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Burden and prevention of viral hepatitis in Bulgaria

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ABSTRACT

A meeting of the Viral Hepatitis Prevention Board in Sofia, Bulgaria on 24–25 March 2011 reviewed the burden and prevention of viral hepatitis in the country. It examined the organization and funding of the health system, the surveillance systems for infectious diseases, and the epidemiology of viral hepatitis, especially the impact of the universal neonatal hepatitis B immunization programme introduced almost 20 years ago. It also looked at the implementation of new prevention strategies, such as the health mediator concept, as well as control measures and monitoring systems. Participants discussed the successes, the way forward and possible obstacles.

1. Introduction

The Viral Hepatitis Prevention Board organized a meeting on the burden and prevention of viral hepatitis in Bulgaria[1] with the following objectives: to provide an overview of surveillance systems for infectious diseases; review the epidemiology of viral hepatitis; and discuss progress in prevention some 20 years after the introduction of universal vaccination against hepatitis B. It also aimed to review implementation of new prevention strategies, control measures and monitoring systems, and discuss the successes, the way forward and possible obstacles.

2. Bulgaria

Bulgaria has a population of about 7.5 million, of whom some 17% are ethnic minorities, with Roma accounting for between 250,000 and one million people, according to different estimates [1–4]. More than 70% of people live in urban areas. The population as a whole is ageing and shrinking. Socioeconomic conditions overall have improved, although the gross domestic product in 2009 was still less than half the European Union average, and the Roma population is generally afflicted by poverty, unemployment and social exclusion. About 4% of the national budget is devoted to health-care expenditure. Civil society has emerged as a recognized actor on all stages in the country. The public health situation has been transformed and universal vaccination of newborns with hepatitis B vaccine was introduced in August 1991, nearly 20 years ago, with consequent striking changes in epidemiological patterns to low levels of incidence of acute viral hepatitis.

3. Health-care system

The health system has undergone radical reform since 1990. An extensive public health legislative framework has been created, with the Health Act being adopted in 2005. Numerous regulations and decrees on public health matters, including surveillance guidelines, health insurance, occupational health, medical devices, and the decriminalization of drug use and harm-reduction programmes such as needle and syringe projects, have been enacted. Policy-making and planning are centralized in the Ministry of Health, but responsibilities for facilities and services are decentralized. The health sector operates as a private–public mixture.

The Ministry of Health exercises its policies and programmes through national centres, parallel public health directorates, and 28 regional health inspectorates. The Health Act 2005 covers surveillance and control of communicable diseases. The National Immunization Programme specifies vaccines and vaccination for 11 communicable diseases; it also details targeted and recommended vaccination for other diseases. The planning of vaccination programmes and the procurement of vaccines are done centrally.

Financing for the health sector derives from mandatory health insurance and central and local budgets, but nearly 13% of the population have no insurance rights because of unpaid contributions. Less than 2% of the population uses private health insurance. The supply of doctors is adequate for the country's needs but the number of nurses and other medical staff is insufficient. General practitioners act as the gatekeepers for referral within the health system to specialized outpatient and hospital care.

4. Epidemiology

The European Union's case definitions from 2002 [5] have been accepted and are used, and overall the surveillance system meets the requirements of EU directives. Data are broken down by age and sex. A defined institutional framework exists for the exchange of surveillance information from peripheral level via regional health inspectorates to the highest level (the national centres on Infectious and Parasitic Diseases and Health Informatics and the Ministry of Health). The link to the highest level uses a web portal and the whole framework is linked to the data-collecting systems of the European Surveillance System and WHO. The National Centre on Infectious and Parasitic Diseases has a web site for influenza

[1] The slides of the presentations are available on the VHPB web site www.vhpb.org in the web page "Meetings and publications".

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Table 1
Seroprevalence of markers of hepatitis B and C virus infection in different risk groups in Bulgaria.

Risk groups	HBsAg+ (%)	Anti-HCV+ (%)
Blood donors		
Bulgaria	2.72%	[Data not presented]
Sofia	1.57%	0.23%
Injecting drug users		
Sofia	5.85%	61.1%
Haemodialysis patients		
Bulgaria	9.1%	25.2%
Health-care workers		
In Bulgarian acute-care hospitals	5%	0%
In Bulgarian hospitals	1.5%	0.4%

Table 2
Seroprevalence of markers of hepatitis B and C virus infection in the general Bulgarian population.

	HBsAg+ (%)	Anti-HCV+ (%)
Seroepidemiology study (1999–2000)		
Bulgaria	3.87%	1.28%
Sofia	1.96%	1.58%
Plovdiv	4.19%	1.13%
Seroepidemiology study (1999–2000)		
Plovdiv	4.80%	0.9%

information (which includes weekly incidence data) and for measles, mumps and rubella, but otherwise transfer of information is done on paper forms or sent by e-mail.

Most acute cases of viral hepatitis are due to hepatitis A, with a steadily falling annual incidence rate over the past 20 years, as seen in other countries in transition [6]. As expected, periodic outbreaks of hepatitis A have been experienced (with recently a particularly serious one in Plovdiv in 2006, in part due to flooding – see below), and anti-HAV seroprevalence rates (national average 68% [7]) show West-to-East and urban–rural gradients. Most of those people at risk are susceptible children aged 1–14 years, with outbreaks in schools, orphanages and institutions. Bulgaria becoming a country of intermediate endemicity for hepatitis A, a status that carries implications for future vaccination strategies [6].

A general picture emerges of steady or declining seroprevalence rates of hepatitis B and C (see Table 1). The data indicate an intermediate endemicity for hepatitis B (2–7% HBsAg carrier rate); an unpublished study in 2010 of unvaccinated people in the Plovdiv region showed a seroprevalence rate of less than 5%, but with a significantly higher rate (7.4%) in people from the ethnic minorities than in Bulgarians (3.8%); contact with an infected member of the family was a significant risk factor. There appears to be an increasing burden of disease due to hepatitis C, even though the latter's incidence rate remains low (58 acute cases in 2010, $<2/10^5$ population) and the seroprevalence rate fell over the past decade in the Plovdiv region. Acute cases of hepatitis B and C are seen in risk groups in most regions of the country, often related to failures of infection control, unsafe injections, haemodialysis [8], and injecting drug use, although in about 70% of acute cases of hepatitis C the route of transmission was unknown.

A major seroprevalence study of hepatitis B and C infection was undertaken in 1999–2000, covering the biggest cities in Bulgaria (see Table 2). Altogether 12,456 people aged from 14 to 59 years of age were serologically tested. The data showed national figures of 3.87% for the HBsAg carrier rate and 1.28% for anti-HCV seropositivity [9], although high rates of anti-HCV seroprevalence have been found in haemophiliacs, injecting drug users and haemodialysis patients.

The seroprevalence data have prompted several calls for the recategorization of Bulgaria by major organizations internationally as being of low rather than high or intermediate endemicity for hepatitis C [10,11]. Nevertheless, questions about the representativeness of the data need answers.

A small number of cases of hepatitis D (five notified in 2010), and about 200 cases in 2010 of "unspecified" viral hepatitis, are reported.

Uncertainty was expressed about the methods used for detecting hepatitis viruses. Validation of such methods is applicable in general.

5. Immunization programmes

The universal immunization programme with hepatitis B vaccine was introduced in August 1991, with full routine newborn vaccination at 0, 1 and 6 months from 1992; Bulgaria was one of the first countries in Europe to do so; Italy being the first to introduce universal infant and adolescent immunization in 1991. The reported annual incidence of hepatitis B declined steadily after the introduction of the vaccine. Whereas in the mid-1980s the annual incidence rate was 35/100,000 (about 2750 acute cases a year), the rate subsequently fell to 5/100,000 in 2010. Among the 0–1 year age group the incidence rate per 100,000 fell from 8.0 in 1992 to zero in 2010, with respective figures for the 1–3 year age group of 23.8 and 1.4 and for the 15–19-year-olds 58.7 and 8.4. With a reported coverage of 95%, some 1.3 million children (about 17% of the population) have been immunized – a considerable success (see Fig. 1). Work on economic analysis of the impact of introducing the vaccine is in its early days.

The epidemiology of hepatitis A is changing, with an increasingly large population of susceptible, un-immunized people and specific issues relating to the Roma population (especially given recent outbreaks) and little evidence of reduced risk. Discussions are continuing about the policy of vaccinating target populations against hepatitis A.

The question of the prices of vaccines and the confidentiality of such data prompted some discussion, with emphasis on the need for transparency, a feature that it was agreed was important for all countries. It appears that in Bulgaria the information about the price in the Government's tenders is available on a governmental web site.

6. Vulnerable populations and hard-to-reach groups

These populations, especially Roma, continue to cause public health concerns, with high prevalence rates of infectious diseases, high morbidity and mortality rates, grinding poverty and numerous other obstacles to integration into society and access to health services.

6.1. Roma

The exact size of the Roma group is uncertain (see above) and questions exist about data: for instance, do national data accurately cover the Roma population, how reliable are figures for a group of such undefined size, how good is reporting? Difficulties in access as well as social, cultural and bureaucratic obstacles to care and other health services are recognized. Often basic sanitation, prevention activities and health insurance (unemployment rates of well over 50% in some regions were quoted) are lacking, and educational levels and knowledge are low.

From 2003 on several PHARE projects have focused on Roma populations, education and health, and have delivered good results and services (including provision of screening and mobile units). Work in Bulgaria was cited as a best practice at a European Union ministerial meeting on childhood immunization (Budapest, Hungary, 3–4 March 2011), which focused on the impact of

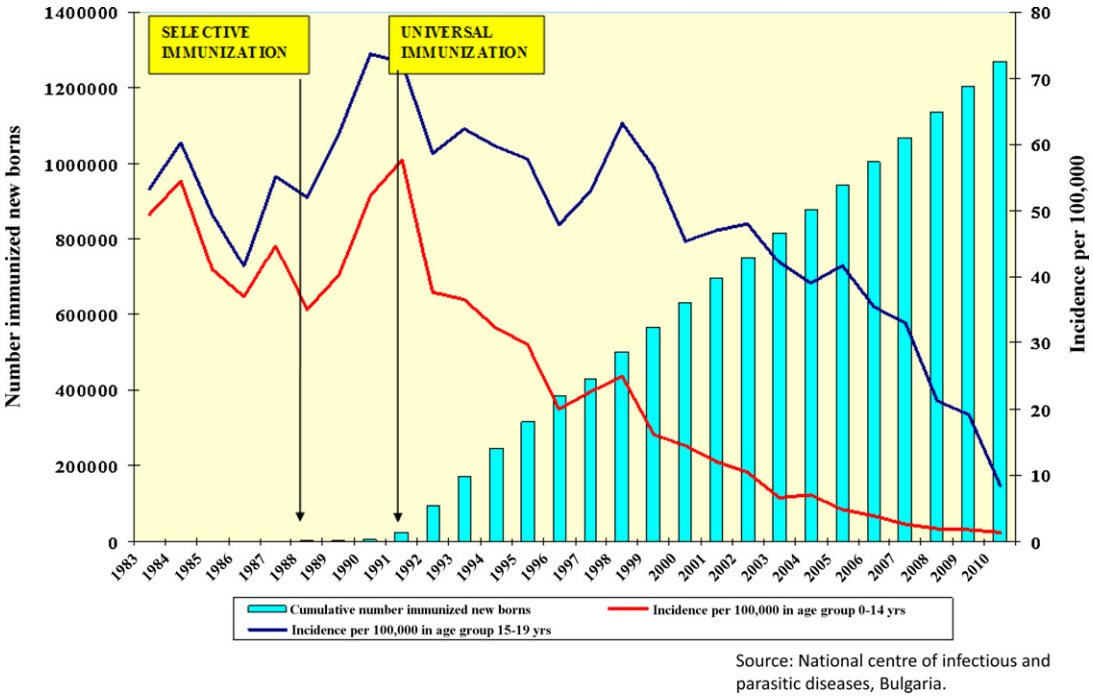

Fig. 1. Cumulative number of immunized newborns with HBV vaccine and hepatitis B incidence (per 100,000) in children 0-14 and 15-19 years of age in Bulgaria, 1983-2010.

childhood immunization across European Union, as well as improving collaboration with the Union on childhood vaccination strategies, especially to reach under-vaccinated populations [12]. The health mediator concept of a coordinating figure between institutional levels, with defined strategic objectives, has been successfully introduced [13] and applied with particular relevance to the immunization of children by general practitioners – and their work has not been limited to viral hepatitis. Continued activities are planned.

A major outbreak of hepatitis A occurred in a Roma community in Plovdiv in 2006 [14], with more than 1000 cases, mostly in children aged 1–9 years. The health services, working with the municipal authorities and civil society, including the Church and a nongovernmental organization, controlled the outbreak using measures that included vaccination and improved housing and sanitation – at considerable cost to the municipality. Five years later the situation causes alarm, as the risk of future outbreaks has returned. Given that risk, administration of hepatitis A vaccine needs serious consideration. Furthermore, a multisectoral approach is needed, as the problem is broader than the health sector alone, including language, education and employment.

One report described the successful application of molecular epidemiology, and the technology could well be adopted in Bulgaria. An investigation of two geographically separated but contemporaneous outbreaks of hepatitis A in communities in the country with high exposure to the virus showed circulation of two closely related but distinct strains of genotype 1a. As in Plovdiv, controlling the outbreaks resulted in high costs for improving sanitation and housing.

7. Other groups

For blood donors rates for HBsAg positivity (see Table 1) and anti-HCV positivity were higher than in neighbouring countries. Relatively high carrier rates were detected in repeat and regular donors (90% of donors are repeat donors), and one reason advanced was failure in communication with donors and in their counselling. Higher rates were found in male donors than in female donors, and in North-East and southern regions compared with other parts of the country. Some donors (4%) are still paid. Successful campaigns have been carried out to increase blood donation by young people. A quality-control system for blood establishments has been introduced in order to meet EU standards and national legislation.

In 1996, the Government abruptly stopped domestic production of cryoprecipitates and other blood clotting factors for haemophiliacs and ordered all necessary supplies from outside the country. Despite the considerable cost, the result was a public health success: no single haemophiliac was infected with hepatitis B virus after that decision.

The number of users regularly injecting heroin is put at between 20,000 and 30,000, but increasingly users are injecting amphetamines and methadone. In Sofia, seroprevalence rates in 2009 of HIV, HBsAg and syphilis lay in the range 3–6% but 61% of injecting drug users are seropositive for hepatitis C virus infection (rates comparable to neighbouring countries). HIV incidence rates are rising. The proportion of injecting drug users who share equipment appeared to decline over the past decade. Nearly 9% of injecting drug users are reported to be infected in first two years after starting injection, with implications for prevention; although there were divergent views, this seemed to be a slow rate of infection compared with other countries and would allow preventive activities to be introduced [15]. Prevention is a government priority, and is backed by legislative mandates. Treatment of HCV-infected drug users is funded by the National Health Insurance Fund whereas that of drug users with hepatitis is available free only to those who have health insurance and who are currently not on substitution treatment with methadone.

Rates of infection of haemodialysis patients with hepatitis C virus are high, with figures comparable to those in other southern European countries, and exceeding that in general population, while those for hepatitis B virus infection (9%) are only slightly higher than general population. Very few patients are vaccinated against hepatitis B before dialysis. One dialysis centre reported finding high rates of infection in its personnel: 12 of 46 were positive for HCV and 34 for HBV infection, suggesting broader issues about infection control and practices and the need for

further studies. Prevention needs application of universal precautions, periodic testing, vaccination against HBV, improved equipment, and increased use of erythropoietin-stimulating agents, latter helps to avoid the need for haemotransfusion.

8. Occupational health

Regulation 4 of 2002 on the protection against occupational exposure to biological agents stipulates the employers should provide vaccine and vaccination to employees who have occupational risk of exposure free of charge. Legislation enacted since 2005 also covers the prevention of nosocomial and other health-care associated infections. It would seem, however, from both the epidemiological data on HBV and HCV in health-care workers and the results of surveys that show high proportions of staff who are not vaccinated (44%) or who are susceptible (36%) [16], that this provision of the law is not being as rigorously practiced as it should be. The number of health-care workers who are not vaccinated against hepatitis B is estimated at 36,500 and those susceptible to infection with hepatitis viruses at about 30,000. Vaccination coverage rates of health-care workers vary significantly and depend strongly on the presence of an infection control nurse and committed leadership in the institution. Measures to improve the situation include, education, aggressive campaigns featuring "champions" and successful approaches, and enhance infection control programmes. For medical personnel in the national military academy, a policy of screening followed by vaccination, if necessary, was found to be ethically and economically justified.

Patient safety is a priority issue in health policies, with need for the development of safe systems, processes and tools; regular update of standards and best practices; and improved self-practice. Issues identified relate to protecting existing, susceptible health-care workers (in particular through continuing education and aggressive promotion of infection control) and future health-care workers (e.g. medical students and trainee nurses) through vaccination and education during their training. Other issues raised included treatment of exposed workers and options for low-risk employment of susceptible or exposed workers.

9. Needs, issues and observations

It almost went without saying that resources remained a major preoccupation, but in the current financial crisis funding was even more problematic. Discussions are focusing on potential mechanisms to reimburse some recommended vaccines of high public health importance (such as those against influenza).

Innovative ways need to be found to extend the coverage of routine immunization programmes in order to reach vulnerable populations (e.g. Roma children, among whom tuberculosis is rife, and in response to the recent measles outbreak).

Although good overall vaccination coverage rates are reported (95% for hepatitis B vaccine), the questions raised about the documentation and validation of those data needed answers in order to provide a sounder base for setting priorities, guiding policy and ensuring more transparency about the epidemiological situation. Similarly, it was recognized that the seroprevalence data for blood donors were not necessarily representative of the general population, and care was needed to allow for that in determining the nationwide epidemiological situation. Bulgaria was to be congratulated on the wealth of data that exists, but more analysis and interpretation are needed, with greater application of the conclusions in policy-making.

The vulnerability to infection of numerous health-care staff, as well as the lack of protection of many medical and nursing students, underlines the need for full implementation of national legislation on protection of the work force. Necessary measures include leadership in medical institutions to educate about infection control and immunization of future health-care workers, strengthening the infection-control teams, and capitalizing on the role and experience of "champions".

Comments in discussion were made about the potential value European-wide dialogue between the governmental health sector and industry and the benefits from transparency about prices and policies. This approach was relevant globally, and national experiences range from complete openness to confidentiality. The Viral Hepatitis Prevention Board has experience of eliciting information about costs paid for vaccines and published such information in the report of a meeting in 2001 on introducing hepatitis B vaccine in central and eastern Europe (St Petersburg, Russian Federation, 24–27 June 2001) [17]. There were calls for all vaccine-related contracts that were paid for with State funding to be published on the government's web site, although in response the Government indicated that the information was available. There would seem to be a need for better communication of that information, which also valid for other countries in the Region. Better data on the costs of treatment as well as socioeconomic costs of viral hepatitis are needed.

Finally it was observed that the information and reports presented combined to make a compelling story of remarkable progress, which reflected the considerable efforts of health workers, politicians and civil society in Bulgaria.

In terms of the global context, in May 2010, the World Health Assembly adopted resolution WHA63.18, which requests WHO to draft a comprehensive strategy and endorses World Hepatitis Day, one of only six official WHO "health days". The resolution legitimates governments to act. Work is well under way for producing materials to support Member States mark the Day on July 28, and steps are being taken at WHO headquarters and the Regional Office for Europe to develop global and regional strategies on viral hepatitis. Together with the European Immunization week "Prevent Protect Immunize" (23–30 April 2011), being organized in almost all European countries, the Day will enable the dissemination of information on the benefits and safety of vaccines, increasing the demand for vaccines and providing further advocacy for political support and financial commitment.

10. Possible future steps and recommendations

A series of recommendations emerged from the meeting.

- At the central level, public health tasks should be better prioritized and the extensive reforms over the past few years should be evaluated.
- Clear guidance should be issued for health education and medical institutions regarding vaccination of medical and nursing students and health-care workers in general and possible restrictions of work practices for infected health-care workers (exposure-prone procedures)[18], with guidance in implementing existing legislation.
- Further work should be undertaken to clarify the risks of transmission of hepatitis C virus in medical interventions, with better implementation of infection control measures and guidelines for health-care workers.
- The legislation on blood safety control should be revised for viral hepatitis, in particular with regard to responsibilities for counselling infected blood donors.
- A special legal framework or regulation should be created for establishing registers of the immune status of health-care personnel and students. Further, a mandate should be given to infection-control teams for leadership in training, and

educational institutions should be fostered. Education about standard precautions should start during training at universities and nursing schools, and the strict application of standard precautions should be subject to continuous monitoring.
- Further attention should be given to prevention for, and treatment of, viral hepatitis in injecting drug users and ethnic minorities, with opportunities for prevention of hepatitis A, B and C identified. Work should focus on innovative approaches for bringing routine immunization programmes closer to vulnerable populations, building on successful models such as the health mediator concept.
- Consideration should be given to use of hepatitis A vaccine as epidemiological pattern changes.
- The low rate of infection of injecting drug users with hepatitis C virus during first two years after starting drug use represented an opportunity for prevention.
- Consideration should be given to introducing and extending the use of web-based reporting systems, irrespective of the necessary investment in training staff and developing or adapting systems.
- Methods for detecting hepatitis viruses should be standardized and validated, and participation in national quality assurance programmes ensured.
- Attention should be paid to quality control in the generation of the data, to improving their analysis (including determination of the extent to which prevalence was possibly under-estimated, as for instance may be the case for hepatitis D), and to the application of results of those analyses. Auditing the quality of data is essential for supporting evidence-based decision-making and providing greater transparency.
- Given the relatively large rural population, seroepidemiological data should be better broken down for rural and urban populations. The age-specific seroprevalence study should be repeated but with expanded aims and be designed to be representative of the whole population in Bulgaria and to examine the impact of the hepatitis B vaccination programmes. Clear protocols should be developed for laboratory testing in acute viral hepatitis surveillance.
- As concern was expressed about the likely insufficiency in trained virologists and epidemiologists in the near future, the Government should consider a "business continuity" plan for training more virologists and epidemiologists – increasing their numbers would bring benefits not just in the field of viral hepatitis but for work in all areas of infectious diseases.
- Given the protean nature of viral hepatitis, cutting across several disciplines, public health experts, epidemiologists and vaccinologists, gastroenterologists, liver specialists, infectious disease specialists, internists, general practitioners, other experts and civil society should be closely involved in the decision-making process, possibly through a strategic committee with a focal point or other forum for discussion, with a view to providing a mechanism for ensuring that objectives were met and coordinating policies and programmes.

The Viral Hepatitis Prevention Board offered to provide support to health authorities and other relevant bodies in formulating proposals for policies on surveillance, control and prevention of viral hepatitis.

It was concluded that Bulgaria is making significant progress in reaching hard-to-reach and vulnerable populations. The country's application of the health mediator model provides a valuable example for accessing hard-to-reach populations. Although 105 such mediators have already been trained and qualified, it was estimated that some 4000 would be needed to reach all vulnerable groups adequately. An even greater advance would be to consolidate the supplementary immunization activities currently being undertaken in that area into more permanent routine activities. Such action would enable Bulgaria to become a regional role model.

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