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The Gastro-oesophageal Reflux Disease Impact Scale: a patient management tool for primary care

R. JONES*, K. COYNE† & I. WIKLUND‡

*Department of General Practice and Primary Care, King's College London, London, UK; †United BioSource Corporation Center for Health Outcomes Research, Bethesda, MD, USA; ‡AstraZeneca R&D Mölndal, Mölndal, Sweden

Correspondence to:
Prof. R. Jones, Department of General Practice & Primary Care, King's College London School of Medicine at Guy's, King's College and St Thomas' Hospitals, 5 Lambeth Walk, London SE11 6SP, UK.
E-mail: roger.jones@kcl.ac.uk

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SUMMARY

Background
Symptoms of gastro-oesophageal reflux disease have a substantial impact on patients' everyday lives.

Aim
To develop and test a short questionnaire to aid patient–doctor communication.

Methods
The Gastro-oesophageal Reflux Disease Impact Scale was developed from a systematic literature review, focus groups of patients and primary care physicians, and patient cognitive interviews. A psychometric validation study was conducted based on two consultations in new (n = 100) or chronic (n = 105) gastro-oesophageal reflux disease patients.

Results
The Gastro-oesophageal Reflux Disease Impact Scale demonstrated internal consistency (Cronbach's alpha ranged from 0.68 to 0.82), reproducibility (intraclass correlation coefficient in stable patients ranged from 0.61 to 0.72) and construct validity (Spearman correlations with Quality of Life in Reflux and Dyspepsia instrument and Reflux Disease Questionnaire: 0.5–0.8 in both patient groups). Effect sizes in new and chronic gastro-oesophageal reflux disease patients ranged from 0.9 to 1.5 and 0.32 to 0.42, respectively. Doctors reported altering their treatment decision based on information provided by the Gastro-oesophageal Reflux Disease Impact Scale in 35% of patients, and 77% of doctors found it to be useful.

Conclusions
The Gastro-oesophageal Reflux Disease Impact Scale demonstrated good psychometric properties in newly diagnosed gastro-oesophageal reflux disease patients and those already receiving treatment. This simple communication tool is a useful aid for managing primary care patients with gastro-oesophageal reflux disease.

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INTRODUCTION

Gastro-oesophageal reflux disease (GERD) is a chronic, painful disease which has substantial effects on the everyday lives of affected individuals. Recent reviews have highlighted that GERD interferes with physical activity (including manual work and exercise), impairs social functioning, disturbs sleep and reduces productivity at work.[1–3] The negative effects of GERD are dependent on the frequency and severity of symptoms rather than the presence of oesophagitis.[4–6] Furthermore, the impact of GERD on patients' lives is comparable with that of rheumatoid arthritis, asthma and back pain.[3]

The impact of symptoms on everyday life is one of the most common reasons for consultation for upper gastrointestinal diseases, alongside anxiety about serious illness and dissatisfaction with treatment.[7–9] Primary care physicians (PCPs) are faced with the need to understand quickly how compromised the patient is, in terms of the severity and consequences of symptoms. During a first consultation with a patient, after diagnosis of GERD, they have to judge whether the patient will benefit from effective treatment, or whether he or she can simply be reassured that the symptoms may resolve spontaneously. For a patient with an existing diagnosis, they have to judge the effectiveness of the management strategy, and whether treatment should be stepped up to a more effective treatment or higher dose, or whether he or she can be stepped down.

Whilst a combination of symptom scoring and endoscopy has been shown to diagnose GERD with high specificity,[10] it is increasingly accepted that management of GERD in primary care can best be addressed based on the patient's report of his or her symptoms. It is well established, however, that patients communicate poorly about symptoms in a wide range of diseases. Thus, the reported agreement between patients and clinicians about the presence and severity of symptoms is at best moderate, across a range of disciplines from gastroenterology to oncology and virology.[11–20]

A recent study has highlighted this issue in GERD patients.[21] McColl and colleagues conducted an analysis of patient–clinician agreement regarding the presence and severity of reflux symptoms in four clinical trials. They found that agreement was poor before treatment and that, in three of the four studies, this was due to clinicians underestimating symptoms reported by their patients. Agreement was worse for heartburn (48–52%), regurgitation (36–43%) and epigastric pain (24–35%) than dysphagia (62%). Underestimation of symptom presence and severity indicates that a communication gap can arise between patients and doctors during a consultation.[2]

Results from a European study of primary care patients with GERD suggest that information gathering can be improved with the aid of a structured questionnaire.[22] The investigators found a striking disparity between the symptoms reported by patients initially, and after specific questioning. Questionnaires may, therefore, be useful aids to communication and prompt patients to provide important information to aid their management in primary care.[23, 24] The use of appropriate symptom descriptors helps to ensure a common understanding of the relevant symptoms.[25]

Five patient-completed questionnaires have been developed in recent years for the assessment of GERD symptoms in clinical practice or the general population.[26–30] All five questionnaires address the frequency and/or severity of heartburn and regurgitation, two asked about extra-oesophageal symptoms such as chest pain,[27, 28] and one included the impact of symptoms on everyday life.[27] One screening tool was short and used straightforward scoring, but did not ask about the impact of symptoms or extra-oesophageal symptoms.[29] All five instruments demonstrated adequate psychometric properties. However, only one of the questionnaires (the Reflux Disease Questionnaire, RDQ) involved input from patients during item selection and development.[30] There is currently a need, therefore, for a short patient-completed questionnaire to help GERD patients communicate the presence and impact of reflux symptoms when consulting in primary care.

The aim of the present study was to develop and validate a short self-report questionnaire to aid patients when describing the presence and impact of reflux symptoms in primary care, recognizing that such an instrument might also prompt clinicians to make appropriate enquiries about patients' symptoms. The validation study was also designed to assess whether the questionnaire provided doctors with useful information to guide their management of GERD.

MATERIALS AND METHODS

Development of the GERD Impact Scale

A systematic literature search was performed to identify available diagnostic and screening instruments for GERD and to identify potential strategies for facilitating

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patient–doctor communication about GERD. The Medline database (1 January 1990 to 31 December 2004) was searched using the following terms in the full Medline record including Medical Subject Headings (MeSH): clinical, guidelines, gastroesophageal reflux disease, GERD, questionnaire(s), communication barriers, communication, question-asking, diagnosis and screening. Three draft questionnaires were developed based on the key themes and potential formats identified in this review.

The draft questionnaires were tested by GERD patients in two focus groups in Cincinnati, Ohio, who were recruited by newspaper advertisement (n = 21). Most patients said that they were reluctant to discuss how GERD impacts their everyday lives with a doctor, because they believed that he or she would not find the information relevant and because they did not think there was enough time. All three draft questionnaires were considered readable and clearly worded.

The questionnaires were also tested in three doctor focus groups held in Chicago, Illinois and Bethesda, Maryland (n = 25: 15 PCPs and 10 gastroenterology specialists), members of which were recruited from a website or health insurance roster or by doctor referral. Both PCPs and specialists stated that patients focus on reporting symptoms, and few mention how their symptoms affect their everyday lives. The PCPs thought that a questionnaire about the impact of GERD would be a useful aid to questioning that could save time in consultation, and that it could be useful when assessing patients' response to treatment.

A final draft questionnaire, the GERD Impact Scale (GIS), was selected and revised based on feedback from the patient and doctor focus groups. The content validity of this questionnaire was assessed in GERD patients (n = 13) recruited by newspaper advertisement. A cognitive debriefing approach was used to understand each participant's interpretation of the questions and response options in the questionnaire. Participants found the instructions clear and easy to understand, and were able to complete the questionnaire quickly and with ease. The full range of response options was used and very few responses were missing.

Psychometric validation of the GERD Impact Scale

A longitudinal, two-visit, multicentre study was conducted to validate the draft GIS in GERD patients from nine primary care clinics in eight states across the USA. A total of 100 newly diagnosed GERD patients ('new GERD patients') and 105 patients with a long-standing GERD diagnosis ('chronic GERD patients') participated from the nine primary care clinics.

New GERD patients were patients consulting their PCP about heartburn, acid regurgitation or other reflux-related symptoms for the first time who were willing to start prescription drug treatment for GERD. Chronic GERD patients had a clinical diagnosis of GERD. Additional inclusion criteria were: age over 18 years, the ability to read and speak English and willingness to provide informed consent. The main exclusion criteria were: a previous diagnosis of irritable bowel symptoms, peptic ulcer disease or any gastrointestinal diseases other than GERD; a history of gastric surgery or cancer; consulting solely for prescription renewal and current participation in a clinical trial.

At the first visit, patients completed the GIS, a demographic questionnaire, the Quality of Life in Reflux and Dyspepsia (QOLRAD) questionnaire and the RDQ. At the second visit, 16 $\pm$ 2 days later, patients completed the GIS and QOLRAD questionnaire a second time, as well as an assessment of overall treatment effect (OTE). Patients completed the questionnaires privately, either in an examination room or another private location during the visits, and visited the same doctor on the two consecutive visits. PCPs collected additional clinical information at baseline and assessed the OTE at Visit 2.

The GIS comprises eight questions asking about the frequency of the following over the past week: acid-related symptoms, chest pain, extra-oesophageal symptoms, the impact of symptoms on sleep, work, meals and social occasions, and the use of additional non-prescription medication. Four response options are provided to describe frequency over the previous 2 weeks: 'none of the time' (1), 'a little of the time' (2), 'some of the time' (3) and 'all of the time' (4).

The QOLRAD questionnaire is a disease-specific quality of life instrument comprising 25 items that ask subjects about the effect of upper gastrointestinal symptoms on five dimensions: emotional well-being, sleep, vitality, eating/drinking and physical/social functioning.[31] Subjects report the frequency of these effects during the previous week using a 7-point Likert scale, ranging from 1 (all of the time/a great deal) to 7 (none of the time/none at all), with low scores indicating a severe impairment of daily functioning. The reliability and validity of the QOLRAD questionnaire have been extensively documented in international studies in patients with upper gastrointestinal symptoms.[31–38]

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The RDQ is a 12-item, self-administered questionnaire designed to assess the frequency and severity of heartburn, acid regurgitation and epigastric pain over the previous week.[30] A GERD dimension can be obtained by combining the heartburn and regurgitation dimensions, while the epigastric pain dimension is also known as the dyspepsia dimension. Symptom frequency and severity are scored on a 6-point Likert scale, with higher scores indicating more frequent or severe symptoms. The reliability and validity of the RDQ have been established in several studies.[30, 39, 40]

The patient OTE was assessed using a GERD-specific version of the OTE Scale.[41] This scale measures changes in GERD symptoms on a scale from −7 ('a very great deal worse') to +7 ('a very great deal better'). A rating of −1 ('almost the same, hardly worse at all'), 0 (unchanged) or +1 ('almost the same, hardly better at all') is considered to represent stable symptoms. The OTE Scale has been used in clinical studies in a range of diseases.[42–44]

To assess whether the GIS provided PCPs with useful information, new GERD patients were randomized in a block design of 2:4 to two groups of 50 patients each. For one of these groups, the PCP reviewed the GIS completed by the patient during Visit 1. For the other group, the GIS completed at Visit 1 was not provided to the doctor until Visit 2 so that the doctor could not use the GIS to inform their treatment decision-making process. For all chronic GERD patients, doctors reviewed the GIS during Visit 1. For all patients, the doctor was asked whether the GIS had provided useful information (Figure 1).

Descriptive statistics (mean, standard deviations and percentages) and all other statistics were calculated using SAS version 8.02.[45] Exploratory factor analyses were performed using a varimax and promax rotation. Items were selected based on the outcome of the factor analysis, keeping items that combined into clear factors and deleting items with low factor loadings (<0.40) or a low internal reliability coefficient. Items with a high ceiling effect were also deleted. Cronbach's alpha coefficients were calculated in each dimension to assess internal consistency.[46] A high alpha coefficient (≥0.70) suggests that the items within a dimension measure the same construct and supports the construct validity. Intraclass correlation coefficients were computed in each dimension in stable patients reporting OTE scores of −1, 0 or +1. Convergent and discriminant validity was assessed using the correlation of GIS dimensions with those of the QOLRAD questionnaire and RDQ, using Pearson correlation coefficients. Responsiveness was evaluated using effect sizes in all patients, in those with a chronic GERD diagnosis and in those with a new GERD diagnosis. An effect size of 0.2 is considered small, at least 0.5 clinically meaningful, and 0.8 or above large.[44]

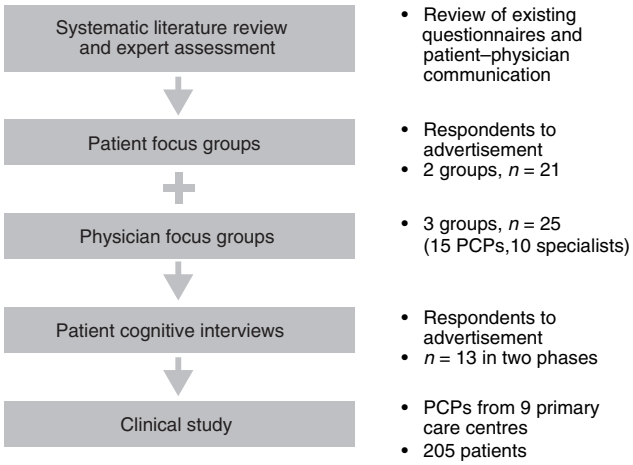

Figure 1. Development and validation of the Gastro-oesophageal Reflux Disease Impact Scale.

The study was performed in accordance with the Declaration of Helsinki,[47] Good Clinical Practice and applicable regulatory requirements. Ethical approval was obtained from local ethics committees at all participating centres. Informed consent was obtained, and patients were free to discontinue participation in the study at any time.

RESULTS

A total of 205 GERD patients (105 with a chronic diagnosis and 100 with a new diagnosis) were enrolled at nine primary care practices (Table 1). Overall, heartburn was the most frequently reported symptom (89.9%) followed by regurgitation of food or fluids into the mouth (75%). Compared with chronic GERD patients, new GERD patients reported symptoms that were significantly more frequent and severe, although the average duration of their GERD symptoms was not significantly shorter. Chronic GERD patients were more likely than new GERD patients to be treated with a proton pump inhibitor (PPI) on entry to the study (86% vs. 4%).

An exploratory factor analysis was performed with a varimax and promax rotation and distinct factors were identified: pain or burning in the chest ('Burning and Pain dimension'), other acid-related symptoms in the

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Table 1. Clinical and demographic characteristics

Characteristic	Chronic GERD patients (n = 105)	New GERD patients (n = 100)	P-value
Age [mean (s.d.); years]	56.5 (15.1)	52.2 (16.3)	0.05
Gender [n (%) male]	36 (34)	37 (37)	0.69
Race [n (%) Caucasian]	84 (80)	84 (84)	0.20
Domestic status [n (%) living with another*]	80 (76)	88 (88)	0.07
Employment [n (%) full- or part-time]	51 (49)	63 (63)	0.19
Presence of comorbid condition, n (%)	97 (92.4)	75 (75)	0.0007
Duration of symptoms [mean (s.d.); years]	10.1 (10.7)	8.1 (12.5)	0.18
Frequency of symptoms [mean (s.d.) days in previous week]	2.8 (2.3)	4.3 (2.2)	<0.0001
Severity of symptoms, n (%)			
Mild	61 (59)	35 (35)	0.002
Moderate	36 (35)	59 (59)	
Severe	7 (7)	6 (6)	
Acid suppressive treatment†, n (%)			
PPI only	78 (74)	4 (4)	<0.0001
PPI plus H_2RA or antacid	12 (11)	0 (0)	
H_2RA only	13 (12)	2 (2)	
H_2RA plus antacid	0 (0)	4 (4)	
Antacid only	1 (1)	30 (30)	
None	1 (1)	60 (60)	

GERD, gastro-oesophageal reflux disease; H_2RA, H_2-receptor antagonist; PPI, proton pump inhibitor.
* Living with a partner or spouse, family or friends; † At Visit 1.

throat and mouth ('Other Acid-related Symptoms dimension') and impact of symptoms ('Impact dimension') (Table 2). Based on this factor analysis and item analyses examining for items with high ceiling effects, four items were deleted ('chronic throat-clearing, cough or sinus-like conditions', 'reducing or avoiding social activities', 'pain or burning in upper stomach' and 'food or liquid coming back up into the mouth'). Some further modifications were made to the GIS, including modification of the recall period to 1 week for consistency with other widely used questionnaires (e.g. the RDQ and QOLRAD questionnaire). Additional minor wording changes were made based on informal feedback during the study (Figure 2).

Mean scores of the 8-item GIS showed that new GERD patients experienced more frequent symptoms and greater impact when compared with chronic GERD patients at the first visit. Overall, mean total GIS scores (s.d.) were 2.3 (0.6) in new GERD patients compared with 2.0 (0.6) in chronic GERD patients. Differences were greater in the dimensions relating to burning [2.5 (0.7) vs. 2.2 (0.7)] and impact [2.4 (0.7) vs. 2.1 (0.7)] than acid [2.1 (0.7) vs. 2.0 (0.7)].

Cronbach's alpha coefficients for the GIS dimensions showed that all single items in a dimension correlated with each other as well as with the total score, demonstrating internal consistency (Table 3). Pearson product moment correlations and intraclass correlation coefficients in patients with stable symptoms demonstrated acceptable homogeneity and stability over time (Table 4).

The GIS dimensions and total score correlated strongly with established measures such as the QOLRAD questionnaire and RDQ, demonstrating concurrent validity (Table 4). All Spearman correlations were statistically significant ($P < 0.001$). Correlations were stronger for scores expected to be related (e.g. the Other Acid-related Symptoms dimension and RDQ Regurgitation, or the Impact dimension and QOLRAD dimensions) than scores not expected to be strongly related (e.g. the Other Acid-related Symptoms dimension and RDQ Dyspepsia, or the Burning and Pain

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Table 2. Factor analysis of the Gastro-oesophageal Reflux Disease Impact Scale completed at the first visit (n = 205; factors with a correlation of ≥0.4 are shaded)

Item	Dimension		
	Burning and Pain	Other Acid-related Symptoms	Impact
Burning in chest	0.69	0.27	0.23
Pain in chest	0.66	0.15	0.21
Sore throat or hoarseness related to other symptoms	0.16	0.68	0.28
Chronic condition related to heartburn	0.09	0.63	0.25
Food or liquid coming back up into mouth	0.37	0.54	0.11
Acid taste in mouth	0.33	0.50	0.25
Reduced productivity	0.15	0.23	0.69
Food and drink problems	0.16	0.17	0.64
Social interference	0.07	0.35	0.64
Sleep disturbance	0.38	0.24	0.56
Use of over-the-counter medication	0.26	0.08	0.46
Pain or burning in upper stomach	0.26	0.27	0.40

dimension and RDQ Regurgitation) demonstrating concurrent validity.

Effect sizes indicated that the GIS is responsive to change in the study population overall but more so in newly diagnosed patients than those with a chronic diagnosis (Table 5). GIS scores changed less in patients with a chronic diagnosis indicating that their symptoms were more stable, probably because they were already receiving treatment.

Primary care physicians found it useful to evaluate the GIS completed at Visit 1 alongside that completed at Visit 2 in 145 of 189 patients (77%). They found it marginally more useful in new GERD patients (77 of 94; 82%) than chronic patients (68 of 95; 72%). PCPs said that the GIS altered treatment decisions over the course of the study in 36% of patients overall (67 of 189): 46% of new GERD patients (43 of 94) and 25% of chronic GERD patients (24 of 95).

DISCUSSION

This study developed and tested a simple, one-page, patient-completed tool to communicate to the doctor the frequency of reflux symptoms and their effect on

Figure 2. GERD Impact Scale (GIS) questionnaire.

patients' lives. The GIS was developed using a rigorous process that involved input from patients as well as doctors at several stages. In a clinical study of over 200 patients, the GIS was shown to have internal consistency, reproducibility, construct validity and responsiveness to change. Furthermore, over three-quarters of PCPs found it useful, and they altered their treatment decisions in over one-third of patients as a result. Overall, the GIS was found to be a useful aid to communication between patients and their doctors.

The GIS has several strengths. First, the extensive input of both patients and doctors means that the GIS focuses on reflux symptoms and impacts most relevant to these groups. Secondly, it has excellent psychometric properties in patients with GERD, and items such as heartburn and regurgitation are highly correlated; users can be confident, therefore, that it accurately measures

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Table 3. Internal consistency (Cronbach's alpha) and stability (Pearson product moment correlation and intraclass correlation coefficient) of the Gastro-oesophageal Reflux Disease (GERD) Impact Scale

GERD Impact Scale dimensions	Cronbach's alpha coefficient (n = 205)	Pearson product moment correlations* (n = 81)†	Intraclass correlation coefficient (n = 81)†
Burning and Pain	0.68	0.67	0.62
Other Acid-related Symptoms	0.72	0.62	0.61
Impact	0.77	0.74	0.72
Total score	0.82	0.75	0.72

* All statistically significant ($P < 0.001$).
† In patients with stable symptoms whose overall treatment effect was unchanged (−1, 0, +1).

Table 4. Correlations of GERD Impact Scale dimensions with the QOLRAD instrument and RDQ at the first visit (n = 205)*

	GERD Impact Scale dimensions			
Dimensions of QOLRAD and RDQ	Burning and Pain	Other Acid-related Symptoms	Impact	Total score
QOLRAD				
Emotional distress	−0.60	−0.48	−0.77	−0.77
Sleep disturbance	−0.57	−0.49	−0.78	−0.77
Food and drink problems	−0.62	−0.51	−0.78	−0.79
Physical limitations	−0.50	−0.41	−0.73	−0.69
Lack of vitality	−0.55	−0.52	−0.72	−0.74
RDQ				
Heartburn	0.68	0.41	0.58	0.68
Regurgitation	0.46	0.74	0.49	0.63
Dyspepsia	0.62	0.40	0.56	0.60
GERD	0.65	0.65	0.61	0.74

* Correlations were negative for the QOLRAD questionnaire because quality of life decreases as symptoms and their impact increase, and positive for the RDQ, because this questionnaire, like the GERD Impact Scale, measures the burden of symptoms directly.
GERD, Gastro-oesophageal Reflux Disease; QOLRAD, Quality of Life in Reflux and Dyspepsia; RDQ, Reflux Disease Questionnaire.

Table 5. Mean scores (s.d.) of the GERD Impact Scale at both visits and effect sizes in all patients (n = 189), those with a chronic GERD diagnosis (n = 94) and those with a new GERD diagnosis (n = 95)

Group	Visit 1, mean (s.d.)	Visit 2, mean (s.d.)	Effect size
All patients			
Burning and Pain	2.3 (0.7)	1.7 (0.7)	−0.87
Other Acid-related Symptoms	2.1 (0.7)	1.6 (0.6)	−0.62
Impact	2.2 (0.7)	1.7 (0.6)	−0.79
Total score	2.2 (0.6)	1.6 (0.6)	−0.87
Chronic GERD			
Burning and Pain	2.2 (0.7)	1.9 (0.7)	−0.42
Other Acid-related Symptoms	2.0 (0.8)	1.8 (0.7)	−0.32
Impact	2.1 (0.7)	1.8 (0.6)	−0.36
Total score	2.0 (0.6)	1.8 (0.6)	−0.39
New GERD			
Burning and Pain	2.5 (0.6)	1.6 (0.7)	−1.46
Other Acid-related Symptoms	2.1 (0.8)	1.5 (0.6)	−0.92
Impact	2.4 (0.7)	1.5 (0.6)	−1.26
Total score	2.3 (0.6)	1.5 (0.5)	−1.49

GERD, gastro-oesophageal Reflux Disease.

the impact of GERD in a consistent, reproducible and responsive way. Thirdly, it is short, making it quick and easy for the patient to complete and for the doctor to review. As a result, doctors rated it a useful aid to their clinical decision-making. It helped to guide PCPs' management decisions in newly diagnosed patients and helped them to identify patients with an established diagnosis who would benefit from a different treatment.

The GIS is likely to have broad value in primary care. The focus groups suggested that patients and PCPs may require prompts to initiate a discussion of the impact of reflux symptoms on daily living. In particular it is envisaged that the GIS could be completed by patients in the doctor's office during the initial visit, after GERD has been diagnosed. PCPs participating in the validation study found the GIS provided useful information that aided patient management. Furthermore, an increasing number of studies suggest that giving patients questionnaires to complete in

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primary care can aid their perceptions of good communication and overall satisfaction.[23, 24]

Further studies with the GIS are needed, in particular to determine whether it leads to changes in patient management that improve patient outcomes compared with usual management in primary care. Whilst we show that the majority of doctors found the GIS useful, studies with long-term follow-up are needed to confirm that the GIS helped doctors to make the correct treatment decisions. Potential end points could include the frequency and severity of symptoms, the presence or severity of oesophagitis, work productivity, satisfaction and overall health-related quality of life. A study is planned that looks at the value of the GIS in a clinical setting in terms of treatment outcomes. Validation in other languages is required for the GIS to be widely used.

In conclusion, the GIS demonstrated good psychometric properties, and was found to be useful by the majority of participating PCPs. By highlighting the impact of reflux symptoms on patients' lives, the GIS can help PCPs to identify treatment needs in patients with a new GERD diagnosis, as well as identifying patients and patients with a chronic GERD diagnosis who need more effective treatment.

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Authors' declaration of personal interests: R. Jones has served as a speaker, a consultant and an advisory board member for AstraZeneca. I. Wiklund was an employee of AstraZeneca at the time when the study was conducted and when the manuscript was drafted.

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