Ulcerative Colitis Symptom Questionnaire: Valid for Use in Adults with Moderately to Severely Active Ulcerative Colitis

Julian Panes, MD, PhD[1]; Anthony Otley, MD MSc[2]; Yuri Sanchez Gonzalez, PhD[3]; Kristina Fitzgerald, MPH[3]; Wen Zhou, MD, PhD[3]; Dapo Ilo, MBBS, MRCS[3]; Triza Brion, MPH[4]; Muna J. Tahir, PhD[4]

[1] Hospital Clinic Barcelona, IDIPABS, CIBERehd, Barcelona, Spain

[2] Department of Pediatrics , IWK Health, Dalhousie University, Halifax, Canada

[3] Abbvie Inc., North Chicago, IL, USA.

[4] ICON Plc., Blue Bell, PA, USA

Corresponding author

Triza Brion
731 Arbor Way, Suite 100
Blue Bell, PA 19422, USA
P: 512-960-5035
E: Triza.Brion@iconplc.com

Digestive Diseases and Sciences

Supplementary Data Content

Supplemental Table 1. Saturation Grid – Key symptoms mentioned during CE & CE/CI Interviews

Symptoms / Participant ID	Round 1 Interviews (CE Only) n=7							Round 2 Interviews (Combined CE/CI) n=15														Total of two rounds N=22
	101-003	100-005	100-002	100-004	100-003	101-001	101-002	100-009	100-001	100-014	100-008	100-010	100-011	100-013	100-006	100-016	100-007	100-012	101-007	101-004	101-005	101-008	
Bowel Urgency	X	X		X*	X															X			5
Bloating			X	X	X	X			X			X		X			X		X	X			10
Cramping	X		X	X	X			X	X	X	X		X	X	X		X		X	X			14
Diarrhea	X	X		X	X	X	X	X	X	X	X	X		X	X	X	X		X	X*	X		18
Blood in Stool		X		X	X	X	X	X	X	X	X	X	X		X	X			X	X		X	16
Nausea	X	X	X	X		X								X		X						X	8
Abdominal Pain	X	X	X	X	X	X	X	X	X			X		X			X	X		X		X	15
Frequent Bowel Movements	X	X	X	X	X	X	X		X			X		X	X		X		X	X		x	15
Constipation	X	X			X		X																4
Lack of Energy / Fatigue		X			X	X	X						X			X		X		X			8
Mucus in Stool	X	X								X										X			4
Loss of Appetite				X																			1
Tenesmus			X*	X*	X*		X*							X								X	6
Joint pain						X							X			X						X	4

Key:

First time code applied | * = probed

Supplemental Table 1. Saturation Grid – Key impacts mentioned during CE & CE/CI Interviews

Impacts / Participant ID	Round 1 Interviews (CE Only) n=7							Round 2 Interviews (Combined CE/CI) n=15														Total of two rounds N=22
	101-003	100-005	100-002	100-004	100-003	101-001	101-002	100-009	100-001	100-014	100-008	100-010	100-011	100-013	100-006	100-016	100-007	100-012	101-007	101-004	101-005	101-008	
Feeling down / worried	X	X	X	X	X*	X*	X*										X		X	X			10
Strenuous physical activities			X		X		X													X			4
Going places outside the home	X	X		X		X		X		X	X	X		X		X			X	X		X	13
Work / school	X	X*		X	X	X	X		X*		X		X		X*		X			X	X		13
Social activities	X*		X		X*	X*	X			X				X								X	8

Key:

First time code applied	* = probed

Supplemental Table 2. Item Tracking Matrix

Item #	Existing Item, Response Options, Hypothesized Meaning	Rationale for Action (prior to CD), KOL Feedback, Patient CE	Action for Cognitive Debriefing	Debriefing Feedback – relevance/correct interp of meaning (n=15)	Rationale for Action (prior to psychometric validation) and Final Draft Item
Instructions 1	*While answering the following questions, please think about **your Ulcerative Colitis** and how you felt during **the past week**.* (Select only one response.)				
#1	During the past week, were your bowel movements more frequent than usual? *Not at all, A little bit, Somewhat, Quite a bit, Very much* Patient reports having frequent bowel movements.	KOL 1: "Yes, I think this is relevant question. Were your bowel movements more frequent than usual. It's a little vague because what is usual?" KOL 2: "It's important. It should be No. 1." Patient CE spontaneous elicitation = 15/22	Retain as is, probe around meaning of frequent/more than usual	Relevant: 15/15; Interpretation: 15/15 101-004: It's just did I have more stools than normal, that I normally think I would have had. When I'm under a lot of stress, I tend to have more frequent, small but more frequent or at least the urgency to feel like I have to go more frequently." 100-007: "I think that's a common enough word that everybody should know what frequent—at least anybody with ulcerative colitis. We've been in the doctor's office, I mean that's the common word that they use."	Retain as is: During the past week, were your bowel movements more frequent than usual? *Not at all, A little bit, Somewhat, Quite a bit, Very much*
#2	During the past week, did you pass gas more than usual? *Not at all, A little bit, Somewhat, Quite a bit, Very much* Patient reports passing gas or experiencing flatulence.	KOL 1: "It's not a very important question, because you are asking about bloating, gas. Gas production, bloating is not a big symptom. It's an important symptom, but it's not a big symptom of ulcerative colitis." KOL 2: "I think that's more of a Crohn's symptom. It's certainly more of an IBS symptom. I don't think it's highly relevant for UC patients." Patient CE spontaneous elicitation = not applicable	Retain as is – debrief around relevance and gas/bloating distinction	Relevant: 15/15; Interpretation: 15/15 101-008: "That's [bloating] when your tummy hurts, that's when the stuff starts. That's usually when you can tell that the stuff is getting worse because that's when starts, if you can't pass gas, you think, oh, my God, if I could just do that, that would make it so, so much better so you try different things to make that happen and it doesn't." 101-004: "I do have flatulence, but I don't feel like that pattern has changed for me this last week."	Retain as is: During the past week, did you pass gas more than usual? *Not at all, A little bit, Somewhat, Quite a bit, Very much*
#3	During the past week, did you have abdominal pain?	KOL 1: "Sometimes rectal pain can also be in Crohn's disease also, or maybe we can just ask them during the past week did you have abdominal pain. So one thing that I would say that maybe you	Retain as is – Debrief on pain concept., abdominal versus cramping and rectal)	Relevant: 13/15; Interpretation: 15/15 101-004: "And some people may understand this question a lot more so than the number 3 question. They may get them confused. People	Retain as is: During the past week, did you have abdominal pain?

	Not at all, A little bit, Somewhat, Quite a bit, Very much Patient reports physical or discomfort pain in abdominal area.	need to ask about rectal pain also along with abdominal pain. I think again this question is fair. It is fair to ask." KOL 2: "Again, I don't think pain is a big component for UC. If they have a lot of pain, it should make you think of other things, like concurrent IBS or maybe you got the diagnosis wrong and it's Crohn's, but I think that depending on how many questions you have, it might find its way in." Patient CE spontaneous elicitation = 15/22		might think that cramping and abdominal pain would be the same thing." 100-008: "Cramping I think of as when having a bowel movement. Where abdominal pain I think of as just pain when you're not having a bowel movement, just like a pain that's there that you can't get rid of."	*Not at all, A little bit, Somewhat, Quite a bit, Very much*
#6	During the past week, have you felt tired or lacking energy? *Not at all, A little bit, Somewhat, Quite a bit, Very much* Patient reports feeling tired, exhausted, or inadequately rested and/or lacking energy to accomplish daily activities.	KOL 1: "Question 4 is a little bit tricky, because when they are tired, the tiredness and lacking of energy does not fluctuate weekly. It is probably more of a monthly." KOL 2: "Yeah, that's important. You've got to ask about fatigue… I think the terms you're using there are good. I don't know if 'exhausted' is better than 'tired' or 'lack of energy,' but I think that that is a pretty good one." Patient CE spontaneous elicitation = 8/22	Retain as is– debrief on word choice (tired/lacking energy/exhausted) applicability during flare vs remission	Relevant: 11/15; Interpretation: 15/15 101-004: "Tired can come from like after you have worked all day and you're just tired. Or lack of energy, like when you get up and you slept all night and you are still lacking energy, you just don't have that energy, you don't usually oomph to go." 100-007: "Definitely in a flare-up, very, very definitely in a flare-up. Not so much in remission, unless it's been a couple days of almost like a mini-flare."	Retain as is: During the past week, have you felt tired or lacking energy? *Not at all, A little bit, Somewhat, Quite a bit, Very much*
#7	During the past week, did you feel nauseated? *Not at all, A little bit, Somewhat, Quite a bit, Very much* Patient reports feeling sick to stomach, as if they might vomit.	KOL 1: It doesn't tell, it doesn't tell me anything about ulcerative colitis activity. Nausea in ulcerative colitis is as usually associated with the disease activity as you having a headache from diarrhea." KOL 2: "I don't think that's a big symptom… if a patient reports nausea, you should think about an ileus before a toxic megacolon, so these are usually very sick patients." Patient CE spontaneous elicitation =	Retain as is – debrief on relevance, applicability during flare vs remission, meaning	Relevant: 6/15; Interpretation: 15/15 100-007: "I just remember standing there shaking and breaking out in a cold sweat and going, please, please don't let me throw up at work." 100-016: "I was thinking like every time I go to the bathroom, if I have to really push because that's usually when I get nauseated."	Retain as is: During the past week, did you feel nauseated? *Not at all, A little bit, Somewhat, Quite a bit, Very much*

#8	During the past week, did you experience loss of appetite? *Not at all, A little bit, Somewhat, Quite a bit, Very much* Patient reports having reduced appetite or lack of interest in food/eating.	KOL 1: "[I]f you want to be more specific, loss of appetite may not be a very specific symptom. But it could be, it could raise the sensitivity of your PRO because loss of appetite, you can tie that to like why they are losing their appetite. But it's not a very specific symptom of ulcerative colitis." KOL 2: "I think you can see it. I mean, certainly weight loss and cachexia, you can see in UC. I don't think—my guess is if that that makes your top 10, it's going to be 9 or 10. It's going to be sort of—my guess is it will be outside of your top 10." Patient CE spontaneous elicitation = 1/22	Retain as is – debrief on relevance, applicability during flare vs remission, meaning	Relevant: 7/15; Interpretation: 15/15 101-008: "I can remember, the two bad flare-ups and then you just don't want to put anything in your body, you just want to sleep. The first one I didn't want to do anything, I didn't want to drink, I didn't want to eat, I didn't want to do anything because it hurt." 101-007:" It's not that I'm not hungry, it's that I'm trying to control my symptoms basically by not eating."	Retain as is: During the past week, did you experience loss of appetite? *Not at all, A little bit, Somewhat, Quite a bit, Very much*
#9	During the past week, did you have joint pain? *Not at all, A little bit, Somewhat, Quite a bit, Very much* Patient reports pain, soreness, aching or other discomfort in joints	KOL 1: "I think Number 7 is a good question. Joint pain is a very important extra to manifestation. Both Crohn's disease and ulcerative colitis. If you can, I think if you are doing the weekly symptoms, I think we can justify that yes, joint pain can fluctuate." KOL 2: "Joint pain can be important for a number of patients, but the majority of patients with UC are not going to have that as part of their flare." Patient CE spontaneous elicitation = 4/22	Retain as is – lower UC prevalence compared to CD, but retain for now to debrief on relevance	Relevant: 10/15; Interpretation: 15/15 100-008: "I don't really know how colitis affects my joint pain, I know it's like a side effect of it." 100-016: "It feels almost like growing pains. So it's not like super unbearable to where I can't sleep or anything, but it's uncomfortable."	Retain as is: During the past week, did you have joint pain? *Not at all, A little bit, Somewhat, Quite a bit, Very much*
#10	During the past week, did you feel down or worried? *Not at all, A little bit, Somewhat, Quite a bit, Very much*	KOL 1: "Feeling down and then asking or worried. So feeling down is something different. Worried is something different. Worry in my mind is more of anxiety, right? So I'm worried about it, I'm anxious about it,	Impact item - retain as is – debrief on change over week time period, feeling down vs. feeling worried.	Relevant: 13/15; Interpretation: 15/15 101-004: "Yes, because somebody may feel down, but they may not be worried. They may be more depressed versus worried, so."	Retain as is for exploratory purposes in quantitative study (impact item):

	Patient's description of experiencing depression or low mood, anxiousness or concern.	I'm nervous about it. Feeling down is more like a bad depression. Less energy, so I don't know if this is a question we need to ask." KOL 2: "[W]ith IBD overall, 25% of our patients have a positive depression screen, so it's very common…How that measures their disease activity, as opposed to their emotional health, I'm not really sure." Patient CE spontaneous elicitation = 10/22		100-006: Well, it's all that gigantic combination of having abdominal, going to the bathroom once an hour every hour and not getting any sleep. That's going to mess with your head after a while and you are going to get depressed.	During the past week, did you feel down or worried? *Not at all, A little bit, Somewhat, Quite a bit, Very much*
#11	During the past week, did you have difficulty with strenuous physical activities like climbing stairs or walking quickly? *Not at all, A little bit, Somewhat, Quite a bit, Very much* Patient reports impact on ability to perform tasks more physically demanding than basic self-care activities.	KOL 1: "During the past week did you have difficulty with physical activities, walking quickly, climbing stairs. Yes, it's a good question and it does, I think it is a good question and it does work for ulcerative colitis, as I was telling you about them having urgency, accidents. I think this is an important question." KOL 2: "Yeah, I think 9, 11, 12 all sort of represent the impact of the disease on your work productivity, and your social life. No. 9 also gets at fatigue a little bit and sort of generalized weakness that a patient may get when they're flaring." Patient CE spontaneous elicitation = 4/22	Impact item - retain as is - debrief on relevance, meaning, underlying difficulty	Relevant 10/15; Interpretation: 15/15 100-009: "I would say somewhat and the difficulty would be ridiculous if I were in a full-blown flare." 100-010: "It was clear to me that they want to know if I can go up and down stairs is all I thought without having trouble."	Retain as is for exploratory purposes in quantitative study (impact item): During the past week, did you have difficulty with strenuous physical activities like climbing stairs or walking quickly? *Not at all, A little bit, Somewhat, Quite a bit, Very much*
#12	During the past week, did you have difficulty going places outside the home? *Not at all, A little bit, Somewhat, Quite a bit, Very much* Patient reports impacts on ability to plan or engage in travel outside the home due to control	KOL 1: "I think it's a good question." KOL 2: "No. 10 really affects—looks at a number of symptoms, but I think really addresses diarrhea and fecal urgency because the more anxiety you have about this symptom, you're going to become housebound." Patient CE spontaneous elicitation = 13/22	Impact item - retain as is - debrief on relevance, meaning, underlying difficulty	Relevant 14/15; Interpretation: 15/15 100-009: "When I was working and had this, I had a real hard time with going to work. And then as a matter of fact, I did go to a class and I was freaking out. I mean literally, I didn't eat or drink anything, enough water to take my pills and that was it and I could make it through the class, it was all-day deal for, a week or two."	Retain as is for exploratory purposes in quantitative study (impact item): During the past week, did you have difficulty going places outside the home?

	over schedule or proximity to restroom.			100-007: "My first thought at reading that was difficulty would be leaving the house because I would have had to go to the bathroom."	*Not at all, A little bit, Somewhat, Quite a bit, Very much*
#13	During the past week, did you have difficulty at work or school? *Not at all, A little bit, Somewhat, Quite a bit, Very much* Patient reports impact on attendance and/or performance at work and/or school.	KOL 1: "I think this is a very general question that happens in both Crohn's disease and ulcerative colitis…Difficulty at work and school is, there are other levels of difficulties. Like concentration, the psychosocial component of it." KOL 2: ""Yeah, I think 9, 11, 12 all sort of represent the impact of the disease on your work productivity, and your social life." Patient CE spontaneous elicitation = 13/22	Impact item - retain as is - debrief on relevance, meaning, underlying difficulty	Relevant: 12/15; Interpretation: 15/15 100-006: You can really easily gauge if you're having 10 to 20 bowel movements a day, this question is irrelevant because obviously you're going to have difficulty wherever you are. 100-008: "If the colitis was flaring up, were you having trouble getting work done or just being there, if you are running back and forth to the bathroom."	Retain as is for exploratory purposes in quantitative study (impact item): During the past week, did you have difficulty at work or school? *Not at all, A little bit, Somewhat, Quite a bit, Very much*
#14	During the past week, did you have difficulty participating in social activities like visiting friends or family? *Not at all, A little bit, Somewhat, Quite a bit, Very much* Patient reports impact on ability to plan or engage in socializing or going out in public.	KOL 1: "To me, what we are checking is their activity related to the symptom and there are three questions, 9, 10 and 12, you are asking the same thing in three different ways. ..Number 12 is also something that can be equally applied between Crohn's and ulcerative colitis, but this is more related to ulcerative colitis than Crohn's." KOL 2: ""Yeah, I think 9, 11, 12 all sort of represent the impact of the disease on your work productivity, and your social life." Patient CE spontaneous elicitation = 8/22	Impact item - retain as is - debrief on relevance, meaning, underlying difficulty	Relevant: 8/15; Interpretation: 15/15 100-007: "I guess the first part of Q14 would be if I can leave the house. Then am I going to have enough energy to do things with family and friends. I mean can I leave the house to go to the doctor's, probably. Can I leave the house to go out to dinner with family and friends, that might be a different story if I'm in a flare." 100-012: It's kind of I think tied into Q12, work and school I think are similar.	Retain as is for exploratory purposes in quantitative study (impact item): During the past week, did you have difficulty participating in social activities like visiting friends or family? *Not at all, A little bit, Somewhat, Quite a bit, Very much*
#15	During the past week, did you have difficulty sleeping? *Not at all, A little bit, Somewhat, Quite a bit, Very much*	KOL 1: "Number 13 is a very good question…Because diarrhea, which is a common symptom, can also affect your sleep when you are going to the bathroom so frequently in the middle of the night, and pain, which is more with Crohn's, can also affect your sleep and would have difficulty sleeping."	Retain as is – debrief on relevance, aspects of difficulty, e.g. falling asleep, waking due to bowel symptoms, or systemic symptoms	Relevant: 5/15; Interpretation: 15/15 100-008: "If my colitis is flaring, it definitely wakes me up." 100-014: "I guess thinking something might happen, which will cause me to stay awake maybe until I feel like if I'm having cramps or something,	Retain as is: During the past week, did you have difficulty sleeping?

	Patient reports UC impacting quantity or quality of their sleep.	KOL 2: "[P]atients with nocturnal awakenings are going to get up, so a lot of those symptoms—a lot of that answer might be related to nocturnal awakenings and maybe necessarily for diarrhea. Having said that, there's probably a link between sleep disturbance and flares." Patient CE spontaneous elicitation = not applicable		then I think something might happen, so I tend to stay awake until I'm really either really tired or I think I'm going to be okay."	*Not at all, A little bit, Somewhat, Quite a bit, Very much*
#16	During the past week, did you experience bloating? *Never, Rarely, Sometimes, Often, Always* Patient reports experiencing abdominal bloating, feeling of fullness or expansion in abdominal area	KOL 1: "It can change week to week. But it's not, it's not telling me anything. If you ask me do we need to ask this question in the PRO for ulcerative colitis, I'd say no." KOL 2: "[B]loating's not—I don't think is that important." Patient CE spontaneous elicitation = 10/22	Retain as is – debrief on relevance, distinction versus gas	Relevant: 11/15; Interpretation: 15/15 101-004: "Sometimes that's how it's relieved, the bloaty feeling, for me, is relieved by the passing of gas." 100-001: "Kind of like being over-full or your belly is real tight and it seems like you've got too much in there and stuff, being bloated."	Retain as is: During the past week, did you experience bloating? *Never, Rarely, Sometimes, Often, Always*
#17	During the past week, did you have diarrhea? *Never, Rarely, Sometimes, Often, Always* Patient reports having diarrhea, i.e. loose or liquid stools	KOL 1: "I think diarrhea is a very important question as long as we are clear in what we asking. I ask do you have more than three bowel movements in a day as a diarrhea question. And then I ask them was the consistency of your stool loose, watery, soft or formed stool." KOL 2: "If you had to pick two symptoms that are absolutely critical, it's blood in the stool and diarrhea." Patient CE spontaneous elicitation = 17/22	Retain as is	Relevant: 14/15; Interpretation: 15/15 101-004: "A true diarrhea is watery, true watery, has no form whatsoever, no bulk or whatever to it. With loose stools is to me watery, but it does have a little bit of bulk to it, a little bit of form, consistency to it." 100-007: "[Diarrhea is] liquid, whereas frequent bowel movements you can have formed or semi-formed is the terms they use."	Retain as is: During the past week, did you have diarrhea? *Never, Rarely, Sometimes, Often, Always*
#18	During the past week, did you have blood in your stool? *Never, Rarely, Sometimes, Often, Always*	KOL 1: "So stool consistency and blood in stool, they are very [relevant to] ulcerative colitis." KOL 2: "If you had to pick two	Change wording to reflect blood in versus in place of stool:	Relevant 11/15; Interpretation: 15/15 100-006: "I think that I do pass blood, but I believe without the stool. I mean, yeah, it's not necessarily in the bowel movement itself." 100-013: "Yeah, if I did have blood there's stool	Retained following previous modification: During the past week, did pass blood or

	Patient reports seeing blood in their stool	symptoms that are absolutely critical, it's blood in the stool and diarrhea." Patient CE spontaneous elicitation = 17/22	During the past week, did pass blood or have blood in your stool? *Never, Rarely, Sometimes, Often, Always*	with it, but I don't have it often though."	have blood in your stool? *Never, Rarely, Sometimes, Often, Always*
#20	During the past week, were you constipated? *Never, Rarely, Sometimes, Often, Always* Patient reports experiencing constipation or infrequent/incomplete bowel movements.	KOL 1: "UC patients do experience constipation and I think we can keep that." KOL 2: "I would rephrase the wording for 17. I wouldn't say 'constipated.' I would say something like during the past week, how often have you either felt the urge to empty your bowels when they were empty, or how often have you had trouble emptying your bowels completely." [tenesmus] Patient CE spontaneous elicitation = 4/22	Retain as is – debrief on overlap with tenesmus, medication SEs, obstruction	Relevant: 4/15; Interpretation: 15/15 100-012: "No, and that's never something, no, it's the opposite. I'm actually trying to get constipated. Yeah, constipation is just a dream." 100-013: "It means when you can't go to the bathroom or you haven't gone to the bathroom. Haven't had a bowel movement in a long time."	Retain as is: During the past week, were you constipated? *Never, Rarely, Sometimes, Often, Always*
	During the past week, did you vomit or throw up? *Never, Rarely, Sometimes, Often, Always* Patient reports throwing up or vomiting.	KOL 1: "18 and 19 are not related to ulcerative colitis." KOL 2: "Eighteen and 19 are not important, I don't think." Patient CE spontaneous elicitation = 0/22 Clinical team agreed to remove for being less relevant	Remove	NA	NA
	During the past week, did your stomach growl or make gurgling sounds? *Never, Rarely, Sometimes, Often, Always* Patient reports that stomach produces growling or gurgling noises or sounds.	KOL 1: "18 and 19 are not related to ulcerative colitis." KOL 2: "Eighteen and 19 are not important, I don't think." Patient CE spontaneous elicitation = 0/22 Clinical team also agreed to remove for being less relevant	Remove	NA	NA

New Items	Concept	Rationale for Item Development – Input from KOLs, Clinical team, Reference to literature where applicable, Patient CE spontaneous elicitation (n=22)	Item/ROs, Action for Debrief	Debriefing Feedback – relevance/correct interp of meaning (n=15) (Patient Quotes	Rationale for Action (prior to psychometric validation) and Final Draft Item
#21	Tenesmus	KOL 1: "[I]n ulcerative colitis mostly the symptoms are, is urgent nature of going to the bathroom and of feeling like incomplete evacuation, inability to distinguish and having accidents. That kind of very common symptom in ulcerative colitis." KOL 2: "Urgency, tenesmus can be a big, big issue." Patient CE spontaneous elicitation = 6/22 Clinical team suggested adding item to capture concept for debriefing Concept cited in literature (Joyce et al, 2008)	During the past week, did you feel that you needed to have a bowel movement - even when your bowels were empty? *Never, Rarely, Sometimes, Often, Always* Debrief on distinction with constipation, meaning of empty	Relevant: 13/15; Interpretation: 15/15 101-008: "I do feel like sometimes I need to [have a bowel movement] and there's nothing there, but that's when it's active." 100-007: "I mean when I was in a flare there were definitely times where I had just gone to the bathroom and I was in there five minutes later thinking that I needed to go and nothing."	Retain as is During the past week, did you feel that you needed to have a bowel movement but had difficulty producing stool? *Never, Rarely, Sometimes, Often, Always*
#22	Bowel Urgency	KOL 1: "[I]f you can tolerate the pain, you can mask the pain, but if it becomes very hard for a patient to control the uncontrolled urgency and pain and bloody stools, that might have a little bit different impact on their daily life if they are symptomatic. KOL 2: "Urgency, tenesmus can be a big, big issue." Clinical team suggested adding item to capture concept for debriefing Concept cited in literature (Joyce et al, 2008, Waljee et al, 2009, Jowett et al, 2003) Patient CE spontaneous elicitation = 5/22	During the past week, did you experience a sudden or intense need have a bowel movement? *Never, Rarely, Sometimes, Often, Always* Debrief, particularly on distinction with incontinence- accidents versus leakage	Relevant: 15/15; Interpretation: 15/15 101-004: "It [bowel urgency] can happen frequently. That's the reason why people with UC like to know where the restrooms are. We usually know the routes that they drive frequently, where the restrooms are." 100-012: "But it comes at a cost because it means I'm really conservative with what I do, where I go, I just turn down everything. When I'm doing bad I just work-home, work-home, like I will avoid pretty much anything that takes me out of the house, so that sucks. It's my strategy."	Retain as is: During the past week, did you experience a sudden or intense need have a bowel movement? *Never, Rarely, Sometimes, Often, Always*

#4	Rectal Pain	AbbVie clinical team suggested adding item to capture concept for debriefing Patient CE spontaneous elicitation = not applicable	During the past week, did you have rectal pain? *Never, Rarely, Sometimes, Often, Always* Debrief on distinction with abdominal pain and cramping	Relevant: 12/15; Interpretation: 15/15 101-004: I have had instances of rectal pain because in the past I have had hemorrhoids. "Yes, so again, this is just asking in the last little while, has the pain been down in my rectum. And I would answer this not at all. Like I told you, the pain that I felt is—I don't know if it's actual pain in my rectum or it's just that I have to wipe so much." [101-007] "Abdominal pain, when you say abdominal or when I read abdominal I think more of just upper and I can feel when material hits the inflamed part. And that triggers, I know I'll be going to the bathroom soon because once it hits the colon and the inflamed area, it's not going to be staying there long. So I'll feel the pain and I can very much feel up until the end and then if the inflammation is bad, I won't feel the pain anymore in the abdominal area, but I'll still feel the pain down towards the rectum, the achiness. Yeah, it's distinct, oh, yeah, definitely." [100-012]	Retain as is: During the past week, did you have rectal pain? *Never, Rarely, Sometimes, Often, Always*
#5	Cramping	KOL 1: [Q: Is there any pattern to abdominal pain that the UC patients experience?] A: "It's usually cramping with diarrhea." Clinical team suggested adding item to capture concept for debriefing Concept cited in literature (Joyce et al, 2008, Waljee et al, 2009) Patient CE spontaneous elicitation = 14/22	During the past week, did you have abdominal cramping? *Never, Rarely, Sometimes, Often, Always* Debrief on distinction with abdominal and rectal pain	Relevant: 8/15; Interpretation: 15/15 101-008: "Because to me, that [cramping] is the same as abdominal pain." 100-012: "The only time I've had cramping and abdominal pain is when I've had flares. So in this case it makes reference of flare because pre-diagnosis I didn't have any of those symptoms."	Retain as is During the past week, did you have abdominal cramping? *Never, Rarely, Sometimes, Often, Always*
#19	Mucus in Stool	Concept cited in literature (Joyce et al, 2008, Waljee et al, 2009) Patient CE spontaneous elicitation = 4/22	During the past week, did you have mucus in your stool? *Never, Rarely, Sometimes, Often, Always*	Relevant: 14/15; Interpretation: 15/15 100-007: "You can pass mucus on its own. So you can have mucus in your stool or you can pass mucus."	Retain as is During the past week, did you have mucus in your stool?

Debrief on whether mucus is accompanied with and how frequent blood is present	100-016: "I guess because it's in water, it almost looks like jelly. And when it's a solid one it looks just like there's a coating on it."	*Never, Rarely, Sometimes, Often, Always*

Supplemental Table 3. Exploratory factor analysis: one factor structure rotated factor loadings for the UC-SQ at baseline

Oblimin rotation Item (N=113)	**Factor$_1$**
i) Polychoric matrix Eigenvalue (% variance explained)	20.37 (61.9%)
UC-SQ Item 3 (Abdominal pain)	0.81*
UC-SQ Item 4 (Rectal pain)	0.70*
UC-SQ Item 5 (Cramping)	0.81*
UC-SQ Item 6 (Lacking energy)	0.73*
UC-SQ Item 7 (Nausea)	0.71*
UC-SQ Item 16 (Bowel movements with empty bowels)	0.69*
UC-SQ Item 8 (Loss of appetite)	0.67*
UC-SQ Item 17 (Bowel movement urgency)	0.66*
UC-SQ Item 11 (Bloating)	0.55*
UC-SQ Item 14 (Mucus in stools)	0.47*
UC-SQ Item 13 (Blood in stools)	0.45*
UC-SQ Item 10 (Difficulty sleeping)	0.43*
UC-SQ Item 1 (Bowel movement frequency)	0.38
UC-SQ Item 12 (Diarrhea)	0.37
UC-SQ Item 2 (Passing gas)	0.35
UC-SQ Item 9 (Joint pain)	0.29
UC-SQ Item 15 (Constipation)	0.22

*Reflect acceptable loadings ≥0.40

Supplemental Table 4. Internal consistency reliability: Cronbach's alpha/Cronbach's alpha with each item deleted and item-total correlations for the 17-item and final 15-item UC-SQ

	Cronbach's alpha[1]		Item-total correlations Pearson Correlations (confidence interval)[2]	
UC-SQ Item Response	**17-Item UC-SQ Total score**	**15-Item UC-SQ Total score**	**17-Item UC-SQ Total score**	**15-Item UC-SQ Total score**
UC-SQ Item 1 (Bowel movement frequency)	0.853/0.856	0.863/0.867	0.49 [0.34, 0.62]**	0.49 [0.34, 0.62]**
UC-SQ Item 2 (Passing gas)	0.854/0.858	0.864/0.870	0.45 [0.28, 0.58]**	0.45 [0.28, 0.58]**
UC-SQ Item 3 (Abdominal pain)	0.839/0.844	0.848/0.854	0.72 [0.61, 0.80]**	0.72 [0.61, 0.80]**
UC-SQ Item 4 (Rectal pain)	0.839/0.845	0.849/0.856	0.69 [0.58, 0.78]**	0.69 [0.58, 0.78]**
UC-SQ Item 5 (Cramping)	0.838/0.843	0.847/0.854	0.72 [0.62, 0.80]**	0.72 [0.62, 0.80]**
UC-SQ Item 6 (Lacking energy)	0.840/0.844	0.850/0.857	0.68 [0.56, 0.77]**	0.68 [0.56, 0.77]**
UC-SQ Item 7 (Nausea)	0.843/0.846	0.853/0.858	0.64 [0.51, 0.73]**	0.64 [0.51, 0.73]**
UC-SQ Item 8 (Loss of appetite)	0.843/0.847	0.852/0.858	0.64 [0.52, 0.74]**	0.65 [0.52, 0.74]**
UC-SQ Item 9 (Joint Pain)	0.860/0.863	-	0.19 [0.01, 0.36]*	-
UC-SQ Item 10 (Difficulty sleeping)	0.851/0.855	0.861/0.867	0.49 [0.33, 0.62]**	0.49 [0.33, 0.62]**
UC-SQ Item 11 (Bloating)	0.846/0.850	0.857/0.862	0.57 [0.43, 0.68]**	0.57 [0.43, 0.68]**
UC-SQ Item 12 (Diarrhea)	0.855/0.858	0.863/0.868	0.45 [0.29, 0.59]**	0.46 [0.29, 0.59]**
UC-SQ Item 13 (Blood in stools)	0.849/0.854	0.859/0.865	0.52 [0.37, 0.64]**	0.52 [0.37, 0.64]**
UC-SQ Item 14 (Mucus in stools)	0.850/0.853	0.861/0.866	0.51 [0.36, 0.63]**	0.51 [0.36, 0.63]**
UC-SQ Item 15 (Constipation)	0.858/0.863	-	0.20 [0.02, 0.37]*	-
UC-SQ Item 16 (Bowel movements with empty bowels)	0.840/0.843	0.850/0.855	0.69 [0.59, 0.78]**	0.70 [0.59, 0.78]**
UC-SQ Item 17 (Bowel movement urgency)	0.845/0.847	0.854/0.858	0.63 [0.51, 0.73]**	0.64 [0.51, 0.73]**
Cronbach's alpha	0.855/0.859	0.864/0.869	-	-

[1] Cronbach's alpha with each item deleted (raw / standardized)

[2] UC-SQ total score with each item deleted

*p<0.05; **p<0.0001

Supplemental Table 5. Test-retest reliability: mean change, t-tests and ICC for the UC-SQ at baseline and week 2 for patients reporting no change on the PGIC

Measure	N	Baseline Mean (SD)	Two week follow-up Mean (SD)	Mean Change (SD)	t-test (p-value)	ICC (95% CI)
UC-SQ total score	21	31.57 (11.80)	28.95 (11.60)	-2.62 (5.32)	0.036	0.88 (0.72, 0.95)

SD=Standard Deviation; ICC=Intraclass Correlation Coefficient

Supplemental Table 6. Convergent/discriminant validity: correlations between UC-SQ total scores and various SF-36 and IBDQ subscores at baseline

Instrument	UC-SQ total score
	r (p-value)
SF-36	
Physical Component Summary Score	-0.48 (<0.0001)
Social Functioning Subscale Score	-0.60 (<0.0001)
Role-Emotional Subscale Score	-0.37 (<0.0001)
Mental Component Summary Score	-0.54 (<0.0001)
IBDQ	
Bowel Symptoms Subscale Score	-0.89 (<0.0001)
Systemic Symptoms Subscale Score	-0.74 (<0.0001)
Emotional Function Subscale Score	-0.65 (<0.0001)
Social Function Subscale Score	-0.65 (<0.0001)