CROHN'S & COLITIS FOUNDATION

Collaborating to Optimize High-Quality, Cost-Effective Care for Inflammatory Bowel Disease

Findings from The Crohn's & Colitis Foundation's 2020-2021 Payer-Provider Roundtables

Jointly provided by CROHN'S & COLITIS FOUNDATION and Impact Education LLC

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EXECUTIVE SUMMARY

Inflammatory bowel disease (IBD) is a chronic, progressive disease with significant clinical and economic consequences that ultimately affect patients, providers, and payers. Payer professionals and affiliated network providers are challenged with implementing strategies that facilitate appropriate clinical intervention for members with IBD. Furthermore, cost-management considerations—especially in a therapeutic space with multiple specialty biologic drug options—exacerbate the challenge of appropriate coverage criteria and care delivery. Payer management initiatives such as prior authorization (PA), step-edits, and benefit design are deemed necessary to flatten the curve of the specialty drug trend in a manner that is sustainable for all health care stakeholders, but often result in perceived delays in access to care borne by patients and providers. These factors contribute to what can sometimes be seen as an adversarial relationship among payers and providers in IBD care coverage and delivery. To address this disconnect, the Crohn's & Colitis Foundation (Foundation), with educational partner Impact Education, LLC, sponsored a series of regional roundtables among payer stakeholders and IBD specialist providers in 2018-2019, with a follow-up series in 2020-2021. These roundtables were aimed at enhancing disease awareness and facilitating collaboration between health plan decision makers and clinical thought leaders. Focusing on 10 U.S. cities/regions, the 2020-2021 IBD payer-provider virtual roundtable series was attended by 45 IBD specialist providers, 13 pediatric IBD specialist providers, and 26 payer decision makers. Cumulatively, these participants had an estimated patient reach of 486,258 covered lives. The initiative was highly successful, with 94% of participants planning to take steps to improve payer-provider collaboration in the coverage and provision of IBD care within 1 year. Recommendations and next steps for future programming included smaller focus groups centered on more specific topics within IBD care coverage and delivery, processes to streamline PA submission and appeal, and steps toward improving the practical utility of care pathways. The success garnered to date from the IBD payer-provider roundtable initiative demonstrates the inherent value of collaboration, but further outreach and education will be necessary for sustaining momentum and continuing enactment of meaningful change in quality improvement and cost management.

INTRODUCTION

Affecting an estimated 1.6 million Americans, inflammatory bowel disease (IBD) is an immune-mediated disorder leading to chronic inflammation and damage of the lower gastrointestinal (GI) tract.[1,2] The prevalence of IBD is increasing, most prominently among younger adults, with as many as 70,000 new cases diagnosed every year.[2] IBD presents as one of two main phenotypes: Crohn's disease (CD) or ulcerative colitis (UC).[3] While both are associated with a dysregulated immune response, the distinguishing factors between CD and UC are the location and nature of the inflammatory activity that manifests in each disease. CD can affect any part of the GI tract, from mouth to anus, while UC is found only in the colon and rectum. Microscopically, UC is restricted to the epithelial lining, or mucosa, of the gut, while CD affects the entire bowel wall, creating transmural lesions. Symptoms of IBD include persistent diarrhea, cramping abdominal pain, fever, and, at times, rectal bleeding. Loss of appetite and weight loss also may occur.[3] The effects of IBD are not limited to the GI tract; the condition may also affect the liver, joints, skin, and eyes.[2,3]

BURDEN OF DISEASE

In addition to the clinical manifestations of IBD in affected plan members, the painful flare-ups of CD and UC result in a substantial economic burden on the entire health care system, including both direct and indirect costs to health care payers and employer purchasers. IBD ranks first among the five most expensive GI disorders, despite having the lowest prevalence among those included.[4] Based on pharmacoeconomic data, the Foundation determined the total annual financial burden of IBD in the United States to be as high as $32 billion in 2014.[2] However, recent longitudinal data and reimbursement information for CD indicate that total costs may significantly exceed these earlier estimates.[5] Furthermore, the cost of IBD care has increased in the last 5 years, driven by specific high-cost therapeutics and delays in care. Compared to those without the disease, insurance plan members with IBD increasingly incur higher costs associated with health care utilization, high out-of-pocket expenditures, and significant workplace productivity losses.[6]

IBD is associated with high resource utilization in virtually every aspect of care. A claims analysis of 52,782 patients with IBD (29,062 UC; 23,720 CD) using data from 2007 to 2016 identified several key drivers of cost for patients with IBD: treatment with specific therapeutics (biologics, opioids, or steroids); emergency department (ED) use; and health care services associated with relapsing disease, anemia, or mental health comorbidity.[6] On a per-annual basis, patients with IBD incurred a greater than 3-fold higher direct cost of care compared with non-IBD controls ($22,987 vs $6,956 per-member per-year paid claims) and more than twice the out-of-pocket costs ($2,213 vs $979 per-year reported costs), with all-cause IBD costs rising after 2013.[6] Beyond economic costs, the unrelenting nature of these illnesses, especially during periods of exacerbations, negatively affects various aspects of the patient's quality of life (QOL), including their daily living, ability to work, and self-perception/body image.[7] Anxiety and depression are common comorbidities, and studies have shown that QOL worsens in association with disease severity. Patients with active disease report lower QOL scores compared with patients in remission.[8]

THE ROLE OF PAYER INTERVENTION IN ENHANCING BEST PRACTICES AND CARE QUALITY

IBD diagnosis is often delayed by inaccurate assessment, limited coverage of diagnostic tests, and/or a deficit in access to specialist care, thereby resulting in worsening outcomes and increased disease-related costs. Among 2,341 surveyed patients with IBD, 68% reported a delay in diagnosis, with 63.9% reporting a delay > 1 year and 48.1% reporting a delay > 2 years.[9] Patients reported seeing a mean of 3.5 physicians before establishing an IBD diagnosis. An uncertain or wrong initial diagnosis by a primary care provider (58.2%) or a gastroenterologist (28.3%) were reported as the most common reason for delay. Demonstrating the effect of delayed diagnosis on outcomes, a diagnostic delay of greater than 2 years was significantly associated with disease complications.[12]

At the next stage of the care continuum, timely delivery of optimal therapy in IBD has been shown to benefit affected members as well as managed care and payer organizations.[10] Conversely, the cost of mismanaged treatment among patients with IBD is substantial, with claims that are more than 2 times higher among members receiving suboptimal therapy.[11] One potential solution to counteract costly treatment variation and deviation from clinical guidelines without compromising patient access to care is to collaborate on the integration of care pathways initiatives. Care pathways are prescriptive decision-support platforms developed to manage patient care, improve quality, reduce variation, and increase the efficient use of health care.[12] In addition, care pathways provide a mechanism for integrating evidence-based medicine into clinical practice.[14] The American College of Gastroenterology (ACG) and American Gastroenterological Association (AGA) have issued clinical practice guidelines for both CD and UC, facilitating evidence-based prescribing among network providers.[13,14] The AGA[15,16] and Foundation have also produced several care pathways.[17,18,19]

Considering current trends toward stricter utilization management, increased member cost-share, and other initiatives that may create barriers to patient access, payer professionals and affiliated network providers must strike a balance between clinical needs and the health care resource utilization associated with IBD. While utilization management initiatives and benefit design may help to manage the drug spend by preventing inappropriate prescribing, they may also result in a significant drain on time and plan resources when network physicians are required to provide the necessary documentation for approval or continued treatment. In surveys of U.S. providers from 2016 and 2017, 67% of physicians who treat patients with IBD indicated the process for obtaining reimbursement had intensified and that the most time-consuming processes were obtaining pre-authorization (47%), gathering data for appeals (16%), and explaining the process to the patient (13%).[20] Furthermore, some gastroenterology practices communicated with payers more than 30 times a day to obtain authorizations, and 63% said a full-time employee spent 25% of their time dealing with these issues.[17] Delays in delivery of optimal medical care are incentivized in the short term for payers (lower up-front costs) but result in worse outcomes for patients in the long term.

RATIONALE FOR PAYER-PROVIDER ROUNDTABLE SERIES

All the aforementioned factors can contribute to an adversarial environment among payers and providers in IBD care coverage and delivery. To address this disconnect, the Foundation, with educational partner Impact Education, LLC, sponsored a series of 8 regional roundtables among payer stakeholders and IBD specialist providers in 2018 and 2019 to enhance disease awareness and facilitate collaboration between health plan decision makers and clinical thought leaders. The in-person meetings involved 20 payer representatives and 40 IBD specialist providers, representing nearly 300,000 covered lives, and generated valuable feedback toward collaboration in the name of high-quality, cost-effective care for IBD. Building upon the success of this initiative, the Foundation sponsored a second series of virtual roundtables in 2020 and 2021 in the wake of the COVID-19 pandemic, this time focusing on 10 U.S. cities/regions and enlisting the input of pediatric IBD specialists in addition to adult-focused providers. Three cities—Ann Arbor, Atlanta, and Las Vegas—were featured in both the 2018-2019 and 2020-2021 roundtable series to assess change in practice and procedures >1 year following the original meeting. These cities were selected after all previous locales were surveyed and the three emerged as having participants who were most willing to collaborate but had not yet made significant advancement.

Table 1. 2020-2021 IBD Payer-Provider Roundtables.

City/Region	Date	Patient Reach
Ann Arbor, MI	November 16, 2020	71,100
Atlanta, GA	December 1, 2020	94,250
Washington, D.C.	December 15, 2020	33,375
Las Vegas, NV	January 13, 2021	10,625
Pittsburgh, PA	February 25, 2021	38,750
Raleigh-Durham, NC	March 8, 2021	38,001
Los Angeles, CA	March 11, 2021	70,127
Sacramento, CA	March 23, 2021	29,501
Miami, FL	April 8, 2021	72,126
Phoenix, AZ	May 5, 2021	28,500

SCOPE, REACH, AND OVERALL OUTCOMES

Similar in format to the 2018-2019 meetings, the 2020-2021 IBD payer-provider roundtable series featured didactic presentations in a virtual format followed by interactive polling, question and answer sessions, and open discussion. Specifically, the discussions were centered on the facilitation of timely diagnosis, appropriate treatment, efficient utilization management criteria, and sustainable coverage and reimbursement policies to improve the quality of IBD care and manage associated costs.

> *"If we have an issue [with prior authorization], I want to hear it. We are your collaborative partners."*
>
> -Payer Participant

Total attendance across 10 cities/regions included 45 IBD specialist providers, 13 pediatric IBD specialist providers, and 26 payer decision makers. Cumulatively, these participants had an estimated patient reach of 486,258 covered lives. Outcomes results from post-surveys indicated that 94% of participants planned to take steps to improve payer-provider collaboration in the coverage and provision of IBD care within 1 year. Specifically, the urgency and need for payer-provider collaboration in IBD management was apparent based on attendee responses, with an overwhelming majority citing intended action within 3 months post-roundtable participation (Figure 1).

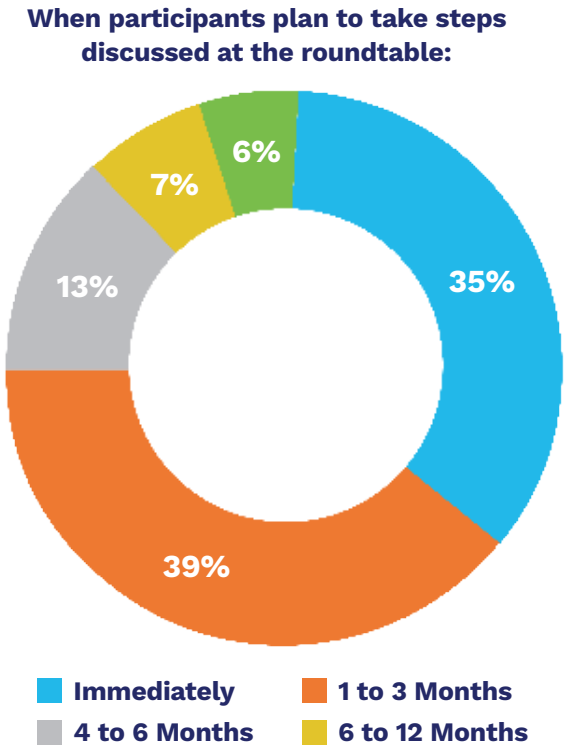

Figure 1. Intended timeframe for participant engagement in identified next steps post-roundtable.

SCOPE, REACH, AND OVERALL OUTCOMES

Likewise, across the entire 2020-2021 roundtable series, participants regarded the educational content as relevant and reported better understanding in terms of key learning outcomes:

PERCENT OF PARTICIPANTS WHO ARE NOW BETTER ABLE TO:	Total
☑ Characterize the clinical and economic burden of moderately to severely active IBD in terms of health care resource utilization, indirect costs, and member quality of life	96%
☑ Demonstrate how appropriate access to moderately to severely active IBD treatment options can improve clinical and economic outcomes for payers	94%
☑ Integrate available IBD care pathways from professional organizations into regional plan and local provider arrangements	86%
☑ Employ collaborative payer/provider decision-support tools for a proactive and personalized treatment approach among plan patients with moderately to severely active IBD	87%

PERCENT OF PARTICIPANTS FOR WHOM THE PROGRAM PROVIDED RELEVANT EDUCATION	Total
☑ The educational material provided useful information for my position	94%
☑ The activity enhanced my current knowledge and competencies	93%
☑ The activity provided appropriate and effective opportunities for active learning (e.g. case scenarios, discussion, Q&A, etc.)	95%

PARTICIPANT-IDENTIFIED BARRIERS TO PAYER-PROVIDER COLLABORATION

Across all 10 roundtables in 2020-2021, several recurring themes emerged regarding the existing barriers to payer-provider collaboration. At their base level, these barriers centered on a scarcity of resources, whether they be time-, personnel-, or funding-related. For payers, IBD is but one disease state among many that necessitate attention and management. In addition, payers often operate across a broad geography with multilayered leadership, resulting in difficulty enacting systemwide change. At the same time, providers deal with a wide range of different payers across a diverse patient population, demonstrating specific challenges in terms of reach. Limited resources were likewise an issue for providers, but a lack of appropriate communication channels with payers was perhaps more prominent, since they already have their resources focused on a single disease state.

> *"The session was highly valuable. There is no other opportunity for clinicians to meet directly with the payer side of the equation. For most doctors it is a black box. By raising awareness of the issues that we face and understanding the issues as they interpret them, we will hope to achieve the same success in terms of improving management of complex GI care similar to that seen in the oncology field."*
>
> -IBD Specialist Provider Participant

Although many participants did not view collaborative initiatives as being pragmatic or feasible, some payer participants noted their current participation in such activities in other disease states and welcomed the notion of participating in quality improvement directives specifically targeting IBD. A set of very specific and clearly communicated next steps after the respective roundtables was cited as being key in overcoming many of these barriers.

PARTICIPANT-IDENTIFIED KEY AREAS FOR IMPROVEMENT

Payer and provider attendees of the 10 regional roundtables identified 3 key areas to facilitate improvement in collaboration toward the shared goal of quality, cost-effective care coverage and delivery for IBD:

1. Enhance communication and transparency between payers and providers for joint decision-making and problem-solving.

2. Improve provider communication with payers and access to timely information for claims submission and appeals.

3. Improve the practical utility of care pathways in real-world coverage decisions and clinical practice.

Enhance payer-provider communication and transparency

A host of recommendations was offered by roundtable participants to enhance payer-provider communication and transparency, beginning with regular events and opportunities for deeper discussions with smaller groups on more focused topics in IBD care coverage and provision. Establishing a more practical way for payers and providers to communicate and have ad-hoc discussions was also cited as being important, potentially leveraging the internet and virtual message board formats. Similarly, an online portal for payer clinical criteria that providers could access on demand was suggested as a means of maximizing efficiency in coverage decisions. At the same time, providers were encouraged to access and share more timely data that payers could use—such as patient-reported outcomes (PRO) data—and improve data sharing capabilities with payers.

> *"Create an online forum for payer and IBD professionals where topics can be created and comments added, AGA community style, [with] bidirectional communication."*
>
> -IBD Specialist Provider Participant

PARTICIPANT-IDENTIFIED KEY AREAS FOR IMPROVEMENT

Improve communication and access to timely information in claims submission and appeals

The time and resource deficits imposed upon providers by prior authorization criteria, denials, and appeals have been well documented. Roundtable participants report that the establishment of standardized and streamlined means of communication with payers throughout the PA process could revolutionize the interaction and reduce the associated time and inconvenience for providers. Suggestions included improving the ability for the medical team to contact a payer point person to discuss PA via phone without being on hold for long periods of time and developing an online portal for payer/provider communication. Furthermore, the designation of a payer contact specific to IBD-related PA can ensure that the interaction is informed and efficient. On the provider end, training a medical team of providers in the specific nuances of PA submission with preemptive documentation was another suggestion offered by roundtable participants to streamline the process for both diagnostic studies and biologic therapies.

> *“Having a point person or group within the payer companies that is easily accessible by medical assistants/providers/nurses for information about preferred medications, PA approvals, etc., would be very cost and time effective and would limit delays and miscommunications in patient care.”*
>
> -IBD Specialist Provider Participant

PARTICIPANT-IDENTIFIED KEY AREAS FOR IMPROVEMENT

Improve the practical utility of care pathways

The utility of care pathways initiatives has been demonstrated across several disease states, but roundtable attendees report that a number of factors limit their real-world effectiveness in IBD. Specifically, existing payer-driven care pathways for IBD may not be aligned with the current clinical practice recommendations and care pathways from professional societies (e.g., ACG, AGA), calling their evidence-based nature into question. In response to these limitations, roundtable participants recommended reviewing and modifying current payer care pathways in place to ensure they agree with consensus guidelines and care pathways issued by these professional societies. Furthermore, the regular input of an IBD specialist provider on payer care pathways and an allowance for updated revisions was suggested as a means of keeping treatment protocols as current as possible.

> *"...allowing more up-to-date revisions of treatment protocols by physicians to guide payers towards appropriate choices of therapy rather than relying on outdated guidelines and limited resources [is critical]."*
>
> -IBD Specialist Provider Participant

RECOMMENDATIONS AND NEXT STEPS

In alignment with the barriers to payer-provider collaboration and key areas for improvement identified by roundtable participants, concrete next steps were sought to take quality-improvement and cost-management solutions in IBD from concept to reality. Specifically, payer and provider attendees asked to identify the programmatic initiatives that they valued the most, and to provide recommendations for specific pilot projects to truly move the needle on collaboration in IBD care coverage and delivery. Overall, several actionable next steps for both groups of stakeholders were identified (Table 2).

Table 2. Actionable next steps toward collaboration for payers and providers.

Payers
Enlist the input of a designated gastroenterology provider or providers in decisions on coverage criteria
Enlist the input of a designated gastroenterology provider or providers to regularly evaluate and revise existing care pathways
Develop an automated system for claims submission and payer response
Develop an online provider portal for communication on matters of PA denials and appeals
Ongoing participation in related collaborative initiatives with provider stakeholders

Providers
Formulate a template for claims submission to identify relevant information that improves the likelihood of approval
Familiarize practice administrative team with policies, procedures, and criteria specific to relevant regional and national payers
Reach out to payers in scenarios where coverage criteria or care pathways may be inappropriate or outdated; Target the top 2-3 health plans the practice interacts with for priority outreach
Request a formal point person within payer organizations to contact in matters of PA denials or appeals
Ongoing participation in related collaborative initiatives with payer stakeholders

RECOMMENDATIONS AND NEXT STEPS

Priority initiatives

Among provider attendees, any initiative that potentially improves timely, evidence-based access to care was given top priority, beginning with efficient PA processes and communications. Related to PA and coverage criteria, transparency was another resounding theme with a desire among providers to understand the specific step edits and algorithms required by payers to ensure timely coverage and access. Acknowledging the high resource utilization associated with the hospital setting, payer attendees prioritized initiatives that directly addressed reducing ED visits and admissions. To this end, same-day gastroenterology provider contacts, telemedicine initiatives, and patient education may all offer value as key areas of focus.

The evolution of care coverage and delivery strategies also received top priority, with roundtable attendees citing value-based care and the medical home model as key initiatives moving forward. While value-based care more broadly represents the healthcare system's continued divergence away from fee-for-service approaches and towards those in which costs are tied directly to outcomes, the medical home model has gained traction in IBD specifically with support in the literature.[21]

RECOMMENDATIONS AND NEXT STEPS

Recommended collaborative pilot projects

Participants indicated a willingness to continue working together towards quality improvement and cost management for IBD in the roundtable format organized by the Foundation, with more regular events or more frequent communication to continue the discussion between payers and providers. Smaller groups focused on more specific topics—such as the value of coverage for diagnostic testing and data elements that should be shared by providers to streamline PA approval—provide one means of keeping meaningful conversations underway among participants. Provider roundtable attendees can be instrumental in advancing these efforts by identifying the top 2 or 3 health plans their practices interact with to set up increased communication perhaps via the Foundation.

> *[You should] identify a couple of folks during roundtables who shared ideas and the ability/desire to want to follow-up on those ideas to see if they come to fruition."*
>
> -Payer Participant

Roundtable attendees also recommended more sophisticated projects stemming from these events moving forward. These suggestions included the aggregation and dissemination of different sets of data, as well as pilot projects to identify best practices. Specifically, the Foundation has the potential to coordinate a data set reviewed by thought leaders in attendance for use in discussion with payers to justify the utilization of specific treatment or diagnostic modalities that often encounter resistance. Specific to PA, a health plan audit of IBD-specific denials may prove valuable to determine the most common scenarios in which barriers are met and may provide insight into the steps necessary to adjust utilization management criteria. Similarly, roundtable participants recommended developing a data template to ease the administrative burden on providers and assist payers in getting the requisite information for coverage approval more efficiently. It is critical to have clear, objective criteria for treatment failure, and timely approval of coverage for a new therapy when this occurs. Often, a patient's only option is to stay on an ineffective IBD therapy. Seemingly confounding delays and denials may seem to save money in the short term for the payer but can lead to long-term harm of the patient. A partnership to develop metrics for treatment approval, access to an efficient approval/appeal process, and streamlined coverage of standard-of-care treatments all represent topics to advance these goals. Future collaboration and educational initiatives are recommended in the aforementioned formats.

RECOMMENDATIONS AND NEXT STEPS

Data-driven approaches remained a common theme. Individual quality improvement pilots were among select practices recommended to identify best practices leading to improved outcomes, ultimately tied to financial or contractual incentives. A pilot to determine cost savings with increased use of fecal calprotectin testing was likewise recommended. In terms of coverage-related barriers, a lack of access to the fecal calprotectin test was one area identified in the initial roundtable series as having the potential to drive immediate improvement in outcomes and one that still resonated with attendees in the recent roundtable series.

To facilitate the momentum of these proposed recommendations, contact with roundtable attendees should remain ongoing, and the assignment of subcommittees among participants to advance specific programmatic initiatives would be beneficial. As evidenced by follow-up actions among attendees at the 3 regional sites featured in both the 2018-2019 and 2020-2021 roundtable series, continued engagement was apparent but demonstrated opportunity for improvement with further outreach and education (Figure 2).

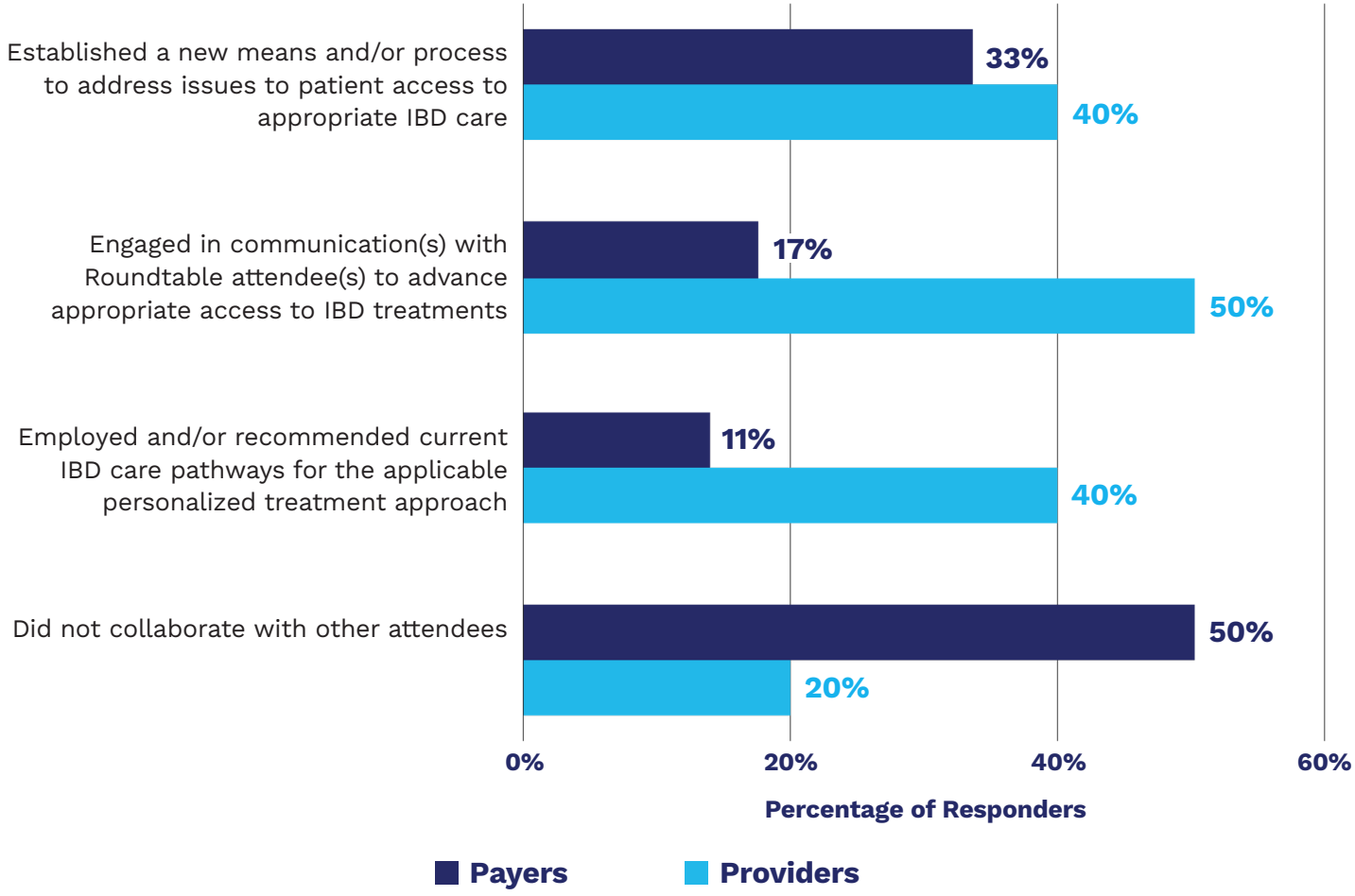

Figure 2. Follow-up actions from 2018-2019 roundtable participants in Ann Arbor, Atlanta, and Las Vegas.

CONCLUSION

In an effort to remain at the forefront of ever-evolving evidence-based treatment in the management of IBD, payer professionals and affiliated network providers must actively work to identify best practices, judicious coverage policies, and opportunities to enact meaningful change. These payer and provider stakeholders are uniquely positioned to collaborate—given the appropriate forum—on comprehensive programming to advance patient outcomes and cost management. Shared goals among the attendees of the Foundation's IBD payer-provider roundtables underscore the fact that collaboration ultimately benefits all stakeholders. Furthermore, the progress thus far as a result of the initiative demonstrates a divergence from the traditional adversarial relationship between payers and providers and a movement toward collaborative interaction, with future educational and outreach initiatives in development will sustain this impetus.

REFERENCES

1. Kappelman MD, Moore KR, Allen JK, Cook SF. Recent trends in the prevalence of Crohn's disease and ulcerative colitis in a commercially insured US population. *Dig Dis Sci*. 2013;58:519-525.
2. The Facts About Inflammatory Bowel Diseases. Crohn's & Colitis Foundation website. https://www.crohnscolitisfoundation.org/sites/default/files/2019-02/Updated%20IBD%20Factbook.pdf. Published November 2014. Accessed May 2021.
3. Centers for Disease Control and Prevention Inflammatory bowel disease website. http://www.cdc.gov/ibd/. Updated December 29, 2019. Accessed May 2021.
4. Stone CD. The economic burden of inflammatory bowel disease: clear problem, unclear solution. *Dig Dis Sci*. 2012;57:3042-3044.
5. Park KT, Colletti RB, Rubin DT, Sharma BK, Thompson A, Krueger A. Health insurance paid costs and drivers of costs for patients with Crohn's disease in the United States. *Am J Gastroenterol*. 2016;111:15-23.
6. Park KT, Ehrlich OG, Allen JI, Meadows P, Szigethy EM, Henrichsen K, Kim SC, Lawton RC, Murphy SM, Regueiro M, Rubin DT, Engel-Nitz NM, Heller CA. The Cost of Inflammatory Bowel Disease: An Initiative From the Crohn's & Colitis Foundation. *Inflamm Bowel Dis*. 2020 Jan 1;26(1):1-10.
7. Gibson TB, Ng E, Ozminkowski RJ, et al. The direct and indirect cost burden of Crohn's disease and ulcerative colitis. *J Occup Environ Med*. 2008;50:1261-1272.
8. Rubin DT, Sninsky C, Siegmund B, Sans M, Hart A, Bressler B, Bouhnik Y, Armuzzi A, Afzali A. International Perspectives on Management of Inflammatory Bowel Disease: Opinion Differences and Similarities Between Patients and Physicians From the IBD GAPPS Survey. *Inflamm Bowel Dis*. 2021 Jan 29:izab006. doi: 10.1093/ibd/izab006. Epub ahead of print.
9. Gallinger Z, Ungaro R, Colombel J-F, Sandler RS, Chen W. P030 Delayed Diagnosis of Crohn's Disease is Common and Associated with an Increased Risk of Disease Complications. *Inflamm Bowel Dis*. 2019;25(Suppl 1):S14-S15.
10. Mehta F. Report: Economic Implications of Inflammatory Bowel Disease and Its Management. *Am J Manag Care*. https://www.ajmc.com/view/importance_of_selecting_appropriate_therapy_inflammatory_bowel_disease_managed_care_environment_report_economic_implications_ibd. Published March 16, 2016. Accessed May 20201.
11. Rubin DT, Mody R, Davis KL, Wang CC. Real-world assessment of therapy changes, suboptimal treatment and associated costs in patients with ulcerative colitis or Crohn's disease. *Aliment Pharmacol Ther*. 2014;39(10):1143-1155.
12. Chawla A, Westrich K, Matter S, Kaltenboeck A, Dubois R. Care Pathways in US Healthcare Settings: Current Successes and Limitations, and Future Challenges. *Am J Manag Care*. 2016;22:53-62.
13. Ulcerative Colitis: Clinical Care Pathway. American Gastroenterological Association website. https://s3.amazonaws.com/agaassets/pdf/guidelines/UlcerativeColitis/index.html. Accessed May 2021.
14. AGA Institute Guidelines for the Identification, Assessment and Initial Medical Treatment of Crohn's Disease. American Gastroenterological Association website. https://s3.amazonaws.com/agaassets/pdf/guidelines/IBDCarePathway.pdf. Accessed May 2021.

REFERENCES

15. American Gastroenterological Association. Medical Management of Adult Outpatients With Moderate to Severe Lunminal Crohn's Disease: Clinical Decision Support Tool. *Gastroenterology*. 2021 Jun;160(7):2509-2510.

16. Pharmacological Management of Adult Outpatients With Moderate to Severely Active Ulcerative Colitis. Clinical Decision Support Tool. American Gastroenterological Association website. Available at: https://gastro.org/wp-content/uploads/2021/01/CDST-UC-mod-sev-final.pdf. Accessed May 2021.

17. Hou JK, Gasche C, Drazin NZ, et al. Assessment of Gaps in Care and the Development of a Care Pathway for Anemia in Patients with Inflammatory Bowel Diseases. *Inflamm Bowel Dis*. 2017;23(1):35-43.

18. Hwang C, Issokson K, Giguere-Rich, C, et al. Development and Pilot Testing of the Inflammatory Bowel Disease Nutrition Care Pathway. *Clin Gastroenterol Hepatol*. 2020 Nov;18(12):2645-2649.E4.

19. IBD Qorus: Care Pathways. Crohn's & Colitis Foundation website. Available at: https://www.crohnscolitisfoundation.org/research/ibd-qorus/care-pathways. Accessed May 2021.

20. Rubin D, Patel S. Clinical Session IIA. Presented at: Advances in IBD; Nov. 9-11, 2017; Orlando, Fla.

21. Regueiro M, Click B, Holder D, Shrank W, McAnallen S, Szigethy E. Constructing an Inflammatory Bowel Disease Patient-Centered Medical Home. *Clin Gastroenterol Hepatol*. 2017 Aug;15(8):1148-1153.