

An interview with Dr. Cristian-Silviu Buşoi, MEP

Host and Chair of the HepBCPPA Elimination day dedicated to the elimination of hepatitis C in Romania by 2030 at the European Parliament, 27th September 2017



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Romanian Elimination Day 27 September 2017

Q1. Dr. Buşoi can you outline the scale of the problem of HCV in Romania?

The situation in Romania is particularly acute, as is the case in Central and South Eastern European Member States that have some of the highest rates of HCV prevalence in the EU but where access to screening, diagnosis and treatment is limited. An overall prevalence rate of HCV infection in the Romanian population was recently estimated to be 3.23% (664,000 infected persons, 75% of them are unaware of the disease), and the mortality and morbidity associated with hepatitis C are extremely high - among the highest in Europe.

Over 90% of patients show no symptoms when infected with the disease and they are not even aware they could transmit the virus.

Q2. What has Romania done to date to combat HCV? Is there a national elimination plan in place?

In recent years, access to diagnosis and treatment has improved but still remains limited in Romania. We must ensure that access rates continue to improve in order to combat HCV and to strive towards elimination.

Starting in 2015, a national program was implemented providing curative treatment

but only for a maximum of 5,000 patients. This year, to date, approximately 12,000 patients were reported to be receiving this treatment.

However, despite its status as a serious public health concern, HCV is under-diagnosed in Romania and there is a lack of public awareness and knowledge with regard to the infection and the alarming prevalence of the disease. For sure we need to do more to encourage people to access testing, to inform them on how to avoid infection, and what is of utmost importance... to ensure access to treatment for greater numbers of infected patients.

Q3. What remains to be done? What can be achieved by 2021?

Prevention remains the main instrument in combating HCV and the reduction of the number of new HCV infections. Secondly, there is an urgent need to ensure early detection, especially for vulnerable groups: injection drug users, (PWIDs), those who undergo transfusion with unscreened blood, sexual transmission or transmission in health and cosmetic care, perinatal infection. Those at risk for hepatitis C should be tested and once diagnosed they should be evaluated for appropriate care and treatment. Then the new treatment protocol must ensure access for an increased number of people, given the high prevalence of the disease. Immediate action is needed to accelerate unrestricted access to treatment for all patients.

Q4. What are the main barriers/ challenges?

For Romania, the high prevalence of HCV remains a great challenge, with a major

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transmission potential and negative and social effects such as direct expenditures in caring for the disease and indirect costs related to lost income for the family of the patient or the patient him/herself. Secondly, the patients who do not qualify for the treatment protocol, cannot afford to pay for the treatment and usually end up with other serious health-related problems or even cancer. This, is, of course if they get diagnosed, which is often not the case....So getting diagnosed is still the main challenge! And, the lack of certainty of the availability of treatment represents a further challenge.

Q5. As a Romanian MEP, can you share with us if you or the Romanian government have any concrete plans to place viral hepatitis on the agenda of the Romanian Presidency of the EU in 2019?

I am not aware of any plan. The agenda of the Romanian Presidency of the EU has not yet been decided, but I am convinced that health will feature among its priorities.

Q6. How do you view the recent declaration of the European Parliament and how could it be used for the benefit of the countries at national level?

At the moment there is still not a homogeneous approach at EU level to fighting viral hepatitis- some Member States do not have a national plan in place, while other Member States have made significant funding commitments and have implemented strategies and developed national plans for a comprehensive response to the burden of viral hepatitis.

In order to minimise the future HCV disease burden Member States need

to implement action plans aimed at increasing the pool of diagnosed people, increase access to therapy, increase the level of therapy/ treatment efficacy, increase capacity of screening and increase capacity of treating more patients by adopting new therapies for hepatitis C together with introducing education programs that would prevent (re)infection.

Our aim at EU level is to raise awareness, and to call on the Commission to launch a multidisciplinary plan together with Member States, to standardise screening, testing and treatment protocols, which will eradicate hepatitis C in the EU by 2030.

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Dr CS Buşoi is a *founding member and Co-chair of the MEP Friends of the Liver Group in the European Parliament**



An interview with Dr. Ricardo Baptista Leite MP,MD,PhD(c) on Hepatitis C in Portugal



Q1. Portugal was acknowledged in 2015 as a European example in terms of access to treatment for all hepatitis c patients. After 2 years, how do you assess the impact of this political decision?

When DAA's became available at the European level back in 2014, they brought tremendous hope of a cure for millions of people living with hepatitis c. However, on the other hand, the tremendously high prices presented by the pharmaceutical industry when these drugs entered the market led most countries to push back

and postpone access to treatment – leaving patients all over the European Union to despair.

In Portugal, following the work and activism from the community and academia, the Government acknowledged the need to intervene and, as of February 2015, all people living with chronic hepatitis c in Portugal became eligible to treatment with DAA's, regardless of their clinical status or personal history. This significant advancement was achieved in a sustainable manner following a negotiation process that led to Portugal having a volume-based agreement whereby the more patients are cured, the cheaper the drug gets. Furthermore, a value principle was introduced so that the Ministry of Health only pays for drugs after the clinical cure outcome is confirmed. This was all made possible by using information technology to develop a digital registry for

all patients, accessible to all physicians with authorization to prescribe DAA's.

As of July 2017, over 17,591 patients have been diagnosed with chronic HCV and included in the Portuguese national HCV registry. All their treatments have been authorized and, of those, 11.792 patients have already initiated treatment. Finally, 6.639 patients have already been proven clinically cured with a 96,5% SVR. [1]

As presented at the EASL International Liver Conference, the treatment program, as of February 2017, ensured that 3.477 premature liver related deaths, 339 liver transplants, 1.951 liver cancers and 5.417 cases of cirrhosis have been averted, 62.869 life years have been gained, and 271.4 million Euros on treatment costs related to hepatitis c complications have been saved.

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Q2. Do you feel that Portugal is on the path to eliminate hepatitis c with its current policies?

It has been acknowledged by all mathematical models that universal access to treatment is a critical aspect to achieve elimination in any country or region. However, it is also very clear that treatment alone is far from sufficient to reach such an ambitious goal. To do so, governments around Europe need to understand the need to implement an elimination action plan that focuses on all steps of the hepatitis c cascade. Elimination will only be achieved if we work effectively on prevention and awareness, testing, diagnosis, and linkage-to-care. After ensuring access to treatment, follow up of cured citizens is equally important to ensure complications are reported and that reinfections are avoided. Lastly, elimination will only be achieved if the base of prescribers is widened and that most vulnerable key populations, from prisoners to substance users, have specific approaches at all levels. On this point, community organizations have a critical role in acting among the general population and especially among those that are hard to reach.

Thus, a holistic effort is needed to achieve elimination of hepatitis c, whatever the initial scenario. And this is what is lacking in Portugal.

We are currently spending millions of Euros on treatment but not acting sufficiently at every other level of the cascade. A robust action plan is needed, with concrete outcomes and resources allocated to these goals, so that Portugal can continue to lead and hopefully achieve elimination of this deadly infection in our generation.

Q3. What are the greatest challenges we are facing at the European level to ensure that all EU Member States and neighboring countries achieve elimination by 2030?

Hepatitis c represents a major international public health threat, as it represents a significant burden on lives, communities and health systems. Moreover, it is acknowledged that hepatitis c is many times a promoter and consequence of inequalities, discrimination and social injustices.

We finally have the scientific evidence and

technological means to eliminate hepatitis c. However, the political engagement and leadership is still lacking. This is precisely where we need to work at the European level. With determined leadership, we will certainly see the science being put to the service of the people.

That is why earlier this year I decided to become founder and president of 'UNITE', a global network of current and former policy makers to raise awareness and advocate for reforms needed to end HIV/AIDS, viral hepatitis and tuberculosis by 2030.

It is our mission to unite political representatives from around the world to give a coordinated, effective and strong impulse towards eliminating these global threats.

Join us. It's time to end hepatitis c. It's time to Unite.

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 Dr. Ricardo Baptista Leite,
 Member of Parliament, Portuguese National Parliament
 Head of Public Health, Católica University of Portugal
 Founder and President, UNITE – Parliamentarians Network to End HIV/AIDS, Viral Hepatitis and Tuberculosis

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How the World Hepatitis Summit 2017 can strengthen efforts to eliminate viral hepatitis

– an interview with Charles Gore
 President of the World Hepatitis Alliance



Q1. There are so many hepatitis meetings nowadays. What is different about the World Hepatitis Summit?

It became apparent in 2011 that these hepatitis meetings had three things in common: they were all industry-sponsored; they were attended by clinicians not the government officials

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in charge of hepatitis programmes nor by people from public health; and the involvement of people with the lived experience of hepatitis was peripheral, not central. We therefore approached the World Health Organization (WHO) and suggested co-hosting a meeting that would fill this gap, in particular bringing together all of our patient group members, now over 250 from more than 80 countries, and key decision-makers from Ministries of Health. We also wanted to give WHO the opportunity to lead on the public health approach to viral hepatitis.

Q2. Why is the World Hepatitis Summit so important?

It's important because it's the only global event, which fills this gap - bringing policymakers, civil society and public health experts together as partners in an effort to eliminate viral hepatitis.

The World Hepatitis Summit is a large-scale, global biennial event to advance the viral hepatitis agenda. It's a joint initiative between WHO, ourselves and a different host country for each Summit. This year, we are hosting the Summit with the Brazilian Government in São Paulo, Brazil, on 01-03 November 2017.

At the inaugural Summit in 2015 over 500 stakeholders including policymakers, patient groups, civil society, funders, public health specialists and others, contributed to the global hepatitis discourse during the broad array of sessions offered which concentrated on helping develop national viral hepatitis plans. By bringing together these diverse groups, the Summit was able to promote much needed collaboration. In particular, the involvement of people living with viral hepatitis helped to define the scope of the Summit and was seen as crucial to its success. This year, a similar approach will be taken whereby people living with viral hepatitis will be at the centre of the agenda.

Q3. What is the theme of the Summit?

The theme of the Summit is *"Implementing the Global Health Sector Strategy on hepatitis (GHSS): towards elimination of*

hepatitis as a public health threat". The first Global Health Sector Strategy on Viral Hepatitis, which was developed by WHO in collaboration with Member States, was adopted at the World Health Assembly in May 2016.

The strategy sets as a goal the elimination of viral hepatitis as a major public health threat, provides a framework for concerted action by WHO and Member States, and has been supplemented by WHO regional plans that contain more detail relevant to the six different regions.

It's very rewarding to see how far we've come in just two years. At the 2015 Summit, we launched the Glasgow Declaration on Viral Hepatitis, which called on governments to develop comprehensive national hepatitis plans to drive action toward the elimination of viral hepatitis as a public health concern. Now, we will be discussing how they can implement these plans.

With over 900 stakeholders in attendance, which include Ministers of Health, hepatitis programme managers, members of international agencies, healthcare organisations, hepatitis-patient organisations and civil society groups, funding agencies and the private sector, the Summit will support the implementation of the strategy and the global response to hepatitis. The programme has been developed in alignment with the strategy, regional plans and accompanying targets and will focus on learning, capacity building and information sharing. It will also highlight the importance of a comprehensive and multi-stakeholder planning process.

Q4. What are the main topics being discussed?

With over 80 expert speakers, the three-day event will include plenary sessions, panel discussions, simulation exercises, workshops and other events to educate and help participants strengthen their efforts to address viral hepatitis at the national level. A particular effort has been made to include countries' experiences so that countries can learn from each other. The topics are organised according to the global strategy and its five strategic

directions of *Information for focused action; Interventions for impact; Delivering for equity; Financing for sustainability; and Innovation for acceleration*. Topics covered will include the data needed to decide on what interventions should be implemented and where to find the data, as well as how to measure the effectiveness of interventions; the interventions themselves in the three key areas of prevention, testing and treatment with examples of what is working and why; how to ensure that the Sustainable Development Goal pledge "to leave no-one behind" and "to endeavour to reach the furthest behind first" is put into practice, especially for marginalised communities like Indigenous peoples, people who inject drugs, incarcerated persons, men who have sex with men and migrant populations; how to finance hepatitis programmes; and innovations on the horizon that will help speed the journey towards elimination.

The main conference will focus on hepatitis B and C as they are responsible for the vast majority of the burden of hepatitis globally. However, there will also be side meetings on hepatitis D and hepatitis E. Other side meetings will look at hepatitis in children, the role of the liver societies in hepatitis elimination, how to integrate hepatitis programmes into existing programmes and infrastructure to minimise costs, UNITAID's increasing involvement in hepatitis C, the Lancet Gastroenterology and Hepatology Commission on accelerating elimination, policy as a tool for hepatitis C elimination and the launch of a new fund to catalyse action called HEP2030.

Q5. Finally, in one sentence, what do you hope the outcome of the Summit will be?

For me, it would be to see this diverse group of stakeholders walk out of there with a sense of purpose and a real belief that, yes, we can; we absolutely can eliminate viral hepatitis.

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EASL HBV Guidelines 2017

George V. Papatheodoridis, MD, PhD

Treasurer of Hepatitis B and C Public Policy Association,
Professor in Medicine and Gastroenterology at Medical School of National and Kapodistrian University of Athens,
Director of Department of Gastroenterology, Laiko General Hospital of Athens, Greece.

Q1. Did we need an update of the 2012 European Association for the Study of Liver (EASL) clinical practice guidelines (CPGs) for hepatitis B virus (HBV)?

An update of the EASL CPGs for HBV was considered to be necessary and timely, because new information on the pathogenesis and management of HBV infection became available after the previous EASL CPGs which were prepared in 2011 and published in 2012^[1]. The objective of the 2017 CPGs was to update the recommendations for the optimal management of HBV infection^[2]

Q2. Have HBV related epidemiology and public health burden remained stable over the recent years?

HBV infection remains a global public health problem but its epidemiology is changing due to several factors. The prevalence of chronic HBV infection has been decreasing in several high endemic countries due to improvements in the socioeconomic status, universal vaccination programs and perhaps effective antiviral treatments. However, population movements and migration are currently changing the prevalence and incidence in several low endemic countries in Europe due to the higher HBsAg prevalence rates in migrants and refugees from outside Europe compared with the indigenous population. The number of HBV related deaths due to cirrhosis and/or hepatocellular carcinoma (HCC) increased between 1990 and 2013 by 33% relating to >686,000 cases in 2013 worldwide.

Q3. Which are the current phases of chronic HBV infection?

Chronic HBV infection is a dynamic process reflecting the interaction between HBV replication and the host immune response. For many years, the

natural history of chronic HBV infection has been schematically divided into five phases, taking into account the presence of HBeAg, HBV DNA levels, ALT values and eventually the presence or absence of liver inflammation. Since the concept of the traditional initial phase of "immune tolerance" has been recently challenged, a new nomenclature was proposed based on the description of the two main characteristics of chronicity: infection versus hepatitis. Thus, the five phases of chronic HBV infection are now named as HBeAg-positive chronic HBV infection (previously HBeAg-positive immunotolerant phase), HBeAg-positive-chronic hepatitis B, HBeAg-negative chronic HBV infection (previously inactive carrier phase), HBeAg-negative chronic hepatitis B and HBsAg-negative phase.

Q4. Are there changes in the end-points of therapy and the indications for treatment initiation?

The end-points of therapy and indications for treatment have practically remained the same as the previous CPGs. The main end-points of therapy remain the induction of long-term suppression of HBV DNA levels, of HBeAg loss with or without anti-HBe seroconversion in HBeAg-positive chronic hepatitis B, ALT normalization, and HBsAg loss. HBV therapy is recommended for HBeAg-positive or -negative patients with HBV DNA >2000 IU/mL, ALT higher than the upper limit of normal (ULN, 40 IU/L) and/or at least moderate liver necroinflammation or fibrosis. Patients with cirrhosis need treatment with any detectable HBV DNA level and regardless of ALT levels, while patients with HBV DNA >20,000 IU/mL and ALT >2xULN can start treatment regardless of the degree of fibrosis. Moreover, HBeAg-positive patients with persistently normal ALT and high HBV DNA levels may be treated if they are older than 30 years irrespective of the severity of liver histological lesions.

Q5. Are there new therapeutic agents and new treatment strategies?

Tenofovir alafenamide (TAF) has been recently approved for the treatment of HBV. In phase III trials, TAF compared to pre-existing tenofovir disoproxil fumarate (TDF) demonstrated similar efficacy in inhibiting HBV replication and superiority in the drug effects on several markers of renal (both glomerular and tubular) function and bone turnover at weeks 48 and 96. TAF is the only agent which can be given to patients with creatinine clearance <50 (15-50) mL/min without dosage modification.

The treatment strategies have generally remained the same. In particular, the long-term administration of a potent nucleos(t)ide analogue (NA) with high barrier to resistance (entecavir, TDF, TAF) represents the treatment of choice. Pegylated interferon-alfa (Peg-IFN α) can be also considered for selected and motivated patients with mild to moderate chronic hepatitis B. Combination therapies are not generally recommended.

Q6. Can patients with chronic hepatitis B discontinue NAs?

NAs are traditionally discontinued after confirmed HBsAg loss, with or without anti-HBs seroconversion, whereas they can be discontinued in non-cirrhotic HBeAg-positive patients who achieve stable HBeAg seroconversion and undetectable HBV DNA and complete ≥ 12 months of consolidation therapy. In addition, for the first time in Western CPGs, it was suggested that discontinuation of NAs may be also considered in selected non-cirrhotic HBeAg-negative patients who have achieved long-term (≥ 3 years) virological suppression under NA(s) if close post-NA monitoring can be guaranteed.

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Q7. What is the optimal course for Peg-IFNa?

The standard duration of Peg-IFNa therapy is 48 weeks, while the extension of the duration of Peg-IFNa therapy beyond week 48 may be beneficial in selected HBeAg-negative patients treated by experts. Peg-IFNa should be stopped at 12 weeks in HBeAg-positive patients and genotype B and C who have HBsAg levels >20,000 IU/mL, or in those with genotype A and D who show no decline of HBsAg levels. Alternatively, Peg-IFNa should be stopped at 24 weeks in HBeAg-positive patients regardless of genotype if they have HBsAg levels >20,000 IU/mL. Peg-IFNa should be also stopped at 12 weeks in HBeAg-negative patients with genotype D who show no decrease in HBsAg levels and <2 log₁₀ IU/mL

reduction in serum HBV DNA levels.

Q8. What is the long-term outcome of chronic HBV diagnosed and treated patients?

The long-term outcome of appropriately treated chronic HBV patients is very good. HCC remains the main potential complication, as its risk decreases but is not eliminated. Therefore, most patients under effective long-term NA therapy or after stopping any type of therapy should remain under surveillance for HCC. HCC surveillance is mandatory for all patients with cirrhosis as well as those with moderate or high HCC risk scores at the onset of any therapy.

Q9. Are there new biomarkers and new potential therapeutic**options under investigation?**

HBV cccDNA, hepatitis B core related antigen and HBV RNA are the main new biomarkers that are currently under evaluation. Over the last few years, there are many research programs which try to develop new treatment concepts for HBV aiming to achieve "cure". Although several definitions of "cure" have been proposed following several international workshops, the new treatment approaches mainly focus on the clearance of HBsAg in a significant proportion of patients, with the principle aims of: i) stopping treatment with no risk of virological relapse and no risk of liver disease progression and, ii) to further decrease the risk of HCC.

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Prof George V. Papatheodoridis is a member of the EASL HBV CPGs panel*

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HBV & HCV and migration into Europe

Manuel Carballo¹, Ina Gudumac¹, Elizabeth Maclean¹

International Centre for Migration, Health and Development, Switzerland

**Q 1. Is migration changing the epidemiological profile of hepatitis B and C in Europe?**

Whenever we talk about migration and its implications for health, it is important to remember that when people move they inevitably carry their medical histories and experiences with them. This is the case for all people, be they migrants, refugees or tourists. What has changed today in Europe is the fact that the pace of migration into the region has accelerated dramatically, and that people are now coming from a wider range of countries than ever before. Some of these countries of origin inevitably have higher rates of

hepatitis B (HBV) and hepatitis C (HCV) than those countries migrants and refugees are moving into, and the health profile of host countries is beginning to reflect this. For example, migrants and refugees currently account for 25% of all reported cases of chronic HBV and 14% of HCV in Europe^[1]. This is largely disproportionate to the number of migrants and refugees and highlights how important it is to target migrants and refugees with healthcare designed around their condition and situation. The epidemiology of HCV in Europe is also becoming more complex because some migrants and refugees are coming from countries that have HCV genotype profiles that are distinct from what was typically the case in the region. Partially as a result of this, HCV genotype 4 (HCV-G4), which is the most common strain of HCV in the Middle East and Africa, is now becoming more common in Belgium, France, Greece, the Netherlands and Spain^[2]. Mapping how

migration is changing genotype patterns is likely to become an important part of treatment policies and standard operating procedures in Europe, with new HCV drugs being tailored accordingly.

Q 2. How much of a risk to public health is this tendency?

Most migrants are healthy and free of HBV and HCV (as well as other diseases) when they arrive in host countries. People coming from countries with high rates of HBV and HCV (or any communicable diseases), are nevertheless more likely to have been exposed to these infections than those living in host countries where the prevalence is low. People arriving from countries where blood screening is not a well-established medical practice, or those moving from countries where ritual practices such as circumcision and scarification are common are also at risk. There is also evidence that HCV rates among migrants in Europe can be higher

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than those in their countries of origin^[3], which suggests that the migration process involves new coping behaviors that expose migrants to HCV. It is important that host countries be more alert to this growing trend and take steps to respond with appropriate and timely actions that take into account the particular needs of migrants and refugees.

Q 3. Do migrants and refugees constitute an HBV/HCV risk to the host population?

The extent to which migrants may or not may be the source of spread of hepatitis B and C to host European populations is likely to depend on their social networking profiles. In the case of TB, research has consistently shown that there is little risk of transmission to host groups^[4], but to what extent the same is true of HBV and HCV is still not clear. In recent years, however, increasing numbers of migrant women have been trafficked or otherwise forced into sex work, and this has clear implications for HBV and HCV transmission, especially if these women are coming from countries with high prevalence rates and poor prevention. As far as HCV is concerned, most European countries have rigorous blood screening procedures in place but injecting drug use is on the rise and people from high HCV prevalence countries who take part in group drug injecting could constitute an added threat^[5]. The fact that in many European countries migrants are disproportionately represented in prison populations where same-sex sex and injecting drug use is common could also be problematic.

Q 4. What can be done to deal with the challenge?

HBV and HCV are life-threatening

diseases and everyone, including migrants and refugees, deserves to be protected against them. Today, these diseases can be either prevented or treated effectively if and when a diagnosis is made. Due to the slow progression of the disease and its asymptomatic nature, however, up to 90% of infected individuals in some European country populations are unaware of their HCV status^[7]. This is as true of migrants and refugees as it is of host populations. Given what we have learned from the public health response to HIV, we nevertheless know how valuable early screening can be, if it offered in conjunction with treatment. Screening migrants and refugees coming from countries where the prevalence of HBV and/or HCV is known or thought to be high should, therefore, be a key part of any public health response to the problem. Other at-risk host society groups who are typically marginalized and not currently well served should also be given greater priority. Offering targeted early screening to a wide spectrum of host country people also deserves to be considered, although the financial aspects of this may be prohibitive

Q 5. What are likely to be barriers or problems encountered in mounting such a response?

The first and most important barrier will be the fact that despite the global importance of HBV and HCV as sources of morbidity, disability and mortality, governments and international bodies have been slow to respond to the challenge. Much, therefore, remains to be done to persuade national health authorities that HBV and HCV deserve more priority than they have been given in the past. In the case of migrants and refugees, the barriers are

likely to be even more significant. Many countries see migrants and refugees as mobile, transient populations and are therefore not immediately inclined to invest major resources in their wellbeing or in providing them with what are seen as “costly” public health interventions. In some settings, there may also be medical insurance requirements that migrants and refugees have difficulty meeting.

Even if screening were to be offered on a larger scale, there could also be ethical, legal, linguistic and cultural issues to be overcome. Medical screening in some parts of the world is used as a criteria to deport or reject migrants rather than to refer them for treatment. This inevitably dissuades people from accepting any type of screening. Some people also come from countries with a history of repression and tend to fear screening because they fear patient information will not be treated confidentially and possibly shared with legal authorities. This has proved to be a limiting factor in other public health outreach initiatives and coupled with linguistic differences can easily constitute a barrier in the case of HBV and HCV, both of which may be poorly understood and seen as socially stigmatizing.

Conclusions

International migration is likely to further influence epidemiological patterns of viral hepatitis in Europe. As it does, enhanced commitment to screening and treatment of migrant and refugee populations will be called for together with more inclusive health policies for this growing population.

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Dr Manuel Carballo is Executive Director of the International Centre for Migration, Health and Development, Switzerland.*

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