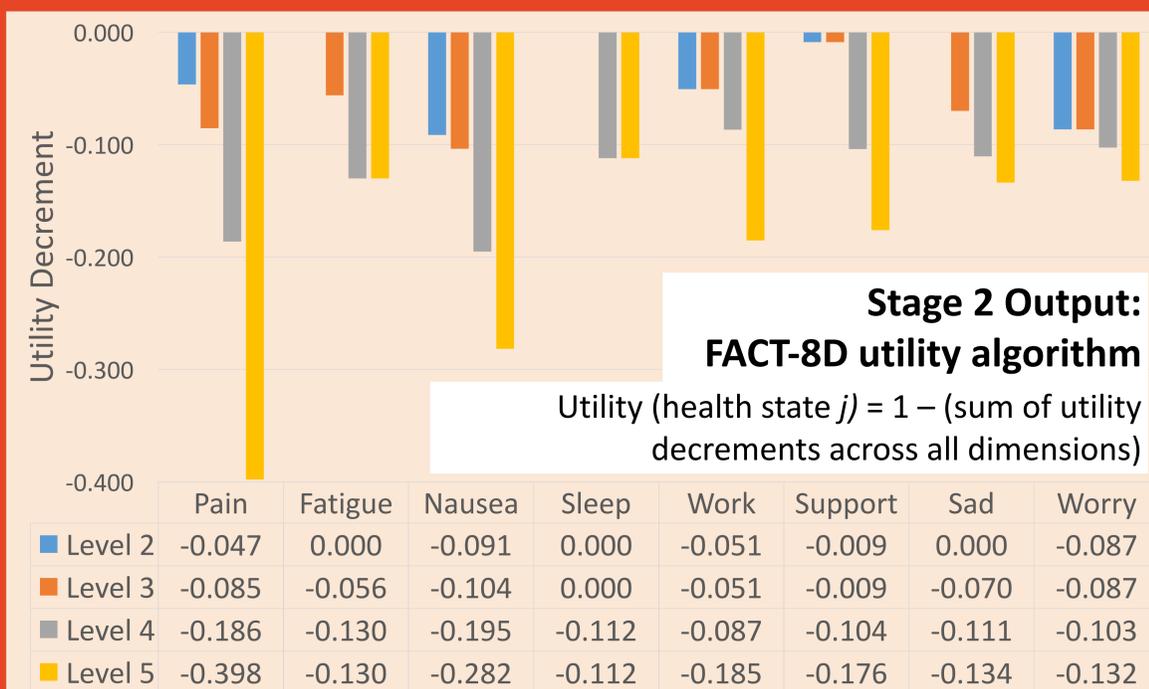
Level 1 BEST	Level 2	Level 3	Level 4	Level 5 WORST
None	A little bit	Some	Quite a bit	Very much

STAGE 2: Deriving the FACT-8D utility set

METHODS: Community valuations were elicited using a Discrete Choice Experiment (DCE) administered in an Australian online panel. The experimental design was built in Ngene, and used a C-efficiency criterion. It imposed a fixed degree of overlap in each choice pair - to make the task cognitively manageable, only 4 of the HRQoL dimensions differed in each choice pair, and these were highlighted in yellow¹. Each respondent completed 16 choice pairs, each containing two health states described by the eight HRQoL dimensions of the FACT-8D plus survival duration. Utility decrements were derived for each level of the eight HRQoL dimensions using conditional logit regression modelling.

RESULTS: Of 1737 individuals recruited to the online DCE valuation task, 93% completed at least one choice set and 90% completed all 16 choice sets. Utility decrements were generally monotonic within dimensions. The largest utility decrements were for the highest levels of pain (-0.42) and nausea (-0.28) The worst health state described by the FACT-8D had a utility of -0.5, considerably worse than death (zero).

1. Norman et al. *Quality of Life Research*. 2016; 25(3): 637-649.



Stage 2 Output: FACT-8D utility algorithm

Utility (health state j) = 1 - (sum of utility decrements across all dimensions)

SUMMARY OF FINDINGS and CONCLUSIONS: The FACT-8D contains dimensions common to generic MAUIs (pain, emotion – both can be profoundly affected by cancer). It also contains fatigue and nausea (both common symptoms of cancer and toxic cancer treatments), and other issues known to affect the HRQOL of cancer patients. The FACT-8D may therefore prove to be more sensitive in cost-utility analysis of cancer therapies than generic MAUIs. Future research should examine the properties and validity of the FACT-8D utility set, and sensitivity relative to generic MAUIs.