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

Sam Leo, Kristin Gentry-Brown, Haita Makanjii, Karim Praslia, Lauren Poither, Steve Cutts

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 re-treatment.
• There has been research demonstrating that administration of directly observed therapy (DOT) has 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 monitor DOT led to high rates of treatment completion and adherence levels in participating patients.
  ▶ Digital tools that are able to accurately measure adherence in treatment; 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 smartphone-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, sofobuvir/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 windows with additional monetary bonuses of up to $60 if they were at least 85% adherent during the preceding month.
  ▶ Members who were offered but did not register were defined as non-participants.

Results of Pilot Study

Retrospective Analysis

• Commercial pharmacy claims data from January 1, 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 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 first day of the 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-participants 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 at least 60 days 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 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 their medication use behavior.

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 telephone call and text message 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, 33 and 58, respectively, were eligible for a retrospective claims analysis to compute 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 differences were 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*.
  ▶ It’s 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 smartphone-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

• Sarpal D. et al. Non-adherence is the most important risk factor for ledipasvir/sofosbuvir HCV treatment failure in the real world. ASLQ Liver Meeting Boston, November 11-15, 2016. Abstract 1978.

Disclosures

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

Retrospective Claims Analysis

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Participants</th>
<th>Non-Participants</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOB – female</td>
<td>69.0%</td>
<td>65.4%</td>
<td>0.295</td>
</tr>
<tr>
<td>DOB – male</td>
<td>31.0%</td>
<td>34.6%</td>
<td>0.295</td>
</tr>
<tr>
<td>Treatment [n=26]</td>
<td>Ledipasvir / sofosbuvir</td>
<td>84 (68%)</td>
<td>111 (82%)</td>
</tr>
<tr>
<td></td>
<td>Glecaprevir / pibrentasvir</td>
<td>4 (3%)</td>
<td>8 (6%)</td>
</tr>
<tr>
<td></td>
<td>Sofosbuvir / velpatasvir</td>
<td>18 (14%)</td>
<td>15 (12%)</td>
</tr>
<tr>
<td>Length of Therapy [n=111]</td>
<td>12 weeks</td>
<td>72 (65%)</td>
<td>59 (53%)</td>
</tr>
<tr>
<td></td>
<td>24 weeks</td>
<td>39 (35%)</td>
<td>52 (47%)</td>
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<tr>
<td>Material – Percentages [n=111]</td>
<td>Oral diabetic medications</td>
<td>96 (86%)</td>
<td>103 (84%)</td>
</tr>
<tr>
<td></td>
<td>Beta blockers</td>
<td>91 (82%)</td>
<td>100 (81%)</td>
</tr>
<tr>
<td></td>
<td>Calcium channel blockers</td>
<td>80 (72%)</td>
<td>92 (74%)</td>
</tr>
<tr>
<td></td>
<td>Renin-angiotensin class drugs</td>
<td>79 (71%)</td>
<td>89 (71%)</td>
</tr>
<tr>
<td></td>
<td>Statins</td>
<td>80 (72%)</td>
<td>92 (74%)</td>
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Chronic Disease Score

<table>
<thead>
<tr>
<th>Age - mean</th>
<th>Participants</th>
<th>Non-Participants</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>70.0%</td>
<td>87.6%</td>
<td>93.9%</td>
<td>0.025</td>
</tr>
<tr>
<td>70.0%</td>
<td>94.4%</td>
<td>96.2%</td>
<td>0.295</td>
</tr>
</tbody>
</table>

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