

IBS GLOBAL IMPACT REPORT 2018

Uncovering the true burden of irritable bowel syndrome (IBS)
on people's lives



This report has been funded and
facilitated by Allergan



With significant contribution
from the Gastrointestinal Society



ABOUT THE IBS GLOBAL IMPACT REPORT 2018

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This report provides insight from peer-reviewed journals and findings from clinical surveys on the impact of living with the symptoms of IBS and individuals' personal experience of the clinical management of their symptoms.

This edition follows the 2016 IBS Global Impact Report,¹ which presented key evidence outlining the individual, societal and healthcare burden of irritable bowel syndrome (IBS) globally. It found that IBS places a significant burden on society due to direct and indirect healthcare costs, and highlighted that despite its high prevalence, IBS does not receive the attention it deserves.¹ Finally, it aimed to stimulate discussion on how people with IBS may receive better management to improve outcomes. The Steering Committee of the report recommended the following actions:¹

- IBS guidelines - there is a need for simple guidelines that are applicable to everyday clinical practice, to help healthcare professionals (HCPs) diagnose and manage IBS with more certainty.
- Documenting the impact - there is a growing body of evidence to suggest that there are significant hidden costs of IBS; more research is needed to reveal the true costs of IBS. HCPs should ask individuals about the impact of IBS on their overall quality of life (QoL), as accurate assessment can be a crucial indicator of condition severity.
- Further research - a greater understanding of inefficiencies in IBS management may lead to an evidence-based, standardised approach to IBS care in the future.
- Allocation of resources - HCPs, commissioners and decision-makers should consider directing resources to those individuals with more severe symptoms and therefore highest need. In some countries, this could be delivered through IBS-specific models of care.

The present report looks beyond an investigation into the impact of IBS on daily life, to wider aspects including the impact on psychological wellbeing, and stigma and attitudes about IBS, as well as the challenges faced by people with IBS in navigating complex healthcare systems to seek appropriate support and management.



Steering Committee Members and Their Roles

This report represents a consensus view of the members of the Steering Committee. Both Professor Maura Corsetti and Professor Jan Tack are clinical experts and sat on the Steering Committee for the 2016 IBS Global Impact Report. Gail Attara is the Gastrointestinal Society's chief executive officer, and Michelle Sewell is a person living with IBS. Together, Gail and Michelle bring the perspective of Canadian individuals living with IBS to the report.



Professor Maura Corsetti

Clinical Professor of Gastroenterology,
University of Nottingham, UK



Professor Jan Tack

Head of Gastroenterology, Professor of
Internal Medicine, University of Leuven,
Belgium.



Gail Attara

President and Chief Executive Officer,
Gastrointestinal Society, based in Vancouver,
Canada.



Michelle Sewell

IBS Support Group representative for the
Gastrointestinal Society, based in Vancouver,
Canada

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Declarations of Interests

Maura Corsetti is a consultant for Allergan and Kyowa Kirin and has acted as speaker for Shire and Menarini. Jan Tack has given scientific advice to Abide Therapeutics, AlfaWassermann, Allergan, Christian Hansen, Danone, Ironwood, Janssen, Kyowa Kirin, Menarini, Mylan, Novartis, Nutricia, Ono Pharma, Rhythm, Shionogi, Shire, SK Life Sciences, Takeda, Theravance, Tsumura, Yuhan, Zealand and Zeria pharmaceuticals; he has received a research grant or support from Abide Therapeutics, Shire, Tsumura, Zeria and has served on the speaker bureau for Abbott, Allergan, AstraZeneca, Janssen, Kyowa Kirin, Menarini, Mylan, Novartis, Shire, Takeda and Zeria.

Gail Attara and Michelle Sewell do not have any declarations of interest.

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FOREWORD

I am the president and chief executive officer of two registered charities, the Gastrointestinal Society and the Canadian Society of Intestinal Research, which was founded in 1976. They have been using the BadGut® brand for more than 20 years.

At the Society, every day we get calls from individuals with digestive problems, many of whom have IBS, which affects approximately 13-20% of Canadians. They share their struggles living with the condition, including how it affects their physical condition, social life, working life, relationships, and psychological wellbeing. They tell us how their journey to diagnosis and finding an effective treatment can be a time-consuming trial. Many express a lack of support from friends, family and employers, whether because of the taboo to talk about their symptoms, or because many don't take IBS as seriously as they should.

I encourage you to read through this thoughtful impact report, which includes many previously unpublished comments in the words of those who experience IBS on a daily, and sometimes hourly, basis. By combining so many patient voices with comprehensive research, this report shows the plethora of ways that IBS affects those with this condition.

Our responsibility to the person with IBS is to work collaboratively with all those involved in IBS management to encourage change within the system. We need to challenge the perceptions that surround IBS, and make sure that individuals are listened to, not teased, when they mention any of the ABCDs of IBS, namely abdominal pain, bloating, constipation, and/or diarrhea. We must end the stigma that surrounds IBS and ensure it is recognized as a true medical condition, one that needs management, effective treatments and understanding.

With our sights set firmly on the future, our vision is for the management and care of those with IBS to be consistent and effective. This report highlights examples of clinical best practices, puts forward a set of patient expectations for care, and makes a series of recommendations aimed at HCPs involved in IBS management. Together, these provide a roadmap for change. Only by working together and encouraging a collaborative approach can the challenges faced by individuals with IBS be addressed so they can transform from a life of striving to one of thriving.



Gail Attara
President and Chief Executive Officer
Gastrointestinal Society



EXECUTIVE SUMMARY

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IBS is a chronic bowel disorder that significantly impacts people's lives. People with IBS frequently report feeling depressed, embarrassed, self-conscious, and an inability to predict symptoms, which places significant burden on daily living. The condition has a negative effect on the quality of relationships and limiting participation in routine social activity.

Many of those with IBS believe that they are not taken seriously and a diagnosis of IBS can leave them feeling stigmatised. Some who have IBS may be discouraged from seeking medical help because they believe that they will not be heard by the HCP, and absence of effective support may also contribute to feelings of social isolation.

On average, it takes four years for individuals with IBS to receive a definitive diagnosis. During this frustrating journey, they will try a range of self-management support options and will search for advice from a range of sources such as the internet and newspaper articles. On receiving a diagnosis, people with IBS can still struggle to get the support and effective treatment that they need.

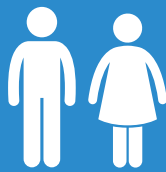
Guidelines for the management of IBS developed by the Rome Working Group, the World Gastroenterology Organisation, and several national gastroenterology societies set out a universal standard of care for IBS but they are not rooted in everyday clinical practice. There is an absence of simple management guidelines to support an individualised treatment approach and the lack of standardised pathways contributes to variation of medical care in terms of symptom control.

Difficulties in communication and lack of time to discuss symptoms or ask questions are the most common problems experienced by people when interacting with their HCPs. The importance of a good patient-physician relationship is increasingly recognised as part of best practice IBS management and improving clinical outcomes.

FAST FACTS: ABOUT IBS

IBS is a chronic functional bowel disorder characterised by symptoms of abdominal pain and altered bowel habit (constipation and diarrhoea), in the absence of structural or biochemical abnormalities that are detectable with the current routine diagnostic tools.²⁻⁴

IBS is the most common condition diagnosed by gastroenterologists and is one of the most frequently seen conditions by primary care physicians (PCPs).^{2,5}



IBS affects both men and women of all ages.⁶ It is thought only a fraction of individuals with symptoms of IBS seek medical attention.⁸ Most individuals will initially consult PCPs for their symptoms, and the factors that drive this consultation are symptom severity, especially pain, and concerns that symptoms might indicate an underlying severe disease, such as cancer.^{2,9}



The prevalence of IBS globally is 11%,⁶ however, it is thought that IBS often remains underdiagnosed.⁷

Symptom-based criteria of IBS were first developed in 1989 by an international working group based in Rome (the Rome criteria).¹⁰ These criteria have been updated in the Rome II, III, and most recently, in 2016, the Rome IV criteria for IBS.^{4,11,12} However, awareness of the criteria by PCPs is limited and the criteria are often perceived as too complex to use in clinical practice.¹³

According to the Rome IV diagnostic criteria, IBS is characterised by recurrent abdominal pain for, on average, at least one day per week in the past three months, associated with two or more of the following:⁴

- Symptoms related to defecation.
- Symptoms associated with a change in stool frequency.
- Symptoms associated with a change in stool form or appearance, based on the Bristol Stool Form Scale (BSFS).



Subtypes of IBS are recognised by the Rome IV criteria based on the person's reported predominant bowel habit, when not on medications, as follows:

- **IBS-C:** with predominant constipation (Bristol types 1 and 2).
- **IBS-D:** with predominant diarrhoea (Bristol types 6 and 7).
- **IBS-M:** with both constipation and diarrhoea (Bristol types 1 and 6).^{4,12}



The symptoms most frequently reported for IBS-D are: abdominal pain and discomfort, abdominal bloating, distension, urgency and diarrhoea.¹⁴



The symptoms most frequently reported for IBS-C are: abdominal pain, bloating and constipation.⁴



The underlying cause of IBS is still unclear¹⁵ and, as there are no diagnostic disease markers for IBS, guidelines recommend HCPs make a positive diagnosis using criteria that are based on the person's symptoms.¹⁶⁻²¹

RECOMMENDATIONS: A VISION FOR INDIVIDUALS WITH IBS

This report captures the immense challenges faced by people with IBS and highlights a need for action that places the needs of the individual at the centre. IBS places a considerable burden on healthcare systems, and clinical knowledge relating to diagnosis and treatments is suboptimal.^{22,23} People with IBS report that they are not listened to by their HCPs, can wait an average of four years for a positive diagnosis, and once finally diagnosed, may receive treatments that do not have proven efficacy or a robust evidence base.^{23,24}

Our vision is to ensure that the care of those with IBS is consistent and effective moving forward. People with IBS deserve the right:



To receive a timely diagnosis such as at the first follow-up visit after the first consultation and, if indicated, investigation cycle.



To feel that they are heard with empathy, that their IBS is taken seriously, and that the impact of their symptoms is validated and acted upon.



To have access to effective, evidence-based treatments that are tailored to meet their individual needs.

These individuals' expectations are the stepping stone of an IBS Patient Charter that puts the individual at the centre of their IBS care. The Steering Committee calls for adoption of this framework into a patient charter by patient groups and professional organisations that support people with IBS across the world.

Healthcare professionals have a critical role to play to support this vision as follows:

1



IMPROVE COMMUNICATION WITH PEOPLE WITH IBS

- Recognising the benefit of a good patient-physician relationship in improving clinical outcomes, physicians should adopt a structured approach, such as the six-point plan produced by the World Gastroenterology Organisation (see page 44).
- HCPs should consider the use of explanatory models to help them articulate the underlying mechanisms, the symptoms of IBS and subsequent treatment approaches in a way that is meaningful for people.
- Professional bodies, medical organisations and patient groups should share the patient materials that they produce to ensure that individuals have access to relevant tools to help them capture and communicate to their physicians the full impact of IBS on their daily lives.
- Objective measures should be adopted to capture the complete burden of IBS, including missed work days and missed social occasions.

2



DRIVE EARLY DIAGNOSIS OF IBS

- There is a need for a simple and practical diagnostic algorithm that can enable HCPs to quickly recognise the symptoms of IBS and equip them with the confidence they need to identify IBS and communicate the diagnosis to their patients.
- National diagnostic criteria and coding systems should be updated to ensure that IBS is coded accurately.

3



DEVELOP SIMPLE, PRAGMATIC GUIDANCE FOR IBS MANAGEMENT

- Design simple management guidelines that are applicable for everyday clinical practice. They should be based on emerging models of care that consist of a stepped approach to treatment tailored to each person, according to individual symptoms, disease impact and preferences.
- IBS management guidelines should prioritise IBS treatments according to their proven efficacy.
- In countries in which it does not already exist, professional bodies, medical organisations and patient groups should join forces to develop and make available evidence-based information for people with IBS to enable them to make informed decisions regarding their IBS treatment.



IMPACT ON QUALITY OF LIFE



Summary*

People with IBS frequently report feeling depressed, embarrassed and self-conscious. Their inability to predict symptoms places significant burden on daily living. IBS limits productivity and performance at work, has a negative effect on the quality of relationships, and limits participation in routine social activity.

Due to the often unpredictable and persistent nature of the symptoms, people with IBS make considerable life-limiting changes, and the full impact of the condition is often under-reported to HCPs.

IBS also has a personal financial burden with individuals sometimes trying multiple over-the-counter (OTC) treatments and alternative therapies in their quest to be symptom-free; costs can be significant due to the lack of information about the effectiveness of these purported remedies.

* This summary reflects consensus opinion of the Steering Committee.

1.1 Impact of the symptoms of IBS: Validating IBS

Those with IBS have significantly impaired QoL.³ The symptoms of IBS can have a substantial ‘dampening’ effect on daily life due to their frequency, severity, unpredictability and persistence, which means that sufferers often need to make lifestyle alterations in order to accommodate their IBS.²⁶⁻²⁹ These significant re-orderings of daily life are not always revealed to treating physicians however, leading to under-reporting of both symptom severity and frequency.²⁶

“Living with IBS is very difficult. I like to travel and I always have to know where a washroom is and I have to travel with a bucket and wet wipes in my vehicle and my purse. I carry extra underwear every day in my purse.”

Canadian person living with IBS²⁵

As symptoms can be unpredictable in nature, people with IBS often worry about when they may occur.^{29,30} In a 2004 study of over 500 IBS-D patients, 37% agreed with the statement **‘I’m constantly worrying about when the IBS symptoms will return.’**³⁰

The American Gastroenterology Association (AGA) conducted a survey of 3,254 IBS patients, both diagnosed and undiagnosed, to understand the impact that IBS has on people’s lives.²⁴ The survey showed that in 65-70% of cases, people with IBS reported being **symptom-free for a few days before their symptoms returned.**²⁴ In an international online survey involving 513 IBS-D patients, **the majority reported that they experience intermittent symptoms anywhere from 8-17 days per month.**³¹ In a European survey of 450 respondents, those with **IBS-C** reported that they experience symptoms for an average of **10.5 days per month.**³²

Daily activities for many people with IBS tend to be centred around two factors: managing symptoms and their treatments.²⁷ A 2009 study identified four main perceptions for the daily activities of patients with IBS: ‘not being in control’, ‘not being able to trust their bodies’, ‘invasion of privacy’ and ‘loss of dignity’.²⁹

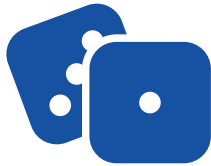


The extent to which managing the daily symptoms takes a toll on daily living can be demonstrated by investigating what individuals would be prepared to give up or risk in order to live symptom-free.²⁸

In an international survey of 1,966 IBS sufferers, on average:



Patients reported they would give up **25%** of their remaining life (approx. 15 years)²⁸



14% said they would risk a 1/1000 chance of death to live symptom-free²⁸

In an international survey involving 513 IBS sufferers, on average:



46% of IBS-D patients agreed with the statement that "I'm willing to try anything to help manage my IBS"³⁰



11% agreed with the statement "when my IBS is bad I wish I was dead"³⁰

Imagine a day where you feel ill from having eaten too much, then imagine that day lasts months at a time.

Australian person living with IBS³³

It's like you're always on a roller coaster. Something that I could eat today with no issues, could cause me to feel like death tomorrow. Fear that the lack of understanding and acknowledgement of this disease can leave me feeling like I can never tell people what is truly wrong.

Canadian person living with IBS²⁵

I have learned thru [sic] some really bad experiences to wear layers of protection. Pads or liners don't do it. You need to wear torn up sheets/towels – anything to keep you from soiling everything.

Canadian person living with IBS²⁵

I spent the night in the hospital in extreme, extreme pain. They did every test possible – they thought it was a burst ovary – and after a CT scan, they said it was just extreme constipation as a complication of untreated IBS.

Canadian person living with IBS³⁴

Effects of symptoms of IBS-D on quality of life

From the findings of the AGA survey (with more than 3,400 respondents), the emotional experiences of patients with IBS-D were characterised by an **inability to predict symptoms** that caused **embarrassment** and patients were forced to be always near a bathroom.³⁵

- **47%** of respondents with IBS-D stated that they had little or no ability to predict their symptoms on a daily basis.
- When asked how IBS-D affects them, 81% stated that they **avoided situations** where there **was no nearby bathroom**.
- In addition to frustration, the most common emotions experienced by respondents with IBS-D included **self-consciousness** and **embarrassment**.³⁵



In an international survey of over 500 IBS-D patients, **25% agreed** with the statement that, **“having IBS-D stops me enjoying life”**.³⁰ A review also showed treating IBS-D can improve health-related quality of life (HRQoL).¹⁴

“ I wake up and need to go to the bathroom, I usually urgently need to go. In the mornings, I need to go five to six times, until about 10 am. Then it calms down a bit and it starts again in the afternoon. ”

French person living with IBS³³



Effects of symptoms of IBS-C on quality of life

From the same survey conducted by the AGA, the emotional experiences of patients with IBS-C were characterised by attempts to **self-treat with numerous over-the-counter (OTC) medications**, leading to **frustration, dissatisfaction**, and **depression**.³⁵ Respondents with IBS-C were likely to be taking two or more types of OTC drugs each month.³⁵



32% of IBS-C respondents reported feeling **depressed** because of their condition almost every day in the previous month.³⁵



When asked how IBS-C affected them, **76%** said **they did not feel 'normal'** and **64%** stated that they felt **'self-conscious'** about how they looked.³⁵

HRQoL for those with IBS-C is low compared to those with chronic conditions such as diabetes, heart failure and heart defects, who have a high rate of mortality,¹⁵ and also those with asthma, migraine and rheumatoid arthritis, with well-known morbidity.³⁶

“Not feeling well most of the time and when going on holidays it's very stressful because I'm dependent on restaurant foods and then dealing with constipation for the entire trip.”

Canadian person living with IBS²⁵

Co-morbidity in IBS:

The symptoms of IBS can overlap with other conditions and research also indicates that IBS can often co-exist with other functional disorders of the upper and lower gastrointestinal system.^{3,37} These include: functional dyspepsia (FD), heartburn, gastroesophageal reflux disease (GORD) and nausea as well as incontinence, and disturbance of pelvic floor muscular coordination (dyssynergia).³ The presence of several functional GI disorders probably reflects underlying physiological processes, such as problems with motility control or intense pain within the inner organs.^{12,38} The overlap between IBS and FD has been found to be between 75% (IBS-D and FD) and 85.5% (IBS-C and FD).³⁹ Meanwhile, in a study of 100,000 individuals, of those meeting the criteria of one or more of the conditions of GERD, FD, and IBS, 30.7% had overlap between two or all three conditions.⁴⁰ With increasing age, the likelihood of co-morbidity increases; this may aggravate the symptoms of IBS, or lead to a delay in the diagnosis of IBS.⁴¹

Fatigue in IBS:

“ Inability to function normally – severe fatigue, severe [gastrointestinal] GI symptoms and urgency, difficulty being out of house, extremely limited diet, no matter what I do symptoms are worsening and regularly flaring. Cannot work, have kids. Have sought medical care over and over with not much help, often dismissed and not taken seriously. ”

Canadian person living with IBS²⁵

“ Exhaustion from lack of sleep when I’m having a bad bout in middle of night. I generally go every 10 minutes for about 4-5 hours then it stops. ”

Canadian person living with IBS²⁵

A 2013 study involving 175 patients with moderate to severe IBS showed that **fatigue was reported as a symptom in over 60% of patients with IBS, compared with 5-20% of the general population.**⁴² Similarly, in a 2016 systematic review across 24 studies, **54% of those with IBS experienced symptoms of fatigue**, with gastrointestinal symptoms, psychological symptoms and reduced HRQoL being the most common correlating with symptoms of fatigue.⁴³ However, the underlying cause for fatigue co-morbidity is not known.⁴³

A 2016 study of 160 IBS patients found that **fatigue affected their ability to perform work, physical activities and domestic activities, and also their ability to interact socially.**⁴⁴ Additionally, more severe fatigue was accompanied by more severe IBS symptoms, depression and anxiety. It was recommended that fatigue, as a symptom of IBS, should be treated to improve patient QoL.⁴⁴

“ I feel teary eyed when I have to tell you this. It really does stop you from a lot of things in life like going away – you’re always afraid that something’s going to happen. Or if I do go away – where is the closest hospital? And am I going to ruin everybody’s good time? ”

Canadian person living with IBS³⁴

1.2 Impact of IBS on working life

Data collected via a 2014 patient reporting, market research and surveys have highlighted that living with IBS affects the ability to work.²² However, there is a surprising lack of studies regarding the impact of IBS on work and loss of earnings.²²

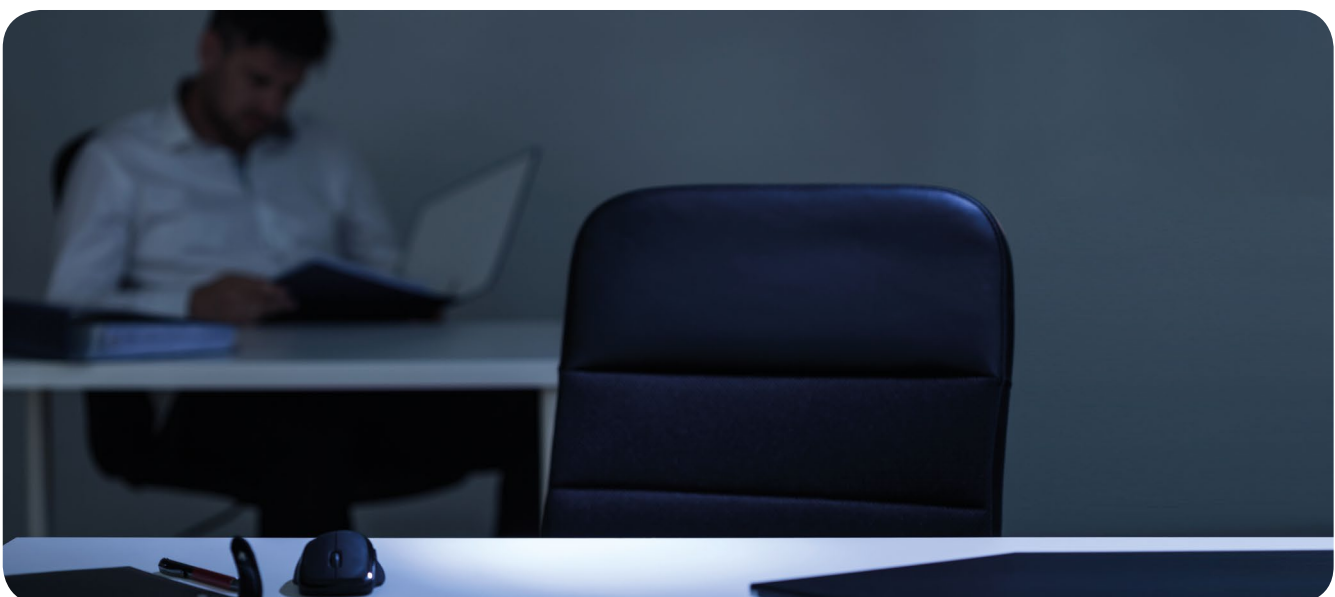
“ Sometimes I cannot do the things I want to do... I've missed out on social events...symptoms affected work, and I missed some days off work. Currently unemployed, partly because of being off sick due to IBS. ”

Canadian person living with IBS⁴⁵

A European survey has shown that **people with IBS are twice as likely to take time off work than those without IBS.**³² Higher rates of absenteeism, presenteeism, and impairment in performing daily activity were observed regardless of IBS subtype compared to non-IBS population.³² Using the work productivity and activity impairment score (WPAI), individuals diagnosed with IBS-D (n=859) and IBS-C (n=450) had an average work productivity loss of 31.4% and 33.3% respectively compared to 19.6% for individuals not diagnosed with IBS (n=59,155).³²

“ I have not been able to work because I am regularly having to use the bathroom for my bowels. When I do have to use the bathroom I am in there a long time, and this would not be acceptable at any job. I also cannot socialize or go to fun places because of this. Therefore, I don't go far away from my home anymore...I know that food often causes issues quickly for me, so I am always scared to eat when I am not at home. ”

Canadian person living with IBS²⁵



The International Foundation for Functional Gastrointestinal Disorders (IFFGD), in collaboration with the University of North Carolina (UnC) Center for Functional GI and Motility Disorders, conducted a survey of 1,966 patients with IBS in the US.⁴⁶ The survey: 'IBS Patients: Their Illness Experience and Unmet Needs' found that:



13% of respondents were unemployed due to their health status.⁴⁶

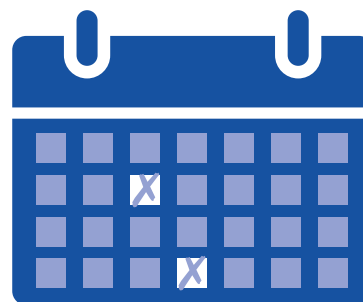


Of those unemployed, nearly one-third (**30%**) of participants with severe symptoms **were jobless** due to their health compared to **5%** for participants with mild symptoms.⁴⁶

In the AGA survey, patients with IBS reported that their symptoms:



Interfered with their productivity and performance during an average of **nine days per month**.²⁴



Caused them to **miss school or work** for an average of **two days per month**.²⁴

Furthermore, a survey of 2,961 patients with IBS (both with and without a formal diagnosis) conducted by the Gastrointestinal Society in Canada showed that **46% had missed work or school** due to IBS symptoms.⁴⁷

A focus on IBS-D and work productivity

20% of IBS-D patients agreed with the statement **'My IBS has badly affected my working life.'** (Survey of over 500 IBS patients in France, Germany, Italy, Spain, UK, Canada, and Australia)³⁰



A 2016 study of 58,161 respondents (859 diagnosed IBS-D; 370 undiagnosed IBS-D; 56,932 controls) showed that patients with IBS-D found that they have **significantly greater impairments in work** productivity and daily activities, compared to controls.⁴⁸



Those with severe IBS-D had a **significantly lower rate of labour force participation (48%)** compared with those with moderate (65%) or mild (67%) IBS-D.⁴⁸



IBS-D patients also reported up to **15 missed work days in a year due to their symptoms** (compared to 11 days for the control group).⁴⁸

A focus on IBS-C and work productivity

In a cross-national survey of more than 271 employed people with IBS-C in the EU, those with IBS-C had a significant reduction in work productivity relative to controls, amounting to almost two hours more of missed work per week and a twofold reduction in work productivity compared to controls.⁴⁹

Another survey³² of 450 patients across Europe with IBS-C found that those with IBS-C had:



33.3% reduction in work productivity vs 19.6% for healthy controls



11.8% absenteeism vs 5.3% for healthy controls

Beyond the effects that the symptoms of IBS have on work productivity and efficiency, the associated psychological distress caused as a result of IBS has been shown to affect general physical and mental health.⁵⁰ A review of the psychosocial impact of IBS, published in 2015, showed that patients with IBS reported high rates of psychological distress, with depression and anxiety, that resulted in reduced productivity at work.⁵⁰

20 *People would be knocking on the door of the loo, 'Come on, the next meeting's about to happen. You've got hurry up, mate.' They didn't get it. I couldn't get out of that loo, until I finished whatever the heck was going on. Eventually, I got so sick because of the diarrhoea, I started to be a bit run-down and I was losing weight. Then, the company moved me to part-time work, said, 'Maybe take a bit of time out, just get yourself sorted.' I went part time. They shifted me to a lower demanding job.*

Australian person living with IBS³³

1.3 Impact of IBS on social life and relationships

People living with IBS often report the significant impact it has on their daily activities, social life, and relationships.^{26,27,47} Much of this has been captured in patient surveys, which allow patients time to provide detailed information on their symptoms and impacts.^{24,46,47} A Canadian survey that was completed in 2016, showed that IBS affects personal, social, and working life.⁴⁷ People with IBS have described difficulties with eating and with basic tasks that require exertion, difficulty interacting socially with friends and family, limitations on their ability to work, and the emotional impact of their condition on themselves and their caregivers.²⁷

It is frustrating, depressing, and controlling. It can take over and prevent any fun in life.

It is socially isolating. It is a dietary nightmare. On bad days, it makes me want to cry.

It rules your whole life. Even when I make plans, I have to cancel at the last minute because of sudden symptoms.

Canadian individuals living with IBS²⁵

In the Canadian survey involving 2,961 respondents, 76% of respondents stated that their symptoms interfered with daily life, with **37% stating that they “did not leave home when they had symptoms of IBS-D”**.⁴⁷

“ I cannot make plans ahead as I never know when it will affect me. [I’m] not able to work because I never know when I will have to call in that I am unable to work. [I]solation, fear, always feeling that I smell. ”

Canadian person living with IBS²⁵

The same Canadian survey also showed that 32% either ‘always’, or ‘often’ experience limitations to their social activities in an average month.⁵¹



A study published in 2017 involving 1,094 respondents into people with IBS-D found that IBS significantly affects QoL.⁵² Of the patients in the study, those with diagnosed IBS-D reported:



“It really sucks because I never know when I’m going to have an attack and IBS continually has me cancelling plans.”

Canadian person living with IBS²⁵

Effects of IBS on relationships:

The symptoms of IBS also affect intimacy and personal relationships.⁵³ For women with IBS, an association with painful sexual intercourse (dyspareunia) has been reported since the 1980s, when a study comparing sexual function in women with IBS, inflammatory bowel disease, and duodenal ulcers showed a prevalence of painful sexual intercourse (dyspareunia) in 83%, 30%, and 16% of women respectively.⁵⁴ The 2016 AGA study highlighted that nearly two-thirds (64%) of IBS-C patients and 55% of respondents with IBS-D reported that they “**avoided having sex**” because of their symptoms.³⁵

“If your internal system is off, your mind is off. It affects your entire day, your mood and can affect relationships.”

Canadian person living with IBS²⁵

“I find it very stressful and it puts a strain on relationships as one never can commit 100% to something.”

Canadian person living with IBS²⁵

Effects of IBS on relationships:

The results of a 2013 study undertaken to quantify the degree of the burden on partners of patients with IBS and to identify the areas of relationship that were affected, found that partners of patients with IBS had a significant personal and psychological burden compared with partners of healthy individuals. This perceived burden increased with severity of IBS symptoms and poorer sexual and relationship satisfaction.⁵⁵ The study also showed that for partners, this burden had a major impact on the sexual relationship.⁵⁵

“It’s very hard on the partner. I have to keep leaving rooms. Very difficult to have a proper social life as there are so few restaurants I can eat at.”

“My husband and two teenage children understand, but no one outside of my household seems to understand if I have to decline invitations.”

“There need to be studies done to help people get their lives back. You should be able to go out and have lunch with family and friends instead of worrying when this will hit you because there is no if, it’s when.”

“You need to talk to your spouse or friends about it. It is amazing how many people suffer the same symptoms.”

Canadian individuals living with IBS²⁵



The Steering Committee note that the impact of IBS on partners, or the perspective of partners/carers in living with or caring for someone with IBS is an important domain and that additional research would be beneficial. While research has shown that those with IBS tend to under-report their symptoms²⁶ and learn to “live with their condition”,³⁰ partners and carers witness first-hand the strain and burden imposed by IBS symptoms and, therefore, may provide a more objective overview. Conducting scientific research into the difference in the reporting of symptoms, between patients and partners, could help provide further understanding.*

* This summary reflects consensus opinion of the Steering Committee.

1.4 Impact of IBS on personal finances

“ [I] only use OTC medication as needed, and try to use natural laxatives (senna) to avoid side effects. [The] financial impact [is]: \$40-45/month for laxatives, stool softeners, and hemorrhoid [sic] treatments. ”

A 45-year-old female patient from Canada with a five-year history of symptoms of IBS-C. The patient is a former social worker, currently unemployed.⁴⁵

Many people with IBS are dissatisfied with conventional medical therapies and will seek alternative methods of treatment in the search for symptom relief.^{30,56} In the lead up to a diagnosis, those with symptoms of IBS will try multiple OTC treatments,³⁰ and even once a diagnosis of IBS has been made, PCPs may also recommend alternative therapies, or dietary adjustments,^{24,57} that have no or limited evidence of efficacy,^{21,56} and which can result in a financial burden for the individuals as they seek any type of relief.²²



Between **15% and 43%** of patients **pay out-of-pocket expenses** for treatment to relieve symptoms of IBS.²²



As many as **47%** of Canadians with IBS report that they **spend more than \$150 per month** on their IBS treatments to relieve their symptoms.⁵¹



Meanwhile, as many as **26%** of Canadian IBS patients admit they can only afford some of the IBS treatments prescribed to them, while **16%** say they **cannot afford their medications** at all.⁴⁷

Prior to a diagnosis, **three-quarters** of patients in the US report to having **tried OTC products before speaking to a HCP** about their symptoms, trying an average of 3.6 OTC products.²⁴ **The majority of patients reported taking OTC medications for a year** or less before consulting a HCP.²⁴

Complementary and alternative medical therapies include, but are not limited to, acupuncture and probiotics.^{21,58,59} For those with IBS, dissatisfaction with current treatment leads them to try alternative approaches.⁶⁰ The fact that more than half of those with IBS report to having used complementary and alternative medicine (CAM),⁶¹ indicates dissatisfaction with current treatment and a willingness to seek non-conventional treatment options.⁵¹



A study conducted in 2014 involving 135 respondents showed that intake of certain foods is recognised to be an important trigger of symptoms in 90% of people with IBS.⁵⁷ However, the relationship between food and IBS still remains undefined⁵⁷ and research continues. A Canadian survey indicated that many have used, or are currently using, dietary changes, including the low-FODMAP diet specifically, as IBS treatment,^{47,57} despite the fact that these diets can be complex, restrictive, and, for some, financially burdensome.⁵⁷



There is a lack of adequately powered and well-designed randomised, controlled trials pertaining to dietary intervention in IBS and while many people use dietary changes in attempt to manage their IBS symptoms, clinical literature highlights that more evidence is required to support any recommendations.⁵⁷



Self-management: The need for guidance and clarity on evidence

In addition to the financial burden of self-management, the Steering Committee note the psychological impact that it can impose on people when their IBS management is unsupported. The Committee noted that there is a tendency among those who have IBS to seek multiple treatments, and to perpetually try new alternative treatment approaches. This journey of cycling through various products and modalities places an additional burden on individuals' lives. They can be bombarded with information, in particular unfounded claims via the internet, and it is difficult to know which, if any, self-management measures carry benefit. Further information should be made available to patients by the medical community that set out which treatment options are the most beneficial, based on clinical efficacy, and research.*

* This summary reflects consensus opinion of the Steering Committee.



PSYCHOLOGICAL IMPACT AND ATTITUDES



Summary*

Many of those with IBS believe that they are not taken seriously and report a lack of belief on behalf of HCPs that their symptoms are real. A diagnosis of IBS can leave people feeling stigmatised and they may often hide their diagnosis from friends and co-workers.

Some individuals with IBS may also be discouraged from seeking medical help because they believe that they will not be heard and understood by the HCP. The common absence of medical information or effective support may also contribute to a person's feeling of social isolation.

The chronic nature of the condition carries a psychological burden. In 40–60% of cases, IBS is accompanied by psychological symptoms that include depression, anxiety disorders, and post-traumatic stress syndrome. Because anxiety and depression increase the chances of developing IBS symptoms, and result from IBS, some people are caught in a vicious cycle of worsening physical and psychological symptoms.

* This summary reflects consensus opinion of the Steering Committee.

“Patients should not be left feeling alone and confused, and ultimately not believed about symptoms and how the patient physically and emotionally feels during flare ups.”

Canadian person living with IBS²⁵

2.1 Psychological impact of a diagnosis of IBS

Patients with IBS suffer psychologically due to the chronic nature of the condition.⁵⁰ They are also affected psychologically by the stigma of a diagnosis of IBS and the lack of belief that IBS is real⁶² and research has shown that depression and anxiety levels in IBS patients are greater than in controls.^{50,63,64}

“ At one time, at the early stage, I lost 20 lbs in about 4 weeks because I could not eat anything without diarrhea [sic]. I was worried I would lose so much weight and be unhealthy or die from weight loss. Then I had a lot of anxiety because I could not go out and do normal things other people take for granted. ”

Canadian person living with IBS²⁵

“ IBS has prevented me from having a life. I was and am still hesitant to go out to dinner or concert or any function. I always get nervous about my IBS and that stress does not help the situation. ”

Canadian person living with IBS²⁵

Research in 2016 indicates that it is necessary to address both the physical and psychological needs of people with IBS as early as possible because improving psychosocial symptoms improves the physical symptoms.⁶⁵

Between 40-60% of people with IBS suffer from psychological symptoms that include depression, anxiety disorders and post-traumatic stress disorder (PTSD).^{50,66,67}



Studies published in 2013, 2014 and 2017 have shown that **anxiety and depression both increase the chances of developing symptoms of IBS** and result from IBS, which means that **some patients with IBS may develop a vicious cycle of worsening physical and psychological symptoms.**^{21,68,69}

Studies on functional gastrointestinal disorders have shown a possible association with early events causing psychological symptoms and the development of bowel symptoms, which go on to form a vicious cycle of cause and effect.⁶⁸



“ I wish I could control my IBS, 16 years living with this condition I’ve lost over 120 lbs, it’s taking a horrible toll on my body physically mentally and emotionally. [It’s] very depressing and draining having to have lots of visits with healthcare professionals, gastroenterologists and emergency room visits just to get the same result: ‘it’s IBS, go home and deal with it.’ ”

Canadian person living with IBS²⁵

2.2

Perceptions and social attitudes to a diagnosis of IBS

There are many people who suffer (from IBS), but it's a taboo topic. I don't know how many people suffer from it in Spain, diagnosed and undiagnosed, but there's no treatment really. How to live with it? De-stigmatise it, so people do not have to suffer in silence.

Spanish person living with IBS⁴⁵

Individuals can view their IBS negatively, which causes a range of emotions and feelings.²⁴ In a study of 3,254 people with IBS, the most common feeling reported when asked how they felt when their GI symptoms were bothering them was feeling “frustrated”, which was cited by three-quarters of the respondents.²⁴ This was followed by 48% who said their symptoms made them feel “self-conscious”, 39% “embarrassed”, 37% “fed up” and 34% “depressed”.²⁴

Can't plan anything. End up cancelling due to pain. Excitement and stress increase painful [sic] symptoms. Bloating and gas is embarrassing. Sharp pains come out of the blue and make you gasp, and [it] is embarrassing in public.

Canadian person living with IBS²⁵

Stigma, or prejudice, can be perceived, experienced or internalised and is the belief or labelling of a person as being different or abnormal.⁷⁰ **Studies conducted in 2009 and 2014 showed that more than half of those that were interviewed were treated differently because of their IBS.**^{71,72} The stigma associated with IBS can also result in being unable to participate in daily activities and social activities.^{62,72}

It's very hard to live with IBS if some of the people around you write you off as using IBS as an excuse for not joining in a lot of activities. It takes my self-confidence away.

Canadian person living with IBS²⁵

The symptoms of IBS can be difficult or embarrassing to discuss,²⁶ and people with IBS hide their condition because they consider it shameful.⁷³



Due to societal taboos around discussions of bowel functioning, and historically viewing digestive disorders as psychosomatic, people may experience stigma.⁷²



These factors can lead to internalised stigma and reluctance to tell others about their diagnosis of IBS.^{29,70}



Some individuals with symptoms of IBS may choose to hide the condition except to inform immediate family members and sometimes friends and co-workers.²⁶

According to research, employers and co-workers are the most likely to make people with IBS feel stigmatised, followed by HCPs and friends.⁷¹

This can severely limit your employment options. It is hard to find a job where you can go to the washroom whenever and however many times that you need to. Regular attendance is impossible and absences are looked down upon. Laziness [sic] and immaturity is often assumed by others when you call in sick for work or can't attend classes.

Canadian person living with IBS²⁵



Due to its intrinsic link to food, social isolation for those with IBS is often related to meal times.^{3,57,73} Enjoying meals with friends and family is a common form of social interaction. Therefore, inability to participate because of a fear of IBS symptoms (pain, urgency, diarrhoea or distension) occurring during, or immediately after, a meal can be devastating and can result in social isolation.^{3,73}

2.3

Perceptions and attitudes of healthcare professionals to people with IBS

People with IBS feel that **they are not taken seriously by HCPs**^{72,74} and feelings of stigma from healthcare providers have been shown to be correlated with more frequent, severe and disruptive IBS symptoms.⁷² IBS sufferers tend not to discuss the condition broadly outside close family and sometimes friends, and few discuss the full extent to which IBS affects their lives with their treating HCP.²⁶ **Individuals perceive that doctors do not give credence to the fact that they are ill and consequently their complaints are not taken seriously.** They also report that they can feel discredited in the eyes of the medical profession when they sense that doctors have failed to recognise the impact of the diagnosis on their QoL and appear unsympathetic to their concerns.⁷⁵

Taft and colleagues have highlighted the differences between perceived, enacted, and internalised stigma in chronic diseases, including IBS.^{70,72} People with IBS perceive more stigma from their healthcare providers when compared with patients with inflammatory bowel diseases (IBD) such as Crohn's disease and ulcerative colitis.⁷⁰ This is due to stigma around discussion of bowel habits which is often perceived as a sensitive issue.²⁶ Social isolation is made worse when physicians appear to provide inadequate information or medical support to people with IBS.⁷⁶

“ It would be nice if [IBS] was not looked at as a woman's psychological issue and treated like the medical condition that it is. ”

“ Medical practitioners have not been overly helpful and it takes too long for someone to take you seriously. IBS symptoms can be very severe and debilitating, and it is exhausting during a flare-up trying to obtain medical assistance. ”

“ Healthcare professionals often say it is all in my head - my naturopath thought otherwise and found supplements that really helped. ”

“ Educating the public would be great - and caregivers, I know more than my family physician. ”

Canadian individuals living with IBS²⁵

Ten patients interviewed in 2014, all attending an outpatient clinic and suffering from severe IBS, reported that their encounters with HCPs were negative, and often induced feelings of confusion and self-doubt.⁷⁴

Patients described positive interactions with their physicians as **“being listened to,” “being believed,”** and **“being taken seriously”**.⁷⁴ Those patients with severe IBS described how they often felt a need to defend themselves and try to retain their sense of self-worth in the face of trivialisation and disbelief by HCPs.⁷⁴

“When it’s bad it can be debilitating; you can’t leave your house, you’re in pain, and it can be very embarrassing. And my doctor has basically said ‘sorry, there is nothing I can do’. Sometimes I’m made to feel like I’m making it up.”

Canadian person living with IBS²⁵

In a survey of over 500 patients with IBS-D:³⁰



32% agreed with the statement: “healthcare professionals do not take IBS seriously.”



25% agreed that “my healthcare professional should invest more time and energy into educating me about my IBS.”



22% agreed that “healthcare professionals say you have IBS when they have run out of ideas.”

In an international survey involving 513 IBS-D patients, **27% agreed that “IBS is a condition that healthcare professionals don’t understand”**.³¹

“I think they’re [healthcare professionals] frustrated. They’d much rather you walk in with something they can fix on the spot. I think they can see IBS patients as a lot of trouble, and I get that. First, IBS patients tend to be people who don’t get really listened to by anybody, because they sound like a bunch of whiners.”

Australian person living with IBS³³



THE PATIENT JOURNEY AND CHALLENGES TO ACHIEVING TREATMENT



Summary*

On average, it takes four years for an individual to receive a definitive diagnosis of IBS. During this confusing and frustrating journey, patients will try a range of self-management support options and will search for advice from a range of sources such as the internet and newspaper articles, many of which are not even proven effective for IBS.

On receiving a diagnosis, people with IBS can struggle to get the support and effective treatment that they need to manage their symptoms. In their lifetime, those with IBS will consult with more than four different physicians or healthcare providers about their IBS symptoms.

Without a collaborative approach to the management of IBS, there is a risk that those with the condition will become lost in the system and left without effective treatment.

* This summary reflects consensus opinion of the Steering Committee.

3.1

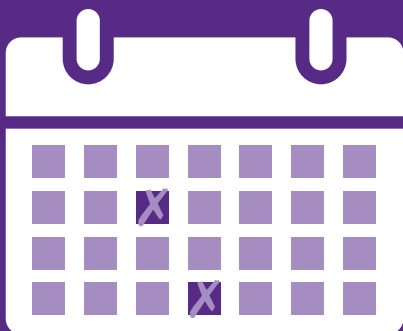
Experiences of navigating the healthcare system as a patient

“My GP didn't help at all... He referred me to a gastroenterologist and there was a three-month wait... I explained the whole story to him; he was pretty good, but he didn't really help me. Some people said he was amazing. I didn't have a choice. I wanted somebody who would have a whole plan in place to deal with IBS. He had no plan at all. He just said [he would do] an endoscopy and colonoscopy and we'll see what happens. They scheduled that, got it done and found nothing. He said hopefully I'll just heal on my own after a few months and, if not, we can get further tests. The last step, because we'd done everything, was to send me for imaging to check the small bowel.”

Canadian person with IBS⁴⁵

Research has shown that people with IBS often experience a confusing and frustrating journey, both in the path leading to diagnosis and following diagnosis, in finding adequate support and treatment.²⁶

Research shows that patients will wait on average for four years before a diagnosis of IBS is established.²³ During this time, patients will often move between seeking self-help support options, searching for advice from the internet²⁸ and from family and friends, before eventually engaging with HCPs.²⁴ In a recent study (2015) of 3,254 people with IBS, **67% stated that they experienced symptoms for more than a year before seeing a HCP.**²⁴



In an online study involving 1,966 respondents, individuals with IBS were found to consult with more than four different physicians or HCPs about their IBS symptoms in their lifetime.⁴⁶ On average, those with IBS reported having seen a physician for their symptoms three times during the previous six months, and during the previous year, they reported seeing a PCP (89%) or a gastroenterologist (55%).⁴⁶

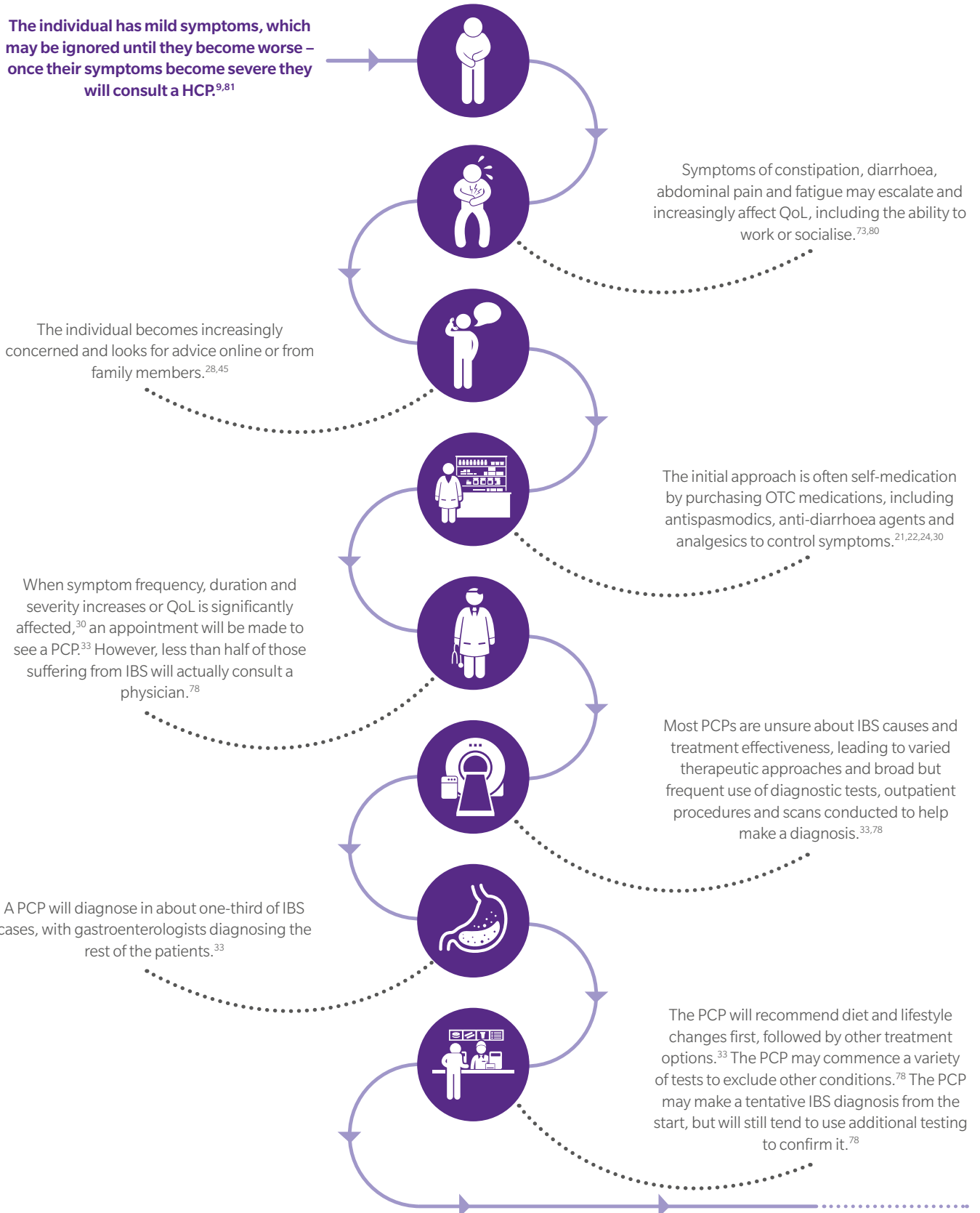
“ I saw a gastroenterologist in 2007 and had a colonoscopy done in 2008 that did not show any physical issues. Diagnosed with IBS straight after the colonoscopy. Only three appointments with the specialist. Told not to worry, because there is little importance associated with IBS (not a cancer), need to ‘learn to live with it.’ Asked if it was temporary or permanent, but told it was chronic but not constant, it could present at any time but not all the time (stress is a factor). Healthcare professionals pay little attention to IBS, [and I’m] not offered any specific treatment. It seems that there is little investigation in this area. ”

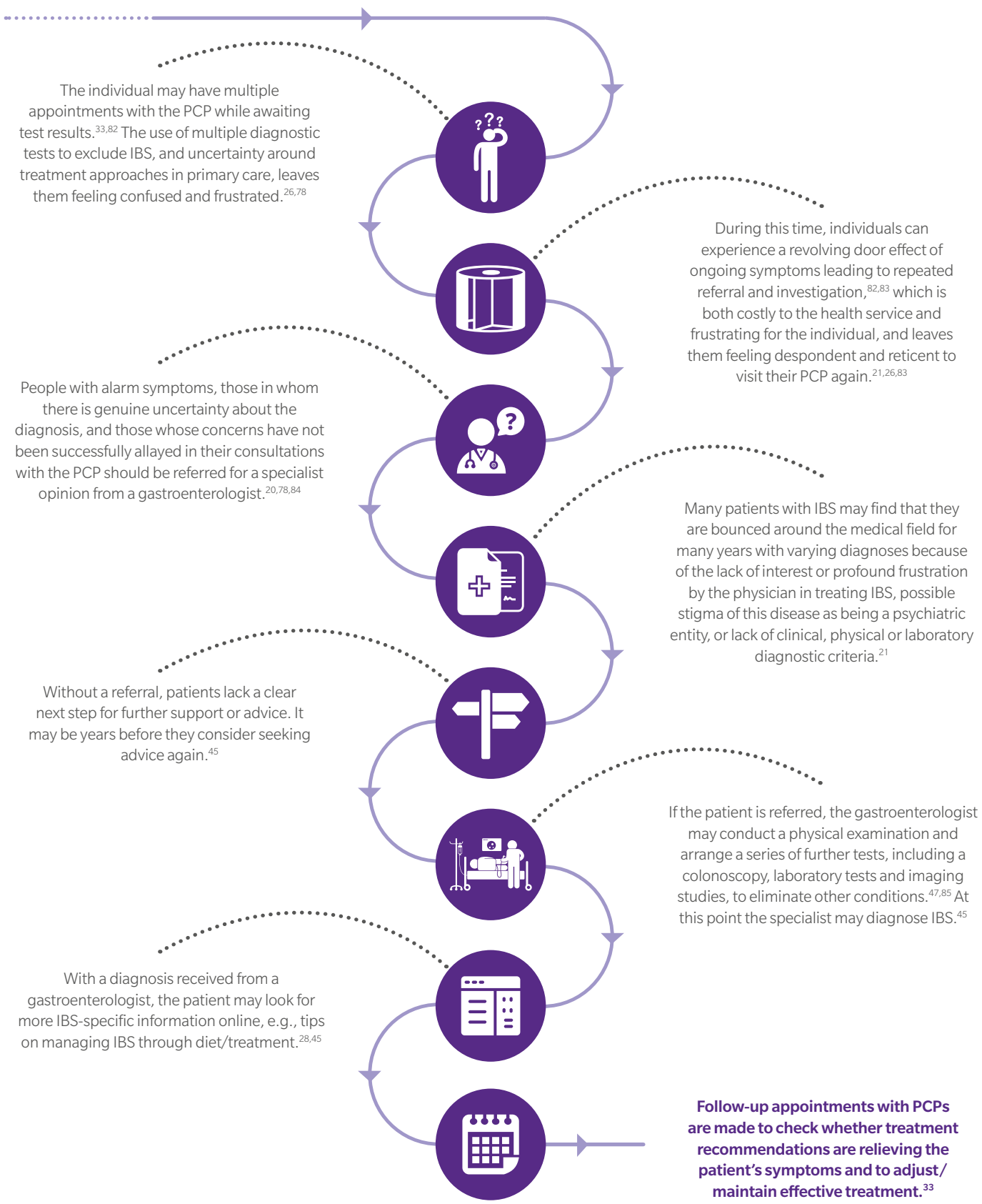
Spanish person living with IBS⁴⁵

From recent literature, management guidelines and patient surveys, it is possible to show the current typical pathway that patients with symptoms due to IBS may experience, to reach a diagnosis of IBS.^{6,17,20,24,46,47,77-80}



The typical pathway to a diagnosis of IBS





There is a requirement for a collaborative approach to the management of patients with IBS between primary and specialist care in terms of referral, diagnosis, treatment choice and ongoing management. Otherwise there is a risk patients will become lost in the system and learn to live with their symptoms.⁴⁵



FINDING SOLUTIONS TO ACHIEVE MORE EFFECTIVE SYMPTOM CONTROL



Summary*

Guidelines for the management of IBS developed by the Rome Working Group, the World Gastroenterology Organisation and several national gastroenterology societies set out a universal standard of care for IBS but they are not routed in everyday clinical practice. There is an absence of simple management guidelines to support an individualised treatment approach.

The lack of standardised pathways contributes to variation of medical care in terms of symptom control. A 2016 patient survey found that when it comes to their symptoms, 79% felt they had either no control, or control over only some of their symptoms.

Difficulties in communication and lack of time to discuss symptoms or ask questions are the most common problems experienced by patients when interacting with their HCPs. The importance of a good patient-physician relationship is increasingly recognised as part of best practice IBS management and improving clinical outcomes.

* This summary reflects consensus opinion of the Steering Committee.

4.1

Achieving more effective symptom control in IBS: What should physicians and other healthcare professionals do?

As highlighted through surveys and through patient reporting, current treatment remains unsatisfactory for most patients²³ and the majority complain of inadequate control of their symptoms.⁵¹ A 2016 survey, involving 2,916 individuals with IBS, found that when it comes to their symptoms, **34% have reported to have no control over any of their IBS symptoms, and 45% had control over only some of their symptoms.**⁵¹



Waking up with cramps that have me doubled over in pain and last several hours, constipation - never feeling empty - bloating, at one point looked like I was pregnant.

Canadian person living with IBS²⁵



People with IBS want to be heard and understood – and therefore physicians should be aware of the negative impact of symptoms on individuals’ daily lives, and the frustration that results from repeatedly trying treatments that have little effect.^{26,30}

However, people often report that they **don’t feel listened to by HCPs**, and feel ‘discredited’ when physicians appear unsympathetic to their concerns and when they sense that the impact of IBS on their QoL has not been taken into consideration.^{30,75} A lack of effective advice and treatment from HCPs can result in people giving up seeking medical help and instead beginning to try either dietary modifications or alternative treatments.⁶⁰ In some cases, dissatisfaction regarding physician visits can lead patients to feeling let down by healthcare services.⁶⁰

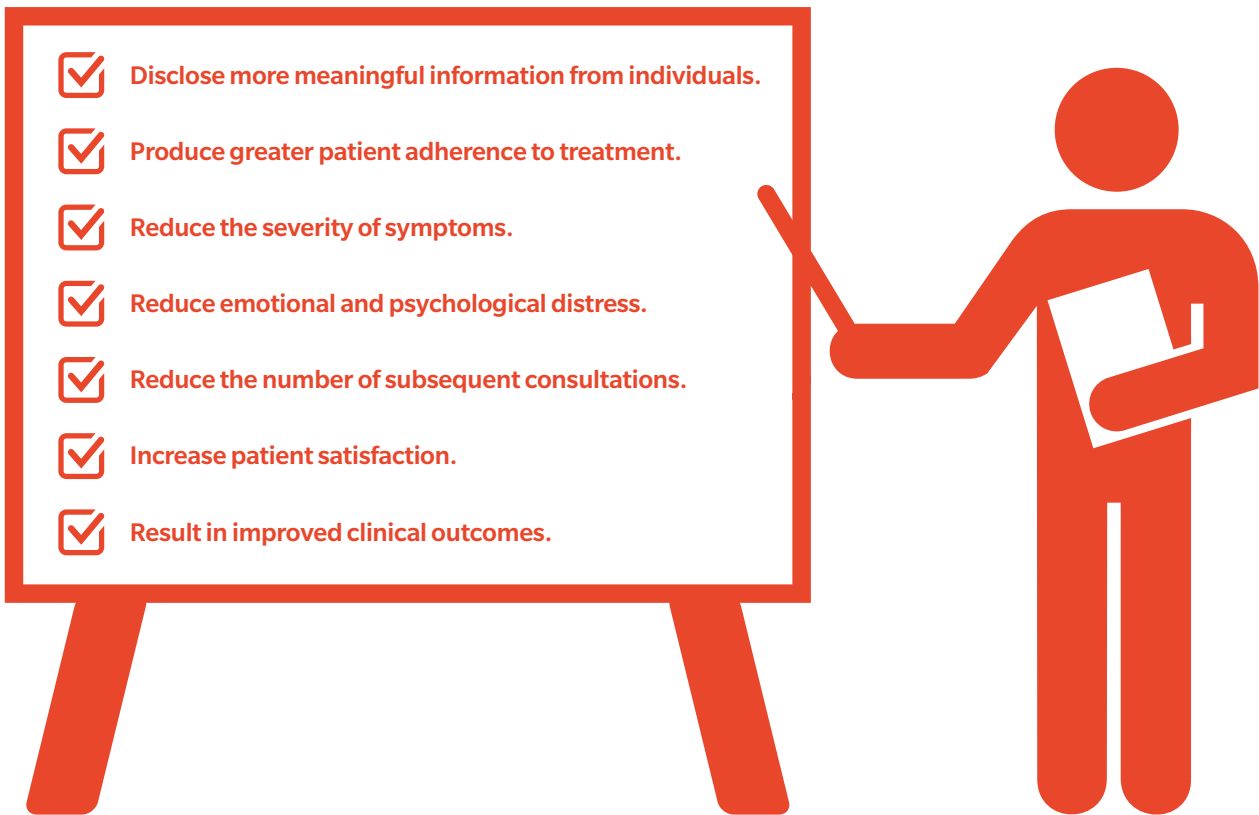


Individuals express the desire to have more time in their healthcare consultations.³⁰ Research conducted on 330 respondents shows that when given time to discuss their symptoms, those with IBS may be more likely to provide details about their experiences, and studies have shown that if uninterrupted, **78% of patients will only need two minutes to complete their initial statement of complaints, even in a busy tertiary referral centre.**⁸⁶ Keeping a food diary or logging events that correlate with the onset of symptoms are increasingly being used to allow people time to provide detailed information.^{21,87}



It is recognised that there is a need for more effective interviewing and communication skills in gastrointestinal medicine.⁸⁸ Increasingly, the importance of a good physician-patient relationship and use of person-centred care principles is being perceived as part of best-practice IBS management.^{56,89}

Adapting communication skills for physicians and improving the relationship between physician and patient has been shown to:^{56,75,90}



- ✓ **Disclose more meaningful information from individuals.**
- ✓ **Produce greater patient adherence to treatment.**
- ✓ **Reduce the severity of symptoms.**
- ✓ **Reduce emotional and psychological distress.**
- ✓ **Reduce the number of subsequent consultations.**
- ✓ **Increase patient satisfaction.**
- ✓ **Result in improved clinical outcomes.**

There is also often a mismatch between individuals' beliefs about their IBS and the physicians' understanding.⁷⁵

It is important that clinicians understand their patients' beliefs and then provide education and reframe their understanding before patient acceptance occurs.^{75,90} However, individuals who remain dissatisfied with information provided about their diagnosis will continue to pursue new diagnostic tests and treatments.^{75,91}

The quality of relationship between physician and patient in IBS is more strongly associated with the way in which individuals feel they are managed by their physician than the physician's ability to offer a successful treatment.²⁶



When healthcare providers take the time to discuss lifestyle changes with their patients, satisfaction with the consultation has been shown to increase.⁴⁵ Quicker referral to a specialist and greater empathy from the PCP also results in increased patient satisfaction with the consultation.⁴⁵

Explanatory models (EM) are useful tools for understanding how individuals relate to an illness and expectations for treatment.²⁶ However, **'failure to address differences between patients' and physicians' EMs can disrupt the treatment process.'**²⁶ Development of an integrated EM which combines the individual's symptom experiences and aetiology of IBS has been shown to have the potential to enhance the physician-patient relationship and improve treatment outcomes.⁹² To improve success, research suggests that the individual's personal EM should be addressed during a consultation and any successive medical interventions should be aligned with the patient's disease perception.²⁶

Drossman has developed a 15-point plan to improve communication between patients and physicians, which can be summarised into four key themes:⁹⁰

- 1 Listening to the patient**
- 2 Providing a positive diagnosis and explaining it simply**
- 3 Creating an optimal individualised management strategy**
- 4 Following up**

The 15-point plan emphasises the need for the following behaviours: active listening, observing, facilitating, accepting the reality of the disorder, eliciting the patient’s viewpoint from their personal and sociocultural perspective, empathy, avoidance of stigma and validation of the patient’s feeling.⁹⁰

The World Gastroenterology Organisation (WGO) has also stressed the importance of the physician–patient relationship and recommended attention to the following, during the initial clinical assessment and follow-up.⁹³

Recommendations from the WGO:⁹³



1

Identify and explore the patient’s concerns and accept that the symptoms are real.



2

Appreciate the impact of the symptoms of IBS on the patient.



3

Discuss the anxieties that the patient has about their symptoms, help to answer questions, reassure, and eliminate unnecessary worries.



4

Identify and help to resolve stressful factors.



5

Reduce patient avoidance behaviour, as this form of behaviour has a negative effect on the prognosis.



6

Provide general guidance on diet and exercise, including where appropriate, high-fibre diets, regular meals, hydration and physical activity.

4.2 Improving communication: What should people with IBS do?

The AGA recommends to patients three steps to improve communication with their physician:²⁴



Speak Up Early: Talk to a HCP as soon as possible after the onset of symptoms, instead of talking to a friend or family.



Speak Up Completely: Detail the symptoms to your HCP, including how the symptoms impact life, mental health, work, and social interactions.



Speak Up Often: Inform the HCP if symptoms return despite initial treatment efforts so that alternative treatment approaches can begin.

Survey studies that have used questionnaires have shown the benefit for patients with IBS of being able to discuss and detail their symptoms in a written form.^{24,46,47} In 2014, Marquis and colleagues advocated the use of an IBS symptom diary and event log for the measurement of the IBS symptom experience from the perspective of the patient.⁸⁷ Those with IBS should record their symptoms, or at least the frequency of them, to help explain the severity of their IBS.

4.3 The need for simple, evidence-based guidelines for IBS

Simple guidelines to support a confident diagnosis

Despite great strides in the understanding of IBS in recent years,²¹ there is still a lack of understanding regarding the causes of IBS and the complex interactions between the gastrointestinal symptoms and associated symptoms.³

Properly diagnosing IBS can be challenging and uncertain for HCPs for several reasons:⁹⁴

- 1 **There is no biological marker of IBS.**
- 2 **The symptoms of IBS are often difficult to quantify objectively.**
- 3 **The symptoms can vary among individuals with IBS.**
- 4 **Many organic conditions can masquerade as IBS.**

The last point in particular, and the uncertainty often prompts HCPs to conduct a series of diagnostic tests, and leads many HCPs to view IBS as a diagnosis of exclusion.⁹⁴ **Additionally, many individuals can fear that some other more sinister diagnosis (especially cancer) has been overlooked.**^{60,75}

Best practice diagnostic criteria recommend clinicians make a positive diagnosis on the basis of symptom criteria, in the absence of any alarming features, and urge physicians not to think of IBS as a diagnosis of exclusion despite its broad differential diagnosis.^{4,56,85,94} This recommendation is based on evidence that diagnostic testing has a generally low yield, is not cost or clinically effective, or supported by evidence.^{56,94,95}

Simple guidelines to support effective management

At this time, there remains no treatment or pathway regarded throughout the world as being universally applicable to the management of all IBS patients.⁹³ Recommendations regarding IBS management have been broad in their application, and directed to all individuals in a one-size fits all approach.⁸¹ There have been several published management guidelines for IBS, but these have mainly focused on diagnosis, with supportive approaches to patient management.^{17,19-21,96}

Because of a lack of standardised pathways for IBS, global variations have been reported in the medical care for people with IBS in terms of control of symptoms.^{21,93,97} More recently however, there has been increasing recognition of the benefit of individualised treatment pathways and management based on tailored approaches for people with IBS.^{56,81,83}



In a step toward supporting clinicians to take more effective treatment approaches, in 2014, the American College of Gastroenterology (ACG) performed a systematic review on the available treatments for IBS.¹⁷ The primary objective of the review was to assess the efficacy of available therapies in treating IBS compared with placebo or no treatment. The secondary objectives included assessing the efficacy in treating IBS according to predominant stool pattern reported (IBS with constipation, IBS with diarrhoea, and mixed IBS), as well as assessing adverse events.¹⁷



The WGO Guidelines on IBS, which were updated in 2015, also include a summary of the evidence of the efficacy pertaining to different treatments used in the management of IBS and set out recommendations for treatments based on this evidence.⁹³ The recommendations align to overall symptoms and to specific symptoms including pain, bloating and distension.⁹³

A step wise approach is now recognised as the optimum approach to IBS management.^{18,56,81} This starts with a confident diagnosis, explanation, reassurance, dietary and lifestyle advice sufficient for milder symptoms, and moves on to pharmacotherapy, selected according to the most predominant symptom, or combination of symptoms, which is considered the 'next step' for those with moderate to severe IBS.^{56,81}

A treatment algorithm published in 2017 developed by a multi-national working group of experts **aims to help primary and secondary care physicians navigate key stages to reaching a positive IBS diagnosis and provide guidance on how to prioritise the use of specific management strategies.**⁹⁸ Through provision of simple visual tools, it illustrates the key stages to reaching a positive diagnosis of IBS and sets out a simple, stepwise approach to patient-centred management targeted toward the most bothersome symptoms, taking into account patient preferences.⁹⁸

Guidelines including those from the ACG and National Institute for Health and Care Excellence (NICE) are beginning to recognise the need for robust evidence to support treatment choices for patients with IBS.^{17,20} However, guidelines that direct physicians as to how to prioritise the use of different agents are still lacking.⁹⁹ Understanding that IBS has a complicated physiology with a complex manifestation of symptoms that vary from individual to individual, is key to future successful management of IBS.^{15,94}

GLOSSARY

Acupuncture: An alternate or complementary medical technique used to relieve pain; an ancient Chinese medicine technique involving the insertion of fine needles under the skin in specific locations.

AGA: American Gastroenterological Association.

Algorithm (diagnostic or treatment): A set of instructions or rules that will help to calculate the answer to a question.

BadGut®: The Gastroenterological Society and The Canadian Society of Intestinal Research are charitable organisations using this brand.

Bloating: A feeling of fullness or swelling in the abdomen that often occurs after meals.

Bristol Stool Form Scale (BSFS): A scoring system to evaluate symptoms related to defaecation, change in stool frequency, and a change in stool form or appearance.

Carer (caregiver): A non-healthcare professional who is involved in caring for a person with IBS.

Clinical efficacy: The extent to which an intervention or treatment is effective when studied under controlled conditions.

Cochrane review: A systematic review of the evidence from primary research in human health and health policy, produced by the Cochrane Collaboration, and which is available electronically from the Cochrane Library.

Coeliac disease: Coeliac disease is an autoimmune condition which is triggered by the protein gluten. Gluten triggers an unusual immune response that leads to damage of the millions of microscopic finger-like projections (villi) that line the inner wall of the small intestine. Common symptoms include anaemia, diarrhoea, constipation, weight loss, nausea, fatigue and abdominal pain.

Cognitive behavioural therapy (CBT): A form of psychotherapy that focuses on thinking, behaviour, and problem-solving, to help people in the ways they think (cognition) and in the ways they act (behaviour).

Colonoscopy: A visual inspection of the inside of the lower bowel using a colonoscope to look for abnormalities of the lining of the bowel; during colonoscopy, a tissue biopsy may be taken for examination by microscopy.

Co-morbidity: The co-existence of more than one disease in an individual.

Compliance (or adherence): The extent to which a person adheres to the health advice agreed with HCPs.

Constipation: Bowel movements are infrequent, hard, dry and difficult to pass.

Crohn's disease: A chronic inflammatory bowel disease (IBD) that can affect any area of the gastrointestinal tract, from the mouth to the anus. The inflammation involves the lining of the digestive system and symptoms include diarrhoea, abdominal pain, fatigue, weight loss and blood/mucus in your faeces. This is unrelated to IBS.

Diarrhoea: Frequent and watery or loose bowel movements.

Differential diagnosis: Two or more diseases, with similar symptoms, that need to be distinguished to determine the definitive diagnosis.

Diverticular disease or diverticulosis: These are interchangeable terms meaning the presence of small sack-like pouches of the colon lining (diverticula) that balloon through the outer colon wall, occurring most frequently in the lower section of the colon, which is located on the left side of the pelvis. Diverticulosis is often present without any symptoms. Many symptoms are similar to those of IBS, and often include changing bowel activities such as constipation or diarrhoea, or alternating between the two extreme stool consistencies.

Diverticulitis: Is when the diverticula (noted above) become inflamed and/or infected. There might be an increase in diarrhoea, cramping and bowel irritability, and symptoms can include intense pain, abdominal cramping, bleeding, bloating and fever.

Dyspareunia: Pain during or after sexual intercourse, due to medical or psychological reasons, found more commonly in women.

Endoscopy: A diagnostic procedure that uses an endoscope to visualise, diagnose or treat a condition of the gastrointestinal tract (gastroscopy, colonoscopy, sigmoidoscopy).

Epidemiological study: A study of how a disease is distributed across different populations, which can be used to plan and evaluate strategies to prevent illness.

Extra-colonic symptoms: IBS symptoms not directly associated with the bowel, such as low back pain, bladder symptoms and gynaecological symptoms.

Flatus: Gas or wind in the intestines, produced by the normal activity of bacteria in the bowel.

FODMAP: Fermentable, oligo-, di-, and mono-saccharides and polyols (FODMAPs) are short-chain carbohydrates that can be poorly absorbed by the small intestine in some individuals.

Functional bowel disorder (FBD): A group of gastrointestinal disorders with symptoms attributed to the mid or lower gastrointestinal tract without a structural or biochemical cause, and includes IBS.

Gluten: A protein found in several types of grains, including wheat.

Gluten intolerance or gluten sensitivity: Non-coeliac gluten sensitivity is a non-allergic response to one of the many other components of wheat, possibly a different protein, or a carbohydrate.

Healthcare professional (HCP): Physicians, nurses and allied health professionals.

Health-related quality of life (HRQoL):

A combination of an individual's mental, physical, and social wellbeing and not just the absence of disease.

IFFGD: International Foundation for Functional Gastrointestinal Disorders.

Inflammatory bowel disease (IBD): Is a term that primarily refers to two conditions or diseases of the intestines: Crohn's disease and ulcerative colitis. These diseases have a few similarities but do differ significantly in two key ways: the area of the digestive tract affected and the extent of the inflammation. These diseases are unrelated to IBS.

Irritable bowel syndrome (IBS): A functional bowel disorder (FBD) which has no structural or pathological 'cause', and is characterised by symptoms that include pain, bloating, diarrhoea (IBS-D) and/or constipation (IBS-C).

Literature review: A summary of the evidence contained in several studies.

Meta-analysis: A quantitative, formal, epidemiological study design used to combine the results of several published studies that address the same question, enabling conclusions to be reached about that body of research.

Prevalence: The proportion (percentage) of people with a particular disease within a given population at a given time.

Prognosis: The likely course or outcome of a disease.

Randomised controlled trial (RCT): A comparative study that includes participants who are randomly assigned to treatment and control groups; patients are followed to examine differences in outcomes between the groups.

Refractory IBS: IBS that does not respond to first-line treatment after 12 months and who develop continuing symptoms.

Stool: Solid waste that is discharged in a bowel movement.

Transit time: The length of time food takes to pass through the gastrointestinal tract.

Ulcerative colitis: A chronic inflammatory bowel disease (IBD) consisting of fine ulcerations developing on the inner lining of the large intestine. This is unrelated to IBS.

WGO: World Gastroenterology Organisation.

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ADDENDUM

Ref 31: IBS-D Quantitative Market Understanding Study (Patients): 260131926-2

IBS-D Quantitative Market Understanding Study, conducted by Kantar Health in the UK, Australia, Canada, France, Germany, Italy and Spain. 30-minute online survey conducted with IBS-D patients throughout January to April 2016. Total sample was 513 IBS-D patients across 7 markets. Patients must be diagnosed with IBS-D and have experienced both diarrhoea and stomach pain/discomfort/spasm for more than 1 year. Patients must also have taken either prescription medicine or OTC treatment for their IBS-D.

Ref 32: Kantar Health – National Health and Wellness Survey

National Health and Wellness Survey is part of the Patient Centered Research Program. NHWS is a cross-sectional survey, representative of the total male and female adult populations in each 5EU market (France, Germany, UK, Italy and Spain) that captures information directly from respondents online. To ensure a representative sample, particularly in the older population (>65), online recruitment was supported by computer assisted web interviews (CAWIs). Data was collected during March – May 2013 and the length of interview was 45 minutes. A total of n=62,000 respondents were interviewed for this study, of them n=2,845 reported being diagnosed with IBS by a physician (IBS-C - n=450, IBS-D n=859, IBS-Mixed – n=1,536).

Ref 33: IBS-D Qualitative Market Understanding Study (HCPs and patients): 260131926-1

IBS-D Qualitative Market Understanding Study, conducted by Kantar Health in the UK, Australia, Canada, France, Germany, Italy and Spain. One-hour in-depth interviews conducted face-to-face for Healthcare Professionals and face-to-face or over the telephone for patients throughout September and October 2015. Sample (each market): n=8 Gastroenterologists; n=6 Primary Care Physicians (PCPs) and n=6 IBS-D Patients. Gastroenterologists were recruited from mix of either office or hospital setting (not in UK) and must see at least 12 patients with IBS-D in a typical month. PCPs must see at least 5 patients with IBS-D in a typical month. All HCPs must prescribe or recommend prescription or OTC treatments for IBS-D patients. Patients must be diagnosed with IBS-D and have experienced both diarrhoea and stomach pain/discomfort/spasm for at least 2 years. Patients must also have taken Imodium (loperamide) in the past 12 months, prescribed or OTC and sample was a mix of mild/moderate/severe IBS-D. Interviews were recorded and partially transcribed, and complete content analysis conducted. During the interviews with both patients and HCPs, a Product Profile of a new class of IBS-D prescription product was shared with respondents.

Ref 34: Improving Constella Patient Persistence in IBS-C: 260141604

IBS-C Qualitative Study, conducted by Kantar Health in the UK, Canada and Spain. 45-minute video-depth interviews conducted with IBS-C patients throughout July and August 2017. Sample (each market): n=1 lapsed user of Constella (linaclotide) after 1 month, n=1 lapsed user of Constella (linaclotide) after 2 months, n=1 continued user of Constella (linaclotide) for at least 1 month. Patients must be diagnosed with IBS-C and have been prescribed Constella (linaclotide) for their IBS-C. Interviews were recorded and partially transcribed. During the interviews, a concept aimed at facilitating discussions between HCPs and patients was tested with IBS-C patients.

Ref 45: IBS Triggers Research

IBS Triggers Research, conducted by Allergan and supported by Cello Health Insight, combines findings from Phase 1 and Phase 2 research in the UK, Canada, Sweden and Spain. Phase 1 involved 2 hour focus groups with a total of 13 IBS-C patients and 10 IBS-D patients across central locations (London, Toronto and Sweden) during January 2017. All research was viewed live by Allergan. Phase 2 involved 60 minute IDIs with a total of 11 IBS-C patients and 11 IBS-D patients across central locations (London, Toronto and Barcelona) during February/March 2017. Research was viewed live by Allergan in London and Barcelona, and remotely in Toronto.

Ref 51: Gastrointestinal Society 2016 Survey Results Irritable Bowel Syndrome (IBS). All data. 2016.

Original data sourced from the Gastrointestinal Society IBS Survey 2016. This data set is available on request from The Gastrointestinal Society at [Gail Attara] info@badgut.org.

Ref 25: Gastrointestinal Society 2016 Survey Results Irritable Bowel Syndrome (IBS). Irritable bowel syndrome patient open-ended comments from survey. 2016.

Patient testimonials sourced from qualitative, written responses to the IBS Survey 2016 conducted by The Gastrointestinal Society. Testimonials are available on request from The Gastrointestinal Society at [Gail Attara] info@badgut.org.

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