Retrospective Analysis to Assess the Impact of the Use of a Medication-Adherence Smart Bottle on Clinical Outcomes in a Rare Disease Population

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Background

According to a 2018 U.S. National Center for Health Statistics survey, almost 38 million Americans over the age of 18 reported that they were limited in performing usual activities due to one or more chronic condition.[1] With these chronic conditions typically comes an array of medication regimens. There's a vast amount of research that has been conducted focusing on some of the most common chronic diseases such as hypertension, type 2 diabetes, and COPD.[2-4] It has been shown that medication adherence plays a pivotal role in improving clinical outcomes in patients affected by these chronic conditions. Similar statements could be said about patients suffering with rare diseases.

With over 7,000 rare diseases and a fraction of available treatment options, those living with a rare disease face a unique challenge.[5] Rare disease patients are among some of the most vulnerable. The path to diagnosis for these patients commonly includes psychological and physical obstacles. Often, when a diagnosis is finally made, patients are faced with the reality that there is little or no treatment options. This makes medication adherence in this population even more critical. However, adherence management strategies have received little attention in this population.

Objective

To determine if the introduction of a medication-adherence smart bottle improves proportion of days covered (PDC) and/or gap days in a rare disease population

Methods

PDC
- Proportion of days where a patient has medication on hand over a given time; minimum industry standard 180 days
- Calculated by taking the number of days with drug on hand divided by the number of days in a specified period

Gap Days
- Length of days that a patient does not have medication on hand based on shipment history
- Calculated by subtracting the medication exhaust date from the medication shipment date

Notification Status
- Type of notifications a patient is currently enrolled in, including a combination of lights, chimes, phone reminders, and feedback text messages

Cohorts

Intervention
Patients who opted into smart bottle program on or before July 2, 2021 and had at least 2 shipments; excluding patients discharged in that time frame

Control
Patients who chose not to use a smart bottle and had at least 2 shipments; excluding patients discharged in that time frame

Pre- Post
Patients from intervention cohort with at least 180 active days on therapy prior to first opt-in shipment with smart bottle

Results

Fig 1. Cohorts by Sex and Avg Age

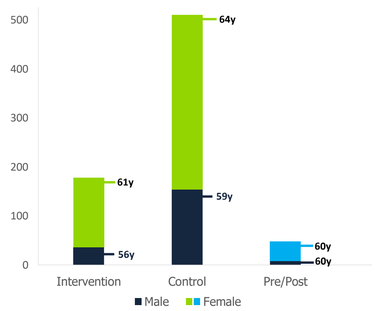


Fig 2. PDC above 80% by Cohort

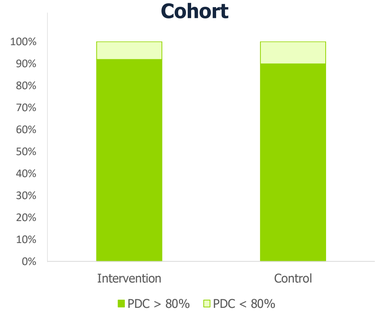


Fig 3. Intervention Notification Status

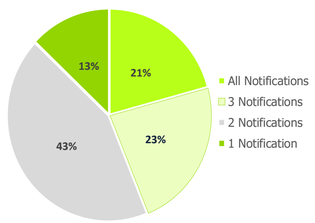


Fig 4. Pre/Post Notification Status

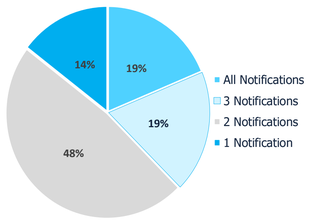
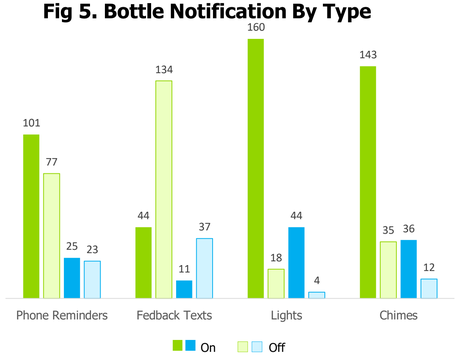


Fig 5. Bottle Notification By Type



Intervention vs. Control

Table 1. PDC Comparison between Intervention and Control Cohort by Dose

Proportion of Days Covered	Total		40 mg		60 mg		80 mg	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
n	178	510	51	138	10	34	117	338
Average PDC	94%	93%	95%	92%	93%	94%	94%	93%
P-value*	**0.0935**		**0.0684**		**0.3894**		**0.2082**	

Table 2. Gap Day Comparison between Intervention and Control Cohort by Dose

Gap Days	Total		40 mg		60 mg		80 mg	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
n	178	510	51	138	10	34	117	338
Average Gap Days Per Rx Per Patient	1.64	2.01	1.46	2.28	2	1.57	1.69	1.95
P-value*	**0.2617**		**0.2355**		**0.4348**		**0.3546**	

Pre-Post Analysis

Table 3. Change in PDC Grouped by PDC Prior to Intervention

Average PDC (n=48)	Before	After	Average Δ	P-value*
60-79% (n=4)	73%	91%	18%	< 0.00001
≥80% (n=44)	97%	98%	1%	0.11289
Total	**95%**	**97%**	**2%**	**0.0011**

* P-value derived from z-score value

Table 4. Change in Gap Days

Gap Days (n=48)	Before	After
Average Gap Days Per Rx Per Patient	1.48	0.83
Average Δ	0.65	
P-value*	**.094929**	

Discussion and Conclusion

The results of this retrospective analysis of the impact of a medication adherence smart bottle showed that there was not a significant difference when comparing the intervention and control group. In some cases, the control group performed better than the intervention. When interpreting these results, it should be noted that a large majority of these patients had higher adherence rates at baseline. Figure 2 shows that for both the intervention and control, at least 90% of patients had a PDC greater than 80%. This highlights the level of attention these patients receive.

The sub-analysis, however, revealed that patients with a lower PDC had a significant increase in PDC after receiving the intervention. This would suggest that this intervention should be targeted to patients with a below ideal PDC at baseline. The type of notification enrollment could also be considered. As noted in the methods, this system has a total of four different notifications. Figures 3-5 show that most patients utilize two of the four notifications. A breakdown of all the notifications is shown in Figure 6 and highlights that slightly more than half of the patients are enrolled in phone reminders and a small majority are enrolled in feedback text messages. In future research initiatives, it would be interesting to see if there is a difference between notification types and adherence rates.

This study was limited, not only by the time frame of 180 days, but the small patient population that were eligible. Ideally, these measures would encompass a years' worth of data and include more patients, but due to the time this program was implemented, that was not possible. With the program still on-going, it may be too early to see the true impact of this adherence tool.

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References

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