# IBS PATIENTS: THEIR ILLNESS EXPERIENCE AND UNMET NEEDS



### AN ONLINE STUDY

conducted by the

International Foundation for Functional Gastrointestinal Disorders (IFFGD)

in collaboration with

the University of North Carolina (UNC) Center for Functional GI and Motility Disorders





This study was conducted by IFFGD and the UNC Center for Functional GI and Motility Disorders.



# DEAR READER,

Irritable bowel syndrome (IBS) is a common yet puzzling medical diagnosis. The many factors contributing to this disorder remain under study and its symptoms vary widely. Yet it poses tremendous challenges to those who are diagnosed with it and live with it every day.

To shed light on this disorder and how patients experience its symptoms and treatment, the International Foundation for Functional Gastrointestinal Disorders (IFFGD) sponsored and collaborated with the UNC Center for Functional GI and Motility Disorders to conduct a comprehensive online survey of patients diagnosed with IBS. The ongoing survey commenced in the second half of 2007. Respondents were invited to participate in the survey from databases belonging to IFFGD and the UNC Center or advertisements on the IFFGD and UNC Center websites.

Response was strong: 1,966 qualifying responses were received over four months during the 2007 period covered in this report. Participation criteria were diagnosis of IBS by a physician and being 18 years or older. Completed surveys were stored in a database housed on the secure IFFGD website server; anonymous responses were then sent to the Biometry Core at UNC for analysis. All data were coded and secured to protect the identities of participants.

The results are extremely interesting and even disturbing. Participants provided us with a vivid profile of their illness experience and how it impacts their lives. They reported on the pervasiveness of pain and how bowel difficulties affect their activities, employment, and personal experiences. They also shared their treatment history and relative satisfaction with those treatments. Only 8% of respondents were very or extremely satisfied with available IBS treatment; one-third were not at all satisfied, indicating the need for more effective treatment choices.

Perhaps for the first time ever in a formal study, these patients defined how they assess success in symptom relief and what risks they might assume to achieve that relief. Some are even willing to accept a chance of death or serious and disabling side effects if offered a medication that would give them total relief of their IBS symptoms. These results challenge conventional assumptions that minimize the burden caused by this disorder and put an entirely different focus on the severity of the condition and how desperately people are seeking freedom from symptoms.

Please take some time to review these thought-provoking results in more detail. This study is in press for publication in the Journal of Clinical Gastroenterology\*, a peer-reviewed journal, in order to more fully share its findings with the medical community.

These results suggest that much more needs to be done to develop and deliver satisfactory treatment to IBS sufferers throughout the world.

Sincerely,

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Drossman DA, Morris CB, Schneck S, Hu YJB, Norton NJ, Norton WF, Weinland <mark>S, Dalton C, Leserman J, \*</mark> Bangdiwala SI. International survey of patients with IBS: Symptom features and their severity, health status, treatments, and risk taking to achieve clinical benefit. J Clin Gastroenterol, 2009 (in press, available online).

### **KEY FINDINGS**

This online survey yielded a wealth of information about IBS sufferers and the impact of the disorder on their lives.

### Some major highlights

Pain: Pain is a dominating symptom for these IBS sufferers; 78% report having continuous or frequently recurring abdominal pain during the last six months. Of those who experience pain, one-fourth describe the pain as constant.

Loss of control: More than 40% of these respondents feel that they are losing a great deal or quite a bit of control over their lives due to their IBS.

Restricted activities: Respondents report an average of more than 73 days (20% of the calendar year) when they need to restrict their usual activities due to their health.

Multiple medications and remedies, low satisfaction: Participants take a variety of medications for their IBS, including non-narcotic pain medications, antidepressants for pain, acid reducers, antidiarrheals, and narcotic medications. In addition, complementary and alternative medicine is being used by 37% of these respondents. Yet only 8% are very or extremely satisfied with all types of IBS treatment.

Impact of removal of IBS drugs: When IBS-targeted drugs were taken off the market by the FDA, 13% of these respondents were taking these drugs at the time of removal. More than four out of ten (45%) found the withdrawal considerably or completely disruptive to the control of their IBS. One-third found the withdrawal considerably or completely disruptive to their daily lives.

Expectations for improvement: Participants report that they would need to feel at least 66% better to continue with an IBS medication. Respondents are very clear about which symptoms needed to be improved for a medication to be used: pain and diarrhea. Bloating, quality of life, and constipation are also heavily endorsed.

Assuming risks for symptom relief: Respondents were asked how much risk they would assume to take a medication providing total relief from IBS symptoms but with serious adverse effects. Their quest for symptom relief is striking: 8% would accept a 1 in 100 chance of death to be symptom-free. Six percent (6%) would accept a 1 in 100 chance of serious and disabling side effects to be symptom-free.

# **DEFINING IBS**

IBS is a chronic or recurring functional bowel disorder in which the key symptom (abdominal pain or discomfort) is associated with defecation or a change in bowel habit. Symptoms can occur over a single long period or in several shorter bouts. It is an extremely common disorder; 10-15% of Americans are estimated to have IBS.

For this online study, all participants were required to have an IBS diagnosis by a physician. Of the responses received, 1,966 report physician-diagnosed IBS and are at least 18 years of age. This sample size (1,966) was used for data analysis unless otherwise noted.

Physicians typically use symptom criteria and a medical evaluation to ascertain and confirm an IBS diagnosis. For this survey and in the absence of physician records, the Rome III criteria, the current standard for diagnosis, were used to verify the participant's report of physician-diagnosed IBS; 91% fit the Rome III criteria for the disorder, thus validating the respondents' diagnosis information.

IBS is often divided into subtypes based on the most commonly experienced bowel symptom. For this study, these standard subtypes are based on the ROME III criteria:

- Diarrhea-predominant
- Mixed diarrhea/constipation/unspecified
- Constipation-predominant



# **ASSESSING IBS SEVERITY**

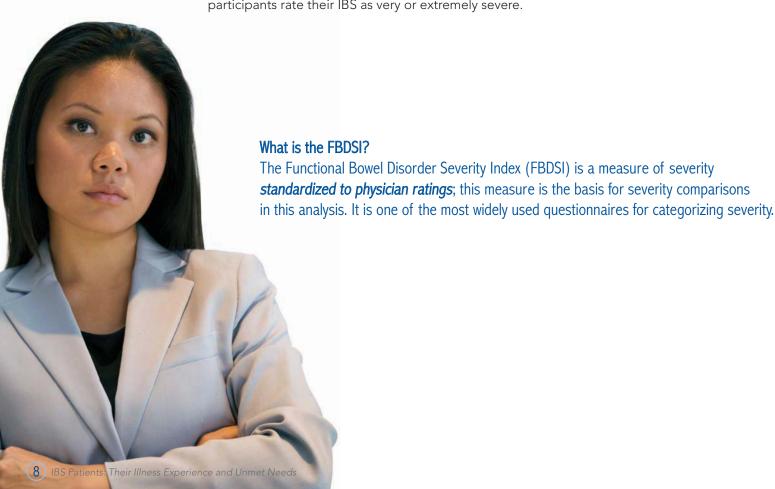
IBS severity levels are often debated and prone to interpretation. In this study, participants' severity levels were measured using a standardized physician tool known as the Functional Bowel Disorder Severity Index (FBDSI).

According to this index, 20% of the sample are rated severe and almost half are rated as moderate.

### Severity levels determined by FBDSI

Severity Index	% of respondents
Mild (less than 36)	31.4%
Moderate (36-109)	48.3%
Severe (equal or greater than 110)	20.3%

Although 20% of this sample had severe IBS based on a recognized clinical index, the respondents actually self-report higher severity levels. For example, 35% of participants rate their IBS as very or extremely severe.



### Pain is key contributor to severity

In order to understand what factors contribute to the severity of their condition, participants were asked to select from several possible factors.

- Pain is mentioned most frequently (by 80% of respondents) as the factor that makes their IBS severe.
- Other frequently mentioned factors reported by 7 out of 10 respondents are bowel difficulties (74%), bloating (69%), and limitations in eating or diet (69%).

### Most frequent factors contributing to severity of IBS

Factors that make your IBS severe	% of respondents
Pain	79.5%
Bowel difficulties	74.4%
Bloating	69.4%
Limits on eating/diet	69.2%

### Other severity factors

Severity is an issue that clearly impacts people's lives. For example, social limitations (62%), the inability to leave home (54%), and work and school limitations (50%) are reported as major factors by at least half of respondents.

### Other frequent factors contributing to severity of IBS

Factors that make your IBS severe	% of respondents
Social limitations	61.5%
Cannot leave home	53.5%
Work/school limitations	50.2%
Limitations in thinking	49.6%
Trouble sleeping	45.4%
Nausea	42.2%
Limitations in home activities	39.2%
Poor quality of life	39.0%
Incontinence	27.3%
Other troubles	10.8%

When asked which item was the  ${\it most\ troubling}$ , bowel difficulties and pain are cited most often.

### ■ Most troubling item that makes my IBS severe

Factors most troubling	% of respondents
Bowel difficulties	29.8%
Pain	29.1%
Bloating	10.7%
Incontinence	10.1%

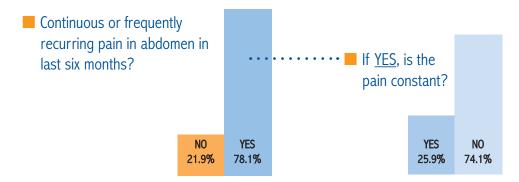
All other factors mentioned by less than 4% of respondents.



### Spotlight on pain

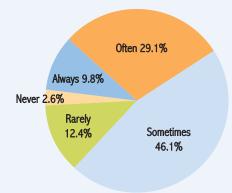
Pain is a dominating symptom for the IBS sufferers in this survey.

For example, 78% report having continuous or frequently recurring abdominal pain during the last six months. Of those who experience pain, one-fourth describe the pain as constant.



Pain definitely interrupts their lives. More than 38% report that abdominal pain interferes with their daily activities always or often; additionally, almost half (46%) report interference sometimes.

■ Interference with daily activities due to abdominal pain



# IMPACT OF IBS ON QUALITY OF LIFE

Quality of life (QOL) is a term often used to describe a patient's daily living experience as related to a chronic medical condition.

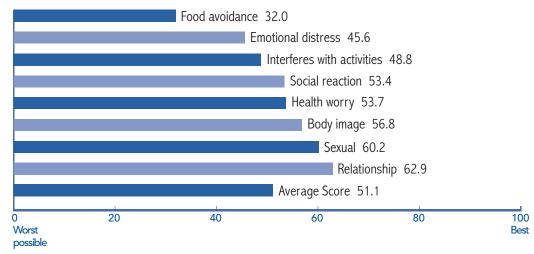
For this study, the IBS-QOL measure was used to assess quality of life impact of the disorder. The average score for this group is 51.1 (out of a possible 100), indicating a markedly impaired health-related QOL.

- Areas of greatest impairment (scoring less than 50) are food avoidance (32), emotional distress (46), and interference with activity (49).
- Average IBS-QOL scores worsened with greater IBS severity, ranging from a score of 60 for the mild subgroup down to a score of 38 for the severe subgroup.

### What is the IBS-QOL Questionnaire?

The IBS-QOL is the most standardized and most recommended disorder-specific quality of life measure for IBS. The overall score, ranging from 0 (lowest) to 100 (highest), and the eight subscales were calculated for this study. A score of 51 is in the moderate to severe range for IBS\*.

### Quality of life scores, lowest to highest. Average score for IBS respondents (out of 100)



Drossman D, Morris CB, Hu Y, Toner BB, Diamant N, Whitehead WE, Dalton CB, Leserman J, Patrick DL, Bangdiwala SI. Characterization of health related quality of life (HRQOL) for patients with functional bowel disorder (FBD) and its response to treatment. Am J Gastroenterol. 2007 Jul;102(7):1442-53.

More than 40% of respondents feel that they are losing a great deal or quite a bit of control over their lives due to their IBS; this finding turned out to be an important indicator of impaired quality of life.

### Significantly restricted activity levels

Respondents report an average of more than 73 days (20% of the calendar year) when they need to restrict their usual activities due to health problems.

- For severe participants, this number jumps to 139 days or 38% of the year.
- Restricted activity differs by main bowel symptom, as diarrhea-predominant participants report 84 restricted days (23% of the year) while constipation-predominant participants report 59 restricted days (16% of the year).

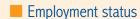
### **IBS** affects employment

The majority of these respondents (70%) are employed. However, 13% of participants are jobless due to their health situation.

Severity level impacts employment; nearly one-third (30%) of participants with severe symptoms are jobless due to their health compared to 5% for participants with mild symptoms.

■ I feel like I'm losing control of my life because of my bowel problems.







# **HIGH MEDICATION USAGE AND SIDE EFFECTS**

Respondents reported taking a range of 0-13 drugs across the sample. Most participants are taking medications, with the average respondent taking two drugs for IBS.

Based on current usage, the most common medications taken are non-narcotic pain medications (31%), antidepressants for pain (31%), acid reducers (28%), antidiarrheals (24%), antispasmodics (19%), and narcotic medications (18%).

Severe or moderate side effects are reported.

- Moderate and severe side effects are greatest with anti-constipation medications (23%), narcotics (13%), and antidepressants (13%).
- It is noteworthy that all of the medication categories caused severe or moderate side effects for respondents.

### Medication usage and side effects

People who			
	Have ever taken this drug	Are taking this drug now	
Medication Type	% of all respondents (N=1,966)	% of all respondents (N=1,966)	% of reported moderate and severe side effects
Non-narcotic Pain Medications	87.7%	31.3%	2.1%
Antidepressants	63.8%	30.8%	13.0%
Acid Reducers	64.3%	27.7%	1.5%
Antidiarrheals	68.5%	23.6%	6.7%
Antispasmodics	43.2%	18.5%	9.4%
Narcotic Pain Medications	76.6%	18.1%	13.2%
Anti-anxiety Medications	44.4%	12.5%	5.3%
Anti-constipation Medications	26.1%	4.6%	23.3%
Anti-nausea and Anti-vomiting Medications	13.6%	1.9%	5.4%
IBS Targeted Drugs*	21.0%	1.8%	2.9%
Antibiotics	25.9%	1.0%	10.0%

<sup>\*</sup>Alosetron and Tegaserod are IBS-targeted drugs currently removed from the market or with restricted access due to FDA.

# **RELATIONSHIPS WITH PROVIDERS**

For these respondents, diagnosis of their IBS was typically made 6.6 years after the symptoms began.

They consulted with more than four different physicians or health care providers in their lifetime about their IBS.

Health care utilization is fairly high among respondents. On average, they have seen a physician for their IBS three times during the last six months.

Most often they saw a primary care physician (89%) or a gastrointestinal (GI) specialist (55%) during the last year. However, a variety of other providers were also consulted for IBS.

### Providers seen in last year for IBS

	Number of respondents	% of respondents
Primary care MD, family practice MD, osteopath	1,755	89.3%
Gl specialist	1,080	54.9%
Gynecologist	673	34.2%
Nurse practitioner/physician assistant/ counselor/psychologist	538	27.4%
Psychiatrist	369	18.8%
Dietician/nutritionist	172	8.7%
Urologist	157	8.0%
Biofeedback therapist	24	1.2%
Other	376	19.1%
Have not seen a provider	68	3.5%

# NON-CONVENTIONAL TREATMENTS

More than one-third (37%) have used complementary and alternative medicine (CAM), indicating a willingness to seek non-conventional treatment for IBS.

Of these, current usage is greatest for dietary supplements (16%) and probiotics (13%), followed by meditation or relaxation therapy (5% each).

### ■ Usage of complementary and alternative medicine

Type of CAM	Ever used Currently using		
Type of Chiri	Number of respondents	Number of respondents	% of respondents
Dietary supplements	599	312	15.9%
Probiotics	477	258	13.1%
Meditation	342	99	5.0%
Relaxation therapy	338	98	5.0%
Massage therapy	301	88	4.5%
Homeopathy	235	59	3.0%
Chinese herbal therapy	182	44	2.2%
Acupuncture	165	29	1.5%
Biofeedback	83	14	0.7%
Colonic irrigation	74	9	0.5%



# **EXPECTATIONS ON** SYMPTOM IMPROVEMENT

To understand patients' expectations for symptom improvement with a medication, respondents were asked: You start taking a medication for your IBS that costs \$50/month. How much better would you need to feel to continue taking this medication?

Overall participants report that they would need to feel at least 66% better to continue with this medication, indicating an acceptable level of improvement for any IBS medication. This finding is similar across all severity levels and IBS symptom subtypes.

Respondents are very clear about which symptoms need to be improved for a medication to be used. Pain is endorsed by 69% as the symptom that most needs to be improved, followed by diarrhea (61%). Bloating (endorsed by 55%), quality of life (endorsed by 47%), and constipation (endorsed by 41%) are also heavily endorsed.

### Symptom reduction priorities

Symptom needs to be reduced/improved to continue with medication*			
	Number of respondents	% of respondents	
Pain	1,177	68.8%	
Diarrhea	1,037	60.6%	
Bloating	933	54.5%	
Quality of life	805	47.0%	
Constipation	706	41.3%	
Incontinence	295	17.2%	
Other conditions	136	7.9%	

#### N=1,711

<sup>\*</sup> Participants require about 65-70% improvement of any of these symptoms to continue to take the medication.

# **SATISFACTION** WITH TREATMENT

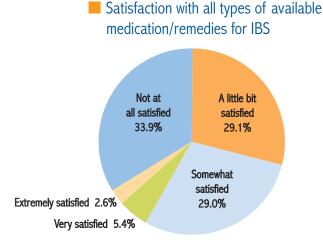
Respondents did not provide high marks of satisfaction regarding available treatment for their IBS.

- Only 8% of respondents are very or extremely satisfied with all types of treatment.
- One-third (34%) are not at all satisfied.

Participants are more satisfied with their current medications, but not overwhelmingly so. Less than one-third (31%) are very or extremely satisfied with their current medications.

Most respondents (95%) report seeing a physician for IBS during the past year.

- Nearly one-quarter (23%) are very or extremely satisfied with the care they received.
- Two out of five (20%) are not at all satisfied with the care they received.





5.4% did not see a physician for IBS in the last year

# EVALUATING RISK ASSOCIATED WITH MEDICATIONS

Respondents were asked how much risk they would assume to take a medication providing total relief from IBS symptoms but with serious adverse effects.

Their responses are striking and suggest just how crucial symptom relief is to their well-being.

- If offered a medication that would give them total relief of IBS symptoms, 8% of all respondents would accept a 1 in 100 chance of death to be symptom-free.
- Six percent (6%) would accept a 1 in 100 chance of serious and disabling side effects to be symptom-free.

These figures are considerably higher among just the group with *severe* IBS, indicating they will accept even higher risk levels.

- One in seven (15%) would accept a 1 in 100 chance of death to be symptom-free.
- One in nine (11%) would accept a 1 in 100 chance of serious and disabling side effects to be symptom-free.



### FDA INFLUENCE

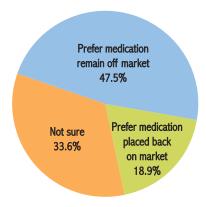
If a drug with a potential but unproven risk were removed from the market, a decision by the FDA has considerable impact on these respondents:

- 57% would feel greatly or completely affected by the decision.
- 38% would be greatly or completely worried to take the medication.
- 56% would believe that the medication may have already caused harm.

Opinions vary about keeping the drug off the market after FDA withdrawal. Nearly one-half (48%) would prefer that the medication stays off the market until the question of potential risk is resolved; nearly one in five (19%) would prefer that the medication be placed back on the market.

If the medication were to become available again, these respondents are open to abiding by several conditions:

- 14% would accept a warning label.
- 18% would agree to sign a waiver form with the physician in addition to the warning label.
- 33% would favor prescribing only by a GI specialist as well as accepting a warning label and signing a waiver form with the physician.
- Do you prefer the medication remains off the market until its risk is established?





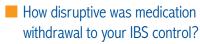
### Impact of drug removal

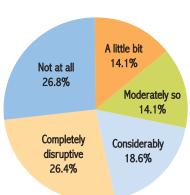
When IBS-targeted drugs have been taken off the market by the FDA, 260 respondents (13%) were taking these drugs\* at the time of removal; 9 individuals were taking both drugs, so the total number of cases in this study is 269.

More than two out of five (45%) found the withdrawal considerably or completely disruptive to the control of their IBS.

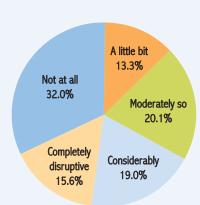
One-third found the withdrawal considerably or completely disruptive to their daily lives.

\* The IBS-targeted drugs were Alosetron and Tegaserod.





### How disruptive to your daily life was medication withdrawal?



# RELIABLE INFORMATION ABOUT MEDICATION RISK

Respondents use a variety of information sources regarding the risk of a medication they are taking or about to take.

- Frequent mentions went to the patient's physician (73%), pharmacists (49%), searching the Internet (38%), and specialty websites run by medical professionals working in IBS (35%).
- The least mentioned sources are news media reports (19%) and direct-to-consumer ads (10%).





Information sources, ranked	Where do you receive good information about medical risk?	
by frequency of response	Number of respondents	% of respondents
My physician	1,430	72.7%
Pharmacist	970	49.3%
Searching internet	738	37.5%
Websites run by IBS professionals	687	34.9%
Patient organizations	626	31.8%
FDA	603	30.7%
Deciding myself	457	23.2%
From news media reports	370	18.8%
Direct-to-consumer ads	205	10.4%
No response	4	-

Respondents were then asked to select their **best** source of information.

• Physicians again topped the list (44%) while the lowest-ranked reliable source remains direct-to-consumer ads (2%).

# **PROFILE OF STUDY PARTICIPANTS**

Respondents report an average age of 40 years and are predominantly:

- Female (83%)
- Caucasian (91%)
- Married (59%)

The average number of years of education is greater than 15, indicating a highly educated group. Most are from North America (72% from the U.S. and 7% from Canada).

### Geographic profile

Country you live in	Number of respondents	% of respondents
U.S.	1,409	71.7%
Canada	132	6.7%
Other*	425	21.6%

<sup>\*</sup>Other countries represented in this sample (at least 5 respondents) are the United Kingdom, Australia, India, Netherlands, New Zealand, Sweden, and South Africa.

### IBS classified by bowel symptom subtype

IBS Subtype	% of respondents
Diarrhea-predominant	29.3%
Mixed diarrhea/constipation/unspecified	61.0%
Constipation-predominant	9.7%

N = 1,787 fitting Rome III criteria

This study was conducted online and involved participants who visited the IFFGD and UNC websites seeking information. Therefore, results of this study may not apply to individuals who do not use the Internet to obtain such information.

### **MOVING FORWARD**

Behind every response in this study is a person struggling to understand and manage IBS on a daily basis. While most are connected to health providers and receiving some type of treatment, their symptoms continue to be troublesome and their lives are seriously impacted by their disorder.

The people who participated in this survey provided candid information on what relief they need and what risks they are willing to assume to achieve that relief. We thank all of our respondents for participating in this survey in the interest of improving IBS treatments.

More needs to be known about IBS and how to effectively treat it. Focused and sustained research is absolutely crucial. That's why IFFGD has been consistently at the forefront of encouraging and funding investigators in the field. We foster scientific exchange among leading researchers and clinicians through our biennial symposium and research awards, and we have collaborated on several projects to evaluate the prevalence of gastrointestinal disorders and to determine the needs of those affected.

Through IFFGD's direct efforts to support research, advocacy, educational websites, publications, and symposia, we provide needed support to IBS sufferers and their families around the world. Our ultimate goal is to help advance a science-based cure available to all patients.





### **Our Mission**

IFFGD is a nonprofit education and research organization. Our mission is to inform, assist and support people affected by gastrointestinal disorders. IFFGD has been working since 1991 with patients, families, physicians, practitioners, investigators, employers, regulators and others to broaden understanding about gastrointestinal disorders and support research.





### International Foundation for Functional Gastrointestinal Disorders IFFGD

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# Visit the UNC Center for Functional GI Disorders at: www.med.unc.edu/ibs

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