International Journal of Colorectal Disease (2019) 34:1233–1240
https://doi.org/10.1007/s00384-019-03317-y

ORIGINAL ARTICLE

Improving treatment of patients with inflammatory bowel diseases: a controlled trial of a multifaceted intervention in two German cities

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Accepted: 15 May 2019 / Published online: 24 May 2019

Abstract

Purpose Many recommendations from clinical practice guidelines are not implemented. We aimed to develop and evaluate a multifaceted strategy for the implementation of guidelines for Crohn's disease (CD) and ulcerative colitis (UC).

Methods In the intervention region (Berlin, Germany), a continuing medical education course was held, brief guidelines for practice were distributed to all family physicians and gastroenterologists, and patient guidelines were distributed to all surveyed patients. Educational outreach visits with local opinion leaders were also conducted. No specific interventions were performed in the control region (Hamburg, Germany). Prior to the intervention and 1 year later, 1900 members of three statutory sickness funds were asked about their treatment according to guidelines with (1) long-term aminosalicylates and (2) immunosuppressants, (3) whether they took long-term glucocorticoids for maintenance of remission, (4) if they smoked, in CD patients, and (5) about the surveillance colonoscopies, in UC patients.

Results Response rate after implementation was 20.1%. Responders differed between intervention and control region by age and by distribution between patients with UC or CD. After 1 year, more patients were treated according to clinical practice guidelines in the control region than in the intervention region. More patients in the intervention region took immunosuppressants after 1 year, and fewer had a surveillance colonoscopy. However, no before–after comparison was statistically significant.

Conclusions This implementation strategy of UC and CD guidelines did not result in a statistically significant effect. Future implementation of guidelines for inflammatory bowel disease might need thorough evaluation of barriers and the support of theory-based concepts.

Keywords Inflammatory bowel diseases · Guideline implementation · Controlled trial · Quality improvement

Introduction

Treatment goals in patients with inflammatory bowel disease (IBD) have changed dramatically in the last 20 years. Today, we not only aim for symptom-free patients with few complications but we also aim to change the course of the disease [1]. In order to reach these goals, IBD patients need optimal treatment. Many countries and international organizations have established clinical practice guidelines, which describe optimal treatment strategies for better patient outcome.

The development of clinical practice guidelines in itself does not change behavior in practice [2, 3]. Several studies have shown that guidelines for clinical practice are incompletely followed in many patients [4]. In an earlier study, we demonstrated that, for instance, only about 60% of all patients receive long-term aminosalicylates as recommended in German and European guidelines, and that under-treatment prevails in patients cared for by a family

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00384-019-03317-y) contains supplementary material, which is available to authorized users.

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physician, especially long-term treatment with immunosuppressants (steroid-sparing agents) [5].

A systematic review recently identified four experimental or quasi-experimental trials focusing on quality improvement in IBD [6]. Walsh et al. conceived a one-page form on prevention of opportunistic infection, which served as a gastroenterologist's checklist for completing patient history as well as for ordering chest X-ray and serological tests. The form also served as communication means with the general practitioner for recommending vaccinations. The authors were able to show increased orders for serology as well as referrals for vaccination [7]. In a series of three trials, one of which included a control group, the influence of online interventions on quality indicators used in the USA was investigated [8–10]. The online interventions included personal feedback sessions with varying combinations of group webinars as well as online/mobile toolkits and continuing medical education (CME) videos and monographs about the rational of applying quality measures. In the controlled trial, which also included the most extensive interventions, the authors were able to show a difference for five out of eight measures between the intervention and control group, reaching up to 20% for pneumococcal vaccination [10]. In addition, at a Danish tertiary IBD center, repeated information at a CME event led to an approximately 20% increase in hepatitis B, influenza, and pneumococcal vaccination [11].

On average, general practitioners in Germany only treat 1.9 patients with IBD per annual quarter [12]. Moreover, half of all patients with IBD are exclusively treated by their family physician rather than by a gastroenterologist [5]. IBD patients under the care of a specialized IBD clinic or gastroenterologist are more likely to be treated according to clinical practice guidelines. We hypothesized that primary care doctors have knowledge gaps in the treatment of patients with IBD as very few of their patients have the disease. Loss in information during transfer of care from inpatient to outpatient, as well as from specialist to generalist, is a serious problem in the German health care system [13, 14].

We therefore designed a guideline implementation strategy to effect change in the practice of primary care physicians.

The study described in this article was conducted to determine whether a guideline implementation strategy geared toward family physicians would result in change in the treatment of patients. Specifically, we wanted to see if five quality indicators drawn from the German IBD guidelines could be improved by our intervention in patients living in Berlin, Germany, compared to the control region Hamburg, Germany. To this end, a multifaceted intervention was designed, composed of a CME event, patient- as well as physician-directed handouts and outreach visits with local opinion leaders.

Methods

Context

Family physicians in Germany can be categorized as primary care physicians or general practitioners, for the most part. Many are general internists, however, and are almost never associated with a hospital. Further, while gastroenterologists working in ambulatory care are also rarely associated with a hospital, only very few hospitals have clinics where IBD patients receive continuous care. An exception to this rule is the university hospital, of which almost all have an IBD outpatient clinic. Nevertheless, only a small number of all IBD patients are treated in these academic centers [5, 14].

Berlin and Hamburg are both large German cities with 3.6 and 1.7 million inhabitants, respectively, surrounded by smaller suburban and/or rural areas. A total of 2800 family doctors and 96 private gastroenterologists work in Berlin and 1100 family doctors and 38 private gastroenterologists work in Hamburg. In addition, Berlin and Hamburg's large university hospitals host three and one specialized IBD outpatient clinics, respectively. Both cities are federal states within the republic of Germany. In 2007, Berlin's gross domestic product per capita was €27,000 and Hamburg's was €52,000.

Surveyed patients belonged to one of three statutory sickness funds: the Allgemeine Ortskrankenkasse (AOK) Berlin, the AOK Rheinland/Hamburg, or the Techniker Krankenkasse (TK). Approximately one third of the German population are insured by the AOK, which is divided according to independent providers in different regions of the country. The TK insures about 10% of the population and offers membership throughout Germany.

Quality indicators

At the time of this study, no widely accepted quality indicators were available in the field of IBD. We therefore extracted five quality indicators from German clinical practice guidelines on Crohn's disease (CD) and ulcerative colitis (UC) [15, 16]. We did not define an expected rate for these indicators. The quality indicators were as follows (for definition, see Table 1):

- Adequate, i.e., treatment according to clinical practice guidelines, long-term treatment with aminosalicylates
- Adequate treatment with immunosuppressants (In this study, we defined azathioprine, methotrexate, and TNF blockers as immunosuppressants as opposed to glucocorticoids.)
- Adequate treatment with glucocorticoids
- Adequate performance of surveillance colonoscopy in UC patients
- Non-smoking in CD patients

Table 1 Definition of quality indicators

Quality indicator	Operational definition
Adequate long-term treatment with aminosalicylates	UC patients: treatment with ≥ 1200 mg aminosalicylates, if flare within the last 2 years or no immunosuppressant use. If a patient was treated with ≥ 1200 mg aminosalicylate, then treatment was automatically considered adequate CD patients: long-term treatment only in patients after intra-abdominal operation
Adequate treatment with immunosuppressants	Treatment with immunosuppressants, if three flares in 1 year or two glucocorticoid induction regimens in 1 year or steroid-dependent or steroid-refractory (UC patients—despite treatment with aminosalicylates) If a patient was treated with an immunosuppressant, treatment was automatically considered adequate
Adequate treatment with glucocorticoids	No long-term treatment unless steroid-dependent during treatment with immunosuppressants
Adequate performance of surveillance colonoscopies in UC patients	Extensive colitis and diagnosis for > 8 y or distal colitis and diagnosis for > 15 y
Non-smoking in CD	All patients

Quality indicators were derived from the German clinical practice guideline for CD and UC from 2003 and 2004

UC, ulcerative colitis; *CD*, Crohn's disease; *immunosuppressants*, all immunosuppressive drugs with the exception of glucocorticoids; *y*, years

Interventions

We performed a multifaceted intervention aimed at changing five core quality indicators in patients with IBD in the city of Berlin with Hamburg serving as a control region.

Patient-directed handout

Using the German clinical practice guideline about UC and CD, we designed a short (two A4 pages) pamphlet explaining in simple language the treatment principles of CD and UC with special emphasis on the five quality indicators (Online resource 1). This pamphlet was sent to all Berlin patients in the study together with the initial questionnaire.

CME event

At the beginning of the intervention, in November 2007, we offered a 2-h CME event with lectures about outpatient treatment of IBD patients. All family physicians as well as private general internists and gastroenterologists in Berlin received an invitation to the event together with a cover letter outlining the project. The invitation was accompanied by a prominent article outlining the background of the problem in the monthly magazine of the Berlin Chamber of Physicians (*Berliner Ärzte*), including an invitation to the CME event.

Physician-directed handout

Based on the German guidelines, we designed another short (two A4 pages) handout directed at physicians. Again, we emphasized the five quality indicators. This handout was sent to all family physicians and gastroenterologists in Berlin together with the invitation for the CME event (Online resource 2).

Outreach visits to opinion leaders

We employed the sociometric method of Hiss et al. to identify opinion leaders in the field of IBD in Berlin [17]. A questionnaire with cover letter was sent to all family physicians in Berlin asking them to identify physicians in the field of IBD based on their communication skills, their knowledge, and their humanism (Online resource 3).

All physicians identified were offered a visit by a member of the study team between December 2007 and March 2008. Topics covered during the visit included

- an overview of the project
- their role as opinion leaders in Berlin
- deficits in the care of IBD patients
- scientific data underlying our quality indicators
- suggestions for family physicians on how to deal with these issues

Given that most of these physicians were recommended due to their expertise in the treatment of IBD patients, the topics above were summarized in a very short presentation, which left time for discussion. All physicians were invited to distribute the aforementioned handouts to physicians and patients.

Study of the interventions

In order to measure quality of care, IBD patients in Berlin and Hamburg were sent a questionnaire in September 2007 prior to, and in September 2008 following, the intervention, which took place in Berlin. Physicians in Hamburg active in the field of IBD and known to the study team were made aware of the study. Hamburg was chosen as a control region to Berlin due to sociodemographic similarities.

Details about patient selection and the patient questionnaire, as well as construction of the database are described in a separate publication [5]. Briefly, members of the AOK or TK in Berlin and Hamburg fulfilling the following inclusion and exclusion criteria were randomly chosen. Inclusion criteria were an International Classification of Diseases, 10th revision (ICD-10) code of K50 or K51 during a hospital stay between 01/2002 and 06/2007 as main or ancillary diagnosis, place of residence in Berlin or Hamburg, and age 18 to 80 years. Exclusion criteria were Operations and Procedure Classification (OPS, German adaptation of the International Classification of Procedures in Medicine) 5-455 to 5-458 that indicate colonic resection in patients with ICD-10 K51 (ulcerative colitis) or the patient was deceased. Patients were asked about (1) their disease, its activity, and prior operations; (2) current drug treatment; (3) smoking status; (4) timing of colonoscopies; and (5) demographics, including the type of physician responsible for treating their disease. The questionnaire was sent to patients by the sickness funds accompanied by a cover letter of the sickness fund and by a letter of the investigators explaining the study. Patients were asked to return the completed questionnaire to the investigators using the enclosed postage-paid envelope.

We chose to only use diagnosis codes reported to the insurance provider by hospitals as the validity of ambulatory diagnosis codes in Germany is low [18, 19]. Diagnosis codes in ambulatory care at the time were irrelevant for reimbursement. Hospitals, on the other hand, rely on diagnosis codes not only for main diagnosis but also for additional diagnoses for reimbursement. Moreover, incorrect encoding is penalized by insurance providers.

Measures

We evaluated the impact of our intervention on the five quality indicators. These were defined as described in Table 1. Treatment according to clinical practice guidelines was assessed for all five quality indicators separately. "Overall quality of care" in each patient was measured with the number of quality indicators, which were fulfilled divided by the number of evaluable quality indicators.

Analysis

All five endpoints were analyzed separately—four for each patient. Secondary endpoints were change of "overall quality of care" as well as change of each single quality indicator in Berlin, and "overall quality of care" in patients treated by a family physician. Statistical analysis was done with Fisher's exact test or Mann–Whitney *U* test depending on data type (binary vs. continuous). To correct for multiple testing using Bonferroni correction, the *p* value for statistical significance was adjusted to 0.0125 for the primary endpoint. For all other endpoints, *p* values were reported without formal assessment of statistical significance.

We assumed a response rate of 66% and the smallest expected difference of 10% for adequate treatment with aminosalicylates in patients with UC, and 15% for adequate treatment with glucocorticoids in patients with CD. To achieve 80% power to detect this difference with an alpha error of 1.25%, 870 UC patients and 270 CD patients were needed. In the original protocol, we planned to only include questionnaires that were evaluable for all four quality indicators. Due to the low response rate and the high rate of questionnaires that did not fulfill these criteria, we decided to use all available questionnaires.

Statistical calculations were performed with IBM SPSS version 24.0, except for comparison of responders and non-responders. Depending upon the variable category, *p* values were calculated using Fisher's exact test or Mann–Whitney *U* test. For the primary endpoint, we used the Bonferroni correction for multiple testing. For some of the contacted patients, only aggregate data were available. Thus, a comparison of responders and non-responders was performed using Fisher's exact test and Student's *t* test with Graphpad InStat version 3.0.10.0.

Results

Population

We contacted 1900 patients (UC 1317; CD 583), 1180 in the intervention region (UC 878; CD 302) and 720 in the control region (UC 439; CD 281). A total of 1104 members of the AOK (intervention region, 740; control region, 364) and 796 in the TK (intervention region, 440; control region, 356) were contacted. Patients identified by our inclusion criteria were older than expected for a population of IBD patients (Table 2). This was most likely due to the fact that we included only patients for whom IBD had been reported to statutory insurance by a hospital as the main or ancillary diagnosis. In addition, the insurance providers identified fewer members with UC in the control region than was initially assumed necessary. Therefore, the proportion of patients with CD was higher in the control region than in the intervention region.

The response rate was relatively low (Table 2). Patients who returned the questionnaire were older than the non-respondents.

Details about the respondents prior to the intervention are described in a separate publication [5]. Relevant demographic details of the respondents following the intervention are summarized in Table 3. Patients in the intervention region were older and there were fewer patients with CD. The median disease duration was more than 10 years in both regions and three quarters of all patients had an indication for immunosuppressants. As

Table 2 Comparison of patients, who responded to the questionnaire with non-respondents

Characteristic	Contacted	Respondents before intervention		Respondents after intervention	
			P value[a]		*P* value[a]
n (%)	1900 (100%)	460 (24.2%)		386 (20.3%)	
Age (y), mean ± SD	54.1 ± 15.2	56.7 ± 17.6	< 0.001[b]	59.2 ± 16.2	< 0.001[b]
Male sex (%)	48.7%	47.3%	0.36[c]	52.9%	0.17[c]
Crohn's disease (%)	30.7%	36.9%	0.003[c]	33.2%	0.50[c]

y, years; *SD*, standard deviation

[a] Compared to non-respondents

[b] Based on Student's *t* test

[c] Based on Fisher's exact test

expected from earlier studies, about half of the respondents were treated solely by their family physician.

Opinion leaders

Family physicians in Berlin identified 108 colleagues as educational influencers. Most individuals were identified equally for their communication skills, their knowledge, and their humanism. The physicians named most frequently were identified by up to 11 family physicians. We chose to perform outreach visits with the top quartile of named physicians. Each of the qualities surveyed were mentioned 2 to 11 times for these "opinion leaders."

Evaluation of effectiveness

Table 4 shows the quality indicators in each region before and after the intervention. The co-primary endpoints were not

Table 3 Comparison of demographics and disease characteristics in intervention and control regions

Characteristic	Intervention region	Control region	*P* value
Age, years (median; quartiles)	67; 52–73	56; 42–68	< 0.001[a]
Duration of disease, years (median; quartiles)	13.7; 6.7–22.7	11.7; 6.7–23.7	0.62[a]
Male sex	52.5%	53.2%	0.92[b]
CD	27.0%	42.8%	0.002[b]
Disease activity			0.32[b]
Acute flare	13.0%	15.3%	
Chronically active	16.3%	10.5%	
Remission	70.7%	74.2%	
Patient with ostomy	3.7%	5.6%	0.42[b]
CD patients with fistula	33.3%	33.3%	1.00[b]
CD patients with previous operations	50.8%	60.3%	0.36[b]
Extent of colitis in UC patients			0.28[b]
Proctitis	35.5%	42.2%	
Distal colitis	23.3%	15.6%	
Extensive colitis	41.2%	42.2%	
Patients with an indication for immunosuppressants	74.8%	79.8%	0.42[b]
Treating physician			0.70[b]
Primary care physician/general practitioner	21.3%	24.5%	
Internist	22.1%	23.7%	
Gastroenterologist	41.3%	40.3%	
IBD clinic	15.3%	11.5%	

Characteristics of respondents following the intervention are shown

CD, Crohn's disease; *UC*, ulcerative colitis; *immunosuppressants*, all immunosuppressive drugs with the exception of glucocorticoids; *IBD*, inflammatory bowel disease

[a] Based on Mann–Whitney *U* test

[b] Based on Fisher's exact test

Table 4 Quality of treatment before and after the intervention in the intervention and control region

Adequate treatment	Before intervention		After intervention		Intervention region vs. control region	Intervention region: before vs. after
	Intervention region	Control region	Intervention region	Control region	*P* value	*P* value
Aminosalicylates	58.7%	63.6%	59.3%	61.9%	0.72[a]	0.92[b]
Glucocorticoids	83.1%	89.9%	83.2%	91.6%	0.03[a]	1.00[b]
Immunosuppressants	71.7%	83.5%	75.5%	83.6%	0.25[a]	0.56[b]
UC: surveillance colonoscopy	95.2%	95.4%	88.4%	90.9%	0.80[a]	0.04[b]
CD: smoking	65.0%	53.7%	75.0%	74.1%	1.00[a]	0.27[b]
Overall quality of care (mean ± SD)	0.76 ± 0.26	0.75 ± 0.25	0.77 ± 0.24	0.81 ± 0.24	0.48[c]	0.24[c]

For the co-primary endpoints, the intervention and control regions were compared following implementation. Surveillance colonoscopy was only evaluated in UC patients, smoking was only evaluated in CD patients. Overall quality of care is the fraction of fulfilled quality indicators in each patient

Immunosuppressants, all immunosuppressive drugs with the exception of glucocorticoids; *UC*, ulcerative colitis; *CD*, Crohn's disease; *SD*, standard deviation

[a] Co-primary endpoints (based on Fisher's exact test; statistically significant *p* value after Bonferroni correction = 0.0125)

[b] Based on Fisher's exact test

[c] Based on Mann–Whitney *U* test

statistically significantly different in the intervention and control regions after the implementation intervention. In addition, no improvement could be seen when comparing the intervention region before and after the intervention.

From the single quality indicators, a single quality measure "overall quality of care" was derived. For each patient, we calculated the fraction of fulfilled quality indicators of all quality indicators evaluable for the respective patient. As can be seen in Table 4, overall quality of care was not statistically significantly different between intervention and control regions or within the intervention region in a before–after comparison. If anything, overall quality of care improved slightly within the control region.

Since this intervention targeted family physicians, we wanted to see if there was a different effect in IBD patients taken care for by their family physician. A subgroup analysis of only patients being treated by a family physician did not show any statistically significant improvement either (data not shown). This was true for the comparison between intervention and control region as well as the before–after comparison within the intervention region.

Discussion

In our population of IBD patients in two large German cities, percentages of patients treated according to clinical practice guidelines ranged from 59% for aminosalicylates to 95% for glucocorticoids. Our multifaceted guideline implementation strategy—composed of a single CME event, a patient- and a physician-directed handout, and outreach visits to local opinion leaders—had no effect on predefined outcome measures comparing intervention and control regions, as well as on a before–after comparison in the intervention region. Generally, the effects of quality improvement initiatives are small, with multifaceted interventions sometimes yielding better results [3, 20–24].

In the studies performed by Sapir et al. and Greene et al., initiation of corticoid-sparing therapy as well as tobacco counseling was one of the investigated quality measures [8, 10]. In their trials of audit and feedback, online interactive CME videos, as well as online toolbox, and a group webinar, no improved prescription of corticoid-sparing therapy was shown in patients with corticosteroids ≥ 10 mg for ≥ 60 consecutive days. This might have been partially due to a high adherence rate in the intervention group of physicians before the intervention. Similarly, there was no statistically significant difference in our population even though the baseline value was much lower in our study.

Outcome measures were in our study not formally derived. Several groups have published and implemented quality indicators for the treatment of patients with IBD. Among the most prominent efforts are those employing quality indicators of the Crohn's and Colitis Foundation of America, which includes ten process measures and ten outcome measures, and outcome measures of the International Consortium for Health Outcomes Measurement, which has set out to become an international standard for epidemiological studies [4, 25, 26]. At the time our study was planned, no widely accepted quality indicators were available; hence, we used German and European clinical practice guidelines to develop quality indicators focusing on core treatment principles of IBD. Four of the five quality indicators we used are also included in process and outcome measures published in 2013, and developed

using the RAND/UCLA appropriateness method by a multidisciplinary panel [25].

Unfortunately, the response rate was rather low in our study. Due to German privacy regulations, we were prohibited from contacting patients who had not responded after being sent the questionnaire. Therefore, no reminders were sent to non-responders. The questionnaire itself consisted of six pages with 45 questions and some of the questions inquired about details of the disease such as location in Crohn's disease or details regarding dosages of medication. This might have been another reason for the low response rate.

Further possible weaknesses of the study are that the questionnaire was not formally validated and no intermediary endpoints were assessed. Thus, we were not able to analyze why our interventions failed to result in a practice change.

Moreover, we may have introduced bias by relying on hospital diagnoses. Patients in our sample were older than expected for patients with IBD and might have higher comorbidity leading to differences in treatment with immunosuppressive drugs [5]. Nevertheless, patients in intervention and control regions were selected in the same manner.

We did not perform a formal appraisal of possible barriers nor did we develop our implementation intervention based on a theory like behavioral, cognitive, or process theory [27, 28]. We and others have shown that family physicians treat on average two patients with IBD, while at the same time half of all patients are treated solely by their family physician, resulting in fewer patients treated according to clinical practice guidelines [5, 12]. We reasoned that a lack of knowledge of the increasingly complex treatment of patients with IBD is a reason for this. The mere distribution of guidelines and hosting of CME events have low effectiveness in terms of guideline implementation [28]. We therefore developed a multifaceted intervention targeting primary healthcare physicians from several angles—via the Berlin Chamber of Physicians, by mail, through their patients as well as through local opinion leaders.

The strength of our study lies in the fact that we did not rely on physicians' self-assessment or on complex chart reviews. We contacted a large number of patients, of whom about half were solely treated by family physicians, and could derive quality measures from a questionnaire sent to patients.

Improving quality of treatment is an important topic for IBD patients. Since each family physician cares for very few patients with IBD, it is unrealistic to implement complex guidelines at this level. Therefore, targeted measures should coincide with diagnosis, namely initiation of a lifelong partnership between the IBD patient and gastroenterologist with experience in IBD care.

Taken together, our data show that the multifaceted guideline implementation strategy did not have a significant effect on quality of care in patients with IBD. Based on our data, we cannot dissect which part of the strategy needs to be changed.

Further research should use validated outcome parameters for the treatment of patients with IBD and the implementation strategy should most likely be based on an exhaustive barrier analysis as well as behavioral, cognitive, or process theory. In addition, intermediary endpoint should be evaluated. This would allow for the identification of crucial steps, where guideline implementation strategies fail to improve patient care.

Acknowledgments We gratefully acknowledge the support of three German statutory sickness funds, the AOK Nordost (Katrin Peise), TK (Christine Vietor), and the AOK Rheinland/Hamburg (Markus Feger), as well as Annegret Schönberg for secretarial assistance and Mary Louise Grossman for English language support. This manuscript is dedicated to the memory of Wolfgang Höhne (1953–2012) and Martin Zeitz (1950–2013).

Funding agency This study was funded by the German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung), through the Kompetenznetz Entzündliche Darmerkrankungen (grant number 01 GI 0486).

Compliance with ethical standards

Conflict of interest J.C.P. served as a consultant for MSD, Pfizer, Takeda, and Biogen and received lecture fees from Vifor, Falk, Janssen, Abbvie, Pfizer, Vifor, MSD, and Takeda. B.S. received a research grant from Pfizer, served as consultant for Falk, Janssen, MSD, Abbvie, Celgene, Lilly, Takeda, Pfizer, and Hospira and received lecture fees from Abbvie, Celgene, Falk, Ferring, Janssen, MSD, Merck, and Takeda; all funds were transferred to the Charité - Universitätsmedizin Berlin, Germany. J.C.H. served as consultant for Amgen, Astra, Falk, Hexal, Janssen, Pfizer, Steigerwald, and Takeda, and received lecture fees from Falk, Janssen, MSD, Pfizer, and Takeda.

Ethical approval All procedures performed in this study were in accordance with ethical standards of the institutional research committee (approval number EA4/092/09) and with the 1964 Helsinki declaration and its later amendments. All patient-related data were anonymized after open questions had been resolved in responders who provided contact information. The local data protection commissioner approved the study protocol.

Informed consent Informed consent was assumed if patients sent in their questionnaire.

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