

A Financial Analysis of Pharmacist Interventions for Patients Using Self-Administered Biologics in a Centralized Specialty Medication Clinic at a Veteran's Affairs Hospital

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Specialty medications associated with high cost continue to be a focal point in many public and private health system pharmacies' strategic priorities for reducing cost.¹ Specialty medications account for 49.4% of prescription expenditures in 2021 with self-administered subcutaneous biologic medications contributing significantly due to rising drug spend.^{2,3} Many private health systems utilize their own integrated specialty pharmacies to retain prescriptions and revenue associated with these medications.⁴⁻⁶ These specialty pharmacists have been shown to increase medication adherence^{4,6}, improve medication safety^{7,8}, and contain costs for both patients and health systems.^{6,9,10} The United States Department of Veterans Affairs (VA) does not have its own specialty pharmacy, and these medications are dispensed either from local sites or Consolidated Mail Outpatient Pharmacy (CMOP), the VA Mail Order Pharmacy.

The William S. Middleton Memorial Veterans Hospital and Clinics (the "Madison VA") utilizes clinical pharmacy practitioners (CPP) in select specialty clinics integrated with scheduling, nursing, and physician teams. Within these specialty clinics, many high-cost, subcutaneous specialty medications are prescribed. Prior to January of 2020, specialty clinics had not had a streamlined approach to ensure every patient received thorough initial education on their injectable biologic medication.¹¹ In addition, specialty CPPs have limited hours dedicated to specialty clinics and may not have adequate time to provide real-time, initial teaching on a

Abstract

Objective: A centralized specialty medication management (CSMM) clinic led by clinical pharmacy practitioners (CPPs) was implemented to address gaps in patient education, improve home-use of biologic medications, enhance patient safety, and contain costs. The CSMM CPPs completed medication counseling and disease-specific monitoring for patients prescribed any of the 12 specialty medications over the first year of therapy.

Objective: To determine the cost avoidance due to CPP interventions from a CSMM clinic at a Veterans Affairs hospital.

Methods: Patients who completed at least one encounter with the CSMM clinic within the first 13 months of service were included in this retrospective review. Chart review was conducted on included patient encounters, including CPP interventions that were documented and categorized. Estimated costs were determined through literature review and the VA National Acquisition Center drug contract prices.

Results: 73 patients were included with 251 unique documented encounters. Overall, 103 CPP interventions were documented, of which 13 interventions (12.6%) had cost avoidance implications. The CSMM CPPs' interventions resulted in an overall cost avoidance of \$57,432 for the evaluation period. The intervention type with the greatest cost avoidance was replacement of products (\$22,511), followed by therapy changes and dose corrections. The cost avoidance related to CPP interventions was 149% compared to the cost of the pharmacist to run the clinic (0.2 full time equivalent CPP salary and benefits).

Conclusion: A CSMM model for patients initiating a specialty medication can effectively lead to health-system cost avoidance through CPP-led interventions.

newly prescribed specialty medication. In specialty clinics where there is not a CPP present, a nurse or other health care team member provides initial teaching, which also varies based on the clinic and available

staff. Initial medication orders and refills are primarily dispensed through CMOP. Once these medications are initiated, they are subsequently monitored with follow-up at their next specialty clinic visit.

The innovative CPP-led video- and telephone-based Centralized Specialty Medication Management (CSMM) Clinic was implemented in January of 2020 to improve patient education, optimize medication use, enhance patient safety, and decrease costs through increased touchpoints with the CPP.¹¹ Within the CSMM clinic, patients who are prescribed a specialty medication complete an initial teaching during a VA Video Connect (VVC) or phone visit and then follow up after 2 weeks of therapy and at 3, 6, and 11 months post-initiation. The 2-week follow-up focuses on medication tolerability, self-injection technique, and storage. Subsequent follow-ups also include medication efficacy and adherence. Since its creation, the CSMM clinic has expanded from its initial 4 specialty medications and 3 specialty clinics to include 12 specialty medications and allergy, cardiology, dermatology, gastroenterology, and rheumatology specialty clinics. At the time of this review, the clinic was staffed with two 4-hour half-day clinics (i.e. 0.2 CPP FTE [full time equivalent]), and the following medications were monitored by the clinic: abatacept, adalimumab, alirocumab, benralizumab, certolizumab, dupilumab, etanercept, evolocumab, ixekizumab, omalizumab, secukinumab, and ustekinumab. The purpose of this evaluation was to determine the cost avoidance due to CPP interventions from a CSMM clinic at a VA hospital.

Methods

A retrospective chart review was conducted to identify outcomes from the CPP in the CSMM clinic to estimate cost avoidance. Cost assumptions were determined based on literature regarding disease control, cost of medications, and pharmacist salary. The primary outcome was the cost avoidance at the health-system level.

Chart Review

A chart review was conducted on all patients followed by the CSMM clinic from January 2020 through February 2021. Patients were included if they had their initial CSMM visit by November 15, 2020, to allow for at least 3 months of data and appropriate intervention capturing. When an intervention with a cost implication made by a CPP was identified, information

was abstracted from the medical record to estimate cost avoidance. Interventions with the potential for cost avoidance but without literature to assign a cost were excluded. An example of an intervention with potential cost avoidance that did not have identified cost for this evaluation was therapy for the management of injection site reactions. It could not be guaranteed that the patient would have switched to another agent, or that the patient's utilization of the medication would have been affected without the CPP intervention.

In cases where cost avoidance could be assigned, the following information was collected: medication, intervention type, refills until next specialty provider appointment, and a qualitative description of the scenario. The number of refills until the next specialty provider appointment was used to determine when the next likely opportunity would have occurred to make the same intervention. This was assumed to be the minimum duration the cost difference would have occurred.

The intervention types included dose correction or device change, therapy change, disease state management, and product replacement. A dose correction or device change intervention was when the CPP intervened on incorrect doses or improper dosing frequency (often due to patient misunderstanding). Disease state management resulted when increased touchpoints/appointments with the CPP enabled a patient to achieve disease state control, or identified the need to change medications sooner than without CPP touchpoints. Disease state control was identified through documented provider assessments in the electronic medical record. These CPP visits often identified allergic reactions or non-responders to therapies, thus accelerating the time to switch biologics and the time to achieve disease state remission.

Literature Search

To evaluate the cost avoidance potential of CPP interventions in a specialty medication management setting, a literature search was performed. Under the assumption that CPP interventions would lead to improved chronic disease outcomes, the search was designed to evaluate cost avoidance associated with disease control. PubMed was searched in

February of 2021. There were no limits to the date of publication. Four separate searches were conducted, aimed at retrieving articles of four disease states that were commonly managed by specialty CPPs, including rheumatoid arthritis, psoriasis, inflammatory bowel disease, and ankylosing spondylitis. The following search terms were used:

1. cost AND ("treatment failure" OR "uncontrolled" OR "failure to respond") AND "rheumatoid arthritis"
2. cost AND ("treatment failure" OR "uncontrolled" OR "failure to respond") AND ("Crohn's" OR "inflammatory bowel disease" OR "ulcerative colitis")
3. cost AND ("treatment failure" OR "uncontrolled" OR "failure to respond") AND ("psoriasis" OR "psoriatic arthritis")
4. cost AND ("treatment failure" OR "uncontrolled" OR "failure to respond") AND "ankylosing spondylitis"

Articles were selected if they had cost outcome data for both uncontrolled disease and controlled disease groups. From the literature review, the financial outcomes identified to track included: dose correction and device changes, product replacement, disease state control, and therapy changes. For each of these interventions, the cost of medications was determined utilizing the VA National Acquisition Center Contract Catalog Search Tool.¹²

Cost Determination

To calculate cost avoidance for dose correction or device change and therapy change interventions, the number of monthly refills impacted by the intervention was determined and multiplied by the normal acquisition cost of the drug product [i.e., cost = (# of months) x (Δ med cost)]. For example, if a device was changed and it was determined to be cost avoidant by \$100 per month, and it was determined that there were 3 months between the CSMM appointment to the next specialty provider appointment, the total cost avoidance would be \$300. Cost avoidance due to disease state management was determined through the literature review by identifying the medical costs of uncontrolled disease

states when compared to well-controlled disease states.¹³⁻¹⁵ Again, the cost difference was determined by the number of refills from when the CPP intervened and their next scheduled specialty appointment. The difference in cost between the new medication and discontinued medication was calculated and multiplied by the number of refills. This was added to the amount saved by achieving disease state control per month based on the literature (Table 1) [i.e., cost = (# of months) x (Δ med cost) + (\$ disease state control)]. As no literature was found related to ankylosing spondylitis, it was assumed the total all-cause medical cost would be similar to rheumatoid arthritis.

When medications were reported to malfunction or break, or patients stored products incorrectly and the CSMM CPP was able to facilitate acquiring replacement products from the manufacturer at no cost to the patient or the VA, it was assumed the intervention resulted in a direct cost avoidance of the normal acquisition cost of the product to the health system. There were no cost adjustments made for inflation.

Analysis

Cost avoidance was calculated for each intervention and summed to find a total over 14 months. This was averaged to determine a mean annual cost avoidance. The mean annual cost avoidance was compared to the cost of staffing the clinic at current FTE levels to determine an annual return on investment (ROI). The University of Wisconsin-Madison Health Sciences Institutional Review Board self-certification tool determined that the evaluation was not required to undergo IRB review, as this project did not meet the federal definition of research and was undertaken for programmatic evaluation.¹⁶

Results

There were 73 patients seen by the CSMM clinic during the 14 months following clinic implementation. There were 251 unique encounters evaluated (i.e., appointments), averaging 3.4 encounters per patient. Of the 103 total CPP interventions identified, 19 (18.4%) had potential cost implications. Of those, 13 interventions (12.6% of total interventions) were able to have a cost difference assigned to them based on the literature and cost

TABLE 1. Cost Assumptions for Disease State Control

<i>Disease State Control</i>	<i>Cost Savings Per Month</i>	<i>Mean All Cause Medical Cost Savings from Cited Source</i>
Psoriasis ¹³	\$115.58	\$1387 per year
Rheumatoid Arthritis/Ankylosing Spondylitis ¹⁴	\$476.67	\$5720 per year
Irritable Bowel Diseases ¹⁵	\$1260.08	\$15121 per year (excluding pharmacy cost)

TABLE 2. Cost Avoidance of the Centralized Specialty Medication Management Service

<i>Cost Category</i>	<i>Number of Interventions</i>	<i>Cost Avoidance</i>	<i>Example intervention</i>
Replacement Product	4	\$22,511	Medication device came with needle guard triggered. CPP managed medication replacement with manufacturer.
Therapy Change	4	\$21,390	Medication lost efficacy and next provider appointment was in 3 months. CPP stopped refill transmission and collaborated with provider to trial new medication.
Dose Correction	2	\$13,075	Patient unaware of need to start lower maintenance dosing.
Disease State Management	3	\$456	CPP facilitated change in medication prior to specialty appointment and patient achieved disease state improvements.
Total Cost Avoidance (14 months)	13 cost saving interventions	\$57,432	
Cost Avoidance (1 year average)	10.2 cost saving interventions per year	\$49,228	

CPP = clinical pharmacy practitioner

of medications adjusted (Table 2). The medications with cost differences assigned were adalimumab, abatacept, benralizumab, certolizumab, etanercept, ixekizumab, secukinumab, and ustekinumab.

The largest cost avoidance category was replacement products, followed by therapy changes and dose corrections. For disease state management, one intervention was found for each of the following disease states: ankylosing spondylitis, Crohn's disease, and plaque psoriasis. There were 2 CSMM CPP therapy changes that resulted in an increased cost (\$1,837) due to the CPP recommending a more expensive medication. However, overall, the CSMM CPPs' interventions resulted in a cost avoidance of \$57,432 over the first 14 months of the clinic (Table 2). When averaged for a 12-month span, the 1-year cost avoidance was \$49,228. This equates to \$4,418 per cost-related intervention and

\$787 per patient.

To calculate the primary outcome, a Level 1 GS-13 CPP salary was used with an assumed 30% additional included for benefits. When adjusted for 0.2 CPP FTE, which is what was needed to maintain the CSMM clinic at the time, the cost was \$33,060 annually. When compared to the clinic cost avoidance of \$49,228, this resulted in a positive 0.49 return on investment over 1 year (i.e., [49,228-33,060] / 33,060 = 0.49).

Discussion

This retrospective review found a positive ROI of 0.49 as the cost avoidance following the implementation of the CSMM clinic was greater than the cost to run the clinic. This cost avoidance is focused on the health-system and pharmacy department budgets and can be re-allocated to improve care for Veteran patients. Typically, the financial

benefits for specialty pharmacies are described by the revenue and prescription capture rates the specialty pharmacy achieves.^{4,6,17} In this case the CSMM clinic was able to demonstrate a positive ROI based on cost avoidance through pharmacist interventions which minimized cost. This supports that there is also a cost avoidance from specialty pharmacist interventions separate from the revenue generated.^{9,10}

The cost avoidance findings in this evaluation were modest compared to the two other studies that have evaluated the financial implications of specialty pharmacists' interventions in a health-system setting.^{9,10} Compared to Lankford et al, who described the cost implications of health-system specialty pharmacist interventions, this evaluation had a lower proportion of patients with cost avoidance interventions made (34% compared to 12.6% in this evaluation).⁹ However, Lankford et al reported a lower cost savings of \$2,757 per intervention, whereas this evaluation estimated \$4,418 saved per intervention. Soni et al described the cost implication of health-system specialty pharmacists from integrated specialty pharmacies within an Accountable Care Organization and reported saving \$1,274 per patient compared to \$787 per patient in the present evaluation.¹⁰ These differences in cost avoidance comparing other models can likely be explained by differences in the medications monitored by the CSMM clinic and the medication pricing specific to the VA system.^{9,12} For example, a large proportion of patients seen by the CSMM clinic in this evaluation are from rheumatology, dermatology, and cardiology services, whereas Lankford et al focused on oncology. Compared to other evaluations of specialty pharmacist interventions, this clinic is not expected to impact patient out-of-pocket costs given that VA benefits ensure a consistent co-pay for these agents.⁶

Limitations

There were several limitations for this retrospective chart review. First, there were limitations in the amounts used to estimate cost avoidance. This evaluation is likely a conservative estimate of the cost avoidance ROI as it only focuses on interventions where a cost could be assigned. There were 6 interventions with the potential for cost avoidance to which we were not

able to assign a cost. Additionally, CPPs in the CSMM clinic perform other roles that were not considered interventions for this review, such as screening and coordination for indicated vaccines or ensuring that appropriate hepatitis B, hepatitis C, and tuberculosis labs were performed. Lastly, in the private sector there may be opportunities for appointment reimbursement, which would further improve the cost benefit implications of a similar clinic.

There were also several key assumptions related to cost, specifically when evaluating disease state control. It was assumed that no medication intervention would have occurred between the time of CPP intervention and the next clinic appointment and assumes patients would have continued to fill their specialty medication regularly. Both assumptions could vary widely in reality and affect the total cost difference. Additionally, no specific cost avoidance data could be found related to disease state control of ankylosing spondylitis. It was assumed the all-cause medical cost would be similar to rheumatoid arthritis and the average monthly cost avoidance for rheumatoid arthritis was used for the one ankylosing spondylitis disease state management intervention.

There were also measurement limitations in this evaluation. There was no comparator group or pre-post analysis, reducing the ability to show the net impact of outcomes directly linked to the CSMM clinic's creation. The time needed to perform the interventions was not collected. Additionally, this is the estimated cost avoidance from a functioning CSMM clinic; it does not take startup time or startup resources into account. Lastly, this data is also limited by being a single site evaluation.

Future Directions

Future directions include expansion to additional specialty medications and disease states as well as expanding data capture to include a comparator group. Additionally, this could be disseminated to other VA hospitals that could benefit from a CSMM strategy. One way to disseminate may be through a hub-and-spoke model for smaller sites that may not have the resources to support a similar clinic where a larger facility is able to offer the CSMM clinic to their patients.^{18,19}

Conclusion

A centralized specialty medication management model can result in cost avoidance for patients initiating a specialty medication through pharmacist interventions. Future directions include clinic expansion to additional VA facilities.

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