PO3/02

Pilot study of a simplified HCV management algorithm in Opioid Agonist Treatment clinics in Ukraine

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Introduction

HCV remains one of the leading infectious disease-related causes of death. In 2017, it was estimated that 3,7% of the population of Ukraine was infected with HCV. Of those infected, only 6% were registered in medical care, and about 2,5% were fully diagnosed and were on the waiting lists at regional health authorities. Availability of HCV treatment in Ukraine was growing steadily. These medications were distributed to specialized infectious disease hospitals, which diagnosed and registered patients and managed the waiting lists. It is well known that people who inject drugs (PWID) have high burden of HCV and due to multiple individual and structural barriers suffer from suboptimal access to accessing life-saving treatments.

Objectives

HCV prevalence among patients receiving opioid agonist treatment (OAT) in Ukraine is 83%. HCV diagnostics and treatment in Ukraine is provided by specialized infectious diseases clinics. Due to stigmatization from medical providers, lack of free medications, and high cost of laboratory tests people with history of injecting drug use are usually not included in the DAA waiting lists. A feasibility study of a Simplified HCV Integrated Management (SHIM) algorithm in OAT clinics in Ukraine was piloted in 2021. For the pilot phase of the project the Lviv Center for Prevention and Therapy of Substance Dependence (Lviv, Ukraine) was chosen. The main criteria were the willingness of the administration to participate in the project and readiness to accept medications for treatment. Clinical staff participated in two introductory online ECHO sessions on viral hepatitis treatment. The preparatory phase of the project included organization of re-distribution of medications from the regional specialized institutions to the study site with facilitation at the national level.

Methods

SHIM algorithm included: 1) Diagnosis confirmation (PCR test); 2) Minimum of pretreatment evaluation (no genotyping and invasive methods); 3) Prescription of pan-genotypic treatment regimens at OAT clinic; 4) On-site treatment monitoring (adherence, side effects, drug interaction assessment), counseling by OAT staff; 5) Sustained virologic response (SVR) confirmation.

Costs of the laboratory tests were not covered, medications were provided for free. Quantitative and qualitative data were collected.

Quantitative data collection included:

1) a structured questionnaire (using the online REDCap platform at enrollment, post-treatment completion and SVR12 assessment)

2) paper-based adherence assessment questionnaire (at treatment initiation, 4, and 8, and 12 weeks after initiation). Treatment adherence assessment forms were also entered into the REDCap retrospectively.

Qualitative data collection included conducting:

1) two focus groups (FG) with 10 program participants each. First FG took place at the baseline (soon after participants had started treatment); second FG was conducted in 3 months

2) in-depth qualitative interviews with 4 health providers at the OAT clinic at baseline and in 3 months: the Narcology Clinic Director, an Infectionist who provided hepatitis C treatment to the participants, a Physician Narcologist, and a Nurse at the OAT site.

IRB: The protocol and informed consent forms were approved by UIPHP IRB#1 on 22 February 2021 (official IRB registration – IRB#00007612, FWA #00029648)

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Results

Out of 32 OAT patients recruited to the pilot study, diagnosis was confirmed in 27 patients, 3 did not start treatment (1 dropout, 2 consent withdrawals).

Of all 24 patients who started treatment, 23 (96%) were men. Median age was 39 years, 79% had injection duration (before starting OAT) of more than 10 years, 83% had college education or higher, 29% were unemployed, and 42% were living with a spouse or partner. At baseline, 19% reported opioid use in the past 30 days, 13% used stimulants, and 25% used other types of drugs without prescription. Overall, 34% were injecting drugs in the past 30 days.

Figure 1. Study enrollment and HCV treatment cascade.

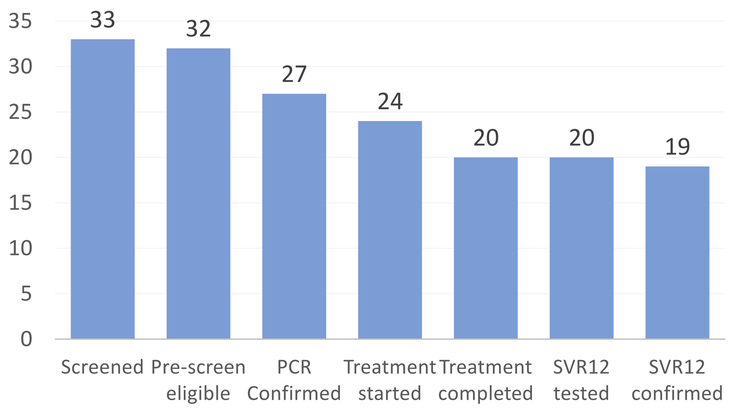


Figure 2. Quantitative data collection.

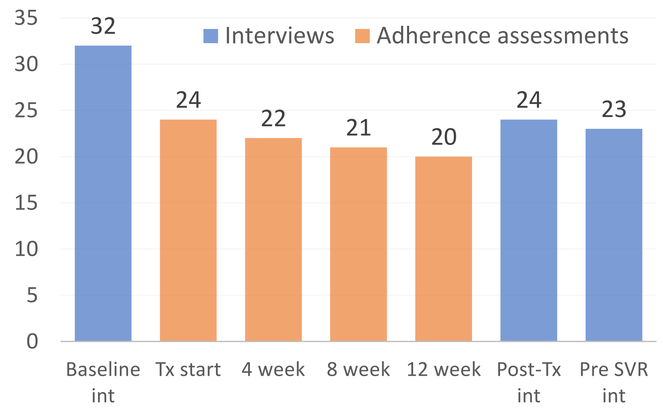
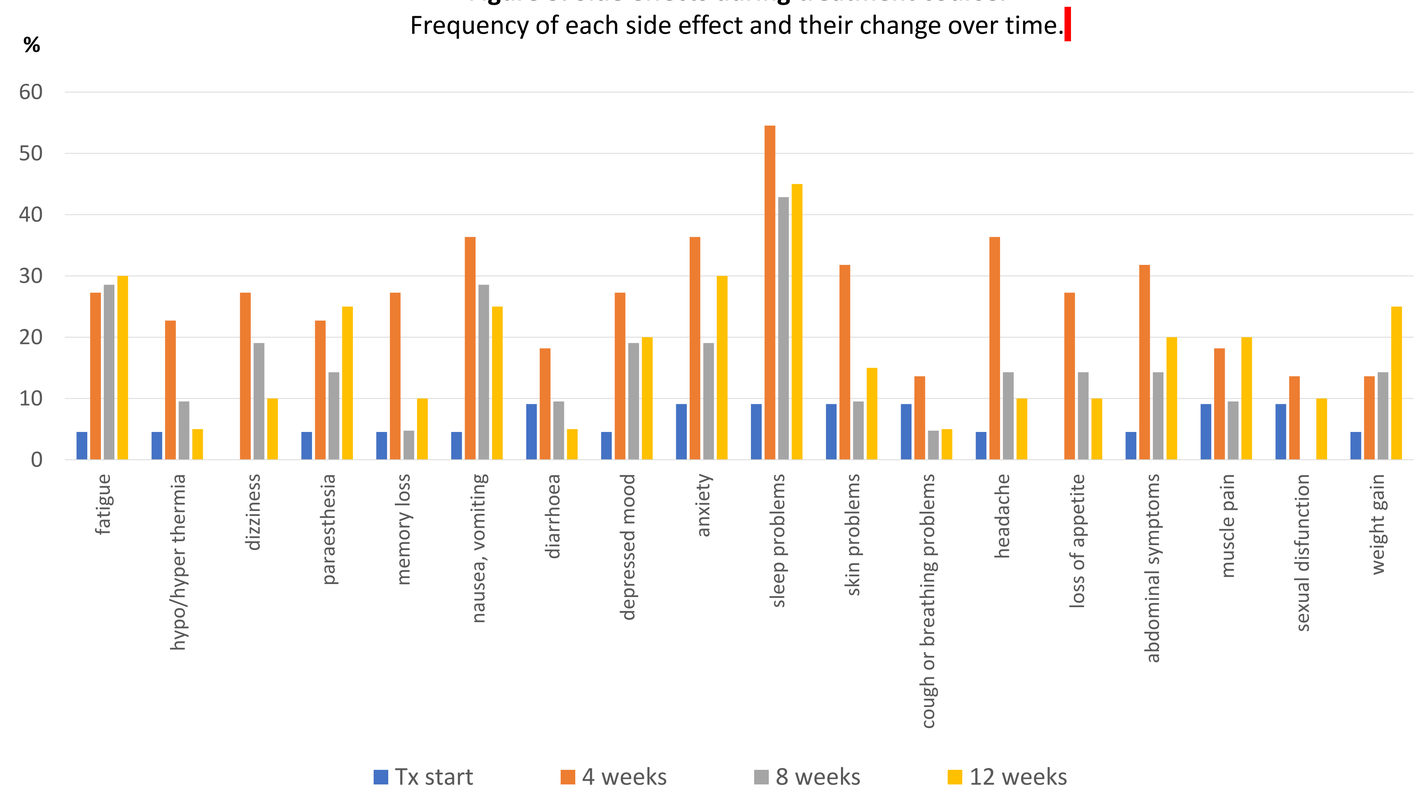


Figure 3. Side effects during treatment course.
Frequency of each side effect and their change over time.



23/24 who started treatment (96%) considered the opportunity to treat HCV in OAT clinic very valuable and the attitude was cited as “a good fortune”.

> ***P1**: I realized at once that we were lucky.*
> ***P2:** There is a good opportunity to be cured. Cured!*
> ***P3:** My brother in Italy was treated with the same medicines. He was cured. Accordingly, I was interested.*
> ***P1:** I've heard that 95% patients recover.* **(FG 1)**

The same 23 patients expressed high confidence in their ability to comply with treatment regimen, and considered the OAT clinic as the optimal place to receive HCV medications (no one preferred a specialized or primary care clinic - “we are just nothing to them”).

> *Previously, to cure hepatitis C, you had to go to your family doctor, then you were sent to an infectionist. And then the labyrinth begins, running in a circle. The one analysis is needed, then another one, then you have to negotiate with the doctor, to beg him. And he was like: "Oh, I don't know whether there is a place for you..."* **(FG 2)**

Treatment completion was 83% (20/24; 2 died to COVID-19 and an accident, 2 dropouts), SVR was achieved in **95%** (19/20).

Conclusions

The first stage of the project was successful in demonstrating the feasibility of SHIM integration in OAT clinics in Ukraine. The availability of free HCV treatment at the OAT site significantly increases the access to this life-saving treatment, improves the attractiveness of the OAT programs. The clinical effectiveness of HCV treatment using the SHIM model in the pilot sample was high and comparable to other studies. A definitive trial with a larger patient sample was needed to confirm these results and recommend dissemination.