A Nationwide 2010–2012 Analysis of U.S. Health Care Utilization in Inflammatory Bowel Diseases

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Background: Implementation of the 2010 Affordable Care Act (ACA) calls for a collaborative effort to transform the U.S. health care system toward patient-centered and value-based care. To identify how specialty care can be improved, we mapped current U.S. health care utilization in patients with inflammatory bowel diseases (IBD) using a national insurance claims database.

Methods: We performed a cross-sectional study analyzing U.S. health care utilization in 964,633 patients with IBD between 2010 and 2012 using insurance claims data, including pharmacy and medical claims. Frequency of IBD-related care utilization (medication, tests, and treatments) and their charges were evaluated. Subsequently, outcomes were put into the framework of current U.S. guidelines to identify areas of improvement.

Results: A disproportionate usage of aminosalicylates in Crohn's disease (42%), frequent corticosteroid use (46%, with 9% long-term users), and low rates of corticosteroid-sparing drugs (thiopurines 15%; methotrexate 2.7%) were observed. Markers for inflammatory activity, such as C-reactive protein or fecal calprotectin were not commonly used (8.8% and 0.13%, respectively). Although infrequently used (11%), anti-TNF antibody therapy represents a major part of observed IBD charges.

Conclusions: This analysis shows 2010–2012 utilization and medication patterns of IBD health care in the United States and suggests that improvement can be obtained through enhanced guidelines adherence.

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Key Words: inflammatory bowel diseases, health care utilization, guidelines, costs

The current U.S. health care system is suffering from a variety of clinical and economic inefficiencies.[1–3] Although the focus of debates on these challenges may vary, such as excessive administration, nonadherence to guidelines, overutilization of resources, uncoordinated care, and broad-based preventive failures, there is an emerging consensus that the U.S. health care system as currently implemented, with a persistent disconnection between high spending levels and discernible improvements in patient outcomes, is not sustainable.

Inflammatory bowel diseases (IBD) are prototypic chronic diseases, affecting around 1.4 million adults and children in the United States. The estimated annual disease-attributable direct costs are largely driven by hospital costs and medication, especially biological therapy.[4,5] Like most chronic diseases, IBD care is beset with wide practice variations,[6] provider expertise differentials (primary and specialty), and a limited evidence base for basic, let alone integrated, standards of care and quality of care.[7] Fragmentation and duplication of services, suboptimal follow-up, and a lack of transparency in adherence to guidelines, particularly regarding overuse and misuse of drugs, could contribute as well to the high spending in IBD care.

We conducted a 2010–2012 insurance claims analysis encompassing 964,633 patients with IBD. The primary study objective was to assess U.S. health care utilization in patients with IBD on a national level to establish a detailed understanding of current practices in IBD management. The secondary objective was to analyze charges encountered for different aspects of IBD management and assess their relative contribution to total IBD-related health care costs.

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METHODS

Claims-derived Care Analysis

We conducted a retrospective analysis of U.S. IBD pharmacy and medical claims data, between 2010 and 2012, from Source Healthcare Analytics LLC (SHA). The data represent a significant proportion of all U.S. medical and pharmacy claims enabling quantitative/qualitative assessments of IBD-related practices and costs. Only fully adjudicated claims by both payers and providers were included. Patients with IBD were identified as having ≥1 medical claim with one of the *ICD-9* codes for Crohn's disease (CD) (555.x) or ulcerative colitis (UC) (556.x) between April 2010 and March 2012. Patients with diagnosis codes for both UC and CD were excluded from the disease specific analyses. We analyzed medical claims for patient identifiers, demographics, procedure details, charge, date, and physician information. Pharmacy claims for IBD-specific drugs (Table, Supplemental Digital Content 1, http://links.lww.com/IBD/A522) were analyzed for patient identifiers, demographics, prescription details, charge, date, insurance, and physician information. A summary of the claims data capture process is shown in Figure, Supplemental Digital Content 2, http://links.lww.com/IBD/A523. Heatmaps were generated based on UC and CD pharmacy claim counts in different U.S. regions, by physician 3-digit zip codes, divided by the assumed population sizes of these regions.

Medications were categorized into 6 groups of ascending potency: (1) aminosalicylates, (2) antibiotics, (3) budesonide, (4) systemic corticosteroids, (5) immunomodulators, and (6) biologic therapy (Table, Supplemental Digital Content 1, http://links.lww.com/IBD/A522). We determined the number of unique patients using these drugs between 2010 and 2012. Biologics, in particular intravenous infliximab and intravenous natalizumab, are commonly charged as medical claims, which were therefore included as well. For each drug group, the percentage prescribed by gastroenterologists was calculated. To determine concomitant medication use, we analyzed prescription rates in 3-month timeframes. In addition, we calculated the percentage of patients using corticosteroids for more than 105 consecutive days. To quantify the volume of patients discontinuing immunomodulators or biologics, we defined stopping as not receiving a refill within 30 days after the end date of the last prescription.

For the analysis of IBD-related procedures and tests, total claim counts, unique patient counts, and charges were extracted from the medical claims data set. IBD-related procedures were defined based on a predefined set of Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System Codes summarized in Table, Supplemental Digital Content 3, http://links.lww.com/IBD/A524. The included CPT codes cover gastrointestinal surgical procedures, anesthesia, and medical procedures; laboratory, pathology, and radiological procedures; and codes for evaluation and management. In addition, we included CPT category 2 codes for IBD-specific quality measures[8] and CPT category 3 codes for gastrointestinal procedures. The included Healthcare Common Procedure Coding System level II codes were A-codes for stoma care, B-codes for (par)enteral therapies, and J-, C-, and S-codes for IBD-specific drugs (Table, Supplemental Digital Content 3, http://links.lww.com/IBD/A524).

Charge Analysis

Since neither costs nor reimbursement rates are publicly known, costs in this study refer to claims-related charges and were used to assess the relative contribution of different medications and procedures to total IBD-related charges. Patient identifiers, and thus information regarding diagnoses, were only available for a subset of all pharmacy claims; therefore, deidentified claims for IBD-related medications prescribed by gastroenterologists were also collected for charge estimations. For each claim, physician and insurance information, prescription details, charges, and claim month were obtained. We corrected for the subset of patients with IBD that is not managed by gastroenterologists, using the proportion of IBD medication prescribed by nongastroenterologists in the IBD patient-identified pharmacy claims data set. To assess the charges of IBD-related procedures and tests, the medical claims data set was used. For claims without a charge, the average of charges per procedure with a known charge was used.

Guidelines-derived Care Analysis

We critically appraised and summarized all available U.S. guidelines, medical position statements, and technical reviews from the American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA). Where different sets of guidelines disagreed on specific management decisions, the most conservative measure was used in our analysis. The guidelines-derived data sets were structured in a way that would enable comparison with the claims-derived data analysis.

Statistical Analysis

Our descriptive statistics consist of patient and physician demographics, medication and medical resources utilization, and charges. All outcomes were analyzed for all patients with a diagnosis of IBD, and per diagnosis specifically (UC versus CD). All statistical analyses were performed on the SHA-retrieved data sets using SAS software (version 9.2; SAS, Cary, NC).

RESULTS

Claims-derived Care Analysis

Between 2010 and 2012, a total of 964,633 patients with IBD was identified: 501,718 patients with CD (52%) and 529,788 patients with UC (55%); 7% had a diagnosis code for both UC and CD. The mean age of the study population was 50.8 (SD 18.1) years (CD, 48.3 [SD 18.3] yr; UC, 52.6 [SD 17.7] yr), and 44% was male (43% CD and 45% UC). In the pharmacy claims data set, a total of 413,334 patients with IBD was identified who had at least 1 pharmacy claim for IBD-related medication; 39% of

TABLE 1. Percentage of Patients with IBD/CD/UC Using IBD Drugs Between 2010 and 2012

	IBD, %	CD,%	UC, %
Aminosalicylates	53.1	42.1	62.3
Antibiotics	23.5	25.2	20.7
Budesonide	8.0	12.0	3.7
Systemic corticosteroids	46.3	47.0	44.4
Long-term corticosteroids	8.8	8.3	8.4
Thiopurines	17.5	21.3	12.3
Methotrexate	2.6	3.4	1.6
Cyclosporine	0.2	0.2	0.2
Biologics	11.0	16.8	3.5

these claims were processed by commercial insurers, 30% by a pharmacy benefit manager, 14% by Medicare, 6% by Medicaid, 8% by an employer group, and 3% paid cash (Table, Supplemental Digital Content 4, http://links.lww.com/IBD/A525). Geographical heatmaps that show the relative amount of claims per 3-digit zip code area are provided in Figure, Supplemental Digital Content 5, http://links.lww.com/IBD/A526 for CD and UC.

Pharmacy Claims Analysis

Table 1 summarizes observed use of IBD medication, subdivided for CD and UC. In our study population, 62% of patients with UC and 42% of patients with CD used aminosalicylates. In total, 32% of all aminosalicylate claims were prescribed for patients with CD. Antibiotics were used by 21% of patients with UC and 25% with CD, and corticosteroids were used in 46% of patients with IBD (CD 47%, UC 44%). Long-term use of corticosteroids was observed in 8.8% of patients (19% of all corticosteroid users) within the study period. Concomitant use of corticosteroid-sparing medication, i.e., immunosuppressives, was low (15% used thiopurines concomitant with corticosteroids, 2.7% used methotrexate) (Table 2). In total, 18% of patients used thiopurines (CD 21%, UC 12%), 2.6% methotrexate, and 0.2% cyclosporine. Of patients with UC receiving thiopurines, 59% continued the use of aminosalicylates; for methotrexate, this was 31%. We observed that 54% of patients who used immunomodulators stopped, of whom 73% restarted again. The number of patients with CD who used infliximab, adalimumab, certolizumab pegol, or natalizumab was 6.0%, 9.2%, 2.5%, and 0.1%, respectively; for patients with UC, these rates were 2.1%, 1.3%, 0.2%, and 0%, respectively. Of patients taking biologics, 48% stopped, of whom 74% restarted. The majority of biologics (69%), immunomodulators (63%), aminosalicylates (64%), and budesonide (69%) were prescribed by gastroenterologists. Nongastrointestinal specialists prescribed most of the corticosteroids (70%) and antibiotics (71%).

Medical Claims Analysis

A total of 12,374,156 medical claims were identified between 2010 and 2012, covering 6405 different claim codes. Of these codes 1750 (27%) were IBD-related, corresponding with 9,818,429 claims (79% of the total claims). The most common claims were 15-minute office visit (684,790 claims), 25-minute office visit (641,367 claims), complete blood count (514,459 claims), venipuncture (513,527 claims), and colonoscopy with biopsies (467,980 claims).

The average rate of annual outpatient clinic visits was 94%, ER visits 11%, hospitalizations 6.5%, and surgeries 2.8% (Table 3). The rate of outpatient clinic visits was higher for CD (97%) compared with UC (74%). Annual colonoscopy rates were 25% for CD and 34% for UC. The annual rate of imaging (ultrasound, magnetic resonance imaging, or computed tomography abdomen/pelvis) was 18%, of complete blood count 32%, and of liver enzyme tests 20%. Annual rates of inflammatory activity assessment using biomarkers were as follows: C-reactive protein 8.8%, ESR 9.7%, fecal calprotectin 0.13%, fecal lactoferrin 0.13%, and fecal leukocytes 0.32%. During the study period, 1.0% of patients underwent a dual-energy x-ray absorptiometry scan. Determination of the rate of thiopurine methyltransferase testing and thiopurine metabolites did not result in reliable results, because multiple CPT codes are used for these

TABLE 2. Concomitant Drug Use

	Aminosalicylates			Systemic Corticosteroids			Thiopurines			Methotrexate			Biologics[a]		
Concomitant Drug Use	IBD Total	CD	UC	IBD Total	CD	UC	IBD Total	CD	UC	IBD Total	CD	UC	IBD Total	CD	UC
Aminosalicylates, %	×	×	×	34	25	42	42	30	59	25	20	31	13	11	24
Systemic corticosteroids, %	15	15	15	×	×	×	19	16	22	29	25	35	13	11	16
Thiopurine, %	14	17	12	15	15	13	×	×	×	3	4	2	10	10	9
Methotrexate, %	1	1	1	3	3	2	0	0	0	×	×	×	3	3	5
Biologics, %[a]	2	3	1	4	6	1	4	5	1	10	12	5	×	×	×

Percentages of patients on drug A (columns) concomitantly using drug B (rows).
[a]Because this analysis was performed using pharmacy claims and infliximab is mostly charged as a medical claim, infliximab use is underestimated in this analysis.

TABLE 3. Observed Average Annual Rate for Hospital Visits, Endoscopies, Surgeries, Laboratory Investigations, and Imaging

	IBD, %	CD, %	UC, %
ER visit	10.7	15.1	4.5
Outpatient visit	93.8	97.4	74.2
Hospitalization	6.5	7.6	4.3
Endoscopy total	42.0	34.1	44.2
Upper GI endoscopy	5.8	6.2	4.7
Colonoscopy	31.3	25.0	33.9
IBD-related surgery total	2.8	3.3	1.6
Resection colon/ileocecal	1.1	1.2	0.8
Fistula/abscess surgery	0.6	0.9	0.1
CBC	32.5	39.5	18.6
CRP	8.8	11.2	4.1
ESR	9.7	12.0	4.8
Liver enzymes	20.4	24.9	11.4
Fecal calprotectin	0.1	0.2	0.1
Fecal lactoferrin	0.1	0.1	0.1
Fecal leukocytes	0.3	0.3	0.3
Influenza vaccination[a]	1.8	1.9	1.3
Pneumococcal vaccination[a]	0.5	0.5	0.4
Hepatitis B vaccination[a]	0.1	0.2	0.1
TB screen[a]	0.8	1.1	0.4
Hepatitis B screening[a]	0.8	1.0	0.4
US/MRI/CT abdomen/pelvis	18.1	22.6	11.3
DXA scan	0.6	0.8	0.3

[a]Might not be billed for independently.
CD, Crohn's disease; CBC, complete blood count; CRP, C-reactive protein; CT, computed tomography; DXA, dual-energy x-ray absorptiometry; ER, emergency room; ESR, erythrocyte sedimentation rate, GI, gastrointestinal tract; MRI, magnetic resonance imaging; TB, tuberculosis; UC, ulcerative colitis, US: ultrasound.

tests and these CPT codes are also used for other tests. The annual observed rate of tuberculosis skin or quantiferon tests, recommended for screening in patients starting with biological treatment was 0.8%, and of hepatitis B screening 0.8%, and annual rates of influenza and pneumococcal vaccinations were 1.8% and 0.5%, respectively. However, many of those might not be billed for independently.

Charges

Annual U.S. medical claim charges for patients with IBD were in total $4.6 billion, of which 86% ($3.9 billion) were directly related to IBD care. The medical claim with the highest share in these charges was infliximab (35%), followed by colonoscopy with biopsies (4.6%) and intravenous infusion of chemotherapy/biologics (3.5%). Furthermore, in total, 22% of the IBD-related medical claim charges were related to endoscopies and surgeries (including pathology and anesthesia charges), 13% to physician consultation services, and 9% were for laboratory tests (Fig. 1A). Patients with a diagnosis code for CD had, on average, higher annual charges and more claims (mean annual charge of $5004 with 6 claims on average) compared with patients with UC (mean annual charge of $2381, with 3 claims on average). Annual IBD-related pharmacy claims were estimated to account for a total of $2.9 billion annually. In total, 54% of those were for aminosalicylates (of which 32% for patients with CD) and 21% for biologics (Fig. 1B).

Guidelines-derived Care Analysis

We identified 7 guidelines/medical position statements published between 2003 and 2010 with recommendations relevant for IBD care; 4 by the American Gastroenterological Association (AGA)[9–12] (all accompanied by technical reviews[13–16]) and 3 by the American College of Gastroenterology (ACG).[17–19] Four focused on IBD management,[10,12,17,18] 2 on colorectal cancer screening,[9,19] and 1 on osteoporosis management in gastrointestinal diseases.[11] None of the guidelines offered detailed recommendations on the

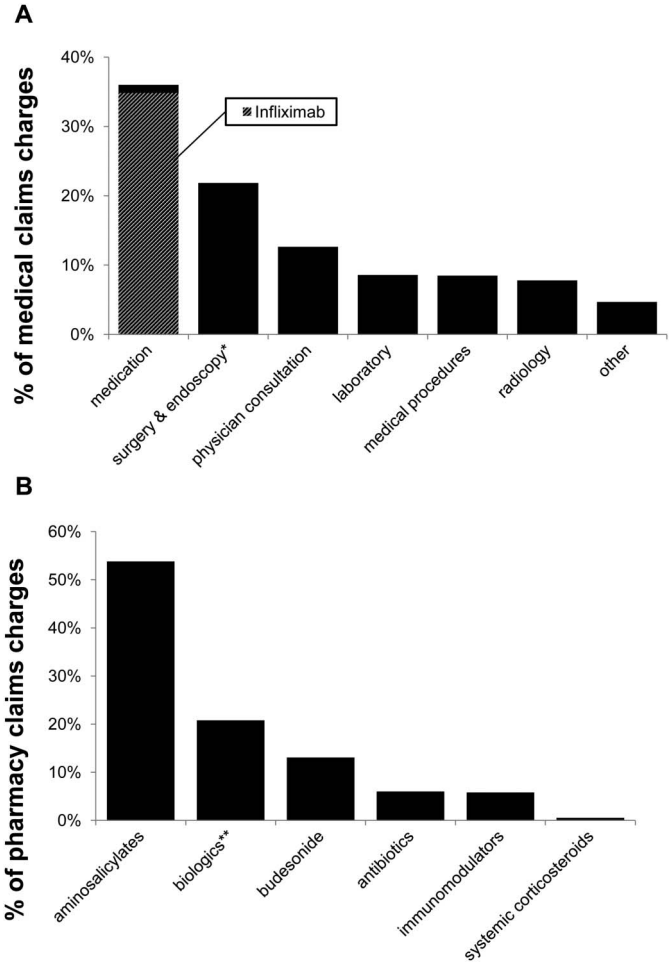

FIGURE 1. Origin of charges in medical claims data set (A) and pharmacy claims data set (B). *Includes anesthesia and pathology. **The majority of infliximab and natalizumab charges is charged as a medical claim and is therefore not included in this graph.

TABLE 4. Expected Medication Use According to Guidelines Compared with Observed Values

Medication	Guidelines	Expected	Observed
Aminosalicylates	Recommended for UC, not/minimally effective for CD	No aminosalicylates for CD	42.1% in CD
Ciprofloxacin/ metronidazole	Only recommended for pouchitis or fistula	Unknown	23.5%
Budesonide	Recommended for UC not for CD	No budesonide in UC	3.7% budesonide in UC
Corticosteroids	For induction of remission, no long-term use	No long-term use	9% long-term use
Immunomodulators/ biologics	Recommended for corticosteroid sparing	46.3% used corticosteroids	15% of corticosteroid users used concomitant thiopurines, 2.7% methotrexate. In total 11.0% biologics use

annual frequency of clinic visits, laboratory visits, and endoscopies, with the exception of colorectal screening protocols. Extracted care recommendations from all guidelines are summarized in Table, Supplemental Digital Content 6, http://links.lww.com/IBD/A527.

An overview of expected rates of medication and medical resource utilization according to guidelines versus the observed rates is provided in Tables 4 and 5, respectively. Summarized, we found that although aminosalicylate treatment is not recommended in patients with CD, 42.1% of patients with CD were prescribed aminosalicylates during the 2-year study period, which alone accounts for at least 17% of total pharmacy charges. Metronidazole and ciprofloxacin, indicated for treatment of pouchitis in UC, active fistulizing disease in CD, and to treat infectious complications, were prescribed to 23% of patients. However, the claims data did not allow a more detailed analysis on indications for antibiotic use.

Corticosteroid-sparing medication was used sparsely in conjunction with corticosteroid therapy (15% thiopurines and 2.7% methotrexate), whereas long-term corticosteroid use was observed in 9% of patients. Although 9% of patients used corticosteroids for more than 105 days consecutively, only 1% underwent a dual-energy x-ray absorptiometry scan. Furthermore, we found a low use of surrogate biomarkers for assessment of inflammation, such as C-reactive protein and/or fecal calprotectin (8.8% and 0.13%, respectively).

DISCUSSION

In this study, we report on U.S. health care utilization in patients with IBD and found unexpected discrepancies with U.S. guidelines. This was demonstrated by a disproportionate rate of aminosalicylate use in CD, common corticosteroid use (including long-term), and a low rate of corticosteroid-sparing drugs. In addition, we found only infrequent usage of surrogate biomarkers, such as C-reactive protein and/or fecal calprotectin.

IBD-related health expenditures are among the highest in the U.S. health care system.[20] A 2012 study based on patient-reported expenditures from 556 patients with IBD estimated

TABLE 5. Expected Rates of Tests and Procedure in the Data Set According to Guidelines, Compared with the Observed Values

Procedures	Guidelines	Expected	Observed
Colonoscopy	1× per 1–3 years, 8 years after diagnosis	Patients with UC >8 yr after diagnosis: 33.3% annual colonoscopy	Patients with UC: 33.9% annual rate
Surrogate activity markers	Fecal calprotectin, lactoferrin, calprotectin, ESR, orosomucoid, or CRP		Annual rates: calprotectin: 0.1%; lactoferrin: 0.1%; fecal leukocytes: 0.3%; CRP: 8.8%; ESR: 9.7%
DXA scan	Patients >3 mo corticosteroids	9% of patients ≥1 episode of long-term corticosteroids	1.0% of patients
Complete blood count	1× per 1–2 weeks initially, then 1× per 3 months	Patients on immunomodulators per quarter: 8.7% thiopurines, 1.1% methotrexate	8.1% 3-mo rate (32.5% annual rate)
Liver enzymes	Patients on thiopurines/methotrexate: routinely/every 1–2 mo	Patients on immunomodulators per quarter: 8.7% thiopurines, 1.1% methotrexate	3.4% 2-mo rate (20.4% annual rate)

CRP, C-reactive protein; DXA, dual-energy x-ray absorptiometry; ESR, erythrocyte sedimentation rate; UC, ulcerative colitis.

annual IBD-related costs in the United States to be $2.9 billion,[20] whereas another claims analysis of 19,420 patients with IBD estimated annual disease-attributable direct costs to be $6.3 billion.[21] Although we were not able to access actual costs in our study, we were able to assess the relative contribution of the different facets of IBD treatment to total IBD-related charges. We identified biologics to be a major cost component in IBD care, although their use was restricted to only 11% of patients with IBD in the observation period. Aminosalicylates accounted for 54% of pharmacy claim charges, while 32% of the prescriptions were prescribed for patients with CD, which is not supported by current guidelines.

Medical insurance claims databases are increasingly used in health outcomes research, and these data present both opportunities and limitations.[22] A major advantage is that claims are anonymous, plentiful, and available in electronic format. Limitations include the focus of claims on reimbursement, which is not designed for research purposes; no health outcomes or treatment goals are available, diagnoses cannot be formally confirmed, and medical utilization without insurance coverage, such as influenza vaccinations at the workplace, is not captured. Also, because only claims processed through medical clearinghouses could be captured in our data set, we were likely not able to capture all U.S. patients with IBD, a fraction of claims for the identified patients might not have been included, and no reimbursement rates were available.

An insurance claims analysis including 19,420 patients with IBD by Kappelman et al[5] found much higher utilization rates because of more stringent inclusion criteria, thereby excluding patients with a mild disease phenotype, patients whom our study aimed to include. In contrast, utilization rates reported in a Northern California study analyzing 8787 patients with IBD were very similar to our observations, except for the number of outpatient visits[23] (Table, Supplemental Digital Content 7, http://links.lww.com/IBD/A528). This study also reported a decline in prolonged steroid exposure from 14% in 1998–1999 to 9% in 2004–2005 annually in CD, and interestingly, an increase in UC from 11% to 14%. Infliximab use increased from 1% to 5% in CD and from <0.1% to 0.4% in UC.[23] Our results are in line with these findings and confirm that similar patterns are observed on a national level.

The observed discrepancies between guidelines and observed care could be explained in different ways. The New England Health Institute identified 4 major barriers to guideline adherence.[24]

1. The current payment system is problematic, because we pay for volume of procedures rather than for outcomes;
2. A lack of information technology systems is a barrier because physicians often have insufficient access to guidelines at the point of care and because information technology does not yet adequately support clinical decision making;
3. The culture, beliefs, and habits of physicians could be barriers because many doctors receive little or no comparative feedback on their performance; and
4. The current process of development of guidelines presents an obstacle to adherence. In particular, the lack of transparency in guideline development leads to a lack of trust among physicians, while guidelines themselves often lack sufficient flexibility and relevance to clinical practice; many guidelines do not reflect the complexity and context in which real-world clinical decisions must be made.[24]

In summary, in our claims data set of 964,633 patients with IBD, unprecedented in size, we found relevant discrepancies between daily care and guideline recommendations on a national level. The guidelines themselves, in this case for a prototypic chronic disease, need to be assessed and updated to enable development of optimal care pathways that are both clinically and economically efficacious. Future research will need to show the effect of improved guidelines on adherence, quality of care, and cost-effectiveness.

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