

Viral Hepatitis Prevention Board

Burden and prevention of hepatitis in Bulgaria

**SOFIA, BULGARIA
24-25 March 2011**

Objectives

- Provide an overview of surveillance systems for infectious diseases
- Review the epidemiology of viral hepatitis
- Discuss progress in prevention 20 years after the introduction of universal vaccination against hepatitis B
- Review implementation of new prevention strategies, control measures and monitoring systems
- Discuss the successes, the way forward and possible obstacles

General observations and context

World Health Assembly resolution WHA63.18 asks WHO to draft a comprehensive strategy and endorses World Hepatitis Day – one of only six official WHO health “days”. Resolution legitimates governments to act

Bulgaria:

- Population (about 7.5 million), including 17% ethnic minorities, with Roma accounting for 0.25-1.0 million according to various estimates
- Overall improved socioeconomic conditions and ageing population
- Transformation of public health situation and numerous reforms
- Universal vaccination with HBV introduced 19 years ago, with consequent changing epidemiological patterns to low levels
- Involvement of civil society

Health-care system

- Reform of the health system since 1990
- Extensive public health legislative framework, including decriminalization of drug use and needle and syringe programmes and numerous Regulations and Decrees on public health matters
- Centralized policy-making and planning, but decentralized responsibilities for facilities and services
- Mixed public-private health sector
- Financing through mandatory health insurance and central and local budgets

Health-care system

- Adequate numbers and capacity of hospitals and supply of doctors but insufficient number of nurses and other medical staff; GPs are gatekeepers
- Services organized by Ministry of Health with national centres (e.g. on Public Health Protection and Infectious and Parasitic Diseases), public health directorates and 28 regional health inspectorates
- National Immunization Programme: Regulation 15/2005 for 11 diseases, with targeted and recommended vaccination for other diseases; Regulation 21 on reporting being amended but will retain viral hepatitis (only acute cases in the future)
- Centralized planning and procurement of vaccines

Epidemiology

- EU case definitions accepted and used and overall the surveillance system meets requirements of EU
- Defined institutional framework for surveillance information from peripheral level via regional health inspectorates to central level (NCIPD, NCHI and MoH); web portal for latter link and influenza information
- Periodic outbreaks of hepatitis A, with West-to-East and urban-rural gradients; most at risk 1-14 year-old cohort of susceptibles – Bulgaria becoming a country of intermediate endemicity with implications for future vaccination strategies
- A general picture of steady or declining seroprevalence rates of hepatitis B and C but increasing burden of disease due to HCV, although still low incidence rate ($<2/10^5$); results lead to questioning of categorization of Bulgarian prevalence rates internationally
- Major seroprevalence study of hepatitis B and C infection undertaken, giving broad national picture; issues regarding representativeness need consideration
- Cases of hepatitis D, and some “unspecified” viral hepatitis
- Acute HBV and HCV seen in risk groups in most regions, often related to failures of infection control and unsafe injections; haemodialysis, IDU and haemophiliacs

Epidemiology - immunization

- Universal immunization programme with hepatitis B vaccine introduced in August 1991: routine newborn immunization at 0, 1 and 6 m from 1992 – with 95% coverage, some 1.3 million children immunized – a considerable success
- Economic analysis (with direct medical costs) of the programme over 20 years showed that costs still exceed benefits in terms of avoided cases and treatment
- Conservative model-based economic assessment of universal vaccination programme showed positive benefit/cost ratio, with break-even after 19 years, i.e. from now onwards; results probably underestimate the benefits, but also conform with epidemiological data on impact of universal immunization at birth
- Discussion about prices of vaccines and the confidentiality of such data, with emphasis of the need for transparency (not just in Bulgaria)
- Changing epidemiology of hepatitis A raises issues about vaccination policy

Epidemiology

- Concern about vulnerable groups, especially Roma, with high morbidity and mortality and great poverty
- Size of Roma group uncertain and questions exist about data
- Access and social and cultural obstacles recognized, including ; lack of basic sanitation, health insurance, prevention activities and knowledge; bureaucracy; and low educational levels and knowledge
- PHARE projects have provided results and services (including education, screening and mobile units)
- Health mediator concept of coordinating figure between institutional levels, with defined strategic objectives, successfully introduced and applied with particular relevance for immunization of children by GPs – and not limited to viral hepatitis
- Continued activities (some described as the best in Europe for increasing vaccination) planned

Epidemiology

- Major outbreak of hepatitis A in Roma community in Plovdiv in 2006: >1000 cases, mostly in children aged 1-9 years, controlled with help of NGO; administration of HAV vaccine needs consideration to prevent future outbreaks – problem is broader than the health sector
- Successful application of molecular epidemiology – good model for adoption in Bulgaria
- Investigation of two geographically separated but contemporaneous outbreaks of hepatitis A in communities with high exposure to virus showed circulation of two closely related but distinct strains of genotype 1a
- Results mean that RNA fingerprinting needs careful re-evaluation
- Outbreaks resulted in high costs for improving sanitation and housing, but concerns exist about imminent potential recurrence of outbreaks

Epidemiology

Blood donor data

- Overall 1.57% (1.00-3.34%) were HBsAg positive and 0.23% (0.05-0.42%) HCV positive – higher than in neighbouring countries
- Relatively high carrier rate in repeat and regular donors – apparent failure in communication to donors and in counselling
- 90% donors are repeat donors
- Paying of some donors still practiced (4%)
- Higher rates in male than female donors, and in North-East and southern regions
- Quality system for blood establishments introduced to meet EU standards and national legislation
- Successful drives to increase donation by young people

Epidemiology

Injecting drug users

- An estimated 315-330 000 people (nearly 5% of the total population) use or have injected psychoactive drugs, predominantly heroin but increasingly amphetamines and methadone
- In Sofia, seroprevalence rates of HIV, HBsAg and syphilis lie in the range 3-6% but 61% of IDU are seropositive for HCV (rates comparable to neighbouring countries); HIV rates rising
- Uncertainty about validation of methods used for detecting hepatitis viruses – applicable in general
- Nearly 10% of IDUs are infected in first two years after starting injection, with implications for prevention
- Prevention is a government priority, backed by legislative mandates

Epidemiology

Haemodialysis patients

- Rate of HCV infection high (25%, similar to other southern European countries), exceeding that in general population
- Rate of HBV infection slightly higher than general population and very few vaccinated before dialysis
- One centre: 12 of 46 dialysis personnel positive for HCV and 34 for HBV infection – suggesting broader issues about infection control and practices
- Prevention needs application of universal precautions, periodic testing, vaccination against HBV, improved equipment and increased use of erythropoietin stimulating agents instead of haemotransfusion
- Need for validation of data for setting priorities, guiding policy and more transparency regarding epidemiological situation

Epidemiology and prevention

- Legislation enacted (2005-2010) to prevent nosocomial and health-care associated infections, and practices in line with European Directive
- Implications of new legislation (provision of vaccine and vaccination) not being reflected in the epidemiological data on HBV and HCV in HCWs
- An estimated 30,000 HCWs are susceptible to infection with hepatitis viruses
- Vaccination coverage rates of HCWs vary significantly and depend on presence of infection control nurse and committed leadership; for medical personnel in military academy, screening followed by vaccination if necessary ethically and economically justified
- Patient safety a priority issue in health policies, with need for development of safe systems, processes and tools; regular update of standards and best practices; and improved self-practice
- Issues relate to protecting existing, susceptible health-care workers (continuing education and aggressive promotion of infection control) and to future health care workers, medical students, nurses, vaccination and seropositivity – including treatment and options for low-risk employment

Needs and issues

- Resources ...
- Consideration of the immunization calendar as new and combined vaccines become available
- Innovate routine immunization programmes in order to reach vulnerable populations (e.g. of Roma children and measles outbreak)
- Increased efforts to expand vaccine coverage to hard-to-reach groups, including new mechanisms for reimbursement of vaccines against diseases of high public health importance
- Documentation and validation of data on overall vaccination coverage
- Data for blood donors are not necessarily representative of the general population
- Need for leadership in medical institutions to educate about infection control and immunize future HCWs

Clinical aspects

- Retrospective anamnestic data on acute HBV transmission indicate a substantial percentage due to sexual transmission (44%) and 17% due to stomatological, gynecological or other interventions. For acute hepatitis C transmission, injecting drug use was recognized as risk factor in 59%, surgical intervention in 14%, and blood transfusion in 8%.
- The amount of HBV DNA is clearly related to the severity of acute hepatitis B infection. A small study showed that the main HBV genotype is D. No association was found between HBV DNA levels and genotypes.
- High sustained response was seen after combined therapy for chronic hepatitis C, as a consequence of an effective patient selection.
- Cyclic therapy for chronic hepatitis B patients (experimental scheme in Bulgaria) achieved better sustained response than 12 month therapy. Duration of therapy and number of therapy cycles are still subject of further study.
- Data showed that the universal hepatitis B neonatal/infant immunization programme reduces significantly the direct medical costs.

Needs and issues

- Although a wealth of data exists, more analysis is needed with application of conclusions in policy-making
- European-wide dialogue with industry and transparency about prices and policies – a global matter, with national experiences that range from complete openness to confidentiality; transparency would benefit many countries, not just Bulgaria. VHPB has experience of publishing costs. All contracts with State funding are published on government web site – would seem to need better communication.
- Costs of treatment as well as socioeconomic costs of viral hepatitis needed

Possible future steps and recommendations

- Prioritization of public health tasks
- Evaluation of reforms
- Education about standard precautions should start during training at universities and nursing schools
- Need for strict application of standard precautions with continuous monitoring
- Statement that legislation on blood safety control needed to be revised for viral hepatitis, in particular with regard to responsibilities for counselling infected blood donors
- Clear guidance is needed for health education and medical institutions regarding vaccination and immunization of medical and nursing students and health-care workers in general and possible restrictions of work practices (exposure-prone procedures); special legal framework or regulation recommended for establishing registers of immune status; leadership and mandate needed for IC team
- Viral hepatitis in HCWs, IDUs and ethnic minorities needs addressing; low rate of HCV infection in IDUs in first two years after starting drug use an opportunity for prevention
- Bulgaria's health mediator model provides a valuable example for accessing hard-to-reach populations; although 105 already trained and qualified, an estimated 4000 would be needed to reach vulnerable groups adequately
- Innovative approaches are needed to bring routine immunization programmes closer to vulnerable populations

Possible future steps and recommendations

- Consideration of web-based reporting systems - a future objective (function of training and staff)
- Repeat age-specific seroprevalence study but with expanded aims and examine impact of HBV immunization and opportunities for prevention of HAV, HBV and HCV
- Data: need for quality control for generating data; close analysis, including determination of possible under-estimation, and application of results, and need for auditing of the quality of data in order to support evidence-based decision-making, greater transparency
- Consideration should be given to use of hepatitis A vaccine as epidemiological pattern changes
- Clear protocols for laboratory testing in acute viral hepatitis surveillance
- Enhanced surveillance of hepatitis E infection

Recommendations - continued

- VHPB is ready and willing to provide support to health authorities/bodies in formulating proposals for policies on surveillance, protection against and prevention of viral hepatitis
- Bulgaria is making significant progress in reaching the hard-to-reach populations; supplementary immunization activities could be consolidated into more permanent routine activities. Such action would enable Bulgaria to become a role model in Europe.