

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

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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 2019¹, 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

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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 2019¹, 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 discharge⁴ 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)

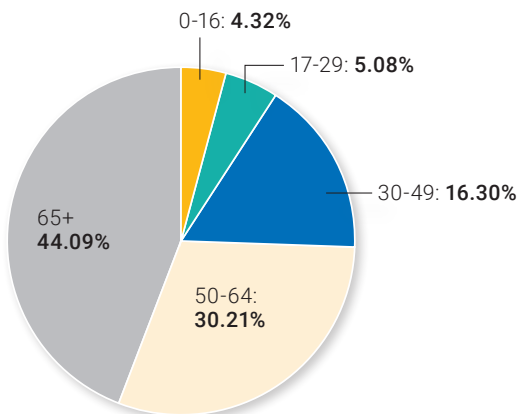


TABLE 1

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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