

# LEFT NOBODY BEHIND

The importance of integrating people who inject drugs into HCV treatment programs.

Arguments from a public health and human rights perspective.



The World Health Organization (WHO) has called the hepatitis C virus (HCV) a “*viral time bomb*.” At the 2010 World Health Assembly, it recognized the viral hepatitis epidemic as “*a global public health problem*,”<sup>1</sup> calling for comprehensive programs that “*enhance access to affordable treatment in developing countries*.” In addition, it adopted a new resolution on viral hepatitis at the 2014 World Health Assembly, noting for the first time that, “*hepatitis C virus, disproportionately impacts people who inject drugs*” and urging member states to “*implement comprehensive hepatitis prevention, diagnosis and treatment programs for people who inject drugs, including the nine core interventions*.”<sup>2</sup> The vast majority of people with chronic HCV infection live in low- and middle-income countries, where access to HCV treatment remains, in general, very limited. While access to HCV treatment is likely to improve over the next few years, if current trends continue, people who inject drugs (PWID) will continue to be more or less systematically excluded from treatment programs.

This document develops core arguments for why it is relevant, feasible, and indeed crucial to include people who inject drugs in national treatment guidelines and programs for chronic HCV infection – from both public health and human rights perspectives.

## THE HCV EPIDEMIC

Hepatitis is a group of viral diseases that kills an estimated 1.4 million people around the world annually<sup>3</sup> – a disease burden very similar that of HIV/AIDS and tuberculosis. Most of these deaths are caused by hepatitis B virus (HBV) and HCV.

HCV alone causes nearly half a million deaths each year, although HCV is curable in the majority of cases. Globally, an estimated 150 million people are chronically infected with HCV.<sup>4</sup> The pandemic is concentrated in middle-income countries, where 73 percent of people with chronic HCV infection live.<sup>5</sup>

People who use drugs – and specifically people who inject drugs – are disproportionately affected by the epidemic and bear by far the heaviest burden of HCV of any population. Among the estimated 16 million people who inject drugs worldwide, approximately 10 million are HCV-antibody-positive,<sup>8</sup> and about 8 million live with chronic hepatitis.<sup>9</sup> Moreover, **hepatitis C is more than three times more prevalent than HIV among people who inject drugs.**<sup>10</sup>

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.**<sup>11</sup>

In addition, people who inject drugs are at very high risk of onward transmission in most contexts around the world. In high-income countries, an estimated 80 percent of new cases of HCV infection occur among people who inject drugs.<sup>12</sup> Accurate incidence data for low- and middle-income countries do not exist, and the proportion is very likely to be lower, as other transmission routes, such as nosocomial infections still play a greater role. Important epidemiological differences exist across different regions and countries. **Generally, HCV trans-**

**mission among people who inject drugs in low- and middle-income countries is certainly important from a public health perspective. The risk of newly acquiring HCV infection is high among people who inject drugs who are often denied access to harm reduction services, and less experienced injecting drug users who may not yet have learned about safe injecting techniques and harm reduction practices.**

Last but not least, coinfection with HIV is a very common problem among people who inject drugs. In fact, an estimated 80 percent of HIV-positive people who inject drugs are also living with HCV.<sup>13</sup> The vast majority of people living with HIV/HCV coinfection acquired both viruses because they did not have access to sterile injection equipment. Although antiretroviral therapy has extended the life expectancy of people with HIV/AIDS, they remain vulnerable to liver disease. In fact, HCV has

**Table 1: Anti-HCV Prevalence Data in 11 Selected Countries**

Country	Adult HCV prevalence among PWID <sup>6</sup>	Adult HCV prevalence in general population <sup>7</sup>
Brazil	39.5–69.6%	1.4%
Estonia	90%	5%
Germany	75%	0.75%
India	92%	1.5%
Indonesia	60–98%	3.9%
Mauritius	95%	2.1%
New Zealand	70%	0.3%
Pakistan	89%	5.9%
Thailand	90%	2.2%
Ukraine	70–90%	4%
United States	50–80%	1.8%

### Documenting treatment needs among people who inject drugs in Tbilisi, Georgia

In October 2012, Médecins du Monde conducted a cross-sectional study in Georgia, with the principal objective of generating new and additional evidence about the HCV epidemic among active injecting drug users in Tbilisi.<sup>15</sup> This work also stressed the need to include this vulnerable and stigmatized population in future HCV treatment programs. Of the 216 participants (mean age was 39.6, and 7.9% were female), 91.9% were found to have HCV antibodies, and 82.0% had a chronic HCV infection. The level of liver fibrosis was assessed by Transient Elastography (FibroScan). Participants were considered to be in need of

urgent treatment if they showed levels of fibrosis equivalent to level F3 or F4. The study showed that almost a quarter (24.2%) of the participating injecting drug users needed treatment urgently. Based on existing size estimations, the authors concluded that around 5,000 people who inject drugs are in immediate need of HCV treatment in Tbilisi, Georgia. In conclusion, this study shows very clearly the need for governments to acknowledge the importance of the hepatitis C epidemic among people who inject drugs and to develop adapted harm reduction and treatment options for this population.

**Table 2: HCV Prevalence, Severe Liver Fibrosis, and Genotype Distribution Among PWID**

		<b>N</b>	<b>Prevalence (%)</b>
<b>HCV antibodies</b>		199	91.9
<b>Current infections</b>		180	82.0
<b>Among current infections</b>	Severe liver fibrosis	40	24.2
	Genotype 1	32	22.0
	Genotype 2	42	20.3
	Genotype 3	126	66.9
	Mixed genotype	20	10.4
N: number of participants			

become a leading cause of death among HIV-positive people. On the other hand, HIV accelerates HCV disease progression and more than triples the risk for liver disease and liver failure. **But, HCV is curable, regardless of HIV status, and treatment is recommended for all HCV/HIV-coinfected people** because it reduces the risk of AIDS-related, liver-related, and all-cause mortality.<sup>14</sup>

### ACCESS TO PREVENTION AND TREATMENT IS A HUMAN RIGHT!

Today, people in low- and middle-income countries (LMICs) remain almost completely without access to HCV-related information, prevention services, diagnostics, and treatment, with very few exceptions, notably Egypt.

### PRICES OF HCV TREATMENT ARE EXORBITANT

HCV antiviral treatment with pegylated interferon-alpha (pegIFN- $\alpha$ ) and ribavirin (RBV) is currently the standard of care for chronic HCV – for the very few who can get treatment at all. Based on this regimen and depending on the genotype, cure rates between 50% and 80% can be achieved. But the price of pegylated interferon in LMICs can be as high as US\$18,000 for a 48-week treatment course. Thus, treatment can cost up to 10 times the average annual per-capita income.

Even though the treatment pipeline is undergoing a fast (r)evolution – with the latest generation of direct acting antivirals (DAAs) showing cure rates over 90% – treatment prices will potentially increase in the near future. As an example, Gilead’s DAA, sofosbuvir, was approved by the European Medicines Agency (EMA) in November 2013, and by the U.S. Food and Drug Administration (FDA) in December 2013. Gilead is charging US\$84,000

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

for 12 weeks of sofosbuvir–US\$1,000 per day. Sofosbuvir needs to be used with other medicines, sometimes for 24 weeks. But sofosbuvir and many other DAAs in late-stage development can be produced generically for a tiny fraction of that price, just like HIV medicines. For example, a generic version of sofosbuvir can be produced for as little as US\$68–136.<sup>16</sup> Treatment prices will determine as well if HCV treatment can be considered a cost-effective intervention in LMICs.

### HARM REDUCTION AND TREATMENT SERVICES ARE SCARCE

More specifically, available data demonstrate considerable barriers to relevant prevention and treatment services for people who inject drugs. One systematic review showed that, globally, only two needle-syringes per month were distributed to individual people who inject drugs, and only 8 per 100 of them received opioid substitution therapy (OST).<sup>17</sup> This is entirely insufficient to make these recognized harm reduction efforts efficient in the fight against either viral hepatitis or HIV transmission. Beyond this important concern for coverage, current harm reduction interventions are very often limited in their quality and insufficient to prevent transmission of HCV. The “one-shot-one-syringe-logic” that was, where implemented at sufficient coverage levels, efficient in the fight against HIV transmission, needs to be developed into a more complex approach when addressing HCV transmission.

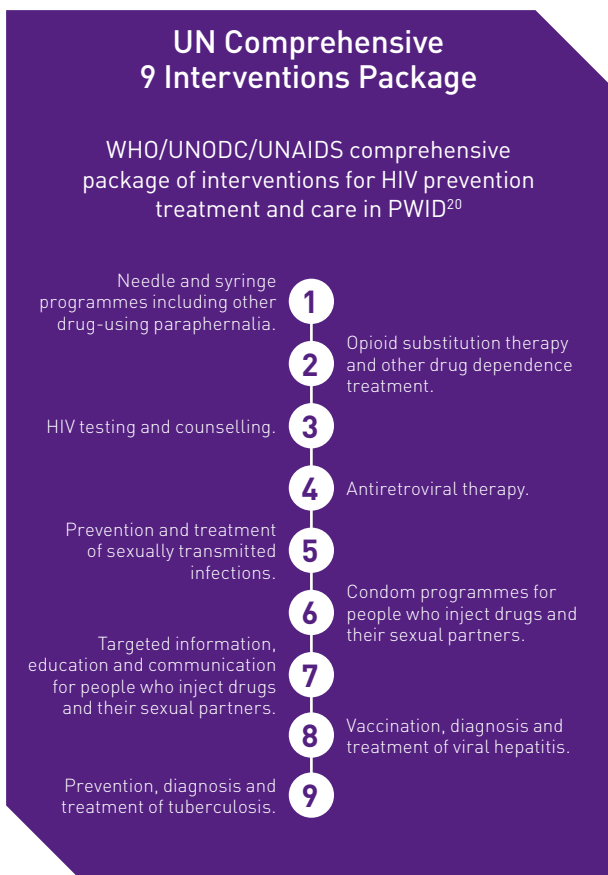
Primarily, it needs to consider the transmission risk through injection equipment other than needles and syringes, the ability of the HCV to remain infective for up to six weeks in dried blood spots,<sup>18</sup> and non-injection drug use. Moreover, even in high-income countries, the annual HCV treatment uptake of people who inject drugs remains very low, at around 1–2 per cent.<sup>19</sup> Treatment uptake in LMICs is clearly even lower. This is partly because this population faces a set of systemic and structural discriminations, stigma, and human rights violations. In addition, unfounded concerns based on stigma and discrimination within the medical professions exist around poor adherence, high frequency of adverse events and reinfection, and the lack of treatment settings that are adapted for the needs of this population.

**Based on our experiences in the last decades, especially in the area of access to HIV/AIDS treatment for people who inject drugs, we fear that this stigmatized group of people will continue to face serious barriers to access at national treatment programs, even though they carry a very high burden of the epidemic and have a high risk of transmission due to an overwhelming lack of access to sterile injection equipment.**

To address these serious access problems (both of treatment and prevention), a growing movement of global activists and advocates, consisting of people living with and at risk for HCV and HIV, people who inject and use illicit drugs, researchers, health care workers, and harm reduction providers are demanding universal access to affordable diagnostics and treatment and a massive scale-up of appropriate prevention and treatment programs.

#### THE NEED FOR NON-CRIMINALIZING DRUG POLICIES

**The current predominance of repressive drug policies and the almost universal criminalization of drug use is the major structural driver of HCV and HIV transmission among people who inject drugs. These laws not only criminalize people who use drugs but, in many settings, the harm reduction programs that they need to protect their health as well.** The consensus statement on “Science Addressing Drugs and HIV: State of the Art” released at the UNODC Scientific Consultation in Vienna in March 2014 notes that “*criminalization of drug use, restrictive drug policies and aggressive law enforcement practices are key drivers of HIV and hepatitis C epidemics among people who inject drugs.*”<sup>21</sup> Accordingly, substantial drug law reform and the dismantling of repressive drug policies are prerequisites for any meaningful attempt to address the HCV epidemic among people who inject drugs. Harm reduction programs can be fully effective only when they operate in



supportive legal environments in which people who inject drugs know that they will not be arrested or face police harassment upon leaving the programs. As such, drug policy reform, the fulfillment of human rights, and the creation of non-criminalizing environments are quite literally “critical enablers”<sup>22</sup> in facilitating any comprehensive attempt to address and reverse the twin epidemics of HIV and HCV currently ravaging the community of people who inject drugs.

### TREATING PEOPLE WHO INJECT DRUGS IS SAFE, AND IT WORKS!

Access to HCV treatment for people who inject drugs is especially difficult given the criminalization and high levels of structural discrimination and general stigma to which this population is subjected. In the specific case of hepatitis C, health care workers and policy makers have often argued that treatment in people who inject drugs is less effective and potentially less safe with more frequent adverse events – especially when psychiatric co-morbidities are present. Other major concerns include the potential risk of re-infection after successful treatment in active drug users and their potentially low adherence to treatment. These arguments are not new and have been raised over many years in the HIV/AIDS field – and they are not based on empirical evidence, but rather on misinformation and stigma.

It is true that providing medical care for people who inject drugs can present particular challenges, including severe co-morbidities with HIV infection or tuberculosis, as well as mental health issues. Moreover, challenges may include issues around stable housing or lack of support from family members. Nevertheless, a review of the evidence shows that many of the concerns noted above are unjustified, and that not only is treating people who use drugs entirely possible

– and effective – but it is a human rights and public health priority. In any case, withholding treatment from this population is a breach of the basic right of all people to the highest attainable standard of health.

### EFFECTIVENESS OF HCV TREATMENT AMONG PEOPLE WHO INJECT DRUGS

The goal of HCV treatment is viral eradication, which is measured by sustained virologic response (SVR). The existing data of several different studies<sup>23,24,25</sup> strongly suggest that treatment with pegIFN- $\alpha$  and RBV is safe and effective in people who inject drugs. The most recent systematic review and meta-analysis<sup>26</sup> found that SVR rates were clearly acceptable among people who use drugs. This meta-analysis is limited to six studies where all or a known proportion of the study participants reported actively injecting illicit drugs. **Among the overall population of people who use drugs in the included studies, the pooled SVR rate**

*Repressive drug policies is the major structural driver of HCV and HIV transmission.*

**was 55.9% after peg-IFN/RBV treatment for chronic HCV. The pooled SVR rate were thus slightly lower than those quoted by the major clinical trials of peg-IFN/RBV treatment in non-drug using populations, but are similar to study results in “real-life” settings.** The authors conclude that treatment effectiveness “*may indeed be slightly lower among people who use and people who inject drugs, but that the difference in real-life settings is likely to be small.*” The authors also suggest that “*decisions about*



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

#### **TREATMENT ADHERENCE, DISCONTINUATION, AND SIDE EFFECTS**

**The same systematic review found a high treatment adherence rate of 82 percent across the different studies included. This and other studies also showed low treatment discontinuation due to adverse effects when compared with large registration trials and the accumulated real-life experience.<sup>27,28</sup>** As with many other pathologies, the evidence shows repeatedly that people who inject drugs are able to care for their health, are motivated to get treatment, and are able to adhere to complex treatment regimens.

Moreover, research has shown that concerns relating to any psychiatric co-morbidity among people who inject drugs and the potential risks related to the neuropsychiatric side effects of pegIFN- $\alpha$ -based treatment are unjustified:

Schaefer concludes in a recent publication that *"there is currently sufficient evidence that PWID do not have in general an increased risk for the development of major or severe depression during antiviral treatment with IFN- $\alpha$ . In addition, psychiatric comorbidity is not associated with an increased risk for early antiviral treatment discontinuation, lower compliance, lower sustained virological response rates, or the development of depression during IFN- $\alpha$  treatment."*<sup>29</sup>

It remains clearly important to assess psychiatric history before starting treatment with pegIFN- $\alpha$ , but most of the relevant psychiatric conditions are manageable before or during the antiviral treatment.

#### **REINFECTION**

HCV reinfection after successful treatment of people who continue to inject drugs is another core argument for potentially denying treatment to people who inject drugs. In a systematic review and meta-analysis, the





pooled reinfection incidence rate was calculated at 2.35 per 100 person-years for all study participants and at 6.44 per 100 person-years among persons who reported continuous injection drug use after treatment.<sup>30</sup> This shows that reinfection risk is low even in persons who continue their injection drug use after treatment. There is certainly a need for further investigation of this issue, but the currently reported reinfection rates do not support a public health argument of withholding treatment from active injecting drug users.

### TREATMENT: ENTRY POINT TO HARM REDUCTION PROGRAMS

From a more general perspective, access to HCV treatment may be an important and much appreciated entry point to the health care system. As with treatment for other conditions such as HIV or tuberculosis, access to treatment for HCV may provide a key incentive to enroll in harm reduction programs or to enter into contact with any other support services when needed. As known from experience with HIV treatment access, getting needed HCV treatment may not only reduce related suffering and death, but may provide an opportunity to link those who wish to voluntarily address their drug consumption and risk-related practices with voluntary, respectful, appropriate, and acceptable treatment- and harm reduction services.

**Evidence from the available scientific data shows that treatment of active injecting drug users living with chronic HCV with peg-IFN and RBV is generally effective and safe, and that adherence in people who inject drugs as well as treatment discontinuation are very similar to those in non-drug-injecting populations; it is equally important to note that the reinfection risk is comparatively low in this population and is certainly not an argument for treatment exclusion.** Based on these findings, the WHO recommends “*that all adults and children with chronic HCV in-*

*fection, including PWID, should be assessed for antiviral treatment.*”<sup>31</sup>

In order to improve treatment outcomes and adherence, the management and care of people who inject drugs should focus on the use of multidisciplinary approaches.<sup>32</sup> These approaches should include peer support to increase treatment adherence,<sup>33</sup> and develop adapted, peer-delivered HCV education on safe injecting and prevention techniques as well as medication reminders.<sup>34</sup>

Future research should look in more detail at ways in which adherence may be enhanced and optimal treatment outcomes further increased. More research needs to be done in order to further investigate issues around reinfection.

### TREATING PEOPLE WHO INJECT DRUGS PREVENTS FURTHER INFECTIONS!

#### TREATMENT AS PREVENTION

Unlike with HIV, the preventive impact of treating HCV has not been scientifically demonstrated in the framework of clinical trials. But as HCV treatment is often curative and not lifelong, it seems highly likely, from a theoretical and virologic perspective, that treating HCV patients may be a potent prevention tool that reduces transmission of the virus in the community, apart from its effects on the patient’s individual health. This treatment-based prevention effect, however, should be considered only in addition to the essential implementation and scale-up of proven harm reduction prevention programs and the reform of legally repressive environments, as biomedical solutions should not be used as an excuse to undermine proven, community-based prevention programs.

Different epidemiological models from high-income countries<sup>35,36,37,38</sup> as well as one model from Vietnam<sup>39</sup> show considerable prevalence reductions over time among people who inject drugs through treatment programs – when allowing for reinfection and when considering classical rates of SVR through treatment with pegIFN/RBV. According to these models, the power of the prevention utility of these programs depends mainly on the baseline prevalence rates among people who inject drugs in a given country and the treatment coverage in this at-risk community. Moreover, programs need to be sustained over at least a decade to achieve considerable prevention effects. The preventive impact may be increased through access to interferon-free, DAA-based treatment regimens<sup>40</sup> or in contexts with predominant genotypes 2 and 3 among people who inject drugs.<sup>41</sup>

Further modelling work by Martin and colleagues<sup>42</sup> investigated the impact of combining OST, high coverage needle/syringe programs (NSPs), and HCV treatment on HCV prevalence and incidence among people who inject drugs. They demonstrated that with very feasible HCV treatment rates, large reductions (over 45%) in chronic HCV prevalence over 10 years could be achieved when HCV treatment was combined with OST and NSPs.

In conclusion, the best available models provide convincing evidence that HCV treatment among people who inject drugs should not be withheld, but rather prioritized, given the potential prevention and cost-effectiveness benefits. However, in all circumstances, the benefits

to the health of the individual should be paramount, and the prevention effects considered as secondary. Furthermore, all treatment must be provided entirely on a voluntary basis.

**Many today start to evoke the potential for eradicating hepatitis C virus – especially with the help of the new all-oral treatment regimens. As a new generation of direct-acting antivirals is entering the market, treatment regimens will become shorter, much more effective, less complex, and safer. Treating people who inject drugs with all-oral, DAA-based regimens will confirm the results made with pegylated interferon-based treatments. Moreover DAA-based treatment will increase adherence rates, reduce side effects, and increase efficacy, even for patients suffering from co-morbidities or advanced liver disease. All-oral treatment regimens may also allow much lower-threshold treatment access – based in harm reduction or opiate substitution programs, or even delivered by general practitioners.**

**But only a fully public health-driven and human rights-based approach can make eradication a reality. This approach would need to include serious price reductions for all available treatment options, the removal of all structural barriers to access to HCV treatment for people who inject drugs in highly repressive legal environments as well as the scaling up of harm reduction efforts as the key tool of HCV prevention, drug policy reform, and the inclusion of people who inject drugs in treatment programs around the world.**

***This will make hepatitis C history!***

NOTES

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