Journal of Crohn's and Colitis, 2022, **16**, 1405–1414
https://doi.org/10.1093/ecco-jcc/jjac056
Advance access publication 9 April 2022
Original Article

Impact of COVID-19 on Healthcare Resource Utilisation Among Patients with Inflammatory Bowel Disease in the USA

Ryan C. Ungaro,[a] Bonnie Chou,[b,*] Jason Mo,[b] Lyann Ursos,[b] Rachel Twardowski,[b] Ninfa Candela,[b] Jean-Frederic Colombel[a]

[a]Henry D. Janowitz Division of Gastroenterology, Mount Sinai Hospital, Feinstein IBD Clinical Center, Icahn School of Medicine at Mount Sinai, New York, NY, USA
[b]Takeda Pharmaceuticals U.S.A., Inc., Lexington, MA, USA

Corresponding author: Ryan C. Ungaro, MD, Henry D. Janowitz Division of Gastroenterology, Mount Sinai Hospital, Feinstein IBD Clinical Center, Icahn School of Medicine at Mount Sinai, New York, NY, USA. Tel.: 212-241-8100; email: ryan.ungaro@mssm.edu
*Current address: Medical Affairs, Deciphera Pharmaceuticals, LLC, Waltham, MA, USA.

Abstract

Background and Aims: The impact of the COVID-19 pandemic on patients with inflammatory bowel disease [IBD] is largely unknown. We characterised the impact of COVID-19 on IBD care by conducting an analysis of US health care claims data.

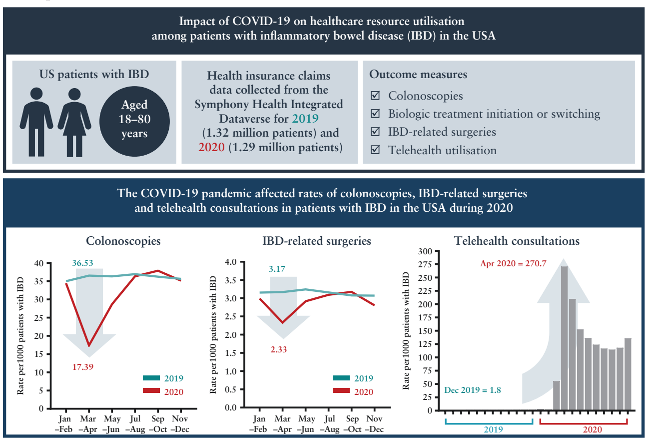
Methods: We obtained de-identified, open-source, health insurance claims data, from January 2019 to December 2020, from the Symphony Health Integrated Dataverse for US adults with IBD, and measured the rates per 1000 patients of five outcomes: colonoscopies; new biologic or small molecule treatment initiations or treatment switches; new biologic or small molecule treatment initiations or treatment switches in patients who had a colonoscopy within the previous 60 days; IBD-related surgeries; and telehealth consultations.

Results: For 2019 and 2020, 1.32 million and 1.29 million patients with IBD, respectively, were included in the analysis. In March–April 2020, the rates of colonoscopies [17.39 vs 34.44], new biologic or small molecule treatment initiations or switches in patients who had a colonoscopy within the previous 60 days [0.76 vs 1.18], and IBD-related surgeries [2.33 vs 2.99] per 1000 patients were significantly decreased versus January–February 2020; significant year on year decreases versus 2019 were also observed. Telehealth utilisation increased in March 2020 and remained higher than in 2019 up to December 2020.

Conclusions: Reduction in colonoscopies and subsequent initiation/switching of treatments during the COVID-19 pandemic suggest lost opportunities for therapy optimisation which may have an impact on longer-term patient outcomes. Increased utilisation of telehealth services may have helped address gaps in routine clinical care.

Key Words: COVID-19; inflammatory bowel disease; health care utilisation; telehealth

Graphical Abstract



List of Non-Standard Abbreviations. 2019-nCoV, 2019 novel coronavirus; aRR, adjusted rate ratio; IDV®, Integrated Dataverse; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; ITS, interrupted time series; WHO, World Health Organization

1. Introduction

In late December 2019, Chinese health authorities reported a cluster of cases of pneumonia of unknown aetiology in Wuhan, Hubei Province.[1] Confirmation that these cases were caused by a novel coronavirus, initially known as 2019 novel coronavirus [2019-nCoV] and subsequently renamed severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2],[2] was provided on January 7, 2020.[1] Soon after, epidemiological data indicated person-to-person transmission of the novel pathogen[3] and on January 20, 2020, a 35-year-old man presenting to a clinic in Snohomish County, Washington, became the first confirmed case of SARS-CoV-2 infection in the USA.[3,4] On March 11, 2020, the outbreak of coronavirus disease 2019 [COVID-19], the disease caused by SARS-CoV-2 infection, was declared a pandemic by the World Health Organization [WHO].[5] According to the WHO interactive COVID-19 dashboard, there have been approximately 384 million SARS-CoV-2 infections and 5.6 million deaths globally as of February 3, 2022.[6]

As the COVID-19 pandemic has progressed, it has had a dramatic impact on health care systems in affected countries, following a pattern observed in previous infectious disease epidemics including the SARS outbreak in Ontario, Canada, in 2003 and the 2014 Ebola outbreak in West Africa.[7–10] As well as direct effects caused by increasing numbers of COVID-19 patients requiring hospitalisation and other medical care, behavioural interventions implemented by governments to mitigate virus transmission [e.g., lockdowns and social distancing measures], updates to clinical procedure guidelines, and changes in public behaviour have produced indirect effects on non COVID-19 related health care resource utilisation.[11,12] A systematic review of health care utilisation from 81 studies across 20 countries including the USA, UK, Germany, China, and Brazil found a median reduction of 37% in overall health service use during the early phase of the pandemic, which included reductions of 42% for clinical visits and 31% for diagnostic procedures.[7] In the USA in particular, significant decreases in non COVID-19 related health care use, outpatient visits and visits to emergency departments were reported during the early phase of the COVID-19 pandemic.[13–16]

In a study by Whaley and colleagues, a relative reduction in colonoscopy use of 69.6% between March–April 2019 and March–April 2020 was reported in the general patient population [46–64 years of age] in the USA; a year on year reduction of 92.9% when restricted to April alone.[15] However, little is known about the specific impact of the COVID-19 pandemic on care in patients with inflammatory bowel disease [IBD] in the USA. According to recent 'treat to target' strategies, patients with Crohn's disease [CD] or ulcerative colitis [UC] typically undergo regular monitoring, including colonoscopies and cross-sectional imaging in the hospital outpatient setting, to allow clinicians to optimise treatment, including deciding whether patients should initiate or switch to a new biologic therapy or if they should undergo surgery. Similarly to other conditions, clinical guidelines and procedures for IBD, including on colonoscopy use, have been affected by the COVID-19 pandemic.[17,18] As a result, COVID-19 related disruption of screening in patients with IBD may have had significant implications for treatment optimisation and potentially damaging effects on long-term patient outcomes.

In this study, we investigated the effects of the COVID-19 pandemic on the rate of colonoscopies, new biologic or small molecule treatment initiations or switches, and IBD-related surgeries in patients with IBD in the USA. We also analysed the monthly rate of telehealth use, to understand how patients adopted alternative forms of health care when in-person care was affected by COVID-19.

2. Methods

2.1 Study design and data source

To assess changes in health care use during the early phase of the COVID-19 pandemic, we conducted a combined cross-sectional and time series study of adult patients with IBD in the USA, using de-identified, open-source, health insurance claims from the Symphony Health Integrated Dataverse [IDV®]. IDV® covers approximately 280 million lives annually and integrates claims submitted to different payer types including commercial health care plans, Medicare Part D, and co-pay assistance programmes. We obtained data for claims between January 2019 and December 2020.

Eligible patients were 18–80 years old and had at least one IBD diagnosis, including CD [ICD-9-CM: 555.xx; ICD-10-CM: K50.xx] or UC [ICD-9-CM: 556.xx; ICD-10-CM: K51.xx], in the 36 months prior to the month in which one of the specified outcome measures was first achieved. IDV® does not include patient insurance enrolment data, and therefore the number of active IBD patients was used as a proxy for the number of enrollees to calculate health care utilisation rates. Active patients with IBD were defined by having at least one claim activity during the study period including in-person or virtual clinic visits or pharmacy refills [including mail-in orders]. Patients whose geographical location, age, or sex were not known were excluded from the analysis.

We assessed the effects of the COVID-19 pandemic on health care utilisation by comparing monthly or bimonthly rates of specified outcome measures. Monthly rates, per 1000 patients with IBD, were calculated by dividing the number of events for each outcome per month by the total number of patients with IBD during the specified month and multiplying by 1000. For bimonthly comparisons, we calculated the rates for each 2-month period [January–February, March–April, May–June, July–August, September–October, November–December] as the mean of the rates for individual months. To compare the rates of the specified outcomes during the COVID-19 pandemic with pre-pandemic time, two analyses were performed. First, we determined changes in outcome rates across 2020 by comparing the bimonthly rates during 2020 with the rate observed in January–February 2020, an appropriate baseline period immediately prior to the onset of the COVID-19 pandemic in the USA. Second, to account for potential seasonal effects in health care utilisation, we compared the bimonthly use rates in 2020 year on year with the same time periods in 2019.

2.2 Outcome measures

We calculated health care utilisation rates per 1000 patients with IBD per month for five outcome measures.

1] Colonoscopies were identified using Current Procedural Terminology [CPT] codes [Supplementary Table 1].

2] New biologic or small molecule treatment initiations or treatment switches [hereafter referred to as new treatment initiations or treatment switches] were identified using Healthcare Common Procedure Coding System codes and National Drug Codes. Eligible treatments included in the analysis were vedolizumab, adalimumab, ustekinumab, certolizumab pegol, golimumab, infliximab, infliximab-dyyb, infliximab-abda, and the small molecule Janus kinase inhibitor tofacitinib. A new treatment initiation was defined as any biologic or small molecule treatment given when the patient had not received any previous biologic treatment in the 36 months prior to the month of treatment initiation. A treatment switch was defined as any new biologic or small molecule treatment given when the patient had received a different treatment in the 36 months prior to the month of treatment initiation.

3] New treatment initiations or treatment switches in patients who had a colonoscopy in the previous 60 days were defined as patients who had a new treatment initiation or treatment switch identified as previously described and who had a colonoscopy, identified using CPT codes, in the 60 days prior to treatment initiation or switch. Measurements for this outcome were performed up to October 2020 to allow for the 60-day look-forward window until the end of our analysis period in December 2020.

4] IBD-related surgeries were identified using CPT codes [Supplementary Table 2].

5] Telehealth utilisation was identified using CPT code modifiers '95', 'GT', 'GQ', and/or virtual service CPT codes maintained by the American Academy of Professional Coders:[19] 99421, 99422, 99423, G2010, G2012, G2061, G2062, and G2063 [Supplementary Table 3].

2.3 Statistical analysis

For colonoscopies, new treatment initiations or treatment switches, new treatment initiations or treatment switches in patients who had a colonoscopy in the previous 60 days, and IBD-related surgeries, we calculated rate ratios to compare rates between pandemic and pre-pandemic time frames. The sample population event distribution was visually inspected for type of IBD diagnosis, age group, sex, and US region. The distributions showed an excess of zero counts [no event] with only a small fraction of patients having more than one event during the measured time interval. Consequently, we used zero-inflated Poisson regression to model the distribution and to calculate 95% confidence intervals [CI] and statistical significance for the rate ratios.[20,21] We modelled the number of events as the outcome and created a binary dummy variable [COVID-19] to represent the exposure of interest, adjusting for type of IBD diagnosis [UC or CD], patient age group, sex, and region. We report the estimated adjusted rate ratio [aRR], 95% CI for the estimated aRR, and *p*-value. Monthly and yearly average event rates are reported as mean ± standard deviation.

To evaluate the overall net impact of the COVID-19 pandemic [up to December 2020] on health care resource utilisation by patients with IBD, we performed an interrupted time series [ITS] analysis using segmented regression. We used the following segmented regression model:

$$Y_t = \beta_0 + \beta_1 T + \beta_2 X_t + \beta_3 T X_t + \varepsilon_t$$

where Y_t is the health care utilisation rate for outcome measures 1–4 at time t, T is the time elapsed in months since the first measurement [$T = 0$], X_t is a binary variable to distinguish pre- [coded 0] and post-intervention time [coded 1], β_0 is the baseline health care utilisation rate at time $T = 0$, $\beta_1 T$ is the rate of change [slope] for each outcome measure that represents the underlying trend over the 24-month study period which would have been expected to occur in the absence of any intervention, $\beta_2 X_t$ is the level of change in health care utilisation rate associated with the intervention, and $\beta_3 T X_t$ is the rate of change for each outcome measure in the period following the intervention. In the case of the COVID-19 pandemic, lockdowns and associated public health interventions [including postponement of scheduled hospital-based procedures] were considered as the policy change variable [X_t] for the analysis. Despite many of the policy changes being implemented at individual state level in the USA, the majority were introduced during March 2020, and therefore this month was considered as the anchor point for the policy change across the USA.

All analyses were conducted in SAS version 9.4. PROC GENMODE with ZIP distribution was used to model zero-inflated Poisson regression. PROC AUTOREG with Newey–West standard errors[22,23] was used to account for autocorrelation and heteroskedasticity. Statistical significance was set at p <0.05 and marginal significance was set at p <0.10.

3. Results

3.1 Trends in IBD-related procedures and treatments

From January to December 2019 and January to December 2020, 1.32 million and 1.29 million adult patients with IBD, respectively, were included in the analysis. The study populations had similar characteristics in terms of age, sex, geographical location, IBD diagnosis, and use of 5-aminosalicylic acid, corticosteroids, or immunomodulators in each year [Table 1]. The rate of colonoscopies performed was stable throughout 2019 with a mean rate across the year of 36.10 ± 0.91 procedures per 1000 patients with IBD per month [Figure 1A]. In January–February 2020, the rate of colonoscopies [34.44 procedures per 1000 patients with IBD] was unchanged compared with the mean rate observed during 2019. We observed an acute reduction in the rate of colonoscopies, to an average of 17.39 procedures per 1000 patients with IBD, in March–April 2020 [Figure 1A]; in April alone, the rate dropped to only 8.4 procedures per 1000 patients with IBD. Using zero-inflated Poisson regression analysis, we calculated estimated aRRs to compare changes in the rate of colonoscopies performed throughout 2020 [bimonthly comparisons with January–February 2020] and year on year changes compared with 2019. The aRR for colonoscopies performed in March–April 2020 showed a significant reduction versus January–February 2020 [aRR: 0.50, 95% CI: 0.50–0.51, p <0.0001] [Figure 2A] and year on year versus March–April 2019 [aRR: 0.48, 95% CI: 0.47–0.48, p <0.0001] [Figure 2B]. We found that the rate of colonoscopies was significantly reduced in May–June 2020 compared with January–February 2020 [aRR: 0.83, 95% CI: 0.82–0.84, p <0.0001] [Figure 2A] and year on year compared with May–June 2019 [aRR: 0.79, 95% CI: 0.78–0.80, p <0.0001] [Figure 2B]. Interestingly, by July–August 2020 [aRR: 1.05, 95% CI: 1.04–1.07, p <0.0001] and September–October 2020 [aRR: 1.10, 95% CI: 1.08–1.11, p <0.0001], the rate of colonoscopies had

Table 1. Summary of characteristics of patients with active IBD in the USA in 2019 and 2020.

	Active adult patients with IBD			
	2019 [*N* = 1318414]		2020 [*N* = 1292459]	
	n	%	*n*	%
Age group, years				
18–34	237717	18.0	227164	17.6
35–44	189168	14.3	186629	14.4
45–54	220077	16.7	212512	16.4
55–64	267998	20.3	259866	20.1
≥ 65	403454	30.6	406288	31.4
Sex				
Female	736134	55.8	720637	55.8
Male	582280	44.2	571822	44.2
US geographical region				
Midwest	317889	24.1	314102	24.3
Northeast	306820	23.3	301289	23.3
South	500476	38.0	489310	37.9
West	193229	14.7	187758	14.5
IBD diagnosis[a]				
CD	579097	43.7	578730	44.0
UC	746654	56.3	737855	56.0
Use of 5-aminosalicylic acid[b]				
Yes	243744	18.5	207509	16.1
No	1074670	81.5	1084950	83.9
Use of corticosteroids[b]				
Yes	351713	26.7	290902	22.5
No	966701	73.3	1001557	77.5
Use of immunomodulators[b]				
Yes	109152	8.3	104126	8.1
No	1209262	91.7	1188333	91.9

CD, Crohn's disease; IBD, inflammatory bowel disease; UC, ulcerative colitis.
[a]Diagnosis within 36 months indexed from the measurement month and attributed to the latest diagnosis during the look-back period.
[b]Used during the specified measurement year.

recovered, with a modest increase observed compared with the rate in January–February 2020. Overall, between July and December 2020, the rate of colonoscopies was comparable to that recorded in 2019, before the onset of the COVID-19 pandemic [Figures 1A and 2B].

We found that the effects of the COVID-19 pandemic on the rate of new treatment initiations or treatment switches were less pronounced than on the rate of colonoscopies. In 2019, the mean monthly rate of new treatment initiations or treatment switches was 9.21 ± 0.77 per 1000 patients with IBD per month. In January–February 2020, the rate of treatment starts/switches [9.88 per 1000 patients with IBD] was similar to the mean rate observed throughout 2019 and the rate observed in January–February 2019 [9.82 per 1000 patients with IBD] [Figure 1B]. In March–April 2020, as the rate of colonoscopies performed fell sharply, the rate of new treatment initiations or treatment switches increased compared with January–February 2020 [aRR: 1.10, 95% CI: 1.07–1.13, p <0.0001]: a significant year on year increase versus March–April 2019 [aRR: 1.20, 95% CI: 1.17–1.23, p <0.0001]. The increase observed in March–April 2020 was followed by a similar magnitude decrease in May–June 2020 when compared with January–February 2020 [aRR: 0.87, 95% CI: 0.85–0.90, p <0.0001] [Figure 2A]: a year on year decrease versus 2019 [aRR: 0.84, 95% CI: 0.82–0.86, p <0.0001] [Figure 2B]. For the remainder of 2020, the rate of new treatment initiations or treatment switches was significantly reduced compared with January–February 2020 [9.8–12.5%]. However, overall year on year comparison revealed similar rates of new treatment initiations or treatment switches across 2019 and 2020 [Figure 1B]; between July and December 2020, rates were increased by 4.9–6.7% compared with the bimonthly rates for 2019.

In patients with an inadequate response, loss of response, or intolerance to conventional treatments or to a first-line biologic treatment, the decision to initiate a new treatment is typically made based upon a clinical assessment of disease activity which includes endoscopic findings.[24] Therefore, to determine if pandemic-related effects on colonoscopies specifically affected rates of new treatment initiations or treatment switches, we measured the rates of treatment initiations or treatment switches that occurred within 60 days of a previous colonoscopy. In 2019, the mean monthly rate of

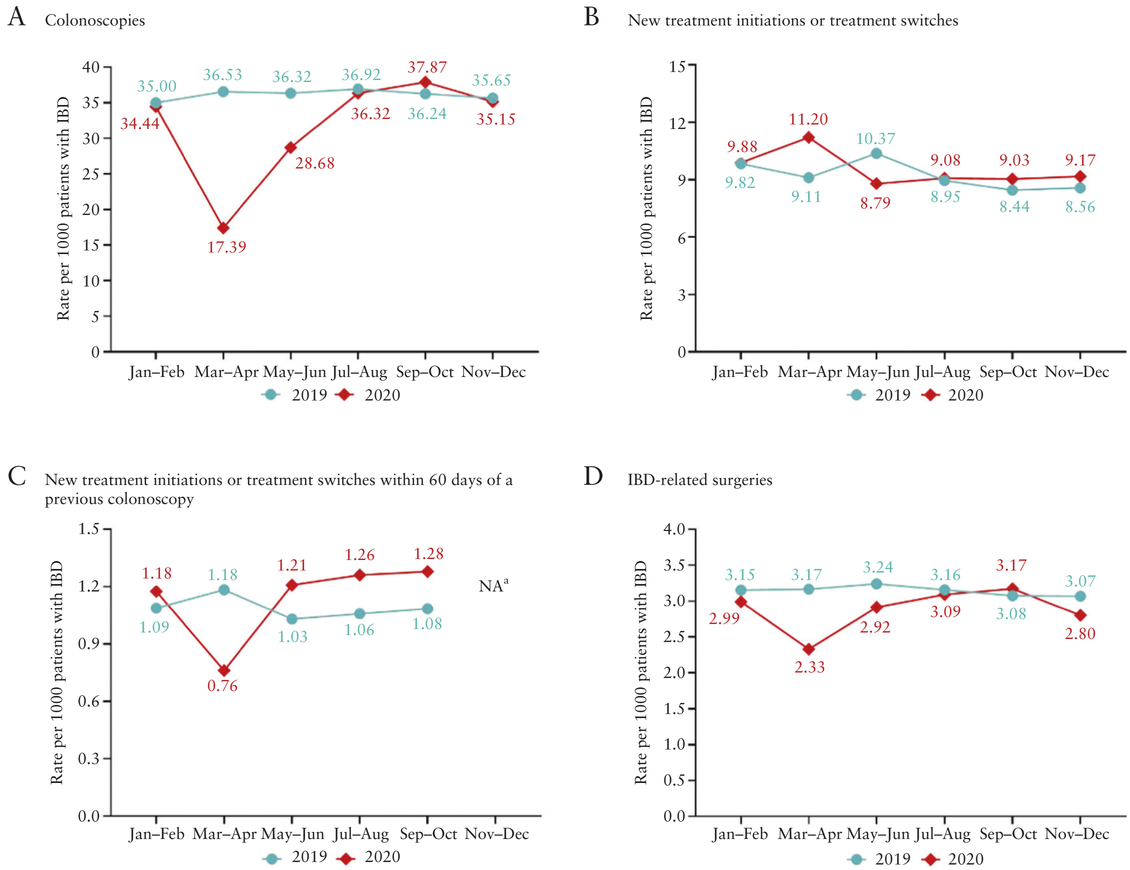


Figure 1. Trends in rates of A] colonoscopies, B] new treatment initiations or treatment switches, C] new treatment initiations or treatment switches within 60 days of a previous colonoscopy, and D] IBD-related surgeries in patients with IBD in the USA during 2019 and 2020. IBD, inflammatory bowel disease; NA, not available. [a]Data for November and December 2020 are not included because the 60-day cut-off extended beyond the specified data collection period.

new treatment initiations or treatment switches in patients with IBD who had a colonoscopy in the previous 60 days was 1.06 ± 0.09 per 1000 patients. In March–April 2020, the rate fell to 0.76 per 1000 patients with IBD [Figure 1C], a significant reduction versus January–February 2020 [aRR: 0.63, 95% CI: 0.58–0.68, p <0.0001] [Figure 2A] and year on year versus 2019 [aRR: 0.63, 95% CI: 0.58–0.68, p <0.0001] [Figure 2B]. Following the initial decrease in March–April 2020 however, the rate of new treatment initiations or treatment switches within 60 days of a previous colonoscopy rebounded to levels previously observed, remaining 1.1–6.8% higher than January–February 2020 [p >0.05 for May–June 2020, July–August 2020, and September–October 2020 vs. January–February 2020] [Figures 1C and 2A]. Between May and December 2020, however, rates increased by 16.4–18.2% year on year versus the same bimonthly periods in 2019 [Figure 2B].

The mean rate of IBD-related surgeries during 2019 was 3.14 ± 0.10 per 1000 patients with IBD per month. In January–February 2020, the rate of 2.99 IBD-related surgeries per 1000 patients with IBD was similar to the same bimonthly period in 2019 [3.15 per 1000 patients with IBD] [Figure 1D]. Similar to the pattern observed for colonoscopies, the rate of IBD-related surgeries decreased to 2.33 per 1000 patients with IBD [Figure 1D] in March–April 2020: a significant reduction versus January–February 2020 [aRR: 0.77, 95% CI: 0.73–0.81, p <0.0001] [Figure 2A] and year on year versus March–April 2019 [aRR: 0.73, 95% CI 0.69–0.76, p <0.0001] [Figure 2B]. By May–June 2020, the rate of IBD-related surgeries had returned to the level observed in January–February 2020 [aRR: 0.97, 95% CI: 0.92–1.01, p = 0.1462] [Figure 2A], although this rate was significantly reduced compared with May–June 2019 [aRR: 0.89, 95% CI: 0.85–0.94, p <0.0001] [Figure 2B]. IBD-related surgeries remained stable throughout the remaining months of 2020, with rates similar to those in January–February 2020 and similar between 2020 and 2019 [Figures 1D and 2A]; a small but significant dip was observed for November–December 2020 when compared with the same bimonthly period in the previous year [aRR: 0.90, 95% CI: 0.86–0.94, p <0.0001] [Figure 2B].

3.2 Overall impact of the COVID-19 pandemic on care of patients with IBD in the USA

ITS analysis using segmented regression revealed that the underlying trend [the change that could have been expected in the absence of the pandemic-related interventions] in the rate of colonoscopies per 1000 patients with IBD in 2019 and 2020 was flat, with little month to month change [−0.061 procedures per 1000 patients per month; Table 2]. However, we found that the policy interventions adopted in the USA to mitigate the effects of COVID-19 [e.g., lockdown] were associated with a significant drop in the level of colonoscopies performed, with a reduction of approximately 17 colonoscopies per 1000 patients

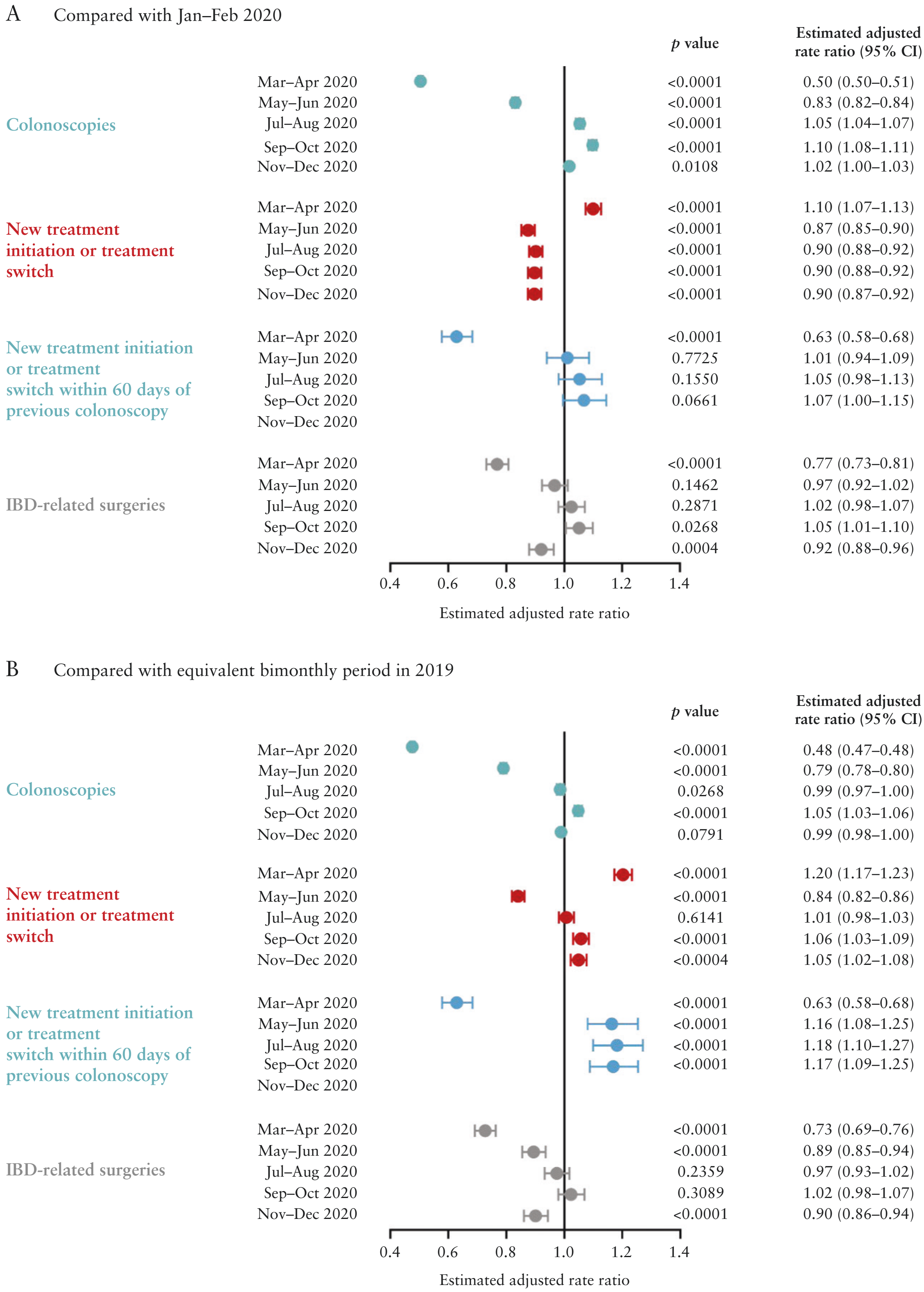


Figure 2. Estimated adjusted rate ratios comparing the rate of colonoscopies, new treatment initiations or treatment switches, new treatment initiations or treatment switches within 60 days of a previous colonoscopy, and IBD-related surgeries in patients with IBD A] during 2020 and B] year on year with 2019. CI, confidence interval; IBD, inflammatory bowel disease.

with IBD between pre- and post-pandemic periods [Table 2]. However, in the period following the pandemic onset [post-March 2020] the colonoscopies performed recovered at a rate of 2.308 procedures per 1000 patients with IBD per month [Table 2, Figure 1A]. Overall, new treatment initiations and treatment switches were not affected by the pandemic; a small, but not significant, increase was observed during the pandemic versus pre-pandemic period [1.479 procedures per 1000 patients with IBD per month; Table 2]. For new treatment initiations or treatment switches that

Table 2. Assessment of the overall impact of the COVID-19 pandemic on care in patients with IBD in the USA using interrupted time-series analysis by segmented regression.

Outcome measure		df	Parameter estimate	Standard error	t value	Approx. *p*-value
Colonoscopies	Underlying trend[a]	1	−0.061	0.084	−0.72	0.477
	Intervention-associated change[b]	1	−16.946	5.519	−3.07	0.006
	Post-intervention trend[c]	1	2.308	0.743	3.10	0.0056
New treatment initiation or treatment switch	Underlying trend	1	−0.052	0.048	−1.09	0.2908
	Intervention-associated change	1	1.479	0.782	1.89	0.073
	Post-intervention trend	1	−0.128	0.112	−1.14	0.2658
New treatment initiation or treatment switch within 60 days of a previous colonoscopy	Underlying trend	1	−0.004	0.007	−0.54	0.5978
	Intervention-associated change	1	−0.278	0.140	−1.98	0.0631
	Post-intervention trend	1	0.081	0.021	3.88	0.0011
IBD-related surgeries	Underlying trend	1	−0.015	0.005	−3.07	0.006
	Intervention-associated change	1	−0.493	0.241	−2.05	0.0539
	Post-intervention trend	1	0.074	0.037	2.03	0.0559

df, degrees of freedom; IBD, inflammatory bowel disease.
[a]Expected rate of change of outcome measure per month over the 24-month measurement period in the absence of policy intervention [$\beta_1 T$].
[b]Change in level of outcome measure associated with implementation of COVID-19 pandemic and related mitigation interventions [$\beta_2 X_t$].
[c]Post-intervention rate of change of outcome measure per month [$\beta_3 TX_t$].

occurred within 60 days of a previous colonoscopy, we observed a non-significant reduction between pandemic and pre-pandemic periods [−0.278 per 1000 patients, Table 2]; the rate of change of new treatment initiations or treatment switches that occurred within 60 days of a previous colonoscopy was significantly increased during the period after the pandemic onset [0.081 per 1000 patients with IBD per month, Table 2]. Finally, the underlying trend in the rate of IBD-related surgeries showed a small, but significant, reduction of 0.015 surgeries per 1000 patients with IBD per month. There was a reduction of 0.493 surgeries per 1000 patients between pre-pandemic and pandemic periods [Table 2].

3.3 Telehealth utilisation

Prior to the onset of the COVID-19 pandemic, when in-person clinical visits were routine, the demand for telehealth consultations among patients with IBD was low, with a mean rate of 1.41 consultations per 1000 patients with IBD per month in 2019. In January and February 2020, the rate of telehealth consultations showed early signs of increasing compared with 2019 levels, but remained low overall [3.1 and 2.4 consultations per 1000 patients per month, respectively] [Figure 3]. In March 2020, a marked increase in telehealth consultations was observed [55.5 consultations per 1000 patients]; this trend continued until April 2020, when a peak rate of 270.7 consultations per 1000 patients with IBD was observed [Figure 3]. Following the peak in April 2020, the monthly rate of telehealth consultations declined to a plateau level of 114.7–136.5 consultations per 1000 patients per month between July and December 2020, a level which remained markedly higher than prior to the pandemic onset [Figure 3].

4. Discussion

The COVID-19 pandemic and associated government actions to mitigate its effects on the population have had a marked impact upon health care systems in the USA and worldwide.[7] Using a cross-sectional and time-series analysis of patient health care claims records, we have shown that the onset of the COVID-19 pandemic in early 2020 was associated with significant impacts on IBD care which may have long-term effects.

In patients with IBD in the USA, we found that colonoscopy procedures were significantly disrupted by the pandemic during spring 2020. Between January [35.2 per 1000 patients] and April [8.4 per 1000 patients] 2020 there was a 76.2% reduction in colonoscopies performed. During the early phase of the pandemic, although routes of SARS-CoV-2 transmission were not fully understood, it was considered highly likely that the virus could be spread via aerosolised particles, droplets, and stool. Consequently, colonoscopy procedures were considered high-risk for exposure to patients and clinical staff.[18,25] Our findings suggest that during the early phase of the pandemic, many planned colonoscopies were cancelled because medical practitioners exercised caution in the face of uncertainties about the virus. Moreover during this phase of the pandemic, with exponentially growing COVID-19 case numbers, health care resources, in particular health care workers, were increasingly diverted away from elective procedures to inpatient care. However, after the initial shock to the health care system in March and April 2020, our analysis shows that the rate of colonoscopies in patients with IBD recovered relatively quickly to pre-pandemic levels; by July and August 2020, the rate was similar to that observed in January–February 2020 and throughout 2019. The reasons

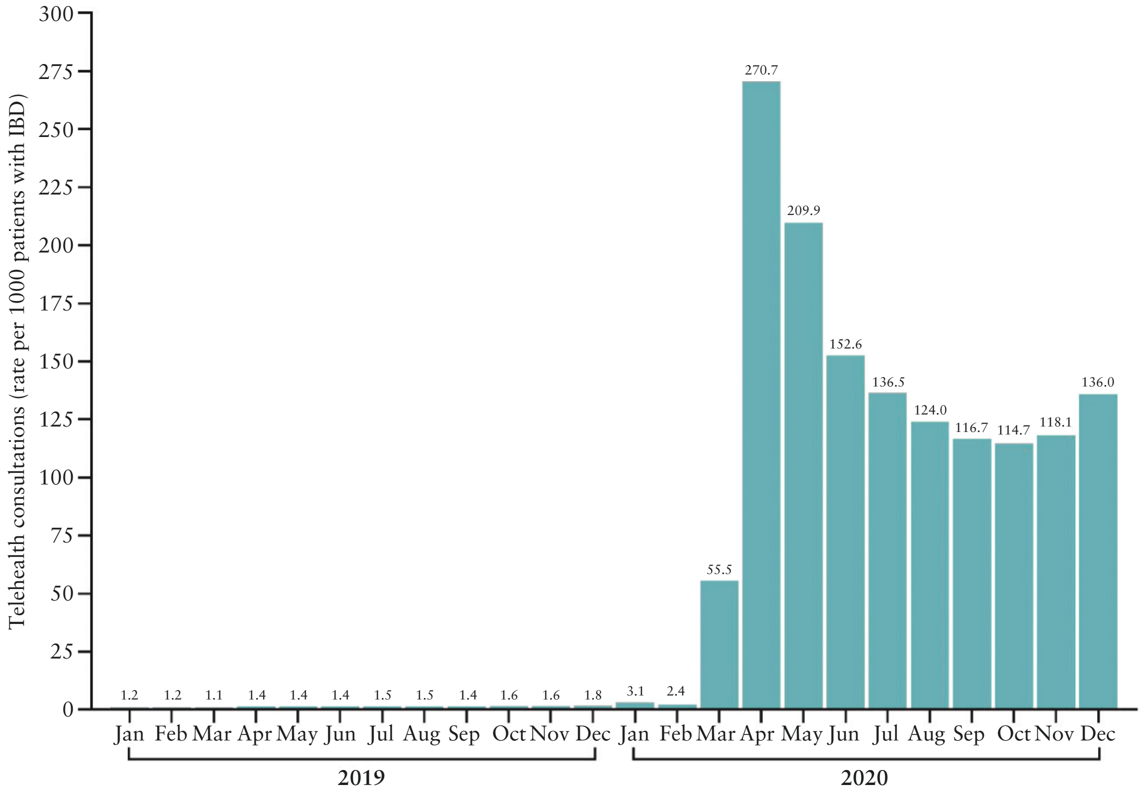


Figure 3. Rate of telehealth consultations for patients with IBD in the USA during 2019 and 2020. IBD, inflammatory bowel disease.

for this are likely 2-fold. First, as public health interventions began to take effect, the level of COVID-19 in the population fell significantly, relieving the overall pressure on health care systems imposed by the very high case numbers in the early months of the pandemic. Second, as global understanding of the SARS-CoV-2 virus and its transmission improved, bodies including national gastroenterology and endoscopy societies and the World Endoscopy Organization released updated recommendations on performing colonoscopies in a COVID-19 safe manner.[18,25]

Our new analysis reveals that the COVID-19 pandemic also had an impact upon the decision to initiate new treatments or to switch treatment in patients in the USA with IBD. We found that in March–April 2020, there was a significant drop in the rate of new treatment initiations or treatment switches in patients who had recent colonoscopies. However, the rate of new treatment initiations or treatment switches between May and October 2020 was significantly increased when compared with 2019. This suggests that IBD flares may have been undertreated during the early phase of the pandemic, but that treatment was delayed rather than missed altogether. This possibly resulted from reluctance among health care professionals to initiate new therapies or switch therapies during the early phase of the pandemic out of concern that it could aggravate COVID-19 outcomes. However, with increasing knowledge of the relatively low risk for adverse COVID-19 outcomes with biologic and small molecule treatments, in particular from the SECURE-IBD registry,[26–28] clinicians were able to approach IBD treatment with renewed confidence. IBD-related surgeries were also acutely decreased in early 2020. Reassuringly, the rate of IBD-related surgeries did not increase in the later months of 2020, suggesting that the treatments that were initially delayed by the pandemic were still sufficiently effective in averting additional surgeries.

Finally, we found that the COVID-19 pandemic was associated with a dramatic increase in telehealth utilisation. Our analysis showed that in patients with IBD, telehealth utilisation was traditionally low, with only approximately 1.5 consultations per 1000 patients per month. However, at the peak of the pandemic in the USA during April 2020, we found a 19 335% increase in telehealth use in patients with IBD compared with April 2019. This increase is consistent with significant increases in telehealth use in the general US population at the onset of the pandemic. For example, the multisite Mayo Clinic saw a 78% reduction in in-person visits between March 11, 2020, and April 20, 2020, accompanied by a 10 880% increase in video appointments with patients at home.[29] Moreover, the International Organization for the Study of Inflammatory Bowel Disease telemedicine survey, conducted by Lees and colleagues, found similar increases in telehealth use in the USA as well as in a range of other countries including the UK, Canada, Australia, and South Africa during the onset of the pandemic.[30] Interestingly, although we observed signs that some clinical services, including colonoscopies, were returning to normal levels later in 2020, the rate of telehealth consultations remained markedly higher than during pre-pandemic period. This trend probably reflects increasing patient awareness and demand for these services, but is also probably the result of continuing unavailability of in-person clinical services which were not captured by our analysis.

This study is subject to certain limitations associated with claims data use. First, the presence of a claim for a filled prescription does not indicate that the medication was consumed or taken as prescribed. Furthermore, the presence of a diagnosis code on a medical claim does not necessarily indicate a positive presence of disease, because the diagnosis code may be incorrectly coded or be included as a rule-out criterion rather than actual disease. Finally, certain information is not readily available in claims data which could influence study outcomes, such as clinical and disease-specific parameters. For example, laboratory tests can be difficult to track in health care claims databases. This makes it challenging to accurately identify procedures, such as tests for biomarkers including faecal calprotectin, which may have been used as surrogate measures during the period of the first COVID-19 wave. Additionally, results of diagnostic imaging tests, including magnetic resonance enterography, bowel sonography, and CT enterography, are also typically not available in claims databases, meaning information about disease-specific parameters such as disease location is not available. However, despite the promise of using these imaging modalities to assess transmural healing in people with Crohn's disease,[31] this is not currently recommended as a formal treat to target diagnostic measure by the latest STRIDE-II guidelines.[32] Therefore, we believe that unavailability of data on these measures in our dataset during the COVID-19 pandemic in 2020 does not significantly detract from our findings and that the outcome measures we selected remain the most useful for determining the effects of the pandemic on IBD care.

Another limitation of the present study is the timespan. The results presented here only capture the effects of the first wave of the COVID-19 pandemic on IBD care. Our data do not capture changes that occurred as the pandemic progressed into 2021 and beyond, which may have had a significant impact on the response of health care services to COVID-19, most critically the introduction of effective COVID-19 vaccines. The duration of our present study also precludes a thorough assessment of any direct link between impacts on health care resource utilisation and COVID-19 case numbers. Although the greatest impacts we report in the present study occurred during the early part of 2020, when COVID-19 case numbers in the USA were high, we cannot distinguish whether these impacts were due to overwhelmed health care systems or because of caution in response to a novel pathogen. In a future analysis, it would be of value to investigate whether the impacts we observed during the first wave of the pandemic were repeated during subsequent waves, where case numbers were high but health care systems were better prepared.

The data found in the IDV® database are aggregated from multiple sources, including multiple payers, health systems, pharmacies, electronic billing relay systems [i.e., billing switches], and other sources. This allows for a unique longitudinal data source that contains individual patient-level data for patients who move between health plans, as well as capturing cash payments for select services. The downside to this methodology is the lack of a patient eligibility or monthly enrolment file that would be commonly found in administrative claims data from a single payer. To overcome this limitation, a quarterly activity variable for each patient has been generated, which provides an indication that the patient had medical or pharmacy claims activity in each quarter.

In conclusion, IBD-related care in the USA was significantly affected during the COVID-19 pandemic, which may have caused lost opportunities for therapy optimisation. Longer follow-up will be needed to fully address the impact of these acute changes on disease progression.

The data underlying this article were provided by Symphony Health under licence/by permission. Data will be shared on request to the corresponding author with permission of Symphony Health.

Funding

This study was supported by Takeda. Medical writing support was provided by Adam Errington, PhD, of Oxford PharmaGenesis, Cardiff, UK, and funded by Takeda.

Conflict of Interest

RCU served as an advisory board member or consultant for AbbVie, Bristol Myers Squibb, Janssen, Pfizer, and Takeda; and has received research support from AbbVie, Boehringer Ingelheim, Eli Lilly, and Pfizer. He is supported by an National Institutes of Health K23 Career Development Award [K23 KD111995-01A1]. BC is a former employee and holds stock/stock options at Takeda Pharmaceuticals U.S.A., Inc. JM, LU, RT, and NC are employees and hold stock/stock options at Takeda Pharmaceuticals U.S.A., Inc. J-FC has received: research grants from AbbVie, Janssen Pharmaceuticals, and Takeda; payments for lectures from AbbVie, Amgen, Allergan, Ferring Pharmaceuticals, Shire, and Takeda; consulting fees from AbbVie, Amgen, Arena Pharmaceuticals, Boehringer Ingelheim, Bristol Myers Squibb, Celgene Corporation, Eli Lilly, Ferring Pharmaceuticals, Galmed Research, GlaxoSmithKline, Geneva, Iterative Scopes, Janssen Pharmaceuticals, Kaleido Biosciences, Landos, Otsuka, Pfizer, Prometheus, Sanofi, Takeda, and TiGenix; and holds stock options in Intestinal Biotech Development.

Acknowledgements

Kyle Null, Senior Director Data Science and Outcomes Research of Takeda US Medical Economics and Outcomes Research, provided advisory support to develop the study protocol.

Author Contributions

Study design and concept: RCU, BC, JM, RT, J-FC. Data acquisition and analysis: BC, JM, RT. Data interpretation: RCU, BC, J-FC. Drafting and critical revisions of the manuscript: RCU, BC, JM, LU, RT, NC, J-FC.

This work was previously presented as a poster at the 16th Congress of the European Crohn's and Colitis Organisation [ECCO], July 2–3 and 8–10, 2021.

Supplementary Data

Supplementary data are available at *ECCO-JCC* online.

References

1. World Health Organization. *Novel Coronavirus [2019-ncov] Situation Report 1*. https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200121-sitrep-1-2019-ncov.pdf?sfvrsn=20a99c10_4 Accessed September 14, 2021.
2. Gorbalenya AE, Baker SC, Baric RS, *et al*. The species severe acute respiratory syndrome-related coronavirus: classifying 2019-ncov and naming it SARS-CoV-2. *Nat Microbiol* 2020;5:536–44.

3. Chan JF-W, Yuan S, Kok K-H, *et al*. A familial cluster of pneumonia associated with the 2019 novel coronavirus indicating person-to-person transmission: a study of a family cluster. *Lancet* 2020;**395**:514–23.
4. Holshue ML, DeBolt C, Lindquist S, *et al*. First case of 2019 novel coronavirus in the United States. *N Engl J Med* 2020;**382**:929–36.
5. Cucinotta D, Vanelli M. WHO declares COVID-19 a pandemic. *Acta Biomed* 2020;**91**:157–60.
6. World Health Organization. *WHO Coronavirus [COVID-19] Dashboard*. https://covid19.who.int/ Accessed September 14, 2021.
7. Moynihan R, Sanders S, Michaleff ZA, *et al*. Impact of COVID-19 pandemic on utilisation of health care services: a systematic review. *BMJ Open* 2021;**11**:e045343.
8. Xiao H, Dai X, Wagenaar BH, *et al*. The impact of the COVID-19 pandemic on health services utilization in China: time-series analyses for 2016–2020. *Lancet Reg Health West Pac* 2021;**9**:100122.
9. Schull MJ, Stukel TA, Vermeulen MJ, *et al*. Effect of widespread restrictions on the use of hospital services during an outbreak of severe acute respiratory syndrome. *CMAJ* 2007;**176**:1827–32.
10. Delamou A, Ayadi AME, Sidibe S, *et al*. Effect of Ebola virus disease on maternal and child health services in Guinea: a retrospective observational cohort study. *Lancet Glob Health* 2017;**5**:e448–e57.
11. Roy CM, Bollman EB, Carson LM, *et al*. Assessing the indirect effects of COVID-19 on health care delivery, utilization and health outcomes: a scoping review. *Eur J Public Health* 2021;**31**:634–40.
12. Birkmeyer JD, Barnato A, Birkmeyer N, Bessler R, Skinner J. The impact of the COVID-19 pandemic on hospital admissions in the United States. *Health Affairs* 2020;**39**:2010–7.
13. Mehrotra A, Chernew M, Linetsky D, Hatch H, Cutler D. *The Impact of the COVID-19 Pandemic on Outpatient Visits: A Rebound Emerges*. https://www.commonwealthfund.org/publications/2020/apr/impact-covid-19-outpatient-visits Accessed September 27, 2021.
14. Baum A, Schwartz MD. Admissions to veterans affairs hospitals for emergency conditions during the COVID-19 pandemic. *JAMA* 2020;**324**:96–9.
15. Whaley CM, Pera MF, Cantor J, *et al*. Changes in health services use among commercially insured US populations during the COVID-19 pandemic. *JAMA Network Open* 2020;**3**:e2024984.
16. Giannouchos TV, Biskupiak J, Moss MJ, *et al*. Trends in outpatient emergency department visits during the COVID-19 pandemic at a large, urban, academic hospital system. *Am J Emerg Med* 2021;**40**:20–6.
17. Soetikno R, Teoh AYB, Kaltenbach T, *et al*. Considerations in performing endoscopy during the COVID-19 pandemic. *Gastrointest Endosc* 2020;**92**:176–83.
18. Neumann H, Emura F, Bokemeyer B, *et al*. Practical advice for management of inflammatory bowel diseases patients during the COVID-19 pandemic: World Endoscopy Organization statement. *Dig Endosc* 2020;**32**:658–62.
19. Verhovshek J. *Telehealth Modifiers gt and gq. American Academy of Professional Coders™*. https://www.aapc.com/blog/38426-lesser-know-modifiers-gt-and-gq/ Accessed September 27, 2021.
20. Lee JH, Han G, Fulp WJ, Giuliano AR. Analysis of overdispersed count data: application to the human papillomavirus infection in men [HIM] study. *Epidemiol Infect* 2012;**140**:1087–94.
21. Lambert D. Zero-inflated Poisson regression, with an application to defects in manufacturing. *Technometrics* 1992;**34**:1–14.
22. Bottomley C, Scott JAG, Isham V. Analysing interrupted time series with a control. *Epidemiol Methods* 2019;**8**:20180010.
23. Newey WK, West KD. A simple, positive semi-definite, heteroskedasticity and autocorrelation consistent covariance matrix. *Econometrica* 1987;**55**:703–8.
24. Negreanu L, Voiosu T, State M, *et al*. Endoscopy in inflammatory bowel disease: from guidelines to real life. *Therap Adv Gastroenterol* 2019;**12**:1756284819865153.
25. Lui RN, Wong SH, Sánchez-Luna SA, *et al*. Overview of guidance for endoscopy during the coronavirus disease 2019 pandemic. *J Gastroenterol Hepatol* 2020;**35**:749–59.
26. Agrawal M, Brenner EJ, Zhang X, *et al*. Characteristics and outcomes of IBD patients with COVID-19 on tofacitinib therapy in the SECURE-IBD registry. *Inflamm Bowel Dis* 2021;**27**:585–9.
27. Agrawal M, Zhang X, Brenner EJ, *et al*. The impact of vedolizumab on COVID-19 outcomes among adult IBD patients in the SECURE-IBD registry. *J Crohns Colitis* 2021;**15**:1877–84.
28. Ungaro RC, Brenner EJ, Gearry RB, *et al*. Effect of IBD medications on COVID-19 outcomes: results from an international registry. *Gut* 2021;**70**:725–32.
29. Demaerschalk BM, Blegen RN, Ommen SR. Scalability of telemedicine services in a large integrated multispecialty health care system during COVID-19. *Telemed e-Health* 2021;**27**:96–8.
30. Lees CW, Regueiro M, Mahadevan U. Innovation in inflammatory bowel disease care during the COVID-19 pandemic: results of a global telemedicine survey by the International Organization for the study of Inflammatory Bowel Disease. *Gastroenterology* 2020;**159**:805–8.e1.
31. Geyl S, Guillo L, Laurent V, *et al*. Transmural healing as a therapeutic goal in Crohn's disease: a systematic review. *Lancet Gastroenterol Hepatol* 2021;**6**:659–67.
32. Turner D, Ricciuto A, Lewis A, *et al*. STRIDE-II: an update on the selecting therapeutic targets in inflammatory bowel disease [STRIDE] initiative of the International Organization for the Study of IBD [IOIBD]: determining therapeutic goals for treat-to-target strategies in IBD. *Gastroenterology* 2021;**160**:1570–83.