

A Multi-Center Time Study of Home Infusion Pharmacist Professional Services for Specialty Infusion Medications

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ABSTRACT

Introduction

Specialty infusion and injection medications are key growth areas in home infusion services. According to the National Home Infusion Association (NHIA), over 315,000 specialty patients were served by home infusion pharmacies in 2019, with specialty infusions consistently representing approximately 10% of total patients. Despite the well-documented positive impact of specialty pharmacists on clinical and non-clinical patient outcomes, there is a lack of data on the specific tasks and time that pharmacists dedicate to furnishing specialty medications in home infusion settings. This study aims to fill this gap by quantifying the time spent and categorizing tasks performed by home infusion pharmacists caring for patients receiving specialty medications.

Methods

A descriptive, multi-center study was conducted by the National Home Infusion Foundation (NHIF). An expert committee determined the specialty therapy types included in the study, dispensing cycles, pharmacist task categories, and examples of tasks within each category. Pharmacists from participating home infusion providers self-reported time spent on clinical and administrative tasks using standardized tracking spreadsheets. The study tracked pharmacist time from the patient referral to the completion of 2 dispensing cycles, with tasks categorized based on clinical care activities, including drug preparation, patient assessments, and care planning.

Results

There were 563 pharmacist tasks provided to 72 home infusion patients across 6 states, with the mean number of pharmacist tasks per patient being 7.82 (SD = 3.404). Drug preparation and compounding activities were the most frequent tasks, followed by patient assessments and care planning. The study revealed that the mean pharmacist time spent per patient was 2 hours and 31 minutes (SD = 1:21). There were notable differences between therapy types. A key finding was that 71.58% of pharmacist tasks were dedicated to patient care, highlighting the intensive clinical involvement required for these medications. The study also showed little difference in the overall pharmacist time between infusion and injectable administration methods. However, care planning and patient assessments were more prominent for self-injectable drugs, indicating a higher degree of clinical management.

Discussion

The findings of this study underscore the critical role of pharmacists in furnishing specialty infusion services, with implications for staffing and reimbursement policy decisions. The data suggests a significant workload associated with clinical tasks and care coordination.

Conclusion

This study is the first to systematically quantify and categorize the professional work of home infusion pharmacists caring for specialty infusion medication patients. The results emphasize the substantial commitment of pharmacist time to clinical care, underscoring the complexity of specialty infusion medications and their management in home settings.

Keywords: Home infusion, specialty, pharmacist, professional services, time study, patient assessment

Introduction

Specialty infusion and injection medications are areas of substantial growth in home infusion. The National Home Infusion Association (NHIA) reported home infusion pharmacies serviced more than 315,000 specialty patients nationwide in 2019.¹ The same report found specialty infusion medications consistently represented approximately 10% of total home infusion patients served year-over-year.¹ Studies have demonstrated the positive impacts of specialty pharmacists on patient care for both clinical and non-clinical outcomes.²⁻⁴ According to recent surveys, specialty pharmacies dispensed 15,000-30,000 prescriptions per year and employed an average of 15.5 pharmacists.^{5,6} Per published reports, specialty pharmacists are tracking their work hours and related tasks, but a review of the literature found a void in published studies on data collected from home infusion providers reporting time and task data for pharmacists furnishing specialty medication prescriptions. Given the increasing number of patients treated with specialty medications, there is a growing need to assess the time pharmacists spend on specific tasks related to caring for this patient population.^{1,7} To provide support for staffing decisions and inform policies for reimbursement for home infusion services, the results of this study can be used in developing workflows that incorporate the pharmacist's time commitment to tasks necessary for caring for a home infusion patient who receives specialty medication.

A professional pharmacy service is defined as an action or set of actions undertaken in or organized by a pharmacy, delivered by a pharmacist, who applies their specialized health knowledge personally or via an intermediary to optimize the process of care with the aim of improving health outcomes and the value of health care.^{8,9} According to the American Pharmacists Association, a specialty pharmacist may work in a variety of practice settings.¹⁰ Some pharmacists in this practice area work in pharmacies dedicated to only drugs considered specialty medications for self-administration, and many pharmacists work in home infusion pharmacies or health-system settings that offer the option of administering specialty infusion medications in the patient's home or outpatient site. In these settings, pharmacists may work in clinical care, dispensing, and medication adherence.¹⁰

Both home infusion pharmacies and specialty pharmacies are state-licensed pharmacies independently accredited for the services provided.^{11,12} NHIA defines a home infusion provider as, "a pharmacy that specializes in provision of medically necessary infusion therapies

to patients in their homes or other alternate-sites."¹¹ Home infusion pharmacies furnish specialty drugs while providing and administering a wide variety of other infusion medications. In contrast, a non-home infusion specialty pharmacy is one that solely or largely provides medications for people living with serious health conditions requiring complex therapies, which are typically self-administered.^{12,13} The complexity of these medications may be due to the drug itself, the administration method, the management of infusion reactions, the condition it is used to treat, special access conditions required by the manufacturer, payor authorization, or patient financial hardship.^{12,13} A national survey of health-system specialty pharmacies defined specialty drugs as those used to treat specific chronic diseases and that meet 4 or more of the following criteria: initiated and maintained by a specialist; generally injectable and/or not self-administered; the need for additional level of care in inventory control; the annual cost of therapy of \geq \$6,000; unique distribution; require reimbursement assistance; or need for extensive or in-depth monitoring and patient education.⁷

NHIA published the first study quantifying and describing the amount and type of pharmacist professional work performed through caring for patients who administer infusion medications in the home setting.⁸ This study only focused on pharmacist time related to the administration of anti-infectives, inotropes, and parenteral nutrition. Due to differences observed in the therapy types and small sample sizes, the data from specialty therapies could not be included in the results and prompted a replication of the initial research that would focus on data from specialty infusion therapies such as monoclonal antibodies and immune globulin administered in the home. A 2020 trends report of national home infusion providers estimated more than 163,000 patients received monoclonal antibody medications in the home or infusion suite and another 138,000 patients received immune globulin in the home.¹ According to the original NHIA pharmacist time study, patient assessments were the most time-consuming tasks pharmacists performed spending roughly 20% of their time coordinating and collaborating with patients and their health care providers.⁸

As described, studies show pharmacist tasks are necessary for clinical and non-clinical outcomes in patients prescribed specialty medications, but published research has yet to address the amount

TABLE 1 | Specialty Therapy and Administration Type and Dispensing Cycle

Therapy Type		Administration Type	Data Collection Time Frame
1.	Infused monoclonal antibody	Administered IV by any method	Starting with a new patient referral for home administration through 2 nd dispensing cycle.
2.	Subcutaneous immune globulin	Ambulatory infusion pump	
3.	Intravenous immune globulin	Ambulatory infusion pump	
4.	HCP Injected specialty medication	IM or SC injection	
5.	Self-injected non-oncology specialty medication	IM or SC injection	

Key: IM – Intramuscular, SC – Subcutaneous

of time and quantity of tasks collected from home infusion pharmacists furnishing specialty infusion medications.²⁻⁴ Therefore, the objective of this research is to determine the amount of time a home infusion pharmacist spends on patient care, specifically, the quantity and type of tasks. Additionally, task differences between therapy type and administration method will also be reported. Finally, data will be analyzed to identify time requirement differences between pharmacist time spent for injectables compared to infusion medications.

Methods

A descriptive, multi-center time study of pharmacist professional services to furnish specialty home infusion medications was administered by the National Home Infusion Foundation (NHIF). The NHIF web page recruited specialty drug home infusion providers to participate in a study that involved pharmacists self-reporting time spent on clinical tasks related to patient care. The pharmacists at the participating provider locations received an orientation video, data entry guide, and patient tracking spreadsheets.

A home infusion pharmacist expert committee was utilized to determine the specialty therapy types (Table 1) to be included in the study, dispensing cycles, pharmacist task categories, and examples of tasks within each category (Table 2). Since it was hypothesized that the amount of pharmacist professional time varies according to the patient therapy type and administration method, time measures were delineated for the 5 therapies and administration types shown in Table 1.

Data Collection

Data collection was completed from June 1, 2023, to December 31, 2023, and involved tracking pharmacist patient care time starting at the time of referral and continuing through the second dispensing cycle. The

goal was to capture time data related to at least 2 dispensing cycles which included the initial dispense at the start of care and at least 1 subsequent dispense. Data collection then continued through the minimum number of days after 2 dispensing cycles were captured. The time for the second dispense to occur varied based on the therapy type.

Pharmacists self-reported the amount of time (minutes) spent on each patient task using a spreadsheet for each patient. The tasks were classified according to predetermined categories (Table 2). Using retrospective recall, pharmacists tracked the time spent on a task category for a given patient immediately after completing the task. For example, if the pharmacist was reviewing the prescribed infusion medication, the task category was “1.” After completing the task, the pharmacist noted the total task time directly related to their role in the task in a tracking form. Once a patient had completed 2 dispensing cycles, the data collection tracking form was submitted to NHIF via a data submission portal.

Using spreadsheets, researchers calculated the patient total days, total patient minutes for each task category, and total patient minutes for pharmacist professional services. Next, the data for all submitted forms was combined and compiled into a single file. This file was imported to IBM SPSS (Statistical Product and Service Solutions version 29.0.2.0) for additional analysis.

Analysis

This study's main objective was to measure how much time home infusion pharmacists spend managing and caring for a specialty home infusion patient and the category of tasks completed. To determine the mean time that a pharmacist spends per patient per day, each patient's total pharmacist time for all tasks were summed and divided by the patient's total study days. All patients' mean pharmacist time per day was totaled and divided by the number of patients in the study. Additional analysis

TABLE 2 | Pharmacist Professional Services Task Category

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

was completed to determine the mean pharmacist time per task and to compare therapy types. To determine the amount of variance in the data, standard deviations were calculated for all mean scores. From the results of the comprehensive analysis, the home infusion pharmacist's workload will be described.

IRB (Internal Review Board) Status

The patient's care plan was not impacted by this study and all patient care data was retrospectively recorded. No identifying patient data was provided by the participating provider locations. Furthermore, the provider's location was also deidentified using a data participation code (DPC) provided by a 3rd party consultant. For these reasons, this study was exempt from IRB review.

Results

This multi-center study included 563 pharmacist tasks provided to 72 home infusion patients with the mean number of pharmacist tasks per patient being 7.82 (SD = 3.404). Six home infusion providers representing 6 states from the eastern, western, and central United States were included in the study. Slightly more than half (n = 38) of the patients received infused monoclonal antibody therapy while 16.67% received intravenous immunoglobulin, as shown in Table 3 and Figure 1. The number of days to complete 2 dispensing cycles ranged from 33.25 to 51.21 days.

Task Category

As viewed in Table 4 and Figure 2, "drug preparation and compounding activities" was the most frequent task performed by the pharmacist followed by "developing,

TABLE 3 | Number of Patients in Each Therapy Type

Therapy Type	Number of Patients	Percent
Infused monoclonal antibody	38	52.78
Intravenous immunoglobulin	12	16.67
Self-injected non-oncology specialty medication	9	12.50
HCP-injected specialty medication	8	11.11
Subcutaneous immunoglobulin	5	6.94
Total	72	100.00

FIGURE 1

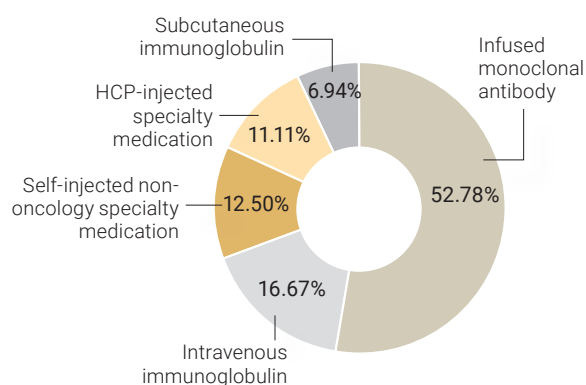
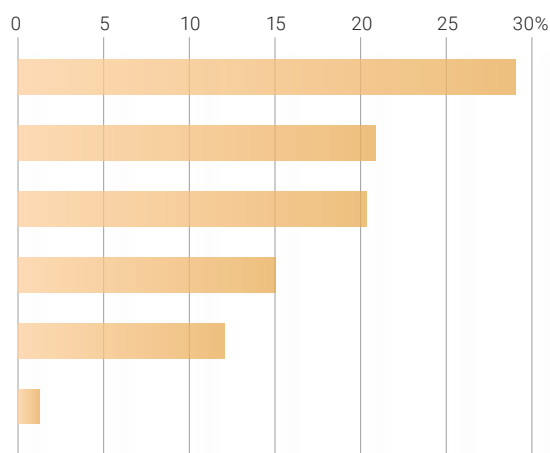


TABLE 4 | Number of Completed Pharmacist Tasks in Each Category

Task Category	Frequency	Percent
Drug preparation and compounding activities	160	28.42
Developing, implementing, and documenting the care plan	121	21.49
Performing patient assessments and documenting the assessment results in the patient EMR	118	20.96
Care coordination and communication	85	15.10
Clinical monitoring and related intervention activities	70	12.43
Other patient-related work tasks	9	1.60
Total	563	100.00

FIGURE 2



implementing, and documenting the care plan," and "performing patient assessments and documenting the assessment results in the patient electronic medical record (EMR)." When the pharmacist tasks are analyzed by therapy type, differences are noted (Table 5). For example, almost half of the tasks involved for caring for a self-injected non-oncology specialty drug patient are in the "developing, implementing, and documenting the care plan" task category while this task category has less than 25% of the tasks for the other specialty therapy types. "Drug preparation and compounding activities" task category is the most prevalent for the other therapies that includes infused monoclonal antibody, subcutaneous immunoglobulin, intravenous immunoglobulin, and health care practitioner (HCP)-injected specialty medication.

Pharmacist Time

The mean time that a specialty pharmacist spends on each patient in their care is 2:31 (2 hours and 31 minutes) (SD = 1:21) with a per patient range of 0:54 to 6:51 (hr:min). The subcutaneous immunoglobulin patient therapy type takes the most overall time (3:06) for the pharmacist while intravenous immunoglobulin and self-injected non-oncology specialty medication takes the least amount of overall time (2:10 hr:min), as viewed in Table 6. As noted in Table 7, some tasks are more time-consuming than others with "developing, implementing, and documenting the care plan" (0:21.54 hr:min) and "drug preparation and compounding" activities taking 0:21.07 (hr:min).

Discussion

Of the 563 total tasks, the combination of care planning activities and patient assessments accounted for 42.45% of the pharmacist's total tasks, showing a high degree of clinical involvement needed for home infusion specialty medications. In the study by Haines et al, 21% of home infusion pharmacists' tasks were from these 2 categories.⁸ We expected similar results for both home infusion specialty and traditional home infusion medications (anti-infectives, inotropes, and parenteral nutrition) because of standardized workflows applied universally across patient therapy types. Instead, the study found that pharmacists reported an increased proportion of care planning and assessment tasks for specialty medications. The differences could be attributed to the complexity of the patient cases, increased pharmacist involvement in tasks related to the insurance process, or coordinating the communication with other professionals on the patient care plan.

For the measurement of total time, "developing, implementing, and documenting the patient care plan" was the most time-consuming task for pharmacists in the study, averaging 21:54 minutes (SD = 17:16). Haines' study of home infusion pharmacist tasks reported 21:37 minutes (SD = 18:48) for the same task. This study's results provided evidence to challenge the perception that furnishing specialty medications requires less care planning and labor time from pharmacists than furnishing non-specialty home infusion drugs.^{14,15} Pharmacists took the same amount of time to complete these tasks for both studies. Overall, the mean aggregate time per task was 19:20 minutes (SD = 17:44) for specialty infusion medications and 22:57 minutes (SD = 28:29) for traditional home infusion medications.⁸

Data related to pharmacist time and tasks was collected and differentiated by 2 administration methods, "injectable" and "infusion." The results showed nearly equal amounts of total pharmacist time were required for each. The mean total time spent by pharmacists was 2:10 to 2:35 (hr:min) for injectable categories compared to 2:10 to 3:06 (hr:min) for infusion medication categories (Table 6). Since care planning and patient assessments were the largest percentage of total tasks and would be individualized by patient and medication, the pharmacists' time commitment was expected to be consistent between injectable and infusion medications in this study. Despite similarities in the total pharmacist time used for injectable and infusion medications, it is worth noting that the care planning and patient assessment task percentages were highest for the self-injectable group (Table 5) and indicated a larger percentage of clinical work involved for the self-injectable medications.

Drug preparation and compounding activities accounted for 28.42% of the pharmacists' total number of tasks. The medications included in the study would either be dispensed as a kit for bedside preparation or compounded in the pharmacy. Pharmacists are responsible for the medication's stability, and specialty medications such as monoclonal antibodies are fragile molecules requiring extra care in packaging for delivery and following specific compounding procedures.¹⁶ The study by Haines et al included home infusion medications with complex compounding procedures (e.g. parenteral nutrition) and reported nearly half of the pharmacist's time was spent on drug

TABLE 5 | Therapy Type by Frequency and Percentage of Tasks From Each Task Category

		Therapy Type					Total
		Infused monoclonal antibody	Subcutaneous Immunoglobulin	Intravenous Immunoglobulin	HCP-injected specialty medication	Self-injected non-oncology specialty medication	
Performing patient assessments and documenting the assessment results in the patient EMR	Count	69	7	13	9	20	118
	%	20.91	15.91	16.88	18.37	31.75	20.96
Developing, implementing, and documenting the care plan	Count	60	6	14	12	29	121
	%	18.18	13.64	18.18	24.49	46.03	21.49
Clinical monitoring and related intervention activities	Count	45	6	7	6	6	70
	%	13.64	13.64	9.09	12.24	9.52	12.43
Drug preparation and compounding activities	Count	91	18	28	16	7	160
	%	27.58	40.91	36.36	32.65	11.11	28.42
Care coordination and communication	Count	60	5	15	4	1	85
	%	18.18	11.36	19.48	8.16	1.59	15.10
Other patient-related work tasks	Count	5	2	0	2	0	9
	%	1.52	4.55	.00	4.08	.00	1.60
Total	Count	330	44	77	49	63	563
	%	100.00	100.00	100.00	100.00	100.00	100.00

TABLE 6 | Pharmacist Total Time by Therapy Type

Therapy	Mean (hr:min)	n	Std. Deviation
Infused monoclonal antibody	2:38	38	1:29
Subcutaneous immunoglobulin	3:06	5	1:31
Intravenous immunoglobulin	2:10	12	0:55
HCP-injected specialty medication	2:35	8	1:46
Self-injected non-oncology specialty medication	2:10	9	0:30
Total	2:31	72	1:21

TABLE 7 | Mean Pharmacist Time Per Task

Task	Mean (hr:min)	n (Tasks)	Std. Deviation
Performing patient assessments and documenting the assessment results in the patient EMR	0:20.55	118	0:16.12
Developing, implementing, and documenting the care plan	0:21.54	121	0:21.16
Clinical monitoring and related intervention activities	0:14.11	70	0:12.40
Drug preparation and compounding activities	0:21.07	160	0:17.14
Care coordination and communication	0:14.31	85	0:16.06
Other patient-related work tasks	0:17.39	9	0:27.39
Total	0:19.20	563	0:17.44

preparation.⁸ For specialty medications in this study, almost one-third of the pharmacists' total tasks were spent on drug preparation, confirming the necessity of pharmacist involvement in this task.

Time to Treatment

Although not directly associated with the pharmacists' time and tasks, the study collected the number of days from date of patient referral to medication dispensing. The average was 14.56 days (SD = 15.791), ranging from 1 to 70 days. There was a wide variability in the number of days needed for onboarding tasks. Compared to non-specialty home infusion medications, Haines et al. studied and reported the time to treatment initiation to be 1 to 6 days, with almost 90% of patients starting treatment within 1 day for non-specialty home infusion medications.¹⁷ Given the similarities in pharmacist time and task totals between the 2 studies, variables other than pharmacist tasks impacted the number of days to treatment. In a recent study, Russell et al reported the mean time to treatment initiation of self-administered specialty medications transferred to an external specialty pharmacy was 18 days (SD = 17) with a range of 1 to 147 days.¹⁸ The authors attributed the length of time and large range to the necessity for coordination between the patient and prescriber and the collaborative process design of specialty pharmacies.¹⁸

Study Limitations

The most common limitation of this self-report time study is the potential for pharmacists to be more productive since their tasks and time were tracked. Even so, self-report is commonly used to collect time utilization data. The study results relating to the method of administration using "injectable" and "infusion" categorical data were limited by a small sample size (n = 17) for the injectable group. Future research should collect larger sample sizes to confirm the findings of our study. Additional work is needed to distinguish pharmacists' tasks by their work environment. Pharmacists performing clinical tasks necessary for furnishing specialty medications may be working in a clinic setting where physical drug preparation and dispensing were not part of the specialty pharmacist tasks. The tasks used in this study were developed to reproduce the study method used in the home infusion pharmacist time study and did not directly define any pharmacist tasks as part of an insurance benefit verification.⁹ Considering the clinically rigorous and potentially lengthy prior approval process, future research should incorporate pharmacist time and tasks related to the prior approval or financial procedures of dispensing specialty medications.

Conclusion

Pharmacists completed 563 total tasks, almost 8 per patient, for the 72 patients in the study. Of the 6 categories of specialty medication related pharmacists' tasks, 71.58% of all pharmacist work was dedicated to patient care, while the remaining 28.42% was involved in drug preparation and compounding. There was little difference between the pharmacists' time and tasks of injectable prescriptions compared to furnishing infusion medications. This is the first study to quantify and describe the amount and type of home infusion pharmacist professional work performed when caring for patients prescribed specialty infusion medications and emphasizes the intensity of pharmacist time devoted to the start of care.

Disclosures

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Commentary

When reviewing a manuscript submitted by one of *Infusion Journal's* editors or staff, the author is deliberately excluded from all aspects of the review process. The Editor-in-Chief or alternate editor is responsible for handling the peer review process independently of the author. The author is not aware of the choice of peer reviewers and is not present when discussing the manuscript at editorial meetings.

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