Viral Hepatitis Prevention Board

Identification and management of persons with chronic viral hepatitis in Europe

BUDAPEST, HUNGARY

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Objectives

- Review screening of chronic diseases
- Apply criteria to chronic hepatitis
- Report on health technology assessments of such programmes
- Weigh benefits against costs and potential harm of screening
- Define conditions for screening and its strengths and weaknesses and public health and social implications, including impact on individual

Background

- Modified Wilson and Jungner criteria still hold true but medical practice has changed, new trends are emerging and new considerations introduced
- No apparent change since 1982 in surveillance for HBV in risk groups – no new risk group has been identified and recommendations remain the same
- Recognition of changing patterns - epidemiology, knowledge of natural history, migration, treatment and clinical developments
- Awareness that current approaches to prevention and control of VH are not working or perhaps this means a lack of awareness that it works…
- Screening programmes in general: lessons have been learnt and some are being re-evaluated
- Costs of treatment resulting from screening have increased the pressure for prevention

Background

- Questions about value of allocation of health spending (e.g. USA)
- Growing use of health economics and modelling
- Numerous guidelines on viral hepatitis exist, but some are inconsistent (e.g. US Preventive Services Task Force and National Institutes of Health)
- Publication of US Institute of Medicine report on a national strategy for prevention and control of hepatitis B and C
- 2010 - "the year of hepatitis" with global policy decisions expected (World Health Assembly in May), including:
  - proposed designation of a World Hepatitis Day;
  - involvement of WHO's Regional Office for Europe in a major conference;
  - consolidation of role and work of the European Centre for Disease Prevention and Control;
  - several major conferences

Burden of disease

- "Silent" diseases - slow, burdensome and costly illnesses
  - HBV: 350 million chronically infected (most in the Asia-Pacific region), 600,000 deaths/year
  - HCV: 130-170 million chronically infected, more than 350,000 deaths/year
    - Together HBV and HCV cause more deaths in USA than HIV
  - HDV: plea not to overlook disease burden – 15-20 million infections world-wide and chronic infection leads to more severe liver disease
- Wide variations in prevalence within and between countries
- High proportions of people do not know that they are infected (65%-75% for HBV and HCV in USA)
- HIV coinfection a problem – disease progression and treatment

Burden of disease

- Weak baseline data:
  - Migrants: 10 million officially in EU (but may be 20 million); UK data suggest doubling of cases of HBV in the next five years; HCV also present
  - Gaps in knowledge about prevalence of: HBsAg in general populations, HBV in low-prevalence countries (possibly underestimated), HBV and HCV in blood donors, pregnant women, and high-risk groups
- Lack of information about national policies (WHO review under way) and effectiveness of policies
- Natural history is becoming clearer, although long-term outcome of asymptomatic hepatitis C virus infection is unknown (who progresses?)
- Long-term outcome of successful treatment of HCV (salvage therapy) is also unknown beyond 5-10 years

Surveillance

- Insufficient epidemiological data to base policy decisions on
- Collection of data at national and regional levels responds to different needs and requests (national, European (ECDC), and global (WHO))
- Lack of validation of data, use of ICD for coding, inconsistent case definitions, in some cases data are coded for reimbursement of costs
- Lack of coordination of surveillance
- Data from surveillance and screening used at three levels:
  - Political - to decide on public health policies and strategies
  - Clinical - for treatment and management
  - Individual - to identify patients who need treatment or who are at risk of infection and preventive interventions (and their families)

Screening

- Principles: need refinement according to circumstances - Wilson & Jungner criteria were intended to be revised
- Programmes must have the following: management, clinical services and laboratory testing
- Decision-making must be based on three aspects: that it be patient-centred, evidence-based and system-driven (in order to ensure practicality and enable the use of routine screening)
- Decision guide for population screening developed for greater transparency and potential revision
- Take advantage of testing already being done (e.g. on pregnant women)

Screening

- Perennial issues: need to consider added benefits; do benefits outweigh harms; what are the opportunity costs; where does a programme fit in the "screening continuum" between mass screening and clinical testing; meet needs and reflect perspectives of individuals, target populations and society in general; being transparent about choices
- Methods - who, how? For instance, migrants: what type to screen and when
- Follow up (e.g. migrants, prisoners): considerations include how to ensure compliance with treatment
- Review of effectiveness of screening showed, inter alia, it to be cost-effective for HCV in IDUs and migrants and for HBV in pregnant women
- Literature review of HCV screening and early treatment showed the potential for increasing life-expectancy
- Primary health-care providers in the USA met under auspices of the Hepatitis B Foundation to design a simple, clear algorithm (based on existing guidelines) for screening and initial evaluation and management of HBV-infected patients and referral for evaluation for treatment

Treatment

- A fluid field - with likely new developments imminent; analysis of data from trials needed to indicate efficacy
- Difficulty in doing trials once efficacious drugs are already licensed

HBV

- HBV: excellent drugs are now available; few if any new drugs or new approaches in development
- Continued reliance on PegIFN and nucleos(t)ide analogues; treatment improves quality of life and most patients respond to treatment
- Resistance an issue with most compounds - resistance develops most rapidly with the cheapest drug: policy issues; eliminate lamivudine as a first-line drug?
- Duration of treatment - for life? Policy and cost implications

Treatment

HCV

- In contrast to the case for HBV, some 30 compounds are in development – with the prospect of 2 being licensed by end of 2011
- 50% of patients are eligible for treatment and 50% will benefit from treatment, with *cure*
- We do have a solution that justifies screening

Treatment issues

- HIV community becoming increasingly involved through meetings on treatment of HBV and HIV infections, development of criteria for treatment of active chronic HB
- Barriers to treatment are related to issues of: access, affordability, eligibility, desire to be treated, completion of treatment (e.g. only 2% in Alaskan VA study)

Stakeholders

- Governments, intergovernmental organizations, bodies and nongovernmental organizations (e.g. the International Centre for Migration Health and Development) – what are their respective roles and state of cooperation?
- Associations: e.g. EASL (global), ELPA (European) - valuable forums, advocates and educators
- Medical and educational institutions (e.g. NICE, CDC, university partners), pharmaceutical industry
- Patients at individual level and their families and contacts

Country studies – common themes

- Denominators not known
- Recommendations vary from country to country but are mostly *not* followed: need for translation into good clinical practice
- Difficult access to screening and therapy is a barrier in many countries
- Need for better disease management by general practitioners and specialists, and for better networking and communication between hospitals, GPs and other relevant care providers
- Compliance with treatment and follow-up remain important issues
- Existing screening programmes should be reinforced and revisited
- Interventions and recommendations should be evaluated
- Screening for hepatitis B is cost-effective
- Interventions are not restricted to treatment:
  - Change behaviour to limit spread
  - Change behaviour related to alcohol consumption
  - Vaccination
- "Think through the numbers"

Issues

- Quality of data - for models as well as current practice
- HBV is not the same as HCV; HBV can be prevented but not cured – HCV can be cured
- Defining criteria for screening is a dynamic, iterative process, reflecting changing circumstances, practices and technological developments
- Alcohol use: major risk factor for death in HCV patients (Alaska)
- How to measure the effectiveness of recommendations
- Does early intervention give real benefits? Where is the evidence for its cost-effectiveness? More analyses should be done on early screening plus treatment

Issues

- Gaps in knowledge of general public, physicians, policy-makers (although several exceptions: European Parliament's written declaration; associations for patients; information and education - web sites, etc)
- Designing and managing screening programmes, including ethical and equity issues
- Outreach to risk groups - tailoring and targeting approaches
- High prevalence rates found in high-risk groups, in particular migrants, in "low-prevalence" countries
- Reluctance of migrants to access health services (ignorance, stigma, etc)
- Greater effort into secondary prevention of HBV and HCV could yield considerable health gains

Issues

- Reliance on selected sets for reviews (e.g. English language literature, scientific publications rather than government documents and other material, exclusion of studies)
- Call for innovative approaches, examples included use of dried blood spots
- Call for European countries that have not done so to draft an action plan
- Is there a value in setting goals in legislation?
- Resources, resources, resources (example of comparatively very small budget allocations for HBV and the costs of screening and testing)

Needs

- Need for greater understanding of decision-making processes at political levels (World Health Assembly, WHO regional offices, European Centre for Disease Prevention and Control, EU entities, national, etc)
- Quality of data need to be substantially improved
- Strong coordination of surveillance, collection and collation of data, and analysis - the need for leadership
- Define targets groups and populations; better risk analysis
- Design policies for special populations, in particular prisoners (including community programmes for continuity of treatment) and migrants
- Prepare for publication a summary of what has been done and that does not work
- Robust standardized screening methods, with ethical screening and treatment follow up

Needs

- Translate existing criteria into the clinical chronic hepatitis picture
- Further research in several areas, including long-term health economic impact of HCV screening and identification of optimal target groups and settings for cost-effective screening, burden of disease and mortality due to liver disease including HCC (especially through registries), effectiveness of screening programmes, laboratory quality control panels for HBV DNA testing, replacement of liver biopsy
- Link screening programmes into primary health care and other programmes
- Reduce the number of top-down decisions and mechanisms in favour of patient-based organizations and community-based programmes

Concluding remarks

- Urge standardization of data and use of a common electronic medium for collection of standardized data
- Prepare to build on the likely adoption (in May 2010) of World Health Assembly resolution on viral hepatitis and the steps it urges, including advocacy, awareness raising, promoting screening, strengthening national surveillance systems and enhancing access to treatment
- Extend concept of cost-effectiveness to a series of screening strategies that includes identification of patients who are good candidates for treatment
- As in HIV/AIDS, the high cost of existing drugs excludes millions of people from treatment; the VHPB urges lower prices for appropriate medicines and increased financial support for programme implementation

Concluding remarks

- The list of risk groups has not changed for nearly two decades
- Transition from a list of recommendations to a managed programme with an action plan that guarantees assignment of responsibility, setting of priorities, adequate funding, necessary medical resources, monitoring and evaluation
- There is no one-fits-all action plan – adapt any plan to local epidemiology, infrastructure and financial realities
- Define the purpose of screening – there are multiple benefits, but also many potential harms
  - identify infected subjects who can then enter treatment programmes and whose families may benefit from counselling and relevant prevention services (e.g. vaccination and healthy behaviour);
  - identify subjects who are not infected but are at risk and offer preventive interventions
- Do not start screening programmes until preparations for the steps to follow are in place - patient management, treatment, access, feasibility