Príklady mikroeliminačných programov pre HCV infekciu u PWID.

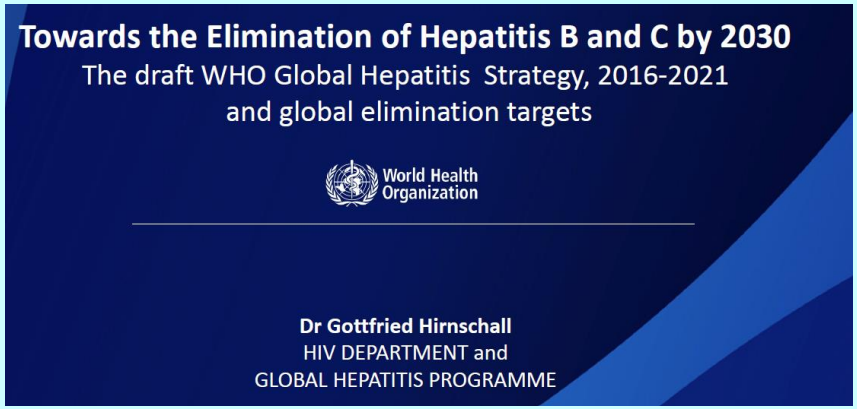
11. AT konferencia

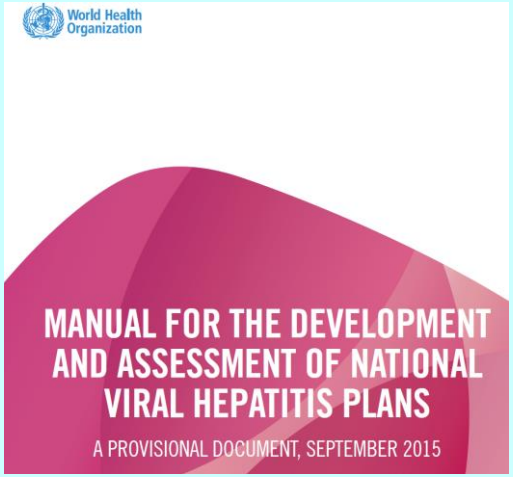
Bojnice 12. 10. 2019

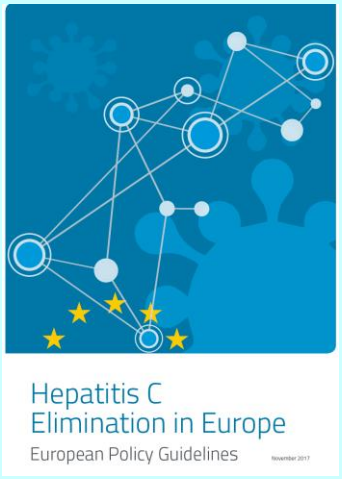
Eliška Lovrantová Oddelenie infektológie FNsP FDR B. Bystrica

Prezentácia vznikla za podpory

Úvod







Národný plán kontroly infekčných ochorení v Slovenskej republike Strategický plán na roky 2018 - 2020

Zlepšenie kontroly infekčných ochorení pre všetkých obyvateľov Slovenskej republiky

Advisory Board – 22.5.2019

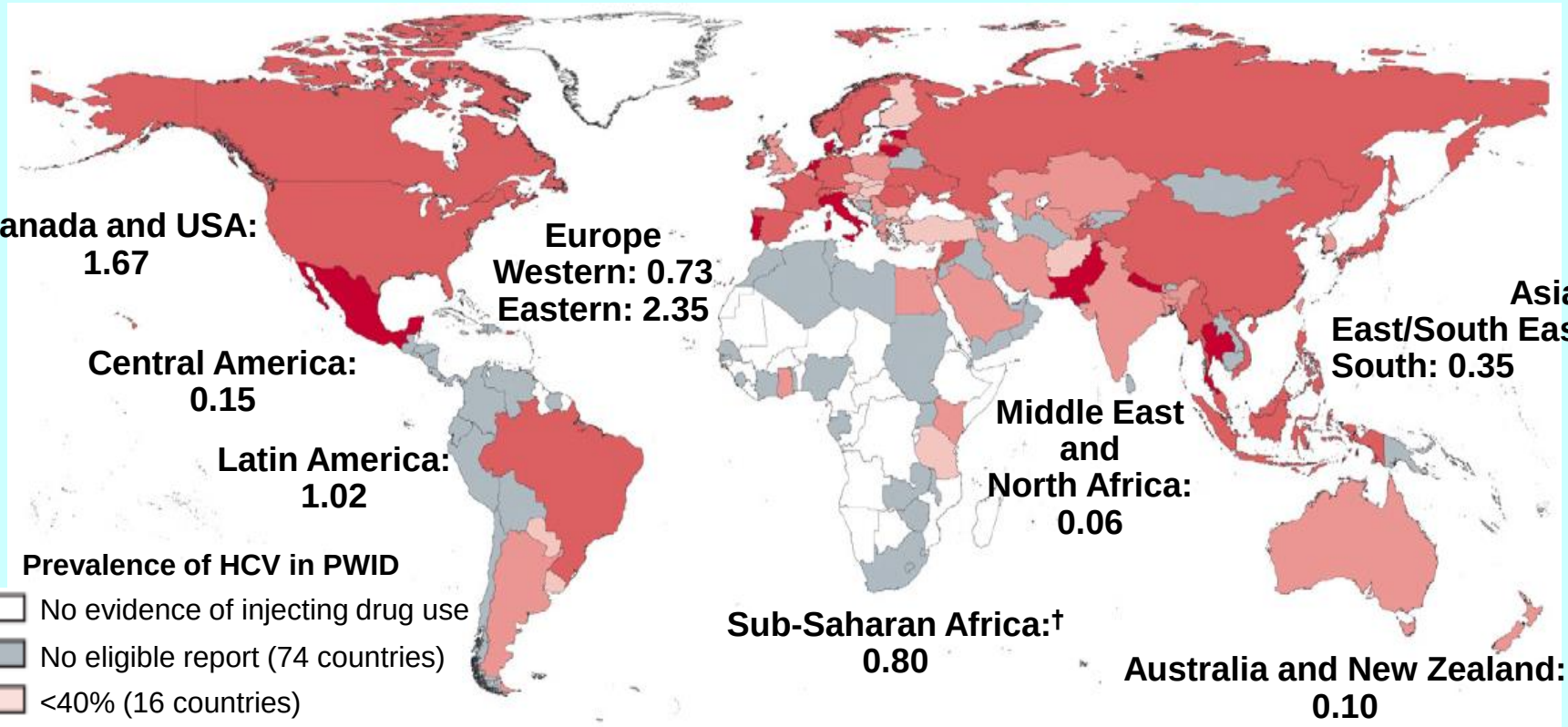
Predsedníctvo:
MUDr. Ľubomír Skladaný, PhD.

Zúčastnení (abecedne):
MUDr. Miroslav Grohol
prof. MUDr. Peter Jarčuška, PhD.
doc. MUDr. Pavol Kristian, PhD.
MUDr. Eliška Lovrantová, PhD.
MUDr. Ľubomír Okruhlica, CSc.
MUDr. Marián Oltman, PhD.
prof. MUDr. Ivan Schréter, CSc.

Hepatitída C a PWID

Globálna prevalencia HCV infekcie u PWID

Predpoklad HCV u PWID (v miliónoch)*



- **Global estimate: ~10.0 million PWID (range 6.0–15.2)**
- **Global prevalence: 67.0% of PWID**

*Data identified in a systemic literature search (up until May 2011) with wider input from relevant organisations; Regional data are PWID positive for HCV antibodies (mid-point estimates);
†Prevalence derived from South Africa, Mauritius and Kenya only.
PWID: people who inject drugs

Grebely J, Dore GJ. Antiviral Res 2014;104:62–72

II. Prevalencia HCV infekcie u PWID

HCV prevalence in PWID in Western European countries (until 2011)*

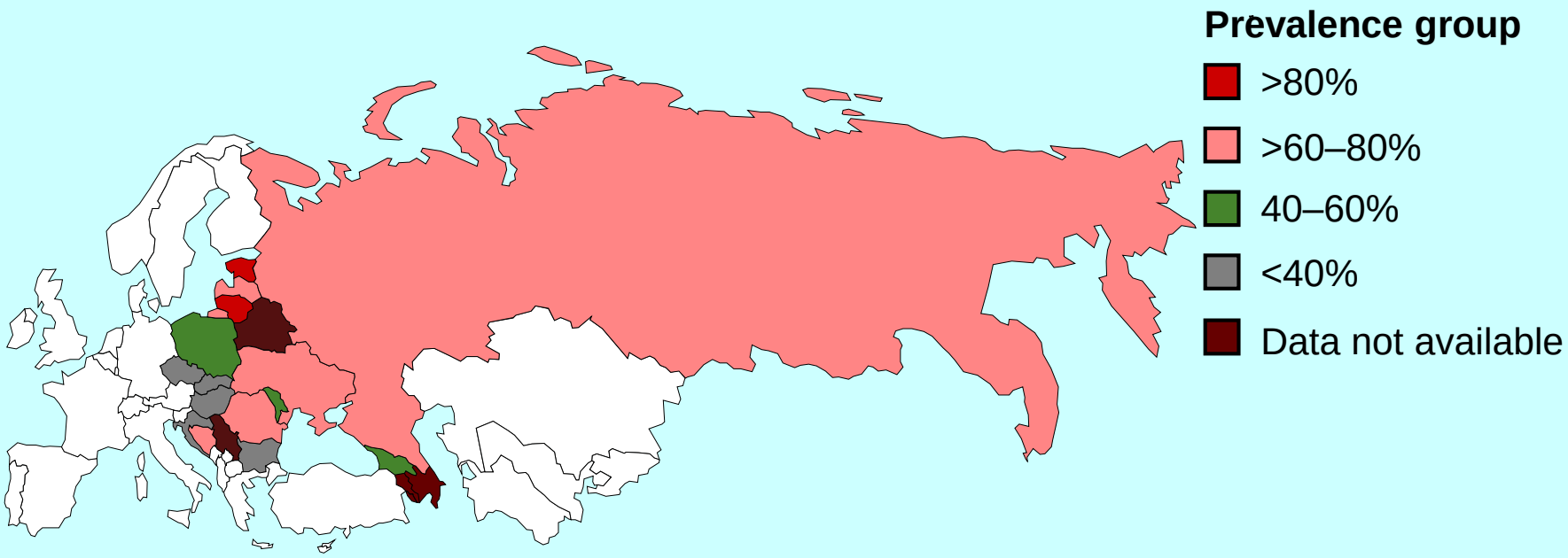
13 Western European countries reported HCV antibodies in >60% among PWID

*Data identified in a systemic literature search (up until May 2011) with wider input from relevant organisations.
PWID: people who inject drugs

Adapted from Nelson PK, et al. Lancet 2011;378:571–83

III. Prevalencia HCV infekcie u PWID

HCV prevalence in PWID in Eastern European countries (until 2011)*



6 Eastern European countries reported HCV antibodies in ≥60% among PWID

Adapted from Nelson PK, et al. Lancet 2011;378:571–83

PWID: people who inject drugs

Prevalencia u PWID v Europe v období 2005–2010 stúpla

HCV prevalence in PWID in Europe from 2005–2010

Austria Graz; Vienna
2005: 49%; 48.9%
2010: 73%; 67.2%

Italy Abruzzo; Valle d'Aosta
2005: 65.7%; 18.1%
2009: 74.2%; 27.4

Greece National: 19 sites; 18 sites
2005: 61.7%; 43.3%
2010: 68.8%; 48.7%

Romania Bucharest
2005: 45.8%
2007: 65.6%

Bulgaria Sofia
2005: 53.6%
2010: 62.3%

Cyprus National
2006: 29.6%
2010: 51.3%

Increased prevalence of HCV infection* in PWID in 6 European countries†

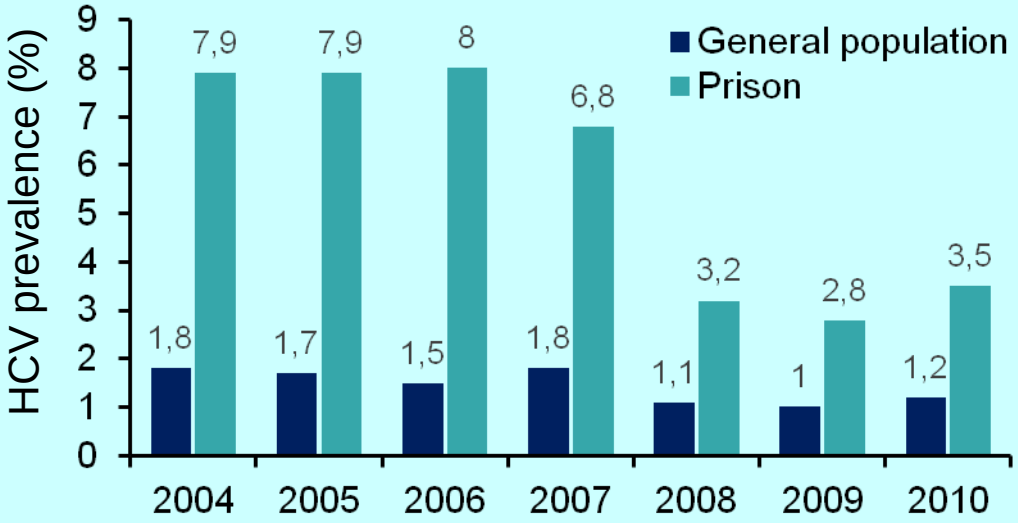
Adapted from Wiessing L, et al. Euro Surveill 2011;16:pii: 20031. Erratum in: Euro Surveill. 2011;16:pii:20037

*According to two sided test, alpha level of 0.05;
†National prevalence declined in Italy but increased in two regions.
PWID: people who inject drugs

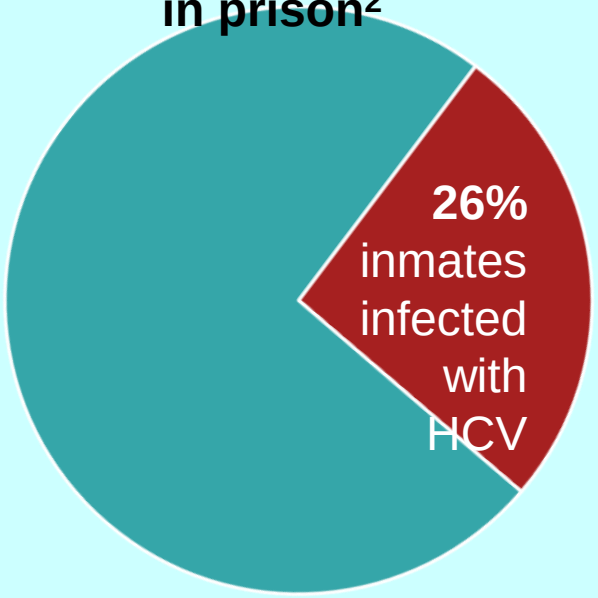
Ktoré faktory potencujú incidenciu a prevalenciu HCV infekcie

Uväznenie je nezávislým rizikovým faktorom pre HCV infekciu u PWID

HCV prevalence in the general population (n=46,125) and the prison population (n=5957)*[1]



Global HCV prevalence in prison[2]

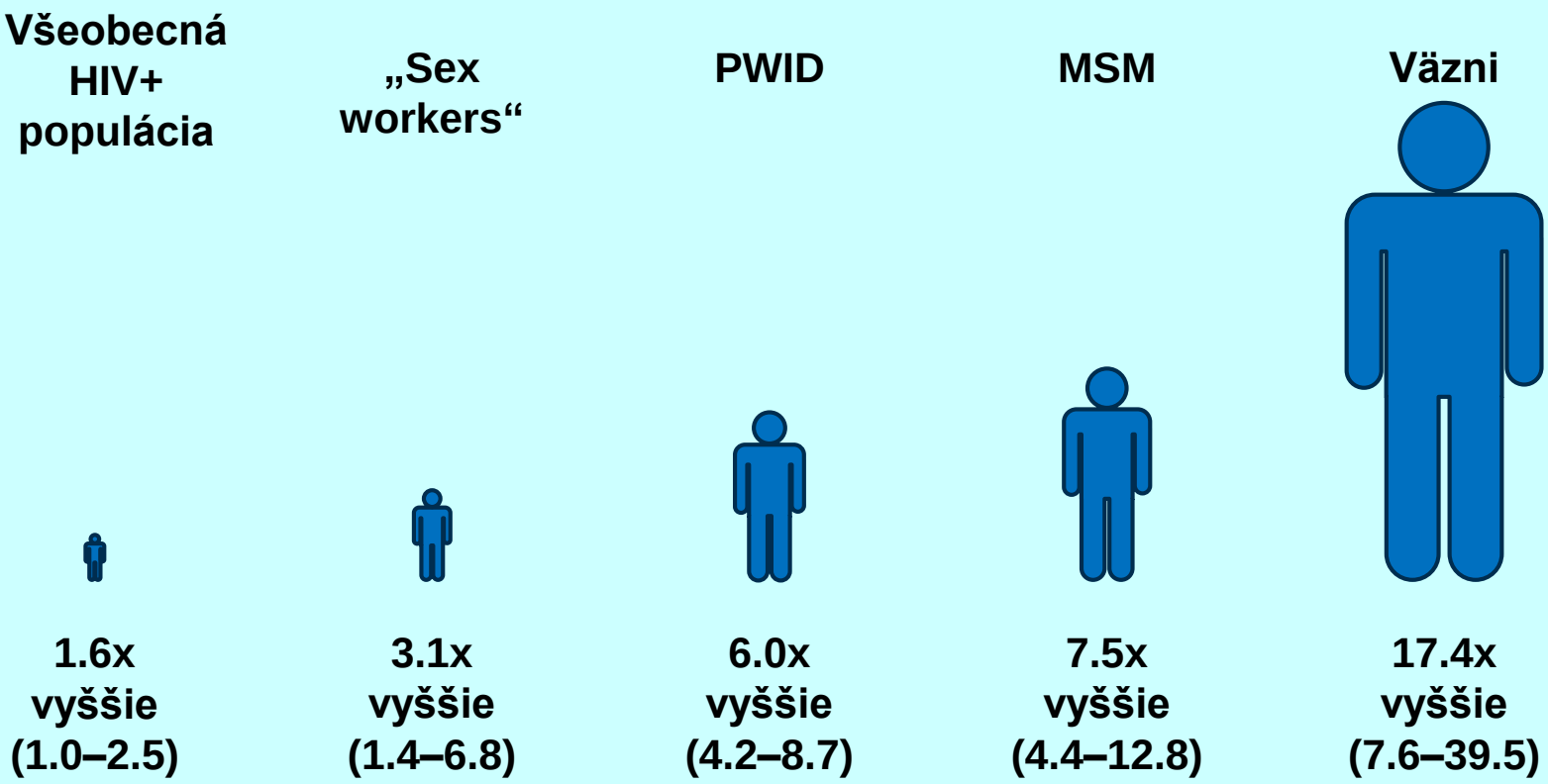


- **HCV prevalence is much higher in prisons than in the general population**
- **Anti-HCV prevalence in inmates ~26%**
- **Many inmates are unaware of their HCV status**

1. Roux P, et al. BMJ Open 2014;19:e005694;
2. Larney S, et al. Hepatology 2013;58:1215–24

*In South-Eastern France.
PWID: people who inject drugs

Riziko HCV infekcie u HIV+ a HIV- osôb je odlišné v rizikových populáciách



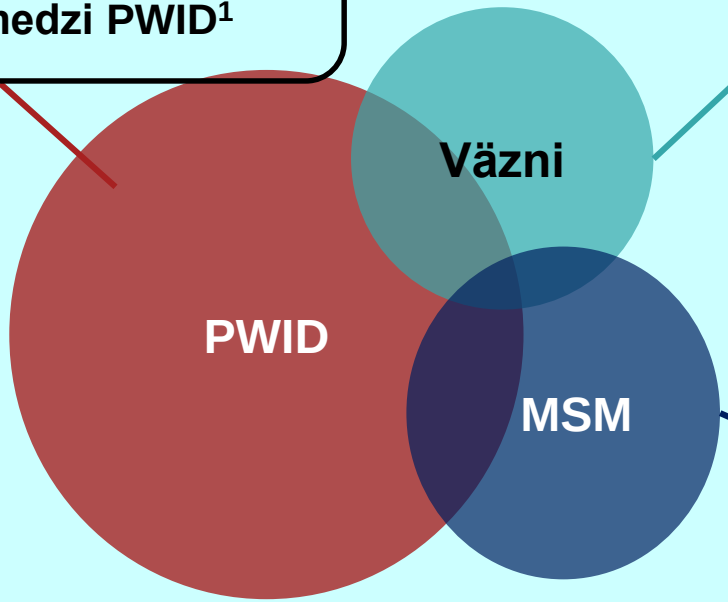
Adapted from Platt L, et al. Lancet Infect Dis 2016;16:797–808

MSM: men who have sex with men; PWID: people who inject drugs

PWID, MSM a internované osoby (väzni) sú v najvyššom stupni rizika HCV infekcie

V ekonomicky vyspelých krajinách 80% nových HCV infekcií je medzi PWID[1]

Globálne 26% väzňov je infikovaných HCV[2].



Vzostup incidencie HCV u osôb HIV+ MSM:
7.3% v r. 2004
9.9% v r. 2011[3]

1. Grebely J, Dore GJ. Antiviral Res 2014;104:62–72;
2. Larney S, et al. Hepatology 2013;58:1215–24;
3. Martin N, et al. Clin Infect Dis 2016;62:1072–80

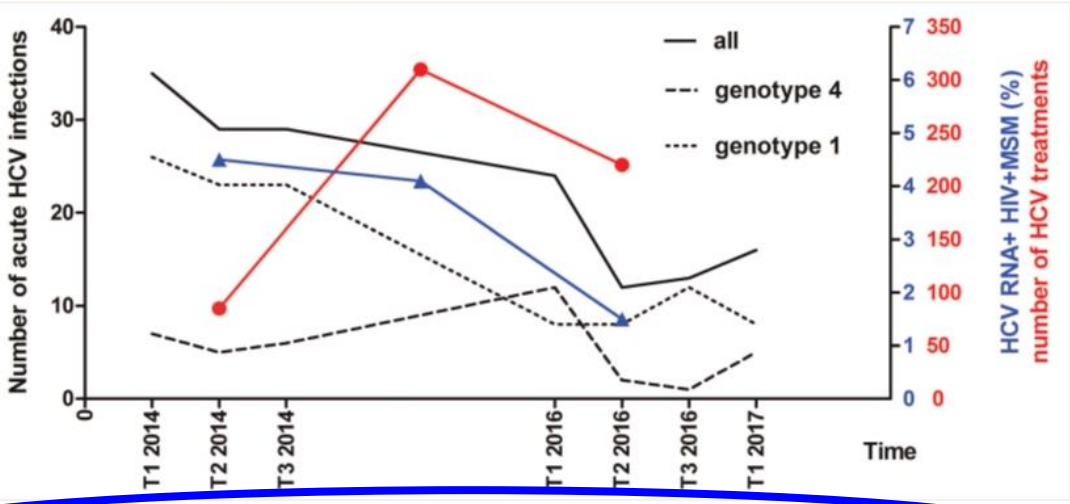
IDU: injecting drug use;
MSM: men with have sex with men;
PWID: people who inject drugs

Liečba ako prevencia HCV infekcie

Liečba ako prevencia: pokles *incidencie*

„*Treatment as prevention*“ *works and* can reduce new infections in high risk groups

unrestricted access to DAA to treat early HCV infection in HIV+ MSM



→ Reduction of new acute HCV infections by 51% in HIV+ MSM

Boerekamps A et al, Clin Infect Dis. 2018 Apr 17;66(9):1360-1365.

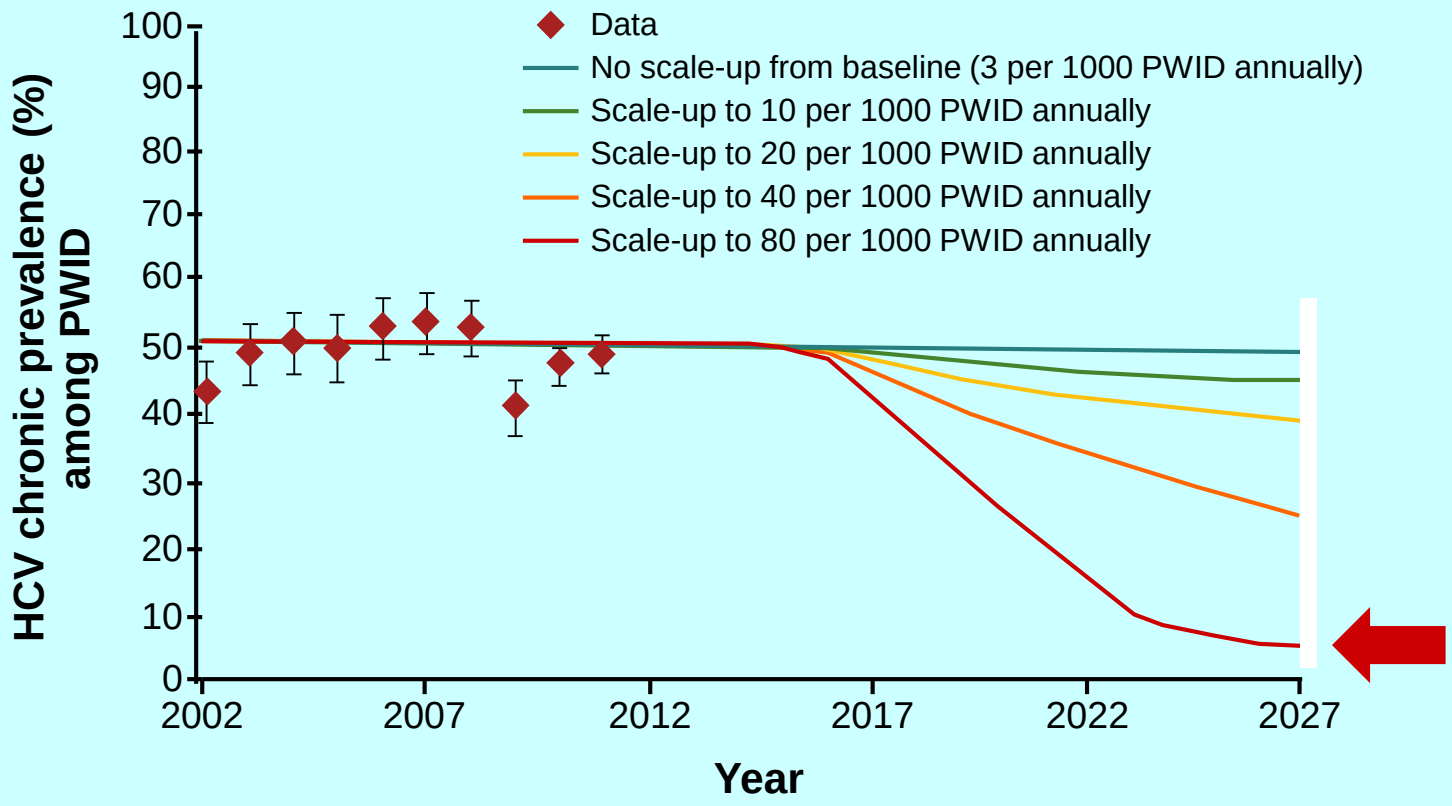
CiiM CENTRE FOR INDIVIDUALISED INFECTION MEDICINE

MHH Medizinische Hochschule Hannover

‡

Liečba ako prevencia: pokles *prevalencie*

TAP Study: Treatment As Prevention HepC study



Burnet Institute
Medical Research. Practical Action.

Martin N, et al. Hepatology 2013;58:1598–609

Study participants from a cohort of over 700 people who inject drugs (PWID)

Assumes IFN-free DAA with 90% efficacy, 12-week duration.
IFN: interferon; PWID: people who inject drugs

Liečba hepatitídy typu C je bezinterferónová

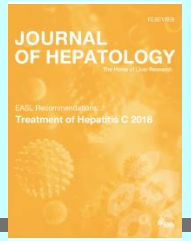
EASL Recommendations on the Treatment of Hepatitis C 2018

	Pangenotypic Regimens			Genotype-Specific Regimens		
Genotype	SOF/ VEL	GLE/PIB	SOF/ VEL/VOX	SOF/LDV	GZR/EBR	3D
Genotype 1a	Yes	Yes	No*	Yes[a]	Yes[b]	No
Genotype 1b	Yes	Yes	No*	Yes	Yes	Yes
Genotype 2	Yes	Yes	No*	No	No	No
Genotype 3	Yes[c]	Yes	Yes[d]	No	No	No
Genotype 4	Yes	Yes	No*	Yes[a]	Yes[e]	No
Genotype 5	Yes	Yes	No*	Yes[a]	No	No
Genotype 6	Yes	Yes	No*	Yes[a]	No	No

*Triple combination therapy efficacious but not useful due to the efficacy of double combination regimens.
[a]Treatment-naive patients without cirrhosis or with compensated (Child-Pugh A) cirrhosis.
[b]Treatment-naïve and treatment-experienced patients without cirrhosis or with compensated (Child-Pugh A) cirrhosis with an HCV RNA level ≤ 800,000 IU/mL (5.9 Log_{10} IU/mL).
[c]Treatment-naive and treatment-experienced patients without cirrhosis.
[d]Treatment-naive and treatment-experienced patients with compensated (Child-Pugh A) cirrhosis.
[e]Treatment-naive patients without cirrhosis or with compensated (Child-Pugh A) cirrhosis with an HCV RNA level ≤ 800,000 IU/mL (5.9 Log_{10} IU/mL).

European Association for the Study of the Liver. *J Hepatol.* 2018;69:461-511.

PWID and patients receiving OST



Recommendations	Grade of evidence	Grade of recommendation
Test routinely and voluntarily for anti-HCV Abs and HCV RNA; test HCV RNA annually and following any high-risk injecting episode	A	1
Provide appropriate access to OST and clean drug injecting equipment as part of widespread comprehensive harm reduction programs, including in prisons	A	1
All HCV-infected PWIDs have an indication for antiviral therapy; DAA-based therapies are safe and effective in HCV-infected patients receiving OST, those with a history of IDU and those who recently injected drugs	A	1
HCV treatment should be offered to HCV-infected patients in prison	B	1
Pre-therapeutic education: include discussions of HCV transmission, risk factors for fibrosis progression, treatment, reinfection risk, and harm reduction strategies	B	1
In patients on OST, DAA-based anti-HCV therapy does not require methadone or buprenorphine dose adjustment	A	1
Provide harm reduction, education and counselling to prevent HCV reinfection following successful treatment	B	1
Monitor after SVR in PWID with an ongoing risk behaviour*	A	1
Retreat if reinfection identified during post-SVR follow-up	A	1

*Ideally bi-annual or at least annual HCV RNA assessment

EASL CPG HCV. J Hepatol 2018;69:461–511.

Potenciál pre liekové interakcie medzi OST a DAA

OST Legálna droga	Elbasvir/Grazoprevir	Glecaprevir/Pibrentasvir	OBV/PTV/r + DSV	Sofosbuvir/Velpatasvir	Sofosbuvir/Velpatasvir/ Voxilaprevir
Buprenorphine	◆	◆	■	▲	▲
Methadone	◆	◆	◆	◆	◆
Naloxone	◆	◆	◆	◆	◆

● Do Not Coadminister ■ Potential Interaction ▲ Potential Weak Interaction ◆ No Interaction Expected ◈ No Clear Data

○ Do Not Coadminister □ Potential Interaction △ Potential Weak Interaction ◇ No Interaction Expected ◈ No Clear Data

●○ These drugs should not be coadministered

■□ Potential clinically significant interaction that is likely to require additional monitoring, alteration of drug dosage or timing of administration.

▲△ Potential interaction likely to be of weak intensity. Additional action/monitoring or dosage adjustment is unlikely to be required

◆◇ No clinically significant interaction expected

http://www.hep-druginteractions.org/

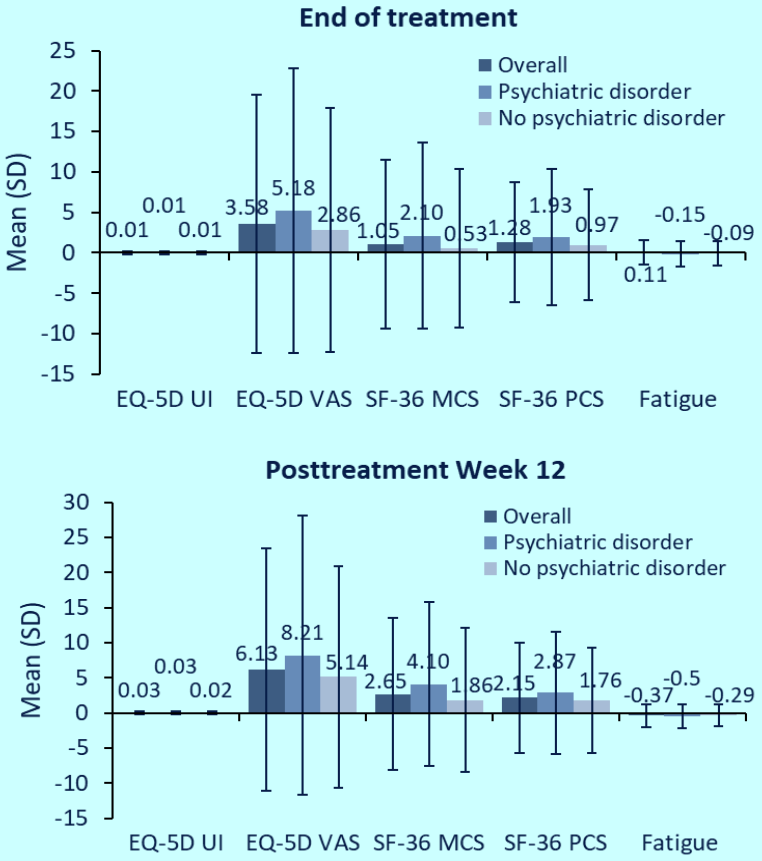
Kvalita života u pacientov s psychickými poruchami: súhrnná analýza z registračných štúdií GLE / PIB

6 registračných klinických štúdií G/P

2570 pacientov: 31% mali v minulosti psychiatrickú poruchu a/alebo užívali lieky na psychiatrickú diagnózu

- Bez ohľadu na psychiatrický stav, pacienti mali **zlepšenie kvality života** na konci liečby a v 12. týždni po liečbe
- Psychiatrické poruchy ukázali **najväčšie zlepšenie** v skóre mentálnych zložiek
- Pacienti s psychiatrickou poruchou majú takmer **dvojnásobný benefit z liečby**

- **Liečba by mohla mať väčší vplyv na tých pacientov s HCV infekciou, ktorí trpia psychickou poruchou**



MCS, skóre mentálnych komponentov; PCS, skóre fyzických komponentov; UI, index utility.

Cacoub P. et al: Quality of Life in Patients with Psychiatric Disorders: Pooled Analysis from Glecaprevir/Pibrentasvir Registrational Studies, AASLD 2018, San Francisco, # 150

Liečba HCV u PWID (clinical data)

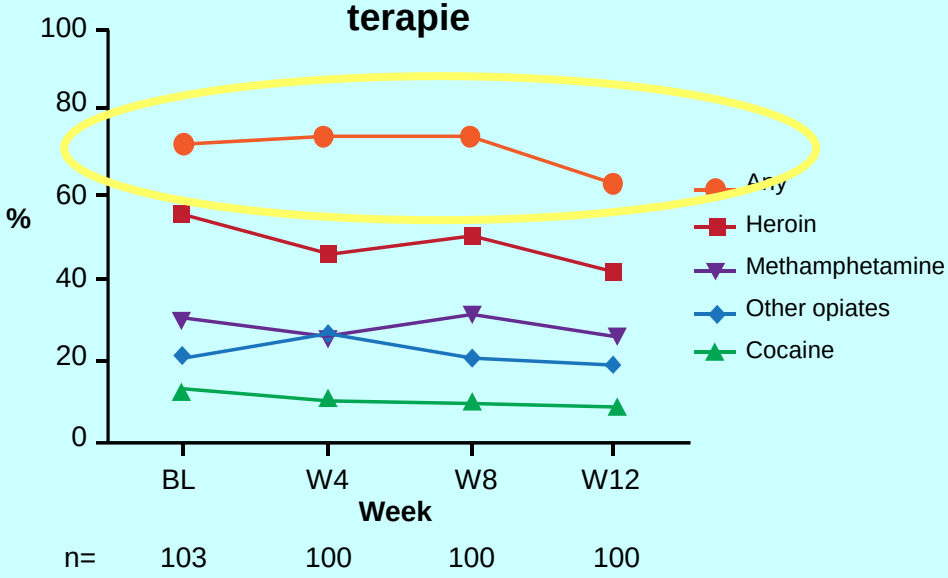
Väčšina pacientov pokračovala v užívaní drog počas HCV liečby (SIMPLIFY)

International, Phase 4, open-label study of 103 patients

Demografia

Age, years (range)	48 (41–53)
Male sex, n (%)	74 (72)
HCV genotype 1a / 1b / 2 / 3 / 4, %	34 / 1 / 5 / 58 / 2
Fibrosis stage (METAVIR) F0–F1 / F2–F3 / F4, %	61 / 28 / 9
Injecting drug use (in the last 30 days), n (%)	76 (74)
Heroin	57 (55)
Methamphetamines	31 (30)
Other opiates	22 (21)
Cocaine	13 (13)
≥Daily injecting drug use (in last month), n (%)	27 (26)
Current OST, n (%)	
Methadone	45 (44)
Buprenorphine	4 (4)
Buprenorphine ± naloxone	16 (16)

Užívanie drog počas terapie



Adherencia k HCV liečbe

- Median: 94%
- Mean: 89%

Grebely J, et al. INHSU 2017; #THU-1040;
Grebely J, et al. Lancet Gastroenterol Hepatol 2018;3:153–61

Mikroeliminačné programy sú súčasťou *Národných stratégií* mnohých štátov

Island – Vogur Addiction Hospital - 2016/2017

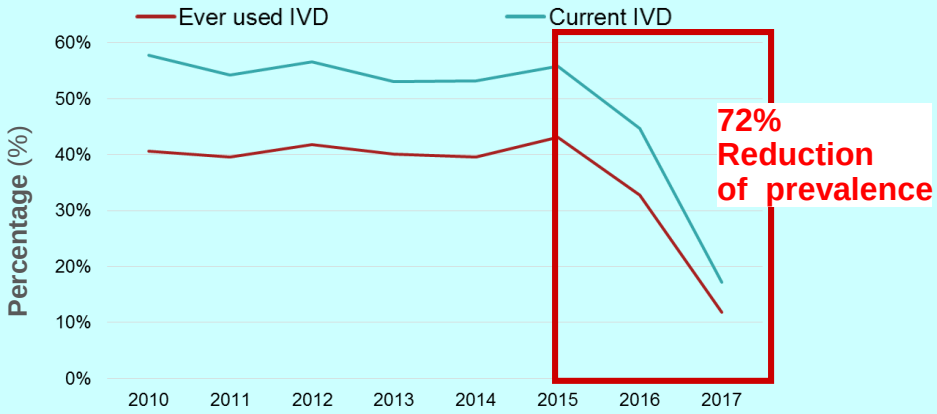
Kombinácia liečby závislosti, VHC a „harm reduction“ vedie k eliminácii HCV u PWID

Iceland

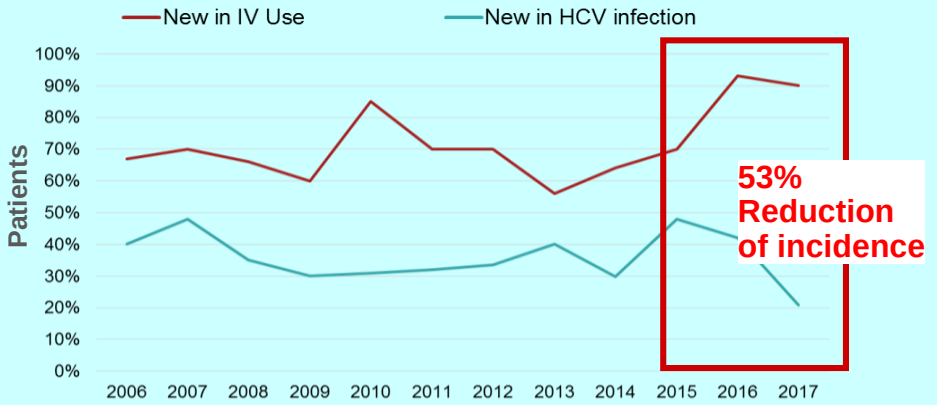
- Population: 340,000
- Estimated HCV seroprevalence: 0.3%
- Treatment to all within 3 years
- Emphasis on those:
  - Actively injecting drugs
  - Incarcerated
  - With advanced liver fibrosis or cirrhosis
- 3rd year for “search and rescue”

Demographics	N=518
Living situation, %	
Home	75
Homeless/halfway house	16
Prison	8
IVDU, %	
Ever	88
Within 6 months	37
Current OST	12
Treatment site, %	
University Hospital	65
Addiction Hospital	30
Penitentiary	5

Proportion of viraemic HCV among PWID



New injection drug users and new HCV infections,



Program *Liečba ako prevencia* sa na Islande premietol do signifikantnej redukcie prevalencie a incidencie v populácii PWID

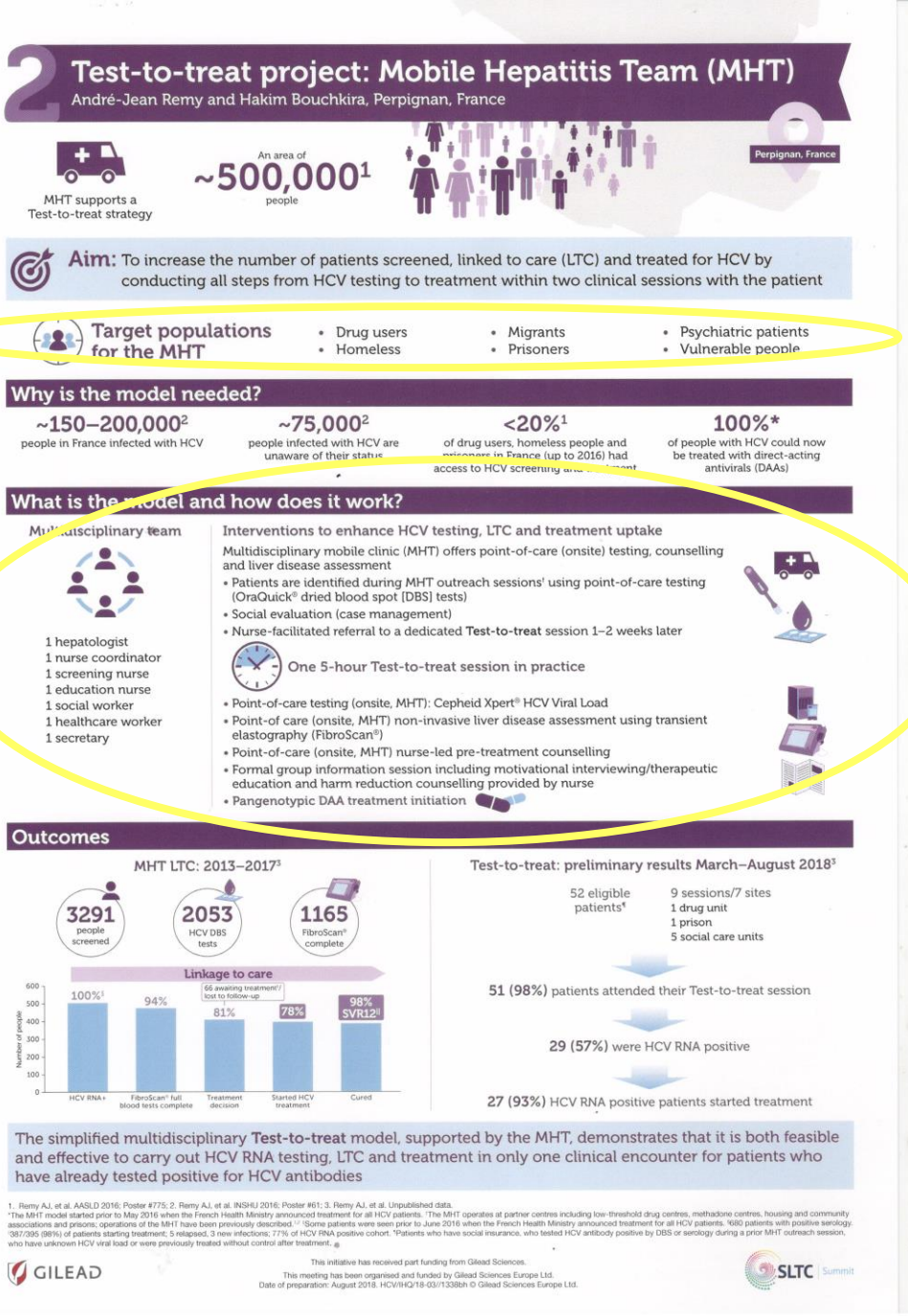
Tyrfingsson T, et al. ILC 2018; Poster #PS-095

DAA: direct-acting antiviral; IVDU: intravenous drug use; OST: opiate substitution therapy; PWID: people who inject drugs

Slide contains treatment data

Francúzsko - Perpignan

One 5-hour Test-to-treat session



Belgicko - Antverpy

Integrovaný model starostlivosti - „not under one roof“

Antwerp Free Clinic

Stefan Bourgeois, Stefan Bratovanov, Tessa Windelinckx, Antwerp, Belgium

20 years of HCV management at the Free Clinic, Antwerp

Holistic Antwerp *'not under one roof'* model for HCV management – started in 2015

Free Clinic — ZNA Stuivenberg

1,200,000[1] people living in the Antwerp Metropolitan Area

Aim: An integrated, multidisciplinary model of care with a strong peer-support programme provides a continuum of HCV care from diagnosis, through to linkage to care (LTC), treatment and prevention of reinfection

Why is the model needed?

Target population: people who inject drugs (PWID)

- One of the leading sources of new HCV infections worldwide[2]
- Stigmatised, hidden population with limited access to mainstream healthcare[2]

What is the model and how does it work?

Interventions used to enhance HCV testing, LTC and treatment uptake

- Integrated HCV care with peer support in a low-threshold setting, including point-of-care (onsite) HCV assessment (rapid HCV antibody testing)
- Community-based nurse-led HCV evaluation, therapeutic education, pre-treatment counselling
- Subsequent referral to hepatitis specialist for HCV evaluation and treatment
- Follow-up (offsite) HCV RNA testing and non-invasive liver disease assessment using transient elastography (FibroScan®) at ZNA
- Peer support provides education, scheduling of specialist appointments, home visits to locate individuals, patient navigation at hospital

Free clinic

- Pre-treatment: counselling, general practitioner/nursing care, social work
- HCV screening
- Information and education
- Referral to specialists
- Harm reduction counselling

Needle exchange

- Prevention
- Sterile injections
- Safe injecting technique
- Referral
- HCV screening
- Harm reduction counselling

ZNA Stuivenberg

- 'Streetwise' specialist hepatologist
- Staging of liver fibrosis and cirrhosis
- HCV diagnosis and treatment
- Referral for other medical issues
- Treatment follow-up

C-Buddy peer support

- Connecting with new patients
- Guide the patient through the process
  - Appointment reminders
  - Patient navigation at the hospital
  - Advice on healthier living
  - Talking about drug use
  - Translating medical terminology

Why does the model work?

- Flexibility – the model can be changed depending on needs
- Team work – every member is important
- Dedication – every member of the team is committed and involved
- Communication – between the team and with the patients
- Peer support – brings extra value to the care cascade (peers need training, support and guidance)

Outcomes: Free Clinic in 2017[3]

90% (n=379) of Free Clinic PWID clients were tested for anti-HCV antibody

76% of PWID tested were anti-HCV antibody positive (n=286)

86% of anti-HCV+ patients underwent HCV RNA PCR testing (n=245)

43% of anti-HCV+ PWID were HCV RNA+ (n=105)

Each member of this dedicated, collaborative team has an important role in improving HCV screening, diagnosis, LTC and treatment among PWID

1. World Population Review – Antwerp. Available at http://worldpopulationreview.com/world-cities/antwerp-population/ (accessed July 2018); 2. WHO. Global Hepatitis Report, 2017. Available at http://apps.who.int/iris/bitstream/handle/10665/255016/9789241565455-eng.pdf;jsessionid=B352A815684E3DF4C3D4FC40CF44302?sequence=1 (accessed July 2018); 3. Bourgeois S, Bratovanov S, Windelinckx T. Unpublished data.

GILEAD

This initiative has received part funding from Gilead Sciences.
This meeting has been organised and funded by Gilead Sciences Europe Ltd.
Date of preparation: August 2018. HCV/IHQ/18-03//1338bi © Gilead Sciences Europe Ltd.

SLTC Summit

Španielsko - Madrid

Mobilná „harm reduction“ jednotka: on-site screening

Cañada Real Galiana shanty town

Pablo Ryan and Jorge Valencia, Madrid, Spain

Cañada Real Galiana, a shanty town on the outskirts of Madrid, has a population of

~40,000[1]

Coordinated effort between Hospital Infanta Leonor (Madrid) and an NGO-operated mobile harm reduction unit (Servicio Móvil de Atención Sanitaria a Drogodependientes [SMASD]) based in Cañada Real

Madrid, Spain

Aim: To provide HCV screening, linkage to care (LTC), treatment and cure in a vulnerable, marginalised and difficult-to-reach population

Why is the model needed?

- **90%[2]** of sales and consumption of illegal drugs in the region occur in Cañada Real
- **~4000–6000[3]** people per day go to Cañada Real to score drugs
- **55%[2]** of recent injection drug users in Cañada Real are infected with HCV

Barriers to HCV care in Cañada Real

- Poor/no access to healthcare
- Lack of knowledge about new direct-acting antiviral (DAA) therapies
- Lack of motivation to seek treatment
- Long waiting times for liver consultation
- Fear of stigmatisation
- Inability to manage and lack of resources to attend multiple medical appointments
- Irregular adherence to long-term treatment

What is the model and how does it work?

1. SMASD: mobile harm reduction unit
   - Low-threshold, non-judgemental service
   - Food, harm reduction services (OST, NSP)
   - Social work: social and legal support
   - Infection screening, other onsite healthcare services
2. Patient navigator (educator/nurse) accompanies HCV+ patient to the Fast Track Clinic
3. Infanta Leonor Fast Track Clinic
   - All tests are completed in <1 hour
   - Results are received in 3–4 days
   - Joint treatment decision between physicians at the hospital and in the harm reduction unit
4. Infanta Leonor pharmacy
   - Patient navigators collect DAA therapy from the hospital pharmacy and deliver it to Cañada Real
5. Mobile harm reduction unit
   - ✓ Follow-up treatment
   - ✓ Harm reduction services
   - ✓ Surveillance (DAA adherence, adverse effects, drug interactions)

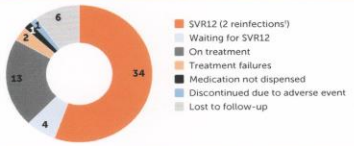
NSP: needle and syringe programme; OST: opioid substitution therapy

Interventions used to enhance HCV testing, LTC and treatment uptake

- Integrated point-of-care (onsite) HCV testing, counselling and education in a low-threshold setting (NGO-operated SMASD harm reduction unit in Cañada Real Shanty Town)
- Patient navigation* and facilitated referral to specialist for HCV evaluation and treatment (Infanta Leonor)
- Offsite non-invasive liver disease assessment using transient elastography (FibroScan®) and confirmatory HCV RNA testing (Infanta Leonor Fast Track Clinic)
- Treatment follow-up as a directly observed treatment, onsite follow-up clinical appointments and blood tests, therapeutic surveillance and education, and reinfection counselling (Cañada Real)

Outcomes: the Cañada Study Group[4]

Intention-to-treat population (n=61)



92% SVR12
mITT cohort
34/37 patients

Low-threshold and non-judgemental services and coordination with the community are essential to build trust in order to improve HCV screening, LTC and harm reduction among this vulnerable, marginalised population

Models of care must be adapted to the needs and circumstances of the target population

1. Frayer L. National Public Radio (27 April 2012). Available at: https://www.npr.org/2012/04/27/150824559/showdown-looms-over-europes-largest-shantytown (accessed 11 July 2018); 2. Ryan P, et al. EACS 2015; Poster #PE13/1; 3. Ryan P. Personal communication; 4. Valencia J, et al. AASLD 2017; Poster #1145.

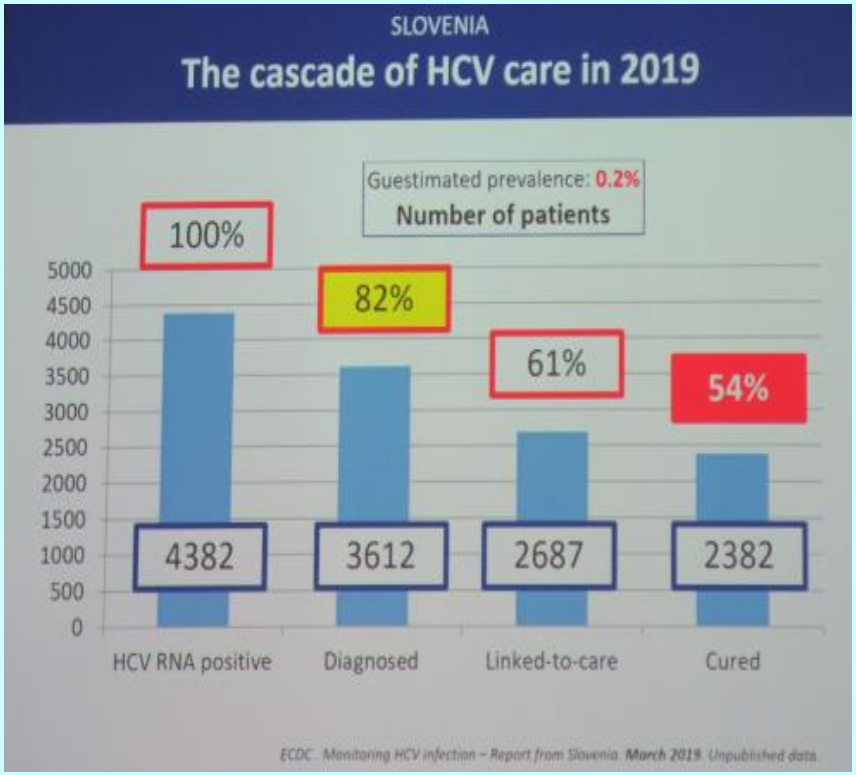
*Patient navigation services include: appointment scheduling, appointment reminders, accompanying patients to Fast Track Clinic, collection of DAA therapy from hospital pharmacy. †Reinfections occurred after the 12-week post-treatment period. mITT: modified intention to treat; NGO: non-government organisation.

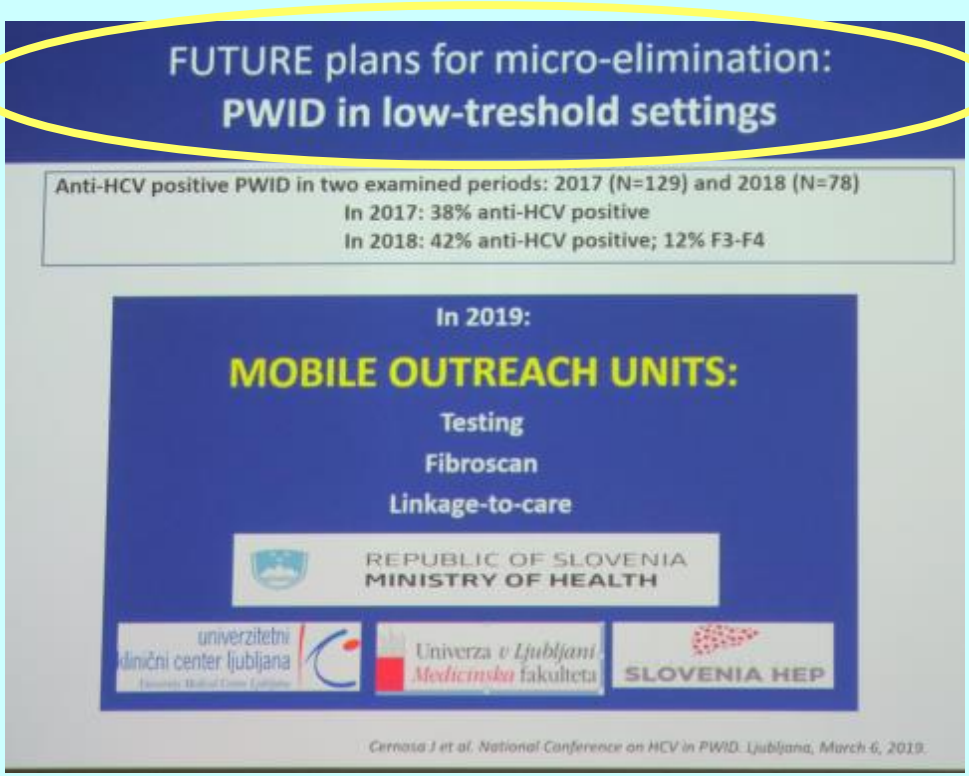
GILEAD

This meeting has been organised and funded by Gilead Sciences Europe Ltd.
Date of preparation: August 2018. HCV/IHQ/18-03//1338bm © Gilead Sciences Europe Ltd.

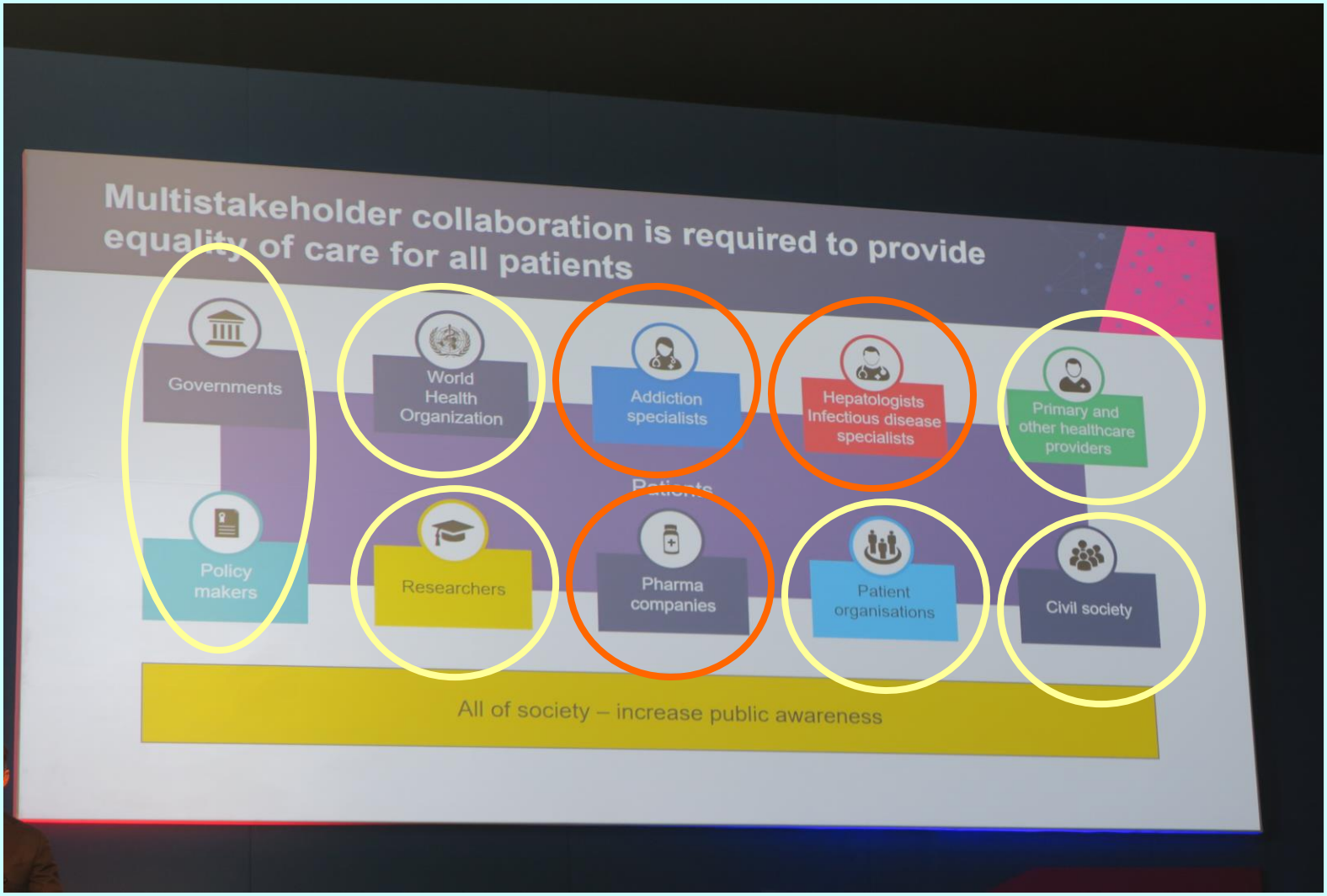
SLTC

Slovinsko


SLOVENIA
The cascade of HCV care in 2019
Guestimated prevalence: 0.2%
Number of patients
100%
82%
61%
54%
5000
4500
4000
3500
3000
2500
2000
1500
1000
500
0
4382
3612
2687
2382
HCV RNA positive
Diagnosed
Linked-to-care
Cured
ECDC. Monitoring HCV infection – Report from Slovenia. March 2019. Unpublished data.


FUTURE plans for micro-elimination:
PWID in low-treshold settings
Anti-HCV positive PWID in two examined periods: 2017 (N=129) and 2018 (N=78)
In 2017: 38% anti-HCV positive
In 2018: 42% anti-HCV positive; 12% F3-F4
In 2019:
MOBILE OUTREACH UNITS:
Testing
Fibroscan
Linkage-to-care
REPUBLIC OF SLOVENIA
MINISTRY OF HEALTH
univerzitetni klinični center ljubljana
Univerza v Ljubljani Medicinska fakulteta
SLOVENIA HEP
Cernosa J et al. National Conference on HCV in PWID. Ljubljana, March 6, 2019.

Eliminácia VHC predpokladá vzájomnú spoluprácu



Záver

Advisory Board – 22.5.2019

Predsedníctvo:
MUDr. Ľubomír Skladaný, PhD.

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doc. MUDr. Pavol Kristian, PhD.
MUDr. Eliška Lovrantová, PhD.
MUDr. Ľubomír Okruhlica, CSc.
MUDr. Marián Oltman, PhD.
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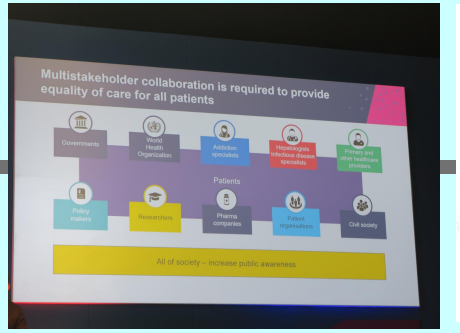

Pacient/ klient:

- PWID
- Epidemiologická anamnéza
- Hepatopatia
- Ideálne každý

Vyšetrenie:

- Bi, AST, ALT, GMT
- Anti - HCV

Centrá pre liečbu HCV infekcie:

www.virusova-hepatitida.sk/liecebna-centra

LIEČEBNÁ CENTRÁ
Odborné pracoviská, ktoré sa špecializujú na diagnostiku
a liečbu vírusovej hepatitídy C

Banskobystrický kraj kraj
Bratislavský kraj
Košický kraj
Nitrianský kraj
Prešovský kraj
Trenčianský kraj
Trnavský kraj
Žilinský kraj

Pracoviská pre liečbu vírusových hepatitíd[1]

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Literatúra: 1. https://www.slovhep.sk/pracoviska/zobrazit-ambulancie/3

SK-VHCV-180003

abbvie

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Pracoviská pre liečbu vírusových hepatitíd[1]

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Ďakujem