Impact of a Smartphone-Based Artificial Intelligence Platform on Hepatitis C Adherence in a Real-World Population

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Background

- There are an estimated 2.4 million people living with hepatitis C (HCV) in the United States.
- Although adherence to new regimens is typically quite good, non-adherence to treatment remains the biggest risk factor for treatment failure and thus a future need for retreatment.
- There has been research demonstrating that administration of directly observed therapy (DOC) have improved adherence in outcomes when used in other infectious diseases, however, managed care plans would be challenged to enact such a requirement across a population.
- Past research has also demonstrated that the use of an artificial intelligence platform (AIP*) embedded within a mobile app to digitally mimic DOC led to high rates of treatment completion and adherence levels in participating patients.
  - Digital tools that are able to accurately measure adherence in real-time, can also lead to more timely interventions to address adherence barriers.
- Despite this evidence, there remains limited research available on patient's willingness to use such a tool and how it would impact outcomes in a real-world population.
- To help answer this question, a pilot program was implemented in members initiating oral HCV therapy, in which members had the choice to use AIP* that visually and automatically confirmed participant identity, the medication, and medication ingestion.

Objectives

- The primary objective was to compare adherence to HCV drugs in members who agreed to use smart-phone-based AIP* compared to non-participants.

Methods

Pilot Study

- The pilot study was completed among commercial members with self-funded insurance who initiated HCV treatment (with ledipasvir/sofosbuvir, sofosbuvir/velpatasvir, or glecaprevir/pibrentasvir) between January 1, 2018 to September 30, 2018
  - Members beginning HCV therapy were identified using prior authorization data and received both telephonic outreach and mailings to register to use AIP*.
  - Members who agreed to participate were eligible to earn $5 for each daily dose taken within pre-set dosing window with additional monthly bonuses of up to $60 if they were at least 85% adherent during the preceding month.
- Members who registered were defined as participants, while members who were offered but did not register were defined as non-participants.

Methods continued

Retrospective Analysis

- Commercial pharmacy claims data from January 1st, 2018 to November 30, 2018 were used to assess adherence outcomes for participants and non-participants from the pilot study who had an initial HCV claim prior to September 1, 2018.
  - Participants and non-participants who were eligible for the pilot but did not initiate therapy prior to September 1, were excluded from the analysis to allow adequate time for therapy completion at the time of claims analysis.
- Adherence, measured as the proportion of days covered (PDC), was calculated for each member. The index date for the PDC calculation was the date of the first HCV claim, while the end date was the first claim date plus the recommended therapy duration. Statistical significance between participants and non-participants was calculated using a Wilcoxon-Mann-Whitney test.
- Demographic characteristics, including six month baseline medication adherence, was calculated and compared between the program participants and non-participates using either a chi-square test of association for categorical traits, or a Wilcoxon-Mann-Whitney test for continuous characteristics.
  - In order to be included in the baseline medication adherence calculations, members had to be continuously enrolled during the six month period preceding the first HCV claim, have two or more claims for the specific drug class of interest, with two or more different dates of service during the six month period preceding the first HCV claim.
    - Baseline medication adherence, defined as a PDC of 80% or greater, was calculated for the following chronic use drug classes: oral diabetic medications, beta blockers, calcium channel blockers, renin-angiotensin class drugs, and statins. The purpose of this measurement was to ensure that neither participants nor non-participants were inherently more likely to be adherent based on past medication use behavior.

Results of Pilot Study

Pilot Study: Engagement

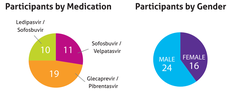
Status	Count
Participants	40 (52%)
Completed therapy using AIP[1][2]	38
Non-Participants	84 (68%)
Inactive[3]	15
Declined[4]	13
No Contact[5]	56

[1]Two patients that did not complete were due to loss of health plan membership
[2]Inactive defined as members who verbally enrolled but never used the app
[3]Declined defined as members who were contacted and verbally refused to participate
[4]No contact defined as members that were unable to be reached and did not respond to invitations to participate

AIP* by the Numbers

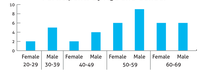
Data milestone	Stat
Pills expected (to be taken)	5,450
Pills visually confirmed by application	5,093
Number of patients >95% adherence	35/40
Number of patients enrolled	40
Number of patients who misused app ("red alert")	1
Percentage of doses taken within 4 hours of reminder time	97%
Percentage of doses taken within 5 hours of reminder time	98%

Participants by Medication

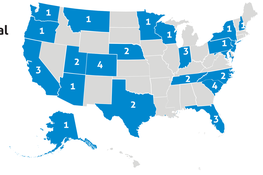


Participants by Gender

Participants by Age and Gender



Participants by Geograpical Location

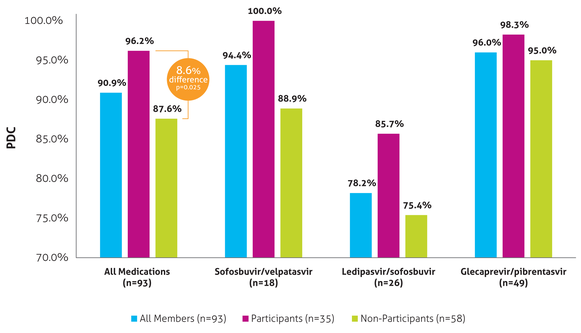


Retrospective Claims Analysis

Baseline Demographics

Baseline Characteristic	Participants	Non-Participants	p-value
n	35	58	
%Female (n)	37.14% (13)	48.28% (28)	0.295
Age - mean	52.74	50.62	0.515
Chronic Disease Score	2.77	2.61	0.320
Baseline – Percentage of Members that Achieved 80% Adherence Across all Chronic Conditions	40.00%	45.83%	0.755

Adherence: Participants vs Non-Participants



Discussion

- During the timeframe of the pilot study, 40 of the potentially eligible 124 members (32%) registered and initiated use of the AIP* during HCV treatment. However, it should be noted that the majority of non-participants were unable to be reached through multiple telephonic attempts. Outreach in certain instances was limited by missing or inaccurate phone numbers. If only members who were successfully contacted are evaluated, the participation rate increases to 59%.
- Among participants, the large majority were able to successfully use the AIP* without challenges with a reported adherence (based on doses successfully taking in the dosing window) of 98%.
- Of the 40 participants and 84 non-participants, 35 and 58, respectively were eligible for a retrospective claims analysis to compare PDC.
- The average PDC across the eligible sample was 90.9%.
- The observed PDC for HCV medications was statistically higher in the subset of members that participated in the pilot program (96.2%) compared to the subset of members that did not participate in the pilot program (87.6%) (p = 0.025).

Discussion continued

- When comparing adherence for specific HCV medications, higher medication adherence was observed in the subset of members that participated in the pilot across the three medication types, however, the observed difference was not statistically significant. Lack of statistical significance may be a result of lower power due to the decrease in sample size.
- Limitations of this study include:
  - PDC measurements may not be fully reflective of patient adherence. However, it should be noted that the PDC measured in participants was similar to that observed through the AIP.*
  - Its possible that monetary incentives may have contributed to increased adherence rather than use of AIP* solely. The design was not built to account for the impact of this possible contribution.

Conclusion

- Members utilizing a smart-phone-based AIP* demonstrated a statistically significant higher PDC to HCV drugs than non-participants.
- Although cure rate data was unavailable at the time of this analysis, it is reasonable to infer that higher adherence would lead to less treatment failures.
- Members agreeing to utilize the AIP* also demonstrated they were successfully able to navigate and use the AIP*-based application. An improved messaging campaign through the member's employee benefit with a lesser focus on incentives may have improved patient uptake and willingness to use the AIP*.
- Further study is warranted to determine the impact of the AIP* independent of monetary incentives, as well as in additional chronic disease states, as the monetary incentives used in this study may not be feasibly maintained across a large population.

References

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Disclosures

- This research was conducted by Magellan Rx Management, Scottsdale, AZ, without external funding.

*AIP refers to AiCure