NOBODY LEFT BEHIND

Global overview of hepatitis C treatment access and people who use drugs

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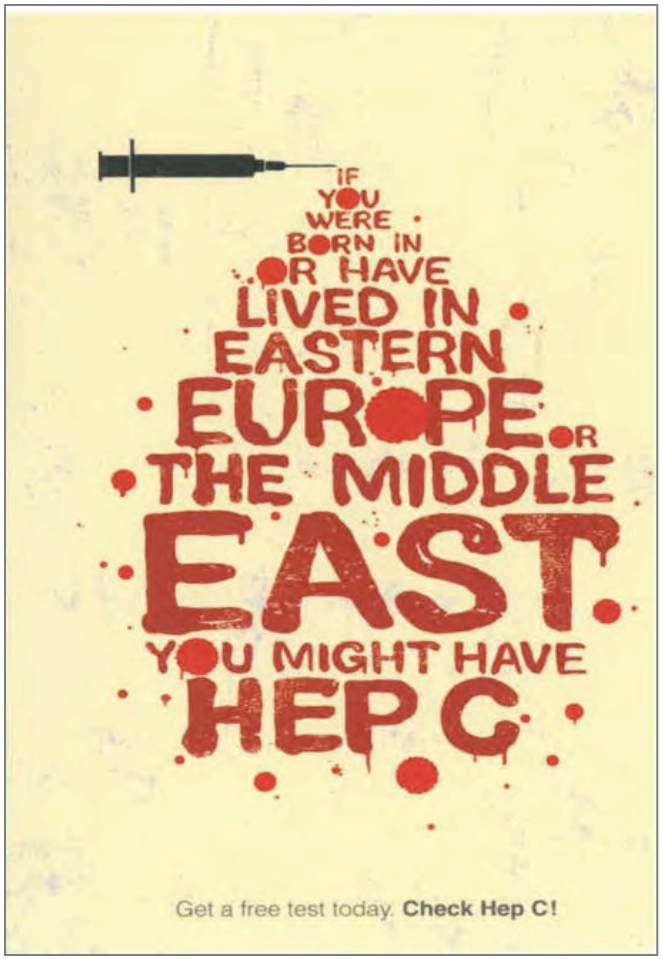
1st European Conference on Hepatitis C and Drug Use
October 23 & 24 - Berlin

PWID are disproportionally affected by HCV



- Among the estimated 16 million people who inject drugs worldwide, approximately 10 million are HCV- antibody-positive, and about 8 million live with chronic hepatitis.
- About 80% of HIV-positive PWID are coinfected with hepatitis C.
- 90% of new infections result from lack of access to sterile injecting equipment.
- People who use drugs – and specifically people who inject drugs –bear by far the heaviest burden of HCV of any population.

Harm reduction services must be massively scaled up!

Grebely J, Dore GJ. Can hepatitis C virus infection be eradicated in people who inject drugs? Antiviral Res. 2014;104:6272. doi: 10.1016/j. antiviral. 2014.01.002.

How many PWID need HCV treatment?

- Treatments needs are invisible because most infections are asymptomatic and there is little or no access to tests & diagnostics

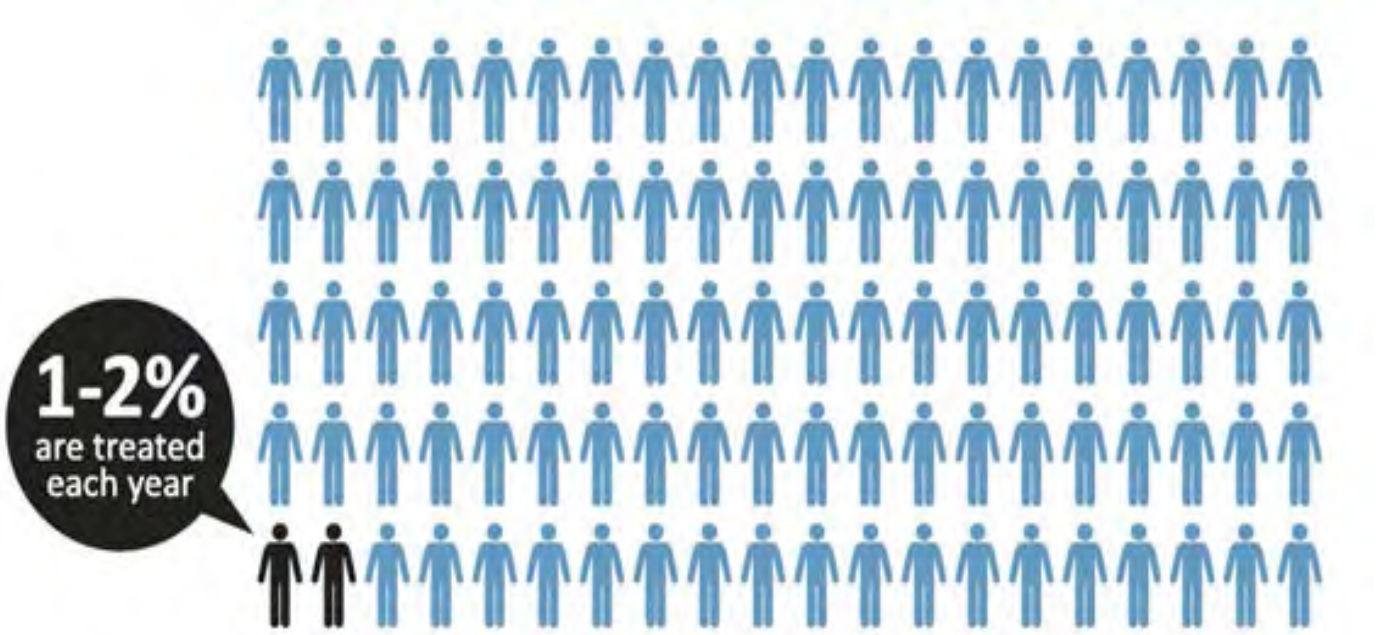
> Treatment needs must be documented to create demand!

- Cross sectional study ran on oct. 2012 by MdM in Georgia among 217 PWID living in Tbilisi (out of 27.000)
  - HCV antibodies : 92 %
  - Chronic HCV: 83%
  - Severe liver fibrosis : 24%
- Based on data from research conducted by Médecins du Monde and complementary clinical and epidemiological information:

We estimate that around 2 million people who inject drugs globally need treatment immediately.

How many PWID DO access HCV treatment?

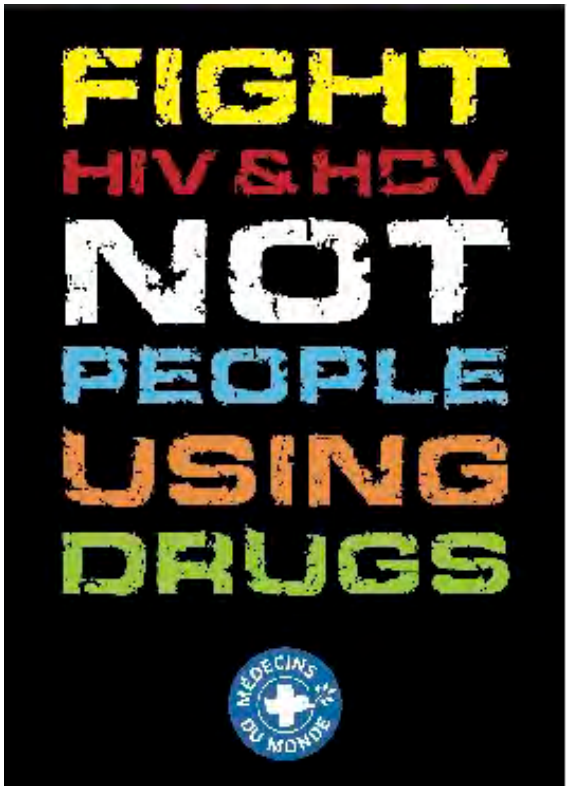
- In high-income countries, the annual HCV treatment uptake of people who inject drugs remains very low, at around 1–2 percent.
- **Treatment uptake in Low and Middle Income Countries is clearly even lower.**



Why so few?

Grebely J, Dore GJ. Can hepatitis C virus infection be eradicated?

Stigma and criminalization



- **Repressive drug policies and the almost universal criminalization** are taking PWUD further away from health care services.
- **Misinformation:** difficulties of PWID to access treatment programs due to concerns about adherence, adverse events and reinfection

Beyond prejudices:

- **Treatment success rate are similar** if you're a PWID or not, active user or not
- **High treatment adherence** rate (82%)
- **Reinfection rate is low** (1-5%) among PWID

"decisions about treatment should be made independently of an individual's injection drug use status."

Treating people who inject drugs is safe, and it works!

Aspinall EJ, Corson S, Doyle JS, Grebely J, Hutchinson SJ, Dore GJ, Goldberg DJ, Hellard ME. Treatment of hepatitis C virus infection among people who are actively injecting drugs: a systematic review and meta-analysis. Clin Infect Dis. 2013;57 Suppl 2:S80–9.

Prices of HCV treatment are exorbitant

- Sofosbuvir's price has generated debates about sustainability even in high income countries
- US: 84,000 USD /12-week course
- UK: 44,000 euros /12-week course
- Germany: 49,000 euros /12-week course
- France:

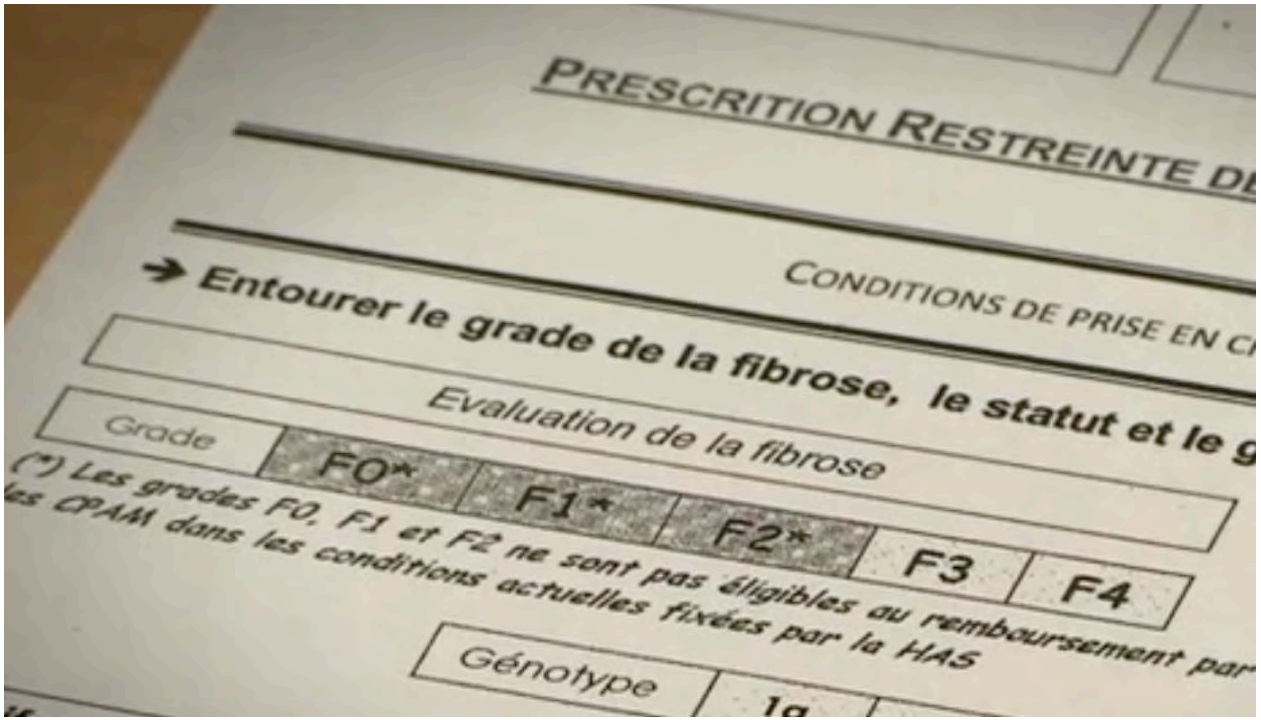
- 56,000 euros sofosbuvir /12-week course
- 90,000 euros sofosbuvir + simeprevir /12-week course
- 90,000 to 150,000 euros sofosbuvir + daclatasvir (12 to 24 weeks)

- This price has led to **treatment rationing and exclusion of key populations** in many places.

Example: treatment rationing in France

- In early 2014, expert guidelines panel has recommended prioritizing treatment ≥ F2 and PWUD regardless their fibrosis stages

- But few months later, the public authority– *la haute autorité de santé (HAS)* – changed these recommendations and endorsed prioritization of people ≥ F3 with no mention of key populations



How to overcome these barriers?

Lessons learned from HIV

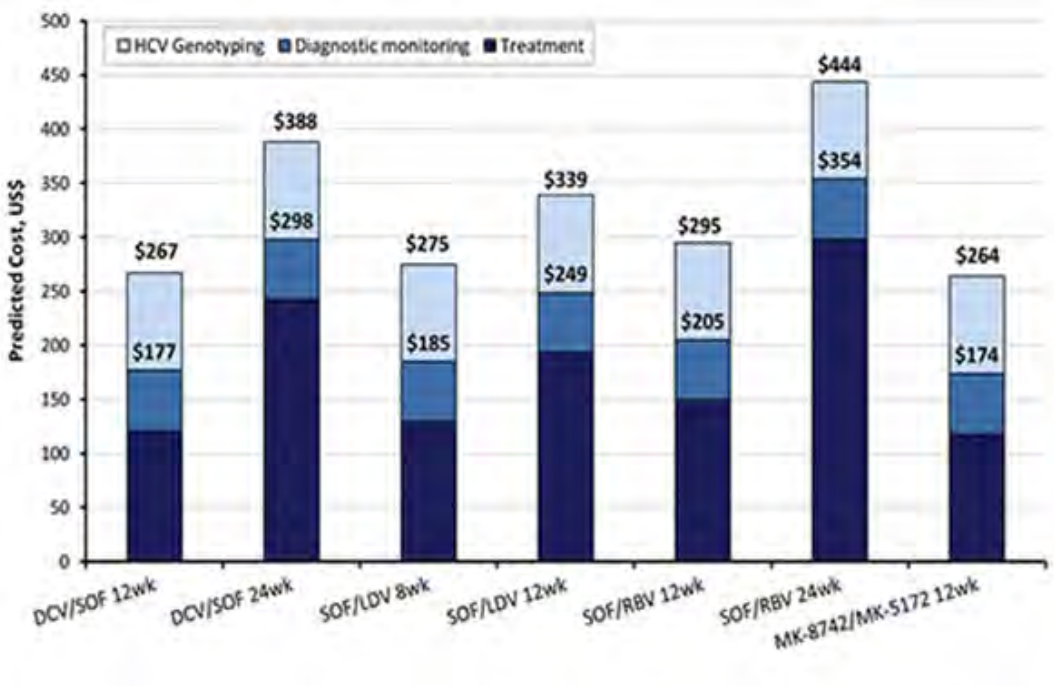
We need a global advocacy movement

- **Advocacy efforts are far behind compared to HIV, even though it is estimated that the hepatitis C affects 5 times more people**.
- Engage AIDS activists in advocating for access to HCV treatment and care (intellectual property expertise, lobbying experience and effective network).

- Involve self-support groups and harm reduction stakeholders in the fight for access to treatment (knowledge HR approach and care of HCV among people who use drugs.

hep Coalition

Able to support production & distribution of generics DAAs



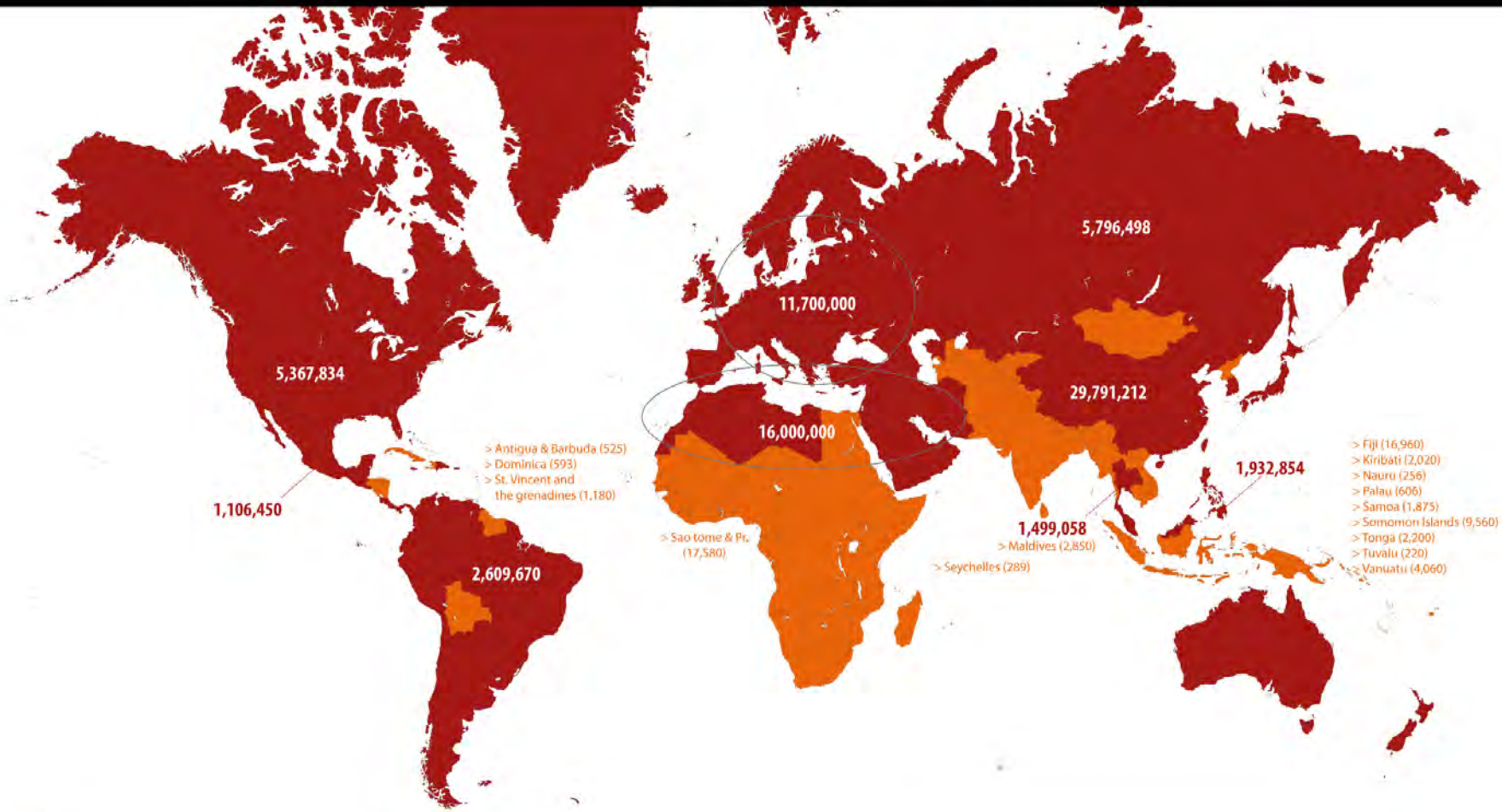
Cost of sofosbuvir: US$101 (12 weeks)
+ Cost of daclatasvir: US$20 (12 weeks)
+ two HCV antigen tests: US$34 (max)
+ Lab safety: US$22 (two FBC / Clin Chem)

Total cost of treatment and care: US$177

Hill, A, et al. Minimum target prices for production of treatment and associated diagnostics for hepatitis C in developing countries . International AIDS Conference; 2014 July 20–25; Melbourne, Australia.

Where there is competition from generics, prices can be driven down dramatically

Gilead's license leaves out nearly 73 million people with HCV who will have to pay Gilead's high prices.



Countries excluded from Gilead's license

Countries included in Gilead's license

1,499,058: No. HCV-infected, in Lavanchy D. Evolving epidemiology of hepatitis C virus. Clin Microbiol Infect. 2011 Feb;17(2):107–15. doi: 10.1111/j.1469-0691.2010.03432.x.

ACCESS, NO BARGAIN!

How: Patent opposition and compulsory license

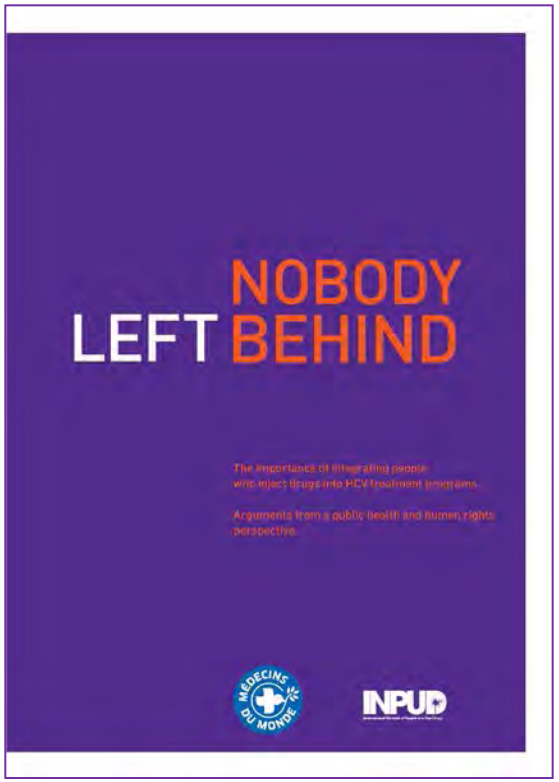
- In the case of HIV, the use of TRIPS flexibilities (patent opposition, compulsory license) has shown great results for opening access and reducing drug prices.
- It even makes more sense for HCV which pandemic is concentrated in LMICs and HICs
- On November 2013, the organizations I-MAK and DNP+ filed a **patent opposition on sofosbuvir** in India. *"Sofosbuvir is not innovative enough at the molecular level to warrant a patent"*
- In **Egypt, the patent hasn't been granted** for lack of novelty
- In France, a collective of civil society organizations, to avoid the rationing, asked the government to issue a **compulsory license** in order to get affordable generic sofosbuvir.

First success

- Nov. 2013: I-Mak's pre-grant opposition on Gilead's Sofosbuvir in India
- May 2014 : WHO resolution on viral hepatitis: inclusion of harm reduction as a key recommendation and supports the use of TRIPs' flexibilities

Next steps

- In France: continue to lobby the french govt against rationing
- Advocacy campaigns should also target BMS, Abbott and Merck
- Lobby for adequate funding for HCV treatment and harm reduction services (UNGASS 2016)
- Lobby on governments to take all available measures (compulsory licenses) to secure access to low-cost generic versions of HCV medicines.
- Engage civil society organizations when feasible to oppose patents



Thank you!

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