Preliminary cure rates from the national HCV pilot program in Vietnam

Thuy Cao1; Thu Nguyen1; Huyen Nguyen2; Dung Nguyen3; Caroline E. Boeke3; Jillian A. Sacks3; Jessica Tebor3; Christian B. Ramers3; Nguyen Van Kinh2
1. Clinton Health Access Initiative, Hanoi, Vietnam
2. National Hospital of Tropical Diseases, Hanoi, Vietnam
3. Clinton Health Access Initiative, Boston, USA.

INTRODUCTION
- HCV prevalence in Vietnam ranges from 0.3-4.7% in the general population, but is estimated to be higher in key populations.
- The majority of patients are infected with Genotypes 1 and 6.
- In 2017 Vietnam launched a pilot program in 5 hospitals (1 national, 3 provincial, and 1 district level) in 3 provinces to increase access to DAA treatment.
  - HIV or HBV co-infected patients, mono-infected patients with F3 and F4 fibrosis or with metabolic disorders (e.g., diabetes, dyslipidemia, high blood pressure), and healthcare workers are prioritized for treatment.
  - All facilities serve PLHIV; 2 sites—Nam Tu Liem and Hai Duong PAC—serve patients on methadone maintenance therapy; complex patients are referred from provincial / district sites to the national hospital.
  - Patients pay out of pocket for part of their treatment and diagnostics.

AIM
The aim of this analysis was to describe the patient cohort and real-world treatment outcomes for those initiating DAA in the first 2 months of the pilot.

METHOD
- The cascade of care from treatment initiation to cure was calculated from the aggregate data of patients initiating DAA in June and July 2017.
- Data was collected prospectively through paper records and analyzed for patients with SVR12 results as of April 2018.
- Treatment regimens and duration were determined by treating clinicians.
- Advanced fibrosis was defined as a Fibroscan >12.5 kPa, or APRI ≥2. All patients were staged using Fibroscan with the exception of patients at Hai Duong PAC, where APRI was used.
- All patients underwent a standard genotypic test.
- Side effects were determined using standardized patient questionnaires at each visit.

RESULTS
- In June and July 2017, 206 patients were initiated on treatment.
  - 99% of patients completed treatment with 2 LTFU / stopped treatment.
  - 162 patients presented for SVR12 at the time of analysis (Figure 1).
- Of the 162 patients with SVR12 results:
  - The genotypic breakdown was 55% GT1, 37% GT6, 2% GT2, and 2% GT3 (Figure 3).
  - 72% of patients were treated with SOF+DCV and 28% with SOF+DCV+RBV.
  - 92% of patients received 12 weeks of treatment; 11 patients were treated for 24 weeks, while 2 patients were treated for 16 weeks.
  - 33% of patients reported side effects during treatment; 59% of these patients reported side effects within the first 4 weeks.
  - 98% of patients in this sample achieved SVR12.

Table 1: Patient Demographics (N=162)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Participants, N [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Median Age 42.0; IQR 38.0-49.0</td>
</tr>
<tr>
<td>Male</td>
<td>140 (86%)</td>
</tr>
<tr>
<td>Female</td>
<td>22 (14%)</td>
</tr>
<tr>
<td>HIV Co-infection</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>112 (69%)</td>
</tr>
<tr>
<td>Injecting Drug User (Prior / Existing)</td>
<td>70 (43%)</td>
</tr>
<tr>
<td>Advanced Fibrosis</td>
<td></td>
</tr>
<tr>
<td>F4; Decompensated Cirrhosis</td>
<td>45 (28%); 2 (1%)</td>
</tr>
<tr>
<td>Treatment Facility Level</td>
<td></td>
</tr>
<tr>
<td>National</td>
<td>92 (57%)</td>
</tr>
<tr>
<td>Provincial</td>
<td>52 (32%)</td>
</tr>
<tr>
<td>District</td>
<td>18 (11%)</td>
</tr>
</tbody>
</table>

CONCLUSIONS
- Early analysis of Vietnam’s pilot program suggests that many patients, though completing treatment, are not returning promptly for SVR12 testing.
- Possible explanations include: high test cost, complex insurance logistics, test kit shortages, and patients assuming they are cured.
- Although subject to selection bias, it does not appear that SVR12 rates differ between national, provincial, and district hospitals. High SVR12 rates at district hospitals suggest that decentralization of HCV treatment may be feasible.
- High cure rates were observed using SOF+DCV to treat PLHIV, PWID, and patients with Genotype 6 infection.
- The current study adds to the limited publications of using SOF+DCV in Genotype 6 patients.

CONTACT INFORMATION
Thu Nguyen (tnguyen@ClintonHealthAccess.org)
Christian B. Ramers (cramers.IC@ClintonHealthAccess.org)