ACCESS AND IMPLEMENTATION OF IFN-FREE THERAPY IN PEOPLE WHO INJECT DRUGS: WHERE TO FROM HERE FOR LOW AND MIDDLE INCOME COUNTRIES

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Médecins du Monde
Outline

Part 1: HCV burden in LMICS and PWID
Part 2: The reality of access in LMICs
Part 3: Case exemple: Georgia
HCV burden in LMICs

- 184 millions people with anti-HCV antibodies, 85% in LMICs

*Burden of disease world map (by MdM, 2015) according to the absolute number of HCV cases (from Lavanchy, CMI, 2011)*
HCV burden among PWID

- 12.19 million (range: 8.48-21.46 million) PWID worldwide
  (UNODC/WHO/UNAIDS/World Bank 2013)

- HCV antibody mid-point prevalence worldwide 67.5% (Nelson, Lancet, 2011)

- PWID-HCV+: 26% live in East/South-East Asia and 23.5% in Eastern Europe (Nelson, Lancet, 2011)
HCV burden in LMICs

- **Georgia**: 0.14 million (25.6% of PWIDs)
- **Ukraine**: 1.1 million (21.5% of PWIDs)
- **Russia**: 4.1 million (40.4% of PWIDs)
- **Myanmar**: 0.64 million (5.6% of PWIDs)
- **Indonesia**: 1.4 million (2.7% of PWIDs)
- **Vietnam**: 2.7 million (9.2% of PWIDs)

(Number of adults with HCV antibodies compared to PWIDs)

*(Luhmann et al. IJDP. 2015)*
The reality of the response

Knowledge from HIV field: Very limited prevention and treatment access for PWID in general

Example East and South East Asia and Eastern Europe (Mathers B et al. 2010, Lancet):

- Percentage of PWID accessing NSP:
  - E/SE-Asia: 7% (6–9); EE 10% (7 – 15)
- Needles and syringes distributed per IDU per year:
  - E/SE-Asia: 30 (7–68); EE: 9 (7 – 14)
- Number of OST recipients per 100 PWID:
  - E/SE-Asia 4 (2–8); EE: 1 (<1 to 1)
- Ratio of PWID receiving ARV/PWID living with HIV:
  - E/SE-Asia 4 (2-8); EE: 1 (<1 to 44)

The right of PWID to HIV prevention, care and treatment has not been respected internationally and especially in LMICS.
HCV treatment access in LMICs is very limited until now

<table>
<thead>
<tr>
<th>Country</th>
<th>Estimated number of viraemic adults</th>
<th>Number of adult patients treated in 2013 (yearly treatment uptake in %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Georgia</td>
<td>106,412</td>
<td>550 (0.52%)</td>
</tr>
<tr>
<td>Ukraine</td>
<td>834,072</td>
<td>900 (0.11%)</td>
</tr>
<tr>
<td>Russia</td>
<td>3,032,392</td>
<td>9,500 (0.31%)</td>
</tr>
<tr>
<td>Myanmar</td>
<td>476,803</td>
<td>1,000 (0.21%)</td>
</tr>
<tr>
<td>Indonesia</td>
<td>1,007,022</td>
<td>350 (0.03%)</td>
</tr>
</tbody>
</table>

(Luhmann et al. IJDP. 2015)
Treatment access in LMICs is very limited - Especially for PWID

<table>
<thead>
<tr>
<th>Country</th>
<th>% of PWID among the patients treated (% of PWID among the HCV+)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Georgia</td>
<td>20-30% (25.6%)</td>
</tr>
<tr>
<td>Ukraine</td>
<td>10-20% (21.5%)</td>
</tr>
<tr>
<td>Russia</td>
<td>&lt;1% (40.4%)</td>
</tr>
<tr>
<td>Myanmar</td>
<td>1-5% (5.6%)</td>
</tr>
<tr>
<td>Indonesia</td>
<td>1-5% (2.7%)</td>
</tr>
</tbody>
</table>

*(Luhmann et al. IJDP. 2015)*
Registration status worldwide of Sovaldi® and Daklinza®

Countries where Sovaldi® is registered
Countries where Daklinza® is registered
Countries where Daklinza® & Sovaldi® are registered
High income countries

September 2015
Obstacles to treatment for PWIDs in RLSs

- Exhorbitant prices

**Costs of diagnostics in USD in 5 selected countries of Eastern Europe and Asia in 2014**

- **Georgia**: $310 (Gross National Income per capita per month), $510 (Cost for antibody test + viral load + genotype + fibroscan)
- **Ukraine**: $297 (Gross National Income per capita per month), $210 (Cost for antibody test + viral load + genotype + fibroscan)
- **Russia**: $280 (Gross National Income per capita per month), $1100 (Cost for antibody test + viral load + genotype + fibroscan)
- **Myanmar**: $105 (Gross National Income per capita per month), $420 (Cost for antibody test + viral load + genotype + fibroscan)
- **Indonesia**: $302 (Gross National Income per capita per month), $600 (Cost for antibody test + viral load + genotype + fibroscan)
## Obstacles to treatment for PWIDs in LMICs

National policies on HCV often omit to mention PWIDs

If not explicitly excluded!

<table>
<thead>
<tr>
<th></th>
<th>Georgia</th>
<th>Ukraine</th>
<th>Vietnam</th>
<th>Russia</th>
<th>Myanmar</th>
<th>Indonesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Existence of a national policy plan for viral hepatitis or HCV?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Prevention strategies for PWID</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>-</td>
<td>Yes</td>
</tr>
<tr>
<td>Treatment inclusion of PWID</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>-</td>
<td>No</td>
</tr>
</tbody>
</table>

(Luhmann et al. IJDP 2015)
MdM work in Georgia

- Population: 3.8 Million
- Around 40,000 PWIDs in the country (*Bemoni Public Union, 2009 report*)
- Around 5-7% of Georgians carry HCV antibodies (*Butsashvili et al. Occupational Medicine, 2012*)

Harm reduction project in partnership with a Georgian peer-support organization – New Vector (since 2011):

- Drop In Center / Outreach work
  - NSEP, health education, HIV and VH testing, psychological and dental care
  - Focus on HCV: testing, fibrosis assessment, secondary prevention, treatment preparation
- Advocacy efforts for access to rights and to health care for PWID

International Symposium on Hepatitis Care for Substance Users
Sydney 2015
# MdM work in Georgia

**Treatment need study 2012 in collaboration with Health Research Union and New Vector**

**RDS survey among 217 PWID (2012)**

<table>
<thead>
<tr>
<th>HCV Prevalence, Severe Liver Fibrosis, Genotype Distribution Among PWID</th>
<th>N</th>
<th>Prevalence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV antibodies</td>
<td>199</td>
<td>91.9</td>
</tr>
<tr>
<td>Current infections</td>
<td>180</td>
<td>82.0</td>
</tr>
<tr>
<td>Among current infections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe liver fibrosis</td>
<td>40</td>
<td>24.2</td>
</tr>
<tr>
<td>Genotype 1</td>
<td>32</td>
<td>22.0</td>
</tr>
<tr>
<td>Genotype 2</td>
<td>42</td>
<td>20.3</td>
</tr>
<tr>
<td>Genotype 3</td>
<td>126</td>
<td>66.9</td>
</tr>
<tr>
<td>Mixed genotype</td>
<td>20</td>
<td>10.4</td>
</tr>
</tbody>
</table>

≈ 5,000 PWID in Tbilissi alone (and 7,900 PWID in the country) chronically infected with severe liver fibrosis requiring immediate treatment

Yearly HCV incidence = 16% [11-22%] (Modeling based on age-specific prevalence data)

*(Bouscaillou et Al. IJDP 2014, Incidence modeling by Kévin Jean, Department of Infectious Diseases Epidemiology, Imperial College, London)*

International Symposium on Hepatitis Care for Substance Users Sydney 2015
Georgian MoH publicly acknowledged that HCV is a main public health problem.

GF: free treatment for HIV/HCV

HCV Treatment program in prison

Announcement of tender and achievement of 60% discount on dual therapy medications (pegINF+RBV) – small increase in access

Discussion about elimination program supported by US-CDC - Launch of the elimination program
National elimination plan 2015-2020

Objective: Georgia HCV-free zone through universal access to prevention, diagnosis and treatment

- Since May: Phase I – 5,000 treatments for patients (F3-F4):
  - Treatment by Sofosbuvir-RBV +/- PegInf according to the genotype in authorized centers
  - Funding by government (30% of testing + follow-up), Cities (PegInf/Riba) and patients (70% of testing and follow-up)

- Population based prevalence survey (7,000 people)
- Inclusion of PWIDs as target group (after negotiations)
MdM work in Georgia

Since May 15th = treatment programme with and for PWID

Objectives:

- Facilitating PWIDs access to and retention in the national program
- Overcoming providers and PWID concerns about HCV treatment (enhance uptake, adherence, prevent reinfections)
- Being affordable and easy to scale-up
- Producing evidence that PWID treatment in Georgia is feasible, effective and affordable: primary endpoint is SVR 12

Program is designed and implemented with our partner organizations NV and HRU

International Symposium on Hepatitis Care for Substance Users Sydney 2015
Georgia: model of care for PWID

PRE SCREENING
- Selection of eligible patients
- Face-to-face interview with a social worker
  - Checklist, social worker form
  - Multidisciplinary meeting

SCREENING
- Medical center: OST, Medical assessment, Alcohol counseling, Psychiatric care
  - HBV vaccination
- HR service: Multidisciplinary meeting, Monitoring, Assistance for referencing

TREATMENT
- Medical center:
  1) Treatment and medical follow-up in accordance with national guidance
     - Patient notebook
     - Adherence to treatment
     - Adverse events
  2) EOT assessment
  3) SVR12 assessment
- HR service:
  - Peer-support intervention delivered by social workers
    - 2 individual counseling sessions Checklist
    - On demand individual counseling Patient notebook
    - Counseling sessions in group Slides
    - Monitoring: track beneficiaries with delayed or missed visit

Retention
Adherence
Reinfection
Georgia: activity flow chart

Screened n=437

- negative HCV RDT n=6
  - FS ≤F2 n=164

→ Eligible to Neolab (HCV RDT/FS) n=267

→ Eligible to treatment n=160/267
  * Not eligible n=53/267
    (6 refusal; 2 comorbidities; 18 negative PCR; 27 not eligible according to second FS or Fib4)

  * Screening not finished n=54/267

→ Dossier submitted n=141/160

Negative response n=0
Positive response n=84/141

Treatment initiated n=84/84
- S + I + R - 12 weeks n=51 (61%)
- S + R - 24 weeks n=24 (29%)
  - S + R - 12 weeks n=6 (7%)
  - S + R - 20 weeks n=3 (3.4%)
Georgia: performance of the screening according to level of liver fibrosis

- FS not assessable (n=37) : 30% eligible to treatment (6/20 with all results available)
- F2-F3 (n=37) : 16% eligible to treatment (4/25 with all results available)
- F3 (n=79) : 93% eligible to treatment (64/69)
- F3-F4 (n=12) : 91% eligible to treatment (10/11)
- F4 (n=102) : 95% eligible to treatment (76/80)
Georgia: description of patients starting treatment

<table>
<thead>
<tr>
<th>Sex</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>83</td>
<td>(99%)</td>
</tr>
<tr>
<td>Female</td>
<td>1</td>
<td>(1%)</td>
</tr>
</tbody>
</table>

| Age       | 45    | (32;60) |

<table>
<thead>
<tr>
<th>IDU last month*</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>24</td>
<td>(31%)</td>
</tr>
<tr>
<td>No</td>
<td>54</td>
<td>(69%)</td>
</tr>
</tbody>
</table>

| Age of first injection* | 18    | (14;30) |

<table>
<thead>
<tr>
<th>Under OST program*</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>32</td>
<td>(41%)</td>
</tr>
<tr>
<td>No</td>
<td>46</td>
<td>(59%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How often do you have a drink containing alcohol?*</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>34</td>
<td>(44%)</td>
</tr>
<tr>
<td>Monthly or less</td>
<td>7</td>
<td>(9%)</td>
</tr>
<tr>
<td>2-4 times a month</td>
<td>13</td>
<td>(17%)</td>
</tr>
<tr>
<td>2-3 times a week</td>
<td>10</td>
<td>(13%)</td>
</tr>
<tr>
<td>≥ 4 times a week</td>
<td>14</td>
<td>(18%)</td>
</tr>
</tbody>
</table>

* 6 missing data

Data are presented as number (%) or median (min-max)

33/54 = 2012 study

Out of these 54 beneficiaries, 19 used cannabis during the last month
Disease progression is fast in PWIDs

PWIDs can’t wait until we discuss their case

**Nov 2012**
PWIDs with chronic HCV infection (82% of PWIDs)

- 59.6% No/minimal liver fibrosis (F0-F1)
- 18.2% Mild liver fibrosis (F2, F2-F3)
- 22.2% Severe liver fibrosis (F3+)

**May 2015**
PWIDs with chronic HCV infection after 2.5 years of progression

- 17.4% evolution to severe liver fibrosis (F3+)
- 1.9% deceased
- 44.4% evolution to severe liver fibrosis (F3+)
- 2.5% deceased

Risk factors of progression: heavy alcohol consumption +++, and VHB and initial level of fibrosis limit significant

References
2 Preliminary data of the MdM cohort
Conclusion

• Historic chance: not leaving PWID behind (again!)
• Access and scale up has to come with all-oral drugs: we need affordable and adapted treatments! And affordable diagnostics!
• Release clear guidances for HCV prevention and treatment among PWID on all levels
• Develop entry points for HCV treatment through low-threshold HR: Access to treatment needs access to prevention and HR
• Develop flexible and adapted health services and train health care workers
• Include PWID at all level of decision making and service delivery
  ▪ Sustain the fight against stigma and criminalization
HEPATITIS C: NO ELIMINATION WITHOUT DECRIMINALISATION
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