NHIF Research Supplement

Rate of Discontinuation from Home Infusion Therapy Due to
Adverse Drug Reactions and Unplanned Hospitalizations –
A Pilot Study

Danell J. Haines, PhD and Michelle Simpson, PharmD, BCSCP

Is My Patient Non-Compliant or Do They Have Low Literacy Skills?
A Case Report

Christina Ritchey, MS, RD, LD, CNSC

A Retrospective Cohort to Demonstrate the Impact of COVID-19
on Compliance Rates Among a Home Infusion Provider's Population
of Multidrug Resistant HIV-1 Infected Patients

Deborah Buonomo, PharmD

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By Danell J. Haines, PhD and Michelle Simpson, PharmD, BCSCP

ABSTRACT

Background: Existing for more than 4 decades, the home and specialty infusion industry is well established. In 2019 alone more than 3.2 million patients were served.[1] Due to COVID-19, more patients and physicians have gravitated to the home setting for drug administration. Even though the number of home infusion patients has increased by 310% from 2010 to 2019[1], safety is still a concern for some physicians and patients. To provide data on the safety of home infusion, this study focused on the rate of home infusion adverse drug reactions (ADRs) and unplanned hospitalizations, 2 parameters that are strong gauges of health care safety.

Purpose: The purpose of this study was to determine the rate of discontinuation from home and specialty infusion due to ADRs and unplanned hospitalizations using "Status at Discharge" data collected by the National Home Infusion Foundation (NHIF). Additionally, the association between ADRs and hospitalizations with therapy types and age categories was observed through cross tabulation analysis of the study variables.

Methods: The first step in this study was to determine the home infusion service discharge variables and their definitions. After a review of the literature and discussion, a research team determined 9 "Status at Discharge" variables that were included in the study. ADRs and unplanned hospitalizations were 2 of the 9 variables. Home infusion providers were invited to participate, of which 17 enrolled and submitted their results using the *Data Entry Guide and Data Entry Form*. The data was analyzed using IBM SPSS. Frequency and percentages were determined for demographic data while cross tabulation analysis was used to gain an in-depth understanding of the "Status at Discharge" data.

Results: This study included data from 5,395 patients who were discharged from a home infusion service July 2020 through March 2021. The patient's mean age was 59.01 (SD=20.00). Most (69.99%) of the discharged patients received anti-infective therapy. Of the study patients, only 20 (0.37%) had an ADR that resulted in discontinuing the home infusion service. Unplanned hospitalizations accounted for 3.67% (n=198) of the patients' reason for discontinuation. The youngest age group (0-16) had the highest rate of unplanned

Background

Existing for more than 4 decades, the home and specialty infusion industry is well established. In 2019 alone, over 3.2 million patients were served.[1] Since its inception, the industry has adapted to a health care landscape that is becoming more focused on value, safety, convenience, and cost-effectiveness. Due to COVID-19, patients and physicians have gravitated to alternative sites of care for drug infusions — specifically, sites with a reduced human-to-human disease transmission rate, such as the home. Even though the number of home infusion patients has increased by 310% from 2010 to 2019[1], the safety of home infusion is still a concern for some physicians and patients.

hospitalizations along with no reported ADRs. Even so, the rate of unplanned hospitalizations seems to be consistent among the age groups with an average rate of 3.65%. The age group with the highest rate of ADRs is the 17-29 while the 65+ population had the lowest rate.

Discussion: Home infusion ADRs and unplanned hospitalizations as a reason for discontinuation showed low rates, 0.37% and 3.68% respectively. These rates are consistent with previous studies that indicate home is a clinically safe alternative site of care for patients requiring infused medications. One limitation of the study is that it did not measure ADRs and hospitalizations that did not result in discharge from service.

Conclusion: Since ADRs and unplanned hospitalizations constitute a significant health care issue, this study aimed to determine the rate of ADRs and unplanned hospitalizations in the home infusion setting. No other research of this type has been conducted or reported. This study provides evidence that the home infusion setting is a safe setting for the patient and should be highly considered by physicians and patients.

The most comprehensive study on the safety of home infusion was conducted in 2017 and involved a systematic review of 13 articles on the safety, effectiveness, and cost savings of home infusion.[2] The authors found that home infusion services can provide safe, clinically effective care; improve quality of life; and reduce overall health care costs. The literature review concluded that patients receiving home infusions were no more likely to experience adverse drug events or side effects (all p >.05) and had as good or better clinical outcomes.[2] To build on these conclusions and to provide additional research on the safety of home infusion, this study focused on the rate of home infusion adverse drug reactions (ADRs) and unplanned hospitalizations, 2 parameters that are strong gauges of health care safety.

An ADR is an undesirable response, other than a known side effect, to the administration of an infused drug that compromises efficacy, and/or enhances toxicity.[3] Known side effects include commonly reported mild and moderate reactions listed in the FDA (Food and Drug Administration) approved drug labeling or reported in published clinical studies. ADRs can be classified by their severity using the terms serious, severe, moderate, or mild and are defined as follows:[3]

- **Serious:** Any adverse event resulting in any of the following outcomes: Death, a life-threatening condition, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

- **Severe:** An experience that requires therapeutic intervention. If hospitalization is required for treatment, it becomes a serious adverse event.

- **Moderate:** An experience that is alleviated with simple therapeutic treatments.

- **Mild:** An experience that is usually transient and requires no special treatment or intervention.[3]

The literature on ADRs is specific to the hospital setting and reports 2 slightly different rates. One article reported a rate of 5% to 10% for patients during hospital admission or at discharge[4] while the other reported that 10% to 20% of all hospitalized patients during their hospital admission had an ADR.[5] This article further states that between 3% and 6% of ADRs are fatal or have serious consequences. The prevalence of ADRs in all health care settings needs to be determined because of the association with morbidity and mortality. Furthermore, determining the association between ADRs and therapy type and age group can be used to develop specialized educational programs for the patient, caregiver, and home infusion staff.

Along with determining the rate of ADRs, the rate of unplanned hospitalizations was also proposed in this study. The overarching goals of home care are to treat patients safely in the home setting while preventing hospitalizations. Home infusion therapy is generally associated with good outcomes. As with ADRs, the prevalence of unplanned hospitalizations is another gauge to determine the safety of home infusion.

The purpose of this study was to determine the rate of home and specialty infusion ADRs and unplanned hospitalizations using "Status at Discharge" data collected by the National Home Infusion Foundation (NHIF). Additionally, the association between ADRs and hospitalizations with therapy types and age categories was observed through cross tabulation of the study variables and data.

Methodology

The first step in collecting "Status at Discharge" data was to determine the home infusion discharge variables and their definitions. A research team comprised of professionals with experience in home infusion nursing, pharmacy, and administration was established. After much discussion and a review of the literature, the research team determined that the following "Status at Discharge" variables would be used when collecting the data. Definitions for each variable were written and included in the Data Entry Guide, which was given to each provider location that participated in the study.

Therapy completed	Applies when a physician discontinues the home infusion therapy because the patient has achieved sufficient clinical improvement and/or met the goals in the plan of care.
Patient expired	Patient expired
Unplanned hospitalization	When a patient requires an unplanned inpatient admission to an acute care facility for any reason. Maybe further classified as "related or un-related" to the home infusion therapy.
Change in home infusion eligibility	Includes, but is not limited to unsafe home environment, no available caregiver, affordability, patient choice, unable to comply with treatment.
Insufficient response/ complication	Applies when the patient stops treatment due to an exacerbation of disease or non-response to therapy.
Adverse drug reaction (ADR)	An undesirable response, other than a known side-effect, that compromises efficacy, and/or causes toxicity.
Access device related	When one of the following access device events (migration, dislodgement, occlusion, phlebitis, skin integrity impairment, infection, damage, breakage, or thrombosis) results in the discontinuation of therapy.
Change infusion provider	Refers to situations where the current provider is unable to meet the patient's needs.
Other	All reasons that cannot be otherwise classified.

Home infusion provider locations were invited to participate. Those who accepted the invitation were given an Excel® data collection form that included the study variables, provider's data participation code, patient age, and therapy type. The data collection forms were submitted to NHIF quarterly.

The data was analyzed using IBM SPSS, a statistical analysis software platform. To better describe patient age, it was recoded into 5 categories: 0-16, 17-29, 30-49, 50-64, and 65+. This also allowed the data to be cross tabulated with ADRs and unplanned hospitalizations. Frequency and percentages were determined for the age groups and therapy types.

Results

Seventeen provider locations submitted their "Status at Discharge" data using the selected study variables, *Data Entry Guide*, and *Data Collection Form*. When signing the benchmarking program agreement, the provider also agreed to let NHIF use the data for research purposes. To maintain provider anonymity, each was given a data participation code, which was submitted with each quarterly data submission.

After the de-identified data was submitted to NHIF by home infusion provider locations, it was checked for errors and to confirm that "Reason for Discharge" data was included with each case. Cases that did not document "Reason for Discharge" were deleted. If a case was missing demographic information, it was still included in the final data set which comprised patients who were discharged from a home infusion service July 2020 through March 2021. The final data set included 5,395 cases.

Patient Age

The mean patient age was 59.01 (SD=20.00) with a range of a few months to 103 years of age. When patient age is grouped into 5 categories, as shown in Table 1 and Image 1, the largest percentage of patients are in the 65+ age group (44.09%) followed by the 50-64 (30.21%) group. According to this data, younger age groups contained a lower percentage of patients. Overall, home infusion patients tend to comprise an older population with 74.30% of the patients 50 years of age or older.

IMAGE 1
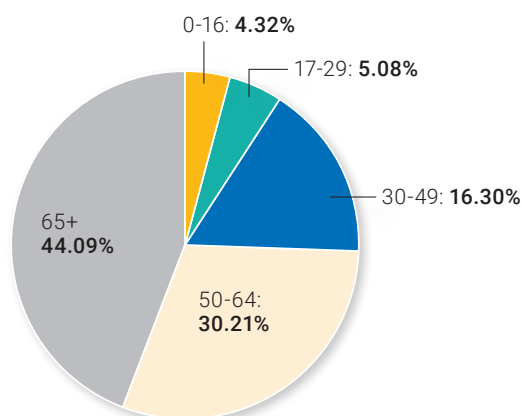### Patient Age Category (n=5,393)

- 0-16: **4.32%**
- 17-29: **5.08%**
- 30-49: **16.30%**
- 50-64: **30.21%**
- 65+ **44.09%**

TABLE 1
Patient Age Category (n=5,393)

Age Category	Frequency	Percent
0-16	233	4.32
17-29	274	5.08
30-49	879	16.30
50-64	1,629	30.21
65+	2,378	44.09
Total	**5,393**	**100.00**

Patient Therapy Type

As expected, most (69.99%) of the patients in this study received an anti-infective therapy followed by enteral nutrition (7.68%) and biologic therapy (5.35%) (Table 2). Each of the remaining therapy types comprised less than 5% of the overall total. It is not surprising the anti-infectives would comprise the largest group as they have a shorter length of stay (a few weeks) compared to other therapies where patients remain on service for months or years. The most common access device was a PICC line (60.91%) followed by a peripheral (PIV) (13.26%).

TABLE 2
Patient Therapy Type (n=5,381)

Therapy Type	Frequency	Percent
Anti-infectives	3,766	69.99
Enteral nutrition	413	7.68
Biologics	288	5.35
Hydration	227	4.22
Parenteral nutrition	190	3.53
Other	144	2.68
Pain Mgt.	132	2.45
Anti-neoplastic chemotherapy	116	2.16
Inotropic	66	1.23
Immune globulin IV & SC	39	0.72
Total	**5,381**	**100.00**

Overall Status at Discharge

The focus of this study was on the rate of ADRs and unplanned hospitalizations. The data that was collected for this study is only for patients who were discharged from their home infusion service, hence the patient's "Status at Discharge." As shown in Table 3, the low ADR as a reason for discharge rate of 0.37% speaks highly of the safety of the home infusion industry where a team of nurses and pharmacists work in unison to ensure the safety of the patient. Out of 5,395 patients who received home infusion, only 20 had an ADR that resulted in discharge. Unplanned hospitalizations accounted for 3.67% (n=198) of the patients' reason for discharge.

TABLE 3.
Status at Discharge (n=5,395)

Status at Discharge	Frequency	Percent
Therapy completed	4,363	80.87
Patient expired	257	4.76
Unplanned hospitalization	198	3.67
Other	184	3.41
Change infusion provider	176	3.26
Change in eligibility	139	2.58
Insufficient response/ complication	29	0.54
Access device related	29	0.54
Adverse Drug Reaction	20	0.37
Total	5,395	100.00

Data on the severity of ADRs was also collected, as shown in Table 4. Of interest is that some mild and moderate ADRs resulted in discontinuation of home infusion.

TABLE 4.
Severity of ADR (n=20)

ADR Severity	Frequency	Percent of ADRs
Mild	6	30.00
Moderate	4	20.00
Severe	5	25.00
Serious	4	20.00
Severity not reported	1	5.00
Total	20	100

Status at Discharge by Therapy Type

To gain further insight to the reasons for discharge from a home infusion service, therapy type was cross tabulated by the "Status at Discharge" data. Only 3 of the 10 therapy types had a reported ADR. Biologics and "other" category had an ADR rate of 0.69 while anti-infectives had a rate of 0.45. This rate equates to the following number of patients: biologics = 2, other = 1, and anti-infectives = 17. No patients receiving parenteral nutrition, inotrope, or anti-neoplastic chemotherapy had an ADR reported as a reason for discharge.

Inotropic patients are known to have multiple comorbid conditions making them more fragile than other home infusion patients. It was somewhat expected that these patients would have the highest rate of unplanned hospitalizations at 15.15% when compared to the other therapy types. It is interesting to note that biologics had the lowest rate of unplanned hospitalizations at 0.35% while pain management therapy has the highest rate of patients who expire due to end-of-life conditions.

TABLE 5
Percent of Patients Discharged from Home Infusion Service Due to Unplanned hospitalization or ADR (n=5,381)

Therapy Type	Unplanned hospitalization	ADR
Anti-infectives (n=3,766)	3.85	0.45
Parenteral nutrition (n=190)	8.42	0
Enteral nutrition (n=413)	0.97	0
Hydration (n=227)	3.96	0
Pain Mgt.(n=132)	1.52	0
Inotropic (n=66)	15.15	0
Anti-neoplastic chemotherapy (n=116)	4.31	0
Immune globulin IV & SC (n=39)	5.13	0
Biologics (n=288)	0.35	0.69
Other (144)	2.78	0.69
Total (5,381)	3.68	0.37

Status at Discharge by Age Group

To investigate the "Status at Discharge" data by age category, the data was cross tabulated as shown in Table 6. Worth noting is that the youngest age group (0-16) has the highest rate of unplanned hospitalizations along with the no reported ADRs. Even so, the rate of unplanned

TABLE 6
Unplanned Hospitalizations and ADRs by Age Category

	0-16 (n=233)	17-29 (n=274)	30-49 (n=879)	50-64 (1,629)	65+ (2,378)	Total (n=5,393)
Unplanned hospitalization	4.29	4.01	3.19	3.19	4.04	3.65
Adverse Drug Reaction	0	0.73	0.46	0.43	0.29	0.37

hospitalizations seems to be consistent among the age groups with an average rate of 3.65%. The age group with the highest rate of ADRs is the 17-29 while the 65+ population has the lowest rate.

Discussion

This study included "Status at Discharge" data from 17 home infusion provider locations and contributes evidence on the safety of home infusion. Additionally, patient age and therapy type data assisted in describing the home infusion patient. Almost 70% of the patients received anti-infectives followed by enteral nutrition and biologics. ADRs and unplanned hospitalizations as a reason for discharge had low rates, 0.37% and 3.68% respectively. These rates are consistent with previous studies that indicate home is a clinically safe alternative site of care for patients requiring infused medications. Also noteworthy is the percentage (80.87%) of patients who completed their therapy as a reason for discharge and the few (0.54%) access device-related reasons for patient discharge.

The main strength of this pilot study was that it measured the ADR and unplanned hospitalization rate for the home infusion industry, thus providing evidence on the safety of home infusion. Moreover, this study provides support for a larger study of its type. More provider locations will be recruited for a future study and data will be collected over a longer timeframe. This will ensure that the data is more generalizable across the industry and more valid for the therapy types with a small sample size due to longer length of stay within the home infusion service. With additional provider location participation, a more detailed analysis can be conducted, shared, and applied to the industry.

Conclusions

Since ADRs and unplanned hospitalizations constitute a significant health care issue, this study aimed to determine the rate of ADRs and unplanned hospitalizations in the home infusion setting. No other research of this type has been conducted or reported.

The findings of this pilot study reveal a very low rate of ADRs (0.37%) and unplanned hospitalizations (3.68%) as a reason for discharge from a home infusion service. These rates should make physicians and patients more confident in using the home setting for infusion therapy.

It is common knowledge that COVID-19 has impacted health care. It is surmised that substantial growth in the home site of care will be one of the outcomes of the pandemic. As health care trends toward services that emphasize value, convenience, and flexibility for the physician and patient—and reduced risk of infection-- the use of home infusion is likely to continue to expand. Having data that supports the safety of this care model was needed for physicians and patients considering home infusion. The low ADRs and unplanned hospitalizations observed in home infusion patients as a reason for discharge from service should provide the impetus needed to select the home over the hospital or clinic setting for infusion services.

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Is My Patient Non-Compliant or Do They Have Low Literacy Skills?
A Case Report

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OUTSTANDING ABSTRACT
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ABSTRACT

Introduction: Literacy is the ability to understand, evaluate, use, and engage with written texts to participate in society, to achieve one's goals, and to develop one's knowledge. Home parenteral nutrition (HPN) patients with low literacy may be considered non-compliant if they are unable to follow their prescription, have negative outcomes, or are readmitted to the hospital often. Studies show patients with low literacy have poorer health, higher hospitalization rates, and increased health care costs. The purpose of this study is to examine the effect of low literacy on compliance for a home infusion patient.

Case Description: A 62-year-old male with a high output enterocutaneous fistula (ECF) was readmitted for acute kidney injury (AKI) related to dehydration, then referred to a national home infusion provider for HPN. The patient had been with another provider and nursing agency, but neither wanted to resume care due to reported non-compliance. The new HPN team reviewed the case and accepted the patient. He was discharged home with HPN, intravenous (IV) antibiotics, and IV hydration. After a short time, the nursing agency reported the patient missed several antibiotic doses and HPN. During the nutrition assessment, the patient revealed to the dietitian he could barely read, and therefore, mixed up his medications.

Results: The nursing agency provided hands-on patient education and daily visits. The patient became independent, confident, and successfully administered all prescribed therapies at home without further readmissions.

Discussion: HPN is a complex therapy requiring significant patient education, reinforcement, and support for success. When additional IV medications are prescribed, complexity increases, especially with low literacy.

Conclusion: The home infusion team can be integral in identifying literacy barriers. The Single Item Literacy Screener (SILS) is a validated tool that may be useful in home care where the patient assumes responsibilities for self administration. It includes a single verbal question and identifies patients needing assistance reading health-related materials. Additional research should be conducted on the home infusion population utilizing the SILS to gain information on literacy.

Introduction

Roughly, 1 in 5 U.S. adults (21%) have low literacy skills.[1] According to the National Center for Education, literacy is the ability to understand, evaluate, use and engage with written texts to participate in society, to achieve one's goals, and to develop one's knowledge.[1] Low literacy also correlates with an individual's health literacy.[2,3] Health literacy is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.[4,5] Health literacy has been shown to be significantly worse than a patient's literacy skills due to the complexity of health-related information.[6] As health professionals, we play an integral role in identifying patients who may have low literacy skills which impacts one's ability to play an active role in their health care.

Low literacy is not unique to one specific demographic, therefore identifying a patient with low literacy skills can be a challenge. Research shows low literacy is more common in patients with lower socioeconomic status, lower education levels, elderly, immigrants, the disabled, and minorities. However, many patients with low literacy skills have adapted and know how to compensate to function in society.[1,5,7,8]

Most patients with literacy challenges do not share this information with others, including family and friends. Marcus reported "more than two-thirds of patients with low literacy in public hospitals said they had never told their spouses about it. Nearly one-fifth said they had "never told anyone."[9] Patients often feel ashamed or embarrassed to admit they are unable to read. It is common for health professionals to treat patients with low literacy and never know the struggle their patient

It is common for health professionals to treat patients with low literacy and never know the struggle their patient is going through.

is going through. Individuals with low literacy may react to complex learning situations by withdrawing or avoiding because it is intimidating and difficult to process. When providing patient education or discussing their health care, patients with low literacy will usually say they understand the material even if they did not.[5,10]
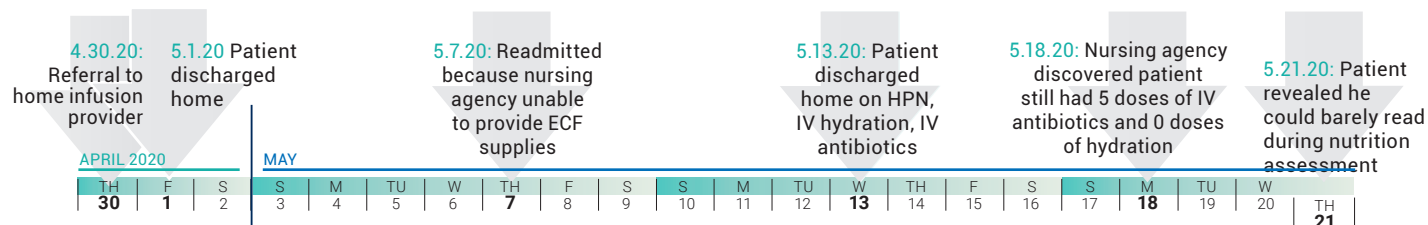
Patients with low literacy skills had poorer health, higher hospitalization rates and higher health care costs.[5,7] The *American Journal of Public Health* reports that, "the inability to read and understand health information accounts for $232 billion spent in health care costs each year."[11] DeWalt and colleagues conducted a systematic review of multiple observational studies investigating the relationship between literacy and health outcomes. They found 16 studies that measured this relationship and found a positive significant association between reading ability and health outcomes.[12] Individuals with lower literacy were 1.5 to 3 times more likely to have an adverse outcome compared to those with higher literacy. Two studies by Baker and colleagues showed the likelihood of being hospitalized was significantly higher for patients with lower literacy than for those with higher literacy; specifically, 1.69 times higher at a public hospital and 1.29 times higher for Medicare enrollees.[5,12]

In addition, patients with low literacy are less likely to understand information about their chronic medical conditions, less likely to understand discharge instructions following an emergency department visit and are more likely to experience medication errors because they are unable to read the prescription labels. According to Baker, 54% of patients with low literacy were unable to answer a specific question about when they should take their medication because they could not read the label. Further, these patients may stop taking a medication or decrease their dose if they do not understand the importance of compliance.[13] These

EXHIBIT 1
Case Description Timeline

4.30.20: Referral to home infusion provider

5.1.20 Patient discharged home

5.7.20: Readmitted because nursing agency unable to provide ECF supplies

5.13.20: Patient discharged home on HPN, IV hydration, IV antibiotics

5.18.20: Nursing agency discovered patient still had 5 doses of IV antibiotics and 0 doses of hydration

5.21.20: Patient revealed he could barely read during nutrition assessment

APRIL 2020 | MAY

| TH 30 | F 1 | S 2 | S 3 | M 4 | TU 5 | W 6 | TH 7 | F 8 | S 9 | S 10 | M 11 | TU 12 | W 13 | TH 14 | F 15 | S 16 | S 17 | M 18 | TU 19 | W 20 | TH 21 |

patients are a high risk for medication errors whether it is missed doses or mixing up their medications.[5] According to the Institute of Medicine (IOM) and The Joint Commission (TJC), miscommunication between health professionals and patients significantly contributes to medication errors, and was the cause of 3,000 sentinel events reported to TJC.[5,14] Another study by Davis et al examined patients' ability to read and understand 5 different label instructions on prescription bottles. Patients with low literacy were less able to understand all 5 labels. Only 34.7% could indicate the number of pills to be taken daily. The results also showed a significant correlation between a greater number of prescription medications and patient misunderstanding of instructions.[15]

Home infusion, specifically home parenteral nutrition (HPN), requires patients to process a significant amount of health-related information, learn how to self-administer, and manage a complex therapy. HPN patients with low literacy skills may be labeled as non-compliant if they are unable to follow their prescription, have negative outcomes, or are readmitted back to the hospital. The purpose of this case report is to examine the effect of low literacy on compliance for a home infusion patient.

Case Description

A 62-year-old male with a high-output enterocutaneous fistula (ECF) was readmitted to the hospital for acute kidney injury (AKI) related to dehydration and high output ECF. On April 30, 2020 a national home infusion provider received a referral from the hospital to provide HPN for this patient. He had a complex medical history which included diabetes mellitus type 2, hypertension, small bowel obstruction, and ventral hernia repair. His high-output ECF was a post-operative complication of his ventral hernia repair (see Exhibit 1 for timeline). The patient had been with another home infusion

provider and nursing agency receiving HPN, but neither wanted to resume care due to reported non-compliance. The patient had recently been in the hospital 4 times prior to the current admission. The new home infusion team met to review the case, which included the general manager, intake coordinator, nutrition support dietitian, pharmacist, nurse, clinical liaison, and acute care specialist (sales representative). The team agreed to accept the patient on service if he expressed willingness to participate in his care and had a safe home environment. He lived alone and did not have a caregiver to assist with his home infusions, but he was assessed as competent to self infuse and manage his therapy. The hospital discharge planner was notified of the decision and arranged a new nursing agency for the patient.

On May 1, 2020, the home infusion nurse met with the patient in the hospital to complete a nursing assessment, review expectations, and provide education regarding administration of HPN. He verbalized understanding, performed return demonstration, and was discharged home. On May 7, 2020, the patient was readmitted back to the hospital because the nursing agency was unable to provide supplies to manage his ECF. While the patient was in the hospital, he was diagnosed with an infection at his ECF site. He was started on intravenous (IV) antibiotics. In preparation for discharge, the provider received updated HPN orders and new orders for IV antibiotics and hydration (Exhibit 2). The home infusion provider set the patient up with a new nursing agency who was experienced in complex cases and IV therapy. On May 13, 2020, the home infusion nurse met with the patient

HPN patients with low literacy skills may be labeled as non-compliant if they are unable to follow their prescription, have negative outcomes, or are readmitted back to the hospital.

EXHIBIT 2
Home Infusion Orders for May 13 Discharge

Admitting Diagnosis	Past Medical History	Home Infusion Medications
• AKI • Dehydration • High output ECF	• DM2 • HTN • SBO • Ventral hernia repair	• 3 in 1 Parenteral Nutrition • Vancomycin 1750mg IV q 24 hours • NS 500ml 3x/week

in the hospital again to complete a nursing assessment, provide education regarding administration of the two new IV therapies, the antibiotic, and hydration. The home infusion nurse also reinforced education regarding HPN administration. The patient verbalized understanding, performed return demonstration, and was discharged home.

On May 18, 2020, the nursing agency reported the patient had mixed up the IV antibiotics with the IV hydration. He missed several doses of IV antibiotics and instead infused multiple doses of IV hydration daily. Although the patient infused more hydration bags than ordered, there were no adverse effects identified. In addition, the nurse was not sure if the patient was administering his HPN correctly because he had extra doses on hand. The home infusion provider notified the infectious disease (ID) physician that the patient missed several doses of IV antibiotics. The ID physician stated he was aware of the patient's non-compliance but would like him to finish out his IV antibiotics. The home infusion provider sent more hydration to the patient and the nursing agency provided additional hands-on education.

On May 21, 2020, the nutrition support dietitian called the patient for his routine nutrition assessment and was aware of the situation earlier in the week. During the nutrition assessment, the dietitian asked the patient to count how many doses of each medication he had at the time to determine if he had been able to infuse all 3 medications properly since May 18th. The patient then revealed to the dietitian that he could barely read. He explained he accidentally infused multiple doses of hydration, missed the antibiotics, and had difficulty hooking up the PN because he was unable to read the labels on the medications.

Results

The dietitian let the patient know a new plan would be developed to help him with his complex regimen. The dietitian immediately informed the home infusion team of the patient's literacy challenges. The team discussed alternative methods to ensure the patient could decipher between his medications such as color coding each medication and changing the method of administration as applicable. The nursing agency was also notified of the patient's low literacy skills. It agreed to provide additional hands-on patient education and daily visits to ensure the patient was infusing as prescribed. The dietitian reinforced education and reviewed HPN administration during weekly calls. The patient became independent, confident in his abilities, and successfully administered all prescribed therapies at home without further readmissions to the hospital. Ultimately this patient's outcome was successful; his ECF output decreased and healed enough to where he was able to have surgery to repair it and was discharged from home infusion therapy as "therapy complete."

Discussion

HPN is a complex therapy requiring significant patient education, reinforcement, and support for success. When additional IV medications are prescribed, the complexity greatly increases along with the likelihood that patients will have difficulty. This is especially true in patients with low literacy skills. Understanding the needs of this patient and adapting to his literacy level allowed the home infusion provider to support the best outcome possible. This positive outcome also decreased health care costs for him and the health care system.

The home infusion team can be integral in identifying literacy barriers. Patients should be screened and identified at the beginning of care to determine their literacy level. There are various types of instruments used to measure reading ability in health care. The most common validated tools are the Rapid Estimate of Adult Literacy in Medicine (REALM), Test of Functional Health Literacy in Adults (TOFHLA) or short version (S-TOFHLA). The REALM only takes 2-3 minutes to complete. It uses word recognition and pronunciation but does not test reading comprehension or functional literacy. REALM was intended for primary care or public health settings and measures literacy levels of patients

EXHIBIT 3
Single Item Literacy Screener (SILS)

Question	Response Range	Scoring Criteria
How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacist?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	Scores greater than "2" are considered positive, indicating some difficulty with reading printed health related material.

who read below the 9th grade level. The TOFHLA or S-TOFHLA measures functional health literacy using health-related materials. TOFHLA takes approximately 20-25 minutes and S-TOFHLA takes 5-10 minutes to complete. They are available in Spanish and English.[12,13]

Another validated tool to measure reading ability is The Single Item Literacy Screener (SILS) (Exhibit 3).[4] The SILS was developed from the S-TOFHLA into a single verbal question to identify patients needing assistance reading health-related materials. The SILS question is "How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?" Responses range from 1 to 5 (1-Never, 2-Rarely, 3-Sometimes, 4-Often, 5-Always). A score of 3 or higher indicates a patient has some difficulty with reading printed health-related material. To measure the validity of the SILS, Morris et al compared the diagnostic accuracy to the S-TOFHLA and analyzed the sensitivity and specificity. Their results indicated a score of 3 or higher provides a sensitivity of 54% and specificity of 83%.[16] The SILS could be useful in home care and could be utilized during the initial evaluation prior to HPN education. Nguyen et al evaluated the association between the SILS and health outcomes in patients with lung cancer. Results showed one-third of patients had limited health literacy, which was more prevalent in patients 70 years and older. Patients with limited health literacy had a higher number of emergency department visits (p = 0.0156) and unplanned hospitalizations (p = 0.0044); and were more likely to have these events sooner (p < 0.0001) (Nguyen et al).[17]

Andrus and Roth suggest routine literacy evaluation be conducted in a private setting since many low literacy patients feel shame and embarrassment.[6] In addition to the above validated tools, some clinicians carry around a prescription bottle and ask the patient to read it.[5,6] Patients may hide their literacy issues by making statements such as "I forgot my reading glasses," "I'll read through this when I get home," "I'd like to discuss this with my family first," or "May I take the instructions home?"[6] These should all be warning signs that an individual may be masking a literacy issue. Once a patient with low literacy skills is identified, it is critical that health care professionals communicate and educate effectively.

Conclusions

Patient education is a critical component of compliance and safety for those with low literacy skills. Oftentimes these patients require more time to learn and understand concepts.[6] With 43 million adults in the U.S. having low literacy skills, this is an important consideration for all health care professionals.[1] Understanding literacy levels in the home infusion population, can help determine the type of patient education, ultimately improving medication adherence, preventing unnecessary hospitalizations, and improving outcomes. There is limited data regarding literacy levels amongst home infusion patients. Additional research needs to be conducted specifically on the home infusion patient population to gain information on literacy. The SILS as a literacy screening tool should be studied in home infusion since it has been successfully used in other patient care settings. In addition, investigating the rates of rehospitalizations and compliance among home infusion patients with low literacy would also provide data to show the impact on health care outcomes and cost.

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A Retrospective Cohort to Demonstrate the Impact of COVID-19 on Compliance Rates Among a Home Infusion Provider's Population of Multi-drug Resistant HIV-1 Infected Patients

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OUTSTANDING ABSTRACT
ACHIEVEMENT AWARD
HONARARY MENTION

ABSTRACT

Background: The objective of this study was to demonstrate the impact of COVID-19 on compliance to ibalizumab-uiyk infusions, oral antiretroviral therapy (ART) regimen, and service discontinuation rate while using previously studied medication compliance strategies.[1] Experts agree, medication compliance is imperative to prevent transmission of drug-resistant HIV and further development of resistance to current treatment options.[2] A retrospective study conducted in 2019 showed 85% compliance to ibalizumab-uiyk and ART regimens in patients utilizing a compliance-focused care model.[1] However, a longitudinal study demonstrated a decrease in access to medications and increased cancellations of health care appointments during the COVID-19 pandemic.[3] Although literature is limited, results of previously published studies show a potential negative impact of COVID-19 on medication compliance among the HIV population.

Methods: This retrospective cohort analysis was conducted by evaluating a home infusion provider's electronic record of ibalizumab-uiyk-treated patients managed by a pharmacist-led, compliance-focused care model previously studied in 2019. Cohorts included patients receiving ibalizumab-uiyk during a pre-COVID-19 period (June 1, 2019 - February 28, 2020) and a post-COVID-19 period (April 1, 2020 - December 31, 2020). Outcome parameters included overall compliance rate of ibalizumab-uiyk, oral ART compliance rate, infusion site-of-care data, and service discontinuation rates.

Results: Overall ibalizumab-uiyk compliance rate between pre- and post-COVID-19 groups were 96% and 97%, respectively, showing no significant difference. Service discontinuation rates were observed at 23% (n=20) and 22% (n=19) between the pre- and post-COVID-19 groups, respectively, showing no significant difference. Oral ART regimen compliance was observed at 86% in the pre-COVID-19 group and 94% in the post-COVID-19 group showing a significant increase in the post-COVID-19 cohort. Site-of-care data showed that 85% of infusions were administered in the home setting for both groups.

Conclusion: Results show that utilization of a compliance-focused care model maintained compliance rates in ibalizumab-uiyk-treated patients during the COVID-19 public health emergency (PHE). More studies are recommended to demonstrate the impact of pharmacist-led compliance programs and how they can potentially avoid costly negative effects of non-compliance during a national pandemic.

Introduction

Over the last several decades there has been a significant increase in the use of antiretroviral therapies (ART) in the treatment of HIV. Newer ART agents have provided more effective options to reach viral suppression with a high barrier to resistance and lower side effect profile. However, drug resistance remains a concern for the HIV population. According to the World Health Organization (WHO) in 2019, an estimated 67% of people living with HIV globally receive ART treatment and 26% of people initiating treatment are infected with first-line ART drug resistant HIV.[2] In the United States, only an estimated 66% of HIV patients are virally suppressed which is concerning for the development of resistance.[4] The WHO warns that drug-resistant HIV jeopardizes the efficacy of ART treatment options and results in increased numbers of HIV infections and HIV-associated morbidity and mortality.[2]

Drug-resistant HIV can be transmitted from one infected person to another. This is considered pre-treatment HIV drug resistance. Drug resistance may develop post-treatment as well due to various causes such as poor medication compliance, inadequate absorption of ART, or initiating an ART regimen with a low barrier to resistance. Experts agree for both pre- and post-treatment HIV drug resistance, medication compliance is imperative to prevent transmission of drug-resistant HIV and further development of resistance to current treatment options. In addition, poor medication compliance is directly related to increased morbidity and mortality in HIV-infected patients.[5]

Several studies evaluated the reason for non-compliance specifically in the HIV population. One article states the most frequent reasons for non-compliance in HIV-infected patients included: the influence of dosing and formulations or "pill burden," ART-related adverse events, provider gap in up-to-date disease and treatment knowledge, poor provider-patient relationship, and lack of access to treatment.[5] In addition to identifying barriers, the article also cites results from several studies on approaches to overcome medication adherence barriers. These recommendations are supported by results of a study that showed increased adherence when a multidisciplinary approach was used.[5] In addition, continued patient education on HIV and open discussion on patient perceived barriers improved adherence. A study conducted by Hirsch et al., evaluated the impact of a pharmacist-managed medication therapy management (MTM) program on medication adherence among HIV/AIDS patients. The MTM program included counseling on adverse effects, evaluating barriers to adherence, and providing regimen recommendations to the provider. The results of the study showed consistently higher medication adherence rates in patients receiving MTM services at rates of 69.4% versus 47.3% in patients who did not receive MTM services.[6]

A retrospective study conducted in 2019 evaluated adherence rates in a home infusion provider's multidrug-resistant HIV-infected patients receiving ibalizumab-uyik infusions while implementing a pharmacist-managed clinical care model focused on compliance. Ibalizumab-uiyk is used in conjunction with oral antiretroviral therapy (ART), approved for individuals with multidrug-resistant HIV-1 who are failing their current ART therapy. The model included scheduled counseling for patients prior to each dispense to discuss medication compliance and adverse effects as well as to identify potential barriers to continued treatment. In addition, verification of oral ART compliance was confirmed with each ibalizumab-uiyk dispense. This model included providing updates and recommendations to the provider where clinically appropriate. The results of this study showed 85% adherence to ibalizumab-uiyk and oral ART regimen in patients utilizing a clinical care model focusing on compliance.[1]

During the COVID-19 pandemic period, studies showed a potential negative impact on adherence rates among the HIV population. A longitudinal study demonstrated a decrease in access to medications and increased cancellations of health care appointments during the COVID-19 pandemic.[2] One study demonstrated the negative impacts from the pandemic that resulted in lower medication adherence in an HIV population due to lack of access to medical services and medications. The results showed 22% of patients experienced at least one negative health consequence due to the impact of COVID-19.[7] Even though literature is limited, results of current published studies have concluded a negative impact on regimen adherence among HIV-infected patients during this period.

Although studies support the role of pharmacists in improving medication compliance and adherence in the HIV/AIDS population, studies are lacking to evaluate if pharmacists could maintain a significant role in positively impacting compliance during a public health emergency (PHE) such as the COVID-19 pandemic. Identifying results of

pharmacist-led compliance programs may be of benefit to support approaches to improving overall patient compliance, but also provide a solution to reduce the negative impact on compliance rates due to the reported lack of access to medical services and medications during a PHE.

Purpose

The objective of this study was to demonstrate the impact of COVID-19 on compliance to ibalizumab-uiyk infusions and oral ART regimen while using previously studied medication compliance strategies in a population diagnosed with multidrug-resistant HIV. Other objectives were to evaluate the impact of COVID-19 on service discontinuation rates and infusion site of care.

Methods

This was a retrospective cohort analysis of a national home infusion provider's ibalizumab-uiyk treated patients. Evaluated data included subjects' electronic record of ibalizumab-uiyk dispense history, oral ART compliance, service discontinuation, and infusion site of care. Cohorts were as follows: pre-COVID-19 patients receiving ibalizumab-uiyk infusions between June 1, 2019 and February 28, 2020 and post-COVID-19 patients receiving ibalizumab-uiyk between April 1, 2020 and December 31, 2020. It is difficult to specifically define the exact start date where COVID-19 restrictions impacted access to medications and medical care because restrictions and implementation dates varied by region. Because this study evaluated a national HIV population, March 2020 was excluded from both cohorts as a pre- and post-COVID transitional period to account for the variation.

Outcome parameters included overall compliance rate of ibalizumab-uiyk based on dispense history, oral ART compliance, service discontinuation rate, and infusion site of care. The electronic pharmacy dispense history of ibalizumab-uiyk for each patient treated between the study periods was evaluated based on receiving infusions at the time of the scheduled dose. Ibalizumab-uiyk infusions evaluated during the study were considered non-compliant if the maintenance dose was missed by more than 3 days based on ibalizumab-uiyk package insert dosing recommendation.[8] In the event a maintenance dose was missed by 3 or more days, a loading dose was provided before resuming maintenance dosing. Ibalizumab-uiyk compliance was calculated as total missed doses out of total infusions during the respective study period. Missed

doses were further categorized as patient non-compliant or missed due to hospitalization or insurance delay where the pharmacist documented the reason for the missed maintenance dose. Patients were considered compliant if an ibalizumab-uiyk dose was missed due to hospitalization or insurance reasons. Additional outcomes included oral ART compliance and service discontinuation rate. Pharmacists verified oral ART compliance with each patient and with each patient's community pharmacy managing the oral ART regimen, prior to each ibalizumab-uiyk dispense.

Pharmacists were directed to document oral ART compliance in clinical assessments as part of the electronic patient record. Patients were considered compliant on oral ART regimen when documented as compliant in clinical assessments. Oral ART compliance rate was calculated by the overall average of individual patient compliance rates. Service discontinuation rates were evaluated in the pre- and post-COVID-19 cohorts to determine significant difference. Patients were considered discontinued from infusion services when documented as inactive within the patient electronic record. Site of infusion was compared between the 2 cohorts to evaluate if there was a significant change during the COVID-19 PHE. Patients included in the study had an option to receive their infusion either in an alternate site infusion center or in the home if the insurance provider allowed. All patients receiving ibalizumab-uiyk during the study periods were included in this study, there were no exclusions.

Results

Study patients are shown in Exhibit 1. The pre-COVID-19 cohort included evaluation of 87 patients and 1,000 infusions and the post-COVID-19 cohort included 88
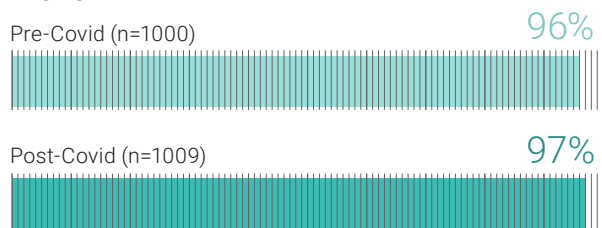
EXHIBIT 1

Inclusion Data

	Pre-COVID-19	Post-COVID-19
Total infusions (#)	1,000	1,009
Patients (#)	87	88
Gender	**Number (%)**	
Male	70 (80.5%)	69 (78.4%)
Female	17 (19.5%)	19 (21.6%)
Age	**Years (SD)**	
Median	56 (12.9)	56 (12.3)
Range	23-79	25-79

EXHIBIT 2
Ibalizumab-uiyk Infusion Compliance
P=0.287

Pre-Covid (n=1000)   96%

Post-Covid (n=1009)   97%

EXHIBIT 4
Service Discontinuation Rates
P=0.413

Pre-Covid-19 (n=20)   23%

Post-Covid-19 (n=19)   22%
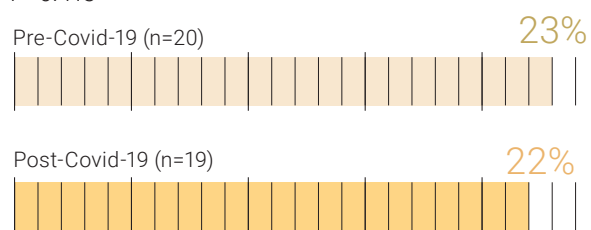
EXHIBIT 5
Oral ART Compliance
P<0.0001 (95% CI)

Pre-Covid-19 (n=87)   86%

Post-Covid-19 (n=88)   94%

patients and 1,009 infusions. There was no significant difference found between age and gender in the 2 cohorts. The median age for the pre- and post-COVID-19 group was 56 years with 80.5% male in the pre-COVID-19 group and 78.4% male in the post-COVID-19 group.

As shown in Exhibit 2, overall ibalizumab-uiyk compliance rates were observed at 96% in the pre-COVID-19 group and 97% in the post-COVID-19 group with no significant difference between cohorts (p=0.287). Further classification of missed doses showed that 38% (n=16) of missed doses in the pre-COVID-19 group and 31% (n=11) of missed doses in the post-COVID-19 group were due to patient non-compliance, resulting in no significant difference (p=0.165) [Exhibit 3].

The remaining missed doses in the 2 groups were classified as patient compliant due to unavoidable hospitalization or insurance delays. Service discontinuation rates were observed at 23% (n=20) for the pre-COVID-19 group and 22% (n=19) for the post-

EXHIBIT 3
Missed Ibalizumab-uiyk Infusions

Patient Non-Compliance

Pre-Covid-19 (n=42)   16

Post-Covid-19 (n=35)   11

Hospitalization/Insurance Reason

Pre-Covid-19 (n=42)   26

Post-Covid-19 (n=35)   24

COVID-19 group (Exhibit 4). This resulted in no significant difference in service discontinuation rates between the 2 cohorts (p=0.413). Oral ART compliance rates for the pre-COVID-19 cohort were observed at an overall average of 86% where the post-COVID-19 cohort was observed at 94%, showing a significant increase in compliance in the post-COVID-19 cohort (p<0.0001) [Exhibit 5]. There was no difference observed in the site of care where 85% of ibalizumab-uiyk infusions were administered in the home for both groups.
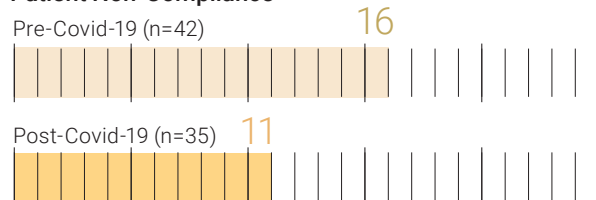
Discussion

Pharmacist-led care models that focus on compliance have the potential to make a positive impact on patient medication compliance as demonstrated in this study. As a primary contact in the patient's HIV care, the pharmacist is a trusted health care professional who can counsel the patient to navigate known barriers to adherence shown in previously mentioned studies. Clinical pharmacists bring solutions by providing a multidisciplinary approach, managing side effects, providing continued patient education, and building patient-provider relationships. These key characteristics have been previously studied and demonstrated as important in preventing missed doses of critical medication in the HIV population. However, prior to this study, there was minimal published data showing the
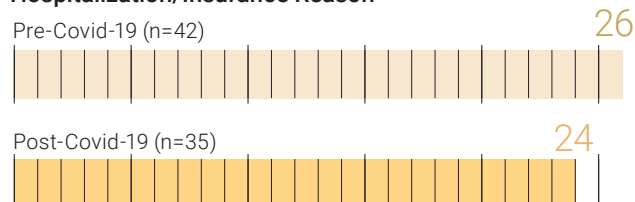
impact that pharmacist-led compliance programs have on patient medication compliance during a PHE.

This study successfully demonstrated that the previously evaluated compliance-focused care model managed by pharmacists in patients treated with ibalizumab-uiyk, sustained compliance to ibalizumab-uiyk infusions as well as increased oral ART regimen compliance during the COVID-19 pandemic. Although it cannot be directly correlated, it is hypothesized that frequent pharmacist-patient interaction and patient follow-up with each infusion to evaluate for adverse effects and barriers to treatment had a positive impact leading to the results. This is consistent with previous study findings where pharmacist-led MTM programs have resulted in an increase in compliance rates.

Limitations include variations in electronic documentation for compliance to oral ART regimen. Although pharmacists were directed to document compliance in custom assessment templates for this patient population, there may be occurrences where compliance may have been documented by an alternate method such as a chart progress note which is not retrievable via reporting methods used in this study. In this research, patients were considered non-complaint if not documented in a custom assessment.

The results of this study prompted a broader evaluation of this multidrug-resistant HIV-infected population to increase the study period and number of patients evaluated. An extension of the original study, a retrospective evaluation of a national home infusion provider's approach to medication adherence of parenteral ibalizumab-uiyk conducted in 2019, was initiated after the result of this study found the positive outcomes with pharmacist-led care models. The extension of a previous retrospective study included all patients receiving ibalizumab-uiyk therapy serviced by an infusion provider since FDA approval in 2019 through March of 2021. This extension addressed the limitation of oral compliance documentation where all methods of documentation were evaluated for compliance. In addition, missed doses and service discontinuation were further categorized for reason of non-compliance to gain insight to the contributing factors to non-compliance. Results of the extension study were consistent with findings from the original study in 2019, where compliance to ibalizumab-uiyk infusions were maintained at 98% and oral ART regimen compliance was maintained at 89%. Service discontinuation evaluation observed 90% of the study population continued ibalizumab-uiyk infusions as expected or transitioned to alternate therapy.[9]

This study along with other published results demonstrate the positive impact of pharmacist-led care models on overall compliance in a population where medication compliance has been accepted as vital to reducing drug resistance, morbidity, and mortality. However, more studies are needed to demonstrate the importance of pharmacist-driven compliance programs during a PHE and whether these models can potentially avoid the costly negative effects of non-compliance. It is yet to be determined how the results from our study will be utilized, however it does support the use of this compliance-focused care model in this national home infusion provider's patient population.

Conclusion

During a public health emergency, studies have shown that access to medical services and medication are reduced, leading to a decrease in medication compliance. Utilizing pharmacist managed care models as part of a multidisciplinary team showed a positive impact on patient medication compliance in a multidrug resistant HIV-infected population.

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1

A Home Infusion Program for Administration of Bamlanivimab in High-Risk Settings

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2

A Retrospective Cohort to Demonstrate the Impact of Coronavirus Disease (COVID-19) on Compliance Rates Among a Home Infusion

Deborah Buonomo, PharmD
Therapeutic Category Manager, Option Care Heal

3

Assessment of Home Infusion Patient Satisfaction

Ryan R. Garst, PharmD, RPh, MBA, BCSCP
Senior Director Clinical Services, National Home Infusion Association

Danell J. Haines, PhD Research Consultant
D.J. Haines Research Consulting

4

Clinical and Quality of Life Effects of Home Parenteral Nutrition Patients During COVID-19

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LaHily Henderson-Davis, RN, BSN, MBA, NE-BC
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5

Diagnosis and Management of Iron Deficiency Anemia (IDA) in Home Parenteral Nutrition Patients: A Clinical Feasibility Study to Determine Treatment and Practice Patterns of Physicians and Pharmacists

Marc Hoffman, MD
Chief Medical Officer, Rockwell Medical

6

Evaluating the Use of Continuous Infusion Elastomeric Pumps as a Replacement for Mechanical Infusion Pumps

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7

Home Infusion Immunoglobulin Patterns and Dynamics in Patients Diagnosed with Primary Immunodeficiency in the United States

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Connie R. Sullivan, BSPharm *President and CEO, NHIA*

Bill Noyes, *SVP, Reimbursement Policy, NHIA*

Bridget Balkaran, *Kantar Health*

Maculaitis Martine, *Kantar Health*

8

Incorporating ASPEN Consensus Recommendations for Refeeding Syndrome into the Home Infusion Setting: Assessing Homestart PN Risk of Refeeding

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Iodine Deficiency in the PN-Dependent Pediatric Patient: A Case Study

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Anaphylaxis Kit Utilization and Evaluation in Infliximab and Vedolizumab Therapy in Home Infusion

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Pharmacy Technicians Engagement and Staffing Model Play Book

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Retention of Pharmacy Technicians with a Work Family

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Retrospective, Multicenter Study of Clinical and Economic Outcomes Associated with Accelerated Infliximab Home Infusion

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