

# Measuring diarrhoea in a cancer setting: the importance of patient-reported tools

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## Aim of research

- To develop and evaluate a PRO to assess treatment-related diarrhoea from a patient's perspective.

## Background

- Treatment-related diarrhoea is debilitating and may cause dose-reduction or non-adherence.<sup>1</sup>
- Up to 50% of patients have  $\geq$  grade 3 diarrhoea (Table 1), resulting in poor QoL.<sup>2,3</sup>
- Accurate reporting is essential for good management, but usually done by clinicians only using the NCI-CTCAE.
- Low agreement between patient and clinician reporting highlights the need for a new PRO.<sup>4</sup>

## Methods

- Phase 1:** construction of the Diarrhoea Management Diary (DMD) using an iterative process of instrument development (Figure 1).
- Phase 2:** evaluation of the DMD in an international RCT for women with metastatic breast cancer receiving lapatinib and capecitabine with or without prophylactic octreotide.<sup>5</sup>
- Sensitivity to change was examined using the Functional Assessment of Chronic Illness Therapy for patients with Diarrhea (FACIT-D).

Table 1. NCI-CTCAE criteria diarrhoea

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Increase $<$ 4 stools per day over baseline; mild increase in ostomy output compared to baseline	Increase 4-6 stools per day over baseline; moderate increase in ostomy output compared to baseline	Increase $\geq$ 7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL	Life-threatening consequences; urgent intervention indicated	Death

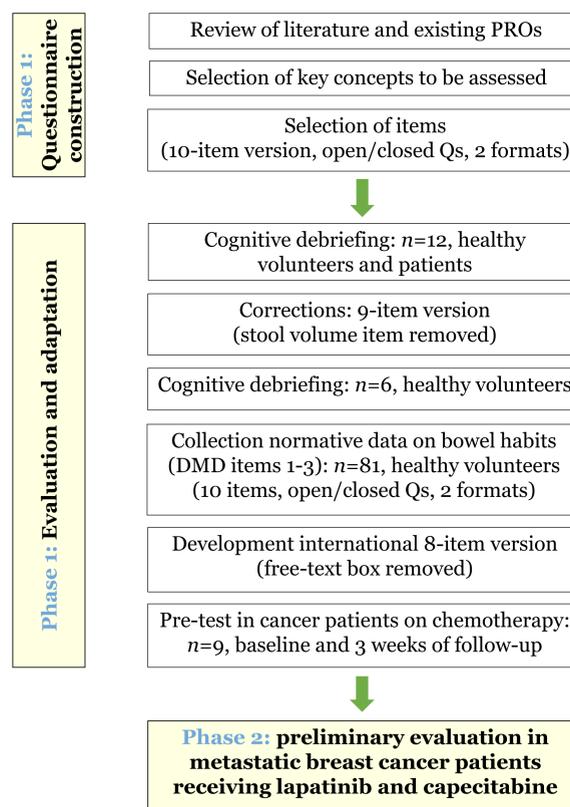


Figure 1. DMD development process

Table 2. Self-reported diarrhoea, FACIT-D and meaningful change

Follow-up*	Wk 3 n=56	Wk 6 n=54	Wk 9 n=49	Wk 12 n=44	Wk 15 n=42	Wk 18 n=40	Wk 21 n=37	Wk 24 n=35
No diarrhoea	41%	41%	49%	43%	45%	52%	54%	43%
Diarrhoea	59%	(59%)	51%	57%	55%	48%	46%	57%
FACIT-D mean (SD)	114 (19.5)	109 (20.4)	111 (21.2)	112 (21.0)	110 (25.5)	113 (22.9)	115 (22.3)	116 (20.0)
DS mean (SD)	38 (6.8)	36 (6.6)	36 (7.6)	37 (5.6)	37 (7.3)	39 (5.8)	39 (5.4)	38 (5.6)
Improvement	9%	5%	5%	7%	5%	8%	8%	12%
Stable	32%	25%	23%	35%	26%	39%	37%	26%
Deterioration	59%	70%	72%	58%	69%	53%	55%	62%
p-value	<b>0.034</b>	<b>0.025</b>	.484	<b>0.007</b>	<b>0.006</b>	<b>&lt;0.001</b>	<b>0.012</b>	<b>0.02</b>

\* Numbers do not equal 62 due to attrition and incomplete response; DS=diarrhoea subscale

## Results

- Phase 1:** content validity was confirmed in cognitive interviews and pilot testing (Figure 1).
- The final 8-item DMD measures bowel habits (3 items), self-management strategies (3 items, 4 sub-items) and treatment adherence (2 items).
- Cross-cultural translations were completed by the FACITtrans group for 8 languages.
- Phase 2:** 62 women (mean age 57) were enrolled and completed the DMD weekly and FACIT-D 3-weekly for 24 weeks.
- Up to 68% reported diarrhoea on the DMD, 19% at every time point.
- Dietary changes (exclusion-, BRAT diet) were most frequently used as self-management support.
- Item non-response 0.9%
- Missing data was associated with study discontinuation
- Sensitivity to change was good at 7/8 time points (Table 2).

## Next steps

- A results and initial validation paper is under review.
- Further evaluation is planned in a QoL study of women receiving abemaciclib for locally advanced/metastatic breast cancer.

## References

- Andreyev J, et al. Guidance on the management of diarrhoea during cancer chemotherapy. *Lancet Oncol*. 2014, 15:e447-e460.
- Tarricone R, et al. A systematic literature review of the economic implications of chemotherapy-induced diarrhea and its impact on quality of life. *Crit Rev Oncol Hematol*. 2016, 99:37-48.
- National Institute of Cancer. Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. 2015.
- Fares C, et al. Low concordance of patient-reported outcomes with clinical and clinical trial documentation. *JCO. Clin Cancer Inform*. 2018, 2:1-12.
- US National Library of Medicine NCT02294786: www.clinicaltrials.gov/ct2/show/study/NCT02294786

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download the DMD here



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