Real-World Observations of Home Infusion Therapy for Gastrointestinal Diseases Through the Use of Patient-Reported Outcome Measures

[1]Timothy P. Walton, MHS, CCRP; [1]Elizabeth Neal, RN, IgCN; [1]Carol Sauerbrun, MBA; [1]Emily Huff, BSN, RN, CRNI, IgCN; [1]Jordan Bruns, PharmD, IgCP; [1]James Sheets, PharmD, IgCP; [1]Randy Broyles, RPh; [1]Edward O'Bryan, MD, MBA, CPE
[1]CSI Pharmacy, Plano, TX

National Association of Specialty Pharmacy (NASP) in**SP**ire**2026** Conference: September 22 – September 25, 2026, National Harbor, MD

BACKGROUND

Gastrointestinal (GI) diseases such as Inflammatory Bowel Disease (IBD) are chronic, immune-mediated conditions characterized by relapsing inflammation and substantial impairment in patient quality of life. Patients frequently experience abdominal pain, diarrhea, systemic inflammation, and extra-intestinal manifestations, contributing to significant disease burden, patient quality of life, and diagnostic complexity.[1]

Biologic therapies targeting specific inflammatory pathways remain central to IBD management, and recent advances, including pharmacokinetic-guided infliximab dosing and the emergence of subcutaneous biologic formulations, have further optimized treatment durability, immunogenicity, and patient convenience.[2,3] Despite these innovations, a subset of patients continues to experience inadequate response, loss of response, or intolerance to conventional immunosuppressive or biologic agents, underscoring the need for alternative therapeutic strategies.[4]

Immunoglobulin (Ig) therapies, including Intravenous Immunoglobulin (IVIg), have emerged as an option for select patients with immune-mediated GI manifestations or medically refractory IBD. Clinical studies demonstrate that IVIg can reduce disease severity, improve inflammatory markers, and provide symptomatic benefit in patients who fail or cannot tolerate standard therapies.[4,5] Mechanistic research further supports IVIg's anti-inflammatory effects, including modulation of macrophage cytokine production and attenuation of intestinal inflammation.[6] In addition to the documented use of IVIg in medically refractory IBD, some clinicians have also begun prescribing Subcutaneous Immunoglobulin (SCIg) in select cases. Although SCIg has not been formally studied as a therapeutic intervention for intestinal inflammation in IBD, its use in this context is generally extrapolated from IVIg experience and from its established role in other immune-mediated conditions requiring long-term immunoglobulin support. Together, these findings highlight the evolving therapeutic landscape in IBD and the potential role of Ig-based therapies (IVIg and SCIg) in complex or treatment-refractory cases.

Home infusion has become an important care model for patients receiving complex therapies such as biologic agents, including infliximab, as well as immunoglobulin therapies such as IVIg and SCIg, by enabling treatment outside traditional hospitals, clinics, or outpatient infusion centers. This care model is supported by specialty pharmacies and home infusion providers, with services delivered by clinicians who receive additional, specialized training.[7]

Providing infusions in the home can reduce disruptions to daily routines, including work, school, and family responsibilities, while serving as a safe and effective substitute for facility-based infusion care. Evidence also suggests that home infusion may help lower overall healthcare costs.[8,9,10] As research continues to show improvements in quality of life and favorable clinical outcomes, the range of therapies administered in the home setting has continued to expand.[11]

PURPOSE

This study evaluated the monitoring of GI patients within a home infusion care model through the collection of Patient-Reported Outcome Measures (PROMs).

METHODS

As part of the proprietary CSI Pharmacy Clinical Outcomes 360[10] program, operated by a national home infusion and specialty pharmacy provider, a multidisciplinary team designed and implemented a structured monitoring initiative for patients with various GI conditions. A retrospective review was conducted for all GI patients enrolled between August 2024 and October 2025.

The program incorporated a proprietary GI Assessment Scale PROM, a 7-item patient-reported questionnaire evaluating disease activity across stool frequency, rectal bleeding, abdominal pain or tenderness, abdominal cramping, activities of daily living, general well-being, and other relevant symptoms, generating a composite score. In 2024, this PROM was administered at baseline and then every 3 months while patients were on service. In 2025, the administration frequency was adjusted to better align with patient treatment patterns, and the typical duration of time patients remain on service. However, due to nature of these patients and their diagnoses, frequency of data collection is currently being evaluated.

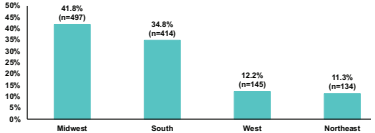
Additional data collected included demographics, dosing patterns, and clinical outcomes obtained through pharmacist-led interviews and nursing documentation. Descriptive analyses were used to summarize findings.

RESULTS

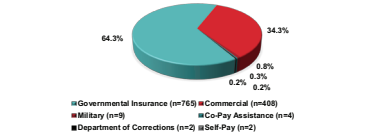
Table 1. Patient Demographics

Variable	GI Patients (n=1,190) (%)
Sex	
Female	660 (55%)
Male	530 (45%)
Age	
Median (Range)	56 (9-96)
Weight (kg)	
Median (Range)	78.1 (25.4-188.24)
Ideal Body Weight (kg)	
Median (Range)	61.5 (13.2-100.3)
Body Mass Index (BMI)	
Median (Range)	27.1 (13.1-112.7)

Graph 1. Geographical Location*



Graph 2. Type of Insurance Payor



Graph 3. Prescribing Physician by Specialty#

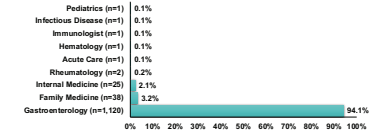


Table 2. Diagnosis, Dosing Information, and Time on Service

Variable	GI Patients (n=1,190) (%)
Diagnoses	
Crohn's Disease	644 (54.1%)
Ulcerative Colitis	299 (25.1%)
Ulcerative (Chronic) Pancolitis	148 (12.4%)
Ulcerative (Chronic) Rectosigmoiditis	33 (2.8%)
Left Sided Colitis	25 (2.1%)
Ulcerative (Chronic) Proctitis	19 (1.6%)
Noninfective Gastroenteritis and Colitis	7 (0.6%)
Collagenous Colitis	3 (0.3%)
Lymphocytic Colitis	3 (0.3%)
Toxic Gastroenteritis and Colitis	3 (0.3%)
Indeterminate Colitis	2 (0.2%)
Microscopic Colitis	2 (0.2%)
Other Specified Diseases of the Digestive System	1 (0.1%)
Pouchitis	1 (0.1%)
Current Therapy^	
Ustekinumab	413 (34.7%)
Vedolizumab	360 (30.3%)
Infliximab	204 (17.1%)
Risankizumab-rzaa	176 (14.8%)
Guselkumab	32 (2.7%)
Golimumab	2 (0.2%)
Adalimumab	1 (0.1%)
Intravenous Immunoglobulin	1 (0.1%) (0.4 g/kg, Weekly)
Subcutaneous Immunoglobulin	1 (0.1%) (0.15 g/kg, Weekly, 4 Injection Sites)
Dispensing Information	
Unique Prescriptions	3,710
Biologics	3,706
Intravenous Immunoglobulin	1
Subcutaneous Immunoglobulin	3
Total Dispenses	8,415
Biologics	8,390
Intravenous Immunoglobulin	13
Subcutaneous Immunoglobulin	12
Months on Service	
Median (Range)	13 (0-56)
0-14	638 (17.2%)
15-29	468 (12.6%)
30-44	81 (2.2%)
45-59	3 (0.1%)

Graph 4. GI Assessment PROM Median Composite Score - 0 - 23 (Lower Score is Better

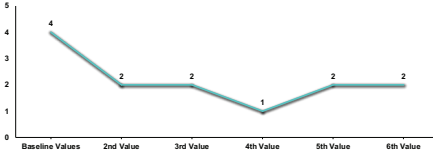


Table 3. GI Assessment Scale PROM – Domain Definitions and Scoring Guide

Variable	
GI Domains - Composite Score = 0 - 23 (Lower Score is Better)	
1. Stool Frequency	6. General Well-Being
0 = Normal Number of daily stools	0 = None
1 = One to two or more stools than normal	1 = Slightly under par
2 = Three to four more stools than normal	2 = Poor
3 = Five or more stools than normal	3 = Terrible
2. Rectal Bleeding	7. Other Symptoms
0 = None	Tachycardia
1 = Blood streaks seen in the stool <1/2 the time	0 =Patient does NOT experience
2 = Blood in most stools	1 = Patient Does experience
3 = Pure blood passed	Fever equal to or over 100° Fahrenheit
3. Abdominal Pain/Tenderness	0 =Patient does NOT experience
0 = None	1 = Patient Does experience
1 = Mild Pain	Weight Loss (5 lbs or greater)
2 = Moderate Pain	0 =Patient does NOT experience
3 = Severe Pain	1 = Patient Does experience
4. Abdominal Cramping	Nausea/Vomiting
0 = None	0 =Patient does NOT experience
1 = Mild or occasional cramping	1 = Patient Does experience
2 = Moderate or more frequent cramping	Abdominal Mass
3 = Severe or constant cramping	0 =Patient does NOT experience
5. Activities of Daily Living	1 = Patient Does experience
0 = None	
1 = Slightly impaired	
2 = Activities restricted	
3 = Unable to work	

Table 4. GI Assessment Scale PROM – Collection Summary

Variable	Value	Baseline PROM Collection	2nd PROM Collection	3rd PROM Collection	4th PROM Collection	5th PROM Collection	6th PROM Collection
Total Number Collected	2,163						
Median Number Collected/Patient (IQR: 1,3)	1 (1,2)						
Count Collected/Visit		1,004	595	348	153	56	7
Completion Rate/Visit		84.4%	50%	29.2%	12.9%	4.7%	0.6%
Non-Completion Rate/Visit		15.6%	50.0%	70.8%	87.1%	95.3%	99.4%
Retention Between Visits			59.3%	58.5%	44.0%	36.6%	12.5%

Table 5. GI Assessment Scale PROM – Complete Distribution

Variable	Count	%
Surveys Completed		
0	186	15.6
1	409	34.4
2	247	20.8
3	195	16.4
4	97	8.2
5	49	4.1
6	7	0.6

DISCUSSION

This study demonstrates that structured monitoring of gastrointestinal patients receiving biologic and immunoglobulin therapies in the home infusion setting is both feasible and clinically meaningful. With close to 1200 patients enrolled across a wide range of GI diagnoses, this evaluation provides a large real-world assessment of home infusion-based GI care. The integration of a GI-specific PROM with pharmacist and nursing documentation offered a comprehensive view of patient-reported disease activity, treatment response, and overall clinical trajectory.

Meaningful improvements in PROM composite scores, from a median of 4 at baseline to 1–2 across subsequent cycles, support the hypothesis that PROM collection enhances monitoring and may help guide therapy optimization. These findings reinforce the value of PROMs as practical, patient-centered tools for capturing real-world outcomes in chronic GI disease, particularly in settings where patients may have limited in-person clinical contact.

The results also highlight the dominant role of biologic therapies in contemporary GI management, with nearly all patients receiving biologics and only two receiving immunoglobulin therapies (IVIg or SCIg). Although the number of Ig-treated patients was small, their inclusion underscores the need for monitoring frameworks capable of supporting diverse treatment modalities. The home infusion setting proved capable of delivering both biologic and Ig-based therapies while enabling systematic outcome tracking.

Several limitations should be acknowledged. As a retrospective evaluation, the study relied on documentation completeness and may be subject to reporting variability. PROM completion occurred during only a subset of visits, which may limit the precision of longitudinal assessment. Additionally, the proprietary GI Assessment Scale PROM has not yet undergone formal psychometric validation across broader GI populations. The extremely small number of patients receiving IVIg and SCIg limits the ability to draw conclusions about Ig-based therapy outcomes. Finally, the study did not systematically evaluate medication-related adverse events, preventing correlation of symptom improvement with treatment tolerability.

Future work should focus on validating the PROM tool, increasing PROM capture rates, and incorporating structured analysis of medication side effects to better understand the relationship between treatment outcomes response and tolerability. More enhanced retrospective analyses and prospective, multi-center studies may help determine how PROM-driven insights can be integrated into clinical decision-making algorithms and may support broader adoption of standardized PROMs across home infusion settings.

CONCLUSION

This retrospective evaluation demonstrates the feasibility and value of structured monitoring for gastrointestinal patients receiving biologic and immunoglobulin therapies within a home infusion care model.

This home infusion providers clinical outcomes program, incorporating a novel GI Assessment Scale PROM, provided meaningful insight into patient-reported disease activity and treatment response across a large, diverse cohort. Biologic therapies were the predominant treatment modality, while IVIg and SCIg were used in select cases, reflecting real-world prescribing patterns.

PROM data showed measurable improvement in composite scores from baseline through subsequent treatment cycles, underscoring both the effectiveness of ongoing therapy and the utility of patient-centered monitoring.

The integration of pharmacist and nursing documentation with PROM collection ensured comprehensive outcome tracking and supported adherence to prescribed regimens.

These findings highlight the essential role of home infusion providers in delivering advanced therapies while simultaneously capturing real-world outcomes that inform clinical decision-making.

Broader adoption of standardized PROMs in home infusion settings may further enhance quality of care, optimize therapy management, and improve the lived experience of patients with chronic GI disease.

Future initiatives should incorporate structured evaluation of medication side effects and expand monitoring frameworks to additional chronic disease states, supporting a scalable model for patient-centered outcome tracking across home-based specialty care.

CSI CLINICAL SPECIALTY INFUSIONS

Abbreviations and Footnotes:
Abbreviations: IQR (Interquartile Range); kg (kilogram); mg (milligram)

Footnotes: * = 43 states are represented; ^ = Biologic therapies were administered according to prescribing information recommendations; # = 612 physicians are represented

References
1. Hasham J G, Lindi J K, Shapiro J M, Shah S A. Medical management of inflammatory bowel diseases *BMJ* 2025; 391:e079050.
2. Dubinsky MC, Mendozaza ML, Phan BL, Moran HR, Tee DS, Mould DR. Dashboard-Driven Accelerated Infliximab Induction Dosing Increases Infliximab Durability and Reduces Immunogenicity. *Inflamm Bowel Dis.* 2022 Sep 1;28(9):1373-1385.
3. Verma A, Patel A, Subramanian S et al. From intravenous to subcutaneous infliximab in patients with inflammatory bowel disease: a pandemic-driven initiative. *The Lancet Gastroenterology & Hepatology* 6, 88-95
4. Merkley SA, Beaulieu DB, Horst S, Duley C, Anna K, Nohl A, Schwartz DA. Use of Intravenous Immunoglobulin for Patients with Inflammatory Bowel Disease with Contraindications or Who Are Unresponsive to Conventional Treatments. *Inflamm Bowel Dis.* 2015 Aug;21(8):1894-9.
5. Horton N, Kochhar G, Patel K, Lopez R, Shen B. Efficacy and Factors Associated with Treatment Response of Intravenous Immunoglobulin in Inpatients with Refractory Inflammatory Bowel Diseases. *Inflamm Bowel Dis.* 2017 Jul;23(7):1080-1087.
6. Kuckzy LK, Menzies SC, Hotte N, Madsen KL, Sly LM. Intravenous immunoglobulin (IVIg) or IVIg-treated macrophages reduce DSS-induced colitis by inducing macrophage IL-10 production. *Eur J Immunol.* 2019 Aug;49(8):1251-1268.
7. National Association of Specialty Pharmacy. NASP Definitions of Specialty Pharmacy and Specialty Medications. Accessed March 2026. https://naspnet.org/wp-content/uploads/2017/02/NASP - Definitions-final-2-16.pdf.
8. Nanes D. Cost Savings From Home Infusion Therapy: A Review of the Literature. *Infusion Journal.* November 2023;23(3):7.
9. Polinski, JM. Kowal, MK. Gagnon M, et al. Home Infusion: Safety, Clinically Effective, Patient Preferred, and Cost Saving. *Healthcare.* 2017;5(1-2):59-60.
10. American Society of Health-System Pharmacists. ASHP Guidelines on the Management of Home Infusion Services. *American Journal of Health-System Pharmacy.* 2022;79(5):380–388.
11. Myers, L., Neal, E., O'Bryan, E., Ying, M., Walton, T.P. Social Determinants of Health Impact on Participant Perception with Home Infusion of Intravenous Immunoglobulin Therapy. Poster Presentation: National Home Infusion Association (NHIA) - March 29 – April 2, 2025, Washington, DC.

Contact Details: timothy.walton@csipharmacy.com

The authors have no conflicts of interest or disclosures to report related to this project.