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Inflammatory bowel disease patient concerns and experiences on transition to home-based infusions during the COVID-19 pandemic

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ABSTRACT

Background: In response to the COVID-19 pandemic, the CDC issued guidance advising patients and providers to adopt social distancing practices such as home-based infusions (H-BI).

Methods: We performed a mixed methods evaluation to summarize perceptions, concerns, and experiences with H-BI among all inflammatory bowel disease patients 18–90 years of age who transitioned to home-based infliximab or vedolizumab infusions between March to July 2020 at a tertiary care center. Semi-structured interviews were conducted and analyzed using an iterative, inductive thematic approach. Baseline characteristics and outcome on safety, COVID-19 transmission, delays in infusions, and H-BI persistence were collected. Results: Of the 57 participants who transitioned to H-BI, 20 (33%) responded. Four major categories and six major themes related to expectations, experience, perceived safety, and logistical factors were identified. Initial perceptions were mixed, however these resolved. One patient developed COVID-19, one patient experienced an adverse event, 12 (21%) patients experienced an infusion delay, and 6 (11%) patients transitioned from H-BI. Discussion: Despite mixed initial perceptions, respondents had a positive experience with most respondents planning to continue H-BI after the pandemic resolves. Several real-world actionable barriers were identified related to scheduling, communication between stakeholders, and nursing quality. No major safety concerns were identified

1. Introduction

Biologic therapy represents the mainstay of treatment for moderate-to-severe inflammatory bowel disease (IBD). Payer-mandated migration of clinic-based infusions (C-BI) to home-based infusions (H-BI) has recently been implemented as a cost-containment strategy, but evaluations of the impact of this policy have been limited. Data on the safety and costs of H-BI have been mixed, with one recently published insurance claims-based evaluation demonstrating high rates of medication

non-adherence and discontinuation without any cost saving. 1-5 Quantitative findings on patient acceptability and satisfaction with H-BI has been moderate, leading to an incomplete understanding for the suboptimal uptake of this approach. 3-6 To date, no study has systematically identified and reported patients' concerns driving sub-optimal uptake and acceptability of H-BI. In response to the Coronavirus disease 2019 (COVID-19) pandemic, the Centers for Disease Control and Prevention (CDC) issued guidance advising patients and providers to adopt social distancing practices such as H-BI strategies. Currently the response and

Abbreviations: Coronavirus disease 2019 (COVID-19), Inflammatory Bowel Disease (IBD); Clinic-based infusions (C-BI), Home-based infusions (H-BI).

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acceptability H-BI strategies for IBD patients has been largely uncharacterized. With this high transition to H-BI during the COVID-19 pandemic, there is a critical unmet need to identify patient concerns and experiences with H-BI in order to recognize and address barriers to more widespread implementation.

2. Methods

We performed a mixed methods evaluation to systematically describe and compare participant perceptions, concerns, and experiences with home-based infusions and clinical outcomes among all IBD patients aged 18–90 years of age who transitioned to home-based infliximab (originator or biosimilar) or vedolizumab infusions between March to July 2020 at a large tertiary care center in the United States. Participant sampling was inclusive of all patients who met inclusion criteria. Willing participants (respondents) were interviewed. Patients who could not be reached or declined to participate comprised the non-respondent population. Process diagrams are provided to illustrate the steps involved in arranging a C-BI (Fig. 1A) and H-BI (Fig. 1B).

We used an exploratory sequential mixed methods design, which involved integrating the qualitative and quantitative strands by building (i.e., using qualitative findings to identify variables of interest in the quantitative phase) and merging (i.e., comparing qualitative and quantitative findings). The qualitative portion of the study consisted of semi-structured interviews designed to characterize participant perceptions and concerns regarding H-BI (Supplemental Table 1).8 Interviews occurred between August and September 2020 and were conducted by telephone, audiotaped, and transcribed verbatim. Transcripts were analyzed and coded by two members of the research team (JJ and DA), using an iterative, inductive thematic approach. 9 Codes were grouped into categories and categories were related to one another to develop themes. This process was repeated to ensure reproducibility and representativeness of the transcripts. These themes were then reviewed by the principal investigator (JAB) and qualitative methodologist (MD) to ensure that the developed themes adequately reflected patient responses to the interview questions. To ensure validity and transferability of our qualitative analysis, contradictory participant perspectives were also incorporated into the final themes to capture the full range of participant experiences.

Findings from the qualitative phase informed the generation of descriptive numeric data collected by electronic health record (EHR) extraction. Quantitative baseline characteristics and outcome data were evaluated by EHR chart review (JJ and JAB). Outcome information was collected (Supplemental Table 2), which predominantly comprised data on safety, COVID-19 transmission, delays in infusions, and H-BI continuation. Data on anti-drug antibody formation and hospitalizations were collected to assess for implications of medication non-adherence. Outcome data was evaluated retrospectively from the date of the patient's first HB-I infusion through January 2021. Data were then merged after statistical analysis and reported using a contiguous approach, with integrated conclusions presented in the Discussion. The study was approved by the Institutional Review Board (IRB) and informed consent was obtained using an approved IRB form.

3. Results

Of the 57 patients with IBD who transitioned to H-BI, 20 patients (33%) responded and engaged in phone based semi-structured interviews (Table 1). Similar proportions of females (54% vs 55%) and IBD type (Crohn's disease: 62% vs 70%) were observed between respondents and non-respondents, respectively. Respondents were comparatively younger (median age 33 vs 47) and had shorter duration of medication prior to transition (28 months vs 14 months). Inductive thematic analysis revealed four major categories with six themes (Table 2).

3.1. Patient expectations regarding H-BI

Within this category, two major themes emerged: 1) expected convenience and comfort with home-based infusions and 2) unknowns surrounding logistical aspects of home-based infusions. According to participants, their initial reactions to switching to H-BI were a mixture of both excitement and uncertainty. Those who described excitement cited that H-BI would allow them to enjoy the convenience and comfort of their own homes while receiving their treatments. One participant noted "I was blown away that this was even an option, I had no idea. I was excited because I thought it would be so much easier to do them at home." Other participants were excited to eliminate the commute. One participant explained, "I live about an hour and a half away [from the clinic] so if someone could come to my house that'd be better". Still, other participants described that they initially felt uncertain about H-BI. Participants raised concerns related to logistics and expenses. One participant asked "my main question was, how would it all work? Do they bring the medication, do they do my labs, where in my house would it happen?", while another stated "I thought that would be more expensive". Other practical concerns were raised ranging from "Would I need to clean off a space for it to happen or does the nurse do that?" to "how many people come to my house?" and "do they bring all the supplies?". Finally, some participants endorsed concern about having a stranger in their home for the entire duration of their infusion. One participant posed "would it be awkward having someone in my house for that long". These concerns seemed to resolve after the transition, as the majority of participants desired to continue H-BI even after the pandemic.

3.2. Improvements in the patient experience during H-BI

Within this category the following theme emerged: experienced comfort and convivence of home-based care. Respondents identified benefits related to logistic factors, such as the convenience of being at home, reduced travel, and 1:1 nursing. "I live pretty far away so I save money on gas, I don't need to find a babysitter ... sometimes I even get some work done" one patient noted. Many patients noted 1:1 nursing care as a benefit and perceived greater level of attention to their medical needs. For example, one participant explained "At home it's just me and the nurse. At the clinic it's one nurse for 4 or 5 people so I feel like you get better care at home". Another commonly cited benefit was saving time. "It takes about 3 hours in clinic vs 1 hour at home" one participant stated.

3.3. Perceived safety during the pandemic

Within this category, the following theme emerged: reduced COVID-19 transmission with H-BI. Many participants endorsed feeling safer receiving their infusions at home than in clinics during the COVID-19 pandemic. Two participants noted "I was glad, since it was a bit scary that I would have to go to a place where I might touch COVID" and "it was perfect since I was nervous about going into the hospital every few months [during the pandemic]". While a couple participants still felt uneasy having a medical professional enter their home, most felt it was safer than clinic. "I just felt safer with one person coming to my house compared to clinic where who knows how many people there are".

3.4. Concerns related to logistic factors

Within this category, two major themes emerged: 1) inefficient scheduling and coordination of care and 2) reduced quality of care. Participants endorsed ongoing concerns about H-BI related to scheduling, perceived nursing quality, and access to rescue medications and emergency services. Several participants, even among those who desired to continue H-BI stated that scheduling could be improved. The main factors driving this were the number of different people the patient was

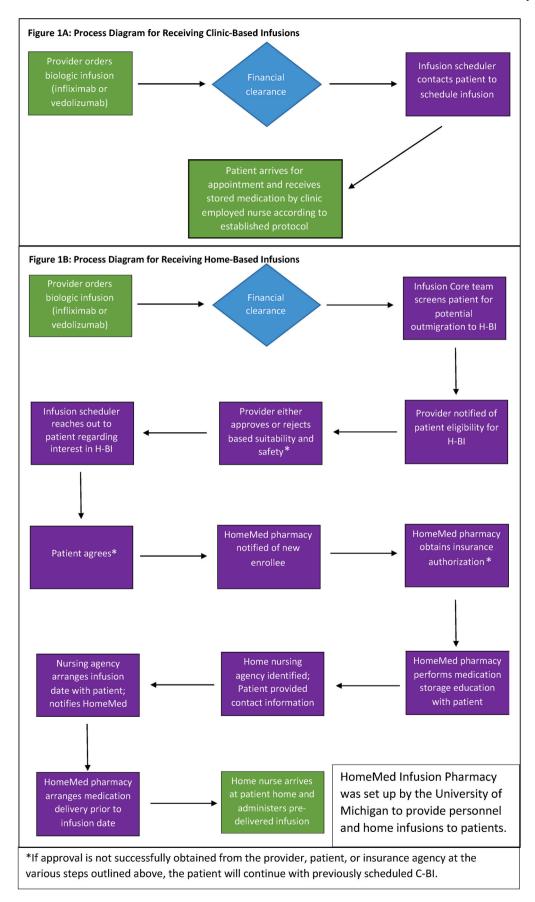


Fig. 1. Process diagrams for arranging a clinic-based infusion (Fig. 1A) and home-based infusion (Fig. 1B).

Table 1Baseline characteristics and outcomes.

Characteristic	$\begin{array}{l} \text{Non-respondents,} \\ N=37 \end{array}$	Respondents N = 20
Female, n (%)	20 (54%)	11 (55%)
Age (yrs.), median (IQR)	47 (37, 53)	33 (24, 41)
IBD Type, n (%)		
Crohn's Disease	23 (62%)	14 (70%)
Ulcerative Colitis	14 (38%)	6 (30%)
Disease Duration (yrs.), median (IQR)	13 (8, 27)	6 (4, 15)
Medication, n (%)		
Infliximab	26 (70%)	15 (75%)
Vedolizumab	11 (30%)	5 (25%)
Duration of medication prior to	28 (12, 50)	14 (2, 31)
transition (months), median (IQR)		
Distance to Infusion Center (Miles), median (IQR)	20 (13, 36)	15 (8, 26)
Number Home Infusions, median (IQR)	4.00 (3.00, 6.00)	3.50 (2.00, 5.00)
Follow-up time (months), median (IQR)	5.22 (3.32, 7.00)	6.05 (4.95, 6.87)
COVID-19 Infections	1 (2.7%)	0 (0%)
Major Adverse Reaction	1 (2.7%)	0 (0%)
ED Presentation	0 (0%)	0 (0%)
Delay in Infusion	6 (16%)	6 (30%)
Development of anti-drug antibodies	0 (0%)	0 (0%)
Returned to clinic-based infusion	3 (8.3%)	3 (15%)

expected to be in communication with, as well as not knowing who to reach out to for particular issues. One participant lamented "There were times the pharmacy would call and tell me the medication would arrive a certain day and I would tell them I wasn't scheduled for another 2 weeks ... so it seemed like the nurse and the pharmacist weren't on the same page". A couple participants also felt the nursing was of a lower quality than in clinic. "It took 3 or 4 tries for them to get an IV ... that never happened in clinic" one patient stated. Another patient said, "Everything seemed a bit disorganized with medical supplies littered all over my kitchen table". Finally, some participants endorsed concern regarding the possibility of an adverse reaction with no direct access to emergency services. One participant endorsed "I like doing it at home, but I do not want to think about what would happen if I had an adverse event".

3.5. Descriptive outcomes

Baseline patient characteristics and descriptive outcomes informed by our qualitative component are reported in (Table 1). To account for baseline differences between respondents and non-respondents, we stratified our analysis by age and gender (Fig. 2). Most notably, female and older patients had positive expectations with H-BI, positive actual experiences with H-BI, and reported perceived positive COVID-19 transmission reduction. No appreciable differences were seen among patients experiencing communication or nursing quality issues between age or gender catagories. Among all 57 patients, one (1.8%) patient developed COVID-19, one (1.8%) patient experienced an adverse event that did not require an ED visit, 12 (21%) patients experienced an infusion delay without developing anti-drug antibodies, 6 (11%) patients returned to clinic-based infusions and one (1.8%) patient transitioned to a self-injectable medication during the study period. The most commonly stated reason for switching back to C-BI among those 6 participants was frustration around multiple points of contact. Participants were expected to communicate with the clinic, the HomeMed pharmacy, the nursing agency, and sometimes the lab to ensure that results were sent to the clinic (see Fig. 1B).

4. Discussion

Despite mixed initial perceptions regarding H-BI, respondents overall had a positive experience, with the majority of respondents planning

 Table 2

 Major categories and themes identified through thematic analysis.

Categories and Themes of Respondent Experiences	Representative Quotes
Category: Patient Expectations Regarding Home-Based Infusions Theme: Expected convenience and comfort with home-based infusions Unknowns surrounding logistical aspects of home-based infusions	"I was blown away that this was even an option." "I live about an hour and a half away [from the clinic] so if someone could come to my house that'd be better." "I thought it would expensive, worried I wouldn't qualify, and maybe it would be weird or awkward with someone in my house for that long." "I thought it would be awkward having
Category: Improvements in the Patient Experience During Home-Based Infusions Theme: Experienced comfort and convenience of home-based care	someone in my house for that long." "Everything went great. Nurse was very professional and polite." "I live pretty far away so I save money on gas, I don't need to find a babysitter sometimes I even get some work done." At home it's just me and the nurse. At the clinic it's one nurse for 4 or 5 people so I feel like you get better care at home." "Comfort; in terms of being in my own home." "I exclusively had 1-on-1 care." "Seamless, convenient, time-efficient, very easy." "It was perfect since I was nervous about going into the hospital every few months [during the pandemic]"
Category: Increased Perceived Safety During the Pandemic Theme: Reduced COVID-19 transmission risk with home-based infusion transitions	"I was glad, since it was a bit scary that I would have to go to a place where I might touch COVID." "It was perfect since I was nervous about going into the hospital every few months [during the pandemic]" "I just felt safer with one person coming to my house compared to clinic where who knows how many people there are"
Category: Remaining Challenges to Home-Based Infusions Theme: Inefficient scheduling and care coordination Reduced quality of care	"There were times the pharmacy would call and tell me the medication would arrive a certain day and I would tell them I wasn't scheduled for another 2 weeks so it seemed like the nurse and the pharmacist weren't on the same page." "I supposed to get my infusion every 8 weeks, and the med arrives every 8 weeks, but sometimes by the time I schedule with the nurse it will be 2 weeks later." "It took 3 or 4 tries for them to get an IV that never happened in clinic." "Everything seemed a bit disorganized with medical supplies littered all over my kitchen table." "I like doing it at home, but I do not want to think about what would happen if I had an adverse event."

to continue H-BI after the pandemic resolves. Despite the concerns identified in the qualitative data, we observed low rates of adverse events, COVID-19 infections, and delays in therapy in the quantitative data. The most common hurdle patients described was related to communication and coordination of care between nursing, pharmacy, and the clinic. A centralized group to manage communications between these three stakeholders would alleviate the burden for patients and potentially make H-BI more appealing. Additionally, perceived nursing competency was an identified barrier. As such, attention should be given to ensure nursing comfort administering biologic medications, particularly if third party nursing agencies are to be utilized. Finally, many patients noted concern regarding the possibility of an adverse reaction. While these patients were initially screened at the initiation of H-BI for prior anaphylaxis or reactions to their particular biologic therapy, concerns could be mitigated by providing a hotline or resources

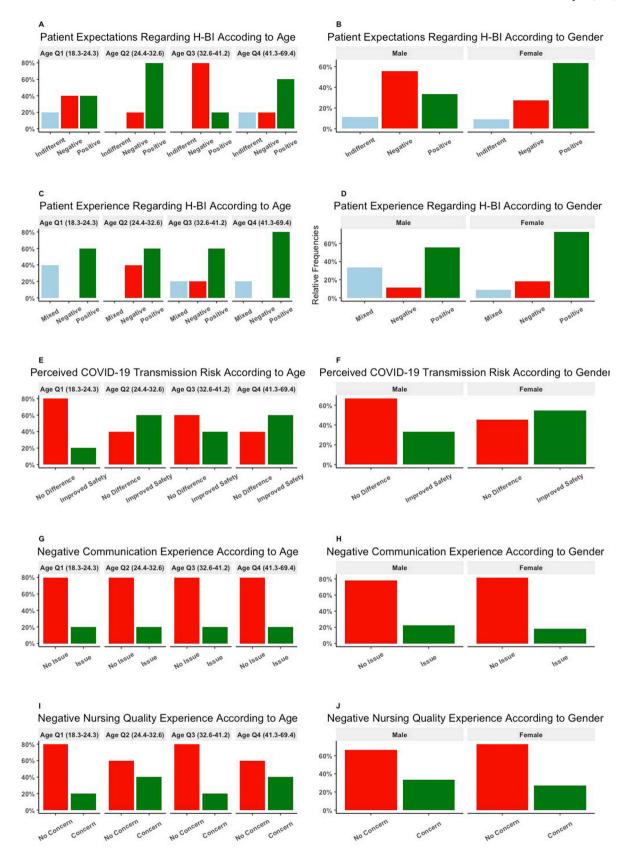


Fig. 2. Variations in patient experiences and perceptions according to age and gender. A) Patient expectations regarding H-BI according to age quartile (Category 1). B) Patient expectations regarding H-BI according to gender (Category 1). C) Patient actual experiences regarding H-BI according to age quartile (Category 2). D) Patient actual experiences regarding H-BI according to gender (Category 2). E) Patient perceived COVID-19 transmission risk reduction with H-BI according to age quartile (Category 3). F) Patient perceived COVID-19 transmission risk reduction with H-BI according to gender (Category 3). G) Negative communication experience according to gender (Category 4). H) Negative nursing quality experience according to age quartile (Category 4). J) Negative nursing quality experience according to gender (Category 4).

for them to refer to in the event of an adverse reaction. It is notable that no adverse reactions occurred during this study period.

Other studies in different patient populations have evaluated patient perceptions of H-BI compared to C-BI. Wolter et al. performed a randomized trial evaluating home versus hospital intravenous antibiotics, evaluating patient perceptions using questionnaires. ¹¹ They found no difference in quality of life, safety, or tolerability, however home-based therapies reduced costs by half. ¹¹ Polinski et al. found no difference in safety or clinical outcomes, but did find an overwhelming patient preference for H-BI and savings of \$2000-\$3000 per course of therapy in systematic review. ¹² Notably, none of the studies included in the final analysis involved IBD patients. Our study, while small and performed at a single center, adds to the currently available literature on H-BI in IBD patients.

Our study findings must be interpreted in the context of its limitations. Other centers may lack the infrastructure for scalable implementation of a H-BI strategy. Our study was not powered to evaluate safety and without a control group it is impossible to make any inferences about how HB-I compares to C-BI. In addition, rates of COVID-19 infection are highly variable according to county, state, and country limiting the generalizability of our findings. ¹³ Eligible patients who did not participate may have had different qualitative experiences with HB-I. Still, our mixed methods study describes the perceptions of patients after the transition to H-BI and highlights the potential for HBI to be used as a strategy in this population.

In conclusion, our patient-centered approach identifies additional real-world actionable barriers and areas for improving more widespread uptake of H-BI throughout the remainder of the COVID-19 pandemic and in the future as we continue to move healthcare away from the traditional brick-and-mortar model to a home-based healthcare approach.

Author contributions

Study concept and design: JJ, DA, SACM, MD, PDRH, JAB. Acquisition: JJ, DA, JAB.

Analysis, or interpretation of data: JJ, DA, MD, SACM, PDRH, JAB. Drafting of the manuscript: JJ, DA, MD, SACM, PDRH, JAB.

Figures/Tables: JJ, DA, MD, PDRH, JAB.
Critical revision of the manuscript: All Authors.

Final approval: All Authors.

Data availability statement

The data underlying this article cannot be shared publicly in order to maintain the privacy of individuals that participated in the study. The data will be shared on reasonable request to the corresponding author.

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Declaration of competing interest

PDRH received consulting fees from AbbVie, Amgen, Genentech, JBR Pharma and Lycera. All other authors report no disclosures.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.sapharm.2022.06.009.

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