

Renovating the Domain Structure of the Inflammatory Bowel Disease Questionnaire

Dahlia Awais, MD¹

Timothy Gathany MEd²

Peter D.R. Higgins, MD, PhD, MSc¹

¹University of Michigan Medical School

²Centocor, Inc.



Disclosures:

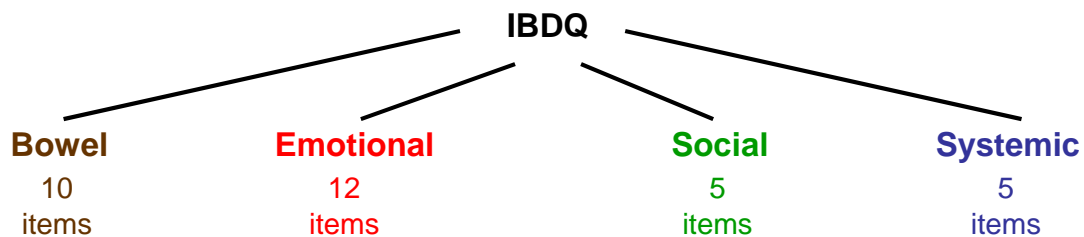
I do not have any relevant financial relationships with any commercial interests

IBDQ Background

- The Inflammatory Bowel Disease Questionnaire (IBDQ) is a widely used measure of disease-specific health-related quality of life in both Crohn's and UC
- Improvement in HrQoL is regarded as an important therapeutic goal in the treatment of IBD
- IBDQ is used in clinical trials to support claims of efficacy

IBDQ Domains

- The IBDQ is composed of 32 items each measured on a 7 point Likert scale
 - Higher scores reflect better QoL (32-224)
- Designed to be divided into 4 domains
 - Each measuring an aspect of IBD patient's life



IBDQ Background

- The general validity and reliability of the *complete* IBDQ has been repeatedly confirmed
- However, the 4 domain structure of the IBDQ has not been validated

IBDQ Domain Structure

- Reasons to question domain structure:
 - Problem questions – mix domains
 - **IBDQ23** How much of the time during the last 2 weeks have you felt **embarrassed** as a result of your **bowel** problem?
 - **IBDQ26** How much of the time during the last 2 weeks have you been **troubled** by accidental **soiling**?
 - FDA has rejected it as a source for patient reported outcomes
 - Although complete IBDQ has been used in many countries, the proposed 4 domain structure has not been successfully reproduced in multiple adaptations including in the UK, Norway, Sweden, Greece, and Spain

IBDQ Domain Structure

- Despite questions regarding the validity of the domain structure, domain subscores are reported in the literature
- Example: Effect of certolizumab on HRQoL
 - IBDQ total score improved
 - Marked improvement specifically in **emotional** and **systemic** domains of the IBDQ
 - “alleviates the **psychological symptoms** associated with Crohn’s disease and improves a patient’s **general well-being**”
 - Conclusion is problematic, depends on the unproven validity of the IBDQ domain structure

Aims

- To determine whether the 4 domain structure of the IBDQ is supported using large IBDQ datasets from randomized clinical trials
- To compare the domain structure of the IBDQ for ulcerative colitis and Crohn's disease
- If the domain structure is not supported, to propose an alternate domain structure

Methods

- Baseline individual patient IBDQ data from the ACT and ACCENT trials (725 patients with UC and 876 patients with Crohn's) were used to analyze the domain structure
- Factor analysis with SAS PROC FACTOR was performed to identify # of factors (domains) in the IBDQ
 - Statistical method that looks for items that group together to identify a smaller number of umbrella variables called “factors”



How Many Factors?

Factor 1
Emotional



frequency
frustration
sadness
loose stools
incontinence
worry

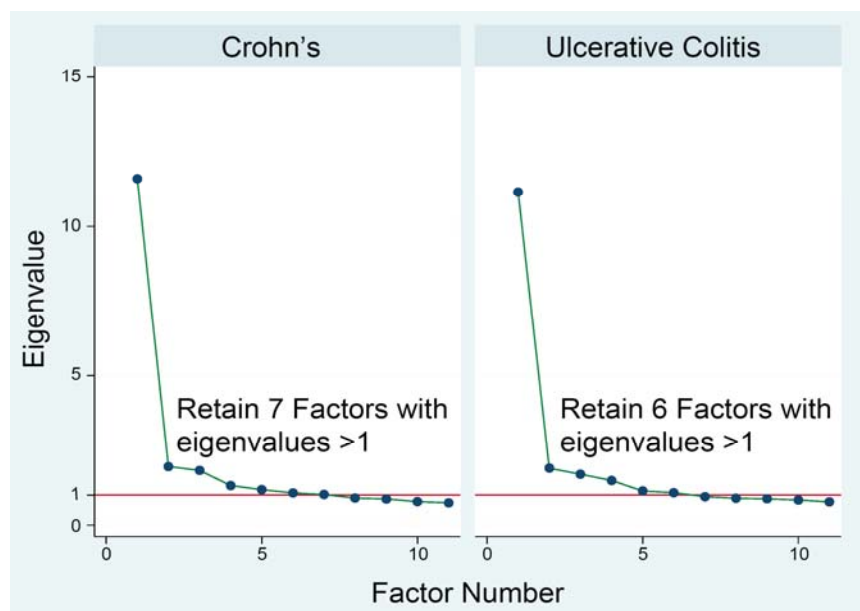
Factor 2
Bowel



Methods

- Our second step was to depict items that cluster together with clustering analysis and dendrograms

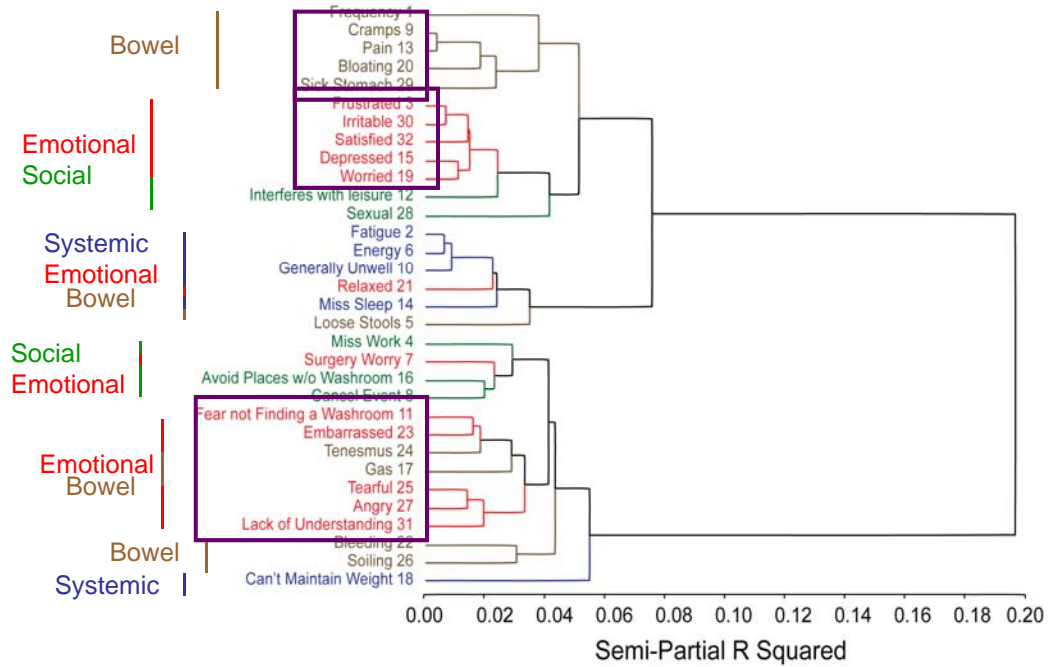
Number of Domains



Factors are assigned values called eigenvalues. By convention, factors with eigenvalues >1 are retained. 7 principal factors were identified in Crohn's and 6 principal factors in ulcerative colitis.

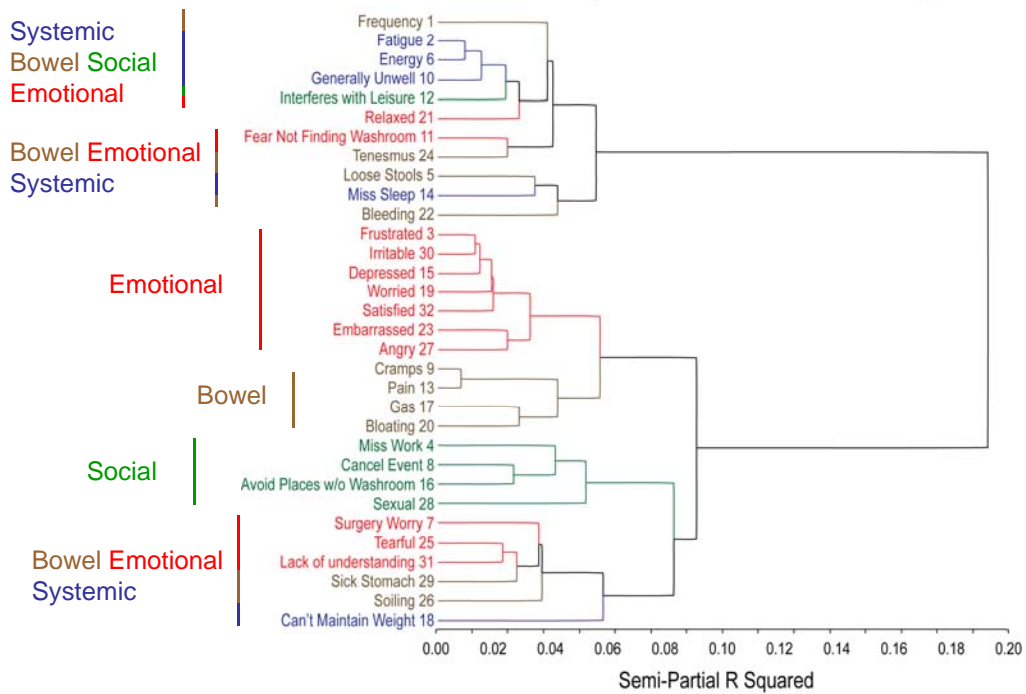
Crohn's – 7 Domains

Crohn's Disease Complete IBDQ - Ward's Clustering



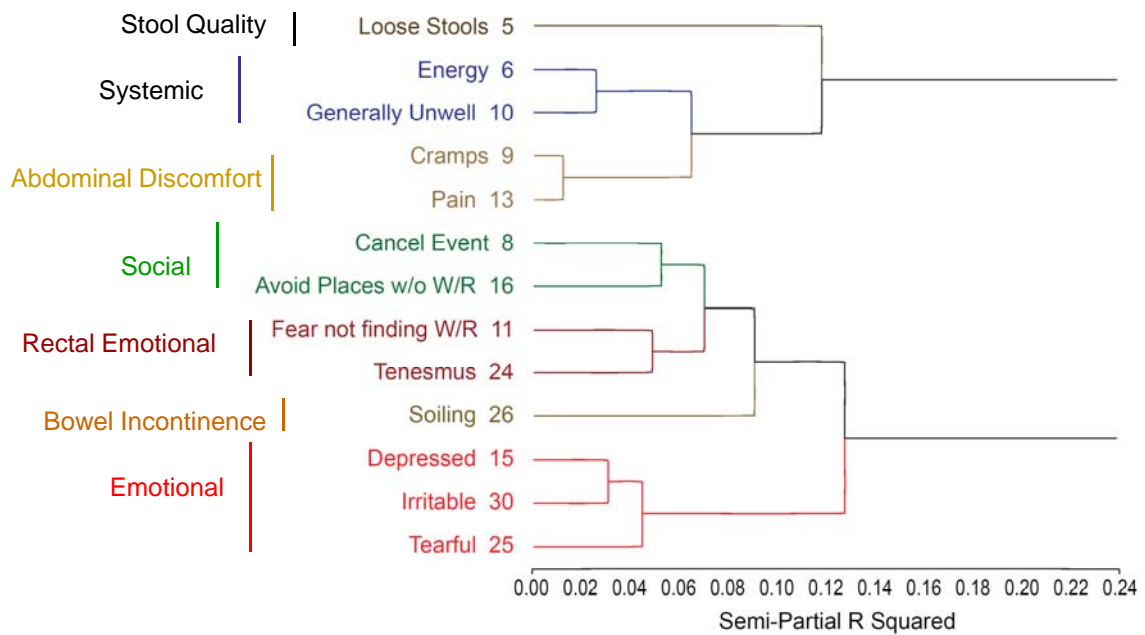
UC – 6 Domains

Ulcerative Colitis Complete IBDQ - Ward's Clustering



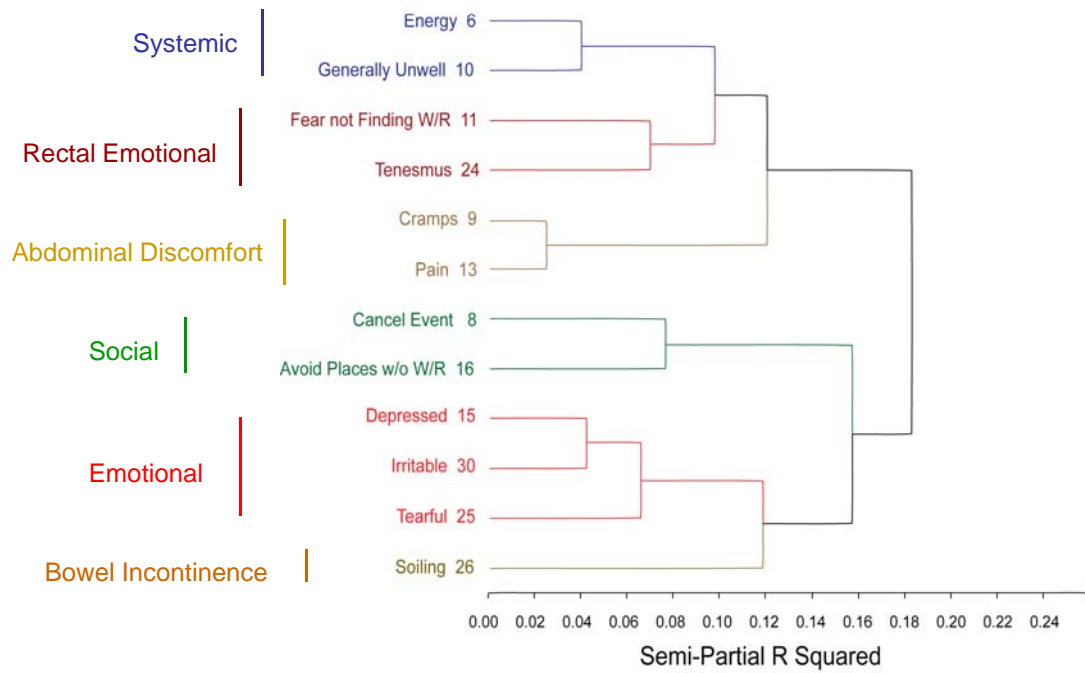
Brief IBDQ – Crohn's

Crohn's Disease Brief IBDQ - Ward's Clustering



Brief IBDQ – UC

Ulcerative Colitis Brief IBDQ - Ward's Clustering



Correlations of BCDQ and BUCQ with Activity and IBDQ

Measure	Mayo Index in UC (ACT 1&2)	IBDQ in UC	CDAI in Crohn's (ACCENT 1&2)	IBDQ in Crohn's
IBDQ	-0.304	1.00	-0.562	1.00
BCDQ	----	----	-0.564	0.957
BUCQ	-0.282	0.950	-----	-----

Conclusions

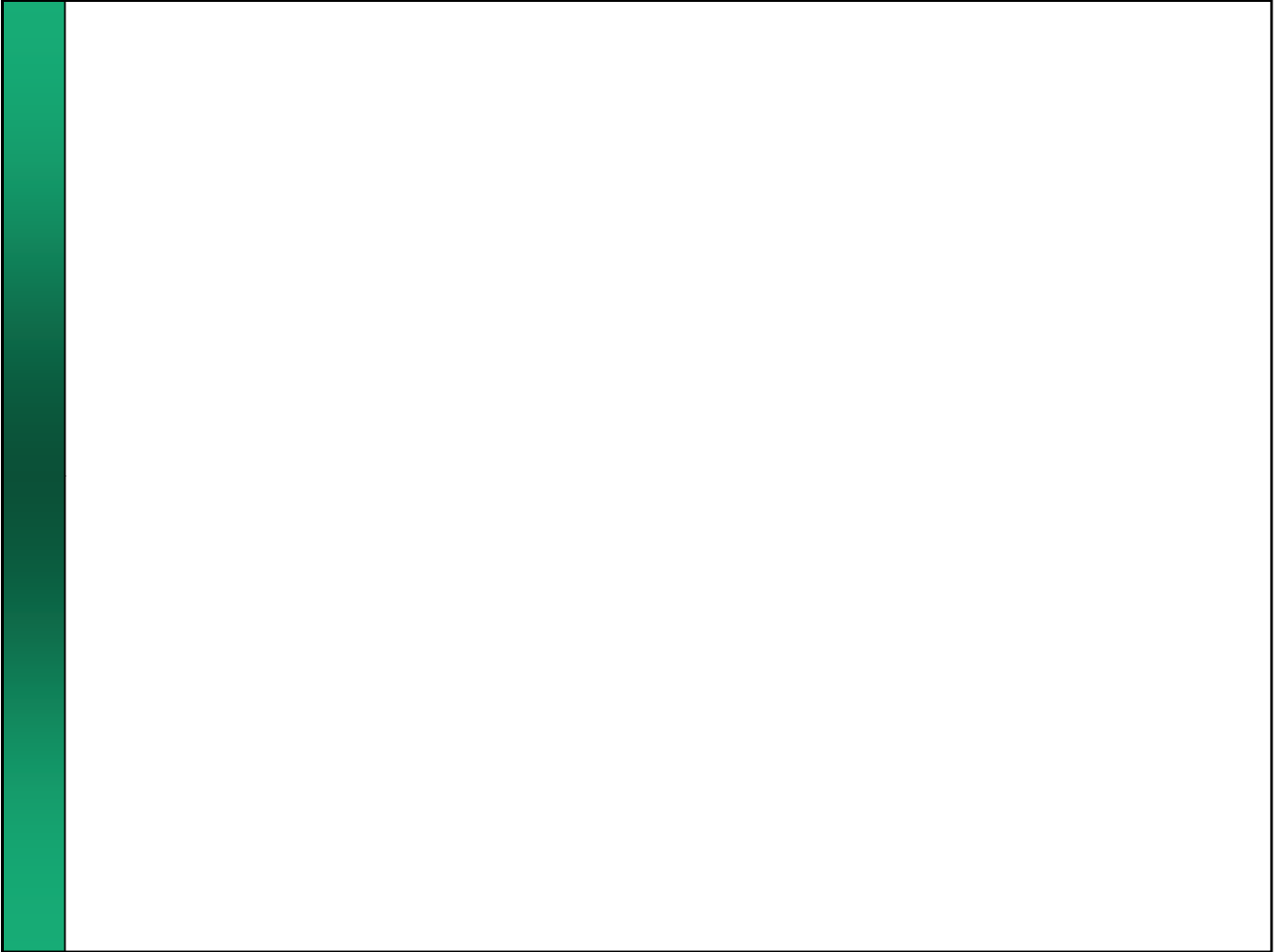
- The intended 4 domain structure of the IBDQ is not valid
- The 4 domain subscores of the IBDQ should not be used
- The IBDQ in Crohn's is better described with a 7 domain structure and the IBDQ in UC is better described with a 6 domain structure

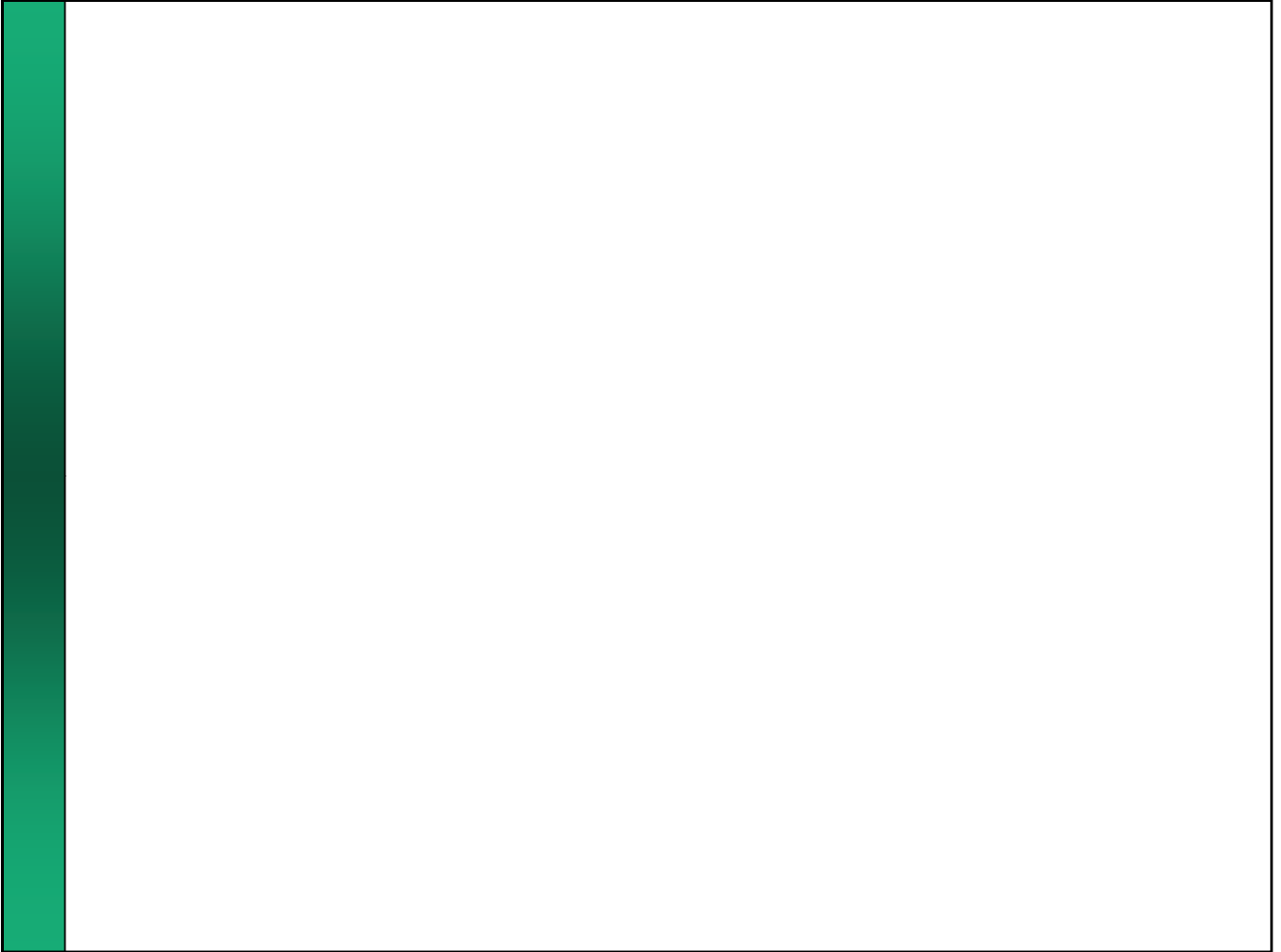
Conclusions

- Both our Brief IBDQ for Crohn's and our Brief IBDQ for UC are highly correlated with the complete IBDQ and DAIs and reflect a clean domain structure
- A modified index with revised domains may be the best approach to the measurement of health-related quality of life in ulcerative colitis and Crohn's disease.

Acknowledgments

- Timothy Gathany, MEd (Centocor)
- Peter Higgins, MD, PhD, MSc (University of Michigan)





Revised Domain Structure

