The Impact of Scheduled Telephonic Clinician Intervention on Medication Adherence and Persistence in Rare Disease Patients.

Samantha Broders, PharmD; Marissa Puc, PharmD; Christina Gabriel; Pamela Koerner, PharmD, BCPS; Abigail Jastrab, PharmD, BCPS; Richard Faris, PhD, RPh

Background

A recent World Health Organization (WHO) report concludes that adherence rates amongst patients are roughly 50%. Medication non-adherence in patients with chronic conditions may lead to an increase in healthcare costs, and excess morbidity and mortality.[1] Reports on adherence-related outcomes approximate that up to 125,000 deaths and 25% of patient hospitalizations each year could be attributed to medication nonadherence.[2,3]

In the United States, there are approximately 7,000 rare diseases, affecting nearly 30 million Americans. Most rare diseases have no FDA-approved treatment options.[4] When a treatment is available, it is important that the patient take the medication as prescribed to achieve the optimal outcomes. Rare Specialty Pharmacies work with patients to create an individualized engagement program to simplify complex problems and ensure they have access to a specialized team of clinicians and non-clinicians who are there to serve them. These programs follow individualized patient outreach schedules based on the unique needs and characteristics of each medication and rare disease. For certain rare specialty medications, additional enhanced outreach may be conducted to achieve various patient-related outcomes. These programs are intended to empower the patient to take the medication in a way that leads to optimal outcomes.

Objective

To determine if enhanced clinician-led telephonic interventions at a Rare Specialty Pharmacy positively impacts patient adherence and persistence.

Methods

This retrospective analysis utilizes a national Rare Specialty Pharmacy's database to identify patients receiving a specified rare disease medication from 1/1/2022 to 12/31/2022. The intervention was the implementation of a clinician-led adherence call after their fourth fill. The intervention call was developed to utilize motivational interviewing and cover topics including common adverse events and mitigation efforts, administration instructions, lifestyle modifications, and disease state information and resources.

For adherence, we measured both the proportion of days covered (PDC) for fills 5 through 7 and the average gap days between each fill. Persistence was measured as a continuous filling behavior with no lapse in therapy greater than the previous days' supply.

Inclusion criteria for analysis included patients who received a new prescription for the medication, had at least 4 fills of the therapy, and had enough time elapse to receive an additional 3 prescriptions. Exclusion criteria included those who were transferred out of the pharmacy or had an otherwise non-preventable reason for discontinuation.

The intervention population are those who met the criteria and received the clinician-led call. Patients who did not receive the call were part of the control group.

Results

Table 1. Eligible Study Population

Cohort	Patients receiving four fills	Patients on therapy for 84 days after fourth fill
Control	337	265
Intervention	320	80

Fig 1. Gender Demographics by Cohort

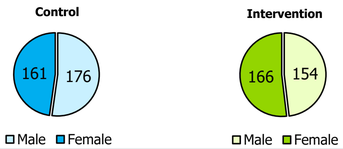
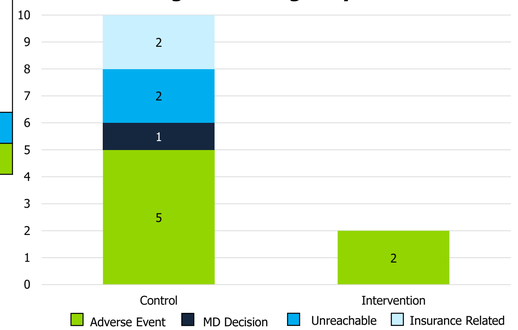


Fig 2. Discharges by Cohort



Adherence*

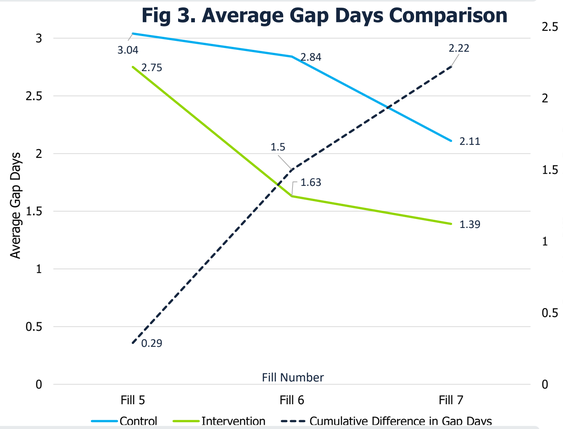
Table 2. PDC Comparison

	PDC ≥ 80%	Average PDC	P-value
Control	223 (84.1%)	91.8%	0.742
Intervention	67 (83.8%)	91.1%	

Table 3. Gap Day Comparison

	Average Gap Days			P-value
	Fill 5	Fill 6	Fill 7	
Control	3.04	2.84	2.11	0.219
Intervention	2.75	1.63	1.39	

Fig 3. Average Gap Days Comparison



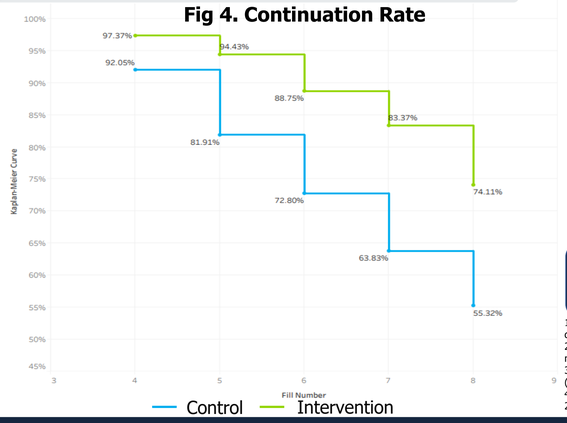
Persistence*

Table 4. Continuation Rate Comparison

	Continuation Rate				P-value
	Fill 4	Fill 5	Fill 6	Fill 7	
Control	92.1%	81.9%	72.8%	63.8%	<0.05
Intervention	97.4%	94.4%	88.8%	83.4%	

*Population size limited due to timing of call launch

Fig 4. Continuation Rate



Discussion

The number of patients receiving at least 4 fills of the targeted rare disease medication was 657. Since the intervention call was not launched until June 2022, the analysis population is smaller than the eligible population. The full analysis population was 265 control patients and 80 intervention patients. The total patient population was split relatively evenly by gender, with 50.2% being male.

Overall, the PDC rates (Table 2) were similar, with 84.1% of the control group and 83.8% of the intervention group having a PDC of 80% or greater. The average PDC was 91.8% for the control group and 91.1% for the intervention arm. These results were not statistically significant. Table 3 and Figure 3 shows the average gap days after the 4th fill. Average gap days were decreased in the intervention group following each fill, although the results were not statistically significant. Over the observation window, the cumulative average difference in gap days was 2.22 days lower for the intervention group, meaning that these patients had better adherence.

Persistence was measured across both cohorts and is shown in Table 4 and Figure 4. The continuation rate for the intervention arm was 83.4% after 7 fills compared to 63.8% for the control group. This result was statistically significant.

Discharge information for the first 3 months following the date of fourth medication fill is presented in Figure 2. There were 12 total discharges among the observed population with 10 (3.8%) discharges in the control group and 2 (2.5%) discharges in the intervention group. Of these discharges, there were 5 discharges due to an adverse event in the control group and 2 discharges due to an adverse event in the intervention group.

The results of this study have several limitations. First, since the enhanced adherence call was launched mid-year 2022 many patients did not meet the inclusion criteria. Second, adherence and persistence measures may not follow a normal distribution. As a result, the statistical analysis of these results may be unreliable. The third limitation was the overall patient sample size. A larger patient population could detect meaningful differences in adherence and persistence.

Conclusion

Rare Disease Pharmacies specialize in caring for patients with complex treatment regimens and difficult journeys. The results from this study suggest that an enhanced clinician-led adherence call could positively impact measures of persistence. While the adherence rates were insignificant due to the short duration of follow up, they suggest a more regular filling pattern. Additional studies should be conducted to expand these results.

References

1. Brown MT, Bussell J, Dutta S, Davis K, Strong S, Mathew S. Medication Adherence: Truth and Consequences. Am J Med Sci. 2016;351(4):387-399. doi:10.1016/j.amjms.2016.01.010
2. Mercadante AR, Lee S, Uh K, et al. Impact of adherence goal awareness intervention on PDC in various settings: Does awareness help modify medication-taking behavior?. Explor Res Clin Soc Pharm. 2021;4:100072. Published 2021 Sep 23. doi:10.1016/j.rcsop.2021.100072
3. Park H, Adeyemi A, Wang W, Roane TE. Impact of a telephonic outreach program on medication adherence in Medicare Advantage Prescription Drug (MAPD) plan beneficiaries. J Am Pharm Assoc (2003). 2017;57(1):62-66.e2. doi:10.1016/j.japh.2016.07.006
4. Rare disease day: Frequently asked questions. https://rarediseases.org/wp-content/uploads/2019/01/RDD-FAQ-2019.pdf. Accessed December 2, 2022.

Defining Rare Pharmacy®