



EASL
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FOUNDATION

40 | **SanPatrignano**

VIRAL HEPATITIS ELIMINATION IN PWID

**A ROADMAP TO ELIMINATION IN ITALY: TREATING THE INFECTIONS AND
PREDISPOSING CAUSES**

Conference Highlights Report

10 October 2018

San Patrignano, Italy

The Workshop

EASL International Liver Foundation joined forces with San Patrignano, Europe's largest drug rehabilitation community, to hold a one-day Viral Hepatitis Elimination in PWID: A Roadmap to Elimination in Italy workshop on 10 October 2018 in Rimini, Italy.

Italy is making significant strides with its viral hepatitis strategy and is one of the 12 countries on track to eliminate viral hepatitis as a public health threat by 2030. This workshop sought to accelerate progress towards national elimination by providing the platform to identify and champion the conditions necessary to fast-track viral hepatitis elimination among people at highest risk of acquiring and transmitting the virus; people who inject drugs (PWID).

The workshop brought together leading experts in viral hepatitis, the drug treatment community and key stakeholders such as government officials, industry representatives, civil society organisations and scientific societies. The programme, presented by international and local experts, provided the latest updates on viral hepatitis treatment in PWID while providing participants with the unique opportunity to network and exchange experiences and ideas for viral hepatitis elimination among PWID in Italy.

Bringing the stakeholders together, this workshop aimed to not only kick-start the call to action for viral hepatitis elimination among PWID in Italy but to also set the foundations for the generation of a roadmap for elimination.

The workshop took place in the San Patrignano rehabilitation community, Rimini, Italy and was accredited by the Italian Ministry of Health Italian Ministry of Health for 6 CME Credits (ID. N. 150-234009).

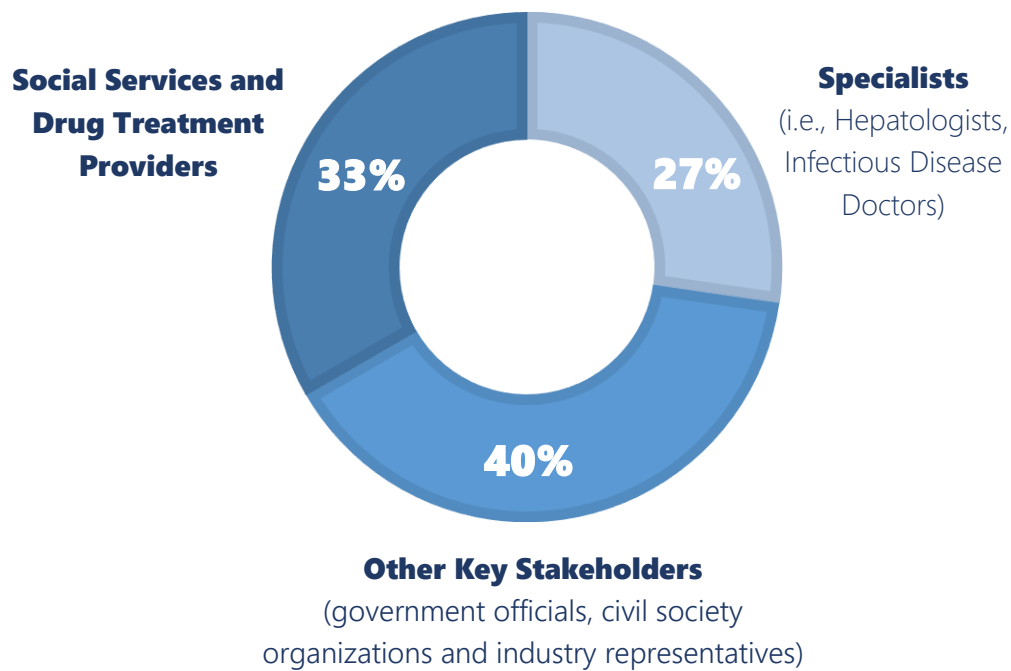


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The Audience

The Viral Hepatitis Elimination in PWID: A Roadmap to Elimination in Italy workshop attracted **85** attendees from **9** countries.



Session 1 Highlights

Welcome and Scene Setting

Chairs: Massimo Colombo and Jeffrey V. Lazarus

Prof. Jeffrey Lazarus, Vice-Chairman of the EASL International Liver Foundation (EILF), opened the workshop, explaining that EILF is committed to proactively take a role in supporting the achievement of the World Health Organisations vision for viral hepatitis elimination by 2030. EILF had organised this workshop to provide a platform for international and national experts to network and strategize on how to accelerate viral hepatitis elimination among the injection drug use population in Italy.

The presentations in the opening session provided an overview of viral hepatitis elimination, the prevalence of the virus in Italy, and the latest diagnostic tools and treatments available. There was one common theme throughout this opening session; we have the tools to eliminate viral hepatitis.



Jeffrey V. Lazarus

Associate Professor, University of Barcelona, Associate Researcher, ISGlobal, Hospital Clinic, University of Barcelona.

HCV Elimination 101

On 28 May 2016, the World Health Organisation (WHO) published a global strategy aiming for the elimination of viral hepatitis as a public threat by 2030, setting targets for screening, diagnosis, treatment, follow-up, and importantly, harm reduction.

With the advent of direct acting antivirals, we have overcome the biomedical challenge to elimination. The two main challenges remaining in high income countries are access and coverage. Prof. Lazarus states that "achieving a sustained virologic response requires much greater attention to health systems challenges."

The idea of viral hepatitis elimination is daunting, it is both costly and complex. EILF posited the pragmatic idea of micro-elimination, which is to define and enact plans for elimination in high-risk populations (e.g., prisoners, PWID, HIV co-infected, haemophilia patients).

Italy is one of the twelve countries currently on track to achieve elimination. Prof. Lazarus hopes that "by 2025, we are able to say that Italy has eliminated viral hepatitis C among PWID."

Session 1 Highlights...



Massimo Puoti

Director, Unit of Infectious Diseases, ASST Grande Ospedale Metropolitano Niguarda, Italy.

HCV Epidemiology and Screening

There are over 15 million injection drug users globally and approximately 8 million are HCV positive.

A recent report by the Italian Ministry of Health suggests that in Italy there is approximately 280,000 injection drug users. The HCV prevalence rate, although uncertain, is estimated to range between 31.5% to 43%.

Prof. Puoti pointed out that for elimination to be a reality, the rate of HCV testing among this population needs to improve. Despite there being approximately 145,000 PWID in treatment in Italy, only 23% are estimated to have been tested for HCV.

Prof. Puoti concludes by stating that "there is approximately 100,000 HCV infected PWID in Italy and new testing strategies are required. Point of care testing is possibly the answer to improving elimination among PWID."



Alessio Aghemo

Director, Unit of Hepatology, IRCCS Istituto Clinico Humanitas, Italy.

Cure: The Standard of Care in PWID

The end point of HCV therapy is the achievement of SVR, which is when HCV RNA is undetectable 12 weeks after treatment completion. Prof. Aghemo highlights that "with the simplified DAA treatments, there is no difference between SVR rates in PWID and SVR rates in people who do not inject drugs".

Although drug-drug interactions were a concern in the interferon era, most DAA's can be used safely in people receiving opioid substitution therapy and people who continue to use drugs.

Prof. Aghemo states that "there is always risk of re-infection, which is estimated at 10% for PWID, but people who get re-infected should be treated quickly without stigma." As highlighted in the EASL guidelines, harm reduction, education and counselling should be provided to reduce the risk of reinfection.

Session 2 Highlights

HCV Treatment Models: What Can Be Learned

Chairs: Maria Buti and Anne Øvrehus

With the understanding that viral hepatitis elimination is possible, Session 2 put this into context by providing real world examples of programmes in action from other European countries.



John Dillon

Professor of Hepatology and Gastroenterology, Ninewells Hospital, University of Dundee, Scotland.

Quickfire Example: Scotland

Scotland has an HCV prevalence of 1% and in 2017, 91% of new HCV transmissions were from PWID. Each of the 14 areas of Scotland have a clinical lead for viral hepatitis elimination. Prof. Dillon and his healthcare manager are responsible for HCV elimination in the Tayside region, which has approximately 450 chronically infected PWID.

Easy diagnostic tests are very important. Across the Tayside region there is more than 250 people trained in blood spot testing across many contact points (e.g., OST clinics, needle exchange, social work departments, minor injury units, outreach), and 81% of tests are carried out by support workers, without clinical qualifications.

Tayside has 5 pathways of care such as the traditional pathway and pathways leading from pharmacies (where OST is administered), drug treatment programmes, prisons and needle exchanges. Prof. Dillon states that "you have to individualise the pathways of care to suit people and put those pathways of care where the people are."

The aim is to treat 500 PWID in 2 years and eliminate HCV in Tayside by 2020. Scotland aims to eliminate HCV by 2025. Prof. Dillon called to the audience, stating that "the race is on can you beat Scotland?"

Session 2 Highlights...



Alberto Moriggia
Doctor, Epatocentro
Ticino, Switzerland.

Quickfire Example: Switzerland

Data from the Swiss Association for the Medical Management in Substance Users (SAMMSU) showed high prevalence of HCV positive patients (65%). Approximately 50% of these patients were treated and cured.

Dr. Moriggia emphasizes the relevance of integrated care in order to manage key challenges involved in HCV treatment among PWID. Specifically, the "All Under One Roof" model as an example of how integrated care is provided in Lugano, Switzerland.

Lastly, Dr. Moriggia highlighted the importance of training and awareness of relevant staff, including nurses and paramedics and pointed to the utility of currently available on-line modules offered by INSHU.



Anne Øvrehus
Professor of Infectious
Diseases, Syddansk
University, Denmark.

Quickfire Example: Denmark

There is an estimated 13,000 PWID in Denmark, with an estimated HCV prevalence of 35-40%.

Treatment restrictions have been in place and has impacted the model of care but from November 2018 all treatment restrictions will be removed meaning that everyone will be able to be treated.

The design principle of the program in southern Denmark was to ensure that people in drug treatment and prison had access to the same HCV care as they would at a hospital. The program runs in drug treatment centres with a doctor and lab technician, there is a fibroscan, a laptop, and treatment is prescribed onsite. Prof. Øvrehus stated that "we moved ourselves, we went to them."

With the removal of the DAA restrictions, the program can now be simplified and expanded.

HCV Italian Drug Use Patterns, Policies and Treatment

Chairs: Pietro Canuzzi and Massimo Puoti

Session 3 provided an overview of current Italian drug use patterns and policies and provided a current state analysis of viral hepatitis screening and treatment in 4 key PWID settings/sub-populations.



Pietro Canuzzi

Director, Unit of Prevention, Ministry of Health, Italy.

Italian Drug Use Patterns and Policy

In Italy, the Departments for Addictions have a multi-professional composition and a network of 570 centres scattered across the country operating at health district level. However, screening for HBV and HCV is extremely low in Italy, with approximately 60-70% of intravenous drugs users not tested.

This situation highlights a major gap and the urgent need for appropriate policies and healthcare interventions. Two in particular are highlighted: the launching of prevention campaigns about the risk of using drugs in coordination with the Ministry of Education and the increase in the use of mobile clinics offering integrated services such as testing, harm-reduction measures and counselling.

The increase of mobile units could increase channelling of relevant patients through the services offered by the Addictions Department.

Session 3 Highlights...



Felice Nava

Director, Unit of
Penitentiary Health, Padova,
Italy.

SER.D.

There are approximately 450,000 high-risk drug users in Italy, with approximately 150,000 in treatment and 300,000 people out of care.

FEDERSED estimates that 63.9% of PWID are HCV positive. However, the services for drug dependency (SER-D) test few service users for HCV (18% tested of which 7% positive). This highlights a major gap in this key public health issue, which requires the development of a proper strategy involving three key elements: effective patient journey, effective model of care, and the inclusion of PWID in a plan for HCV elimination.

Prof. Nava calls for an HCV elimination plan stating that in order to make HCV a rare disease it is important to promote testing, referral, treatment and harm reduction for high-risk group populations, link services across specialities and promote holistic/integrated models of care.



Giordano Madeddu

Professor of Infectious
Diseases, University of
Sassari, Italy.

Prisons

There are 190 prisons across Italy, with a total population of over 100,000 prisoners in 2017. It is estimated that approximately 35% of prisoners use drugs and the prevalence of HCV is estimated at 38%.

The WHO, EASL and national society guidelines recommend screening and treatment in prisons, yet rates remain low across Italy. Estimates from 2017 suggest that only 4% of infected people in Italian prisons have been treated.

A recent study demonstrated that it is possible to screen and treat in prison. The study showed that out of 142 patients (mostly cirrhotic due to treatment restrictions), more than 90% achieved SVR and that the major cause of no response was due to loss during follow-up.

Prof. Madeddu put it to the audience to “think about prison as a revolving door. If we can make a difference in prison, we can have significant impact in the community.”

Session 3 Highlights...



Antonio Boschini

Doctor of Infectious Disease, San Patrignano Community, Italy.

Residential Treatment Communities

1200 drug users are currently in treatment in San Patrignano with 350 people entering treatment every year.

HCV treatment in residential therapeutic communities may provide certain advantages such as the possibility to run a test & treat strategy especially considering that abstinence from alcohol and drugs lowers risk of reinfection and possibly improves adherence.

Data from San Patrignano shows a 63.9% prevalence of HCV among PWID and 1.8% among non-IDU. However only 37% are able to be offered treatment due to AIFA requirements. The experience of San Patrignano highlights the need to overcome existing AIFA protocol restrictions, regional budget limitations and bureaucracy in providing access to the treatments.



Elisabetta Teti

Doctor, Unit of Infectious Diseases, Fondazione Policlinico Tor Vergata, Italy.

Out of Care

Out of care refers to people who are not in a care/assistance pathway, are engaged in a chaotic way, or have dropped out. They face many barriers that prevent and impact their ability to remain in care.

For this population, non-profit organisations have a large role to play as they act as bridges to medical services. Not only can they implement HCV screening, but they can provide referrals, co-ordinate treatment, provide counselling and motivation and assist with necessary paper work. In addition, they may offer rehabilitation and social support services.

Treatment adherence is usually raised when talking about this population. However, Dr. Teti points out that "it is not true that people who inject drugs are not adherent to treatment. Even out of care populations achieve adherence rates greater than 80% and achieve similar SVR rates to non-injection drug users."

Session 4 Highlights

A Roadmap for HCV Elimination Among PWID in Italy

Chairs: Jeffrey V. Lazarus and Massimo Puoti

An open floor discussion was held to lay the ground work for a roadmap for viral hepatitis elimination among PWID in Italy. The aim being to collectively identify key barriers, requirements and recommendations for elimination.

Key findings:

- A strategy is needed but it must account for regional approaches and sub-populations and settings.
- Fibroscan requirement for treatment prescription is a major barrier and needs to be amended.
- Expansion of prescriber base will enable increased access and coverage.

The EILF, session panellists, and session chairs agreed to follow up by preparing a list of recommendations currently in place, a list of recommendations to consider and the steps needed to implement them in the Italian context.

Prof. Lazarus called on the audience to take action, stating that “in the absence of a strategy and as we work to systematize our response, we have a room full of champions who need to take this discussion and start making it happen.”



Session 5 Highlights

How Do We Make It Happen?

Chairs: Andrew Amato and Jeffrey V. Lazarus



Andrew Amato

Head, HIV, STI and Viral Hepatitis Programme, European Centre for Disease Prevention and Control, Sweden.

Lessons Learned from HIV

There are 4 key lessons to be learnt from HIV epidemiology and scientific evidence.

Firstly, adequate levels of harm reduction are essential. Dr. Amato states that “you must have adequate harm reduction measures and sustain them, or the benefits of treatment will be lost.” Secondly, PWID, when given the right support, will likely adhere to lifelong HIV treatment, so HCV treatment should be easier as it has the advantage that it is time limited. Third, treatment among PWID cannot be carried out effectively by the traditional medical outpatient models. From the HIV experience, the effective treatment programmes depend on their ability to attract, motivate and retain clients and need the right location and appropriate attitude by the provider. Lastly, good data is vital to know where you are and plan accordingly.

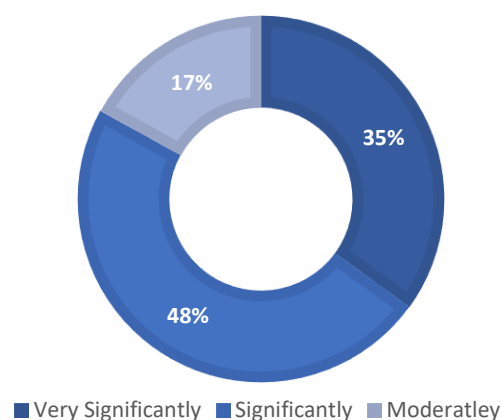
Dr. Amato concludes by stating that “with the right level of dedication and persistence, both HIV and HCV can be significantly brought down in this risk group.”

How Do We Work Together to Make HCV Elimination Among PWID a Reality?

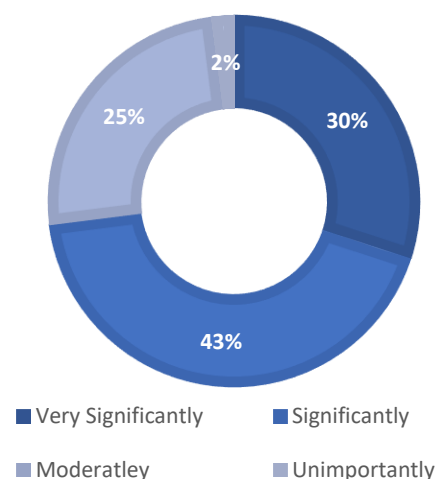
Many gaps were highlighted throughout the day covering all aspects of the continuum of care, ranging from screening, to follow up, and surveillance. The need to engage and collaborate with stakeholders was viewed to be essential in efforts to boost viral hepatitis elimination.

Recommendation: Formation of a common platform, whereby clinicians can join the many key stakeholders involved in the treatment, care and support of PWID to drive elimination of viral hepatitis.

100% of workshop participants reported **increased awareness and knowledge** of viral hepatitis screening and linkage to care among PWID at the end of the event.



98% of workshop participants stated that the knowledge and information gained from the workshop would be **useful/applicable to their work**.



Roadmap Development

International and national experts use the information gained during the workshop to now develop a roadmap for the elimination of viral hepatitis among PWID in Italy to champion and aid the implementation of the conditions necessary to fast-track elimination.

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