

Viral Hepatitis Prevention Board

A hepatitis-free future: how to make it feasible and affordable

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Objectives

- To review current health care systems and the implementation of a national or regional hepatitis plan
- to consider financial mechanisms for making treatment affordable in Europe
- to review the hepatitis control plans of different international organizations
- to examine where hepatitis fits in EU's projects and calls
- to look at the economic impact of hepatitis control
- to discuss the feasibility, cost and prerequisites for elimination of hepatitis
- to analyse the lessons learnt from other disease control and health programmes
- to investigate how decision-makers can be convinced to raise the priority of control of viral hepatitis in health care

Background

- The hepatitis C landscape is complex and changing rapidly
- Diverse epidemiology and responses
- The burden of disease is heavy and likely to increase, and many subjects are unaware of infection; liver transplants (much related to HCV) in Europe have increased substantially over 2 decades and increase is limited now by donor availability
- New drugs are a “technological breakthrough” offering public health gains – no medical reason to withhold therapy, only expense and limited resources (human and financial); cure can be achieved within 3 months, with little risk of resistance and no relapses
- A time of enthusiasm and opportunities, with a plethora of meetings, summits; a tide of publications, with guidelines and almost a dozen papers on cost effectiveness of therapies in 2015 already
- Much mathematical modelling has been done

Background - continued

- Countering these positive aspects are the continuing lack of solid data on prevalence and burden of disease, the fact that only a small minority of patients known that they are infected, the cost of and limited access to the new oral, interferon-free antiviral agents, austerity and shrinking budgets, barriers and restrictions to access, difficulties with marginalized subgroups, and the fact that a short regimen resulting in cure limits long-term returns for pharmaceutical companies
- Need (still) to increase visibility of viral hepatitis
- Lack of priority given to health at highest levels of European Commission
- Need to expand expertise into areas such as trade, industry, finance and tax

Stakeholders and activities

- Recent changes within ECDC have given greater prominence and backing to viral hepatitis work; ECDC has developed networks of experts and strong collaboration and partnerships, and aims to exploit its niche position within the epidemiological data through improved routine surveillance, supporting regional prevention and control initiatives, and generating evidence-based guidance and support to States
- Many other entities actively engaged, from WHO at headquarters and regional levels, the European Centre for Disease Prevention and Control, organizations such as EASL and ELPA to groups of parliamentarians
- At UN level, viral hepatitis has been included in the proposed health SDG; proposed principles of universal health coverage and equitable access could be helpful
- European Commission, Parliament – joint negotiations and procurement; but doubts about commitment at highest levels
- Global Fund for AIDS, Tuberculosis and Malaria – allowed funds to be used for treatment of hepatitis C in co-infections, but new guidelines of HIV treatment may put pressure on that opening

WHO

- WHO, in response to Member States' requests, is drafting a global health strategy based on a vision of elimination of viral hepatitis as a public health concern; it forms part of a suite of global strategies (on HIV, tuberculosis and malaria) for 2016-2030
- Taking a health systems approach to expanding treatment
- Achievements include inclusion in 2015 of six hepatitis C medicines/combinations were included in the WHO List of Essential Medicines
- Ambitious targets, especially “90, 90, 90”, but questions raised about feasibility
- Challenges include removing structural barriers in health systems, implementing universal immunization policies, verification of attainment of targets

WHO EURO

- WHO's European Regional Office is holding a consultation on regional targets in the context of the draft global strategy
- The Regional Office is supporting the development of national strategies (e.g. Turkey, Georgia, Albania and Lithuania in 2015), building national capacities, enhancing surveillance, improving information on disease burden and outcomes, prevention (including harm reduction), expanding screening and ensuring equitable access to treatment, and developing a regional plan on hepatitis B control as an adjunct to the European Vaccine Action Plan 2015-2020
- Strategic activities for hepatitis B prevention include mobilizing and sustaining political commitment, ensuring universal vaccination in all countries in the Region, preventing perinatal transmission and facilitating a network of partners

Experiences in different sets of European countries

- Reports from four high-income and four middle-income European countries were presented in parallel groups covering burden of disease, treatment of hepatitis C, status of national plans, health care system aspects, expectations of intergovernmental organizations and obstacles each country faced
- Debate about issue of negotiations on price of medicines, differential pricing, tailored pricing, the dangers of parallel trading and VHPB's contribution to transparency about prices of hepatitis B vaccine
- More general discussion of policy considerations regarding expensive medicines (not just against hepatitis C) and the need to seek efficiency gains and efficiency in their introduction and use
- Need to set priorities from the public health perspective and explore innovations or alternatives in financing models and strategies

Costs and prices

- All the new direct-acting antivirals are cost-effective, but not cost-saving, and cost-effective does not mean cheap – cost per QALY is near threshold of cost-effectiveness
- Cost-effectiveness is sensitive to cost of medicine, stage of fibrosis and age at initiation of treatment and sex, and may be lower in certain subpopulations and groups, such as subjects infected with genotype 1 and little or no clinical progression
- US data appear to support forecasts of mortality rising to a peak around 2030, and modelling indicates that treatment should lower but not eliminate mortality
- Some costs not considered in some models: e.g. monitoring and indirect costs such as those due to absenteeism and suboptimal performance at work while infected.
- New HCV treatments increase marginal returns
- At current prices treatment of all HCV-infected subjects is projected to add massive costs to overstretched medical care budgets, **but** prices are falling, and in the USA there has been no surge in demand for treatment despite better quality of treatments; no adverse financial consequences seen for private health insurance companies or Medicaid

Costs and prices (continued)

- Numerous discounts have been negotiated with pharmaceutical companies
- What is a “fair price”? Should all countries pay the same, lowest negotiable price or is differential pricing feasible and ethical?
- Need for a debate between the concepts of a “fair price” and “fair profits”
- Countries in Europe have substantial HC burdens and total health care costs are projected to increase; modelling studies of France and Romania (despite poor infrastructure for treatment in the latter) show decreased morbidity and mortality and economic value and demonstrate that optimal strategies may differ between countries
- Alternatives to existing pricing mechanisms and policies exist and are being proposed

Potential solutions

- Price competition and competitive tendering
- Negotiated contracts
- Bulk purchase at full price with payments spread over time
- Government intervention
- Identify segments of patients and tailor responses
- Use of medical registries to demonstrate effectiveness (e.g. for diabetes treatment in Italy)
- Set priorities for treatment (those who need treatment most, those who present with disease, base decision of patient's willingness to comply – e.g. PWIDs)
- Different models for payment – e.g. for performance, risk sharing and managed entry schemes

Potential solutions (continued)

- Alternative approach to pricing based on treatment volume, a block contract that takes into account real health care costs avoided through treatment, and an average price per volume
- Other financing proposals: tiered pricing, generic manufacture, product donation
- Proposed bond finance initiative (public-private partnership)
- Compulsory licensing (TRIPS flexibility)
- GAVI model with attention to middle-income countries
- PAHO Revolving Fund (enabling even middle-income countries in the Region of the Americas to obtain vaccines at the lowest price)
- More partnerships and multisectoral cooperation
- More technology transfer and local production

Issues

- Feasibility of action plans and attaining ambitious targets
- Visibility of viral hepatitis (programmes) – “most marginalized, easiest to ignore”
- WHO analysis showed multiple ways to deliver hepatitis care – no optimal model
- Screening: what policies to adopt if screening indicates early pathology of HCV disease? What message to such patients and how to communicate it? How to counter loss to follow-up, especially in marginalized populations?
- Need to identify asymptomatic cases; linking newly discovered positive subjects to care
- Attempts to protect budgets sometimes leads to paradoxical policy responses on reimbursement (USA) (e.g. denial of payment for patients who test positive for methadone)
- Patents, generic issues in European countries

Issues (continued)

- Existing structures resistant to new funding mechanisms and reluctant to see mandate creep
- Further advocacy with donors to existing structures to expand or change mandates
- Increased and sustained political commitment especially at times of economic austerity (advocacy and communication)
- Would taxpayers in the industrial world agree to transfer of funds to treating adults with hepatitis C in the same way as they did for vaccinating children in developing countries through GAVI?
- Balance and fairness – not only prices and profits, but economic impact of treatment versus economic pressures
- Outcome measures such as end-stage liver disease – key performance indicators
- Does restricting treatment to late-stage disease miss treatment as prevention?

Lessons learnt from HIV/AIDS

- The need for: a public health approach
- task shifting and decentralization,
- robust data, strong standardized surveillance,
- heightened awareness (from general public and politicians to health professionals) including good communication,
- reduction of stigmatization and discrimination,
- advocacy and activism,
- an action plan,
- consideration of treatment as prevention,
- delivery of treatment and care is as important as what is delivered
- simplification of regimen to a single pill,
- universal access

Next steps

- Generation of more accurate and reliable data on burden of disease
- Preparation of national plans where none exist, further pressure to ensure submitted plans are approved at health ministry level, and support for implementation of plans
- Prioritization
- Prepare to build on the health element of the draft UN post-2015 development agenda once it is adopted in September 2015 and plan for means of achieving the relevant (VH) targets
- VHPB to hold meeting with IFPMA on innovative financing approaches and prepare a project as well as a briefing note for decision makers
- VHPB and partners to prepare EU proposal

- Thank you for your attention