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## **Abstract**

**Background:** Patients with inflammatory bowel disease have lifelong needs to learn how to manage their symptoms and life situation. The range of actions that patients take in order to manage daily life and maintain health is referred to as self-care. Assessment of self-care in patients with inflammatory bowel disease could allow targeted support and education by health care professionals. There are no existing measures assessing self-care in patients with inflammatory bowel disease.

**Objectives:** The aim was to develop and evaluate the self-care questionnaire for assessment of self-care among patients with inflammatory bowel disease.

**Methods:** Qualitative and quantitative methods were used to develop inflammatory bowel disease self-care questionnaire. The development and evaluation process was performed in three phases: (1) item generation based on interviews with patients with inflammatory bowel disease (n=20), (2) content validation in a panel of experts (n=6) and patients (n=100) assessed with the content validity index, cognitive interviews and quantifying and ranking the items to determine the usability of the questionnaire, and (3) final evaluation through a pilot study (n=93) with test-retest evaluation (n=50). An expert review group of three nurses and one physician continuously discussed the result during the development process.

**Results:** A total of 91 patients with Crohn's disease and 102 with ulcerative colitis participated. The final self-care questionnaire consists of 22 items. Assessment of content validity indicated that the items were adequate and easy to understand. Test-retest reliability was confirmed with intraclass correlations above 0.6 after a three week interval, for all items except one.

**Conclusion:** An inflammatory bowel disease-specific self-care questionnaire was developed using structured methods. The evaluation indicated good validity and reliability. The questionnaire may be a useful tool to assess the ability of patients with inflammatory bowel disease to perform routine self-care.

## **Disciplines**

Behavioral Medicine | Digestive, Oral, and Skin Physiology | Digestive System Diseases | Gastroenterology | Medical Humanities | Medicine and Health Sciences | Nursing

## **Author(s)**

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**Conclusion:** An inflammatory bowel disease-specific self-care questionnaire was developed using structured methods. The evaluation indicated good validity and reliability. The questionnaire may be a useful tool to assess the ability of patients with inflammatory bowel disease to perform routine self-care.

### **What is already known about the topic?**

- Patients need planning their life to be able to participate in daily activities.
- Health care professionals must consider patients' potential and desire for self-care when giving advice on self-care activities. Doing so may be effective in promoting a healthier life-style.

### **'What does this paper adds?'**

- This paper presents the first questionnaire to assess self-care in patients with inflammatory bowel disease.
- Self-care may be increased by support from health-care professionals by using the inflammatory bowel disease specific self-care questionnaire.

## **INTRODUCTION**

Inflammatory bowel disease including Crohn's disease and ulcerative colitis are chronic conditions involving inflammation of the gastrointestinal tract (Gomollon et al., 2016). There is increasing incidence and prevalence of inflammatory bowel disease around the world and the highest incidence is in northern Europe (Burisch et al., 2014, Kaplan, 2015, Molodecky et al., 2012).

Patients with inflammatory bowel disease experience both physical and psychological symptoms, especially when the disease is active (Farrell et al., 2016). The symptoms depend on the activity of the inflammation, disease location and intestinal complications. The disease activity varies over time and remission is often followed by periods of relapse. The most burdensome symptoms are diarrhea, bowel urgency, abdominal pain and lack of energy (Farrell et al., 2016, Gomollon et al., 2016). Psychological symptoms, such as anxiety and depression, are also common among persons living with inflammatory bowel disease, although the pathophysiology underlying the interaction between psychological symptoms and inflammatory bowel disease is unknown (Bernstein, 2016). The inflammatory bowel disease symptoms may constrain the ability to perform everyday activities, causing worry and concern about the future and thereby also affecting quality of life (Devlen et al., 2014, Faust et al., 2012, Pihl-Lesnovska et al., 2010).

To manage daily life, patients with inflammatory bowel disease need to maintain physical as well as psychological health through the use of self-care (O'Connor et al., 2013, Van Assche et al., 2013). Self-care is a process by which patients can maintain and improve their health (Riegel et al., 2012). Self-care has been shown to be associated with better treatment outcomes and higher life satisfaction (Plevinsky et al., 2016, Strömberg A, 2012). However, self-care can have different meanings for patients and may not necessarily be consistent over time (Riegel et al., 2012).

Self-care for patients with inflammatory bowel disease focuses on factors that can prevent relapses, relieve symptoms or help with managing daily life. Patients engage in a range of activities such as taking medication, restricting diet, modifying behaviors that could trigger symptoms, and maintaining close proximity to a toilet (Devlen et al., 2014). A previous study showed that self-care for patients with inflammatory bowel disease could be divided into four categories: symptom recognition, symptom management, planning life, and seeking new options (Lovén Wickman et al., 2016). Patients with inflammatory bowel disease have lifelong needs to learn how to manage their symptoms and situations (Lesnovska et al., 2014). Being one step ahead and planning make life with inflammatory bowel disease easier (Lovén Wickman et al., 2016).

A variety of approaches and theoretical perspectives for self-care interventions have been used in inflammatory bowel disease research, and self-care has been deemed important for patients with inflammatory bowel disease (Conley and Redeker, 2016). Self-care interventions such as web-based health care plans have increased treatment adherence and disease knowledge as well as disease-specific quality of life (Elkjaer, 2012).

Promotion of self-care is best performed following a holistic assessment in which the patients perspective and priorities are determined (Kralik et al., 2010). Health care professionals can help patients with inflammatory bowel disease by acknowledging that self-care is a process that gradually evolves. Physicians and nurses need to acknowledge the patients desires and abilities when they give advice on self-care (Conley and Redeker, 2016). To identify the need of advice and support, the patient's self-care abilities must be assessed.

Self-care assessments for chronic diseases other than inflammatory bowel disease have been developed (Riegel et al., 2009). Questionnaires for assessment of self-efficacy regarding knowledge, medication use and skills have previously been developed for patients with inflammatory bowel disease (Zijlstra et al., 2013). However, a validated questionnaire

designed to assess self-care of inflammatory bowel disease is lacking and the National Board of Health and Welfare regulations in Sweden has called for the development of a questionnaire for clinical assessment of self-care (National Board of Health and Welfare, 2009). To be useful in clinical practice, such a questionnaire needs to be relevant to both patients and health care professionals, and the questions should be easy to understand and respond to by patients

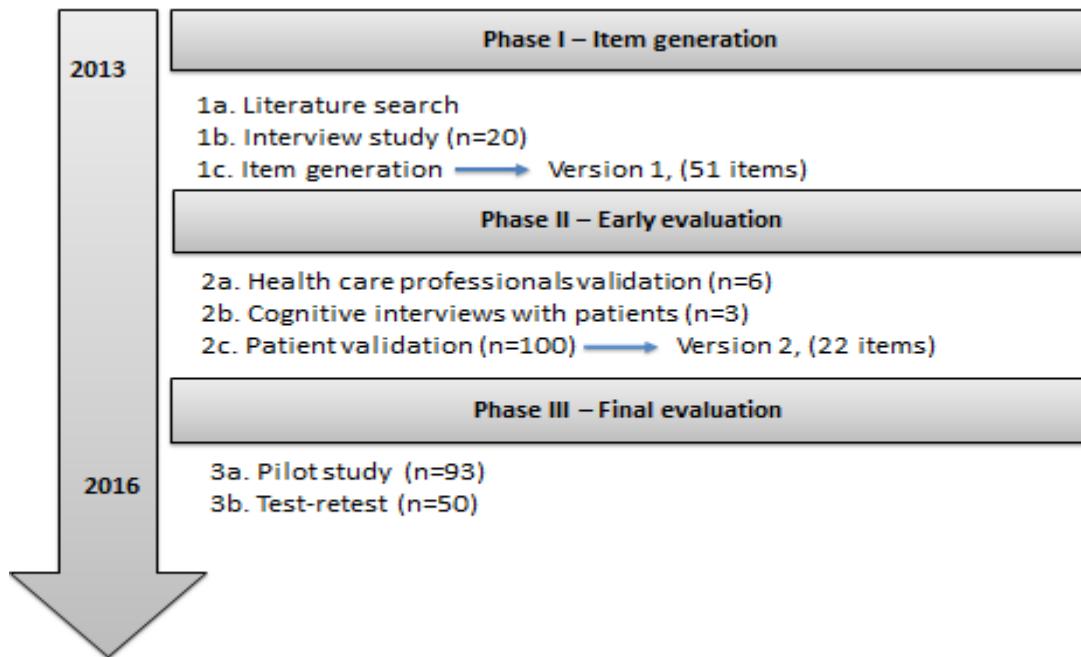
## **AIM**

The aim of this study was to develop and evaluate a questionnaire for assessment of self-care among patients with inflammatory bowel disease.

## **METHODOLOGY**

### **Design**

The self-care questionnaire was developed and evaluated using qualitative and quantitative methods (Polit and Beck, 2012, Streiner et al., 2014). The development and evaluation process was performed in three phases during the period of 2013 to 2016 (Figure 1), and the first phase (phase 1a, 1b) was previously published (Lovén Wickman et al., 2016). An expert review group with three nurses and one physician continuously discussed the results during the process of developing the self-care questionnaire.



**Figure 1. Inflammatory bowel disease self-care questionnaire development and evaluation**

### **Participants**

Adult patients with inflammatory bowel disease from three gastroenterology clinics in south-eastern Sweden were invited to participate (phase II and phase III, Figure 1). If they agreed to participate they returned a written consent form and the completed questionnaires in a postage-paid return envelope. The characteristics of patients who participated in the three study phases are shown in Table 1.

**Table 1. Patient characteristics in phases II and III**

	<b>Patient validation</b>	<b>Pilot study</b>	<b>Test-retest</b>
	<b>phase II 2c n=100</b>	<b>phase III 3a n=93</b>	<b>phase III 3b n=50</b>
<b>Age, median (range)</b>	54 (18-83)	48 (19-77)	48 (20-77)
<b>Gender, n (%)</b>			
Men	52 (52)	48 (52)	28 (56)
Women	48 (48)	45 (48)	22 (44)
<b>Diagnosis, n (%)</b>			
Crohn´s disease	51 (51)	40 (43)	19 (38)
Ulcerative colitis	49 (49)	53 (57)	31 (62)
<b>Years since diagnosis, median (range)</b>	13 (0.5-54)	10 (0-62)	10 (0.5-47)
<b>Marital status, n (%)</b>			
Married/cohabiting	66 (66)	71 (76)	39 (78)
Living alone	28 (28)	17 (18)	8 (16)
Other alternatives	6 (6)	5 (6)	3 (6)
<b>Education level, n (%)</b>			
Compulsory school	32 (32)	18 (19)	10 (20)
Upper secondary school	29 (29)	43 (46)	25 (50)
High school or university level	39 (39)	31 (34)	14 (28)
Item non-response		1 (1)	1 (2)
<b>Occupation, n (%)</b>			
Full-time	38 (38)	47 (51)	25 (50)
Part-time	10 (10)	11 (12)	7 (14)
Retired	41 (41)	18 (20)	11 (22)
Unemployed	1 (1)	6 (7)	4 (8)
Sick-leave	4 (4)	5 (5)	2 (4)
Item non-response	6 (6)	6 (5)	1 (2)
<b>Surgical procedures n (%)</b>			
Surgery	42 (42)	26 (28)	12 (24)
No surgery	56 (56)	67 (72)	37 (74)
Item non-response	2 (2)		1 (2)

The health care professionals in the early evaluation (Phase 2a, Figure 1) included three clinical nurses and three physicians (age range 41-59) from four hospitals, with long clinical experience (11-37 years) of inflammatory bowel disease patient care. Four of the health care professionals had academic and research experience. The participants in the cognitive interviews (Phase 2b, Figure 1) included three patients with inflammatory bowel disease (ages 53, 65, 74 years).



## Measurement and statistical methods

The patients in the validation, pilot study and test-retest phases (Table 1) answered a questionnaire including the self-care questions as well as questions on their characteristics such as gender, age, diagnosis, duration of inflammatory bowel disease, education, occupation and previous surgery. In test-retest (phase 3b, Figure 1) patients also completed a symptom registration form with nine items to calculate two validated disease activity indices. The Simple Clinical Colitis Activity Index was used for ulcerative colitis (scores  $\leq 5$  indicating remission) (Walmsley et al., 1998). The Harvey Bradshaw index was used for Crohn's disease. The Harvey Bradshaw index was modified, excluding abdominal mass, to enable self-assessment in this postal survey (scores  $\leq 5$  indicating remission) (Harvey and Bradshaw, 1980).

Descriptive statistics were used for patient characteristics, the self-care items and symptom registration. Continuous variables are presented as median and percentiles or range, and categorical variables are presented as numbers and frequencies (%). In addition, validity was assessed in terms of face validity (interview study, health care professionals and patient validation) and content validity (literature search, interview study, health care professionals and patient validation).

Content validity index was used to assess content validity in the health care professionals validation phase (Lynn, 1986, Polit and Beck, 2006, Polit et al., 2007). The content validity index for each item was calculated as the percentage of experts rating the item as often or always relevant. The lowest accepted value of the content validity index was 0.83, assuming that at least five of the six experts would rate an item as often or always relevant. (Lynn, 1986, Polit and Beck, 2006).

Percentage agreement was used to assess test-retest stability using frequency and percentage for test and retest (Bland and Altman, 1986, Field, 2014). A percentage agreement  $> 70\%$  was considered acceptable.

Intraclass correlation coefficient was used as a measure of test-retest reliability that account for systematic error (Koo and Li, 2016). An intraclass correlation coefficient close to 1 indicates high similarity between items and low intraclass correlation coefficient close to zero means low similarity. An intraclass correlation coefficient more than 0.6 was considered as acceptable (Weir, 2005). In retest, patients responded to an additional question asking if

they had implemented a change in self-care after the first test. A Wilcoxon signed rank test was used to explore the difference in disease activity at baseline and after three weeks in the test-retest evaluation.

The data were analyzed using Excel, and SPSS, the statistical package version 23-24 for Windows (IBM SPSS Inc, Chicago, IL US).

## **QUESTIONNAIRE DEVELOPMENT AND EVALUATION**

### **Phase I - Item generation**

To explore relevant themes and issues regarding self-care for patients with inflammatory bowel disease, an overview of the literature was performed. Then we analyzed an interview study with qualitative content analysis to explore self-care among patients with inflammatory bowel disease (n=20) (phase 1b, Figure 1) (Lovén Wickman et al., 2016). Based on this study and a continuously updated literature search, items to describe self-care for inflammatory bowel disease were generated. This phase led to a first draft of the self-care questionnaire with 51 items (phase 1c, Figure 1).

### **Phase II - Early evaluation**

#### *Health care professional validation*

The first version of the questionnaire with 51 items was evaluated by health care professionals. They were given information about the study, the items of the questionnaire and instructions on how to assess each item. They were asked to consider the relevance of each item by rating it on a four-point ordinal scale: (1) not relevant, (2) sometimes relevant; (3) often relevant; (4) always relevant. They were also asked to consider whether the questionnaire measured all important aspects of self-care among patients with inflammatory bowel disease and to reflect on improvements of the present items as well as suggesting new items (phase 2a, Figure 1).

The content validity index for the whole questionnaire was 0.55 while 22 items had content validity index for the items  $\geq 0.83$  (Polit and Beck, 2006). The remaining 29 items (range 0.17-0.67) were discussed in the expert review group, with a decision to keep them to ensure that the patients evaluations of items were considered in the final selection of items. In two cases two items with similar content were combined into a single item. One item (avoid sex) was added.

### *Cognitive interviews*

Thereafter, cognitive interviews with three patients with inflammatory bowel disease were performed (phase 2b, Figure 1). All participants agreed and gave both written and oral consent. The interviews took place in a health care setting with the first author. The interview started with a think-aloud phase which was followed by retrospective probes such as “Can you tell me more about...”. The cognitive interviews were audio-recorded and transcribed verbatim and analyzed by discussion in the expert review group (Collins, 2015). A few difficulties in understanding the items emerged and reformulations were made to some items. For example: *I know who I will turn to when I do not feel well* was changed to *Do you know whom to contact if you experience symptoms of inflammatory bowel disease?* and *I change my medical treatment based on my own decisions?* changed to *Do you take medication for inflammatory bowel disease as prescribed by a doctor?*

### *Patient validation*

Data were consecutively collected during 2015 and 2016 at three gastroenterology clinics in southeastern Sweden (Table 1). The invitation to participate was offered to 100 patients for validation by both physicians and nurses (phase 2c, Figure 1). The patients were asked to answer, on an ordinal scale, how often they performed the different self-care: (1) never, (2) sometimes, (3) often, or (4) always. The patients were also invited to suggest improvements for the items and to suggest new items. The median age of the participants was 54 years, the range being 18-83 years (Table 1). There was no purposeful selection of patients in terms of age, gender or socioeconomic factors. Item non-response was low in the returned questionnaires (0-3%) and no new items were suggested by the patients (phase 2c, Figure 1).

At the end of phase II, the expert review group made a final evaluation and items were put together into the final form of the self-care questionnaire. There was a consensus on the relevance of issues according to patients and health care professionals (phase 2a, Figure 1) and the final questionnaire consists mainly of the issues with a content validity index  $\geq 0.83$  and most commonly used by patients. In some cases, several more detailed items were covered by a single overarching item in the final questionnaire for example, an item addressing diet adaptations. The expert review group judged it as reasonable that the items on tobacco use, avoiding alcohol, avoiding sex and use of natural remedies should remain in the questionnaire even if they were relatively uncommon among the patients since they could

contribute to a more comprehensive picture of patient's self-care. Also, a question on confidence in determining whether intestinal symptoms are due to inflammatory bowel disease were added as ability to assess intestinal symptoms is basic in inflammatory bowel disease self-care.

The expert review group also decided to keep the two items to be near a toilet and pay attention to psychological symptoms since these were common among patients. The final revision was also focusing on getting the questions to work together as a comprehensive questionnaire. Two summarizing questions were therefore added on other performed self-care and how often self-care is helpful to relieve symptoms.

### **Phase III - Final evaluation**

Data for the pilot study and the test-retest study were consecutively collected between 2015 and 2016 from a total of 93 patients with inflammatory bowel disease. These patients were enrolled from three gastroenterology clinics in south-eastern Sweden (Phase 3, Figure 1, Table 1).

#### *Pilot study*

The pilot study was initially intended to test the final version and the layout of the questionnaire before the test-retest (phase 3b, Figure 1). After the first 30 patients, a brief evaluation was conducted, which showed that the questionnaire and layout was working well. A decision was then made to regard this as the final version and continue the pilot study while also inviting patients to participate in the test-retest evaluation (phase 3b, Figure 1).

Altogether, 93 patients participated in the pilot study, of which 63 also were invited to do the test-retest validation. Out of the 93 patients in the pilot study, 90 completed all items in the questionnaire. There were no answers or comments indicating problems understanding or answering the questions. Patients were able to answer the questions and there were few comments about unclear items and no comments about aspects missing in the questionnaire. Thus, the questionnaire seems to reflect a valid view of a patient's self-care.

**Table 2. The final items of the inflammatory bowel disease- specific self-care questionnaire (nine questions including 22 items)**

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<b>1. Do you pay attention to symptoms of inflammatory bowel disease?</b> I pay attention to intestinal symptoms/physical symptoms unrelated to the intestines/psychological symptoms <i>Scored: from 1 (never) to 4 (always) and 5 (not applicable)</i>
<b>2. How often do you feel confident that you are able to determine whether intestinal symptoms are due to inflammatory bowel disease?</b> <i>Scored: from 1 (never) to 4 (always) and 5 (not applicable)</i>
<b>3. How often do you adapt your day to problems caused by inflammatory bowel disease?</b> I adapt my diet, I avoid various activities, I avoid sex, I avoid alcohol, I plan my day so that I am always near a toilet, I plan my day in view of the fact that I have inflammatory bowel disease <i>Scored: from 1 (never) to 4 (always) and 5 (not applicable)</i>
<b>4. How often do you administer self-care to prevent or relieve symptoms of inflammatory bowel disease?</b> Self-care to make sure I sleep well, self-care to manage stress, I find out more about inflammatory bowel disease, I look for new approaches to living with inflammatory bowel disease, I use natural remedies, I perform other self-care. <i>Scored: from 1 (never) to 4 (always) and 5 (not applicable)</i>
<b>5. Do you take medication for inflammatory bowel disease as prescribed by a doctor?</b> <i>Scored: from 1 (never) to 4 (always) and 5 (no prescription of medication),</i>
<b>6. Do you know whom to contact if you experience symptoms of inflammatory bowel disease?</b> <i>Scored: from 1 (no) and 2 (yes),</i>
<b>7. How familiar are you with the symptoms for which you should contact a healthcare provider?</b> <i>Scored: from 1 (not familiar) to 4 (totally familiar)</i>
<b>8. Tobacco use:</b> Do you smoke? Do you use snuff? <i>Scored: from 1 (daily use) to 4 (I never have)</i>
<b>9. How often does self-care help you relieve symptoms of inflammatory bowel disease?</b> <i>Scored: from 1 (never) to 4 (always) and 5 (not applicable)</i>

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#### *Test-retest reliability*

For those 63 patients who consented to participate in the test-retest part of the pilot study, the second (retest) self-care questionnaire was sent after 15-17 days and 50 patients responded to both questionnaires within 3-4 weeks (Bland and Altman, 1986, Field, 2014) (phase 3b, Figure 1).

Disease activity was measured using appropriate clinical disease activity indices (Phase 3b, Figure 1) (Harvey and Bradshaw, 1980, Walmsley et al., 1998). One patient was excluded due to incomplete symptom registration. No significant differences in disease activity were shown between baseline and after three weeks, either for patients with Crohn’s disease or ulcerative colitis (Table 3). However, all patients had low disease activity both in the test and retest.

**Table 3. Disease activity indices for with Crohn’s disease and ulcerative colitis**

<i>Harvey–Bradshaw Index* (n=22)</i>	
Median (Q1,Q3) Test	5.5 (1-8)
Median (Q1,Q3) Retest	4.5 (2-7.25)
Range test	0-15
Range retest	0-15
<i>Simple Clinical Colitis Activity Index* * (n=27)</i>	
Median (Q1,Q3) test	2 (0-3)
Median (Q1,Q3) retest	1 (0-3)
Range test	0-10
Range retest	0-8

\* *Harvey–Bradshaw Index for patients with CD*

\* \**Simple Clinical Colitis Activity Index for patients with UC*

In the retest, participants were asked an additional specific question if they had changed their self-care since the last time they filled out the questionnaires. Two persons reported that they had changed their self-care during the three-week period with more accurate medication usage and a modified diet. Test-retest statistics of all responses on each item showed 72-98 % agreement between test and retest. Excluding those two patients who had changed their self-care, the percentage agreement increased to 75-100%. Intraclass correlation coefficients were over 0.6, except for one item: I plan my day in view of the fact that I have inflammatory bowel disease (Table 4).

**Table 4. Intraclass correlation coefficient**

<b>Item</b>	<b>Self-care</b>	<b>Intraclass correlation (95% confidence interval)</b>
1a.	I pay attention to intestinal symptoms	.855(.758-.915)
1b.	I pay attention to physical symptoms unrelated to the intestines	.667(.482-.796)
1c.	I pay attention to psychological symptoms	.882(.802-.932)
2.	How often do you feel confident that you are able to determine whether intestinal symptoms are due to inflammatory bowel disease	.673(.487-.801)
3a.	I adapt my diet	.749(.595-.849)
3b.	I avoid various activities	.757(.607-.855)
3c.	I avoid sex	.681(.499-.805)
3d.	I avoid alcohol	.928(.876-.958)
3e.	I plan my day so that I am always near a toilet	.789(.656-.875)
3f.	I plan my day in view of the fact that I have inflammatory bowel disease	.426(.178-.626)
4a.	Self-care to make sure I sleep well,	.742(.585-.845)
4b.	Self-care to manage stress,	.788(.652-.874)
4c.	I find out more about inflammatory bowel disease	.839(.734-.905)
4d.	I look for new approaches to living with inflammatory bowel disease	.815(.695-.891)
4e.	I use natural remedies	.827(.714-.896)
5.	Do you take medication?	.874(.788-.926)
6.	Do you know whom to contact?	1.000
7.	How familiar are you with the symptoms for which you should contact a healthcare provider?	.879(.797-.929)
8a.	Do you smoke?	.954 (.921-.974)
8b.	Do you use snuff?	.917(.859-.952)
9.	How often does self-care help you relieve symptoms of inflammatory bowel disease?	.847(.744-.911)

## **Ethical considerations**

Approval was obtained from the Regional Ethical Review Board in Linköping University (Study code: 2011/288-32, 2012/161-32, 2014/366-31 and 2015/369-31). All participants gave their informed consent and confidentiality for the participants was accomplished (WMA, 2013).

## **DISCUSSION**

To the best of our knowledge, this is the first study to develop and validate a questionnaire for assessment of self-care among patients with inflammatory bowel disease. It resulted in a disease-specific self-care questionnaire consisting of 22 items. The early and final evaluation of the questionnaire showed good content validity and test-retest reliability in a Swedish population.

### **Importance of involving both patients and health care professional in the development process**

To become engaged when answering a questionnaire, patients often emphasize the importance of being able to contribute relevant and correct information (Wenemark et al., 2010). Starting out with an interview study ensured that patients points of view were given high priority early in the process (Lovén Wickman et al., 2016). Keeping all the items during the cognitive interviews and the patient validation process was important in order to rigorously value the patients' perspectives. Patient involvement is important to achieve a useful questionnaire that minimizes measurement errors due to misinterpretations. In this study, cognitive interviews were used to ensure that the items were easy to understand and respond to (Collins, 2015). Other questionnaires have relied only on assessments of content validity index from the health care professionals perspective which may differ from the patients perspective (Johnson et al., 2015), although this was not found in our study. Involving health care professionals is important as they will discuss and give advice on self-care to the patient based on the patients' responses to the items. The health care professionals are responsible for giving accurate, sufficient and timely information and support in a culturally appropriate way to the patients. Accordingly, health care professionals involvement during the development process of the questionnaire is important as they have disease-specific knowledge, have experience



advocating self-care among patients with inflammatory bowel disease, and know what information is valuable to the patients in their clinical practice (O'Connor et al., 2013).

### **Theoretical perspective of the content of the inflammatory bowel disease self-care questionnaire**

The results of this study are consistent with the middle range theory for self-care in chronic illness (Riegel et al., 2012). *Self-care maintenance* corresponds to the inflammatory bowel disease self-care questionnaire items such as adapt diet, take prescribed medication and plan the day. *Symptom monitoring* is related to items about paying attention to and recognizing symptoms related to inflammatory bowel disease itself, associated extra-intestinal manifestations, side-effects or psychological or psychiatric disorders. *Self-care management* is related to items about self-care to prevent or relieve symptoms, knowing whom to contact if symptoms worsen, and how often self-care helps to relieve symptoms. Another factor of importance for self-care is confidence (Riegel et al., 2012) and the inflammatory bowel disease self-care questionnaire includes an item about how often the patient feels confident in determining whether intestinal symptoms are due to inflammatory bowel disease.

### **Methodological strengths and limitations**

It can be problematic to find a balance between bringing all items together in a questionnaire and obtaining a manageable number of items. However, one strength of this questionnaire is the high degree of consistency between the health care professionals' assessment of item relevance and the patients' assessment of the frequency of different self-care. This ensures that the questionnaire reflects both patients' and health care professionals' views, despite the reasonable number of items. There is always a risk that other aspects of self-care may be of great importance to individual patients. With broad questions, it is easier to cover a problem that can then be discussed in more detail in the meeting with the patient. Another strength was that the pilot study was based on a sample of patients from three different gastroenterology clinics.

The performance of the questionnaire was strengthened with the process of systematic development, using the interview study as a base and various methods during the questionnaire development phases I-III (Streiner et al., 2014). The content validity index has been criticized as a measure of agreement since it does not account for chance agreement (Beckstead, 2009). We used the expert ratings as indicators of the importance of an item and

chose experts with various professions to make sure to capture different experiences. Content validity index is here used as a measure of the proportion of experts who rated an item as often or always relevant and not primarily as a measure of agreement between the experts.

One limitation is that more cognitive interviews could have been performed to ensure that the questions were accurate, understandable, and easy to answer. It is sometimes recommended in the literature to do 5-10 cognitive interviews (Collins, 2016). Since the cognitive interviews were only one of several evaluations we found three patients to be enough. If these interviews had shown problems or a wide variety of problems more interviews would have been done. Although the patients participating in the cognitive interviews were older than the mean age of the participants in the study, which may have influenced their opinions about and expressions of the items, younger patients may have other thoughts and be familiar with other expressions. Thus, it is important to further validate the questionnaire.

Test-retest stability was evaluated and was shown to be adequate. The three-week period for test-retest stability was considered appropriate as a longer period would increase the risk of changed self-care due to changes in disease activity (Streiner et al., 2014). In test-retests of questionnaires there is always a risk that respondents may be influenced by answering the first questionnaire, and the answers to the second questionnaire will include differences due to an intervention effect. For example, in this case, it is possible that some patients got new ideas about self-care from the first questionnaire and therefore changed their self-care before the retest questionnaire; however, this was not evident in our results (Bland and Altman, 1986).

### **Practical use of the self-care questionnaire**

The questionnaire is primarily developed for assessment of self-care among patients with inflammatory bowel disease for use in both inpatient and outpatient settings. The patients with inflammatory bowel disease are in a vulnerable situation and this disease-specific questionnaire for self-care assessment may help the health care professionals, in a structured way, to meet the patients' need to strengthen their self-care ability. Based on the pilot study, 97 % answered all items, which may indicate the usefulness and functionality of the structured self-care assessment and may facilitate establishment of a care plan. The questionnaire is not intended to function as a scale it is instead aimed to be used for a

structured assessment of self-care in the discussion between health care professionals and the patient. We suggest that the questionnaire is answered before visiting the clinic, giving the patient time to reflect on their self-care needs, which could facilitate the discussion on self-care during the visit.

No other self-care questionnaire for patients with inflammatory bowel disease is available. It is therefore not possible to validate the new self-care questionnaire against a gold standard. To be used in another context the questionnaire needs further validation in groups speaking other languages and in other cultures. Future research could examine how patients and health care professionals experience the benefit of the questionnaire in clinical practice, and also examine the ability of scores to predict differences in clinical outcomes and between groups in intervention studies.

### **Conclusion**

The inflammatory bowel disease–specific self-care questionnaire was developed and evaluated by a variety of methods and with the involvement of both patients and health care professionals. This resulted in a questionnaire with a reasonable number of questions that are considered as relevant by patients and health care professionals for assessing self-care among patients with inflammatory bowel disease.

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