

Event Report: EHC Round Table of Stakeholders on 'HCV and Haemophilia'

About the event

On Tuesday 14 June 2016, the European Haemophilia Consortium (EHC) held a Round Table of Stakeholders at the European Parliament in Brussels, Belgium, to discuss the access to hepatitis C (HCV) treatment in Europe and in particular for people with haemophilia (PWH).

Some 50 participants attended the event, including patient representatives, healthcare professionals and industry representatives. The event's agenda, list of speakers and presentations can be consulted online on the [EHC website](http://www.ehc.eu).

The event was kindly supported by Members of the European Parliament (MEPs) Dr Cristian Buşoi (Romania/ EPP) and Dr Andrey Kovatchev (Bulgaria/ EPP).

On HCV and Haemophilia

Haemophilia is a rare and congenital bleeding disorder caused by a genetic defect resulting in a lack of or insufficient coagulation factors VIII or IX in the body. This causes, in affected individuals, an inability to clot blood, leading to bleeds in the joints, muscles and soft tissues. If left untreated, this can cause disability and sometimes death.

In the 1980s and early 1990s the quasi-totality of the haemophilia patient population worldwide was contaminated with HCV¹ due to the widespread contamination of their treatment. A majority of these patients were also contaminated with HIV through the same contaminated treatments. This was due to poor medical knowledge about the viruses and their mode of transmission resulting in no or ineffective blood donor screening and testing methods. Furthermore, there were no viral removal or inactivation techniques in the manufacturing process of plasma-derived coagulation factor concentrates. Finally, early warning signs of this contamination were ignored by government agencies, pharmaceutical companies and healthcare professionals. This resulted in one of the biggest health crisis of all times.

Thirty years on from this tragedy, better safety measures have been implemented to avoid viral contamination through coagulation factor concentrates. Although this is true for Europe and North America, concerns remain for countries outside these regions.

Many of the surviving patients that were contaminated during this tragedy are still living with the consequences of these viral infections. Furthermore, most patients that contracted HCV through government-provided treatment were never offered any official financial compensation.

The advent of direct acting antivirals (DAAs) has made it possible to completely cure HCV. DAAs are very effective, easy to take and have few side effects, which enhances treatment adherence. DAAs are now being marketed in Europe, however, although cost-effective compared to other medical interventions to manage HCV, their financial impact on healthcare systems is high. This is due to both their cost and the high number of patients requiring treatment. Therefore patients are being prioritised for treatment access based on the severity of HCV and liver damage.

As HCV-related morbidities, such as liver cancer, are currently the primary cause of death in the European

¹ HCV is a viral infection of the liver, which over time can lead to liver damage and failure.



haemophilia population, the EHC decided to hold a Round Table of Stakeholders to better understand what treatment options are available and to demonstrate why it is important to treat PWH and HCV.

Although this event focused specifically on haemophilia it was also acknowledged that people affected by other rare bleeding disorders (e.g. von Willebrand Disease) had also been contaminated (albeit in lower numbers) with HCV and HIV through their treatment.

Findings and discussions

It is estimated that HCV causes 500,000 deaths annually and globally. HCV also causes 28 per cent of cirrhosis and 26 per cent of liver cancers globally. Furthermore, HCV increases the risks of other co-morbidities such as, for example, thyroid-, prostate- and oesophageal cancers as well as circulatory diseases. Clearing the virus from an individual (i.e. achieving sustained virological response or SVR) will considerably reduce mortality, the need for liver transplant and the risks of developing hepatocellular carcinoma. However if the liver is already damaged by HCV, patients are still at risk (although at a lower level than prior to achieving SVR) of developing these conditions and therefore they should receive regular medical check-ups. In short, HCV is a global public health problem that needs to be addressed.

A new generation of pangenotypic and interferon-free medicinal products curing HCV, called DAAs, is now available in Europe.

An informal survey carried out amongst 29 EHC member patient organisations in 2015 revealed that an estimated 25 per cent of PWH are infected with HCV. Although this percentage seems high, it is small compared to the total number of people infected with HCV in any given country. This means that the eradication of HCV in PWH is feasible and should be done to remedy for the contamination tragedy. In addition, PWH with HCV should be prioritised for treatment because haemophilia can accelerate the progression of HCV.

Some countries in Europe, such as Ireland for example, are already planning to achieve HCV-free PWH population in the medium to short term.

As noted above, one of the main barriers to access to treatment is the financial strain that these treatments put on healthcare budgets. In fact, at the moment, manufacturers of these products are pricing them according to the perception of the ability of a country to pay for these treatments. This leads to great differences in pricing both within and outside the European region. Another challenge to treatment is the lack of infrastructure and medical personnel to manage such a large number of patients in need of treatment. Nonetheless some countries and regions in Europe (e.g. Portugal and Scotland) were able to implement strong HCV treatment programmes and are now offering treatment to a large number of the HCV population affected. This was made possible thanks to good planning and price negotiations as well as political will and public support².

Finally, it was noted that some patients are now purchasing cheaper medicines online and that this may be problematic if the medicine is counterfeit. Additionally, these treatments work best when treatment regimens are adapted to the specific genotype of the patient and therefore patients should be careful about which product they take.

Conclusions

HCV eradication is now possible thanks to new therapies that are efficacious, easy-to-take and cost-effective compared to other medical interventions to manage HCV. This condition could be effectively eradicated and become a rare disease in the foreseeable future.

Treatment should be provided to all patients irrespectively of their HCV progression. This is to preserve liver health and limit transmissions.

To achieve all this, European countries should implement national strategies to encourage HCV

² Due to its mode of transmission, people affected by HCV are often stigmatised and their treatment is not prioritised.

prevention, improve screening of potential HCV patients and offer treatment to patients affected by HCV. Treatment protocols should be implemented not only to achieve HCV SVR but also to further manage patients that have achieved SVR but that have HCV-induced liver damage.

Identifying the correct genotype and providing adapted treatment is key to ensuring a maximum rate of SVR. A national registry to track new transmissions and monitor known patients' health outcomes is an effective tool to support the development of national strategies to eradicate HCV. National HCV plans should be developed in consultation with healthcare professionals and patients.

Thanks to its small patient population size, eradication of HCV in PWH is achievable in the short term. National haemophilia organisations should support access to treatment through evidence-based advocacy.