# A review of the Clinical Economics of Irritable Bowel Syndrome

Beth A. Hahn

## SUMMARY

Gastroenterologists are increasingly called upon to consider the clinical economic aspects of disease and intervention strategies in their medical decision-making. The clinical economics of IBS have not been comprehensively reviewed since 1997. The current paper integrates post-1997 findings on the direct, indirect, and intangible costs of IBS with earlier research and considers the extent to which knowledge of the clinical economics of IBS has advanced. The data show that little progress has been made in quantifying the direct and indirect costs of IBS in monetary terms. However, understanding of the impact on patients' quality of life and functional ability has advanced. Recent data are consistent with previous findings in suggesting that IBS can significantly impair patients' well-being and ability to function both at home and in the workplace. The magnitude of impairment of quality of life and functional ability is related to the severity and/or frequency of bowel symptoms. New evidence also suggests that psychological symptoms in IBS predict quality-of-life impairment. Thus, understanding of some of the clinical economic aspects of IBS has advanced, although more work is needed. Developing a solid foundation of clinical economic data regarding IBS will be particularly important in providing a baseline against which to evaluate IBS-specific pharmacotherapies now in development.

Key words: Clinical economics, Quality of life, resource utilization

# INTRODUCTION

To improve the cost-conscious delivery of health care, gastroenterologists and other health care providers are

increasingly called upon to consider the clinical economic aspects of disease and intervention strategies in their medical decision-making. Clinical economics encompasses three types of costs of disease: (1) direct costs of primary, secondary, and tertiary health care for diagnosing and managing the disease; (2) indirect costs of lost workplace because of premature death; and (3) intangible costs comprising the physical, mental, and social toll of the disease on the patient. Direct and indirect costs are often quantifiable in monetary terms; intangible costs are often quantified in terms of impact on health-related quality of life.

A 1997 clinical economics review concluded that irritable bowel syndrome (IBS), one of the most frequently encountered disorders in gastroenterology practices, is associated with high direct, indirect, and intangible costs but that numerous factors make the accurate quantification of cost difficult.<sup>1</sup> The review also identified several areas in which understanding of the clinical economics of IBS - specifically, its effects on health-related quality of life and workplace functioning - could be improved with additional research. Since the 1997 review appeared, IBS and other functional bowel disorders have increasingly been a focus of research and clinical attention.<sup>2</sup> The current paper integrates post-1997 findings on the direct, indirect, and intangible costs of IBS with earlier research and considers the extent to which knowledge of the clinical economics of IBS has advanced since the 1997 assessment.

# DIRECT COSTS

### Health Care Utilization

Research assessing rates of health care utilization by patients with IBS is central to assessing the direct costs of the syndrome. Pre- and post-1997 research shows that patients with IBS have higher rates of health care utilization for gastrointestinal symptoms than do patients with

Author for correspondence:

Beth A. Hahn, PhD, GlaxoSmithKline, Research Triangle Park, Norton Carolina 27709

other digestive disorders or individuals with no functional gastrointestinal disorder.3-5 One early study used data from the National Ambulatory Medical Care Survey, which periodically samples the ambulatory medical services provided by physicians in office-based practices throughout the continental United States.<sup>3</sup> In selected years from 1975 through 1985, IBS was estimated to be diagnosed in 1.8 million to 4.7 million visits to officebased physicians in he United States. Among the digestive-disease diagnoses, IBS was the most common diagnosis made by gastroenterologists and the seventh most common made across all physician specialties. In any given year, the majority of patients with IBS (at least 75%) were prescribed gastrointestinal medications, which were given at least 20% more frequently for patients with IBS than for patients with other digestive diseases. A similar pattern of results was obtained in the 1990 US householder survey, a stratified probability random sample of US householders given a self-administered questionnaire regarding gastrointestinal disorders.<sup>4</sup> Among the 5,430 respondents, patients reporting symptoms consistent with criteria for IBS, compared with those not meeting criteria for a functional gastrointestinal disorder, had paid significantly more visits in the previous year to a physician for gastrointestinal symptoms (1.64 versus 0.09 mean visits).

These data show that patients with IBS are more likely to utilize health care for gastrointestinal symptoms than are patients with other digestive diseases or without functional gastrointestinal disorders. Several studies show that patients with IBS also report and seek medical attention for non-bowel symptoms more often than individuals without IBS.<sup>4,6-9</sup> For example, in the US householder survey, patients meeting symptom criteria for IBS were more likely than those not meeting criteria for a functional bowel disorder to visit a physician for non-gastrointestinal symptoms in the previous year (3.88 versus 1.77 mean visits).<sup>4</sup> This finding was consistent with a populationbased study using data from the Dutch National Survey of Morbidity and Intervention in General Practice which found that patients with IBS, compared with the general population, were more likely to have consulted (for unspecified reasons) the family physician, the physical therapist, and the alternative therapist.<sup>6</sup>

These data add to a growing body of evidence showing that patients with IBS experience more psychosocial problems and non-bowel symptoms than do individuals without IBS.<sup>10,11</sup> Whether or not these non-bowel problems are manifestations of IBS is currently being actively debated. Correspondingly, whether or not health care utilization associated with these non-bowel symptoms should be included in determinations of the direct costs of IBS is also a matter of debate.

The possibility that these non-bowel symptoms are important determinants of the direct costs of IBS is consistent with data showing that severity and frequency of bowel symptoms appear not to predict health care utilization among patients with IBS.<sup>12,13</sup> Although more research is required to corroborate this finding, the data reported to date suggest that factors other than severity of bowel symptoms determine rates of health care utilization.

#### Monetary Estimates of Direct Costs

While data suggests that IBS is associated with higher direct medical costs relative to those incurred by patients without a diagnosis of IBS, few attempts have been made to quantify the direct medical costs in monetary terms. Attempts to extrapolate costs to the population are hampered by the inability to obtain precise estimates of IBS prevalence, which varies from 5% to 25% depending on the definition of IBS, the source of the data (e.g., patient reports versus physician reports), and the population studied (e.g., consulters versus non-consulters).<sup>1</sup>

Two studies, both of which are discussed in the 1997 clinical economics review, assessed the direct medical costs of IBS.<sup>1,14</sup> In the first study, the cost of IBS to the UK National Health Service in 1995 was estimated at £45.6 million, including £13.1 million for general practitioner consultations, £12.5 million for medication, £16.6 million for hospital outpatient attendances, and £3.4 million for inpatient admissions.1 These costs, which averaged £95 (or \$145 in 1995 dollars) per consulting patient, amounted to 0.1% of the UK National Health Service spending. A 1992 community-based study in Olmsted County, Minnesota reported a much higher per-patient cost of US \$742 for IBS compared with US \$429 for patients with "some gastrointestinal symptoms" and US \$429 for patients without gastrointestinal symptoms.<sup>14</sup> The disparity in per-patient direct costs of IBS in these two studies may be attributed to methodological differences such as inclusion of prescription costs in the UK study, but not the US study, but also general differences in cost of health care and cultural differences in practice patterns and use of diagnostic techniques such as colonoscopy.

Aside from a study assessing direct medical costs for a sample of patients with severe, refractory IBS,<sup>12</sup> no research has attempted to estimate the direct costs of IBS in the past 5 years. However, the new research described above continues to support earlier findings of high rates of health care utilization for both gastrointestinal and non-gastrointestinal symptoms among patients with IBS.

# Indirect Costs: Absenteeism and Workplace Functioning

IBS can impair physical, social, and psychological well-being and functioning and therefore would be expected to affect patient's ability to perform in the workplace. Several studies show that IBS increases absenteeism and patients' functioning when they continue to work with symptoms; however, indirect costs arising from the impact on activities such as work at a paid job have not been systematically quantified in monetary terms.

For example, in the 5,430-respondent US Householder Survey conducted in 1990,<sup>4</sup> patients meeting diagnostic criteria for IBS reported missing an average of 13.4 days from work or school in the previous year compared with 4.9 days for individuals not meeting criteria for a functional gastrointestinal disorder. Over twice as many individuals meeting diagnostic criteria for IBS reported currently too sick to work or go to school compared with individuals not meeting criteria for a functional gastrointestinal disorder (11.3% vs. 4.3%, respectively). Likewise, in the population-based survey conducted in the Netherlands, patients with IBS compared with the general population were twice as likely to have missed work in the past 2 months (32% versus 18%).<sup>6</sup>

Data suggests that the magnitude of impairment of workplace functioning among patients with IBS is directly related to frequency and severity of bowel symptoms. For example, in a clinic-based study of 126 patients with IBS diagnosed according to Rome criteria, patients reported experiencing IBS symptoms on more than half of the days during a 2-week reference period.<sup>13</sup> Both the number of missed work days and the percentage effectiveness while working with IBS symptoms were directly related to patient-perceived severity of symptoms, a relationship that was statistically significant despite the small numbers of patients in some of the severity groups. Patients with very severe symptoms (n=25) reported that they missed 0.5 days from work in the past 2 weeks because of IBS and that they worked at about 50% of normal effectiveness while experiencing symptoms. For patients with severe or very severe symptoms, the number of days in bed in the previous 2 weeks was greater than the number of missed work days (1.2 versus 0.4 days for patients with severe symptoms; 2.1 versus 0.5 days for patients with very severe symptoms). This higher number of days in bed compared with the number of missed work days may suggest that patients develop coping mechanisms to allow them to remain at work - possibly to minimize the financial impact of their disorder.

Data from samples of patients with severe IBS also show a direct relationship between frequency/severity of bowel symptoms and impairment in the workplace. For example, in a study of 257 patients with severe refractory IBS, 27% were found to be unemployed because of poor health.12 Compared with employed patients with severe, refractory IBS, the unemployed patients reported worse abdominal symptoms and more days with pain. A second study assessed self-reported workplace functioning among 500 members of the International Foundation for Functional Gastrointestinal Disorders in the United States and 500 members of the IBS Network Support group in the United Kingdom – a sampling base that, because it includes individuals motivated enough about their symptoms to join an IBS-related group, would be expected to contain a disproportionate number of severely impacted individuals.<sup>15</sup> Among the US respondents, bowel symptoms were cited as the reason for "cutting back" some days at work by 46% of patients; for losing or quitting a job, by 12% of patients; and for working fewer hours, by 15% of patients. Irritable bowel symptoms were responsible for 1.7 days of missed work and 3.0 days cut back in the previous 4 weeks per patient, or 22.1 days of missed work and 39 days cut back per patient per year.

In addition to data that shows that the severity of the disease is associated with workplace functioning, other research suggests that workplace challenges can precipitate IBS symptoms. In a survey of patients with clinically diagnosed IBS,<sup>16</sup> difficulties at work were cited more often than any other factor as an important precipitant of irritable bowel symptoms (17% of sample) and were named as the most common current "social" (authors' term) problem (21% of sample). Regardless of the reciprocal relationship, the financial implications of workloss and impaired workplace functioning associated with IBS has yet to be delineated for the patient, the employer and society.

#### Intangible Costs: Health-Related Quality of Life

In addition to costs associated with workloss, there are also intangible costs of IBS. Measures of health-related quality of life are used to quantify these costs and include the effect of disease on patients' physical, mental and social well-being and functioning. Since 1997, several new studies assessing the effects of IBS on healthrelated quality of life have been published.

Many of the studies employed the Short Form-36 Health Survey, a generic, validated, widely used instrument that assesses 8 dimensions of health-related quality of life: physical functioning, role physical (i.e., ability to function in typical physical roles), bodily pain, general health, vitality, social functioning, role emotional (i.e., ability to function in emotional contexts), and mental health.<sup>17</sup> Across studies, the health-related quality of life of patients with IBS is significantly impaired relative to general-population norms for all 8 dimensions.<sup>12,13,15,18</sup> Furthermore, the quality-of-life effects of IBS differ from those of other chronic diseases. In a study of 877 patients consulting a bowel-disease clinic and meeting Rome or Manning criteria for IBS, patients with IBS, compared with a group of patients with diabetes mellitus, had significantly poorer scores for role physical, bodily pain, mental health, role emotional, vitality, and social functioning but better scores for general health perceptions and physical functioning.<sup>18</sup> Compared with a group of patients with gastroesophageal reflux disease, patients with IBS had significantly lower scores for all dimensions except physical functioning, and compared with a group of patients with depression, patients with IBS had significantly lower scores for bodily pain but higher scores for mental health, role emotional, and vitality. Considered in aggregate, the Short Form-36 data show that IBS impairs multiple aspects of quality of life and that the pattern of quality-of-life impairment differs from that observed with other chronic diseases.

Despite the usefulness of general measures for comparing disease states, questionnaires designed to capture the specific impact of IBS provide greater insight on particular aspects of quality of life that are affected by the condition. Several disease-specific instruments have been developed and validated for use in IBS.<sup>19-22,27</sup> The Irritable Bowel Syndrome Quality of Life Questionnaire (IB-SQOL), for instance, comprises 30 questions measuring 9 dimensions of quality of life: emotional functioning, mental health, sleep behaviors, energy, physical functioning, diet, social role, role physical functioning, and sexual relations. For each question, respondents indicate the extent to which IBS interfered with their health during the previous 4 weeks. Data obtained with the IBSQOL and other disease-specific instruments extend the findings of the Short Form-36 by showing that the magnitude of quality-of-life impairment in IBS is directly related to severity and frequency of bowel symptoms. For example, in a survey of 126 patients meeting Rome criteria for IBS, patients with self-reported severe symptoms scored significantly lower than patients with moderate symptoms on the physical functioning, role physical, role emotional, social functioning, energy, and mental health dimensions of the IBSQOL<sup>13</sup> Compared with patients with severe symptoms, those with very severe symptoms scored significantly lower on the physical functioning and role emotional dimensions. Comparable results were obtained with the 34-question IBS-QOL (as distinct from the IBSQOL) in a survey of 156 patients meeting Rome criteria for IBS.<sup>22</sup> In this study, qualityof-life impairment was directly related to self-reported frequency of bowel symptoms, bothersomeness of symptoms, and functional bowel disorder severity index.

Besides severity of bowel symptoms, psychosocial and psychological factors predict quality-of-life impairment in patients with IBS.<sup>12,23</sup> For example, psychological symptom severity predicted quality-of-life impairment in a study of 257 patients with severe, refractory IBS.<sup>12</sup> Symptom Checklist-90R somatization scores and depression as well as severity of abdominal pain, age, and global symptom severity scores were significant, independent predictors of quality-of-life impairment, measured with the Short Form-36.

These and other quality-of-life data have contributed to an emerging biopsychosocial model of IBS according to which biological, psychological, and social factors contribute to the clinical presentation, course, and outcome of IBS.<sup>10,11,24,25</sup> The degree to which psychosocial factors cause and/or result from IBS in undetermined. Nevertheless, the consistent finding that psychosocial difficulties are related to severity of symptoms and to patients' clinical status highlights the need for clinicians to take psychosocial factors into account in the management of patients with IBS.

# CONCLUSIONS

Little progress has been made in the past few years in quantifying the costs of IBS in monetary terms.<sup>26</sup> Issues regarding defining IBS as well as a clear methodology for inclusion of direct and indirect costs continue be problematic and contribute to wide disparity in estimates. However, understanding the toll of IBS in terms of impact on patients' quality of life and functional effectiveness has advanced and the findings are consistent. Recent data support previous research in suggesting that IBS can significantly impair patients' well-being and ability to function both at home and in the workplace. The magnitude of the impairment in quality of life and functioning is directly related to frequency and/or severity of bowel symptoms. Some evidence also suggests that psychological symptoms predict quality-of-life impairment for patients with IBS. Psychological evaluations and quality-of-life assessments for patients with IBS are helping to quantify the psychological and social sequelae of IBS and have contributed to the emerging biopsychosocial model of the syndrome. Unknown is the extent to which these assessments are currently used in clinical practice or the extent to which such assessments could be used to improve treatment.

Although the past few years have witnessed advancement in the understanding of some of the clinical economic aspects of IBS, more work is need. Developing a solid foundation of clinical economic data regarding IBS will be particularly important in providing a baseline to evaluate the costs and benefits of pharmacotherapies for IBS currently in development. IBS-specific pharmacotherapy could considerably change the way that IBS is managed. Unlike the generally ineffective and inexpensive therapies currently available, they are likely to have a significant impact on the direct, indirect, and intangible costs of IBS.

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