IS THE AVAILABILITY OF DIRECT ANTIVIRAL AGENTS (DDAs) ENOUGH TO TREAT CHRONIC HEPATITIS C (CHC) AND ACHIEVE HCV ELIMINATION AMONG PEOPLE WHO USE DRUGS (PWUD)? WHAT DO THE REAL WORLD DATA SUGGEST?

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Introduction

- Several prospective and post hoc analyses have clearly showed that PWUD with Chronic Hepatitis C (CHC) who are treated with DAAs achieve similar SVR rates with non-PWUD.
- PWUD usually are excluded from clinical trials while even after approval of the drugs, access to treatment for them is not guaranteed due to reasons related both to patients and providers.
- Expansion of DAAs availability in real life offers an opportunity to identify factors related to treatment acceptability, initiation and adherence of the affected population.

Methods and Materials

- We retrospectively analyzed data of a PWUD cohort with CHC in two OST clinics in Athens, with a total capacity of 400 patients: One buprenorphine clinic with a capacity of 130 patients and one methadone clinic with a capacity of 270 patients.
- DDAs were offered to all patients who fulfilled the current national reimbursement criteria. More specifically for the period from January 2016 to June 2017 treatment with DAAs was reimbursed by the National Health System only to patients with liver stiffness (F) ≥10kpa while after July 2017 and till the end of the study period (December 2017) the national reimbursement criteria were expanded allowing treatment for all HIV/HCV patients and for HCV monoinfected with F≥7kpa or concomitant extrahepatic manifestations.
- Treatment was provided by a multidisciplinary team: All patients visited hepatologist at outpatient Liver Unit while internist, nurse and therapist were located at the OST clinics.

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Results

- Overall 104 consecutive PWUD offered the opportunity to DAAs treatment after fulfilling the current national reimbursement criteria. Patients' characteristics are shown in Table 1.
- From the total number of 104 patients who were offered treatment, 71 (68.3%) initiated DAAs.
- Regimens were based on genotype and DAAs availability in Greece during the study period. More specifically 47 patients received sofosbuvir containing treatment (32 patients received VEL/SOF ± RBV, 10 received SOF + DCV±RBV, and 5 SOF/LDV ± RBV) while 16 patients received 2 or3D ± RBV and 3 EBR/GZR.
- Reasons for not initiating treatment are presenting in Table 2.

Table 1. Basic characteristics

Patients' characteristics	N(%) (Total n=104)
Gender, male	93 (89.4%)
Age (mean ± SD, years)	51 ± 9
Genotype	
1	18 (17.3%)
2	1 (1%)
3	50 (48%)
4	16 (15.4%)
Unknown	19 (18.3%)
Cirrhosis	47 (45%)
Fibrosis (median stiffness, kPa)	10.7
HIV positive	12.5%
Methadone/buprenorphine	69/35 (66%/34%)
Psychiatric co-morbidity	13 (12.5%)
Ongoing drug use	
None	27 (26%)
Opioids only	10 (10%)
Benzodiazepines ± Opioids	65 (62%)
Unknown	2 (2%)

Table 2. Reasons for not initiate DAAs

Reasons for not initiate DAAs	%
Patients' personal decision	51.5%
Patients **inability** to comply with the pretreatment procedures needed (i.e. come to the appointments for prescribing the drugs, go to the central pharmacy to obtain the drugs etc)	18,2%
Decision-making **physician** other than hepatologist (i.e. infectiologists for patients with HIV/HCV coinfection)	18.2%
Other health related priorities	6.1%
Imprisonment before treatment initiation	6.1%

- In the multivariate analysis treatment initiation was associated positively with cirrhosis (OR:4.81, 95%CI 1.72-13.48, p=0,003) and negatively with continuing use of benzodiazepines (BZ) with or without heroin (OR:0.26, 95%CI 0.07-1.00, p=0,049) (Table 3).
- Identification of factors affecting compliance was not possible due to small numbers of patients who discontinued treatment [8 / 71(11.3%): 6 patients' personal decision, 1 imprisonment, 1 no liver related death]

Table 3. Multivariable logistic regression analysis for treatment initiation

Factor	OR	95% C.I.	P value
Cirrhosis	4.81	1.72-13.48	0.003
Ongoing drug use			
Opioids (only)	0.40	0.06-2.66	0.345
Benzodiazepines±Opioids	0.26	0.07-1.00	0.049

Conclusions

Our real life data confirmed that:

- ✓ A proportion of PWUD with CHC do not initiate treatment despite DDAs availability.
- ✓ More efforts are needed to improve acceptance of treatment among PWUD.
- ✓ Factors related with ongoing drug use may affect negatively the final uptake of DAAs suggesting that a more flexible, simplified and patient friendly approach is necessary in order to increase treatment initiation.
- ✓ Indentifying factors affecting treatment acceptability and adherence might help in planning targeted actions in the context of the HCV microelimination strategy.