

## **Assistance with Injectable Medications (AIM): Implementation of a Pharmacist-Run Specialty Pharmacy Injection Clinic**

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### INTRODUCTION/BACKGROUND

Specialty pharmacies provide outpatient medications for a variety of chronic, complex, and rare diseases. These medications have a high annual cost of therapy and many are self-administered injectable medications with varying degrees of user-friendliness. MUSC Specialty Pharmacy services consists of a centralized call center with decentralized clinical pharmacy specialists. Once a prior authorization or appeal for the specialty medication is approved, standard-of-care is for pharmacists to provide both general education and injection teaching via telephone. Pharmacists also give the option for in-person teaching through the AIM clinic. Pharmacists are available for further questions during regular business hours and an on-call pharmacist is available 24/7 for after-hours questions and concerns. Both patients and providers have begun requesting in-person administration, education, and direct oversight for the initial injection. The patient may also follow up with the drug manufacturer for further assistance from a nurse or other healthcare professional.

There is precedence for nurse-led patient support programs improving adherence for certain medications.<sup>1</sup> However, there is little literature to support pharmacist-led programs, particularly for in-person injection coaching and administration. Mullican et al detailed the pharmacist's role in the specialty medication use process, as patients need to be educated regarding dosing, administration, storage & disposal, adverse effect management, considerations for illness/planned surgeries.<sup>2</sup> Pharmacists also function to assist in financial and clinical management including drug procurement, management of lab values, and immunization screening. Adherence-focused drug therapy management (DTM) programs are documented in literature. Stocki et al detailed a pharmacy benefit manager-implemented DTM with the goals of improving adherence, maximizing therapeutic outcomes, and improving patients' quality of life. Similar to the structure of MUSC Specialty, patients in this study had 24/7 access to a highly trained clinical pharmacist.<sup>3</sup>

Two commonly used measures of patient adherence are medication possession ratio (MPR) and proportion of days covered (PDC). Both measures can be determined using the prescription fill record. MPR is the sum of the days' supply for a drug in a set time period divided by the total number of days in the time period.<sup>4</sup> PDC is a measure of the days covered in a given time period and does not account for overlaps with early fills. MPR can be greater than 100%, whereas PDC is capped at 100%.<sup>5</sup>

The goal of this project was to establish a novel injection clinic where patients can schedule an appointment with a pharmacist to receive assistance with administration. The clinic aims to resolve patient-specific barriers to administration, such as fear of injection or physical impairment. An ultimate goal is to improve adherence for patients who may not otherwise use the medication without coaching and training.

## METHODS

This was a prospective, observational, single-center study taking place from January 1, 2019 to April 30, 2019. Institutional Review Board (IRB) approval conferred December 14, 2018. Patient identification occurred directly through our clinical pharmacy specialists via referrals and informational flyers. Eligible patients were over the age of 18 years and must have filled a qualifying prescription for a subcutaneous injection via the internal Specialty Pharmacy. The clinic was designed to have its own department in the electronic health record (EHR) where patients could be scheduled. **Figure 1** includes further details surrounding the clinic implementation.

An injection protocol kit was available in the event of an adverse injection reaction. This was in accordance with South Carolina immunization protocol requirements and included the following: epinephrine, diphenhydramine (injectable solution and tablets), syringes with needles, alcohol swabs, bandages, blood pressure cuff, stethoscope, adult pocket mask, flashlight, and a time-keeping device.

The primary outcome of interest was patient adherence. Secondary outcomes included pain score, patient satisfaction, number of emergency department/urgent care visits, and revenue generation for our specialty pharmacy department. Adherence data was collected from insurance claims data 4 months after the start of the clinic through outpatient retail pharmacy software. Survey data was verbally collected from patients and entered into RedCap. Data points included pain score (0-10), visit satisfaction (0-10), injection perceptions, and recent emergency/urgent care visits related to disease state of interest. Patients' injection perceptions were also evaluated. Descriptive statistics were employed to summarize the data. Responses were stratified by specialty service (Gastroenterology, Rheumatology, Cardiology, Neurology, or Dermatology).

## RESULTS

The clinic became available for patient visits beginning January 2019. From January 1, 2019 to April 30, 2019, 17 patients had completed 24 clinic visits. Each patient's survey responses are detailed in **Table 2**. Baseline characteristics for patients seen in clinic are detailed in **Table 1**. The average age of patients in this study was approximately 57 years (range 20-81 years). The majority of patients (64.7%) reported no history of self-injection. The highest proportion of patients (76.5%) were referred from Cardiology or Rheumatology services (**Figure 2**). The two most common medications administered in clinic (28%) were Humira® and Praluent® (**Table 2**).

## DISCUSSION

Common reasons for patients to attend clinic included: fear of needles, confirmation of first-dose technique, administration, and training for patient's caregiver to assist with administration. Frequent post-injection perceptions were that patients expected devices to be more complicated to use and that injection site pain was lower than expected. Four patients (23.5%) scheduled recurring appointments every two weeks with the pharmacist. One returning patient (Patient #3) discontinued their medication due to side effects, and another (Patient #1) felt comfortable injecting on her own after 3 appointments (**Table 2**). The variety of patient ages and high proportion of African American patients is in line with our typical Specialty population at MUSC. Study patients attended 100% of scheduled appointments, which is impressive given standard no-show rates across health systems.

A major limitation of this study involved complications with the EHR during implementation including building the department, scheduling, and billing insurance for an administration fee. As a result of delays, this observational study did not reach its intended sample size of 100 patients. The limited time frame also did not yet allow for full assessment of adherence and emergency visit outcomes. The subjective nature of patient responses is another limitation of this project. Satisfaction scores can be affected by non-clinical factors, such as trouble with parking or navigating the large health system.

Only 14% of patients elected to participate in a PBM facilitated DTM program via telephone, which is higher than our capture rate of 7% for all medication first fills from January 1 to April 30, 2019. However, this was an acceptable capture rate given a significant percentage of our patients do not live close to the medical center and that all visits were in-person. Ideally, more patients will be reached when additional insurance contracts are obtained with the growth of MUSC Specialty.

Future directions include evaluation of emergency department and urgent care visits after clinic utilization once a larger time frame is available for comparison. There will be utility to assessing insurance reimbursement rates for billed encounters as well as evaluate the benefit of using MUSC Specialty Pharmacy versus an outside pharmacy. An eventual goal is the implementation of telehealth video visits for first-time injections and follow-up appointments for patients who are unable to travel to the hospital to receive care. Another future direction could be the implementation of an automatic electronic consult service to generate a referral to the specialty injection clinic. A similar consult process in a PCSK9 inhibitor service is detailed by Atanda et al. In their project, a consult order was attached to each electronically prescribed prescription. Upon receipt of the consult order, a pharmacist performed a full clinical review then facilitated insurance processing and medication procurement.<sup>6</sup> MUSC Specialty Pharmacy already has many of the components in place to provide a similar high quality of service.

## CONCLUSIONS

The AIM clinic was successfully implemented with an appointment-based referral system from clinical pharmacy specialists and physicians. This valuable service results in high patient satisfaction and improved continuity of care. Pharmacy residents will continue to run the clinic longitudinally, and clinical pharmacy specialists now have a department in which to schedule and bill patient insurance. With the continued expansion of MUSC Specialty Pharmacy this service could eventually provide teaching for pediatric patients and expanding service lines.

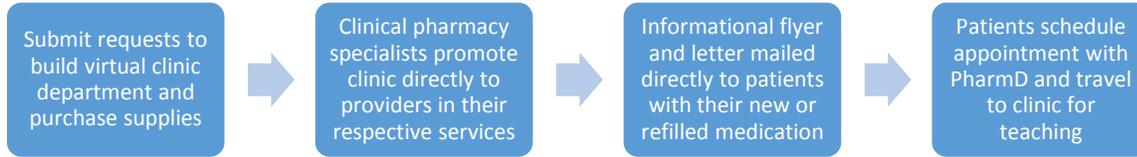
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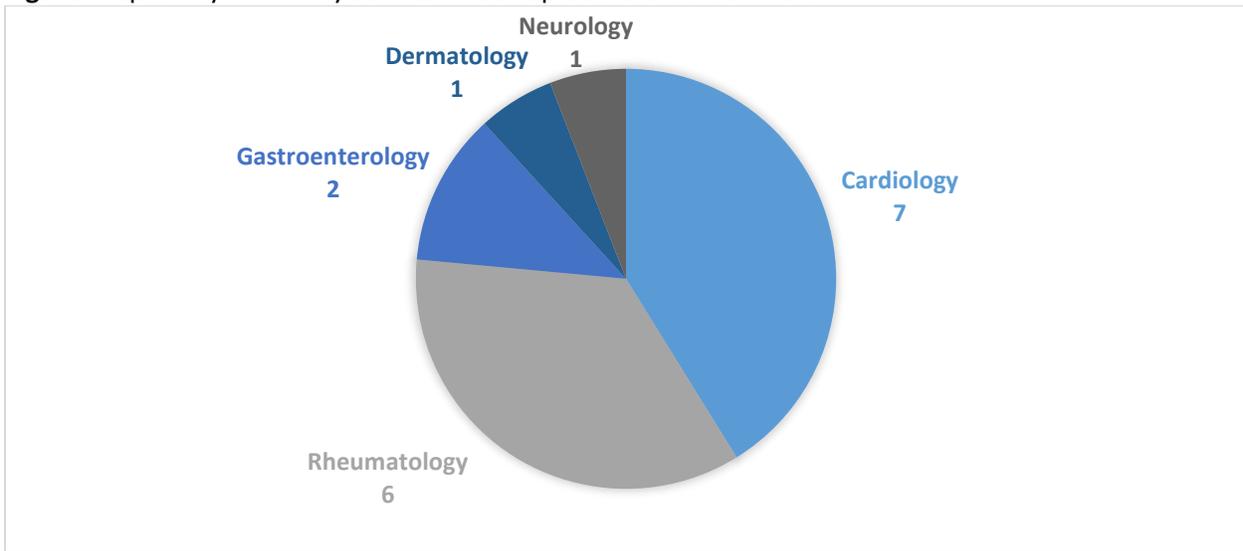
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APPENDIX A – Tables & Figures

**Figure 1:** Steps for Clinic Implementation



**Figure 2.** Specialty Pharmacy Service Lines Represented at Each Visit



**Table 1: Patient Demographics**

|                                  |           |
|----------------------------------|-----------|
| Total patients                   | 17        |
| Visit total                      | 24        |
| Age, mean, years                 | 57.1      |
| Female, n (%)                    | 14 (82.4) |
| African American race, n (%)     | 11 (64.7) |
| Return visits, n (%)             | 8 (33.3)  |
| First self-injection, n (%)      | 11 (64.7) |
| ED visit in the past year, n (%) | 4 (23.5)  |
| Pain score (0-10), mean          | 2.5       |
| Visit satisfaction (0-10), mean  | 9.6       |

**Table 2: Patient Visit Data Summary**

| #                | Age | Medication | # of Visits | Pain Score | Satisfaction Score | Injection Experience? | ED Visit in the Past Year? |
|------------------|-----|------------|-------------|------------|--------------------|-----------------------|----------------------------|
| Cardiology       |     |            |             |            |                    |                       |                            |
| 1                | 59  | Praluent®  | 3           | 0, 5, 5    | 10, 10, 10         | Yes                   | Yes                        |
| 2                | 81  | Repatha®   | 1           | 0          | 10                 | No                    | No                         |
| 3                | 63  | Repatha®   | 3           | 0, 5, 2    | 10, 10, 10         | No                    | No                         |
| 4                | 52  | Praluent®  | 1           | 1          | 8                  | Yes                   | No                         |
| 5                | 67  | Praluent®  | 1           | 0          | 10                 | No                    | Yes                        |
| 6                | 57  | Repatha®   | 5           | 5, 3, 10   | 10, 10, 10         | Yes                   | No                         |
| 7                | 63  | Praluent®  | 4           | 7, 4       | 10, 10             | No                    | No                         |
| Rheumatology     |     |            |             |            |                    |                       |                            |
| 8                | 31  | Humira®    | 1           | 0          | 10                 | No                    | Yes                        |
| 9                | 28  | Humira®    | 1           | 3          | 10                 | No                    | No                         |
| 10               | 57  | Humira®    | 1           | 5          | 10                 | No                    | No                         |
| 11               | 78  | Actemra®   | 1           | 1          | 10                 | No                    | No                         |
| 12               | 80  | Humira®    | 1           | 1          | 10                 | Yes                   | No                         |
| 13               | 31  | Humira®    | 1           | 1          | 9                  | No                    | No                         |
| Dermatology      |     |            |             |            |                    |                       |                            |
| 14               | 75  | Dupixent®  | 1           | 1          | 7                  | No                    | No                         |
| Gastroenterology |     |            |             |            |                    |                       |                            |
| 15               | 20  | Stelara®   | 1           | 0          | 9                  | Yes                   | No                         |
| 16               | 64  | Stelara®   | 1           | 3          | 9                  | No                    | Yes                        |
| Neurology        |     |            |             |            |                    |                       |                            |
| 17               | 66  | Aimovig®   | 1           | 3          | 9                  | Yes                   | No                         |