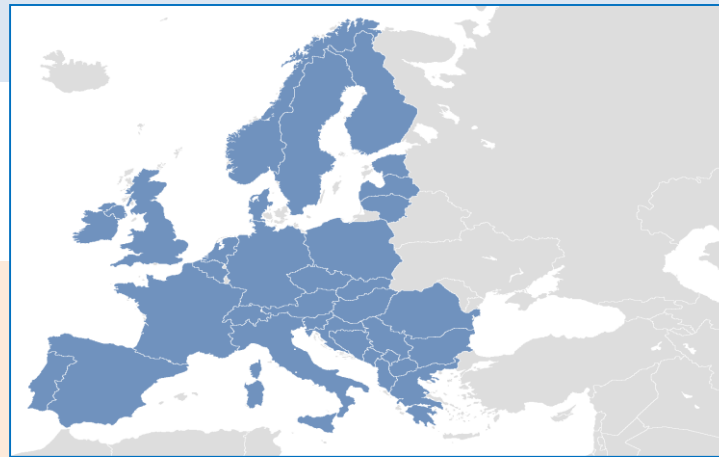


Are there national strategies, plans and guidelines for the treatment of hepatitis C in PWID?

A survey of 33 European countries



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Disclosure

Within the last 36 months:

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

No conflict of interest regarding this presentation

Efficacy of HCV TREATMENT in PWID

Individual:

- cure
- prevention of life-threatening complications (cirrhosis, liver cancer)
- improved quality of life
- is cost-effective

Prevention of HCV-related morbidity and mortality

Epidemiological (modeling study):

- even modest rates of HCV treatment may effectively lower HCV prevalence (even with re-infection / treatment failure)
- combination of HCV treatment with needle/syringe programs and OST is critical

Prevention of HCV transmission

Perry C, Jarvis B. Drugs 2001; 61: 2263.
Heathcote E, et al. N Engl J Med 2000; 343: 1673.
Ghany MG, et al. Hepatology. 2009;49:1335-1374.
Stein K, et al. Gut 2002;50:253-8.

Swain M et al. Gastroenterology 2010; 139: 1593-601.
Hellard M et al. Clin Infect Dis 2009; 49: 561-73. Zanini B et al. Clin Ther 2010; 32: 2139-59.
Grischenko M, et al. Int J Technol Asses Health Care 2009; 2: 171-80.
Martin JK et al. J Hepatol, 2011;54: 1137-44.

Reluctance to treat HCV infection in PWID

- Past two decades: HCV treatment for PWID **controversial**
- Low treatment uptake in developed countries:
3-4% of current or former PWID treated for HCV
- Barriers: patient
practitioner
system: NO national strategy / action plan / clinical guidelines

Concerns about:

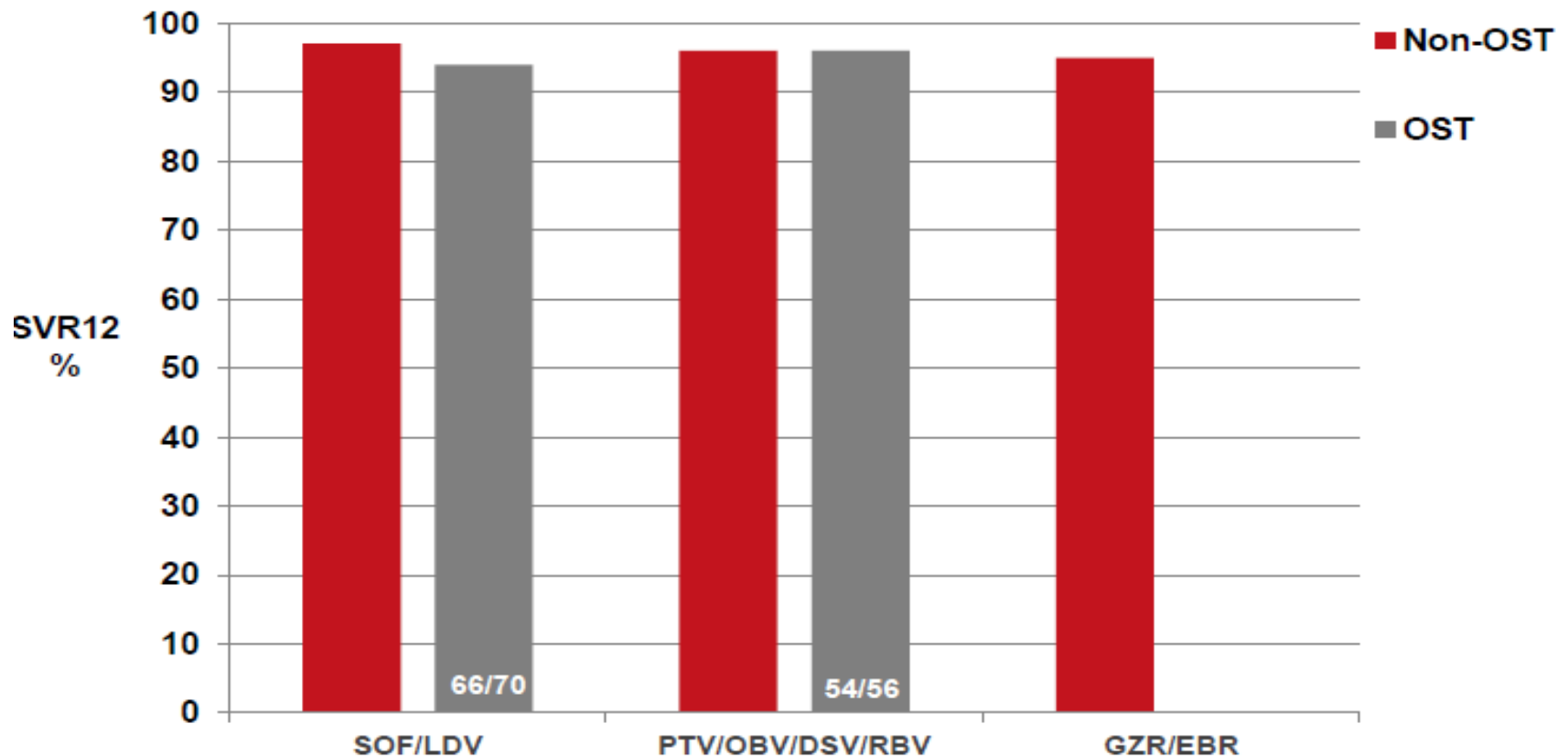
- Severe adverse events
- Non-efficacy
- Premature treatment completion
- Poor adherence to treatment
- Influence on increased drug use
- Reinfection

HCV treatment in PWID WORKS!

- In former and current PWID, **PEG/RBV** treatment is comparable to general population:
safe
effective (54-56%)
- Treatment uptake effective and cost-effective also in **low threshold settings**
- A history of IDU does **not compromise : adherence**
treatment completion
- **No influence** of HCV treatment on: increase in drug use
treatment of drug use
- After successful treatment **re-infections are rare :**
1-5% per year; 13.2% in 5 years

IFN-free DAA treatment in PWID

G1, th naive, F0-4; 12 wks

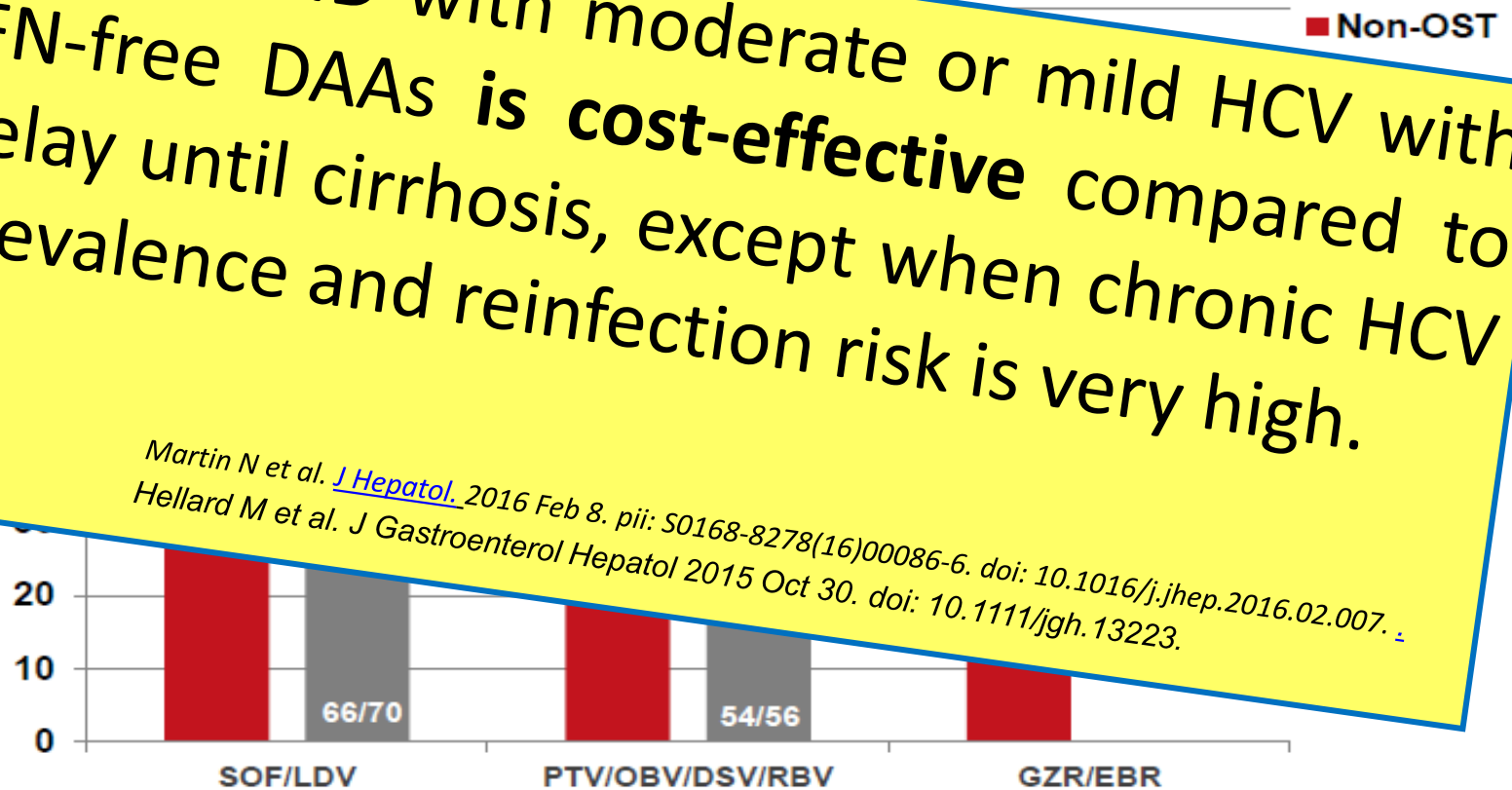


*Afdhal N et al, NEJM 2014; Feld J et al, NEJM 2014; Lelazari J et al, IAC 2015.
Zeuzem S et al, ILC 2015; Jacobson I et al, AASLD 2014.*

IFN-free DAA treatment in PWID

G1, th naive, F0-4; 12 wks

Treating PWID with moderate or mild HCV with IFN-free DAAs **is cost-effective** compared to delay until cirrhosis, except when chronic HCV prevalence and reinfection risk is very high.



Martin N et al. *J Hepatol*. 2016 Feb 8. pii: S0168-8278(16)00086-6. doi: 10.1016/j.jhep.2016.02.007. -
Hellard M et al. *J Gastroenterol Hepatol* 2015 Oct 30. doi: 10.1111/jgh.13223.

Afdhal N et al, NEJM 2014; Feld J et al, NEJM 2014; Lelazari J et al, IAC 2015.
Zeuzem S et al, ILC 2015; Jacobson I et al, AASLD 2014.

International guidelines call for HCV treatment in PWID

- EMCDDA 2010
- EASL 2014
- WHO 2014



**GUIDELINES FOR THE SCREENING,
CARE AND TREATMENT OF PERSONS
WITH HEPATITIS C INFECTION**

APRIL 2014

GUIDELINES



EASL Recommendations 2015. doi: <http://dx.doi.org/10.1016/j.hep.2015.03.025>

Wiessing L , Blystad S. Euro Surveill 2010, **15**:48.

WHO 2014. <http://apps.who.int/iris/bitstream/10665/111747>

EASL. J Hepatol 2014; 60: 392-420.

European Association for the Study of the Liver, 2015 Recommendations on treatment of hepatitis C

Treatment priority	Patient group
Treatment is indicated	<ul style="list-style-type: none">• All treatment-naïve and treatment-experienced patients with compensated and decompensated liver disease
Treatment should be prioritized	<ul style="list-style-type: none">• Patients with significant fibrosis (F3) or cirrhosis (F4), including decompensated cirrhosis• Patients with HIV coinfection• Patients with HBV coinfection• Patients with an indication for liver transplantation• Patients with HCV recurrence after liver transplantation• Patients with clinically significant extra-hepatic manifestations• Patients with debilitating fatigue• Individuals at risk of transmitting HCV (active injection drug users, men who have sex with men with high-risk sexual practices, women of child-bearing age who wish to get pregnant, haemodialysis patients, incarcerated individuals)
Treatment is justified	<ul style="list-style-type: none">• Patients with moderate fibrosis (F2)
Treatment can be deferred	<ul style="list-style-type: none">• Patients with no or mild disease (F0-F1) and none of the above-mentioned extra-hepatic manifestations
Treatment is not recommended	<ul style="list-style-type: none">• Patients with limited life expectancy due to non-liver related comorbidities

2015 INHSU recommendations for the management of HCV in PWID

International Journal of Drug Policy 26 (2015) 1028–1038



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journal homepage: www.elsevier.com/locate/drugpo



Editors' Choice

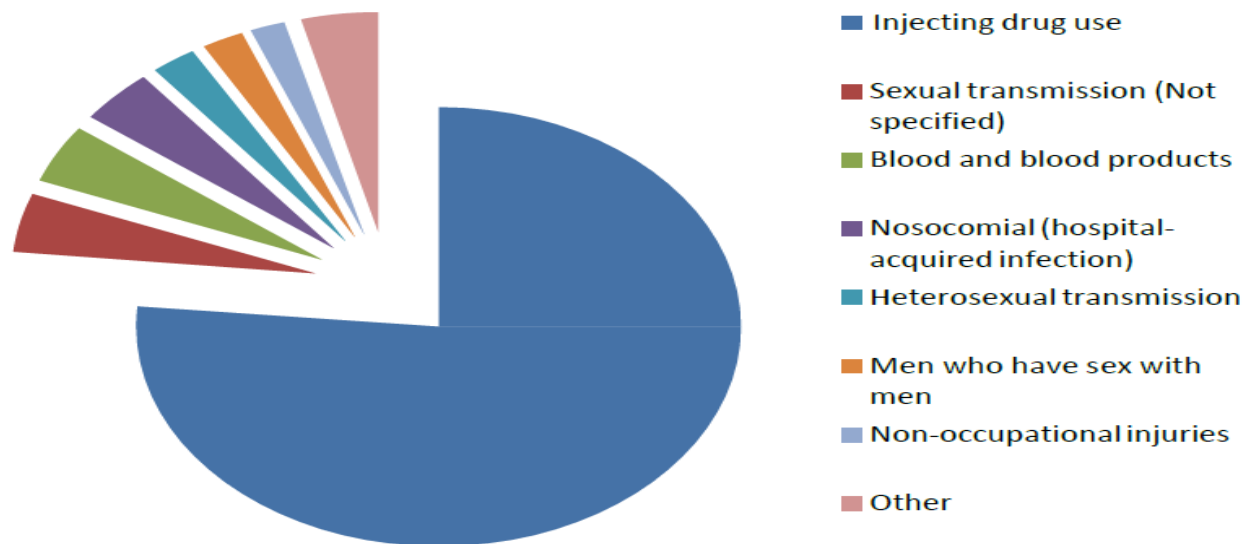
Recommendations for the management of hepatitis C virus infection among people who inject drugs



Jason Grebely^{a,*}, Geert Robaey^{b,c,d}, Philip Bruggmann^e, Alessio Aghemo^f,
Markus Backmund^{g,h}, Julie Bruneauⁱ, Jude Byrne^j, Olav Dalgard^k, Jordan J. Feld^l,
Margaret Hellard^{m,n}, Matthew Hickman^o, Achim Kautz^p, Alain Litwin^q, Andrew R. Lloyd^r,
Stefan Mauss^s, Maria Prins^{t,u}, Tracy Swan^v, Martin Schaefer^{w,x}, Lynn E. Taylor^y,
Gregory J. Dore^a on behalf of the International Network for Hepatitis in Substance Users

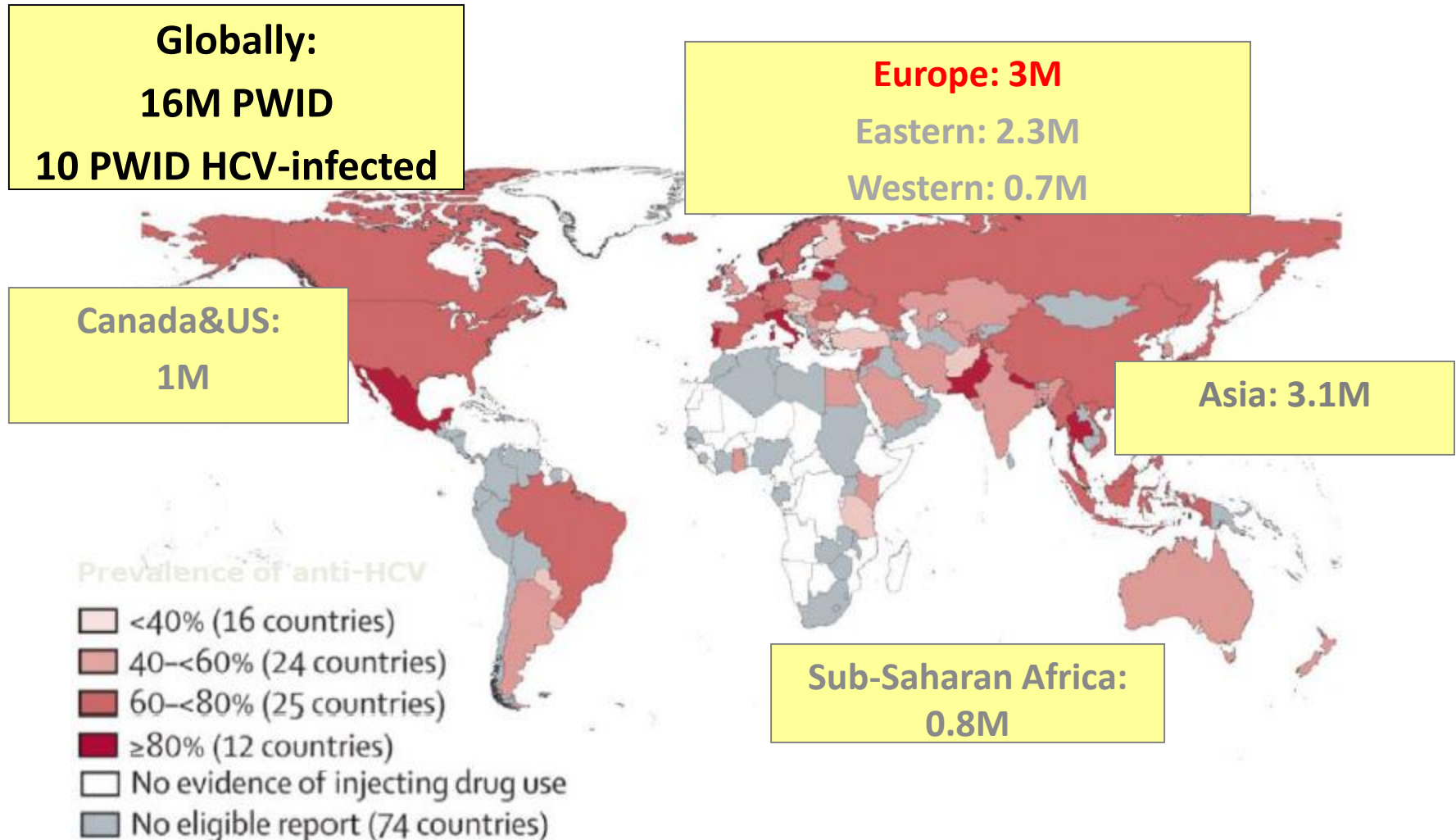
Current transmission route of HCV cases in EU/EEA countries, 2012

- Last decade: new infections **not** common in general population
major problem people who inject drugs (PWID)

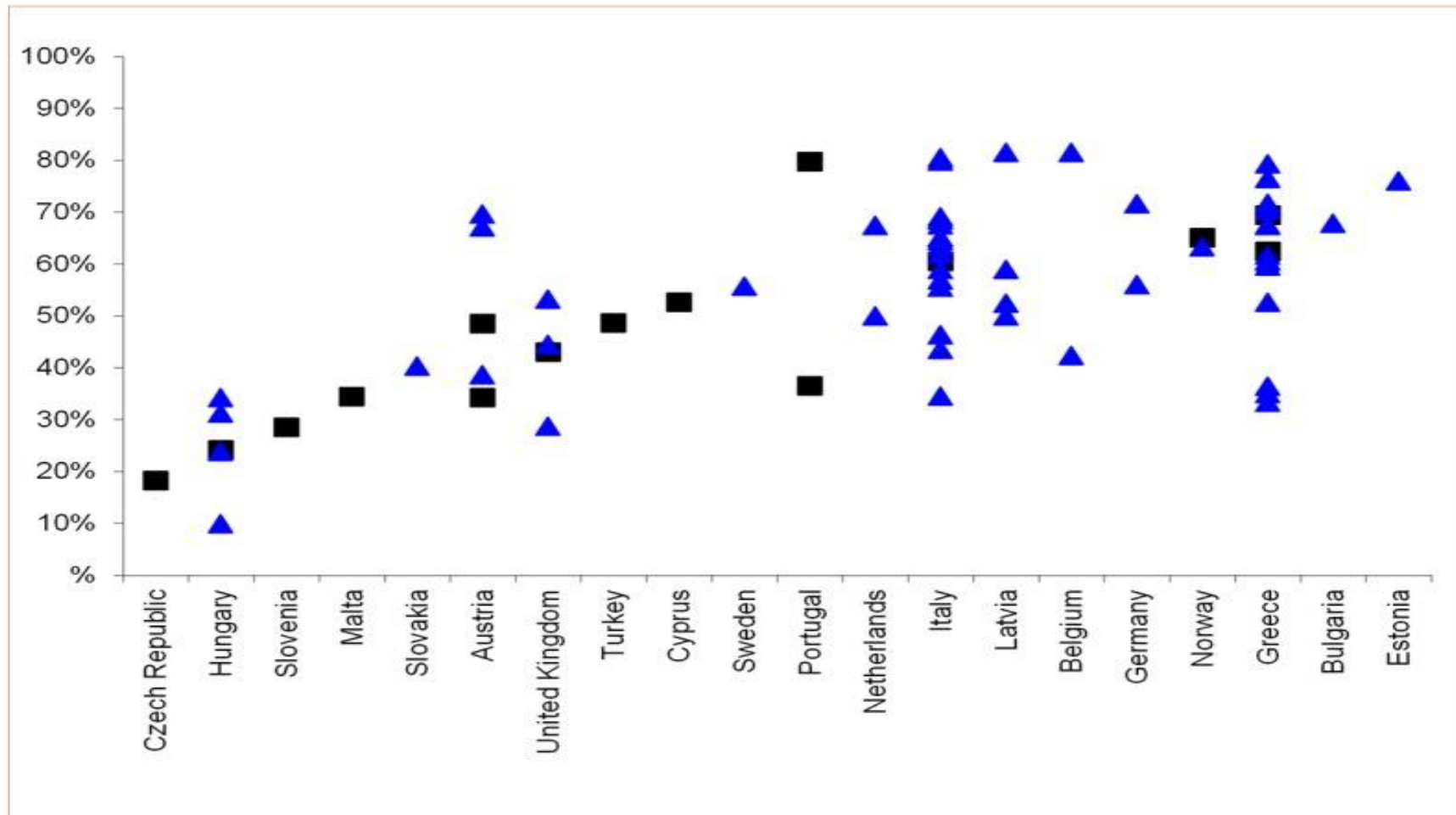


Route of transmission: injecting drug use **78.1%**

Global burden of hepatitis C in PWID

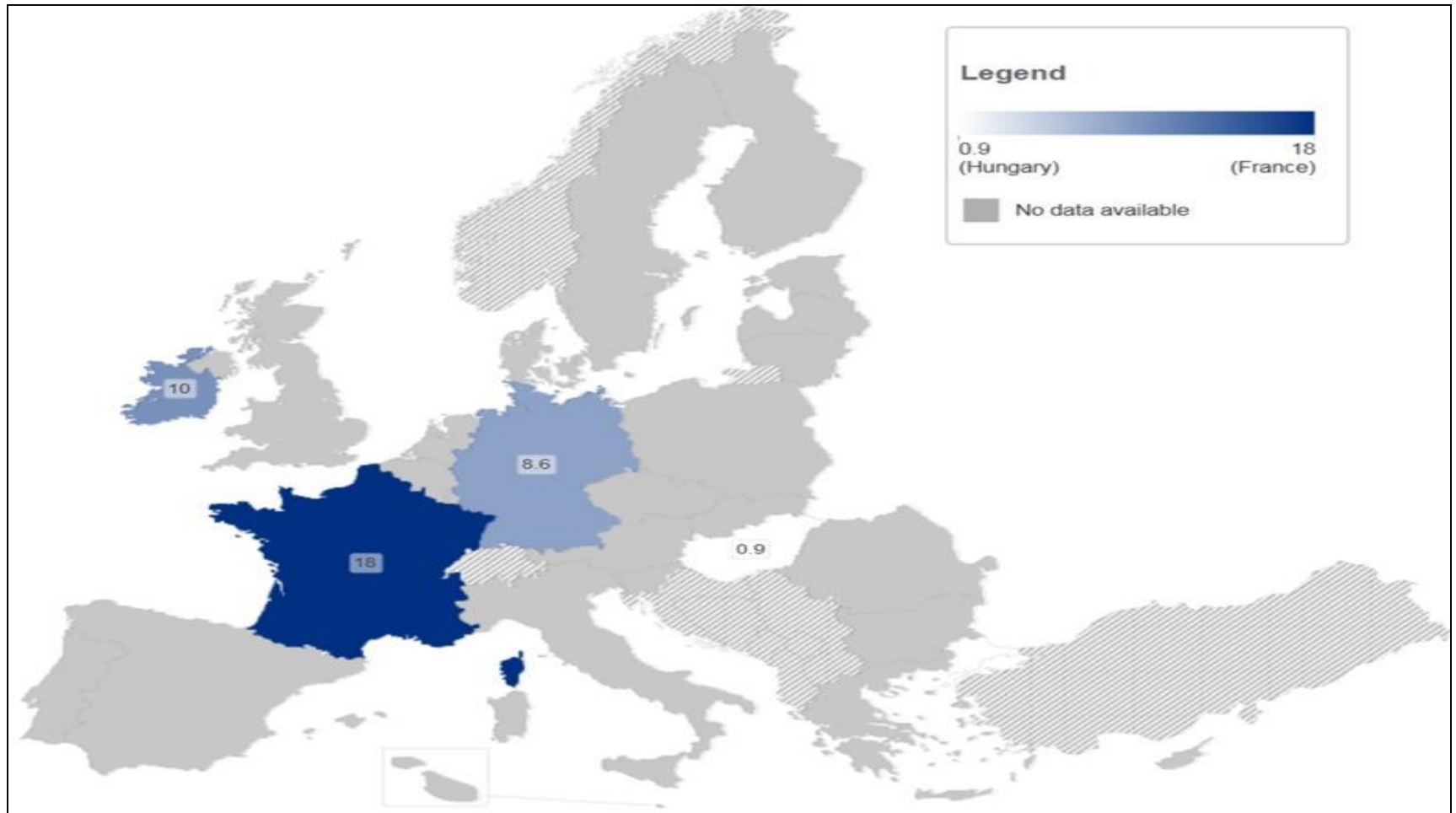


HCV seroprevalence among PWID in the EU 2006–2011



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

Proportion (%) of HCV-infected PWID in Europe entering **antiviral treatment** in observational studies in non-clinical settings



HCV treatment of PWID

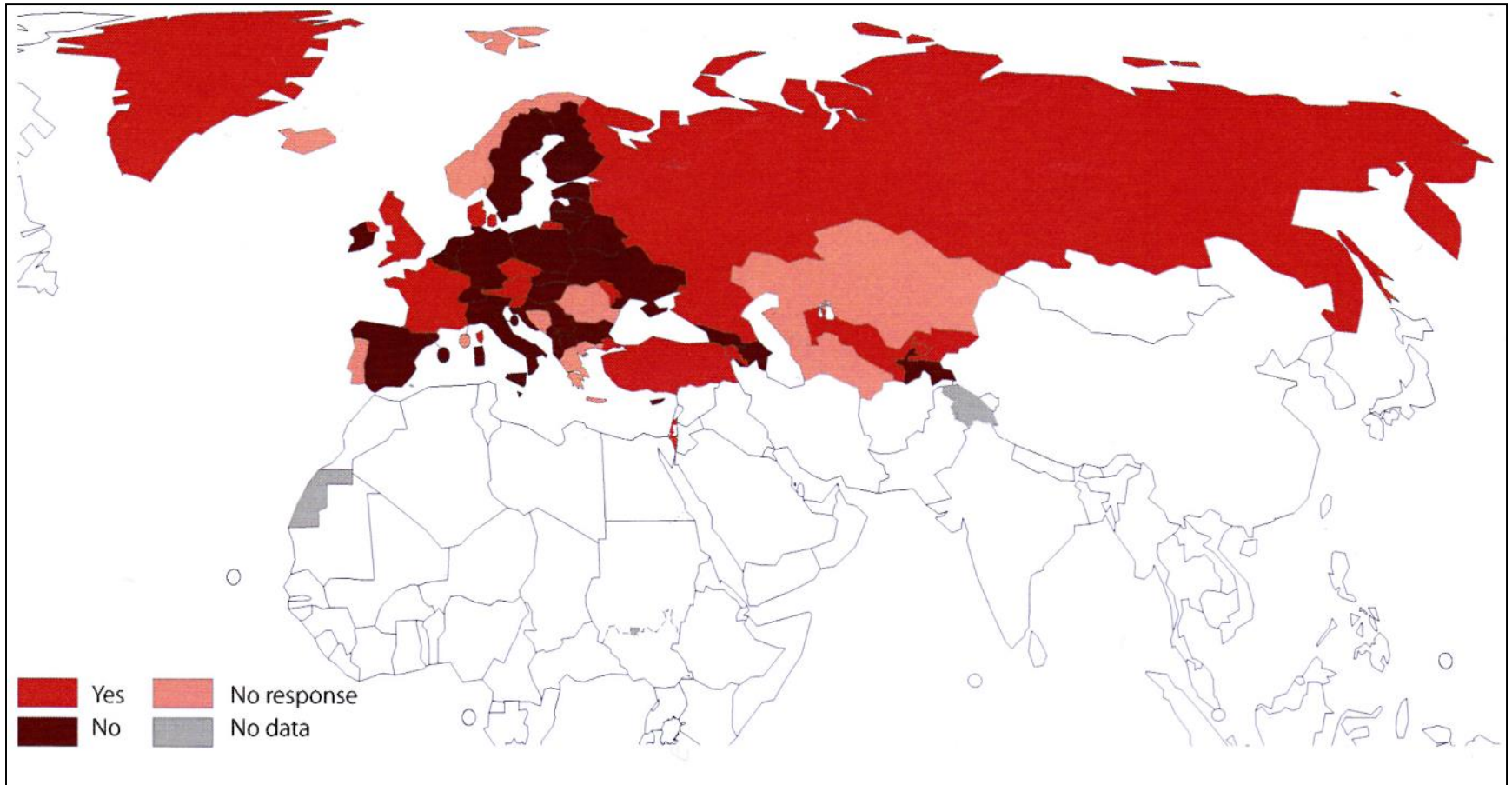
Needed:

- National strategy
- National action plan
- National clinical guidelines

WHO 2013 Global policy report on the prevention and control of viral hepatitis

- **Objective:** To obtain data on the existence of the **national strategies** to control viral hepatitis and **guidelines in general**
- **Data collection:** governmental institutions of the European member states
- **Period:** July 2012 - February 2013

**WHO 2013 : No national strategy
on the control of viral hepatitis
in the majority of European countries**



A survey of 33 European countries

- **Objective:** To collect data on the existence of the national **strategy, action plan, clinical guidelines** on HCV treatment in **general population and PWID**
- **Data collection:** non-governmental institutions
- **Period:** September-December 2013

A survey of 33 European countries

METHODS

- Prospective study
- **Informants:** from a database of contacts from
“HCV Initiative of the Correlation Network”
- **Data collection:** a structured electronic questionnaire
sent via e-mail to individuals in
33 European countries

A questionnaire

1. Does your country have a national strategy for treatment of HCV? <input type="checkbox"/> Yes <input type="checkbox"/> No
2. If yes, does it include action with regards to PWID? <input type="checkbox"/> Yes <input type="checkbox"/> No
3. Does your country have a national action plan of HCV (in place of or in addition to a strategy)? <input type="checkbox"/> Yes <input type="checkbox"/> No
4. If yes, does it include actions in regard of PWID? <input type="checkbox"/> Yes <input type="checkbox"/> No
5. Does your country have national guidelines for treatment of HCV? <input type="checkbox"/> Yes <input type="checkbox"/> No
6. If yes, does this include guidelines in regard of PWID or are these separate guidelines in regard of PWID? Guidelines in regard of PWID are included <input type="checkbox"/> Yes <input type="checkbox"/> No Separate guidelines in regard of PWID <input type="checkbox"/> Yes <input type="checkbox"/> No
7. In case there are separate guidelines in regard of PWID, are they applicable to: PWID on opiate substitution treatment <input type="checkbox"/> Yes <input type="checkbox"/> No Active PWID <input type="checkbox"/> Yes <input type="checkbox"/> No

A questionnaire

1. Does your country have a national strategy for treatment of HCV?

- ☐ Yes
☐ No

2. If yes, does this include action with regards to PWID?

- ☐
☐

place of or in addition to a strategy)?

5. Does your country have a national strategy for treatment of HCV?

- ☐ Yes
☐ No

6. If yes, does this include guidelines in regard of PWID?

Guidelines in regard of PWID are included

- ☐ Yes
☐ No

Separate guidelines in regard of PWID

- ☐ Yes
☐ No

7. In case there are separate guidelines in regard of PWID, are they applicable to:

PWID on opiate substitution treatment

- ☐ Yes
☐ No

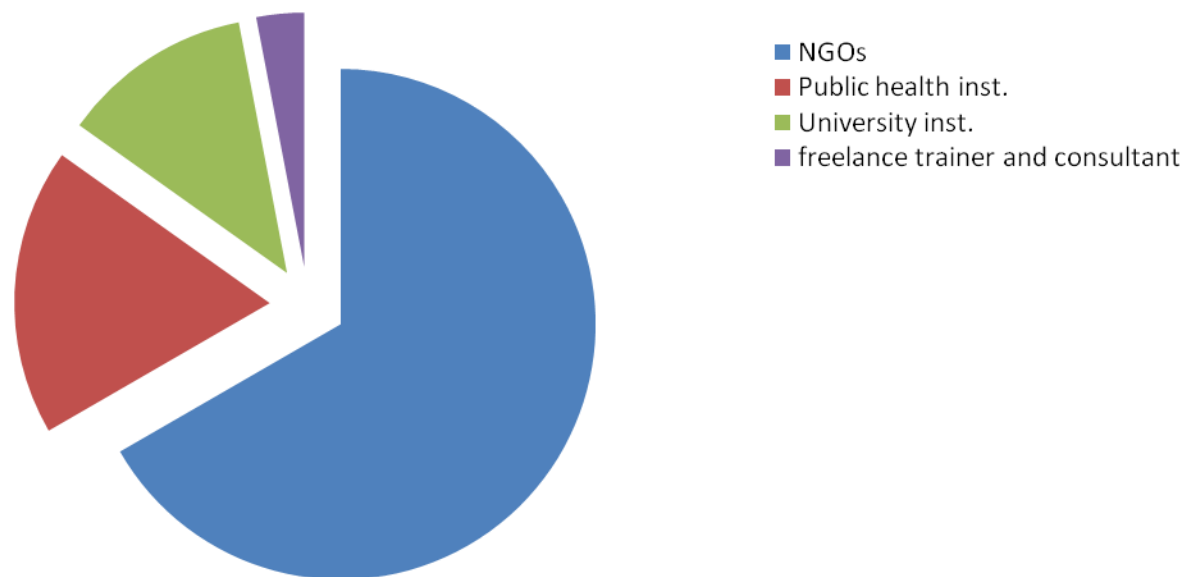
Active PWID

- ☐ Yes
☐ No

Definition of PWID: active (drugs in past 6 months) and former injectors (including active non-injectors, and/or those on OST)

A survey of 33 European countries

Affiliation of respondents



NGOs: 22 (67%)

Public health institutions: 6 (18%)

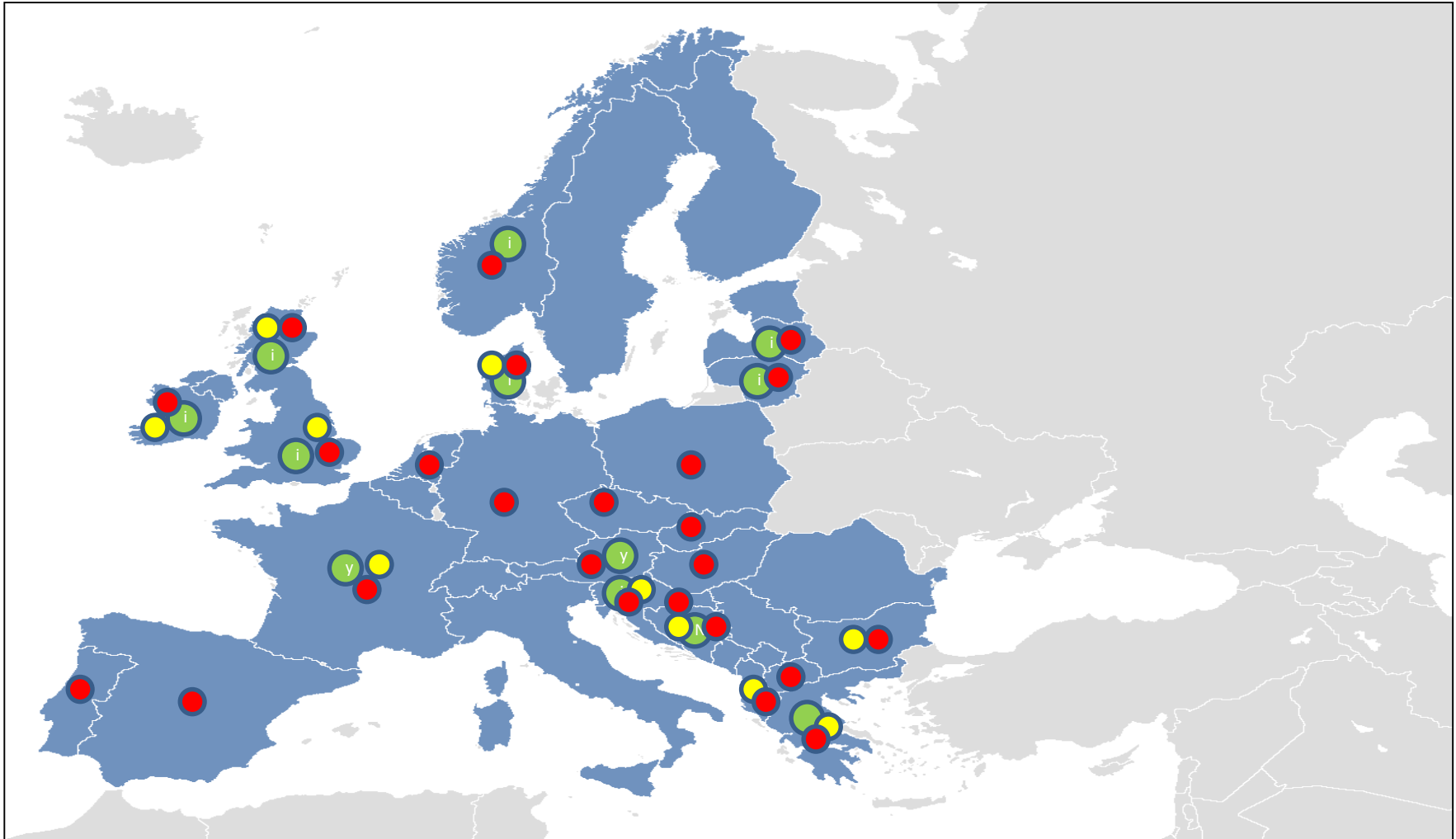
University institutions: 4 (12%)

Freelance trainer and consultant: 1 (3%)

National level activities on HCV management

A survey of 33 European countries

● National strategy, 12 (10 PWID) ● National action plan, 10 (7 PWID) ● National treatment guidelines, 24 (20 PWID)



*Scotland was treated separately from UK

National level activities on HCV treatment in PWID

A survey of 33 European countries

National strategy for HCV treatment: 12/33 (**36%**) countries, PWID included in 11/12 countries:
Austria, BiH, Denmark, France, Greece, Ireland, Lithuania, Norway, Slovenia, Scotland, UK, Latvia (PWID not included)

National action plan for HCV treatment: 10/33 (**30%**) countries, PWID included in 7/10 countries:
BiH, Denmark, France, Greece, Slovenia, Scotland, UK, Albania, Bulgaria, Ireland (PWID not included)

* Croatia and Finland: action plan in development

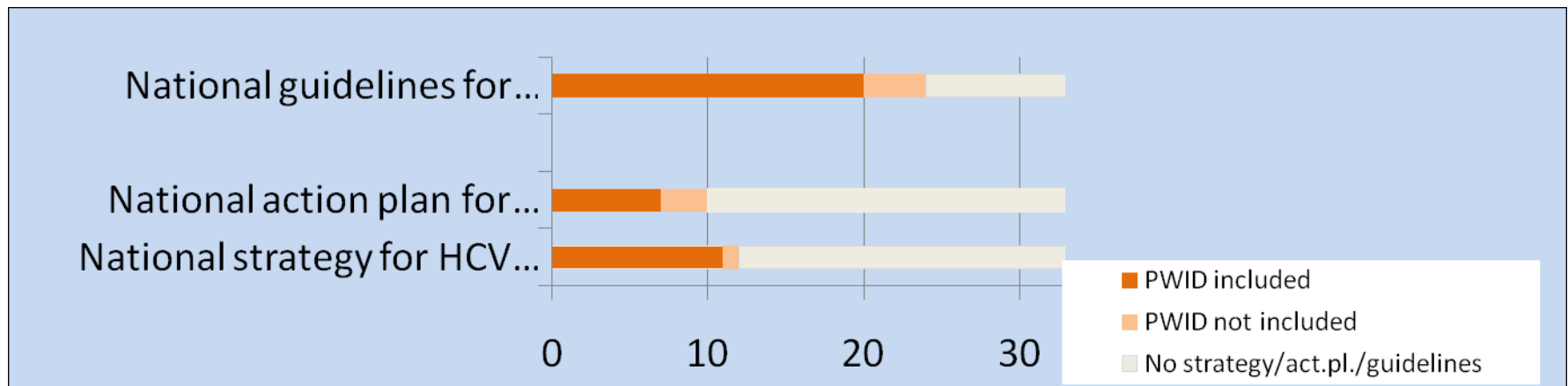
**Italy: awaiting for governmental approval

National guidelines for HCV treatment: 24/33 (**73%**), PWID included in 20/24 countries:
Albania, BiH, Croatia, Denmark, France, Germany, Greece, Hungary, Latvia, Lithuania, Macedonia, Norway, Poland, Portugal, Slovakia, Slovenia, Scotland, Spain, Netherlands, UK (PWID not included)

*Italy: guidelines prepared, to be approved by the government

**Romania: non-governmental document in use

***Finland and Switzerland: guidelines under development



A survey of 33 European countries

- **National strategy** for HCV treatment: 12/33 (36%)
PWID included: 11/12 (92%)
- **National action plan** for HCV treatment: 10/33 (30%)
PWID included: 7/10 (70%)
- **National guidelines** for HCV treatment: 24/33 (73%)
PWID included: 20/24 (83%)

Separate guidelines for HCV treatment in **PWID on OST**: 15/33 (45%)

Separate guidelines for HCV treatment in **active drug users**: 9/33 (27%)

National level activities on HCV treatment in PWID

A survey of 33 European countries

- Compared to 2013 WHO global policy report

Country	Albania	Austria	Belgium	Bulgaria	Croatia	CZ	Deenmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Macedonia	Montenegro	Norway	Poland	Portugal	Romania	Scotland	Serbia	Slovakia	Slovenia	Spain	Sweden	Switzerland	Netherlands	K
Natinal clinical guidelines for HCV th	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	n i	Y	N	N	Y	Y	Y	N	n i	Y	n i	n i	n i	Y	Y	Y	Y	N	Y	Y	N
National strategy for HCV th	n d	Y	N	N	N	Y	N	N	N	Y	N	n i	N	N	N	N	N	N	N	n i	N	n i	n i	n i	N	N	Y	N	N	N	N	Y
National clinical guidelines for HCV th	N	Y	N	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	Y	Y	Y	N	N	Y	Y
National strategy for HCV th	N	Y	N	N	N	N	Y	N	N	Y	N	Y	N	Y	N	Y	Y	N	N	Y	N	N	N	Y	N	N	Y	N	N	N	N	Y



WHO report



33-countries survey



discrepancy

National level activities on HCV treatment in PWID

A survey of 33 European countries

- Compared to 2013 WHO global policy report

Countries with **good adherence to EASL guidelines** reported on national guidelines for HCV treatment that also **include PWID**

funding

Adherence to EASL guidelines

Y:yes, N: no, ND: no data, NI:no information, 3=good, 2=so-so, 1=not-so-good

WHO 2013 global policy report on viral hepatitis

- Publicly funded treatment of HCV

Country	Albania	Austria	Belgium	Bulgaria	Croatia	CZ	Deenmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Macedonia	Montenegro	Norway	Poland	Portugal	Romania	Scotland	Serbia	Slovakia	Slovenia	Spain	Sweden	Switzerland	Netherlands	UK
National clinical guidelines for HCV th	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	n i	Y	N	N	Y	Y	Y	N	n i	Y	n i	n i	n i	Y	Y	Y	Y	N	Y	Y	N
National strategy for HCV th	n d	Y	N	N	N	Y	N	N	N	Y	N	n i	N	N	N	N	N	N	N	n i	N	n i	n i	n i	N	N	Y	N	N	N	N	Y
Availability of publicly funded treatment	n d	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	n i	Y	Y	Y	Y	Y	Y	Y	n i	Y	n i	n i	n i	Y	n d	Y	Y	Y	N	Y	Y



WHO report



33-countries survey

WHO 2013 global policy report on viral hepatitis

Publicly funded treatment of HCV

- In all countries of the European WHO region, but Switzerland (data for Albania and Slovakia not available)
- **active injection drug use is an absolute contraindication for publicly funded treatment in Finland**
- **only 75% of total treatment cost is publicly funded in Latvia**

	Albania	Armenia	Azerbaijan	Belarus	Bulgaria	Croatia	Czechia	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	UK
National clinical guidelines for HCV treatment																												
National strategies for HCV treatment																												
Availability of publicly funded treatment	nd	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y



WHO report

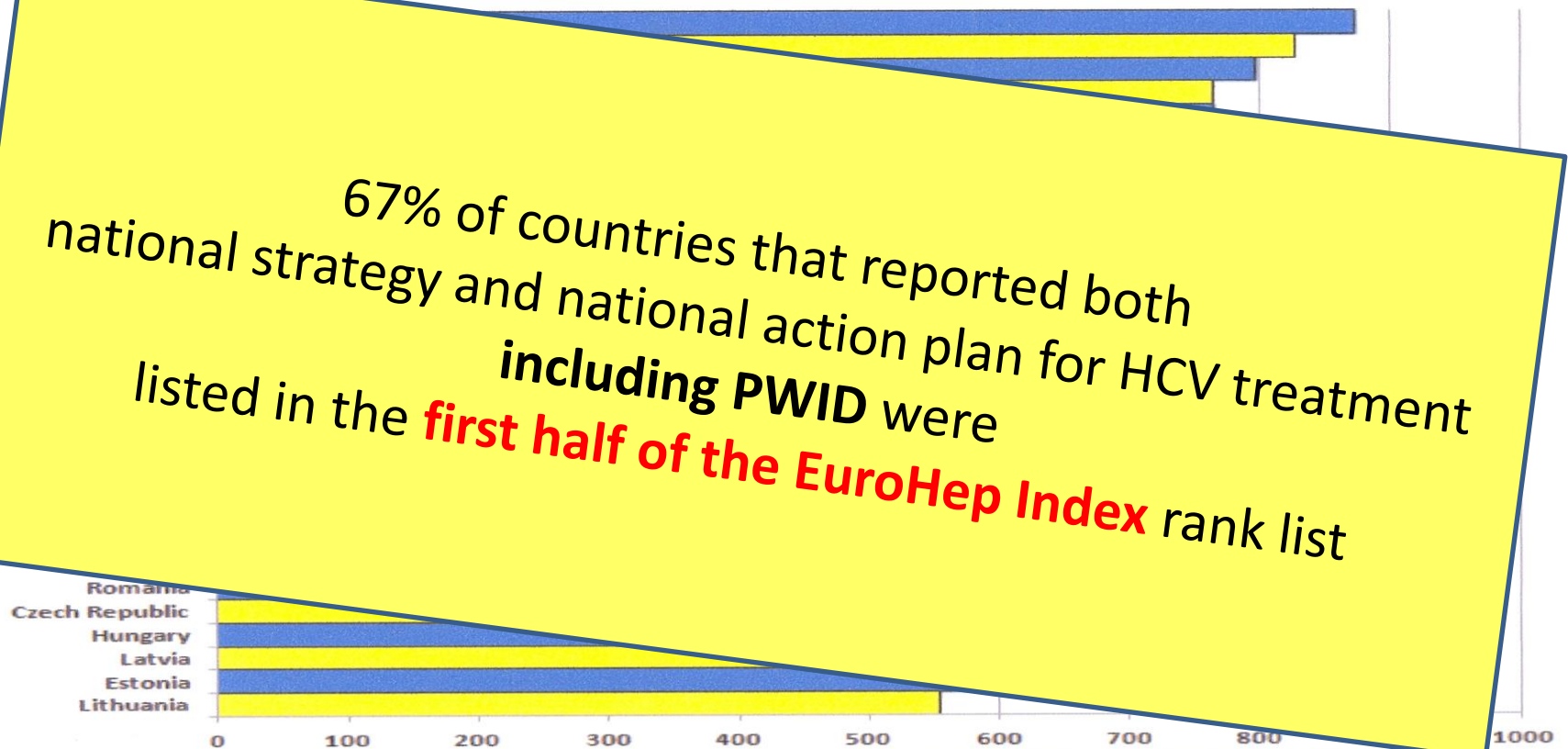


33-countries survey

A survey of 33 European countries

- Compared to Euro Hepatitis Index report, 2012

Euro Hepatitis Index 2012 Total Scores



Conclusions

- HCV treatment is safe and effective in population of PWID, with low risk of reinfection in former and current PWID
- International guidelines for the management of HCV in PWID exist and call for treatment
- National strategies, action plans and clinical guidelines on HCV treatment have not been introduced in all European countries; they are needed for general population as well as for PWID
- The introduction of new drugs for all in need are crucial for future management of HCV infection in PWID