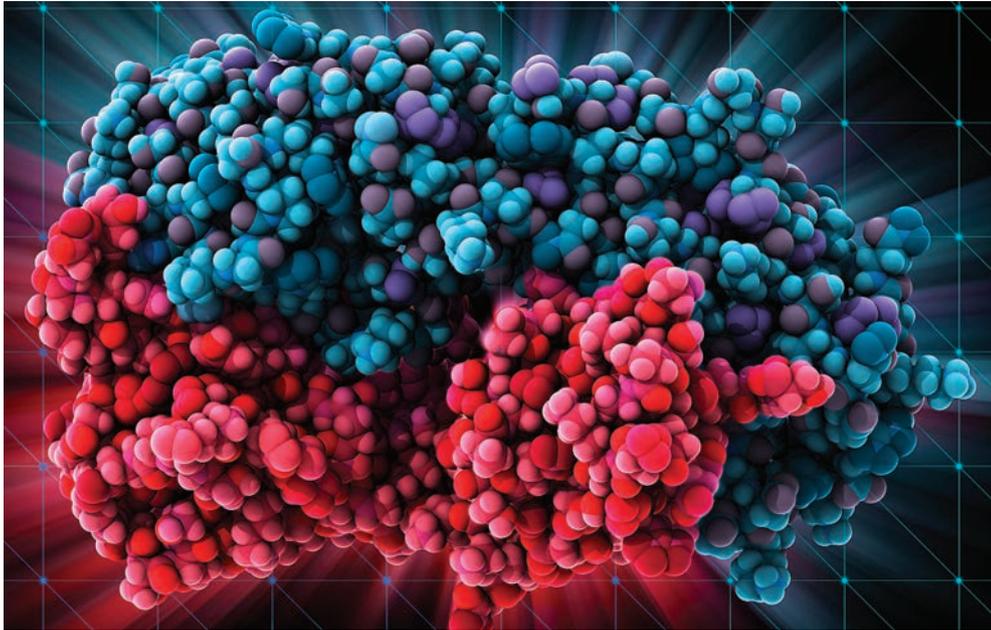


# Infusion Journal

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## About the cover:

Monoclonal antibodies (mAbs) can marshal the immune system to fight cancer, autoimmune diseases, and certain viral infections, including SARS-CoV-2. Because they are biologic products, mAbs can potentially elicit immune-mediated reactions and are typically approved and marketed with warnings and/or restrictions regarding where and under what conditions they should be administered. Evidence from home-based administration—accelerated by COVID-19—is beginning to indicate that the incidence of reactions is lower than originally postulated.

## Adverse Drug Reaction Gender Differences in Patients Treated with REGEN-COV (Casirivimab/Imdevimab) for Treatment of COVID-19

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## A Pilot Study of Ocrelizumab Infusion Reaction Rates Among Multiple Sclerosis Patients Treated in a Hospital and 2 Outpatient Sites of Care

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*Nominations are due Jan. 6, 2023*

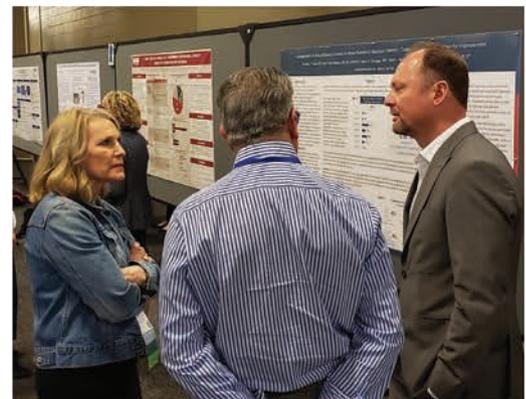


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# Infusion Journal

## Infusion Journal

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### Correction

In "An Investigational Study on the Use of a Sporidicidal Disinfectant to Decontaminate Hazardous Drug Residues on IV Bags" (Volume 1 Issue 2) author Kate Douglass, MS, RN was listed as being affiliated with Contec, Inc. She is employed at Cognitive Design Associates, which is a consultant on retainer to Contec.

Special thanks to Baxter  
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## From the Editor

# The Importance of Case Reports—Writing from Relevance

Michelle C. Simpson, PharmD, BCSCP, MWC

Editor-in-Chief, *Infusion Journal*

One report is an event; 2 are a coincidence, and a third is a potential association. Case reports are one of the most relevant types of manuscripts. A PubMed analysis of a 30-year span (1991 – 2020) found more than 1 million articles of primary literature, with case reports representing 27.54%.<sup>1</sup> Case reports describe new diseases or disease mechanisms, therapeutic approaches, and adverse or beneficial effects of drugs. They are short communications intended to share experiences with an interesting or unusual patient case. A case report tells a real-world story that can be applied to similar scenarios. If applied and the outcome is repeated, it leads to further evaluation and larger study designs.

Case reports reflect clinical experience and support medical progress. Case-based research is at odds with the population-based nature of research studies, where findings may have little relevance to an individual patient. Large research studies have narrow inclusion criteria and the absence of comorbidities. This design creates a disconnection between typical research patients and the patients expected to be prescribed the medication. Case reports supply enough detail on 1 or a small number of patients for clinicians to relate it to their own practice.

Clinicians will use case reports to direct the care provided to patients, including home infusion patients. Case reports can offer solutions to individualized problems when dealing with rare diseases or new medications. Home infusion professionals regularly receive prescriptions for off-label indications or medication doses, and they may find the only information supporting it is a single case report. Despite its long history, the home setting for infusion of many medications and therapeutic classes of drugs is considered cutting-edge. It is perceived as administering medications in circumstances

where it was previously unthinkable. Interesting and unique patient cases are a common occurrence in home infusion.

*Infusion Journal* wants to publish case reports from home infusion professionals. When you are collaborating and solving potential barriers to onboarding a patient to home infusion services, those innovations can be written into a case report. The patient with a specific reason for previously being ineligible for home infusion might be the case report that raises awareness of a protocol to safely manage other patients with the same issue. Case reports are shorter and easier to write than other types of manuscripts. The focus is on an exceptional patient situation and discusses it in detail, adding a literature review to the topic. Authors should write about why the main message is important and provide descriptions of the symptoms, signs, diagnosis, treatment, or follow-up of an individual patient. Well-written and transparent case reports reveal early signals of potential benefits, harms, and information on the use of resources; provide information for clinical research and clinical practice guidelines; and inform medical education.<sup>2</sup>

The home setting for infusion medications offers an ample supply of topics for interesting and unique patient cases to report. If you have a patient case or idea for writing a case report or questions about submitting a manuscript to *Infusion Journal*, contact: [infusionjournal@nhia.org](mailto:infusionjournal@nhia.org)

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# Adverse Drug Reaction Gender Differences in Patients Treated with REGEN-COV (Casirivimab/Imdevimab) for Treatment of COVID-19

Danell Haines, PhD  
Research Consultant

Ryan Garst, PharmD,  
MBA, IgCP, BCSCP  
NHIA

## ABSTRACT

### Introduction

The FDA provided an emergency use authorization for the monoclonal antibody (mAb) REGEN-COV, which is casirivimab and imdevimab, administered together either intravenously or subcutaneously for the treatment of SARS-COV-2. NHIF retrospectively collected and analyzed data from the REGEN-COV patient charts. Data analysis showed that home infused REGEN-COV achieved comparable outcomes to other sites of care and provided improved access to treatment. For this study, NHIF conducted additional analysis of the REGEN-COV data to include gender-related factors. This study answered the question, “Does a significant difference exist between men and women and the rate of adverse drug reactions (ADRs) from REGEN-COV?” If a significant difference does exist, what variables might have caused the difference between the genders, such as patient age, infusion time, vaccination status, and the number of days between the onset of COVID-19 symptoms and the first dose of REGEN-COV?

### Methodology

Home infusion providers participated in this study from July 2021 through October 2021, collecting the following REGEN-COV data; patient age and gender, date symptoms started, date of infusion, infusion time, vaccination status, 7-day follow-up, and adverse events. Analysis was conducted to determine if a significant difference ( $p=.05$ ) existed between the mean age of the genders, rate of ADRs and genders, infusion time and genders, infusion time and rate of ADRs, vaccination rate and

genders, and the mean number of days between the onset of COVID-19 symptoms and the first dose of REGEN-COV and genders. Descriptive statistics were used to analyze demographic data. An ANOVA was conducted to determine if the mean ages of the men and women in the study were significantly different. This statistic was also used to determine if the mean time between the onset of COVID-19 symptoms and the first dose of REGEN-COV was significantly different between the genders. Fisher’s Exact Test was used to determine if a significant difference existed between gender and the occurrence of an ADR.

### Results

There were 459 patient cases representing 5 home infusion providers. No significant difference ( $p=.615$ ) was observed between the mean ages of the genders. Males had a significantly ( $p=.022$ ) higher rate of reported ADRs when compared to females (6.94% versus 2.47%). This is contrary to previous gender and ADR studies which have shown that females have a higher rate of reported ADRs when various therapy types and illnesses are investigated. There was a significant difference ( $p=.009$ ) in infusion times between the females and males. However, the infusion time that was predominantly for females, which was 20-minutes, was noted to have fewer overall ADRs. There was a significant difference ( $p=.001$ ) between females and males in the number of days between the onset of COVID-19 symptoms and the first dose of REGEN-COV. Even so, there was no

significant difference ( $p=.078$ ) between the overall mean number of days between the onset of COVID-19 symptoms and the first dose when cross tabulated by ADRs.

### Discussion

Due to the possible confounding variables that might have caused the differences in the rate of ADRs among the genders, such as the potential difference in health status and the low rate of ADRs in the patients, the investigators are hesitant to conclude that gender and the infusion rate caused the difference in the rate of ADRs. It is recommended that future mAb studies should match genders by health status and compare various infusion times with the rate of ADRs.

### Conclusion

As noted in the literature, females typically have a higher rate of ADRs than males. This study showed the opposite. When the rate of ADRs was compared by infusion time, the 20-minute time had a 0.42% ADR rate, while the 30-minute time had a 10.95% rate. Even though males had a higher rate of ADRs compared to females, more than half of the males (56.91%) had an infusion rate of 20 minutes. Of the reported ADRs, all but 1 was classified as mild. As recommended in previous ADR research, investigation of gender differences needs to be a standard protocol for all studies.

**Keywords:** COVID, REGEN-COV, gender-differences, home infusion, infusion rate, ADR

### Introduction

The first case of COVID-19 in the U.S. was reported on January 21, 2020. Since then, there have been over 92 million reported cases and 1 million deaths.<sup>1</sup> A combination of the high mortality rate and the debilitating effects of the virus has led to the development of various treatment options, including monoclonal antibodies (mAbs). The first mAb, muromonab-CD3 (OKT3), was produced in 1975 and fully licensed in 1986. Today, more than 100 mAbs have been approved by the U.S. Food and Drug Administration (FDA) and are used in treating various diseases and conditions, including cancer, chronic inflammatory diseases, transplant rejection, infectious diseases, and cardiovascular diseases.<sup>2</sup> When used to treat COVID-19, mAbs assist in preventing viral progression in patients at risk for serious outcomes,<sup>3</sup> especially those 65 and older with underlying comorbidities such as cardiovascular disease, obesity, diabetes, chronic kidney disease, and chronic lung disease.<sup>4</sup> As reported by the National Institutes of Health (NIH), the major benefit from mAb therapy in the treatment of COVID-19 appears to be a reduction in the viral load, subsequently preventing hospitalizations and death.<sup>3</sup> The NIH further states that the benefit of this type of therapy is that it is well-tolerated with minimal risks, with the most reported adverse events being injection site reactions and infusion-related reactions.<sup>3</sup>

On November 21, 2020, the FDA provided an emergency use authorization (EUA) for the mAbs REGEN-COV, which is casirivimab and imdevimab, administered together either intravenously or subcutaneously.<sup>5</sup> This therapy was used for patients who tested positive for COVID-19 and were at high risk for progressing to severe COVID-19, hospitalization, or both, and had mild-to-moderate COVID-19 symptoms.<sup>5</sup> A phase 3 adaptive trial was conducted on REGEN-COV and showed that COVID-19 related hospitalizations or death from any cause occurred in 18 of 1,355 (1.3%) patients in the REGEN-COV group compared to 62 of 1,341 (4.6%) patients in the placebo group.<sup>6</sup> The trial concluded that REGEN-COV reduced the risk of COVID-19-related hospitalizations or death from any cause, resolved symptoms, reduced the SARS-CoV-2 viral load more rapidly than placebo.<sup>6</sup>

To ease access to treatment and due to the contagious nature of COVID-19, many patients and care takers gravitated to home health care. Furthermore, with changes in the Centers for Medicare and Medicaid Services (CMS) reimbursement for home COVID-19 treatment, home infusion providers could administer REGEN-COV in the home. As a novel COVID-19 treatment, the National Home Infusion Foundation (NHIF) retrospectively collected and analyzed data from the REGEN-COV patient charts. From the results of this analysis, it was reported that home infused REGEN-COV achieved comparable outcomes to other sites of care and provided improved access to treatment for SARS-COV-2 infection.<sup>7</sup> Furthermore, it was concluded that home infusion providers played an essential role in reducing exposure, saving lives, and reducing hospitalizations.<sup>7</sup>

NHIF decided to conduct additional analysis of the REGEN-COV data after noting the adverse drug reaction (ADR) recommendation in the medical literature that advocated for reporting systems to expand their focus to include gender-related factors to understand, prevent, or reduce the occurrence of ADRs in all people.<sup>8</sup> Without these reporting systems, ADRs that are more common among certain groups, such as women, may remain undetected for years, increasing the possibility of unanticipated risks.<sup>8</sup> It was further stated that research is needed to identify the relationships between gender-related factors in the occurrence and reporting of ADRs to adequately detect and prevent ADRs.<sup>8</sup> Subsequently, this study aimed to answer the research question, “Does a significant difference exist between men and women and the rate of ADRs from REGEN-COV?” If a significant difference does exist, what confounding variables might have caused the difference between the genders, such as patient age, infusion time, vaccination status, and the number of days between the onset of COVID-19 symptoms and the first dose of REGEN-COV.

Prior to conducting this investigation, literature on gender differences and ADRs was searched. A recent study that reviewed 33,147 patient charts with an ADR-related hospital admission

between 2005 and 2017 determined that women accounted for 55.72% of ADR-related hospital admissions while men accounted for 44.28%.<sup>9</sup> It was also revealed a significant difference between the mean age of the men and women (Women = 72.1 years, Men = 71.3 years) and in the types of therapies that men and women were using. Both variables are known to skew the rate of ADRs in patients, evident by research that shows that the elderly are thought to be predisposed to ADRs.<sup>10</sup> Another ADR study that included 513,608 patients who were prescribed a newly marketed drug, concluded that women tend to have a 1.5-1.7 times higher risk of developing ADRs.<sup>11</sup> These results are in line with conclusions from other researchers.<sup>12-14</sup> The only study that addressed the rate of ADRs in home infused patients was a 2022 study by NHIF that had a sample size of 6,045 and concluded that the rate of ADRs that result in discontinuation from therapy is 0.33%.<sup>15</sup> Unfortunately, this study did not report the ADR rate by gender. Overall, the research on gender and ADRs concludes that women have a higher rate of ADRs than men, though most studies did not control for age and therapy differences between the genders.

### Research Question

Does a significant difference ( $p \leq .05$ ) exist between men and women and the rate of ADRs from intravenous infusion of REGEN-COV in the home setting? If a significant difference does exist, what other factors might have caused the difference between the genders, such as patient age, intravenous infusion rate, vaccination status, and the number of days between the onset of COVID-19 symptoms and first dose of REGEN-COV.

### Methods

For the initial REGEN-COV study conducted and reported by NHIF in 2022, home infusion providers were given information about participation in the study, with those interested completing an online survey.<sup>7</sup> A unique data participation code was assigned to each selected location using a third-party to deidentify the provider and their data. Each location entered its patient data into a formatted Excel® file. No

patient identifiers were included in the Excel® file forwarded to NHIF. The variables collected included patient age and gender, date symptoms started, date of infusion, infusion time, vaccination status, 7-day follow-up, and adverse events. This study used the NHIF Standard Definition for an ADR, defined as an undesirable response, other than a known side effect, to the administration of an infused drug that compromises efficacy and/or enhances toxicity.<sup>16</sup> Known side effects include commonly reported mild and moderate reactions listed in the FDA-approved drug labeling or reported in published clinical studies.<sup>5</sup> Since the patient cases and provider locations were deidentified before being uploaded to NHIF's data depository; this study was exempt from IRB review.

The data collection was from July 2021 through October 2021. Each provider location was responsible for assessing patient eligibility per EUA, providing drugs and supplies for administration, coordinating nurses, and billing Medicare or commercial payers for administrations. After the study data was aggregated, differences in drug infusion times were noted. To gain insight into why the differences occurred, a follow-up survey was issued to each participating provider to better understand the intravenous administration protocols used for REGEN-COV. Survey results showed that intravenous infusion times for REGEN-COV were determined either by company protocol or based on patient clinical presentation, or both. Data collection for the infusion time was driven by either the physician order or the nurse documentation.

### Data analysis

Descriptive statistics (means and standard deviations) were used to analyze demographic data. An ANOVA was conducted to determine if the mean ages of the men and women in the study were significantly different. This statistic was also used to determine if the mean time (days) between the onset of COVID-19 symptoms and the first dose of REGEN-COV was significantly different between the genders. In the initial study, ADRs were recorded by the type of ADR. This data was recoded as dichotomous data (yes, the

patient had an ADR or no, that patient did not have an ADR) so that Fisher's Exact Test could be used to determine if a significant difference existed between gender and the occurrence of an ADR. This statistic was also used to determine if a significant difference existed between gender and infusion rate and gender and vaccination rate. SPSS (Statistical Package for Social Sciences) was used to analyze the data set.

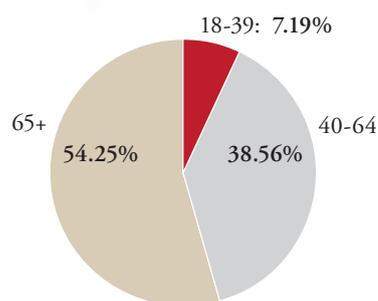
### Results

This study had 464 patient cases representing 5 self-selected home infusion providers. Since the study focused on an adult population (18+ years of age), 4 patient cases were deleted from the original data set. It was also determined that only intravenous infusion rates of 20 and 30 minutes would be included, thus, the 1 patient case with a 50-minute infusion rate was deleted since it was deemed an outlier. The remaining 459 cases used in this study included patients 18 years of age and older with a REGEN-COV infusion rate of 20 or 30 minutes.

### Patient Demographics

The mean patient age was 64.21 years (SD=15.99), with slightly more than half (54.25%) of the patient cases in the 65+ age group, as shown in Figure 1.

FIGURE 1 | Patient Age Group (n=459)



Women and men accounted for 52.94% and 47.06%, respectively of the COVID-19 patients treated with REGEN-COV. There was no significant difference ( $p=.615$ ) between the mean ages of the genders, which was 64.56 (SD=16.83) for women and 63.81 (SD=15.04) for men. Thus, age would not be considered a confounding variable that would skew the results when gender was cross tabulated by ADRs.

### Intravenous Infusion Time

Fisher's Exact Test showed a significant difference ( $p=.009$ ) between gender and intravenous infusion time (20 or 30 minutes), as shown in Figure 2. Females had a higher percentage of 20-minute infusions than males. Conversely, males had a higher rate of 30-minute infusions than females. As shown in Table 1, 10.95% of patients with an infusion time of 30 minutes had an ADR while only 0.42% of those with a 20-minute infusion time had an ADR. Fisher's Exact Test analysis showed a significant difference ( $p<.001$ ) between infusion time and adverse events.

FIGURE 2 | Infusion Time by Gender (n=373)

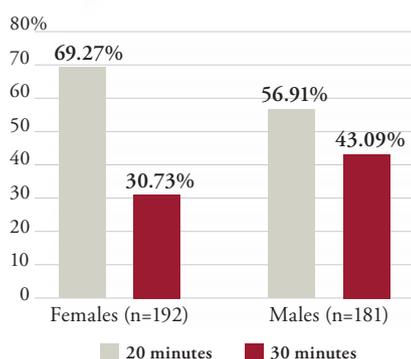


TABLE 1 | Infusion Time by Adverse Drug Reaction (Yes/No) (n=373)

		Infusion Time (minutes)			
		20	30	Total	
Adverse Drug Reaction	No	Count	235	122	357
		%	99.58	89.05	95.71
	Yes	Count	1	15	16
		%	.42	10.95	4.29
Total	Count	236	137	373	
	%	100.00	100.00	100.00	

### Gender and Vaccination Status

The vaccination rates were almost identical for females and males. No significant difference ( $p=1.0$ ) was detected between the genders. Males' vaccination rate was 78.82%, while females were 78.65%. Additionally, there was no significant difference ( $p=.061$ ) between overall vaccination status and the rate of ADRs.

### Days Between Onset of Symptoms and First Dose

The mean number of days between the onset of COVID-19 symptoms and the first dose of REGEN-COV was significantly different ( $p=.001$ ) between the females and males, with females having almost 1 day less time between symptoms and the first dose of REGEN-COV. The mean number of days for females was 5.61 (SD=2.652) and 6.50 (SD=2.699) for males. Furthermore, there was no significant difference ( $p=.078$ ) between the mean number of days between the onset of COVID-19 symptoms, the first dose of REGEN-COV, and the rate of reported ADRs. The mean number of days for those with an ADR was 7.11 (SD=2.69), and those without, 5.98 (SD=2.70).

### Gender and Adverse Drug Reactions (Yes or No)

Fisher's Exact Test shows a significant difference ( $p=.022$ ) between gender and ADRs from REGEN-COV, as shown in Table 2. Females had a lower rate of reported ADR than males, with the overall rate being 4.58%. All but 1 of the ADRs reported in this study were classified as mild using the World Health Organization (WHO) rating scale, which defines a mild ADR as an experience that is usually transient and requires no special treatment or intervention.<sup>17</sup>

TABLE 2 | Gender by Adverse Drug Reaction (Yes or No) (n=459)

		Gender			
		Female	Male	Total	
Adverse Drug Reaction	No	Count	237	201	438
		%	97.53	93.06	95.42
	Yes	Count	6	15	21
		%	2.47	6.94	4.58
Total	Count	243	216	459	
	%	100.00	100.00	100.00	

### Gender and Post-infusion Outcome

Of the 391 patient cases with post-infusion outcome data, only 5 (1.28%) required hospitalization (3 females and 2 males), and 1 male patient expired. There was no significant difference ( $p=.546$ ) between the genders and 7-day outcome, which showed that 200 (98.52%) of the females and 185 (98.40%) were not hospitalized or expired.

## Results Summary

This study investigated the gender differences in the reported rate of ADRs from REGEN-COV used to treat COVID-19 patients in the non-acute setting. Overall, a significant difference was observed between genders and the rate of reported ADRs, with females having a lower rate than males. Age was not a confounding factor since there was no significant difference between the mean age of the females and males. There was a significant difference between intravenous infusion time between females and males. However, the infusion time that was predominantly for females, which was 20 minutes, was noted to have fewer overall ADRs. There was a significant difference between females and males in the number of days between onset of COVID-19 symptoms and first dose of REGEN-COV. Even so, there was not a significant difference between the overall mean number of days between the onset of COVID-19 symptoms and the first dose when cross tabulated by ADRs, which was recoded as a dichotomous variable (Yes or No). Worth noting is that the mean number of days to treatment was 7.11 for the patients with a reported ADR versus 5.98 days for those without.

## Study Limitations

Data regarding pre-COVID-19 patient health status was not collected and could bias the rate of ADRs. As reported by the CDC, there are underlying medical conditions that put people 18 years and older at higher risk of severe illness from COVID-19. These illnesses and risks could affect the rate of ADRs, hospitalization, and death. The males might have had more pre-COVID-19 medical conditions than females, which might have accounted for more of the reported ADRs. ADR data was self-reported by providers which could lead to reporting bias. There is also the possibility of gender bias in the reporting of ADRs. As noted, historically, females tend to have more reported ADRs than men. However, this study showed the opposite results, with males reporting more ADRs than females. Finally, a univariate analysis model was primarily used in this investigation which has the advantage of simplicity of interpretation but fails to account for the covariance/correlation in the data.

## Discussion

The most notable finding in this study is that males had a significantly higher rate of reported ADRs when compared to females. This is contrary to previous gender and ADR studies which have shown that females have a higher rate of reported ADRs when various therapy types and illnesses are investigated. It is surmised that males might have had more underlying health conditions, which might have skewed the results. Future studies should control for pre-COVID-19 health conditions by matching genders on health status. Furthermore, fewer males than females had an infusion time of 20-minutes versus 30-minutes. This is notable because a significant difference ( $p < .001$ ) was found between infusion time and adverse events, with the 30-minute time demonstrating fewer reported ADRs than the 20-minute time.

Due to the possible confounding variables that might have caused the differences in the rate of ADRs among the genders, such as the potential difference in health status and the low rate of ADRs in the patients in this study, the investigators are hesitant to conclude that gender and/or the infusion rate caused the difference in the rate of ADRs. It is recommended that future mAb studies should match genders by health status and compare various infusion times with the rate of ADRs. A unique aspect of REGEN-COV was using different infusion times to administer the medication. Typically, mAbs approved by the FDA have 1 recommended infusion rate. This study provides a rare opportunity to collect outcome data from patients receiving treatment using different infusion times.

## Conclusion

This investigation provides evidence that REGEN-COV administered in the home setting was generally well tolerated and produced similar outcomes compared to other studies, as noted by the ADR rate. In females and males, the rate of ADRs was 2.47% and 6.94%, respectively. As noted in the literature, females typically have a higher rate of ADRs than males. When the rate of ADRs was compared by infusion time, the 20-minute time had a 0.42% ADR rate, while the 30-minute time had a 10.95% rate. Even though males had a higher rate of ADRs when compared to females, more than half of the males (56.91%) had an infusion rate of 20-minutes. Of the reported ADRs, all but 1 was classified as mild. As recommended in previous ADR research, investigation of gender differences needs to be a standard protocol for all studies.

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# A Pilot Study of Ocrelizumab Infusion Reaction Rates Among Multiple Sclerosis Patients Treated in a Hospital and 2 Outpatient Sites of Care

Sofia Shrestha  
PharmD, CSP  
Fairview Home Infusion

Dana Simonson  
PharmD, BCPS  
Fairview Pharmacy Services

Alicia Zagel  
PhD, MPH  
Fairview Pharmacy Services

## ABSTRACT

### Objectives

Economic data on site of care optimization is well-established, yet limited data exist on the safety of administering ocrelizumab in home infusion settings. Ocrelizumab is administered for the treatment of multiple sclerosis and carries a warning for the risk of infusion-related reactions (IRRs) during administration. The study objective was to measure the incidence and severity of infusion-related reactions in patients receiving ocrelizumab administered in both hospital-based and outpatient sites of care.

### Methods

This was a retrospective study of patients who received ocrelizumab infusions for multiple sclerosis between March 2017 and September 2019. Patient and infusion characteristics were compared by infusion setting using appropriate nonparametric tests and z-tests.

### Results

There were 85 patients with 230 ocrelizumab infusions. Patients were similar demographically. Outpatient sites of care had a higher proportion of maintenance infusions than hospital-based sites of care (outpatient: 81.1%, hospital: 43.0%,  $p=0.0001$ ). There were 25 IRRs reported, a majority of these in the hospital setting (92.0%), with encounter rates similar across infusion settings (outpatient: 5.4%, hospital: 11.9%;  $p=0.24$ ).

### Conclusion

This study demonstrated similar incidence, severity, and management of ocrelizumab IRRs regardless of infusion setting. Although limited by the small sample size, safety results endorse clinical support for administering ocrelizumab in outpatient sites of care. Patient access to ocrelizumab infusions in their home or ambulatory infusion suite may improve adherence to the medication therapy and improve disease outcomes.

**Keywords:** *infused specialty medication, home infusion, infusion site of care (SOC), safety outcomes, infusion-related reaction (IRR)*

### Key Points:

- Site of care optimization as a utilization management strategy encourages the use of lower-cost, convenient care settings, however, data on real-world utilization and clinical outcomes is limited.
- This retrospective pilot study demonstrated that infusion-related reactions from ocrelizumab are infrequent and mild.
- Current data supports the safe and cost-effective administration of ocrelizumab in an outpatient, ambulatory, or home infusion setting.

## Background

Since 2010, the number of specialty medications available in the United States, including infusion medications, has grown exponentially, which has driven infusion site of care (SOC) optimization programs focusing on therapeutic areas such as autoimmune, inflammatory, and oncology disease states.<sup>1</sup> SOC optimization aims to reduce the total cost of care and promote positive clinical outcomes for patients receiving infused or injected therapies, including specialty medications and biologics.<sup>2-4</sup> Home infusion allows for administration of intravenous, subcutaneous, and injectable medications by patients or skilled nurses in an individual's home. Home infusion has emerged as an ideal setting for SOC programs due to increased patient accessibility and convenience of care as well as reduced exposure to infectious agents. The majority (85%) of commercial health plans direct patients toward home infusions.<sup>5-7</sup> Additionally, home infusion offers considerably less expensive care; for example, the estimated cost per claim for infliximab and ustekinumab, commonly utilized inflammatory specialty infused medications, are considerably less when administered through home infusion compared to a hospital-based infusion center (infliximab: \$6,692 vs. \$11,081; ustekinumab: \$15,564 vs. \$31,385, respectively).<sup>1</sup>

Multiple sclerosis and autoimmune diseases have been a large focus of SOC programs.<sup>6</sup> Multiple sclerosis has been estimated to affect nearly 1 million American adults and has several high-cost, Food and Drug Administration (FDA)-approved injectables and infused disease modifying therapies (DMTs) available, making it a great candidate for SOC programs.<sup>8</sup> FDA-approved infused medications include Lemtrada® (alemtuzumab), Tysabri® (natalizumab), and Ocrevus® (ocrelizumab). Alemtuzumab and natalizumab have required Risk Evaluation Mitigation Strategy (REMS) programs.<sup>9</sup> Ocrelizumab, a CD20-directed monoclonal antibody, has become a widely used DMT for treating relapsing and primary progressive forms of multiple sclerosis since its FDA approval in 2017.<sup>10</sup> Ocrelizumab offers convenient twice-yearly dosing and demonstrated lower rates of clinical disease progression in clinical trials.<sup>10-13</sup> However, ocrelizumab infusions have been noted to carry a high risk of infusion-related reactions (IRR), which range from minor issues like pruritis and fever to severe reactions like tachycardia and bronchospasms. In clinical trials, the incidence of IRRs for ocrelizumab was

34-40%, with the highest incidence occurring during the first infusion; additionally, 58-70% of patients developed at least one infection related to the infusion, such as respiratory tract, skin, or herpes infections.<sup>13</sup>

Previous literature has evaluated infliximab, a highly utilized biologic therapy with indications for several inflammatory disease states that carries a possible risk of IRRs.<sup>14</sup> In a retrospective chart review of patients who received infliximab infusion in community clinics, severe infusion reaction events were rare, the majority being mild-moderate reactions and none requiring hospital admissions.<sup>15</sup> Similarly, a retrospective chart review of Crohn's disease and ulcerative colitis patients who received infliximab demonstrated that IRRs were adequately managed in a community setting without provider intervention.<sup>16</sup> Another large population of specialty infusion medications includes enzyme replacement therapy. Enzyme replacement therapy has been shown to be infused safely in the home.<sup>17</sup> A study in Australia has similarly demonstrated no clinically significant difference in safety and effectiveness of natalizumab infusions in the clinic versus home infusions in patients with multiple sclerosis.<sup>18</sup> By examining ocrelizumab infusions and infusion reaction rates, this study adds to the limited body of evidence that supports specialty medication administration through home infusion.

More recently, several health care systems across the United States have established programs to administer ocrelizumab either at an ambulatory infusion suite or in the patient's home.<sup>19</sup> Although the cost-effectiveness of transitioning patients to home infusion is well-established, there is limited research on the safety of administering ocrelizumab infusions in the patient home.<sup>14-18,20,21</sup> This pilot study collected data on administration of ocrelizumab in a hospital-based site of care and outpatient sites of care. Hospital-based sites of care are within the hospital setting. Outpatient infusions are administered in the patient home or ambulatory infusion suite. Ocrelizumab infusions were categorized by initial infusion and maintenance dose administration and then measured by rates and characteristics of IRRs. The research will support the growing interest in SOC programs for specialty infusions and engage the needs of multiple sclerosis patients prescribed ocrelizumab.

## Methods

**Study Setting and Population.** This was a retrospective cohort study of adult patients presenting to a large, Midwestern health system with both hospital-based infusion sites of care and outpatient infusion sites of care. For this study, the hospital-based infusions were administered by a nurse and included physician oversight and immediate access to emergency services. The outpatient infusions were administered by a nurse in an ambulatory infusion suite or patient home. Inclusion criteria for patients included those who received at least one dose of ocrelizumab for multiple sclerosis between March 2017, when ocrelizumab was FDA-approved, and September 2019. Patients were excluded if they were concurrently using other DMTs in addition to ocrelizumab. This study was approved by the health system's Institutional Review Board (IRB).

**Infusion procedures.** Institutional protocol for ocrelizumab administration and management of IRRs were the same across infusion settings. Patients received oral acetaminophen, IV or oral diphenhydramine, and IV or oral steroid premedication as ordered prior to each infusion. Initial infusions were administered over 2.5 hours and maintenance infusions were administered over 3.5 hours per manufacturer-recommended rate titration steps and all patients were monitored for 1 hour post-infusion.<sup>10</sup>

**Data collection:** Eligible patients were identified through the electronic medical record; a manual chart review was completed to document patient demographics and characteristics on infusion encounters. The chart review was conducted by a single pharmacist trained in the health system's electronic medical record systems. Data collection was maintained securely within the health system.

**Variables of interest.** A predictor of interest was the setting in which patients received ocrelizumab infusions (hospital or outpatient). Patients who switched infusion settings had encounters included only at their most recent infusion setting.

The primary outcome was adverse events occurring during infusion and included IRRs, severity of reaction, reaction management strategy, and

new or recurrent infections occurring due to ocrelizumab therapy. Reaction severity was assessed using Common Terminology Criteria for Adverse Events (CTCAE) version 5.0, which standardizes and defines the severity of IRRs as Mild (Grade 1), Moderate (Grade 2), Severe (Grade 3), Life-threatening (Grade 4), and Death (Grade 5).<sup>22</sup> Other variables assessed with respect to infusion setting included patient demographics such as age, gender, and race, and clinical information such as type of multiple sclerosis (relapsing or primary progressive), treatment history including prior DMTs and reason for the switch to ocrelizumab, infusion duration, and total infusion visit time.

**Data analysis:** Data were summarized using traditional methods, including the expression of categorical data by frequency and percent; continuous variables were assessed for normality using the Kolmogorov–Smirnov test and then summarized using median and interquartile range (IQR) after deemed non-normally distributed. Data were compared by infusion setting using appropriate nonparametric statistical tests, which included chi-squared, and Fisher's exact tests for categorical data and Mann-Whitney U tests for continuous data. Z-tests compared proportions of IRRs occurring across infusion settings. We estimated the odds of an IRR and associated 95% confidence intervals (CIs) with respect to site of care and infusion dose using logistic regression. The significance level was set *a priori* as  $\alpha=0.05$ .

## Results

**Patient characteristics.** There were 85 patients with 230 ocrelizumab infusions who met the study criteria. Patient baseline demographics and clinical characteristics by care setting are outlined in Table 1. Patients were largely similar across infusion setting by demographic and clinical characteristics. Study patients were predominantly male (n=48, 56.5%), white race (n=75, 88.2%), with a median age of 47 years (IQR: 38- 55). Within this population, 24 (28.2%) patients were treated through outpatient infusion sites of care, and 61 (71.8%) patients were treated in hospital-based infusion sites of care. Of outpatient infusions, nearly all (n=23, 95.8%) occurred in the ambulatory infusion suite. One patient received infusions in their home. Additionally,

TABLE 1 | Characteristics of Patients Treated with Ocrelizumab Infusions, March 17 through September 2019

		Total population, n=85	Outpatient Infusion Site(s), n=24 (28.24%)	Hospital-based Infusion Site(s), n=61 (71.76%)	p value
Age, years; Median (IQR)		47 (38, 55)	48.5 (37.5, 52.5)	47 (38, 55)	0.70
Race/Ethnicity	White	75 (88.24)	24 (100.00)	51 (83.61)	0.11
	Black	9 (10.59)	0 (0.00)	9 (14.75)	
	Hispanic	1 (1.18)	0 (0.00)	1 (1.64)	
Sex	Male	48 (56.47)	12 (50.00)	36 (59.02)	0.45
	Female	37 (43.53)	12 (50.00)	25 (40.98)	
Diagnosis	Primary progressive MS	32 (37.65)	8 (33.33)	24 (39.34)	0.61
	Relapse remitting MS	53 (62.35)	16 (66.67)	37 (60.66)	
Previous DMTs	Interferon Beta	41 (48.24)	11 (45.83)	30 (49.18)	0.78
	Glatiramer acetate	35 (41.18)	10 (41.67)	25 (40.98)	0.95
	Other DMTs	35 (41.18)	11 (45.83)	24 (39.34)	0.58
	None/Unknown	12 (14.12)	4 (16.67)	8 (13.11)	0.67
Reason for switch to ocrelizumab among patients with previous DMTs	Disease progression	46 (63.01)	12 (60.00)	34 (64.15)	0.18
	Side effects	17 (23.29)	3 (15.00)	14 (26.42)	
	Other (noncompliance, insurance, etc.)	10 (13.70)	5 (25.00)	5 (9.43)	
Number of infusions during study period; median (IQR)		2 (2, 4)	1 (1, 2)	3 (2, 4)	<0.001

IQR = Interquartile range; DMT = Disease modifying therapy

of the outpatient infusions, 13 (54.2%) transitioned from a hospital-based infusion SOC specifically due to SOC utilization management strategies by their health plans.

Many patients (n=41, 48.2%) had previously been treated with interferon beta or glatiramer acetate (n=35, 41.2%) for their multiple sclerosis. Among patients who had used DMTs previously, the primary reasons for switching to ocrelizumab infusion therapy included disease progression (n=46, 63.0%) or intolerable side effects of previous therapies (n=17, 14.1%). Hospital-based infusion patients underwent a greater number of infusions during the study period (median: 3,

IQR: 2-4)) compared to the outpatient infusion group (median: 1, IQR: 1-3;  $p<0.001$ ).

**Infusion characteristics.** There were 230 ocrelizumab infusions during the study period, including 37 (16.1%) outpatient infusions and 193 (83.9%) hospital-based infusions. Maintenance doses of ocrelizumab occurred more often in the outpatient sites of care compared to hospital-based infusions (n=30, 81.1% vs. n=83, 43.0%, respectively;  $p=0.0001$ ).

Infusion and total visit times were similar by infusion setting and dose type. Median total visit time for initial infusions was 4 (IQR: 3.75-4) hours

TABLE 2 | Description of Infusion Encounters for Ocrelizumab Across 85 Patients, March 2017 through September 2019.

		Total encounters, n=230	Outpatient Infusion Site(s), n=24 (28.24%)	Hospital-based Infusion Site(s), n=61 (71.76%)	p value
Dose timing	Initial Day 1	60 (26.09)	4 (10.81)	56 (29.02)	0.0001
	Initial Day 15	57 (24.78)	3 (8.11)	54 (27.98)	
	Maintenance	113 (49.13)	30 (81.08)	83 (43.01)	
Infusion time (hours), Initial doses; Median (IQR)		3 (2.75, 3)	3 (2.5, 3)	3 (2.75, 3)	0.31
Total visit time (hours), initial doses; Median (IQR)		4 (3.75, 4)	3.75 (3.5, 4)	4 (3.75, 4)	0.10
Infusion time (hours), maintenance doses; Median (IQR)		3.5 (3.5, 3.75)	3.5 (3.5, 4)	3.5 (3.5, 3.75)	0.55
Total visit time (hours), maintenance doses; Median (IQR)		4.5 (4.5, 5)	4.5 (4.5, 5)	4.5 (4.5, 4.75)	0.88
Any IRR	Yes	25 (10.87)	2 (5.41)	23 (11.92)	0.24
Timing of IRR	Acute	22 (88.00)	2 (100.00)	20 (86.96)	0.61
	Delayed	3 (12.00)	0 (0.00)	3 (13.04)	
	Initial Dose	17 (73.91)	1 (50.00)	16 (76.19)	0.42
	Maintenance Dose	6 (26.09)	1 (50.00)	5 (23.81)	
Severity of reaction	Mild	10 (31.82)	2 (100.00)	8 (25.00)	0.20
	Moderate	14 (63.64)	0 (0.00)	14 (70.00)	
	Severe	1 (4.55)	0 (0.00)	1 (5.00)	
Post-infusion Infection	Yes	9 (3.91)	0 (0.00)	9 (4.66)	0.18

IQR = Interquartile range; IRR = Infusion-related reaction

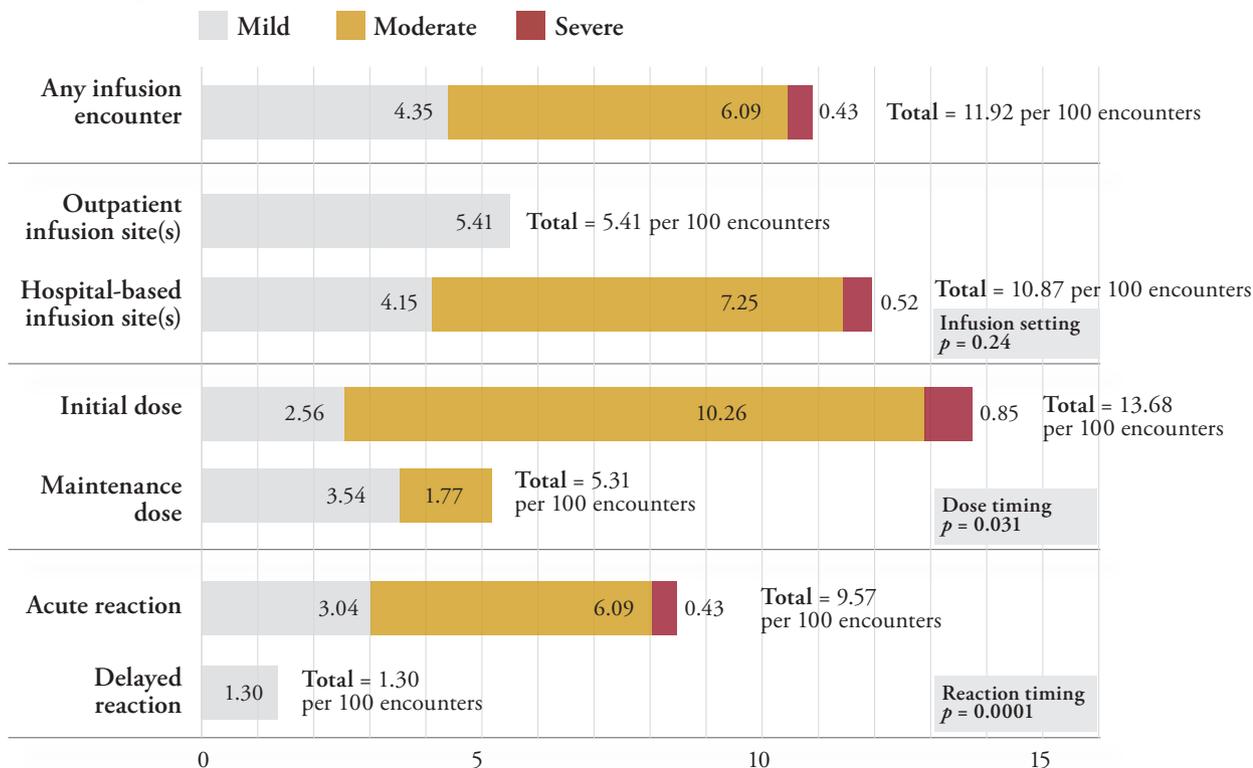
and for maintenance infusions was 4.5 (IQR: 4.5-5) hours. Comparisons of encounter characteristics by infusion site are available in Table 2.

*Infusion-related reactions (IRRs)*

There were 25 IRRs noted among 20 patients during the study period; 22 IRRs (88.0%) were acute and occurred during the observation time following the infusion and 3 (12.0%) were delayed and occurred ≥24 hours after infusion administration. Only 2 IRRs occurred among outpatient infusions and both were acute and mild. Nearly two-thirds of IRRs were moderate (n=14, 63.6%), with 10 (31.8%) being mild and only 1 (4.6%) being severe. The 3 delayed IRRs were all mild and consisted of symptoms such as aches, rash, and nausea. The rate of IRRs per encounter was

5.4 per 100 encounters for outpatient infusions and 11.9 per 100 encounters for hospital-based infusion encounters (p=0.24). Most (72.7%) IRRs occurred during initial infusions, at a rate of 13.68 per 100 encounters compared to 5.31 maintenance dose IRRs per 100 encounters (p=0.031). Moderate severity IRRs had physician consult and the single severe IRR resulted in emergency medical attention. Figure 1 indicates the breakdown of IRRs by severity and dose administration. Based on regression models depicted in Table 3, site of infusion was not significantly associated with IRR when controlled for timing of dose (initial versus maintenance). In fact, initial infusion doses were 3 times more likely to result in an IRR independent of infusion site when compared to maintenance doses (Model 1). Adjusting for both infusion site and timing

FIGURE 1 | Incidence of Ocrelizumab Infusion Reactions per 100 Infusion Encounters



of dose, initial dose was still 2.8 times more likely to result in an IRR compared to maintenance dose (Model 2). Reviewing only the initial (Model 3) and maintenance (Model 4) doses, infusion site, again, was not significantly associated with risk of IRR.

**Infections**

No intravenous line infections were reported at any site of care (hospital or outpatient), though 7 patients

treated across 10 hospital-based infusion encounters reported viral or bacterial agents causing chronic or acute infection. These infections included upper respiratory tract, pneumonia, herpes simplex, and urinary tract infections. Recurrent infection was noted in 3 patients; multiple infections were noted in 2 patients. No infections were documented for outpatient infusions.

TABLE 3 | Regression Models Examining Effect of Site of Care on IRR with Respect to Initial and Maintenance Ocrelizumab Infusions

	Model 1	Model 2	Model 3	Model 4
	All infusions, univariate	All infusions, adjusted	Initial Dose	Maintenance dose
	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Hospital-based infusion site(s)	reference	reference	reference	reference
Outpatient infusion site(s)	0.47 (0.11, 2.09)	0.71 (0.15, 3.35)	0.98 (0.11, 8.68)	0.54 (0.06, 4.80)
Maintenance dose	reference	reference		
Initial dose	3.03 (1.15, 8.00)	2.84 (1.04, 7.75)		

## Discussion

Home infusion therapy is well-established and accepted by health care providers as safe and clinically equivalent to hospital based infusions, with approximately 829,000 patients receiving 1.24 million home infusion therapies annually, of which >15% are specialty medications.<sup>7</sup> The current pilot study evaluated the safety profile of ocrelizumab infusions in multiple sclerosis patients and found similar rates of adverse reactions and infections within outpatient sites of care and hospital-based infusions, supporting the outpatient settings for infusion therapy for treatment of multiple sclerosis. The home may be an ideal choice for patients seeking more personalized and convenient medication administration and for payors looking to decrease costs while increasing value to their patients.

The landscape of home infusion indicates equal or superior patient and clinical outcomes compared to hospital-based infusion. Specifically, a systematic review of 13 studies evaluated the utility of home infusion versus clinic-based infusion as a mechanism to affect the triple aim of better health, better health outcomes, and lower costs, and demonstrated that home infusion patients on anti-infective medications were no more likely to experience adverse drug events or side effects, had equal or better clinical outcomes including lower rates of hospitalizations.<sup>21</sup> The review also noted higher quality of life for patients and significantly lower costs within home infusion compared to infusions within medical settings. However, the review predominantly included patients with anti-infective infusions. Specialty medications and biologic infusion therapy outcomes were not evaluated. Similar to the review, however, our study was able to demonstrate that patients receiving ocrelizumab outpatient infusions were not at added risk for adverse reactions and have comparable safety outcomes. Although it could not be evaluated in this pilot study, it is likely that outcomes with regard to cost savings and increased access to specialty therapies are more pronounced in this study given the inherent high cost of ocrelizumab, which has a list price of \$68,000/year<sup>23</sup> and reduced costs for providing home infusion services, in general.<sup>3</sup> To date, limited evidence exists examining the safety of administering specialty infusions through home infusion. Our study provides added support to current literature by evaluating home infusion utility through the lens of specialty infusions and demonstrated that infusing

ocrelizumab in outpatient site is comparable to hospital-based infusion centers. Outpatient infusion does not result in higher rates of IRR.

In our study, reported IRRs for ocrelizumab were similar in all infusion settings, and reactions that occurred during outpatient infusions were managed by skilled nurses without direct provider intervention. Our study reported 9% of infusions resulting in an IRR. The incidence of IRRs noted in this pilot study is lower than reported in the clinical trials. In clinical trials, the incidence of IRR for patients on ocrelizumab was 34.3% and 39.9%, respectively.<sup>10-13</sup> In clinical trials, the incidence was highest with the first dose and decreased with each subsequent dosing, which is reflective of this study population and 80% of reactions occurring with the initial dose. Regression models on study data also demonstrate that initial doses are more likely to result in an IRR compared to maintenance doses regardless of infusion site, which further supports site of care optimization for maintenance doses through use of outpatient sites of care.

Limitations of this study include the small and homogenous patient population overall and a single patient in the home infusion setting. Provider office is also a common outpatient site of care for specialty therapies but was not an infusion site included in this study. While this pilot study involved robust data collection techniques, larger, multicenter studies of ocrelizumab and other specialty infusion therapies are important to further evaluate their safety profiles in the home setting across more diverse population groups. Further, home infusion services in this health system use an electronic medical record (EMR) separate from the institution's EMR, thus, infections may have been tracked inconsistently across infusion settings. As such, the chart review for these patients also examined clinic visit records surrounding the infusion date to examine the presence of infections when documentation was available. Outcomes were collected by unblinded nurses delivering infusions at both sites of care.

## Conclusion

This pilot study is a key step in understanding the safety of administering biologic specialty therapies through home infusion, specifically for patients with multiple sclerosis. This study demonstrated that ocrelizumab can be administered with a low rate of IRRs in the hospital

or outpatient sites of care. Compared to hospital-based infusions, ocrelizumab had similar risk of adverse effects including IRRs and infections when administered in outpatient sites of care. Notably, the overall observed incidence of IRRs within the study population was lower than what has previously been documented in clinical trials. Data support administration of ocrelizumab outside a hospital-based infusion site. Additional research on SOC programs will not only advance clinical insight for home infusion clinicians but also improve accessibility and quality of care to immunocompromised patients who may benefit from receiving infusions in an ambulatory infusion suite or in the comfort of their own home.

## Disclosures

The authors have declared no potential conflicts of interest.

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## Lead Author Contact/Affiliation:

Fairview Home Infusion,  
711 Kasota Avenue SE, Minneapolis,  
MN, 55414  
[sofia.shrestha@fairview.org](mailto:sofia.shrestha@fairview.org)

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# Pharmacists' Role in Onboarding Patients for Home Infusion Therapy

Danell Haines, PhD  
Research Consultant

Ryan Garst, PharmD,  
MBA, IgCP, BCSCP  
NHIA

## ABSTRACT

### Introduction

The home infusion patient onboarding process is essential to patient care. For the pharmacist, the patient onboarding process is uniquely extensive, time-consuming, and inherently complex. A literature review shows a void in studies focusing on pharmacist time and the tasks used to onboard a home infusion patient. Time utilization data is valuable for understanding the typical work required to efficiently provide a high-quality health care service. The objectives of this study were to quantify the categories of professional services (tasks) the pharmacist provides and to determine the amount of time and the number of days the pharmacist spends onboarding the patient. The results from this investigation will determine the home infusion pharmacist's time commitment to tasks involved with onboarding a home infusion patient.

### Methodology

Data collection was completed from January 2021 through October 2021. It involved tracking pharmacist time spent on patient care starting at the time of referral and continuing through the first dispensing of the home infusion medication. A home infusion pharmacist expert committee determined the pharmacist onboarding tasks, task categories, and examples of tasks for each category. This information was included in the pharmacist data entry Excel® file. Using retrospective recall, pharmacists tracked the start and end time for each task category for each patient serviced.

### Results

Pharmacists completed 163 patient onboarding tasks for a total of 30 patients in this study. The mean completed tasks per patient is 5.40 (SD=1.90) with each task averaging slightly more than a half hour with the mean total time being 2:43.34 (SD= 0:50.46). Performing patient assessment and documentation is the most time-consuming task category. The number of days to onboard a home infusion patient ranged from 1 to 6 days, with 89.57% of the patients being onboarded in 1 day.

### Discussion

The time invested up front by the pharmacist, and other personnel, is instrumental in achieving the goals of therapy, avoiding adverse events, and ensuring a positive overall experience for the patient. While different individuals such as nurses, pharmacy technicians, reimbursement staff, administrative support, and warehouse personnel are typically involved in the onboarding process, this study provides the first assessment of the pharmacist's time spent onboarding the home infusion patient.

### Conclusions

The home infusion pharmacist's role in patient care extends beyond dispensing medications. It involves many tasks that begin with the initial referral and conclude once the therapy is completed. Having data supporting the pharmacist time commitment to the patient onboarding process will assist with scheduling home infusion pharmacists. Finally, this data is evidence of the involvement and importance of the home infusion pharmacist contributions to home infusion patient care.

**Keywords:** *Time study, patient onboarding, home infusion pharmacist, patient assessment, infusion*

## Introduction

The home infusion patient onboarding process is essential to the patient's success. It involves extensive multidisciplinary tasks that begin once the patient is referred for services. Onboarding is a term typically associated with newly hired employees and is the process by which employees gain the knowledge and skills they need to become effective members of an organization.<sup>1</sup> Within health care, "patient onboarding" is a term typically used when the patient needs to be taught skills and knowledge prior to treatment. In the home infusion context, the term is broadened to include activities professional staff performs to arrange the home treatment. To ensure that the home infusion onboarding process is seamless, a team of infusion experts works simultaneously to determine patient eligibility, verify insurance coverage, design the therapy and monitoring plan, compound/prepare the medications and supplies, establish treatment goals, and coordinate the home nursing services. The home infusion pharmacist performs a wide range of onboarding tasks, including consulting with the patient, physician, and nurse as needed and initiating changes to the prescribed treatment and monitoring plan.

For the pharmacist, the patient onboarding process is uniquely extensive, time-consuming, and inherently complex. The pharmacist must be knowledgeable of vascular access devices, infusion pumps, administration protocols and supplies, and maintain expertise in sterile compounding. Designing an effective infusion therapy requires adapting the prescribed medication to the individual patient's needs and abilities while also considering the administration methods that are cost effective and suitable for the drug's physical and chemical properties. Additionally, these functions are often completed in a short timeframe to facilitate an expeditious and seamless transition from hospital to home.

A review of the literature shows a void in studies focusing on pharmacist time to onboard a home infusion patient. Studies that investigate tasks and quantify the amount of time to complete are known as time utilization or time and motion studies. They are common in health care because they assist in understanding the time requirements specific to a health care profession.<sup>2</sup> These studies were initially used to determine costs and inefficiencies in health

care delivery and then expanded the focus toward patient safety and quality.<sup>2</sup> Time utilization studies offer a precise standard in quantifying health care workers' time expenditures on clinical activities and provide valuable insight into system specifications<sup>3</sup> and workflow design.<sup>4</sup> In brief, time utilization data is valuable for understanding the tasks required to provide a high-quality health care service efficiently.

There is a common understanding of the home infusion pharmacist's professional contributions to onboarding the home infusion patient. However, the pharmacist's overall time commitment to the various onboarding tasks is unknown. In 2022, the National Home Infusion Foundation (NHIF) conducted a time study that tracked 400 pharmacist tasks associated with 30 home infusion patients from 5 unique provider locations.<sup>5</sup> The study concluded that pharmacists spend an average of 35.85 minutes per patient per day for an average of 12.23 study days per patient.<sup>5</sup> However, this study did not delineate pharmacist onboarding tasks, or the amount of time or days needed to complete these tasks. A literature review shows that pharmacist time has been the main focus of some studies.<sup>3,6</sup> Unfortunately, the investigations did not include home infusion pharmacy as the work setting and did not delineate onboarding time.

This multi-center descriptive study was conducted by NHIF to better understand the pharmacists work required to onboard a home infusion patient. The study objectives were to quantify the categories of professional services (tasks) the pharmacist provides, determine the amount of time the home infusion pharmacist spends onboarding the patient, and the number of days it takes to onboard a home infusion patient. This descriptive study will improve understanding of the type of work, amount of time, and number of days a pharmacist spends onboarding the home infusion patient.

## METHODOLOGY

The NHIF web page invited all home infusion providers to participate in this descriptive study involving the self-reported time spent by their pharmacists on clinical tasks related to patient care. The pharmacists at these locations received an orientation video, data entry guide, and patient

FIGURE 1.  
Onboarding Task Categories with Examples

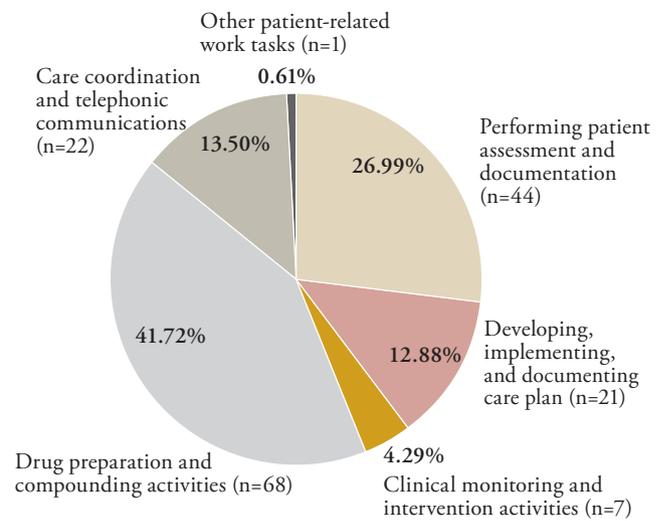
Task Category	Examples
<p>1. <b>Performing patient assessments and documenting the assessment results in the patient EMR</b></p>	<ul style="list-style-type: none"> <li>• Review of current illness</li> <li>• Review of past medical history</li> <li>• Review of current medication list</li> <li>• Review of prescribed infusion medication</li> <li>• Assessment of home environment/caregiver status</li> <li>• Assessment of ambulatory status and other physical limitations that may interfere with self-administration</li> <li>• Assessment of vascular access device compatibility with prescribed medication</li> <li>• Interventions to facilitate initiation of home infusion therapy</li> </ul>
<p>2. <b>Developing, implementing, and documenting the plan of care</b></p>	<ul style="list-style-type: none"> <li>• Selection of administration method</li> <li>• Establishing goals of therapy</li> <li>• Reviewing existing, and obtaining supplemental physician orders for prevention of acute infusion reactions, access device de-clotting agents, access device maintenance solutions, etc.</li> <li>• Developing a monitoring plan</li> <li>• Developing an access device maintenance plan</li> <li>• Patient education plan</li> <li>• Interventions performed</li> <li>• Documenting and updating the care plan in the EMR</li> </ul>
<p>3. <b>Remote monitoring and related intervention activities</b></p>	<ul style="list-style-type: none"> <li>• Obtaining, tracking, and trending lab results</li> <li>• Lab evaluations</li> <li>• Interventions performed</li> <li>• Recommendations made because of monitoring activities</li> <li>• Documentation of monitoring and interventions in the EMR</li> </ul>
<p>4. <b>Drug preparation and compounding activities</b></p>	<ul style="list-style-type: none"> <li>• Dispensing</li> <li>• Determining appropriate beyond-use dates</li> <li>• Compounding process oversight (patient specific)</li> <li>• Supply selection</li> <li>• Shipping</li> <li>• Documentation of compounding, dispensing, and delivery activities</li> </ul>
<p>5. <b>Care coordination and communication</b></p>	<ul style="list-style-type: none"> <li>• Telephonic interactions and the time spent performing the task</li> <li>• Patient communication</li> <li>• Prescriber communication</li> <li>• Internal communication (i.e., billing)</li> <li>• Only include if not able to fit into a category above</li> </ul>
<p>6. <b>Other patient-related work tasks</b></p>	<ul style="list-style-type: none"> <li>• Case conferences</li> <li>• Work not covered above</li> </ul>

tracking Excel® spreadsheets. Since the providers, pharmacists, and patient data was deidentified before submission to NHIF, this study was exempt from Institutional Review Board (IRB) review.

### Data Collection

Data collection was completed from January 2021 through October 2021. It involved tracking pharmacist patient care time starting at the time of referral and continuing through the first dispensing of the home infusion medication. Patient demographic data was collected, including age, therapy, and administration method. Prior to data collection, a home infusion pharmacist expert committee was utilized to determine the pharmacist onboarding tasks, task categories, and examples of tasks for each category (Figure 1). This information was included in the pharmacist data entry Excel® file with a separate file for each patient. Pharmacists tracked the start and end time for each task category for each patient serviced. For example, if the pharmacist reviewed the prescribed infusion medication, the task category was “1” and the start time for the task was noted. After completing the task, the pharmacist noted the end time for the task in the Excel® tracking form (Figure 2). The design of the time study (time data were tracked at the start and end of each task) ensured that the risk of recall bias was minimized. Once the onboarding process was completed for the patient, as noted by the first drug dispense, the

FIGURE 3. Pharmacist Onboarding Tasks by Category (n=163)



data collection tracking form went through a deidentification process and was submitted to NHIF via a data submission portal.

Researchers calculated the patient total onboarding days, total patient minutes for each onboarding task category, and total patient onboarding minutes for pharmacist professional services, all within the Excel® file. Next, the data for all submitted forms was combined and compiled into a single Excel® file. This file was imported to IBM SPSS (Statistical Product and Service Solutions) for additional analysis.

FIGURE 2. Home Infusion Pharmacist Onboarding Professional Services Excel® Tracking Form

Temp					
Location DPC		Patient ID #			
Patient ID #		Patient Therapy Type Codes			
		1: Anti-infective using an ambulatory infusion pump 2: Anti-infective utilizing IV push administration 3: Inotropic using an ambulatory infusion pump 4: Anti-neoplastic chemotherapy (i.e.5-Fu) using ambulatory infusion pump 5: Parenteral nutrition patient 6: Monoclonal antibody administered intravenously with initial home dose 7: Subcutaneous immune globulin-pump administered 8: Intravenous immune globulin-pump administered			
Patient Age		Care Activity Task Codes			
Patient Data Start Date		1: Performing patient assessments and documentation 2: Developing, implementing, & documenting care plan 3: Remote monitoring and intervention activities 4: Drug preparation and compounding activities 5: Care coordination and telephonic communications 6: Other patient related works tasks			
Patient Data Stop Date					
Patient Therapy Type Code					
Secondary Therapies (IV)					
	Therapy	Medication	Date Added	Administration Method	
Data Entry					
*Please enter start time and end time in military time (00:00-24:00)					
Date	Task Code #	Start Time	End Time	Comments/Notes	

### Results

This multi-center study focused on determining the mean pharmacist onboarding time per patient, mean pharmacist time per task category, and the number of days the pharmacist spends onboarding the patient. To meet the objectives of this investigation, pharmacists tracked their time providing professional services for 30 home infusion patients representing five self-selected provider locations. Patient therapy category and administration type was the following: anti-infective using an ambulatory infusion pump (n=4); anti-infective using an IV push administration (n=18), inotropic using an ambulatory infusion pump (n=1); and parenteral nutrition using an ambulatory infusion pump (n=7). The mean patient age was 59.53 (SD=13.81), with a range of 27 to 77 years of age.

TABLE 1.  
Mean Onboarding Task Time by Task Category

Pharmacist Onboarding Task Category	Mean	N	Std. Deviation
1. Performing patient assessment and documentation	0:43:15.00	44	0:36:08.55
2. Developing, implementing, and documenting care plan	0:21:08.57	21	0:18:38.20
3. Clinical monitoring and intervention activities	0:07:08.57	7	0:03:58.56
4. Drug preparation and compounding activities	0:29:04.41	68	0:34:38.57
5. Care coordination and telephonic communications	0:23:19.09	22	0:20:44.51
6. Other patient-related work tasks	0:20:00.00	1	
<b>Total</b>	0:30:06.26	163	0:32:05.40

A total of 163 pharmacist onboarding tasks were completed for the 30 home infusion patients. Drug preparation and compounding tasks comprised 41.72% of all onboarding tasks, while 26.99% of the tasks involved performing patient assessments and documentation, as shown in Figure 3. The mean number of onboarding tasks per patient was 5.40 (SD=1.90), with a range of 3 to 9 pharmacist tasks per patient. The number of days required for the pharmacist to complete onboarding tasks ranged from 1 to 6 days, with 89.57% of the patients being onboarded in 1 day while 5.52% were onboarded in 2 days.

The mean time for each of the 163 pharmacist tasks performed for the home infusion patient was 30.06 (minutes/seconds). The task category that took the most time was “Performing patient assessments and documentation,” followed by “Drug preparation and compounding activities,” as observed in Table 1. The mean total pharmacist time to onboard a home infusion patient was 2:43.34 (SD=50.46), with a range of 1:24.00 to 4:20.00.

Study Limitations

As with any research, this study is not without its limitations. The most common limitation of this self-report time study is the potential for the pharmacist to be more productive since their tasks and time were tracked. This phenomenon is noted as the Hawthorne effect and is common in self-report research.<sup>7</sup> Even so, self-report is commonly used to collect time utilization data. Provider locations were self-selected rather than from a random sample, thus affecting the generalizability of the data. The study results were limited to the following types of infusion patients,

which are most often referred after a hospitalization (referring entity information was not collected): anti-infectives using an ambulatory infusion pump, anti-infective utilizing IV push administration, inotropic using an ambulatory infusion pump, and parenteral nutrition using an ambulatory infusion pump. The sample size for each therapy type was insufficient to determine how the therapy type may influence the onboarding time. Chronic (i.e., specialty) therapies were not included in this study, thus it is unknown if patients referred for non-acute therapies would have similar onboarding times.

Discussion

From the results of this study, it was revealed that the mean number of pharmacist tasks needed to onboard a home infusion patient is 5.40 (SD=1.90) with each task averaging slightly more than a half hour with the mean total time being 2:43.34 (SD= 0:50.46). Performing patient assessment and documentation is the most time-consuming task category, followed by drug preparation and compounding activities. Data has supported that pharmacist professional services are far more multifaceted than drug preparation and compounding alone. Home infusion providers make significant up-front financial investments in onboarding new patients.

Home Infusion Provider Response Time

Despite the extensive work required to onboard a home infusion patient, most were onboarded in 1 to 2 days which is typical for the therapies and administration methods represented in this study. This data is consistent across the different providers and reflects expectations of referral sources that infusion providers can execute a rapid response once home infusion is

prescribed. Being responsive to new referrals requires significant infrastructure and availability of staff to perform the onboarding functions. Infusion providers can use the data from this study to quantify and evaluate their ability to recover the up-front costs associated with bringing a new patient to service.

### Impact on Patient Outcomes

The time invested up-front by the pharmacist and other personnel is instrumental in achieving the goals of therapy, avoiding adverse events, and ensuring an exceptional overall patient experience. Previous studies have demonstrated the importance of a thorough pharmacist assessment for home infusion patients. In one study of 94 patients with orders for home infusion of vancomycin, 50% of patients required a dose reduction after evaluation by a pharmacist.<sup>8</sup> Time spent by pharmacists designing an individualized care plan contributes to the overall positive experience patients report in home infusion satisfaction surveys. Results from the 2019 and 2020 NHIF Patient Satisfaction Survey Benchmarking Program showed that 97.53% of the patients in 2019 (n=6,353) and 97.85% in 2020 (n=7,381) “Agreed” or “Strongly Agreed” to the statement, “Overall, I was satisfied with the overall quality of the services provided.”<sup>9</sup> Just as important, Home Infusion Status at Discharge Benchmarking Results conclude that 91.23% of the anti-infective patients (n=4,412), which represent nearly half of all home infusion patients<sup>10</sup>, were discharged after completing the therapy as prescribed by their physician.<sup>11</sup>

### Pharmacist Time - A Partial Picture of the Onboarding Process

The investigators speculate that the study data may provide a conservative estimate of the pharmacist onboarding time since onboarding stopped with the first dispensing of medications, and data was not collected to document when the first actual dose of medication was received in the home. In most cases, this would be the same day as the initial dispense or the next day. Additional work by the pharmacist may be performed beyond the initial dispensing and when the home nurse finally admits the patient.

In reviewing the data, it is difficult to overlook the fact that the mean pharmacist times had a large standard deviation. It is somewhat expected given the complex and individual nature of the home infusion patient and the variety and difficulty of the pharmacist tasks performed. Even so, it is known that as the sample size increases, the standard deviation of the means decreases. A study with a larger home infusion patient sample is needed to ensure that the data is generalizable and to determine whether a significant difference exists between therapy type and the time required to onboard the patient. Furthermore, it needs to be investigated if patient age, gender, and past medical history make a significant difference in the onboarding time and number of tasks needed to complete the process. While other individuals, such as nurses, pharmacy technicians, reimbursement staff, administrative support, and warehouse personnel, are typically involved in the onboarding process, this study provides the first assessment of the pharmacist’s time spent onboarding the home infusion patient.

### Conclusions

Patient onboarding typically occurs over 1 to 2 days, with the most time-consuming pharmacist task being patient assessments and documentation. Of the total pharmacist onboarding tasks (n=163), 58.28% are considered patient care tasks (Task Category 1-3, 5, and 6), while the remaining task category, drug preparation, and compounding, involved 41.72% of the tasks. Having data that describes the type of tasks the home infusion pharmacist provides during the onboarding process and the time commitment for each illustrates the significant contributions of home infusion pharmacists to the home infusion onboarding process and ultimate outcomes for the patient. Furthermore, knowing that the mean time to onboard a home infusion patient is almost 3 hours, this data provides insight into the home infusion pharmacist’s workload and will assist in evaluating the up-front costs associated with onboarding patients.

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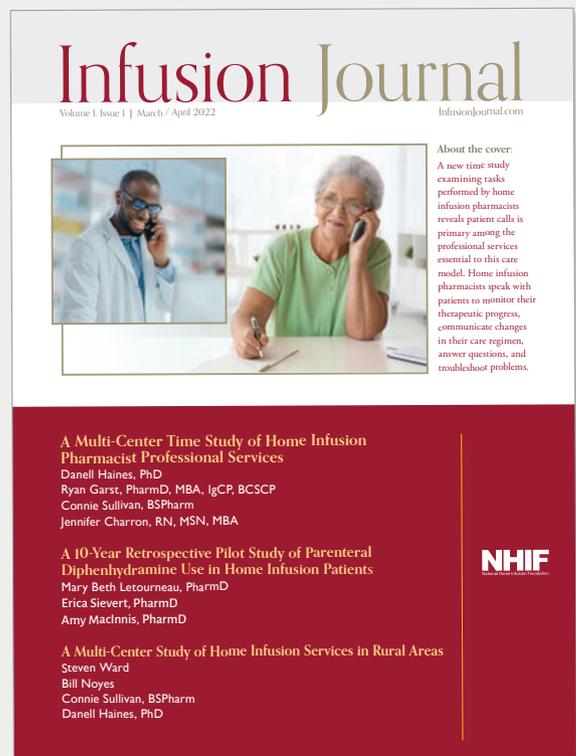
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