A national multidisciplinary healthcare network for treatment of hepatitis C in PWID in Slovenia

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Disclosure

Within the last 36 months:

• Lecturer: Abbvie, Bayer, Boehringer-Ingelheim, Gilead, Janssen, Merck, Roche
• Manuscript preparation: Abbvie, Gilead, Janssen, Merck, Roche
• Travel/accommodational meeting expenses: Abbvie, Gilead, Janssen, Merck, Roche

No conflict of interest regarding this presentation
Drug users: est. 10 000

Injectors: est. 6-8 000

Inhabitants: 2 million

Gross national income per capita (2012): 27,240 $

Life expectancy at birth m/f (2011): 77 / 83 years

Probability of dying under five (2012): 3 / 100 000

Probability of dying between 15 and 60 years m/f (2011): 118/51 / 1 000

Total expenditure on health/capita (2011): 2,519 Intl $

Total expenditure on health as (2011): 9.1 % GDP

http://www.who.int/countries/svn/en/

Injecting Drug Users: 29% (N=1050)
Hemophiliacs: 26.7% (N=374)
Prison inmates: 26% (N=378)
HIV-positives: 7.6% (N=579)
Health care workers: 0.7% (N=281)
General Population Adults: 0.4% (N=2 million)
Pregnant women: 0.09% (N=31,849)
Blood donors: 0.025% (N=1.4 million)

HCV RNA: 15.6%

HCV seroprevalence among PWID in the EU 2006–2011

- black squares are data with national coverage, blue triangles are data with sub-national (local, regional) coverage.

HCV seroprevalence among PWID in the EU 2006–2011

Slovenia:
- Harm-reduction programmes since early nineties
- OST since 1995

SLOVENIA 1993-2007

Anti- HCV seroprevalence according to gender and age
N=1504

Dynamics of HCV-1 and HCV-3 genotypes
N=1504

*genotype 1 = blood transfusion before 1992*

OR, 3.28 [95% CI, 2.18-4.95]; P < 0.0001

*genotype 3 = PWID*

OR 3.71 [95% CI, 2.97-4.65]; P < 0.0001

SLOVENIA
Management of hepatitis C
An integrated approach

- National Institute of Public Health of Republic Slovenia
  (Ministry of Health: Law on communicable diseases)
  Surveillance of communicable diseases
  Strategies for reducing transmission and harm (drug use)

- National Viral Hepatitis Expert Group
  (Interdisciplinary team of highly involved professionals, self-founded in 1997)
  National strategy
  Action plan
  Consensus clinical guidelines

http://www.ivz.si/gradiva_nalezljive_bolezni
National Viral Hepatitis Expert Group

National strategy for complex management of HCV infection

- **Testing**: - special populations: case finding, surveillance
  - general population: **voluntary free-of-charge testing**
    (routine + campaigns)

- **Treatment**: - availability, access, process, follow-up
  - systematical **analysis** of treatment efficacy and safety (since 1997)

- National consensus **guidelines** on management of HCV infected

- **Research**

- **Education** (professionals, general population)

- **Mass media campaigns** (World Hepatitis Day, etc.)

SLOVENIA
Management of HCV infection during period 1997 - 2015

- Slovenian Viral Hepatitis Expert Group
- National Healthcare Network for the Management of HCV infection in PWID
- National campaigns on free anonymous HCV testing
- Financial assessment of Th
- Modeling approach to HCV elimination

- National Strategy and Consensus Guidelines for the Management of HCV Infection
- National Consensus Guidelines for HCV Treatment: An update
- National Consensus Guidelines for HCV Treatment in PWID
- National Consensus Guidelines for the Optimization of HCV Treatment with PEG/riba
- National Consensus Guidelines for HCV treatment with new DAAs

Timeline:
1997
1999
2007
2008
2012
2014
2015
Clinical management of patients with HCV infection

- 5 clinical centers for viral hepatitis: infectologists, (hepatologists)

Referential:
Clinic for Infectious Diseases nad Februle Illnesses, University Medical Centre Ljubljana
Clinical management of patients with HCV infection

**THERAPY** for HCV:
- IFN (1993)
- IFN/RBV (1999)
- PEG/RBV (2001)
- BOC/TVP (2012)

- Liver transplantation (since 1998)

**FINANCING** of HCV management:
- Public Health Insurance System:
  - Nominated specialists to prescribe P/R, DAAs
  - National consensus guidelines for the management of HCV infection
- National register: all the HCV treated patients (since 1997)
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Centres for Prevention and Treatment of Drug Addiction
Number of PWID managed per year

16% HCV RNA positive
3% treated for HCV

Coordination of Centers for Prevention and Treatment of Illicit Drug Abuse, Slovenia 2011.
Kastelic A et al. 2nd Slovenian Conference on HCV Infection in IVDU, Ljubljana 2007
SLOVENIA 2007

National healthcare network for managing HCV in PWID

INTEGRATED already existing facilities: 18 Drug Treatment Centers
5 Viral Hepatitis Centers

Maticic M, Kastelic A. Zdrav Vestn 2009; 78: 529-39
A multidisciplinary team for HCV treatment in PWID

- Viral hepatitis specialists: infectologists, hepatologists
- Addiction specialist
- Specially trained nurses
- Psychiatrist / psychotherapist
- Councilors: social workers, peers
- Other support system: family, friends, co-workers
- Clinical virologist
- Clinical pharmacist
- Clinical pharmacist

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Maticic M, Kastelic A. Zdrav Vestn 2009; 78: 529-39
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National Conferences “HCV in PWID”
for integrated providers of HCV treatment

• 1st Slovenian Conference on HCV Infection in IVDU (Jan 2006):
  basic medical and supportive education strategies, interventions

• 2nd Slovenian Conference on HCV Infection in IVDU (Mar 2007):
  set up National guidelines for the management of HCV in IVDUs

• 3rd Slovenian Conference on HCV Infection in IVDU (Apr 2008):
  vulnerable groups

• 4th Slovenian Conference on HCV Infection in IVDU (Feb 2010):
  experiences/improvements of the National guidelines
  future perspectives

• 5th Slovenian Conference on HCV Infection in IVDU (Dec 2011):
  role of addiction programmes, new drugs for HCV, HIV and IVDUs in Slovenia

• 6th Slovenian Conference on HCV Infection in PWID (Mar 2015):
  indications for new DAAs, increase HCV testing, Inauguration of Slovene Liver Patient Association

Maticic M, Kastelic A. Zdrav Vestn 2009; 78: 529-39
Hepatitis C in drug users on substitution treatment:

National guidelines for clinical management and treatment

March 2007
SLOVENIA
National healthcare network for managing HCV in PWID
An integrated approach

- **Un-infected**: counselling to prevent HCV infection
  - testing for HCV infection (every 6-12 mths)
  - HBV/HAV vaccination

- **Chronically infected**: identification of treatment eligible
  - motivation
  - linkage-to-care
  - medical evaluation (Fibroscan)
  - clinical management
  - counselling, motivation
  - treatment

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National healthcare network for managing HCV in PWID
An integrated approach

Viral hepatitis specialist

Drug addiction therapist

drug user
HCV RNA +

First visit

Follow up visits-report

Start HCV treatment - report

Monthly FU visits - report

drug user
HCV RNA +

First visit “fill-in form”

Follow up “fill-in form”

“Fill-in form” on psycho condition, adherence

If necessary introduction of psycho-socio-pharmacotherapy
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National healthcare network for managing HCV in PWID

Written communication between viral hepatitis and drug addiction specialists
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National healthcare network for managing HCV in PWID

Coordination of Centers for Prevention and Treatment of Illicit Drug Abuse, Slovenia 2011.
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Four prospective national studies on currently recommended treatment of all naive patients with chronic hepatitis C

<table>
<thead>
<tr>
<th>Standard of care treatment</th>
<th>Period</th>
<th>Among all the treated patients in Slovenia % of treated PWID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interferon</td>
<td>1997-1999</td>
<td>5 %</td>
</tr>
<tr>
<td>Interferon/ ribavirin</td>
<td>1999-2001</td>
<td>16 %</td>
</tr>
<tr>
<td>Peginterferon/ribavirin</td>
<td>2001-2004</td>
<td>36 %</td>
</tr>
<tr>
<td>National healthcare network for PWID</td>
<td>2007</td>
<td></td>
</tr>
<tr>
<td>Optimised peginterferon/ribavirin</td>
<td>2008-2010</td>
<td>78 %</td>
</tr>
</tbody>
</table>

DAAs: Sofo, 3D, Sofo/Ledipa

1. URGENT:
   - Decompensated cirrhosis
   - HCC on waiting list for Tx
   - Cirrhosis on waiting list for Tx
   - Hepatitis C in Tx liver

2. PRIORITY:
   - HCV relapse in Tx liver
   - HCC for resection/other treatment
   - HIV/HCV co-infection
   - HCV with serious extra-hepatic manifestations

3. REGULAR INDICATIONS:
   - Compensated cirrhosis
   - METAVIR > F2

   - Updating the guidelines:
     Expected in June 2016 (DAAs for F≥2?)

PegIFN/riba, Sime

NO limitations
(except medical contraindications)

SLOVENIA 2014
CLINICAL PRACTICE GUIDELINES FOR HCV TREATMENT

National Viral Hepatitis Expert Group, December 2014.
SLOVENIA 2016
National healthcare network for managing HCV in PWID
An integrated approach

- **Un-infected**: counselling to prevent HCV infection
testing for HCV infection (in the last 6 mths)
HBV/HAV vaccination

- **Chronically infected**: identification of treatment eligible
motivation, FIBROSCAN
linkage-to-care
medical evaluation (Fibroscan)
clinical management
counselling, motivation
treatment

Conclusions

• National healthcare network for HCV treatment in PWID increases identification of HCV treatment eligible PWID, significantly increases the proportion of treated and enables high HCV treatment adherence, efficacy and safety.

• Already existing facilities and a multidisciplinary team of providers can be used to set up a national healthcare for HCV treatment in PWID

• Close cooperation of a multidisciplinary team is crucial

• A comprehensive national policy is needed to set up national strategies, action plans and clinical guidelines for the integrated management of HCV infection in PWID
Thank you!