Introduction of Sofosbuvir based HCV treatment in Ukraine

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<table>
<thead>
<tr>
<th>Speaker Name</th>
<th>Statement</th>
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<tbody>
<tr>
<td>Sergii Filippovych</td>
<td>As a part of expanding access to treatment of hepatitis C from April 2015, the ICF «International HIV/AIDS Alliance in Ukraine» is implementing the project «Scaling up accessible and effective HCV treatment through community-based treatment model for most vulnerable populations in the resource constrained Ukraine». Alliance Ukraine has received a grant from Gilead Sciences Inc. to finance the implementation of the project. It should be noted that Sergii Filippovych has no personal interest in the grant of Gilead. Salary for his work in Alliance Ukraine is not paid from the budget of the Gilead project.</td>
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Date 1/12/2015
Population: 43 million

218,000 HIV-positive people or 0.58% of estimated adult prevalence (2015, Bul. #44)

**HCV/HIV co-infection** is registered in 38.4% among all new registered HIV cases (2014, Bul. #43)

**124,279 PLWH** currently under medical supervision in AIDS clinics (2015, does not include AR Crimea)

The epidemic is driven primarily by injecting drug use, although heterosexual transmission also plays an important role.

Estimated # of PWID in Ukraine is 310,000, Main injectable drug of abuse – home-made acetylated poppy straw extract (opioid)

PWID receiving **OST** - 8 385 (55% HCV positive, n=4 606)

**HCV** prevalence among **PWID** is 55% (AU, BBS 2013)

**HCV** prevalence among **CSW** is 13% (2014, Bul. #43)
The results of the express Hepatitis C testing in the Ukrainian towns within the framework of all-Ukrainian «We demand Treatment!» campaign

July 2014

Reference designations

8.8% % of positive results' rate from the total amount of those who had testing

*regions, where testing hadn't took place
October 2013 – introduction of HCV treatment with pegylated interferons for HIV positive OST patients

December 2014
- 135 patients out of them:
  - 119 – ART+OST (57% methadone, - 43% buprenorphine)

Genotyping: 1\textsuperscript{st} - 56%
2\textsuperscript{nd} - 6%
3\textsuperscript{rd} - 38%

33% - undetected HCV RNA at week 24 with 1, 2 and 3 genotypes
42% of patients drop out of the treatment

Reasons for discontinuation of treatment
Scaling up accessible and effective HCV treatment through community-based treatment model for most vulnerable populations in the resource constrained Ukraine

**Overall goal:** to ensure access to HCV treatment for Most at Risk Populations and develop innovative community based service delivery models to include medical and social support of treatment with Directly Active Antiviral (DAA) regimen.

**Main activities:**

- Organization of medical and social support for patients receiving Sofosbuvir based HCV treatment
- Trainings for medical and social staff
- Laboratory diagnostics for treatment monitoring and follow-up
- Operational research to identify the most effective model
- Integration of Sofosbuvir into National HCV treatment protocol
Launching Sofosbuvir based HCV treatment

**Project start:** April 2015

**Implementation plan:**
- Phase 1 – **250**, 8 healthcare facilities
- Phase 2 – **500**, 17 healthcare facilities
- Phase 3 – **750**, to be selected

**Phase 1 results:**
- Training for medical and social staff
- Laboratory monitoring of the HCV treatment (HCV RNA Quantitative) with provision of the 50% testing discount
- Cooperation with MoH on Peginterferon allocation for the Project from the National HCV Program
- Social support to the patients during the treatment
- Inclusion of the Sofosbuvir in the national clinical protocol
Integrated care model

Integrated Care Center

HIV/AIDS diagnostics and treatment

Case Manager

OST

Hepatitis diagnostics and treatment

NGO/MPSS for OST

NGO/HR

NGO/prevention, harm reduction
Inclusion criteria phase 1:

- HIV/HCV Confection (250)
- ≤F2, F3-F4 METAVIR
- PWID, OST, other MARPs, receiving ART

**Treatment regimens:**

<table>
<thead>
<tr>
<th>Group of patients</th>
<th>Treatment regimen</th>
<th>Treatment duration</th>
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<tbody>
<tr>
<td>Genotype and 4</td>
<td>sofosbuvir + ribavirin + Peg-IFN-alpha</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Genotype 2</td>
<td>sofosbuvir + ribavirin</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Genotype 3*</td>
<td>sofosbuvir + ribavirin + Peg-IFN-alpha</td>
<td>12 weeks</td>
</tr>
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* In exceptional cases, for HCV genotype 3: without cirrhosis and / or with absolute contraindication to PEG-IFN-alpha, possible regimen is sofosbuvir + ribavirin for 24 weeks.
Enrollment rates, Phase I

- **# of patients**
- **# completed treatment**

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<thead>
<tr>
<th>Month</th>
<th># of patients</th>
<th># completed treatment</th>
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<tbody>
<tr>
<td>June</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>July</td>
<td>85</td>
<td></td>
</tr>
<tr>
<td>August</td>
<td>129</td>
<td></td>
</tr>
<tr>
<td>September</td>
<td>172</td>
<td>29</td>
</tr>
<tr>
<td>October</td>
<td>214</td>
<td>78</td>
</tr>
<tr>
<td>November</td>
<td>271</td>
<td>125</td>
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<tr>
<td>Target</td>
<td>250</td>
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Patients' characteristics (1)

- **Genotype 1**
  - F4 (A): 14%
  - F3: 21%
  - F2: 49%
  - F1: 16%
  - Total: 100%
  - Count: 57

- **Genotype 2**
  - F4 (A): 27%
  - F3: 33%
  - F2: 33%
  - F1: 7%
  - Total: 100%
  - Count: 15

- **Genotype 3**
  - F4 (A): 21%
  - F3: 25%
  - F2: 34%
  - F1: 21%
  - Total: 100%
  - Count: 53
98% patients have HIV/HCV co-infection
91% out of HIV/HCV are receiving ARV treatment
6 OST patients

Results:
Overall 125 – have completed HCV treatment
112 patients have received HCV RNA test result
111 have undetected HCV RNA result End of Treatment (EOT)

SVR 12 W:
1 patient – G1, F 4 (A), experienced (SOF+PEG+RBV, 12 W)
1 patient – G3, F 4 (A), naïve (SOF+PEG+RBV, 12 W)
Challenges:
• Financial burden of the pretreatment diagnostics for MARPs patients
• Strong beliefs among patients related to the HCV treatment such as “not effective”, “accompanied by lots of side effects”

Lessons learned:
• Sofosbuvir based HCV treatment in PWID cohort has shown high retention rate and treatment adherence
• 99% of all patients who have completed 12w HCV treatment course have undetected HCV RNA at the End of the Treatment

Next steps:
• Launching Phase 2: scale up for 17 healthcare facilities, 689 treatment courses
• Operational research on the Sofosbuvir based treatment program
• Continue building capacity of the healthcare institutions by establishing cooperation with community based NGOs, provision of trainings for medical staff
Thank you!

– Dr. Sanjay Bhagani
– Dr. Karine Lacombe
– Dr. Jonathan Schapiro
– T. Barnard
– O. Burgay

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