

Home Infusions for Inflammatory Bowel Disease Are Safe: US Experience and Patient Perspectives

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Background: Home infusions (HIs) for biologic medications are an option for inflammatory bowel disease (IBD) patients in the United States. We aimed to describe the population receiving HIs and report patient experience with HIs.

Methods: We conducted a retrospective cohort study in the Quintiles-IMS Legacy PharMetrics Adjudicated Claims Database from 2010 to 2016 to describe the population receiving infliximab (IFX) and vedolizumab (VDZ) HIs and determine predictors for an urgent/emergent visit post-HIs. We then administered a cross-sectional survey to IBD Partners Internet-based cohort participants to assess knowledge and experience with infusions.

Results: We identified claims for 11 892 conventional IFX patients, 1573 home IFX patients, 438 conventional VDZ patients, and 138 home VDZ patients. There were no differences in demographics or median charges with IFX home and conventional infusions. Home VDZ infusions had a greater median charge than conventional VDZ infusion. Less than 4% of patients had an urgent/emergent visit post-HIs. Charlson comorbidity index > 0 (odds ratio [OR]: 1.95; 95% confidence interval [CI], 1.01–3.77) and Medicaid (OR: 3.01; 95% CI, 1.53–5.94) conferred significantly higher odds of urgent/emergent visit post-HIs. In IBD Partners, 644 IBD patients responded; 56 received HIs. The majority chose HIs to save time and preferred HIs to conventional infusions. Only 2 patients reported an urgent/emergent visit for HI-related problems.

Conclusions: HI appears to be safe in IBD patients receiving IFX and VDZ. However, patients with fewer resources and more comorbidities are at increased risk for an urgent/emergent visit post-HIs. The overall patient experience with HI is positive. Expansion of HIs may result in decreased therapy-related logistic burden for carefully selected patients.

Lay Summary

Inflammatory bowel disease patients receiving home biologic infusions did not have a greater risk for needing emergent care after their infusion compared with patients receiving healthcare facility-based infusions. Separately, we surveyed patients receiving home infusions and they reported positive experiences.

Key Words: Crohn's disease, ulcerative colitis, inflammatory bowel disease, home infusion, treatment, therapy, home health services, safety

Introduction

The use of biological agents for the treatment of Crohn's disease (CD) and ulcerative colitis (UC) is increasing as the prevalence of inflammatory bowel diseases (IBD) is increasing.^{1,2} Biological agents constitute the mainstay of treatment for moderate to severe IBD.^{3,4} Currently, there are 3 classes of biological agents that are commonly used in practice: anti-tumor necrosis factor (TNF) inhibitors, such as infliximab (IFX), anti-integrin inhibitors, such as vedolizumab (VDZ), and an anti-interleukin (IL)-12/IL-23 inhibitor, ustekinumab. Some biological agents require administration intravenously, whereas others are administered subcutaneously.⁵ Some subcutaneous agents can be administered in a facility, but the majority are administered at home by the patient. Intravenous biologic agents have been traditionally administered in a facility with direct clinician supervision.

Currently, there is a global push to increase care for IBD patients in a home setting.⁶ IBD is an expensive condition with as much as a third of the cost burden attributed to medications.⁷ Furthermore, intravenous biologic agents, such as IFX and VDZ, pose a large burden to patients in the form of days missed from work and transportation, among other logistics.^{8,9} To minimize the burden, home infusions (HIs) of biological agents are now available. Interest in HIs is especially increasing in light of the COVID-19 pandemic. The Crohn's and Colitis Foundation encourages patients to check with their insurances and physicians about HIs.¹⁰ However, a formal position statement raises concern about the safety of HIs, likely due to the paucity of available data.¹¹

While the process of receiving HIs varies by payer and region of the country, it typically involves scheduling over the phone, receiving the medication and supplies by mail, and

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having a nurse visit in a scheduled time frame to start an intravenous line, collect blood work, administer the medication, and monitor vital signs until the end of the infusion. In the United States, payers are expanding home-based health services as a cost-efficient solution, especially for those with chronic conditions.¹² The existing literature, albeit sparse and in small cohorts, demonstrates that HIs of biological agents used to treat IBD may be safe and cost-effective and can result in high patient satisfaction.^{13,14} However, one recent administrative claims-based study concluded that home IFX infusions were associated with suboptimal outcomes.¹⁵ However, safety outcomes were not evaluated in this study.

In order to address the knowledge gap regarding the safety of HIs, we performed a mixed-methods study. We conducted a retrospective cohort study in a large administrative claims database and a separate cross-sectional survey study in an IBD patient-powered research network, IBD Partners (www.ibdpartners.org). In the retrospective cohort, we aimed to describe the population receiving home-based IFX and VDZ infusions across the United States and report safety and charges associated with HIs. In the cross-sectional survey study, we aimed to better understand the patient experience with intravenous biological agents using a large Internet-based cohort of IBD patients that includes patients from every US state.

Methods

We assessed HIs for IBD in 2 ways: through a retrospective cohort study in an administrative claims database and through a cross-sectional study in patients who participate in a large Internet-based cohort of IBD patients.

Retrospective Cohort Study

Data source

We conducted a retrospective cohort study in the Quintiles IMS Legacy PharMetrics Adjudicated Claims Database from January 2010 to June 2016. This dataset includes variables that are routinely collected for the purposes of insurance billing such as age, sex, geographic location, prescription medications, international classification of disease (ICD) codes and charges associated with procedures, and other healthcare utilization. Prior research has reported that this database is representative of the national commercially insured population reflecting a variety of demographic factors.¹⁶ This database has been used previously in epidemiological studies of IBD.^{17,18} At the time of this analysis, the database contained enrollment information on over 27 million people across the United States, including nearly 130 million person-years of follow-up data.

Study sample

We included individuals 18 years or older, who have a diagnosis of CD or UC. The diagnosis was defined by those individuals who have at least 2 healthcare contacts on different days with an associated ICD-9 or ICD-10 code for CD or UC. If there are claims for both diagnoses, disease assignment was made based on the majority of the last 9 claims. Previous studies using administrative claims data have defined an IBD disease cohort with this definition.^{19–21} We stipulated 6 months of continuous enrollment in order to ensure an adequate amount of time to assess charges and determine outcomes. For IFX users, we included all patients from 2010

onward. Since VDZ is a newer agent that was approved for use in 2014, we included patients from May 2014 onward. We used J codes, injection/infusion codes, for IFX and VDZ, to identify IBD patients receiving these infusions. The HI cohort was defined as those who had a code for a home health service on the same day as the index infusion code. The conventional infusion cohorts were those who did not have a code for a home health service on the same day as the index infusion. Cohorts were defined at the time of index infusion.

Outcomes of interest

The primary outcome of interest is emergency department (ED) or urgent care visits in the 2 days following an IFX or VDZ HI. We also described the population receiving HIs and reported charges associated with HIs.

Covariates

Patient demographics such as sex, age, region of the country, and type of IBD were assessed and reported. We evaluated primary payer type; Medicaid insurance status from claims data has been used as a proxy for socioeconomic status in prior work.²² To include a marker of comorbid illness, selected to be a surrogate for higher health care utilization, we assessed the Charlson comorbidity index (CCI), which has been validated as a marker for comorbid illness in studies using large administrative databases.^{23,24}

Analysis

We constructed a multivariable logistic regression model to determine predictors of an urgent care or ED visit in the 2 days following a HI, adjusting for sex, IBD type, payer, and the CCI. The variables in the model were selected a priori based on clinical judgment; furthermore, these are variables that are often used in similar studies. These analyses were performed using SAS (version 9.3) statistical software (SAS Institute).

Cross-Sectional Survey Study

Separately, we conducted a cross-sectional survey study using the IBD Partners cohort. This is a longitudinal Internet-based cohort of people with IBD. To date, more than 15 000 participants have enrolled from across the United States. In this cohort, more than 4000 participants frequently update their information on the portal and respond to periodic survey questionnaires. In this subgroup of active patients, 25% report currently being on IFX, IFX biosimilar, or VDZ. We designed a short survey instrument for patients receiving IFX and VDZ to assess their knowledge of HI services. Patients completed this survey electronically; a hard copy of the survey with the skip logic detailed is presented in [Appendix A](#). For the patients who receive HI services, we asked about their experience, including reasons why they receive HIs, their preference compared with conventional infusions, and problems they have encountered with HIs. This short survey was included with patients' baseline or biannual updates from June 2018 to April 2019. The primary data are available through trained data managers at IBD Partners. The Institutional Review Board (IRB) of the University of North Carolina-Chapel Hill, the data management center for IBD Partners, approved this study. We provide a descriptive summary of the results, including quotations from patients when notable. When correlations between patient characteristics and

responses to questions were strong, we performed bivariate analysis to detect significant differences.

Results

Retrospective Cohort Study

In a retrospective cohort study conducted in the Quintiles IMS Legacy PharMetrics Adjudicated Claims Database from January 2010 to June 2016, we identified 11 892 patients who received IFX in a conventional setting and 1573 patients who received IFX with home health services. CD patients consisted of 70% of the conventional IFX and 68% of the home IFX cohorts. The median age in the conventional IFX group was 45, and 52% were female; the median age in the home IFX group was 44, and 53% were female. The majority of patients in both cohorts had commercial insurance as a primary payer. The median charges for infusions were similar for the convention IFX and home IFX arms: \$5981 and \$6000, respectively. Of those who received IFX infusions, 3.1% of those in the conventional infusion arm and 2.9% of those in the HI arm had an urgent care or ED visit in the 2 days following an infusion. These results are summarized in [Table 1](#).

In the same database, we identified 438 conventional VDZ users and 138 home VDZ users, between May 2014, when the medication was approved, and June 2016. CD patients consisted of 59% of the conventional VDZ and 67% of the home VDZ cohorts. The median age in the conventional VDZ group was 44, and 56% were female; the median age in the home VDZ group was 45, and 57% were female. In the conventional VDZ arm, 65% had a primary payer that was a commercial insurer and 18% had Medicaid as the primary

payer; similarly, in the home VDZ cohort, 82% had a commercial insurance, while 14% had Medicaid as the primary payer. The median charges for conventional VDZ infusion were \$7500, while the median charges for home VDZ infusion were \$10 700. Of those who received VDZ infusions, 2.5% of those in the conventional infusion arm and 1.4% of those in the HI arm had an urgent care or ED visit in the 2 days following an infusion. Overall rates of ED/urgent care visits following infusions were significantly higher for patients receiving IFX compared with patients receiving VDZ (3.1% vs 2.2%, $P = .04$).

In a multivariable logistic regression model, the following factors predicted a significantly higher odds for an urgent care or ED visit in the 2 days following a HI: a CCI > 0 (odds ratio [OR]: 1.95; 95% confidence interval [CI], 1.01-3.77) and Medicaid as a primary payer (OR: 3.01; 95% CI, 1.53-5.94). These results are presented in [Table 2](#).

Cross-Sectional Survey Study

In a separate survey of participants from the IBD Partners Internet-based cohort, 644 respondents who identified the current use of an infused biologic completed the HI module. Of the respondents, 137 reported receiving infusions at a clinic, 440 received infusions at an infusion center, and 56 reported receiving infusions at home. Characteristics of the population responding to surveys are presented in [Table 3](#). Demographics and disease characteristics were similar between both groups.

Of the 577 patients who do not receive HIs, 54% reported that they would be interested in a HI if that were an option for them. Patients who were interested in HIs were significantly

Table 1. Characteristics of inflammatory bowel disease patients receiving biologic infusions in the Quintiles IMS Legacy PharMetrics Adjudicated Claims Database between January 2010 and June 2016

	IFX Home infusions	IFX Conventional infusions	VDZ Home infusions	VDZ Conventional infusion
N	1573	11 892	138	438
% Crohn's disease	68	70	67	59
% Female	53	52	57	56
Median current age in years (IQR)	33 (32-59)	45 (32-59)	45 (33-57)	44 (34-57)
Region				
% East	8	20	5	23
% Midwest	20	34	29	43
% South	43	30	15	18
% West	29	16	51	16
Charlson Comorbidity Index				
% 0	88	90	80	87
% 1	11	9	20	11
% ≥2	1	1	0	2
Primary payer				
% Commercial	80	76	82	65
% Medicaid	7	9	14	18
% Medicare	2	2	2	1
% Self insured	7	7	0	1
Median charges in US\$ (IQR)	6000 (3960–10 470)	5981 (3920–9328)	10 700 (5364–12 770)	7500 (6920–11 230)
% of ED ^a visit after infusion	2.9	3.1	1.4	2.5

Abbreviations: IFX, infliximab; IQR, inter-quartile range; VDZ, vedolizumab.

^aAny urgent care or emergency department (ED) visit from the time of infusion up to 2 days after.

Table 2. Adjusted odds of seeking urgent or emergent care after a home infusion for infliximab or vedolizumab in the Quintiles IMS Legacy PharMetrics Adjudicated Claims Database between January 2010 and June 2016

	aOR ^a	95% CI
Female	0.85	(0.49-1.49)
Crohn's disease	0.94	(0.51-1.75)
CCI >0	1.95	(1.01-3.77)
Commercial	Referent	
Medicaid	3.01	(1.53-5.94)
Medicare	0.76	(0.10-5.68)

Abbreviations: aOR, adjusted odds ratio; CCI, Charlson Comorbidity Index; CI, confidence interval; IBD, inflammatory bowel disease. ^aORs are adjusted for sex, IBD type, CCI, and payer.

younger than those who reported no interest in HIs (44 vs 48 years, $P = .03$). The most common reasons for interest in HIs were that it may save time and be less disruptive to a normal schedule (39%), ease and comfort of being at home (36%), and transportation issues (11%) (Figure 1). Two patients also wrote in that they were interested in HIs due to ease of childcare logistics. Of those who do not receive a HI, 28% reported that they would not be interested in a HI if it were available to them. The most commonly cited reason for no interest was having concerns about getting intravenous (IV) access (32% of respondents). Concerns about safety (15%) and concerns about privacy (15%) were other leading reasons for not wanting a HI. Many patients reported that they liked going to an infusion center: "I like going to an infusion room at the clinic every 8 weeks! I see my favorite nurses and get to relax in a quiet environment for a couple of hours" one patient wrote. Others felt that a HI would be a reflection of "feel[ing] like a homebound patient." Another patient wrote "seems inefficient (I live in a rural area) for provider and unnecessary for me as I am mostly healthy and can travel to clinic."

Of the 56 patients who had received a HI, 45% reported that they have a HI because their insurance company requires that it, 39% reported that they chose to receive it at home, and 16% reported that their doctor recommended it. The most common reason that people chose to receive a HI was that it saved time and was less disruptive to their schedule (59%). One patient reported that they chose HIs because they could not get days off from work and another person chose HIs because it was cheaper for them. One patient wrote: "I like to avoid the hospital when getting my immunosuppressant so that I can minimize my exposure to illness."

The majority (86%) of patients who received HIs also had infusions in a conventional setting like a clinic or hospital prior to having HIs. The majority (69%) of these patients received 11 or more infusions at an infusion center prior to their HIs. Of those who received infusions in a conventional setting, 69% prefer receiving HIs; 12% reported not preferring HIs, while 19% reported that the setting of the infusion did not matter to them.

Of the 56 patients who receive HIs, 27% reported having a problem with the HI. We asked respondents to describe the problems that they had with their HIs. The following are quotations from respondents:

Table 3. Characteristics of IBD Partners survey respondents from June 2018 to March 2019

	Home infusions	Conventional infusions
N	56	577
Median current age in years (IQR)	39 (32-48)	44 (33-58)
% Crohn's disease	66	65
% Female	80	73
% White	93	95
% ≥College	73	77
% Infliximab	64	63
Median disease duration in years (IQR)	13 (8-21)	14 (8-23)
% History of IBD hospitalization	70	65
% History of IBD surgery	34	38
Median SCCAI (IQR)	1 (0-2)	2 (1-3)
Median sCDAI (IQR)	139 (93-184)	93 (58-156)
Concomitant IBD medications		
% Oral steroids	0	6
% Oral mesalamine	16	18
% Immunomodulators	25	27

Abbreviations: IBD, inflammatory bowel disease; IQR, inter-quartile range; SCCAI, Simple Clinical Colitis Activity Index; sCDAI, Short Crohn's Disease Activity Index.

I...have a very complicated, very strict schedule...for home infusions, you schedule the appointment for a specific day, but not a time slot and they don't call you until the day before to tell you what times are available. That doesn't work for me and I have had to reschedule appointments because of this.

usually logistical problems—difficulty getting the medication delivered from the pharmacy, difficulty scheduling with a home health nurse

Nurse was inexperienced in home infusions and was unable to figure out the infusion pump

Of the patients who reported having a problem with a HI, only 2 patients reported having an urgent care or ED visit for a problem related to the HI.

Discussion

In our mixed-methods study of HIs for biologic agents used to treat IBD in the United States, we found that HIs were not associated with an increase in subsequent urgent care or ED visits. Having a CCI greater than 0 or having Medicaid as a primary payer conferred significantly higher odds for urgent care/ED visits after HI. These factors could be considered by physicians to help guide infusion location choice for individual patients. However, without specific data on the cause of urgent care/ED visit, it is unknown whether a hospital- or clinic-based infusion location would alter or prevent these complications. In our survey study, the majority of patients who received HI preferred HIs to infusions in a conventional setting. A minority of patients who received HIs reported a problem with it. More than half of patients who received infusions in a conventional setting were potentially interested in receiving HIs.

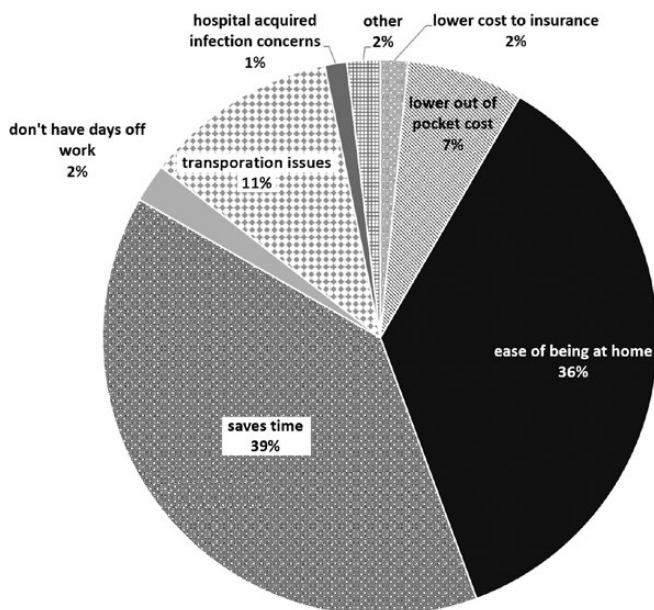


Figure 1. Primary reasons why patients with IBD are interested in home infusions of biologic agents ($n = 311$).

A prior study of modality preference for anti-TNF agents concluded that the majority of patients with IBD preferred subcutaneous anti-TNF agents to the intravenous option (IFX).⁸ A follow-up study prospectively investigating the reasons behind this finding reported that IFX often required that patients take a day off work as they were spending a median of 6.5 hours out of their house for an infusion.⁹ This clearly poses a large burden of disability to IBD patients requiring IFX. Many of our survey respondents cited transportation-related issues as a reason to be interested in HIs. As the number of therapeutic agents available to treat IBD is rapidly expanding, it is also important to better understand the various options for medication administration available to our patients.

In contrast to a published report of 69 patients receiving HIs through the Mt. Sinai IBD Center in New York City, we did not find an increased risk of adverse events in those receiving HIs.²⁵ In the Mt. Sinai study, 2/3 of patients received IFX infusions. In our study, we found a significantly higher rate of urgent and emergent visits after all IFX infusions, regardless of location, compared with VDZ infusions (3.1% vs 2.2%). Therefore, the higher rate of IFX infusions in the Mt. Sinai cohort may explain the disparate findings. Our study reports on the experience of HIs in 2 separate cohorts across the United States in various practice settings and geographic locations. Furthermore, both factors we identified as conferring a significantly higher risk for an urgent care or ED visit after HI have been reported to increase healthcare utilization in general.^{23,26} Interestingly, a retrospective chart review performed by an infusion company concluded that fewer than 1% of home IFX infusions for IBD patients resulted in an infusion reaction requiring an ED visit or discontinuation of infusion.²⁷ Therefore, it is possible that the findings from the Mt. Sinai study are due to the complex nature of patients seen at a tertiary care center. Certainly, there is a possibility of selection bias in our study as well, where the higher-risk patients could be receiving infusions at a center, thereby making rates of ED or urgent care visits in the 2 days following an

infusion similar across groups. This speaks to the need to continue to have options for both clinic/hospital-based infusions and HIs for IBD patients with ability for patient and provider input on the selection of infusion location.

Similar to our study, a prior study of IFX HIs in a small cohort of pediatric IBD patients concluded that HIs were safe and preferred by patients and families.¹³ A more recent European study of home IFX infusion in 13 adults also reported high patient satisfaction with HIs.¹⁴ In both studies, patients receiving home IFX infusions were carefully selected by clinicians. Again, this is most likely the key to success for HIs: allowing clinicians to select patients who have a preference for and would be good candidates for HIs.

Insurers often cite lower healthcare costs as a reason to encourage HIs.¹² Our findings demonstrate that median charges did not differ dramatically between the home and conventional infusion groups. Another recent claims-based study of HIs supports this finding as well.¹⁵ In fact, home VDZ infusions incurred higher median charges than conventional VDZ infusions. Given the nature of claims-based data, we are not able to provide the actual costs incurred; however, further work to understand associated costs would be beneficial to inform policies for utilization of home health infusions in patients with IBD.

We also identified themes in patient perspectives regarding HIs. A number of patients felt that HIs implied being homebound. Some patients thought that a HI meant that they had to infuse the medication themselves. Other patients voiced concerns that it was unsafe to receive such potent medications at home. A large number of patients reported liking the experience of an infusion center or clinic, including the social aspect of it. Understanding patient perspectives and concerns regarding HIs will help clinicians and insurers better explain HIs to patients.

There are several strengths to our study. We included a large cohort of IBD patients from geographically diverse settings across the United States, which lends to generalizability of our results. Including patient-reported outcomes and anecdotes about their experience with HI adds a qualitative perspective. Our study certainly has limitations. Using administrative claims data does not allow for assessment of disease activity and other such factors that may have a role in the success and safety of infusions. As noted, we only have data for charges and not actual costs incurred. Furthermore, this study is not powered to detect safety. Given the rarity events, we cannot provide granular details on reasons for urgent/emergent visits. Despite these limitations, this is a novel study comparing home and conventional infusions for biologic agents used in the treatment of IBD in the United States.

We found that home IFX and VDZ infusions are safe without an increase in urgent care or ED visits following infusions. Patients with a CCI greater than 0 and those who had Medicaid as a primary payer had significantly higher odds of an urgent care or ED visit following an infusion. The majority of patients who receive HIs are satisfied with the experience. Over half of the patients not currently receiving HI reported an interest in HIs, particularly younger patients. These data can help both clinicians caring for IBD patients and payers provide patient-centered care among individuals receiving infusion-based therapies.

Supplementary Data

Supplementary data are available at *Crohn's and Colitis* 360 online.

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Author Contributions

B.K.: study concept and design, analysis and interpretation of data, drafting of manuscript, and obtained funding; Y.J.: acquisition of data, analysis and interpretation of data, and critical revision of manuscript; W.C.: acquisition of data, analysis and interpretation of data, and critical revision of manuscript; Y.B.: analysis and interpretation of data; E.L.B.: study concept and design and critical revision of manuscript; M.D.L.: study concept and design, acquisition of data, critical revision of manuscript, and study supervision.

Conflicts of Interest

B.K.: No personal conflicts of interest, but potential financial conflict of interest having served on an advisory board for Pfizer, Inc.; Y.J.: No personal or financial conflicts of interest; W.C.: No personal or financial conflicts of interest; Y.B.: No personal or financial conflicts of interest; E.L.B.: No personal conflicts of interests, but the following potential financial conflicts of interest due to consulting for AbbVie, Gilead, Pfizer, Takeda, and Target RWE; M.D.L.: No personal conflicts of interests, but the following potential financial conflicts of interest due to consulting for Takeda, Pfizer, AbbVie, Janssen, UCB, Prometheus, Salix, Valeant, and Target Pharmsolutions, and grant support from Takeda and Pfizer.

Data Availability

The claims data are from the IMS Health Real-World Data Adjudicated Claims database (now PharMetrics Plus), which are not publically available; the study authors have obtained the data under a prior data use agreement from the data source. The data from the IBD Partners cohort are housed at the Center for Gastrointestinal Biology and Disease Data Management Center and may be available upon reasonable request.

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