

Response Criteria Attachment 5. Patient reported outcome measures recommended for chronic GVHD response evaluations

Instrument*	Lee Chronic GvHD Symptom Scale	Human Activity Profile (HAP)	Activities Scale for Kids (ASK)	Medical Outcomes Study Short Form-36 version 2 (MOS-SF-36v2)	Functional Assessment of Cancer Therapy-Bone Marrow Transplant (FACT-BMT)	Child Health Ratings Inventories (CHRIs) generic core and Disease-Specific Impairment Inventory (DSII)-HSCT
Outcome Measured	Chronic GvHD specific symptom bother (adults)	Functional performance and activity limitations (adults)	Functional performance and activity limitations (pediatrics)	Self reported general health status (adults)	Health related quality of life (adults)	Health related quality of life (pediatrics)
Content Domains	30 symptoms common in cGVHD. Seven subscales (energy, skin, nutrition, lung, psychosocial, eye and mouth) and items are summed to produce a summary score of chronic GVHD-specific symptom bother.	94 oxygen-demanding activities of daily living. The activities are arranged in a hierarchical fashion beginning with getting in and out of bed and progressively more physically demanding ending with running or jogging 3 miles in 30 minutes or less.	Personal care, dressing, eating and drinking, miscellaneous, locomotion, stairs, play, transfers and standing skills.	The 36 items evaluate: physical functioning, physical role functioning, emotional role functioning, social functioning, bodily pain, mental health, vitality, and general health.	FACT-G has four domains: Physical Well-Being, Social Well-Being, Emotional Well-Being, and Functional Well-Being. BMT Module: 18 areas of concern specific to hematopoietic stem cell transplant recipients.	CHRIs has four domains: physical, emotional and role functioning and energy. Two versions: ages 5-12 years and an adolescent version. The DSII-HSCT has three domains: hassles, body image and worry.
Number of Items	30	94	30	36	45 Items (27 for FACT-G and 18 for BMT module)	CHRIs -20 items, DSII-HSCT - 10 items
Response Frame	Degree of symptom bother experienced within the past month.	The last time they had an opportunity to perform the activity independently.	Within the past week.	Within past four weeks.	Within the past seven days.	The past week.
Languages Available	English. Spanish translation available but not yet validated.	English	English, French, Spanish and Dutch.	English, Spanish, and more than 50 other languages.	English, Chinese, Spanish and more than 20 other languages.	English, Spanish translation is in development.
Advantages/Disadvantages	Chronic GvD-specific, brief, strong face validity and thorough preliminary psychometric evaluation.	Ceiling and floor effects are limited, ease of questionnaire administration and scoring. Values for health age matched samples available for adjusted activity score.	Use in children as young as 5 years of age. Limited ceiling effects and no floor effects.	Reliability, validity and sensitivity to change extensively supported. Extensively used in clinical trials.	Reliability, validity and sensitivity to change extensively supported. Extensively used in clinical trials.	Brief and easy to score. This instrument is exceptional for its highly sophisticated but simple computer based administration for children age 5-12.
Time Required to Complete	5 minutes	7 minutes	9 minutes	7 minutes	5-10 minutes	10-15 minutes
Questionnaire Procurement/ Costs	No costs. Contact: sjlee@fhcrc.org	No costs. Contact: ddaughto@unmc.edu	Free to graduate students. Contact: nyoung@laurentian.ca	Needs an annual license to use. Visit: sf-36.org	Scoring and interpretation manuals have a nominal cost. Visit: facit.org	Information is available by contacting: SP@parsons@tufts-nemc.org

*The recommendation to use these instruments as a response measure in chronic GVHD does not imply permission for their use in clinical trials. Investigator teams wishing to collect these data should follow the procedure established by the organizations that hold copyright for each instrument.