NEWSLETTER

High Level Meeting

Economic crisis and healthcare ensuring access to public health services The case of hepatitis B and C

3-4 June 2014 Athens Greece



SEPTEMBER 2014 ISSUE

Note by the Co-Chairman of the Hepatitis B and C Public Policy Association Professor Angelos Hatzakis

The Hepatitis B and C Public Policy Association brings together thought leaders and stakeholders from across the board to reflect on recent advances and challenges in understanding, measuring, preventing, diagnosing and treating hepatitis B and C and to develop specific policy responses that can effectively and measurably address these challenges.

Over the past 5 years, it has organized two High Level Meetings in cooperation with the EU Presidency of Belgium and the EU Presidency of Cyprus and has instigated and agreed with its partner associations on two Calls to Action addressed to the European Commission, the EU Member States and the Mediterranean Countries. The Association also participates in related international and European scientific and policy meetings and lobbies to increase the visibility of challenges and the urgency for responses.

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High Level Meeting Summary Report 3-4 June 2014 Athens, Greece Economic crisis and healthcare-ensuring access to public health services: The case of hepatitis B and C In June 2014, the Hepatitis B and C Public Policy Association in cooperation with the EU Presidency of Greece and the Ministries of Foreign Affairs and Health held a High Level Meeting in Athens to discuss how health care systems can better understand the challenge posed by hepatitis B and C and make informed, evidence-based decisions on where to invest to successfully address it, even in circumstances of severe resource constraints.

The economic crisis has impacted on public health spending more than on any other public life sector – shrinking budgets necessitate austerity. In turn, austerity calls for cuts. Governments are faced with a dilemma: spend now to save later? When and how? On what? With what return on investment?

In an environment such as this, each public funding decision has to be solidly grounded on evidence so that it can gain political legitimization and societal acceptance. Addressing barriers to preventing, diagnosing and treating hepatitis B and C in crisis stricken Europe in an evidence based, hard to dispute, integrated manner that optimizes limited available resources is becoming a burning issue for policy makers across the continent.

Hepatitis is a persisting, urgent public health challenge, with approximately 28 million people living with chronic hepatitis in WHO-EURO Region and over 120,000 dying each year because of it. Worryingly, up to 80% of people chronically infected are unaware of their condition – and are at serious risk of developing liver cirrhosis and cancer. Hepatitis and its sequelae pose a major challenge for health care systems also for financial reasons – the cost of managing untreated hepatitis that progresses to compensated cirrhosis and liver cancer is grave and the benefit to be acquired by patients elusive. And this when recent advances in medicine confirm that hepatitis B is treatable and hepatitis C is curable – at a cost. Yet, is this a cost or an investment to avoid more costs?

The Athens High Level Meeting discussed barriers to addressing the challenge of hepatitis at the health service level and agreed on a Call to Action to address gaps related to measuring, preventing, diagnosing and treating hepatitis B and C, especially in times of economic crisis. The Call to Action will form the basis on which to continue working with policy makers and stakeholders to ensure sustainable, evidence based policy making on viral hepatitis.

This issue of the Hepatitis B and C Public Policy Association Newsletter is dedicated to the Athens High Level Meeting proceedings, discussions and outcomes, presented through a summary meeting report. We invite you to read the meeting summary, share your thoughts with us and join in the effort to raise the bar for the management of viral hepatitis in Europe.

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High Level Meeting

Economic crisis and healthcare ensuring access to public health services The case of hepatitis B and C

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Meeting Summary Report

Background

The Hepatitis B and C Public Policy Association in cooperation with the Hellenic Center for Disease Control together with representatives from partner organizations, CORRELATION, EASL, ECDC, ELPA, EMCDDA, INCMHD, VHPB, WHA, WHO, and the WORLD BANK, met in Athens on June 3 and 4, 2014 to discuss recent policy developments and persisting and emerging challenges related to the prevention and management of viral hepatitis. The discussion highlighted urgent priorities for action to tackle the public health, economic and social impact of hepatitis B and C, particularly in circumstances of economic crisis, that were reflected in the Call to Action endorsed by all partner organizations at the end of the meeting. http://www.hepmeeting2014.org.

Meeting overview

Despite the fact that chronic hepatitis B can be controlled and chronic hepatitis C can be cured, there are still many patients who are or will be infected with, and die from these chronic infections (Thomas H, 2014). This is largely due to a lack of organized screening programmes, under-diagnosis, barriers to access and linkage to care and, ultimately, high cost of care, particularly for HCV, which may limit the benefit of treatment to selected patients only (Thomas H, 2014).

This situation is further exacerbated by increasing budgetary constraints. As health care systems are striving to meet current demand with decreasing human and financial resources, prioritization in resource allocation within health care budgets and across public spending becomes not only a highly economic but also a highly political exercise.

Yet, if health buys wealth and 24% of economic growth is attributable to better health (Wilson D, 2014), the first and foremost responsibility of health care systems is to ensure high levels of health are attained by populations in a cost-effective, sustainable manner – especially with regard to viral hepatitis. The burden of hepatitis B and C is very much comparable to that of HIV/AIDS (in number of deaths per year). Nonetheless, the difference in investment to effectively manage viral hepatitis versus HIV/AIDS is substantial (Wiktor S, 2014). Data from the WHO confirm that twice the funds would be invested in every person that dies from tuberculosis than in every person that dies from viral hepatitis.

This could be attributed to a series of persistent and emerging challenges related to the messaging, political communication and understanding of viral hepatitis, such as a) its complex epidemiology and natural history, b) insufficient advocacy in the field, c) the crisis in global health funding and d) the global economic crisis (Wiktor S, 2014). To this end, waiting for evidence to be produced by sophisticated tools that can further inform decision making at the local level and that national health systems currently lack or are slow at developing, is delaying the achievement of measurable, evidence-based improvements in the health of the population as well as increasing the overall burden of viral hepatitis.

Participants at the Athens High Level Meeting agreed that data currently available at the global level are enough to act upon. Now more than ever, when universal vaccination coverage for HBV is reaching new heights, when harm reduction programmes continue to reduce exposure to the risk of HBV and HCV, when HBV can be clinically treated and HCV can be cured, with a promise for eradication in the near future, when cirrhosis and hepatocellular carcinoma (HCC) can be effectively prevented, there is a case for optimism and a need for urgent action.

As the "tide is turning", the call to action on health care systems to develop adequate responses is becoming as pressing as it is justified. Representatives from patient associations presented best practice examples of working with policy makers and clinicians to reach consensus on the need to act on viral hepatitis and act now (Kautz A, 2014) – adapting published tools and increasing the level of "noise" related to understanding hepatitis B and C challenges and responses.

Such action can significantly improve control of hepatitis B and C in a cost-effective manner now, while with the support of patient registries and through further integration and realignment of health care services to respond to actual patient need, especially in the framework of a national hepatitis plan, more evidence can be put into action.

Persisting challenges in controlling Hepatitis B and C

Hepatitis B and C affect 2-3% of the world population (Koskinas J, 2014), with its prevalence ranging from very low to high across different countries. The true prevalence of viral hepatitis is elusive, particularly as chronic hepatitis remains asymptomatic in its early stages for what can be a very long time (Koskinas J, 2014).

Differences in the definition of the disease, in surveillance systems,

publication bias related to available published data and lack of analysis of high-risk populations also affect our understanding of the true extent of the disease. Nevertheless, data agree that there is an increase in the global

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prevalence of HCV seroprevalence, with more new cases, in which the main route of transmission is Intravenous Drug Use (IDU). The global burden of HBV has also increased, despite the decreasing trend of HBsAg prevalence, whereas the impact of vaccination on seroprevalence is shown to be impressive especially in younger ages (Degertekin, B, 2014).

The health, economic and social burden of viral hepatitis is growing: in the near future, an increase of 50% in total prevalence of liver cirrhosis and an increase of 100% in decompensated liver cirrhosis and transplantations is estimated (Koskinas J, 2014), whereas today at least 50% of patients with chronic hepatitis are unaware of their condition (Degertekin, B, 2014). This increase in the health burden of hepatitis B and C is expected to further affect the economic burden placed on health care systems to manage the disease and its sequelae.

On the other hand, wide access to universal vaccination coverage for HBV combined with improved blood safety policies and extended availability of harm reduction services for People Who Inject Drugs (PWIDs) has impacted positively on overall disease prevalence. This, in combination with the increased availability of effective, safe and welltolerated treatments, is creating a positive environment for the "turn of the tide" in the management of viral hepatitis.

Still, health care systems and policy makers are called upon to face persisting challenges that are disallowing the positive impact of prevention, screening and care to be reflected on actual disease burden data. Such challenges refer to:

• Migration, as one of the consistent routes of moving people and the disease.

Migration across Europe and the world is taking on new proportions. It has become part of the social evolution and "is here to stay" (Carballo M, 2014). Currently, 1/3 of the population in the world is a migrant, whereas over 70 million migrants are living in Europe. If migrants were added together, their total population would equal that of the 5th largest country in the world (Carballo M, 2014). Apart from this growing number of migrants, a growing number of tourists, students, women and children trafficked into or through Europe each year, as well as soldiers participating in peace keeping operations move between countries with high prevalence, either at origin or destination. Access to and use of care services may be deficient for such populations, thus resulting in higher prevalence of both HBV and HCV amongst non-nationals than nationals. For instance, in Germany, only 13% of the population are migrants, yet they account for over 42% of HBV prevalence (Carballo M, 2014). As migrants largely fall outside the scope of health care services (many are undocumented or do not have medical insurance) or are affected by legal, cultural, language and political barriers in accessing screening and care services, the burden they pose on public health is growing graver.

The sheer magnitude of migration facts and figures explains why most of the countries across Europe are choosing to not prioritize migration-related health policies, both because they were caught by surprise and misunderstood the extent of the challenge or because they fear it is too costly to address. Still, the challenge persists and requires urgent action.

• Intravenous Drug Use and vulnerable groups, amongst which HBV and HCV prevalence is persistently high.

Over 65% of PWIDs are also affected by HCV – in absolute numbers, there are currently over 10 million IDU /HCV people in the world (Goulis I, 2014). It is also accepted that IDU is the most common route of HCV transmission. This is a population in dire need of linkage to care - not only for their addiction but also and most critically for their co-morbidities. It has been estimated that providing treatment to 80 out of 1000 PWIDs results in an over 90% reduction in HCV prevalence in the years to come (Goulis I, 2014). Yet, only 30% of PWIDs are offered HCV testing and only 12% are monitored for their condition - approximately 1% or less are in treatment for hepatitis C (Schatz E. 2014). Such low detection and treatment uptake rates are influenced by public perceptions about PWIDs as well as severe shortcomings in their linkage to care, also related to stigma and discrimination and unstable housing arrangements (Schatz E, 2014).

The same applies to other vulnerable groups and especially people in detention and jails. It is estimated that 3/4 of the total jail population are infected with HBV or HCV - with very limited access to diagnosis and treatment services. This lack of interventions in prisons, where injecting does take place, is undermining the investment in care in the community setting due to the circulation of population (Pirona A, 2014). Addressing the pressing care needs of these vulnerable groups, linking them to care and keeping them in treatment would measurably and positively impact on overall hepatitis B and C prevalence (Pirona A, 2014).

Lack of data analyses on these specific population groups, limited data comparability and validity and challenges related to methodology consistency across populations and studies undermine the political argument that needs to be urgently made on behalf of these population groups (Carballo M, 2014). Moreover, as they have a very weak voice in society, and are heavily under-represented in political discussions, they fail to raise support and advocacy from the general public and are the first to be targeted by cuts in services amidst budgetary constraints.

• Prevention, blood safety and access to screening services, as essential means to control further transmission of the disease.

Increasing the coverage of universal HBV vaccination across European countries, and particularly in the north of Europe, is a persistent challenge for the primary prevention of HBV, which has been shown to be the most effective measure in reducing the burden of HBV globally (Papaevangelou V, 2014). In recurrent resolutions, the WHO and the WHA stress the need for universal vaccination of all infants as soon as possible after birth, followed by a primary vaccination series, that are critical in preventing infection in infancy and are positively correlated to preventing chronic infection. Across Europe, in countries where universal vaccination is adopted, infant vaccination is high and its impact measurable in an over 92% reduction in incidence of HBV in Italy and decreases in incidence amongst adolescents in Bulgaria.

Still, high levels of immigration and lack of uniformity in vaccination policies may Continued

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affect the containment of the spread of HBV. Austerity measures imposed on health care systems across Europe have resulted in decreased access to health care services, particularly amongst children and immigrants. The new dynamics of transmission of viral hepatitis indicate that transmission cannot be confined to immigrant communities (Papaevangelou V. 2014). To this end, strengthening screening and ensuring cost-effective preventive services are provided to high-risk groups remains very much a challenge for health systems to adequately and effectively address.

Safe blood donations are an equally critical component of HBV and HCV transmission prevention. Safety of blood supply appears to be positively correlated to the economic conditions of a country. In resourcerich countries, blood supply is safe whereas in resource-poor countries it is not. In developing countries, the situation is worse. WHO data indicate that 47% of blood donations are not properly tested, over 39 countries still do not routinely check all blood donations and over 40 countries collect less than 25% of blood supplies from unpaid donors (Prati D, 2014). Additional blood tests for HBV and HCV, including Nucleid Acid Testing (NAT) are performed in resource-richer countries and contribute to improved diagnosis of HBV and HCV. Yet, recent cost-effectiveness data on NAT may indicate that the incremental benefit of NAT may be minimal, due to its high costs per Life Year Gained (LYG) (Prati D, 2014). This may be impacting on NAT wide availability, especially in resource-poorer settings, despite it constituting an important element of appropriate disease diagnosis to the benefit of critical patient groups, such as thalassemia patients.

• Access and linkage to care for people diagnosed with hepatitis B and C, so that they can effectively manage their condition.

Getting a hepatitis diagnosis is already a hard feat. A small percentage of people infected with hepatitis B and C is offered screening to diagnose the condition. Of them, even less will accept screening and get diagnosed with viral hepatitis. Of them, even fewer will be linked to care or further enrolled to treatment through to the attainment of a Sustained Viral Response (SVR) (Papatheodoridis G, 2014).

Persisting barriers to linkage to care for people diagnosed with hepatitis B and C infection are either patient-driven, such as the limited awareness of their condition as well as cultural communication barriers, such as language, beliefs and the fear of discrimination and stigma, or health care provider-driven, related to lack of training in recognizing the condition, diagnosing and referring to, or offering treatment, particularly on the basis of common guidelines and recommendations. Lack of insurance coverage and limited understanding of pathways to care through health care system bureaucracies and processes may further hinder linkage to care for people infected with hepatitis B and C (Papatheodoridis G, 2014).

Nonetheless, the cost effectiveness of both screening for and beyond high-risk groups and care provision, including treatment for hepatitis B and C, has been confirmed in various settings, ranging from resource-rich to resource-poorer countries – therefore, improving diagnosis and linkage to care continues to constitute an urgent priority and a persisting challenge for health care systems.

• Disease management frameworks, which include agreed upon minimum standards to control viral hepatitis, coordinated by, implemented with the support of, and measured against a national action plan on hepatitis.

In the context of wide EU health care systems variations, the need for standards that depict an agreed and measurable level of practice, below which service provision and system performance would be deemed unsatisfactory, is brought forward by "minorities": a minority of hepatitis B and C patients is diagnosed, a minority of them is in specialist care, a minority

receives treatment and a minority of PWIDs remains infection-free once their hepatitis C is cured (Goldberg D, 2014). Health care systems need to define specific, measurable standards on prevention, case finding, treatment, care and data monitoring and coordinate their implementation across multi-disciplinary teams (Goldberg D, 2014). These could be coordinated centrally by the European Centre for Disease Control (ECDC) and implemented and monitored locally by the EU Member States. The ECDC, under the direction of the EU Commission, could be called upon to support Member States with monitoring such standards, as integrated in a comprehensive hepatitis framework (Duffel E, 2014).

Basing such standards on best practice and guidance already available and incorporating their planning, implementation and monitoring in national hepatitis action plans remains a challenge for most health care systems in Europe.

 Lack of advocacy and activism that could help raise the level of noise related to viral hepatitis. Recalling lessons learned from the HIV/AIDS case and the immense impact of activism across the world on improving treatment conditions, increasing access to treatment and making treatment affordable as well as effective and safe, further highlights the dire need for patient and civil advocacy on viral hepatitis. Even though activism in viral hepatitis is beginning to grow around guaranteeing access to newer, safer, more effective treatments that materialize the promise of the cure, global ambassadors and wider support movements are largely lacking.

This lack of large scale activism and advocacy impacts not only on the level of political pressure exerted on policy makers to address viral hepatitis as a policy priority but also on the global health financing of projects to effectively manage it.

Emerging challenges in managing hepatitis B and C

In addition to these persisting challenges, policy makers are called upon to deal with emerging challenges that are related to:

Treating hepatitis B and C: from treatment efficacy in individuals to treatment effectiveness in populations.

Clinical studies confirm that treatments for hepatitis B and recently and increasingly for hepatitis C are efficacious, safe and well tolerated at the individual patient level. They offer over 90% treatment in the case of hepatitis B (Cornberg M, 2014) and over 90% cure in the case of hepatitis C, both in Sustained Viral Response (SVR) terms (Flisiak R, 2014). Treatments are also shown to be able to revert the progress of cirrhosis and prevent HCC (Bernardi M, 2014). Yet, can this treatment efficacy be maintained as treatment effectiveness in larger populations, in the community, thus measurably impacting on the overall prevalence, particularly of hepatitis C, and contributing to an eradication strategy?

Studies from the US indicate that despite very high treatment efficacy rates of 40-80% in chronic hepatitis B and 60-90% in chronic hepatitis C, effectiveness rates are much lower, ranging at a mere 3.5% for chronic hepatitis B and 4-5% for chronic hepatitis C (Papatheodoridis G, 2014)

Very recently, RAND UK estimated that HCV prevalence will continue to grow and care coverage must increase 4 fold – by quadrupling HCV treatment, models predict that HCV prevalence could be measurably decreased at a net benefit, health, social and economic (Wilson D, 2014). For this to be achieved, health care systems need to be ready and able to invest in treating hepatitis C. At a cost.

It is clear that clinical success in fighting hepatitis B and C is largely dependent on early diagnosis and easy and consistent access to treatment (Carballo M, 2014). It is also clear that for this to be achieved a substantial, evidence-based and future cost-saving investment is required now.

It would appear that policy makers and policy advisors across the world are standing on the threshold of an immense choice, as experience confirms that systems are standing today with hepatitis C where they were standing with HIV/ AIDS back in the 1990s (Wilson D, 2014). Their dilemma is not whether they should be providing such "miracle care" (Wilson D, 2014) but rather to whom they should be providing it, as public spending cuts do not allow global coverage of all those in need.

The challenge is thus to develop a case, structure evidence and support access to treatment for more patients in need, not just end-stage cirrhotic patients (Papatheodoridis G, 2014), thus contributing to a decrease in the overall health and economic burden of hepatitis B and C (Cornberg M, 2014).

The financial engagement of stakeholders in addressing communicable diseases as a whole and viral hepatitis in particular and the sustainability of health care systems in circumstances of economic crisis.

The persisting economic crisis has impacted on public spending and more specifically on public health spending, thus posing challenges for the sustainability of health care systems as a whole. Health care systems' sustainability was already severely affected by the ageing of the population, the scale up of non-communicable diseases and the rise in the prevalence of communicable diseases, together with the increased availability of innovative medical and diagnostic technologies. The increase in funding that is required to meet such growing and diversified needs cannot be met by current funding mechanisms – much less in circumstances of economic crisis.

This economic crisis has interrupted years of economic growth in Europe (Wilson D, 2014) and has had a negative impact on both health indicators as well as availability and accessibility to health services. Under-funding, budget cuts and resource constraints have created significant difficulty in meeting current demand for health care. In such circumstances, health care systems are severely challenged to meet emerging or new needs (Papanikolaou C, 2014).

When budgets are not sufficient to meet need, rationing of health care services and prioritization in resource allocation are commonly performed with the support of increasingly sophisticated decision making tools that range from risk sharing to social dividends (Kanavos P, 2014).

All such schemes aim to ensure that access to services and technologies will be guaranteed to those most in need, through complex, value based models. Increasingly, such models are requested to be developed and used to predict the cost and the benefit of health care interventions in public health and communicable diseases, with a view to rationalizing expenditure and ensuring optimal return on resources actually invested (Kanavos P, 2014).

The economic crisis and the cuts in global health funding it has resulted in, combined with austerity measures imposed on national health systems and budgets across all European countries and, critically, those most affected by viral hepatitis, has impacted gravely on the health promotion, primary and secondary prevention, diagnosis and treatment of communicable diseases, including hepatitis B and C.

This impact of the economic crisis on aggravating existing barriers in the prevention, diagnosis and treatment of viral hepatitis needs to be managed effectively, measured consistently and evaluated carefully as a matter of health priority.

Options for the future

To these persisting and emerging challenges, participants at the Athens High Level Meeting called upon health care systems and policy makers to develop urgent responses.

Such responses would need to include continuing actions to maintain high levels of primary prevention, e.g. through consistently high universal vaccination coverage and blood safety, increase ethical screening, targeted particularly at high-risk and vulnerable groups, improve diagnosis rates and strengthen linkage to care to provide equitable, evidencebased treatment to patients infected with hepatitis B and C.

Integrated approaches to care provision that cover the continuum of care from prevention to diagnosis through to linkage to care and treatment provision are a critical step in sustainable policy making in viral hepatitis – and one that can measurably improve system performance and outcomes. In the Netherlands, integrated care approaches for IDUs infected with HCV resulted in an increase in screening rates from 16% to 60% and in treatment rates from 30% to 60% (Robaeys G, 2014), thus improving the cost effectiveness ratios of targeted interventions and maintaining low rates of HCV reinfection post cure. Further, treatment uptake and retention in treatment in such integrated settings was shown to be influenced by peer support, even despite ongoing drug use and specialist nurse availability (Robaeys G, 2014).

Such an integration of care provision needs to be supported with the appropriate tools. Patient registries can provide solid, real life and real time data on the impact of health interventions on managing viral hepatitis and, thus, constitute the stepping stone for integrated, evidence-based policies on the basis of national action plans, implemented and measured against defined standards.

Addressing barriers in diagnosis, access and linkage to care and providing evidence- based treatment to people infected with hepatitis B and C in integrated care settings with the support of solid tools will impact positively on treatment rates and improve retention in treatment and, thus, treatment outcomes and cost effectiveness, also reflected in low reinfection rates. Such outcomes will contribute immensely to the social de-stigmatization of people infected with hepatitis B and C - they will also, most critically, impact on the political legitimization and the funding prioritization of viral hepatitis as a whole.

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