# **Burden of Disease in US Patients** With Irritable Bowel Syndrome With **Diarrhea (IBS-D)**

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# **OBJECTIVE**

Our study examined disease burden, care-seeking behavior, treatment, and satisfaction with control of symptoms, care, and treatment for those with IBS-D

# CONCLUSIONS

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# This large survey study demonstrates that the health impact of IBS-D is high

learly 1 in 5 patients sought care at an emergency room or were hospitalized for their symptoms, and abdominal pain was the most reported reason for their care



Abdominal pain and discomfort were common bothersome symptoms with patients reporting better control with prescription medications compared to over-the-counter agents

## INTRODUCTION

Background · Symptoms of IBS-D impose a significant burden to patients, impacting their quality of life and creating an economic burden<sup>14</sup> Information is limited on the patient's perspective of living with IBS-D

## **METHODS**

A. Data Collection An observational, cross-sectional study design used data cted through an online survey of United States (U.S.) adults aged ≥18 years

# RESULTS

Cohort and Control Populations Of 29,359 participants, 2.4% (n=699) met Rome IV criteria for IBS-D

 Matching resulted in 669 patients and 669 controls (Figure 1) Characteristics

 IBS-D patients and controls were primarily female (74.6%, n=499), White (84.0%, n=562), and had a mean age of 41.9 (SD 15.0) years (Table 1)

(Table 1):

- Depression scores (11.4 [SD 7.3] vs. 7.9 [SD 7.1])
- Incidence of insomnia (45.6% vs. 21.1%)
- Incidence of GERD (34.2% vs. 10.6%)

- 25.9 [SD 31.4])
- Health impact on daily activity ratings (4.3 [SD 3.2] vs.
- 2.6 (SD 3.11)



- Survey participants were recruited from a research panel that used digital fingerprinting and multiple quality control measures to ensure each participant was unique and valid, and to identify fraudulent responses All data were self-reported
- B. Survey Design

(Table 1)

12 months

COVID-19

Symptoms

(Figure 2)

was 3.2 (SD 2.4) (n=391)

 An IBS/CIC module was developed by AbbVie. Ironwood and experts in IBS/CIC and was included in a larger national

health research survey Survey participants selecting "IBS" "constipation (chronic, or more than occasional)" (constipation) or "diarrhea (chronic, or more than occasional)" (diarrhea) in the comorbid conditions section of the survey were routed to the module. Participants who did not select these conditions continued with the survey questions asked of all participants

· Compared to controls, IBS-D patients had significantly lower

- Mental health scores (36.7 [SD 12.5] vs. 43.9 [SD 11.8])

- Physical health scores (40.3 [SD 11.2] vs. 44.4 [SD 10.6])

Care Due to Bowel Movement Related Symptoms and/or

· Of IBS-D patients, 91.5% (n=612) sought medical care for

symptoms, and 59.3% (n=397) sought care in the past

Of those with a visit in the past 12 months, 34.8% (n=213) reported cancelling a healthcare visit for symptoms due to

· Mean number of visits for symptoms in the past 12 months

· Of IBS-D patients, 35.0% (n=234) had been to an ER or were

Mean number of ER visits or hospitalizations for symptoms in

visit or hospitalization in the past 12 months (87.1%) (n=101)

· Abdominal pain was the most common reason for an ER

the past 12 months was 2.5 (SD 1.8) (n=115)

hospitalized for symptoms, and 17.3% (n=116) had been to an ER or were hospitalized in the past 12 months

Emergency Room (ER) Visits or Hospitalizations Due to

Abdominal Symptoms (Symptoms) Visits With a Healthcare Provider Due to Symptoms  The initial questions of the module screened for IBS-D using Rome IV criteria and Bristol Stool Form Scale (BSFS) stoo types. Module questions assessed the following endpoints: abdominal symptoms, medication use, healthcare use due to IBS-D symptoms, and satisfaction with symptom control using escription (Rx) vs. over-the-counter (OTC) medications Survey questions asked of all participants included nographic and socioeconomic questions, comorbid ditions, Generalized Anxiety Disorder scale 7 items (GAD-7).5 Patient Health Questionnaire 9 items (PHQ-9).6 and Veterans RAND 12 items (VR-12),7 and the Work Productivity and Impairment (WPAI) questionnaire

 The module and survey were reviewed by an Institutional Review Board before fielding began in August 2020 · A pilot of the module confirmed the questions and response options were easily understood and the module length was

## Figure 2. Symptoms Leading to an Emergency Room Visit or Hospitalization in the Past 12 Months (n=116)





Current Treatment for Symptoms 65.9% (n=411) of IBS-D patients reported currently taking a prescription and/or an over-the-counter medication for their symptoms (Figure 3)

- 27.1% (n=181) currently take a prescription medication with or without an over-the-counter medication for
- 38.9% (n=260) currently take an over-the-counter medication without taking a prescription medication for
- symptoms Mean number of medications currently taken for symptoms was 2.1 (SD 1.3) (n=441)

## Figure 3. Treatments Currently Taken for Symptoms



## Table 2. Symptoms Experienced in the Past 7 Days

	Symptom experience, severity and frequency			
	Experienced N=669 % (N)	Severity* Mean (SD) (N)	Frequency "all" or "mo of the time"** % (N)	
ominal pain	71.0% (475)	5.5 (1.9) (475)	50.1% (238)	
ominal discomfort	70.9% (474)	5.3 (2.0) (474)	46.8% (222)	
ominal bloating	52.8% (353)	5.2 (2.3) (353)	47.9% (169)	
el urgency	44.4% (297)	6.3 (2.3) (297)	45.5% (135)	
nge in the number of bowel movements	43.0% (288)	5.8 (2.3) (288)	45.1% (130)	
ol consistency	39.6% (265)	6.2 (2.3) (265)	54.3% (144)	
ling of incomplete emptying	33.2% (222)	5.6 (2.4) (222)	49.5% (110)	
ining	32.7% (219)	5.2 (2.2) (219)	41.6% (91)	
ful bowel movements	30.2% (202)	5.5 (2.2) (202)	39.1% (79)	
al expansion of belly or abdominal area (distension)	23.9% (160)	5.6 (2.4) (160)	48.1% (77)	
ning	16.7% (112)	5.2 (2.7) (112)	26.8% (30)	
er	1.2% (8)	6.0 (2.5) (8)	62.5% (5)	
e of these	2.4% (16)	NA	NA	



## Table 1. Rome IV IBS-D Cohort and Control Characteristics

	Rome IV IBS-D Cohort (N=669)	Control (N=669)	Significance
Female	74.6%	74.6%	1.000
Age, mean (SD)	41.9 (15.0)	41.9 (15.0)	0.990
Black or African American	7.8%	7.8%	
White	84.0%	84.0%	1.000
Other	8.2%	8.2%	
Hispanic, Latino or Spanish origin	7.8%	8.5%	0.617
Northeast	17.2%	17.2%	
Midwest	22.6%	22.6%	4 000
South	42.8%	42.8%	1.000
West	17.5%	17.5%	
Charlson Comorbidity Index score, mean (SD)	0.6 (1.1)	0.6 (1.1)	1.000
Body Mass Index (BMI) (lbs/in <sup>2</sup> ), mean (SD)	30.2 (9.0)	27.9 (7.4)	< 0.001
Proportion educated more than high school	76.8%	72.8%	0.089
Median household income (Census derived from zip code), mean (SD)	65,468 (28,360)	65,459 (26,647)	0.996
Anxiety (GAD-7) score, mean (SD)	9.9 (6.1)	6.8 (5.8)	< 0.001
Depression (PHQ-9) score, mean (SD)	11.4 (7.3)	7.9 (7.1)	< 0.001
Chronic Pain	65.2%	39.2%	< 0.001
Migraines	38.1%	19.3%	< 0.001
Insomnia	45.6%	21.1%	<0.001
Gastroesophageal Reflux Disease (GERD)	34.2%	10.6%	< 0.001
VR-12 Mental Component Summary (MCS), mean (SD)	36.7 (12.5)	43.9 (11.8)	< 0.001
VR-12 Physical Component Summary (PCS), mean (SD)	40.3 (11.2)	44.4 (10.6)	< 0.001
VR-12 Health utility (VR-6D), mean (SD)	0.60 (0.11)	0.67 (0.12)	<0.001
Proportion employed" Absenteelism (hours), mean (SD) Presenteelism (hours), mean (SD) Overall work loss (hours), mean (SD) Health affected work productivity (0-10 scale), mean (SD)	54.2% 9.0 (20.6) 31.4 (29.1) 35.5 (31.1) 3.1 (2.9)	58.7% 6.6 (17.6) 20.9 (27.7) 24.5 (30.3) 2.1 (2.8)	0.187 0.163 <0.001 <0.001 <0.001
Daily activity impairment (hours) <sup>a</sup> , mean (SD)	43.2 (31.6)	25.9 (31.4)	< 0.001
Health affected daily activities (0-10 scale) <sup>a</sup> , mean (SD)	4.3 (3.2)	2.6 (3.1)	< 0.001
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Those with IBS-D reported lower quality of life than the control group, and had more productivity loss

Disclosures

## References

- Compared to controls, IBS-D patients had significantly higher
- Anxiety scores (9.9 [SD 6.1] vs. 6.8 [SD 5.8])
- Incidence of chronic pain (65.2% vs. 39.2%)
- Incidence of migraines (38.1% vs. 19.3%)
- Presenteeism (hours: 31.4 [SD 29.1] vs. 20.9 [SD 27.7])
- Overall work loss (hours: 35.5 [SD 31.1] vs. 24.5 [SD
- Daily activity impairment (hours: 43.2 [SD 31.6] vs.
- Health impact on work productivity ratings (3.1 [SD 2.9] vs. 2.1 [SD 2.8])

	Rome IV IBS-D Cohort (N=669)	Control (N=669)	
Female	74.6%	74.6%	
Age, mean (SD)	41.9 (15.0)	41.9 (15.0)	
Black or African American	7.8%	7.8%	
White	84.0%	84.0%	
Other	8.2%	8.2%	
Hispanic, Latino or Spanish origin	7.8%	8.5%	
Northeast	17.2%	17.2%	
Midwest	22.6%	22.6%	
South	42.8%	42.8%	
West	17.5%	17.5%	
Charlson Comorbidity Index score, mean (SD)	0.6 (1.1)	0.6 (1.1)	
Body Mass Index (BMI) (Ibs/in²), mean (SD)	30.2 (9.0)	27.9 (7.4)	
Proportion educated more than high school	76.8%	72.8%	
Median household income (Census derived from zip code), mean (SD)	65,468 (28,360)	65,459 (26,647)	
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Depression (PHQ-9) score, mean (SD)	11.4 (7.3)	7.9 (7.1)	
Chronic Pain	65.2%	39.2%	
Migraines	38.1%	19.3%	
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Gastroesophageal Reflux Disease (GERD)	34.2%	10.6%	
VR-12 Mental Component Summary (MCS), mean (SD)	36.7 (12.5)	43.9 (11.8)	
VR-12 Physical Component Summary (PCS), mean (SD)	40.3 (11.2)	44.4 (10.6)	
VR-12 Health utility (VR-6D), mean (SD)	0.60 (0.11)	0.67 (0.12)	
Proportion employed*	54.2%	58.7%	
Absenteeism (hours), mean (SD)	9.0 (20.6)	6.6 (17.6)	
Presenteeism (hours), mean (SD)	31.4 (29.1)	20.9 (27.7)	
Overall work loss (nours), mean (SD) Health affected work productivity (0-10 scale), mean (SD)	35.5 (31.1) 3.1 (2.9)	24.5 (30.3)	
Daily activity impairment (hours)*, mean (SD)	43.2 (31.6)	25.9 (31.4)	
Health affected daily activities (0-10 scale)* mean (SD)	43(32)	26(31)	
	/	. (411)	

# Figure 1. Rome IV IBS-D Cohort and Control Populations IRS-D initable howel syndrome with diarrh

### C. IBS-D Cohort Criteria

Inclusion

- · To participate in the survey, participants were required to be aged ≥18 years and to reside in the U.S. To qualify as an IBS-D patient, participants had to meet the
- following inclusion/exclusion criteria:
- Self-reported IBS, constipation, or diarrhea as a comorbid condition
- Meet Rome IV criteria for IBS-D9 Exclusion criteria:
- Self-reported IBS, constipation, or diarrhea as a comorbid condition but did not meet Rome IV criteria for IBS-D articipants not self-reporting IBS, constipation, or diarrhea as a comorbid were eligible to be matched controls. Controls were matched, 1:1, by age, sex, region, and Charlson Comorbidity Index (CCI)10,11 score with cases from the general

### D. Rome IV Criteria for IBS-D<sup>9</sup>

- Experienced abdominal pain on average at least ≥1 day per week in the past 3 months
- Abdominal pain was associated with the following: - Having a bowel movement
- Change in the number of times of bowel movement (too few, too many)
- Change in the form of bowel movement (looseness or hardness of stool Experienced ≥2 of the above for >6 months, either on-and-
- off or continuously Had BSFS stools 6 and/or 7 on the BSFS ≥25% of the time
- and BSFS stools 1 and/or 2 ≤25% of the time

### Analyses

- · Outcomes comparing IBS-D patients vs. controls were analyzed for anxiety (GAD-7), depression (PHQ-9), health-related quality of life (VR-12), and productivity (WPAI). Categorical and continuous variables were analyzed using chi-square and analysis of variance, respectively. Statistic comparisons were made with two-sided tests at the a = 0.05 gnificance level
- Outcomes analyzed for the Rome IV IBS-D Cohort included bealthcare wists, canceled visits and symptom impact due to COVID-19, and medication use (prescription vs. over-the-counter). Categorical data were described by percentage and continuous data were described by mean and standard leviation
- · All analyses were carried out with unweighted data

97.6% (n=653) of IBS-D patients experienced ≥1 symptoms

- Abdominal pain was the most reported symptom that was experienced in the past 7 days (71.0%) (n=475) (Table 2) Bowel urgency received the highest severity rating (6.3 [SD 2.3]) (n=297) (Table 2)
- Of symptoms experienced in the past 7 days, stool
- consistency was experienced with the greatest frequency (54.3%) (n=144) (other response options; sometimes, rely, and never) (Table 2)
- Abdominal pain was ranked the most bothersome symptom (34.5%) (n=225) (Figure 4)

Symptom Experience

in the past 7 days



Satisfaction

wel syndrome with diarrhea

- IBS-D patients were more dissatisfied than satisfied wit control of bowel (48.1% vs 24.7%) and abdominal (48.9% vs 26.2%) symptoms (Figure 5)
- IBS-D patients were more satisfied than dissatisfied with their healthcare provider's management of their bowel (40.4% vs 26.0%) and abdominal (41.8% vs 23.4%) symptoms (Figure 5)
- Those currently taking a prescription with or without an OTC were more satisfied with the control of bowel (39.2% vs 21.5%) and abdominal (40.3% vs 22.7%) symptoms than those taking only an OTC (Figure 5)

### Limitations

- Data were self-reported and participants were limited to those with computer access
- Bowel and/or abdominal symptoms could have been attributed to more than just IBS-D
- The study was undertaken during the COVID-19 pandemic which may have impacted outcomes
- Some outcomes had a small sample size and must be interpreted with caution





### Figure 4. Ranking of the Most Bothersome Symptom (n=653)