

## 4.2

### CLINICAL MANAGEMENT OF DRUG USERS WITH CHRONIC HEPATITIS C "TREATMENT AS PREVENTION" (TASP) STRATEGY IN AN INTEGRATED MODEL OF CARE BETWEEN "COMMUNITY" (SERDS) AND "HOSPITAL"

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#### Background

The World Health Organization (WHO) has set up the elimination of hepatitis C virus (HCV) worldwide by 2030 (WHO. Global health sector strategy on viral hepatitis 2016-2021). This goal may be reached thanks to the introduction in the clinical practice of direct anti-viral drugs (DAAs) that are able to heal the disease reducing the public health costs. People who inject drugs (PWID), universally identified as the most at-risk population for acquiring HCV infection, are a largely stigmatised group who have limited access to conventional health-care. Currently, the technologies required to achieve HCV elimination exist, but the infrastructure to deliver them is not generally available or of insufficient scale outside of specific areas.

#### Introduction

For over a year Italy is part of that group of countries where access to antiviral treatment is guaranteed to all HCV subjects, regardless of the severity of the disease (AIFA, Criteri per il trattamento dell'epatite C, April 2017). The high cure rate obtained by the new Directly Acting Antivirals (DAA) treatments in HCV-positive patients has induced the Italian Ministry of Health to express the need to contribute to the public health objective of eradicating hepatitis C, target set by the World Health Organization (WHO) in the 2030 (Grebely et al J. Int AIDS Soc. 2017 Jul 28; 20 (1): 22146. doi: 10.7448 / IAS.20.1.22146). The achievement of this objective depends on the implementation of interventions in areas regarded as strategic such as special populations like PWID, universally identified as the true reservoir of infection.

#### Discussion

It has been demonstrated that an early and intensive treatment on these people can generate a significant impact on the global HCV epidemic in terms of decrease, avoiding the development of cirrhosis, hepatic insufficiency, and liver transplantation. Several studies in literature also have established that treating PWIDS with HCV is cost-effective (Scott N, et al., J Gastroenterol Hepatol, 2016 Apr; 31 (4): 872-82; Daniëla K. van Santen, PLoS One, 2016; 11 (10)). In addition, treatment associated with harm reduction policies can help reduce HCV incidence and prevalence in this population (Gountas, I. et al., Addiction. 2017 Jul; 112 (7): 1290-1299; Hannah Fraser et al., Journal of Hepatology, 2018 vol. 68: 383-385) and improve the quality of life through the progressive abandonment of practices at high risk for himself and possible source of contagion.

It should also be emphasized that pharmacological treatment aims to achieve both clinical and economic health care outcomes, namely: complete recovery from HCV-related liver disease through a short-term therapy able to improve both quality and free of sickness life prospect insurance; reduction of assistive activity made possible because the treatment leads to a complete regression of the disease; a considerable saving of resources by the Italian National Health Service (Servizio Sanitario Nazionale, SSN) due to: progressive decrease - up to the annulment - of newly occurring cases and reduction of costs associated with the progression of the disease or costs generated by the need for diagnosis and care in the assistive services.

The main barriers that prevent an efficient linkage of these "difficult to reach" at-risk population include a lack in a multidisciplinary model of care based on a working group (expert in addiction medicine, hepatologist, infectivologists, psychiatrists, psychologists and nurses) to coordinate the treatment of the drug addict and HCV-positive people. This kind of organization in Italy exists from the middle of 80's and represent the ideal setting of the cure of the patients who use illicit drugs, are enrolled in a detoxification program and are HCV infected.

For these reasons, at the end of 2017 Federserd, with the collaboration of medical hepatologists and infectious disease specialist, developed an algorithm for taking charge of the population at risk with HCV (A. Nava, A. Alberti, M. Andreoni, S. Babudieri, G. Barbarini, PF D'Egidio, C. Leonardi, A. Lucchini Mission - Italian Quarterly Journal of Addiction 2018; 49: 56-61) with the aim to facilitate the interaction between hospital specialists and territorial services in order to support a hepatitis C elimination program in the population at risk (PWIDS and prisoners), in the logic of both national and regional eradication plans.

The centrality of the Addictions Services (Ser.D) and of the professional figures working there, is the background of this model of integrated care, able to guarantee a privileged medical-patient relationship and where serological controls can be performed to screen patients who are candidates for treatment and followed during and after the therapy.

We recently reported the results of a study aimed to evaluate the health saving costs of HCV treatment in a population consisting of HCV-positive patients treated by two Territorial Social-Health Units (Ser.Ds ASST-“Melegnano” and “Martesana”) including 54 Municipalities (comprising roughly 650,000 inhabitants) in Milan hinterland (northern Italy).

We analyzed selected cases of reported e.v. drug use-positive and/or HCV-positive patients to demonstrate feasibility and effectiveness of HCV treatment in PWID directly followed in local Addiction Services and public health and economic benefit in terms of saving social/health costs following HCV-patients treatment. We demonstrate that the HCV treatment in PWID can significantly reduce over the years not only the individual costs but also the health community costs.

Moreover the study shows that an integrated and effective patient’s journey, together with harm reduction measures, can be further effective and costs for the health care system (in press).

This study was conducted with IFN based HCV treatment universally recognised as complex, associated with frequent side effects, and lengthy (24 to more than 48 weeks).

Current HCV therapy is once-a-day dosing for 8 to 12 weeks and there are few side effects, yielding a cure in > 95% of patients.

In our opinion the simplicity of current DAA therapy allows SERDs to move into the primary position for treatment at least for first-line therapy in non advanced disease.

Following this principle, in 2018 we obtained the authorization as prescribers of DAA and we realize a network model of care with the hospital specialists aimed to treat PWID attending our service directly with a “fast track” procedure of screening and diagnosis.

At present we treated with DAA over 40 patients including OST (patients following substitution therapy with methadone or buprenorphine), ex PWID or never PWID (i.e injection partners), currently e.v. user, cirrhotics, HIV/HBV coinfecting with a 100% compliance, 100% SVR 12 for the patients who complete the observation, no treatment discontinuation or interruption for any reason, on death for cause unrelated to liver disease or treatment. Time of follow-up is too short to define the rate of reinfection.

## Conclusions

Treatment as prevention with highly effective new DAA is a prospective HCV elimination strategy. Literature indicates that injecting drug use is responsible for 23% of new infections and that each HCV positive PWID become infected within the first two years of activity with an incidence rate a thousand times higher than the general population and he is able to infect at least 20 others subjects within the first three years of infection. It should also be considered that drug users have an average age of less than 20 years compared to the general population (Lazarus JV et al. BMC Infect Dis, 2014;14 (suppl.6):S16), thus creating a significant additional difference in terms of saving direct healthcare costs.

It is therefore clear that to reduce the impact in terms of early mortality it is essential to act on the reduction of the prevalence of infection (cure of the disease) but also on the reduction of transmission.

In the absence of an improvement in screening in high-risk population and in the allocation of resources for the most cost-effective intervention strategies, turning the tide on the HCV epidemic will be challenging.