Scaling up Accessible and Effective HCV Treatment through Community-based Treatment Model for Most Vulnerable Populations in the Resource Constrained Ukraine

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Alliance for Public Health
Epidemiological Background (Ukraine)

Population: 42 590 879 million

- WHO estimates 3% of HCV prevalence in Ukraine (1 280 000)

- According to official web of the Cabinet of Ministers national epidemiologists estimate HCV prevalence in Ukraine at around 7-9% of general population (2 980 000-3 830 000 individuals)

- According to the Center of Medical Statistics of the Ministry of Health of Ukraine number of HCV patients in 2016 reached 46 883

- In 2016 among new cases of HIV-infection (n=14 334) Viral Hepatitis C Markers were detected in 21.5% of cases (n=3080)

- 30 826 persons were HIV/HVC co-infected as of January 1st, 2017

- HCV prevalence rate among PWID in Ukraine exceeds overall average, reaching 56% (2015, Alliance bio-behavioral research)

- Estimated number of PWID in Ukraine is 346 900

- Estimated number of PLWH 238 000
### Overview of Alliance Activities Aimed at Increasing Access to HCV/HBV Diagnostics and Treatment among MARPs:

<table>
<thead>
<tr>
<th>Year</th>
<th>Events</th>
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<tbody>
<tr>
<td>2009</td>
<td>• HBV and HCV rapid testing and HBV vaccination interventions incorporated into HIV prevention services package</td>
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<td>2012</td>
<td>• National advocacy campaign “Demand Treatment” with RDT launched among general population (9,6% positive results)</td>
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<td>2013</td>
<td>• “National Program on HBV and HCV Diagnostic and Treatment” advocated and drafted with Alliance input; approved by the Government (state budget funding at the amount of 34 mln hryvna)</td>
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<td>2014</td>
<td>• Reduction in ribavirin and PEG-interferon pricing advocated (2,5 times less - from $ 13 200 to $ 5 000), treatment for more than 150 OST HIV+ patients • Alliance advocated and negotiated DAAs price reduction for Ukraine</td>
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<td>2015</td>
<td>• Alliance behavioral research on HIV prevalence among PWID and their partners proved 56% HCV prevalence among PWID • Project on HCV treatment with DAAs among MARPs launched • Sofosbuvir based regimens incorporated in National Clinical Guidelines for Hepatitis C treatment</td>
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<td>2016</td>
<td>• Designed model of community-supported DAAs-based HCV treatment for key groups successfully implemented • Sofosbuvir/ledipasvir - based regimens incorporated in National Clinical Guidelines for Hepatitis C treatment</td>
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<td>2017</td>
<td>• Project on HCV treatment with DAAs among MARPs started treatment with Harvoni</td>
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Project start: April 2015

Geographic coverage: starting from 8 healthcare facilities in 7 regions of Ukraine the Project is expanded for 25 medical settings in 19 oblasts of Ukraine

Main objectives:

• Implementation of community-supported DAAs-based HCV treatment model for MARPs

• Access to laboratory diagnostics (treatment monitoring and follow-up)

• Operational research “Effectiveness of HCV Treatment Program for MARPs in the Resource Constrained Ukraine”

Key populations: PWID, OST, CSW, MSM.

Inclusion criteria: Fibrosis ≥ F2 (priority F3, F4), METAVIR
Multidisciplinary Approach to Patient Oriented Integrated Services

**Services before Treatment**
- Informing on the program
- Testing and examinations
- Communicating doctor/HCF
- Counseling on treatment regimens and possible side effects
- Linking ART and OST

**Doctor & Nurse**
- Consultations
- Diagnostics
- Administering treatment
- Dispensing medicines
- Clinical monitoring
- Laboratory monitoring

**Social Support at the Time of Treatment**
- Counseling
- Scheduling visits to doctors
- Prevention of re-infection sessions
- Linking ART and OST (if necessary)

**Case Manager**

**Patient**
Community-based treatment model

- Counseling before treatment
- Doctor’s examinations and consultation
- Laboratory diagnostics and examinations
- Treatment/regimen identification
- Social support, re-infection prevention
- Treatment laboratory monitoring
- End of treatment
- Treatment results (SVR12)
- Involvement of patients from harm reduction & OST sites and medical facilities

Multi-disciplinary team
Interventions of HCV Re-infection Prevention

3 sections:

1. Referral, linkage and access to harm reduction program:
   • Needles, Syringes Program (NSP)
   • Opioid Substitution Treatment (OST)
   • Condoms Distribution (CD)

2. Safe health behavior intervention aimed at raising awareness on HCV risk factors and adherence to treatment:
   • Informational sessions on HCV transmission
   • Breaking myths about HCV treatment
   • Filling in HCV awareness gaps

3. Communications with relatives, partners, friends
   • Informational sessions on HCV transmission
Laboratory Diagnostics & Laboratory Monitoring

4500 Diagnostic Forms
Distributed before treatment:
50% discount on hepato-panel
at SYNEVO

3270 TESTS
Treatment monitoring:
HCV viral load FREE
HCV Treatment Project Coverage (I, II, III phase)

Enrolled in Phase I, II, III

New regions enrolled in Phase III

Not involved
HCV Treatment Project: *plan and fact*

![Bar chart showing planned, recruited on Sovaldi, and recruited on Harvoni numbers for different phases.](chart.png)

- **Phase I (completed)**: 250 (Planned), 450 (Recruited on Sovaldi), 0 (Recruited on Harvoni)
- **Phase II (completed)**: 500 (Planned), 757 (Recruited on Sovaldi), 0 (Recruited on Harvoni)
- **Phase III (ongoing)**: 750 (Planned), 226 (Recruited on Sovaldi), 431 (Recruited on Harvoni)
As of July 1st, 1870 patients involved in treatment (out of them are 28 retreated after virological failure or treatment termination within the Project):

- 30 (1,6%) patients terminated treatment
- 1441 (77.1%) patient finished full treatment course
- 399 (21.3%) patients continue treatment
- 1130 of those, who finished full treatment course, have received HCV RNA test result within 12W after end of treatment and 1067 (94.4%) had SVR12
**Cohort Data (n=1870)**

- **Male**: 72% (n=1346)
- **Median age, years**: 39
- **HIV/HCV**: 74.5% (n=1393)
- **Out of them receive ART**: 97% (n=1353)
- **HCV/HBV**: 9.2% (n=173)
- **HIV/HCV/HBV**: 8.5% (n=158)
- **TB in treatment history**: 20.7% (n=388)

**MARPs distribution**

- **PWID (n=1343)**: 71.81%
- **PWID OST (n=163)**: 4.33%
- **PWID Partners (n=149)**: 7.97%
- **CSW (n=81)**: 8.72%
- **MSM (n=68)**: 3.64%
- **Others* (n=66)**: 3.53%

* Others = PWID rights advocates, war veterans and military forces servicemen
**HCV Treatment Project: Cohort Data (n=1870)**

### Distribution by Genotype

- **G1** (n=1016): 54.33%
- **G2** (n=79): 4.22%
- **G3** (n=758): 40.54%
- **G4** (n=9): 0.48%
- **Not detected** (n=6): 0.32%
- **Mixed** (n=2): 0.11%

### Distribution by Fibrosis

- **F1** (n=103): 5%
- **F2** (n=872): 47%
- **F3** (n=490): 26%
- **F4** (n=405): 22%
HCV Treatment Project Outcomes

- Designed model of community-supported DAAs-based HCV treatment for key groups successfully implemented in 25 health care facilities in 19 oblasts of Ukraine

- Increased accesses to treatment (against initially determined) resulted from successful cooperation with government

- Sofosbuvir and sofosbuvir/ledipasvir based regimens incorporated in National Clinical Guidelines for Hepatitis C Treatment and included in the list of drugs for the state procurement

- Medical staff gained unique experience to treat key groups with DAAs

- Ongoing operational research will evaluate effectiveness of HCV Treatment Program (sample size 750 persons)
  - Effectiveness of HCV treatment program as such
  - Effectiveness of the community-based model of care
  - Effectiveness of treatment regimens based on Sovaldi and Harvoni
Viral Hepatitis Focus: Next Steps towards Elimination

- Political Commitment and Good Governance for Financial Sustainability

- Country Strategic Document based on the Action Plan for the Health Sector Response to Viral Hepatitis in the WHO European Region

- Robust Surveillance

- Transparency in Price Reduction and State Procurement

- Human Rights Protection (key and prison populations equity in access to affordable services)

- Partnerships: GF, donor and CCM broader mission in Viral Hepatitis Control
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Thank You

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