Burden and prevention of hepatitis in Bulgaria

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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
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
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
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
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.