Hepatitis B and C Public Policy Association

NEWSLETTER

APRIL 2013 ISSUE

Dear Colleagues,

This first Newsletter of the Hepatitis B and C Public Policy Association in 2013 carries a summary of the conference on Hepatitis B and C in Mediterranean and Balkan countries which the Association hosted in Cyprus in December 2012 under the auspices of the Cyprus EU Presidency.

Our next Newsletter will be issued in May and will include a detailed analysis of the anti-HCV health care programs in Europe. This year the newsletter format has been reshaped to comply with the need of expanding our reach to countries like Asia and the Americas, where hepatitis is a major health care issue. In line with our aim to build closer links between health care providers, policy makers and Academy, several opinion leaders from America, Europe and Asia have been nominated as Associated Editors, who are in a position to better highlight all the initiatives that have been taken in their geographical areas to prevent and effectively manage viral hepatitis.

Massimo Colombo
Alessio Aghemo

Newsletter Contents

EASL EUROPEAN ASSOCIATION FOR THE STUDY OF THE LIVER

Highlights from the International Liver Congress

Mark Thursz, EASL Secretary General

With EASL's 48th International Liver Congress almost here it is a good time to reflect on the topics which will make most impact in the field of viral hepatitis following the meeting. Most people will focus in on the phase III trial data for new direct acting antivirals for hepatitis C virus infection. No one will be disappointed in the amount of emerging data that will be presented in Amsterdam but I think we need to look at the trial results carefully to see how clinical practice in Europe will change. Sustained virological response rates over 90% in 12 week courses of Sofosbuvir with Pegylated Interferon and Ribavirin for genotypes 1,4,5 & 6 are impressive but I am not sure how rapidly Interferon-free regimens will enter the clinic for genotype 2 & 3. Price will undoubtedly play a major role. Although the current generation of protease inhibitors for HCV genotype 1 are a major advance in terms of SVR over Pegylated interferon and Ribavirin data will be presented from several groups showing that the side effect profile of these regimes is far from ideal and it therefore good to see phase III data on the next generation of protease inhibitors.

I am delighted to see that some very high quality work in Hepatitis B is going to be presented; with all the attention on DAAs for HCV, HBV has looked a little neglected recently. The new work focussed on cccDNA and how it might be eliminated. It will be good to see how this work develops in the coming years and whether it translates into 'cures' for HBV infection so that long term viral suppression may become redundant.

The International Liver Congress has, for many years, hosted the Virgil joint workshop on the Wednesday morning prior to the full congress commencing. This has proved to be a really popular event even though the Virgil network has now disappeared. However, EASL recognises how important it is to provide quality education on viral hepatitis and will continue to provide a state of the art independent review on viral hepatitis topics in the Viral Hepatitis Workshop.

Finally, I would like to draw your attention to two special Early Morning Workshops at the ILC this year. On Friday the International Hepatitis/HIV Policy & Advocacy Treatment Action Group (TAG) will hold a workshop on Hepatitis C Treatment Access in Low – and Middle – Income Countries: Strategies for Success and on Saturday Medecins sans Frontiers will hold a workshop on Increasing access to HBV and HCV diagnosis and treatments in resource limited settings. For those of us interested in the care of patients in resource limited settings these should be unmissable.

Prof. Mark Thursz
EASL Secretary General

Summit Conference Hepatitis B and C in Mediterranean and Balkan Countries

5-7 December 2012 Nicosia Cyprus

Call to Action

December 7th, 2012

This Call to Action is endorsed by:

- Takis Hatzigeorgiou MEP
- Stephen Hughes MEP
- Alojz Peterle MEP
- Viral Hepatitis Prevention Board
- European Association for the Study of the Liver
- European Liver Patients Association
- World Hepatitis Alliance
- International Centre for Health, Migration and Development
- Hepatitis B and C Public Policy Association.

The Conference on Hepatitis B and C in Mediterranean and Balkan Countries has united a range of stakeholders to urge the formulation and implementation of effective policies and targeted actions by national governments, healthcare providers and civil society in the fight against hepatitis B and C.

The Conference commends previous work in the domain of hepatitis B and C, in particular the 63rd World Health Assembly's resolution on Viral Hepatitis of May 2010, MEP Thomas Ulmer's Call to Action on Hepatitis B launched at the European Parliament in 2006, the European Parliament's Written Declaration on Hepatitis C in 2007, the Call to Action launched at the Brussels Conference on Hepatitis B and C in Europe in 2010 and the WHO Prevention and Control of Viral Hepatitis Infection: Framework for Global Action, launched in July 2012.[1]

The Steering Group of the Conference on Hepatitis B and Hepatitis C in Mediterranean and Balkan Countries, together with its partner associations, calls on the countries of these regions to create national viral hepatitis strategies and action plans and, in particular, to:

1. Involve all sectors of society in the fight against hepatitis B and C
2. Place the fight against hepatitis B and C within a Right to Health framework
3. Actively participate in World Hepatitis Day
4. Improve awareness of the health and economic impact of hepatitis B and C
5. Strengthen surveillance of hepatitis B and C
6. Build inter-country research capacities dedicated to hepatitis B and C
7. Make prevention and control of hepatitis B and C a key part of public health action
8. Invest in better case detection and treatment programmes in primary health care
9. Develop outreach programmes to ensure more voluntary counselling and testing
10. Explore innovative ways of reaching all vulnerable groups, including migrants
11. Ensure universal access to treatment
12. Create community-based programmes to support people living with viral hepatitis

Opening Address of Cyprus Minister of Health, Mrs Androulla Agrotou «Hepatitis B and C in Mediterranean and Balkan Countries» 5-7/12/2012, Nicosia, Cyprus

Ladies and Gentlemen

It gives me a great pleasure being here today to declare the opening of this well promising Conference in the crucial area of prevention and control of Hepatitis B and C at regional level.

Available statistical data indicates that approximately 2 billion people worldwide have been infected with hepatitis B and more than 350 million people live with a chronic form of the disease. Additionally, the World Health Organisation (WHA63.18) recognises Hepatitis B and C as a global health problem leading to chronic disease in hundreds of millions of people and consists one of the most common causes of liver cirrhosis and cancer.

Hepatitis B and C belong to the category of communicable diseases which do not recognise borders and turned to become major diseases affecting mankind today. Thus, further actions towards their prevention and control shall be taken.

This is also confirmed in the case of Cyprus, where statistical data for the period between 2006 and 2012 shows that 67% and 90% respectively of the cases of Hepatitis B and Hepatitis C were imported.

At this point, allow me to inform you on one of the Cyprus Presidency's priorities in the field of health which is related to cross-border health threats with focus on communicable diseases and is interrelated with this Summit Conference's aim.

The Ministry of Health, acknowledging the efforts of the European Commission, the European Parliament and the European Council for adopting a Decision on Cross Border Threats to Health and having in mind that the increasing interconnectedness of the world creates unavoidable risks such as the re-emergence of communicable diseases on a cross border basis, has included the issue of the Cross border Health threats with focus on communicable diseases among its main priorities.

In addition, the Ministry of Health recognizes that the geographical position of Cyprus, being located in the eastern part of the Mediterranean Sea with its coastlines defining the south eastern border of the European Union, mandates a role to promote and safeguard public health security in the region. For this reason, an expert level Conference on "Cross Border Health Threads in the EU and its neighbouring countries-focus on Communicable Diseases" was held in Nicosia, on July the 5th 2012, in the framework of the Cyprus Presidency of the Council of the EU.

The participants of the conference were experts from EU Member States, neighbouring EU and non-EU countries and international organizations or institutions, which had the distinctive opportunity to share expertise and best practices in the area of prevention and effective control of communicable diseases on a cross border perspective and to highlight the regional dimension of these diseases.

Based on the deliberations of the Conference, the Presidency proceeded with the issue of Conference Conclusions and Recommendations which underlined among others, the following:

- The identified need to upgrade inter regional cross border collaboration and coordination to face communicable diseases, in the areas of information sharing, joint intervention, institutional links, mutual technical assistance and joint human research development and operational research.
- Promote active vaccination campaigns targeting vulnerable population groups and anti-vaccine groups, in order to master vaccine preventable diseases and achieve and maintain high immunization coverage.
- Strengthen Public Health Capacity through training, including further development of programmes in the field of epidemiology and microbiology, flexible enough to support and complement national initiatives.
- International Collaboration and Communication is necessary for disease control and outbreak response and this requires strong leadership and a global vision. Areas for collaboration between EU and WHO have been identified and more linked communication networks need to be developed.
- The impact of the Financial Crisis on Preparedness and Response to cross border public health threats is recognized. There is an identified negative effect on controlling and treating communicable disease. Further research is needed to study this relationship. National and European policies need to mitigate the impact of the financial crisis.

Dear participants, I hope that with the information provided, I was able to highlight the intensive efforts of the Ministry of Health Cyprus to address the need for coordinated actions for the prevention and control of Communicable diseases, including Hepatitis B and C at regional level. It is clear that in the case of communicable diseases in general and Hepatitis B and C in particular, countries cannot act effectively if they act alone and, as for that, cooperation is indispensable.

Allow me to close my speech and declare the opening of today's Summit Conference by wishing you every success to your deliberations, from which I am sure that important outcomes will be delivered for the health security of the citizens both at European and regional level.

MINISTRY OF HEALTH CYPRUS
NOVEMBER 2012

Conference on Hepatitis B and C in Mediterranean and Balkan Countries, Nicosia, Cyprus 5-7 December 2012

The Hepatitis B and C Public Policy Association asbl is grateful for the financial support provided by Bristol–Myers Squibb, Gilead, Janssen and MSD for this event.

REPORT

The Conference on Hepatitis B and C in Mediterranean and Balkan Countries brought together stakeholders from government, health care and civil society from 26 countries to share evidence and best practice on the epidemiology, prevention and control, diagnosis and treatment of hepatitis B and C in the Mediterranean and Balkan regions. It followed on from the 2010 Summit Conference on Hepatitis B and C. The conference provided a ground-breaking opportunity to review the viral hepatitis situation, and delegates and partner organisations issued a **Call for Action** urging governments and stakeholders in the region to create viral hepatitis strategies and action plans and, in particular, to:

1. Involve all sectors of society in the fight against hepatitis B and C
2. Place the fight against hepatitis B and C within a Right to Health framework
3. Actively participate in World Hepatitis Day
4. Improve awareness of the health and economic impact of hepatitis B and C
5. Strengthen surveillance of hepatitis B and C
6. Build inter-country research capacities dedicated to hepatitis B and C
7. Make prevention and control of hepatitis B and C a key part of public health action
8. Invest in better case detection and treatment programmes in primary health care
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THE IMPACT OF VIRAL HEPATITIS IN THE MEDITERRANEAN AND BALKAN REGIONS

Epidemiological comparison between European countries is limited by variations in case definitions used and in the data sets collected by national surveillance authorities. The European Centre for Disease Prevention and Control ((ECDC) is working to develop standardised surveillance definitions across the European Union. Future efforts to harmonise data collection and case definitions between ECDC, WHO Europe and WHO-EMRO would also limit the reporting burden at national level and enhance the accuracy of international and regional comparisons.

Epidemiology of viral hepatitis

Approximately 14 million people are estimated to be infected with hepatitis B and 9 million with hepatitis C in the WHO European region, and the two forms of viral hepatitis cause around 122,000 deaths a year in the region[i]. There is limited information regarding the burden of liver disease attributable to viral hepatitis and the resultant health care resource utilisation in the Balkan and Mediterranean regions.

The epidemiology of viral hepatitis in the Mediterranean and Balkan region is heterogeneous. An ECDC literature review of published epidemiologic studies carried out in the European Union and neighbouring countries (2010) found a gradient towards greater HBV and HCV prevalence in southern and eastern Europe, but population sampling may under-represent high-risk groups such as migrants and injecting drug users[ii]. There are insufficient data to arrive at estimates for hepatitis B and/or hepatitis C prevalence in 19 countries in the European Union (predominantly in eastern and southern Europe) and the Balkans.

Nevertheless current best estimates suggest that population prevalence varies from:

- Less than 1% for HBV surface antigen the Netherlands, United Kingdom and Scandinavia to between 2 and 4% in Greece and between 4 and 6% in Romania. Prevalence in countries in the Mediterranean region ranges from 0.8% in Algeria (blood donors) and 1.69% in Lebanon to 9.9% in Jordan.
- Less than 1% for HCV antibody in Scandinavia, the Netherlands and the United Kingdom to greater than 2% in Romania. In the Mediterranean region general population prevalence appears to be low in many countries, such as Lebanon, Algeria (0.20 – 0.5%), although Libya (1.3%) and Morocco (3.3%) have observed higher levels. Egypt is severely affected by hepatitis C due to an iatrogenic epidemic that has been amplified by transmission through the blood supply and in medical settings; current prevalence is estimated at around 109%, rising to 25% in the 55-59 age group.

PREVENTION OF TRANSMISSION: KEY PREVENTION NEEDS

The risk of transmission of the blood-borne viruses hepatitis B and C varies somewhat across the Balkan and Mediterranean regions according to local epidemiology and the level of health system development. Research presentations at the meeting identified a number of key prevention needs across the regions.

Blood and donor organ safety

The introduction of testing of donors or pooled samples has greatly reduced the risk of HBV and HCV transmission through blood transfusion and organ donation.

HCV antibody and HBsAg screening has been implemented throughout the Balkans and EMRO region, but concerns remain regarding weaknesses in the health system that could lead to persisting transmission through blood transfusion and organ transplant. These weaknesses include:

- Persistence of paid blood donation in some countries (e.g. Albania).
- High prevalence of viral hepatitis among first-time donors and low levels of donation among repeat, regularly screened donors.
- Fragmentation of national transfusion services leading to scarce and inadequate data on donors, transfusion safety, haemovigilance, and lack of information on best practices in the use of donated blood.
- Frequent emergencies in the requirement for donated blood due to civil unrest and wars in the region
- Lack of local data on prevalence in first-time donors, general population or other categories of donors.
- The use of low sensitivity diagnostic tests

Consistent implementation of infection control practices in health care settings Viral hepatitis transmission has been documented through the inadequate sterilisation of instruments in the following settings, and hepatitis C outbreaks have been documented in a wide range of European and Mediterranean countries:

- Dentists
- Gynaecologists
- Surgery
- Kidney dialysis
- Bronchoscopy

Health care workers frequently acquire HBV or HCV through needle stick injuries and blood splashes, when universal precautions are not practised rigorously.

However, re-use of needles and other improperly sterilised injecting equipment may account for the greatest number of infections in health care settings. Based on a mathematical model published by Hauri AM et al. in 2004 it is was estimated that In the Eastern Mediterranean WHO region approximately 2.5 million HBV infections and 645,000 HCV infections could be attributed to unsafe injections yearly.[iii]

Prevention activities to address transmission in healthcare settings must address:

- High rates of re-use of needles and syringes
- Improper sterilisation procedures
- Financial pressure to re-use needles and syringes
- Lack of implementation of universal precautions and lack of facility-wide procedures
- Lack of accountability at facility and health system level for failures in infection control.
- Immunisation of health care workers against HBV

Consistent implementation of infection control practices in non-health care settings

Barbers, hairdressers, beauticians and tattooists require education and regulation to ensure that exposure to blood-borne viruses is minimised as a result of their work. Other

practices less amenable to regulation, such as ritual scarification and 'wet' cupping (hijama, a form of Arabic traditional medicine in which cups are applied to the skin so as to create a vacuum that will aid in drawing blood from an incision), also pose risks for viral hepatitis exposure in the Mediterranean region.

Harm reduction for injecting drug users

In most European countries viral hepatitis is highly prevalent in current and former injecting drug users. However sub-national and national epidemiologic surveillance suggests large variations in prevalence, ranging from less than 25% prevalence among injecting drug users in Hungary, Czech Republic and Slovenia, to greater than 75% prevalence in Italy, Romania and Belgium in 2009-2010 (EMCDDA, 2012). Between 2005 and 2010 national epidemiological surveys reported rising HCV antibody prevalence in Austria, Bulgaria, Cyprus, Greece and Romania. Preliminary and unconfirmed data suggest high or rising HCV antibody and HBsAg prevalence in injecting drug users in some Balkan countries. There is little evidence regarding the size of drug-injecting populations or viral hepatitis prevalence among injecting drug users in the eastern Mediterranean and North African region, and very limited harm reduction activities are currently reported.

In addition, there are recent reports showing significant HIV outbreaks among drug users in Greece and Romania which may be related to the economic crisis and reduction of budgets in the health system. National harm reduction guidelines are absent in many European countries, including some where injecting drug use is the predominant mode of HCV transmission. ECDC and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) issued *Guidance on the prevention and control of infectious diseases in people who inject drugs* in 2011, which recommended seven key interventions:

- Provision of clean injecting equipment
- Vaccination
- Opioid substitution treatment and other forms of effective drug dependence treatment
- Voluntary and confidential testing for viral hepatitis and HIV
- Antiviral treatment for viral hepatitis and HIV
- Health promotion
- Targeted delivery of services to meet the needs of users

Prevention efforts among injecting drug users continue to be challenged by the need to achieve sufficient scale and coverage in order to interrupt transmission.

Syringe and needle exchange, and opioid substitution therapy, which can withdraw drug users from the pool of active injectors and sharers of equipment, do not exist or have low coverage or remain inaccessible because they are not adapted to the needs of the target group in many countries in central and eastern Europe, the Balkans and Eastern Mediterranean.

There is suggestive evidence from modelling studies indicating that improvements in HCV treatment coverage among injecting drug users have the potential to reduce HCV prevalence over time and to reduce the burden of HCVrelated disease.

Vaccination

Vaccination against hepatitis B is a powerful prevention strategy. The World Health Organization recommended routine vaccination of infants in 2004 and reinforced this advice in 2009, calling for regional targets for hepatitis B control.

High levels of infant vaccination coverage have been achieved in the countries of the Mediterranean region, and the adoption of vaccination policies in the Balkan and Mediterranean region has resulted in measurable reductions in HBV prevalence. Policies on offering vaccination to adults at high risk of infection remain inconsistent across the European region. Vaccine access has been accomplished in some settings with support from the Global Access to Vaccines Initiative (GAVI); future access may depend on continuing donor support.

Investment in screening programmes

Screening policies for viral hepatitis vary across the European Union and its neighbours. While 33 countries screen blood donors for HBV and HCV, there is no consistent approach towards offering screening for either HBV or HCV to high-risk groups such as current and former injecting drug users, migrants from highburden settings or men who have sex with men, and a lack of evidence to support an age-based approach to general population screening for HCV, as recently recommended for the 1945-1965 birth cohort in the United States by the US Centers for Disease Control and Prevention.

The development of national screening recommendations in the European Union, Mediterranean and Balkan countries will require cost-effectiveness analysis of this approach, together with the generation of

more comprehensive health information on HCV (including prevalence) and the impact of viral hepatitis on morbidity and mortality, as well as improvements in access to treatment. The development of more comprehensive screening programmes would also be assisted by advances in point-of-care rapid diagnostics for both HCV antibodies and RNA.

Comprehensive viral hepatitis prevention strategies

In view of the limited resources available for prevention it is important that comprehensive strategies for the prevention of viral hepatitis should be developed at national level, and attention should be paid to the ways in which prevention strategies for other blood borne viruses, most notably HIV, can support the prevention of viral hepatitis.

MIGRATION AND VIRAL HEPATITIS

Blood-borne hepatitis viruses (B, C and D) occur at varying prevalence in populations in all regions of the world. Hepatitis B infection is endemic in some Asian countries, while a high prevalence of both hepatitis B and C has been identified in some African countries. Evidence is now accumulating that global population movements, caused by economic migration, war and civil unrest are changing the global distribution of viral hepatitis.

Economies in the European Union are likely to be increasingly dependent on migrant labour to preserve the ratio of employed to dependent adults as populations age in the EU. A forward-looking policy on migration and health will require European Union countries to put in place screening and treatment programmes for the chronic diseases that are endemic in the regions that are providing migrant support for European economies. Many migrants come from countries of the Mediterranean and Balkan regions, or beyond, so the benefits of investments to support prevention, screening and treatment of viral hepatitis should not be viewed as limited to one country.

The cost of screening and treatment needs to be viewed as a long-term investment in the European workforce, and as a means of preserving the economic base which guarantees the right to health of all Europeans, whatever their country of origin.

RECENT CLINICAL ADVANCES

Treatment

Without antiviral treatment chronic HBV and HCV infection may result in progressive liver disease, cirrhosis, hepatocellular carcinoma or death. Recent improvements in antiviral therapy have resulted in cure of hepatitis C infection in up to 75% of previously untreated patients. Although hepatitis B infection remains incurable in the vast majority of chronically infected patients, antiviral therapy suppresses viral activity and stabilises or reverses liver damage.

Treatment for both forms of viral hepatitis now has the potential to avert a substantial burden of morbidity and mortality, and over the longer term to reduce the prevalence and incidence of HCV.

The new HCV treatment regimens present a number of challenges to patients and health systems, including high rates of adverse events, complex adherence schedules, complex treatment algorithms and the need for confirmatory HCV RNA testing with rapid provision of results. Drug-drug interactions are complex and problematic, particularly in HIV/HCV coinfection, and the regimens are substantially more costly than previous therapies.

Preliminary studies indicate that newer investigational agents for HCV therapy have the potential to increase the rates of cure to 95-100% in some patient populations when used in combination, but larger registration studies are required, and a number of challenges will have to be overcome in order to achieve the promise of these therapies at a population level:

- Improved rates of diagnosis of viral hepatitis in all countries.
- Improvements in access to hepatitis expert care and increased capacity for the provision of expert care in Europe.
- Improvements in health information to inform the case for HCV treatment
- Increased capacity for patient advocacy to demand access to treatment
- Political willingness to fund HCV treatment
- Pharmaceutical company and European Union pricing policies which enable the widest possible access whilst rewarding innovation.

Developing the case for HCV treatment access

Treatment access is highly variable across the European and Mediterranean region due to the cost of treatment and variations in the resources available for health care. Triple-agent therapy costs range from €36,452 in France to approximately €50,000 in Italy, while the cost of a 48-week course of pegylated interferon/ribavirin ranges from €2,000 in Egypt to €7,000 in Serbia, €12,000 in Morocco, €13,812 in Greece and up to €16,000 in Italy, according to data

from national programmes presented to the meeting. Similar variations in the cost of antiviral drugs for HBV treatment were also reported. Reimbursement approval for newer drugs used in HCV and HBV treatment is still awaited in many European Union and Mediterranean countries.

The cost and availability of treatment in each country is determined by a number of factors:

- GDP and overall resources for health
- Membership of the European Union. Countries in the EU are bound to a reference pricing system for medicines which imposes high drug prices on recent EU entrants relative to GDP.
- Speed of reimbursement approval for new medicines
- National treatment guidelines
- Expanded access arrangements organised by pharmaceutical companies

Urgent action is required at EU Commission and Council levels in order to address the health inequalities in access to treatment that are being caused by the current pricing policies.

RAISING AWARENESS AND POLICY INITIATIVES

World Hepatitis Day (July 28) is an official WHO disease awareness day, and provides an important opportunity to raise awareness through educational and screening activities at national level. World Hepatitis Day also provides an important platform for civil society and professional lobbying of government.

Addressing the burden of viral hepatitis in the Balkan and Mediterranean regions will require national commitments in the form of strategic plans, financial and human resources, as well as normative guidance and technical support from regional/global agencies.

A number of European countries have already developed national strategic plans or action plans to address viral hepatitis. Key lessons and questions raised from these processes include:

- Collaboration and involvement of all stakeholder groups, including medical and public health professionals, drug treatment services and patient associations, has proved successful in influencing government to give greater priority to viral hepatitis in a wide range of European and Mediterranean countries at all levels of economic development.
- Patient associations have proved highly influential political actors in several countries and at EU level; support for the development of patient advocacy is a key element in the promotion of wider access to hepatitis diagnosis and treatment.
- Civil servants, as well as politicians, need to be convinced by the evidence of public demand and the economic costs of inaction.
- At both international and national level viral hepatitis is 'cross-cutting' - it will involve people working across a variety of disciplines and services to come together as problem-solving teams in order to address complex systemic problems.
- The generation of evidence through research has been critical in making the case for scaling up hepatitis treatment in countries that have taken the boldest steps towards expanding screening and treatment; a greater emphasis on advocacy for enhanced research support at the national and international level is needed.
- Evidence of impact needs to be gathered from the earliest stages of interventions in order to convince policymakers of the value of sustained action.
- Adoption of international standards within independent national guidelines on treatment also acts as a form of pressure on governments.
- Learn from success stories and comparative 'benchmarking' of national performance through independent audits, such as the Hepatitis Care Index developed by the European Liver Patients Association, can also act to raise standards and generate debate.
- Tracking of funds: a consistent framework is needed for disaggregating and tracking resource allocations at country level in order to monitor performance.
- How can other health system resources be leveraged in order to support viral hepatitis services? For example, given the high rate of HIV and HCV coinfection, how can HIV-related infrastructure be used to improve hepatitis care?
- Increase awareness in future healthcare workers (medical and paramedical students), include hepatitis prevention and control in the curricula.

Guidance and policy support: WHO initiatives

As a result of World Health Assembly resolution 63.18, which called on WHO to develop a comprehensive

approach to viral hepatitis prevention and control, the WHO created the Global Hepatitis Programme in 2011. *Prevention and Control of Viral Hepatitis Infection: Framework for Global Action* was published in 2012, together with *Guidance on Prevention of Viral Hepatitis B and C in People Who Inject Drugs*, and WHO is now in the process of developing hepatitis C screening, care and treatment guidelines, due for publication in the second half of 2013.

The Framework for Global Action has four axes:

Axis 1: Raising awareness, promoting partnerships, and mobilizing resources

Axis 2: Evidence-based policy and data for action

Axis 3: Prevention of transmission

Axis 4: Screening, care and treatment

WHO is developing a Global Hepatitis Network to develop collaborative exchanges that will contribute to a Global Hepatitis Work plan.

WHO Eastern Mediterranean Regional Office established a Viral Hepatitis Control programme following a regional committee resolution in 2009, with the aim of reducing the prevalence of chronic HBV infection among children under 5 to below 1% by 2015, chiefly through the promotion of vaccination, with a particular emphasis on extending birth dose vaccination throughout the region.

Patient groups

Patient advocacy has played a key role in a number of European and Mediterranean countries including Scotland, Bulgaria and not least in Egypt, in persuading policy makers to devote resources to the treatment of viral hepatitis.

In Egypt the national patient association, founded in 1995, was instrumental in demanding a national prevention campaign to raise awareness of hepatitis C and to provide access to treatment, and has also played the key role in educating and supporting people diagnosed with HCV.

There is a need for greater advocacy from patients in many settings, particularly those who already have a media profile and the ability to influence national awareness. Viral hepatitis, particularly hepatitis C, continues to be highly stigmatised in many countries, with low public visibility, a strong public association of the infection with injecting drug use, and poor and inaccurate perceptions of how the infection is transmitted. World Hepatitis Day (July 28) provides an annual opportunity for raising awareness.

CONCLUSION

"The research has been done, the evidence is there, we need to act!"

Stephen Hughes MEP.

1. There has been welcome progress towards developing European-level and international strategic approaches to viral hepatitis. These include general surveillance and risk-group specific monitoring (ECDC and EMCDDA), research (EC DG Research & DG Health) and the development of guidance (WHO, ECDC and EMCDDA). Nevertheless the growing burden of liver disease caused by viral hepatitis requires further urgent action at European and international level. Viral hepatitis is now estimated to cause more deaths than HIV in the WHO Europe region.

2. In particular, concerted action is required in order to achieve universal access to prevention, care and treatment for viral hepatitis. Recent improvements in the treatment of viral hepatitis, and the future promise of new therapies that could cure the majority of people with HCV infection, could remain out of reach for the majority of people with viral hepatitis in Europe and the Mediterranean region without actions on the part of governments, normative authorities, pharmaceutical companies and advocates to promote and expand access.

3. An extension of screening for hepatitis B and C will be required in order to reduce the future burden of liver disease in Europe, since most people with viral hepatitis do not know they have been infected. Undiagnosed people cannot benefit from treatment.

4. Migrant populations and people who inject drugs in Europe and the Mediterranean are at high risk of viral hepatitis and liver disease and require diagnosis, prevention measures (including vaccination) and treatment.

[i] Source: http://www.euro.who.int/en/what-we-do/health-topics/communicablediseases/hepatitis

[ii] ECDC 2010. Hepatitis B and C in the EU neighbourhood: prevalence, burden of disease and screening policies. http://ecdc.europa.eu/en/publications/Publications/TER_100914_Hep_B_C %20_EU_neighbourhood.pdf

[iii] Hauri AM, Armstrong GL, Hutin YJ. The global burden of disease attributable to contaminated injections given in health care settings. International Journal of STD and AIDS, 2004, 15:7–16.