CORRELATION
EUROPEAN NETWORK
SOCIAL INCLUSION & HEALTH

POLICY BRIEF ON HEPATITIS C INFECTION AMONG INJECTING DRUG USERS

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EXECUTIVE SUMMARY

Hepatitis C (HCV) infection, documented to be 10 times more infectious than HIV, has infected injection drug users (IDUs) at rates up to 90% in many European countries due to the sharing of needles/syringes and other injection equipment. Because HCV is initially asymptomatic, and likely undiagnosed, today IDUs at epidemic levels are rapidly developing symptoms requiring immediate treatment and care.

HCV screening among IDUs has been shown to be effective and cost effective. Early diagnosis, detection and treatment with expanded easy access to such services can save lives and minimize healthcare costs. However, policies in response to this disease are still inconsistent or non-existing, and often exclude needs of drug users.

Key objectives and recommendations for European and National Action Plans should include interventions and/or activities to prevent HCV transmission, to reduce the percentage of undiagnosed people, to increase the percentage of people receiving treatment, and to monitor and evaluate the efficacy of prevention, testing and treatment services.

International bodies like WHO fail to give sufficient attention and guidance on the disease, while European institutions provide guidance on policy, management and treatment levels, including treatment for people who use drugs.
It is recommended to tackle the situation by developing unified Hepatitis C strategies and action plans, designed to improve disease surveillance and prevention, to improve early diagnosis and access to treatment.

INTRODUCTION

This policy briefing paper is developed in accordance with the mission and framework of Correlation – European Network Social Inclusion & Health. The paper is prepared to offer information and guidance for policy makers, health care professionals and others who work in regard to the management of the epidemic of Hepatitis C (HCV) among injecting drug users (IDUs).

This paper has two main objectives:

- To provide a brief summary on HCV infection and its current impact on the European population, specifically focusing on people who inject drugs; and
- To advocate for effective hepatitis C policies, based upon current scientific evidence.

For this purpose, we have reviewed numerous medical and scientific journals, international and national action plans and strategies, as well as guidelines and recommendations prepared by well-known experts.

The policy briefing paper is divided into three parts:

1. Current Situation of HCV: Infections among IDUs in Europe
2. Review of Existing Global Policy Recommendations
   - Global HCV Policy and International Recommendations
   - European Response to Hepatitis
   - Civil Society Response to HCV on the European Level
3. Conclusions and Recommendations
   - Policy Level
   - Practical Level

1. CURRENT SITUATION:

Why HCV infection among IDUs is a serious matter in the European Union

In the European Union (EU), hepatitis C (HCV) has been showing a significant increasing trend in incidence. Each year there are 27,000 to 29,000 new cases diagnosed with HCV. Within a ten years time period the number of newly reported cases has increased significantly, from 4.3 cases per 100,000 to 6.9 cases per 100,000 population[1]. In 2007, 12 million EU citizens were reported to be infected with HCV. Therefore, based upon the data provided, today in 2012 we can estimate at minimum there have been over 130,000 new infections throughout the EU since 2007.

Mortality from HCV liver disease is expected to increase during the next decade when people who were infected in the 80s or 90s enter their second or third decade of infection[2]. Initial infection is frequently asymptomatic or mild among 70%–90% of cases, which is why HCV has been compared to an awakening giant. Of those infected, 50–80% will develop chronic infection, up to 50% cirrhosis, and 1 - 5% liver cancer over a period of 20 to 30 years[3]. Because of this many who remain undiagnosed, will develop symptoms when the disease has progressed to advanced stages, causing the likelihood of treatment to be less effective[4].

In the 1990s, after the introduction of hepatitis testing among blood donors, almost 90% of infections in the EU were related to drug use, especially injecting drug consumption[5]. HCV infection prevalence among national samples of injecting drug users (IDUs) from countries in the EU vary from 10 to 95%, with half of the countries reporting levels in excess of 40%[3] Increasing age, increasing years of injecting drug use, and imprisonment were all identified as infection risk factors[6].

The hepatitis C virus is highly contagious, documented to be 10 times more infectious than HIV[7]. A person with HCV can infect others from one to several weeks before symptoms show.
In cases of chronic infections, infectivity may persist indefinitely. Most drug injectors acquire HCV early in their injecting careers. Up to 50% of those who have been injecting for less than 2 years become infected with HCV[8]
Sharing needles/syringes, injection equipment (cookers, filters, water) to prepare drugs for injection and even the sharing/splitting of drugs when prepared for injection with tainted equipment has been documented to cause HCV infection[9]. Furthermore the sharing of smoking and sniffing drug paraphernalia (glass pipes and straws) is known to spread HCV[10,11]. Other documented means of transmission are tattooing and body piercing[12,13,14,15]

Because HCV, HIV and HBV share the same routes/means of transmission, and depending on the country and/or region where there is a considerable number of people co-infected, all this can increase the natural evolution of HCV disease progression and effect treatment prognosis[16,17].

Prescribed treatments, like substitution therapy (OST) for heroin users and needle and syringe programmes (NSP) have proved to be cost-effective in regard to HCV prevention, as long as they reach high levels of coverage and provide easy access[18]. Unfortunately these two conditions, coverage and access vary greatly among countries and among regions within countries of the EU.

HCV screening among IDUs has been shown to be effective and cost effective[19]. However drug injectors are a highly stigmatized and socially excluded population and as a result they have poor access to health care. Access to HCV prevention, testing and treatment is significantly much lower for this group than for other at risk populations. In the EU when testing is provided, it is often inconsistent. The low uptake or interest in treatment can be explained by the fact that despite recent changes in treatment guidelines, physicians still remain reluctant to treat patients who inject drugs[25]. This is critically important because since the last decade effective treatments have been developed, and early diagnoses is essential to the likelihood of good clinical response to such treatments (Serological Viral Response, SVR)[20,21].

However despite the recent advances in HCV treatment, treatment is usually withheld from drug injectors, even those who are stable in drug substitution therapy[22]. Compliance and treatment responses of IDUs have been found to be comparable to former IDUs[23]. Recent studies show that when

treatment is provided in a multidisciplinary setting using an integrated approach, drug users with chronic HCV infection can be treated successfully[24]. At the same time it appears that treating current IDUs is likely to be more cost effective than treating former IDUs[25]. Successful HCV treatment not only results in individual benefits by preventing disease progression, it may also help to contain the epidemic by eliminating a potential source of infection[26].

The criteria among many clinicians for including drug users in HCV treatment often coincides with their personal attitudes and opinions rather than following a scientifically based standardized criteria. Health policy documents and clinical guidelines often at times reflect this discriminating and flawed approach[26,27]. Moreover, hepathologists and infectious diseases specialists are neither used to, nor trained to deal with drug using patients therefore they often feel awkward and do not know how to respond appropriately when drug users sometimes do not attend appointments, have difficulties complying with medication prescribing requirements or they lack social support[31]

While the HIV epidemic has reached a high level of concern among professionals and among the general population, the awareness and interest of HCV infection still remains low even among many health care professionals, and drug workers. One reason for this is because in the EU HCV infection affects almost exclusively IDUs (contrary to HIV) who happen to have a low capacity of mobilisation and advocacy support due to their highly marginalized lifestyle. Additionally, IDUs are unlikely to be aware of all the risks HCV presents as they are for HIV.

Furthermore many drug injectors are likely to have a history of being incarcerated, in prison or jail, where the scarcity of prevention measures and equipment is even at higher levels than it is in the community. Any time spent in prison or jail can offer ideal opportunities to provide access to direly needed prevention information services, including health education and most importantly HCV screening and treatment.

In addition to all that has been mentioned herein, we have to take into account that current HCV drug therapy is expensive, which also makes access to treatment difficult, especially if we are talking about a population that is stigmatised and discriminated against. Many health care professionals and policy makers might think "Do these people deserve this treatment?" if so we have to face financial and/or resource constraints, and it is very likely that this particular population will be judged as a low priority for treatment. Despite these concerns, treatment for this population has been considered cost effective as it prevents much higher costs of treating chronic hepatitis, cirrhosis or even providing liver transplants which are rarely provided even for this population[29]. Providing modest rates of HCV treatment among active IDUs could effectively reduce transmission[27].

The administration of disease surveillance for hepatitis B and C varies widely across countries. It needs to be noted that EU case definitions are not consistently implemented. Plotting trends and comparing data between countries is difficult and needs to be done with caution, as surveillance systems differ considerably and recent changes may impact the presented data3. Most countries collect a basic set of data, but detailed data on risk factors or the source of infection remain missing, this specific type of information is crucial for informing and guiding prevention policies[2,3].

It is also astonishing that only 2 states in the EU have a particular Strategy and/or Action Plan for HCV (UK[28,29,30] and France[31]).

Summarising the current situation regarding HCV infection, the lack of awareness by relevant decision makers and the treatment system, as well as not having a unified approach towards the most affected group – injecting drug users – calls for immediate action.

In the following chapters we will describe recommendations for HCV policies, issued by high-level agencies and institutions. We will also present recommendations from practitioners, advocating for the overall improvement of the situation and providing recommended evidence based best practices.

2. REVIEW OF EXISTING GLOBAL POLICY RECOMMENDATIONS

2.1 Global HCV Policy and International Body Recommendations

Hepatitis C infection receives far less attention from international stakeholders than any other global epidemic. Before the World Health Assembly (WHA) of 2010, HCV has never been categorized as a special topic of a global high-level policy document; it usually appears as a "satellite" disease, in the context of HIV-infection and among other drug-related harms. The reason why HCV remains on the margins of international health policies is attributable to the fact that HCV significantly affects marginalized populations.

In 2010 the global burden of viral hepatitis infections received attention from the World Health Assembly (WHA). The WHA is a governing body of World Health Organisation (WHO) that meets annually in Geneva and sets the framework for the international health policies. The fact that this high-level meeting issued a special resolution on viral hepatitis – Resolution 63/18 - is a significant step forward. However it is still questionable whether the resolution will make a change in terms of better access to prevention and treatment

The special resolution issued talks about the general necessity of surveillance, prevention and treatment measures, including that member states should "support or enable an integrated and cost-effective approach for the prevention, control and management of viral hepatitis considering the linkages with associated co-infection such as HIV through multi sectoral collaborations among health and educational institutions, non governmental organizations and civil society". The special resolution also requests that the WHO Director-General "establish[es] in collaboration with Member States the necessary guidelines, strategies, time-bound goals and tools for the surveillance, prevention and control of viral hepatitis" and a progress report should be made available at the 65th Session of the WHA in 2012[32].

Despite all this, WHO hasn't achieved any significant success in implementing decisions of Its governing body; its global bureau has not dedicated or assigned a single person whose duties would be focused on viral hepatitis; the hepatitis-related work is currently coordinated by a WHO staff person who deals with other infectious diseases including HIV and TB. The lack of dedicated efforts has caused hepatitis related activities to remain on the margins of WHO work, whereby causing the development of international guidelines on prevention, control and treatment to remain unavailable. At the present time, WHO international guidelines on HCV treatment would be critically important for countries with resource-limited settings where chronic hepatitis is often either not treated at all or treated with sub-standard non-pegilated interferon.

The current lack of international guidance for a global response to viral hepatitis epidemics, specifically HCV leads to the unsolved issue with funding. With rare exceptions, countries with limited resources receive almost no support from international donors to cover HCV related costs. *Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users*[33] issued by WHO, UNAIDS and UNODC in 2009 defines "vaccination, diagnosis and treatment of viral hepatitis" among nine key interventions, the whole complex of which "will prevent or reverse HIV epidemics". At the same time, the Technical Review Panel of the Global Fund, the primary advising group to determine funding priorities has not recommended to provide dedicated funding for HCV treatment for people living with HIV in countries where HCV treatment isn't available to the general population[34]; and since HCV treatment is generally not available in most of the countries that submit proposals to the Global Fund, this recommendation leaves little chance for people with HIV/HCV co-infection to receive any treatment,

In fact, the extremely high price of pegilated interferon makes HCV treatment unaffordable for many patients, as well as for a majority of national government health care systems and for international donors to support. One course of 12 months treatment with a combination of pegilated interferon and ribavirin costs 10,749 – 16,123 USD at average, and adding a protease inhibitor will raise the price up to 45,000 USD[35]. A possible step forward to decrease prices would be inclusion of anti-HCV drugs into the WHO Model List of Essential Medicines[36]; also, inclusion of pegilated interferon into the WHO List of Prequalified Medicinal Products would simplify the process of registration of biosimilar (generic) drugs[37]. Again, WHO has neither started to take a lead on these processes nor actively responded to calls for action from members of civil society groups.

2.2 European response to HCV

If compared to the situation with the global response to HCV, the European Union pays much more attention to the problem of viral hepatitis.

In 2010, a political document to identify the regional framework with regards to HCV is a *Call to Action to European member states produced by the Summit Conference on Hepatitis B and Hepatitis C*[38] in Brussels (Belgium). The Summit was organised by the Belgian presidency of the EU and gathered representatives of the European Union member States, the WHO, the European Commission and Parliament

The Call for Action echoes the WHA Resolution 63/18 and calls on the EU Member States and the European Commission to:

1. *Improve awareness of the threat posed by hepatitis B (HBV) and HCV*
2. *Integrate HBV/HCV prevention programmes into existing public health frameworks*
3. *Enhance surveillance for HBV and HCV across Europe*
4. *Support development and integration of cost-effective technologies and procedures for use in viral hepatitis prevention, vaccinations, control and management, including screening high risk individuals according to scientific and epidemiological based evidence*
5. *Ensure universal access to early counseling and treatment for persons infected with HBV or HCV*
6. *Expand research resources for HBV and HCV*

Previously, hepatitis C was mentioned in a number of EU policy documents including the Declaration of the European Parliament [39] of 29 of November 2006 and the Drug Addiction Plan 2009-2012 of The Council of the European Union [40]. The last includes the objective to "*ensure access to harm reduction services, in order to reduce the spread of HIV/AIDS, hepatitis C and other drug-related blood-borne infectious diseases and to reduce the number of drug-related deaths in the EU*" (aim number 10).

Current European guidelines are unanimous about providing HCV treatment for people who use drugs – such patients should consider treatment, though an individualized approach is needed here. A statement by the European Society for the Study of the Liver in their *Clinical Practice Guideline Management of Hepatitis C Infection*[41] was made in March 2011 saying that "active drug users should have an individualized approach after evaluation and close monitoring by an experienced multidisciplinary team of hepathologists and addictologists is recommended". Other references can be found in *"Guidelines for Treatment Management of Hepatitis C and HIV Co-infection in the Clinical Protocol for the WHO European Region"*[42] *and in "Peglinterferon alfa and Ribavirin for the Treatment of Mild Chronic Hepatitis C"*[43] *by National Institute for Health and Clinical Excellence of the United Kingdom.*

In the Guidelines for Treatment; Management of Hepatitis C and HIV Co-Infection; and Clinical Protocol for the WHO European Region[44] it is clearly mentioned:
"Initiation of HCV treatment in active drug users should be considered on a case-by-case basis".

In March 2011 the European Society for the Study of the Liver issued a clinical practice guideline *Management of Hepatitis C Infection*[45] saying that active drug users should have an individualized approach after evaluation and close monitoring by an experienced multidisciplinary team of hepathologists and addictologists is recommended

In 2007 the National Institute for Health and Clinical Excellence of the United Kingdom has updated the document: *Peglinterferon alfa and Ribavirin for the Treatment of Mild Chronic Hepatitis C*[46] *where it now says: The Committee was persuaded by the experts that the previous guidance (TA 75) on treating people with moderate chronic hepatitis C who continue to use intravenous drugs and/or misuse alcohol and people co-infected with HIV should be extended to members of all such groups who have mild disease.*

The most recent paper issued by a European institution, is the *Guidance Report by EMCDDA and ECDC* which explores good practices that can support effective policies to reduce infections, including HIV, hepatitis B and C. The document identified evidence based good practises for prevention and control of infection diseases among people who inject drugs and recommend seven key interventions including harm reduction approaches, opioid substitution treatment, voluntary testing and targeted delivery of services. It is currently most outspoken document in that context so far.[47]

2.3 Civil Society response to HCV on the European Level

The World Hepatitis Alliance is a guiding coalition of advocacy groups for people living with viral hepatitis B and C and is a key initiator of the annual World Hepatitis Day. The association established 'World Hepatitis Day' which is now organised in many European countries as well.

The European Liver Patient Association (ELPA) promotes the interests of people with liver disease and in particular highlights the size of the problem, promotes awareness and prevention and addresses the low profile of liver disease as compared to other areas of medicine.

The Eurasian Harm Reduction Network (EHRN) is operating in Central and Eastern Europe, an area with high prevalence and infection rates of HCV, in particular among injecting drug users. EHRN also provides technical support and advocacy on hepatitis throughout its region.

The Correlation Network created an expert group on HCV and published several materials on hepatitis C and drug use, including a training manual for service providers and 12 key messages for a good Hepatitis C policy and practise[48].

Given the progress in HCV prevention and treatment policies in the EU, the European civil society needs to become actively involved in advocacy work on the national and global level: promote effective prevention and treatment models, as well address the issues of insufficient funding for HCV-related services whereby initiating and supporting campaigns targeting the European Commission, WHO, Global Fund and other international key stakeholders.

3. CONCLUSIONS AND RECOMMENDATIONS

Hepatitis C is a very serious health problem among drug users especially among injection drug users. Within drug users social networks, individually amongst themselves and even among drug workers there is still today a low level of awareness and inconsistent knowledge pertaining to the severity and magnitude of health problems resulting from HCV infection.

There are currently effective measures to prevent and treat drug users with HCV however access to these services in many European countries continues to be systematically restrained due to the lack of funding, political will power and discriminatory attitudes and practices among professionals.

As a consequence there is a dire need to urgently increase primary prevention programmes, and access to HCV screening and treatment for all drug users. HCV treatment for all drug users must not be banned, it should be provided as recommended and indicated in numerous studies allowing a case-by-case individual assessment be the norm in provision of standardized care.

If we want to achieve more than reducing the impact of this epidemic among drug injectors and really want to stop the spread of HCV among all drug users including the general population, than a serious upgrade to all these measures must be made a priority.

From practitioners in the field point of view, "we see need for action on different levels".

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3.1 Policy level

- **Hepatitis C strategies**
  The European Union should develop a European HCV Strategy based on scientific evidence, and encourage member states to develop and implement national strategies accordingly. National and European drug strategies should include actions, guidelines and strategies for integrating and providing HCV prevention, diagnosis and treatment services.

- **Action plans**
  Key objectives for Action Plans should include interventions or activities to prevent HCV transmission, to reduce the percentage of undiagnosed people (reduce the time between infection and diagnosis), to increase percentage of people receiving treatment, (reduce time between diagnosis and treatment access), and to monitor and evaluate the efficacy of prevention, testing and treatment services. Adequate funding needs to be allocated to effectively implement recommended interventions outlined in revised action plans.

  Action plans must also include interventions designed for overcoming stigma, discrimination and marginalization of HCV prevention and treatment for injecting drug users.

3.2 Practical level

- **Disease surveillance**
  Incidence and prevalence rates of HCV infection, and burdens related to the disease need to be further assessed by strengthening and enhancing current HCV surveillance reporting mechanisms throughout the EU. Enhanced reporting systems should not only improve monitoring of the disease, they need to also interpret epidemiology data, and evaluate prevention programmes more efficiently. Additional surveillance reporting should also include detailed data on risk factors and the source of infections.

- **Prevention**
  The general scope and coverage of harm reduction interventions need to be upgraded, and expanded since similar interventions such as NSP used to prevent HIV infections, are also very effective in preventing HCV infection. NSP services should include HCV education and distribution of alcohol swabs, sterile water, clean cookers, filters and tourniquets. Harm reduction prevention interventions should also be enhanced offering greater coverage and accessibility to HCV testing and treatment for IDUs, and substitution therapy (OST) with optimal doses. Expansion and provision of harm reduction services should include inside jails/prisons and services targeting young drug users, new injectors, crack users and cocaine injectors

- **Early diagnosis**
  Because of HCV is initially asymptomatic for many years, interventions specifically designed to seek out and identify individuals infected with HCV so they can be offered treatment need to be increased. Early diagnosis, detection and treatment with expanded easy access to such services will increase treatment benefits, save lives and minimize healthcare costs.

  Viral hepatitis testing, vaccinations and specialist referrals need to become routine screenings and integrated in all drug care services, harm reduction programmes, and other related drug programmes. Additional testing, treatment and vaccination services should also be regularly provided in jails and prisons.

  Drug treatment centres, rehabilitation programs and other services targeting former drug users should also be included in enhanced hepatitis vaccination, testing and treatment services

  New technologies such as dried blood testing and rapid oral testing should be provided for increased coverage of HCV testing.

- **Access to treatment**
  Injection drug users should no longer be denied access to treatment because they use drugs. Individualized case-by-case assessments should be provided to determine the benefits and the risks of treatment. Successful individual treatment plans should include a comprehensive multidisciplinary approach offering: access to substance use treatment, psychiatric/mental health assessment, social support (e.i.: stabilizing housing and financial situation), nutritional support, individual counselling and self-help support groups. Some guidelines (ref) describe it as a community based management.

  Early diagnosis and referrals to treatment services should be integrated in all settings targeting high risk IDUs including jails and prisons. Early treatment improves the probabilities of long-term responsiveness to treatment (achieving a Serological Viral Response –SVR-).

Sensitivity trainings for Hepathologists and other clinicians in charge of HCV treatment should be provided regularly on how to treat drug users effectively. Sensitivity trainings for health professionals should be provided in collaboration with professionals from substance use centres, clinicians with experience treating HIV positive drug users and drug users.

Individual's co-infected with HIV or/and HBV must also be included in early diagnosis and treatment services. Furthermore vaccination services should be established to minimize co-infections of viral hepatitis.

To increase HCV treatment opportunities for at risk vulnerable populations, especially drug users, measures should be taken among government officials to negotiate lowering the prices of HCV treatment medications with pharmaceutical industry representatives in Europe.

- **Research and monitoring**

  Continued and on-going research is needed especially among drug users to identify evidence determining what best circumstances are for treatment, especially regarding responsiveness to treatment and compliance, and interactions between illicit drugs and medications

  Monitoring and evaluation of prevention, screening and treatment interventions should be improved, and include coverage and accessibility to these services.

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