Viral Hepatitis Prevention Board

Prevention and control of viral hepatitis in Albania and neighbouring countries:

lessons learnt and the way forward

TIRANA, ALBANIA 27-28 October 2016

Objectives

- To provide an overview of the health care system in Albania
- to review the epidemiological situation in the country
- to examine the current prevention and control measures, the progress made, and the possible implementation of new strategies, measures and monitoring systems
- to discuss the development and implementation of a national viral hepatitis plan and the possible implications for neighbouring Balkan countries
- to determine steps needed to achieve the goal of eliminating viral hepatitis set by the WHO Regional Office for Europe
- to identify success factors and issues and barriers to progress as well as necessary next steps

Context

- In the European Region an estimated 150,000 viral hepatitis-related deaths/year
- At last viral hepatitis high on public health agendas included in Sustainable Development Goal 3 (which includes "combating viral hepatitis")
- Commitment to universal health coverage and equitable access in 2030 Agenda for Sustainable Development
- WHO global strategy on viral hepatitis adopted (2016), urging Member States to draft, adapt and align national strategic and action plans; WHO Regional Committee for Europe adopted action plan to eliminate viral hepatitis in the Region by 2030, including milestones for 2018 and essential targets for 2020 (September 2016)
- European Union's programmes and actions
- Numerous summits and meetings devoted to viral hepatitis

Context (continued)

 Publication of various guidelines on a range of related topics – screening, surveillance, treatment; including (27 October 2016) of WHO's global report on treatment access to hepatitis C medicines



 Willingness of WHO to provide support in areas such as strategic planning and choice and application of case definitions

Albanian national situation

- Progress towards the end of "a dark journey"; good momentum towards prevention and control of viral hepatitis, but still a way to go...
- Viral hepatitis is a public health priority; political support, active health ministry, enthusiastic and committed public health experts
- Legislative framework exists and political climate permits introduction of new laws (e.g. March 2016 law covering inter alia case definitions and reporting system)
- Funding through payroll taxation
- Introduction of new direct acting antivirals with policies for reimbursement of treatment costs
- Acceptance and engagement of civil society
- Existence of opportunities learning from previous lessons, best practices, potential for cooperation with neighbouring countries
 - Successes (e.g. hepatitis B vaccination), but a long list of "lack of" and weaknesses

Epidemiology

- Two-fold surveillance system (disease- and syndrome-based) in place and working well, with weekly and monthly reporting
- Transition from paper-based to web-based system for reporting of hepatitis B vaccination in progress in Albania and being extended to whole country
- Epidemiological situation dissimilar to that in neighbouring countries
- Country experiencing an epidemiological transition, in particular for hepatitis A
- All hepatitis viruses present; caveat about incidence and prevalence rates because of doubts about the quality of the data
- Hepatitis A: pool of susceptible subjects increases with improved socioeconomic conditions and outbreaks continue to occur – an example of a country in epidemiological transition - due to contaminated drinking water and poor sanitation systems (which will take several years to improve); incidence rate of about 3.5/100,000 in 2015; more cases in rural than urban areas

Epidemiology (continued)

- Hepatitis B: still high prevalence rate:
 - 2015 data indicate a HBsAg prevalence of between 7% and 9%
 - a significant decrease from a decade before
 - chronic hepatitis B similarly declining
- HBV transmission linked to (para)medical procedures
- Collaborative studies (HEPAGA) continuing
- Genotype D2 predominates, but GT D3 which is also circulating is associated with fulminant disease
- Reactivation of hepatitis B in co-infections is an issue for prevention and treatment
- Hepatitis C:
 - prevalence is low in the general population (about 0.5-1.5%), but higher in some risk groups (e.g. PWIDs although the rates are not as high generally as in other countries)
 - genotype 1b predominates in multi-transfused subjects although GT3 is common in PWIDs
- Rising trend of HIV infection is associated with increased incidence of co-infections with HBV and/or HCV. For HIV-positive patients co-infected with HCV difficulties in access to treatment for HCV (not direct and involving the health insurance funds), whereas they have direct access to treatment for HIV.

Epidemiology (continued)

- Data presented for Kosovo, Serbia and Macedonia (although results are based on a limited number of studies)
- Hepatitis A: in Kosovo, transmission pattern associated with poor sanitary conditions and in Macedonia periodic outbreaks reported in the past six years
- Hepatitis B: in Kosovo (2-3% prevalence), transmission linked with contaminated blood and medical procedures; in Macedonia (prevalence about 1%) was reported; in Serbia, generally low rates (estimated at <1% with not much higher rates in risk groups (PWID, MSM and haemodialysis patients) but limited number of studies)
- Hepatitis C: in Kosovo and Macedonia, low rates in general population (<0.7%) but higher rates (27-38% and about 80%, respectively) in PWIDs; in Serbia, rates of chronic disease increasing steadily
- Viral hepatitis-related HCC recognized as a problem in Serbia and Macedonia
- DAAs have been introduced (in a small number of patients, in private sector) in Kosovo and Macedonia
- Macedonia has a national plan and Serbia has a draft national strategy

Issues and challenges

- Sustainable funding in all sectors, from education and awareness raising to prevention (including vaccination and harm reduction measures), serological surveys, surveillance, reporting systems, diagnostics, care and treatment
- Reporting systems paper-based and forms are outdated
- Data quality: need to know burden of disease: without sound data, no forecasts, investment cases, planning or funding; data need to be in compatible formats for comparisons
- Services are centralized; need to take services to clients (e.g. of mobile service van)
- Issues of how to access and win confidence of hard-to-reach groups (e.g. health visitors for Roma populations)

 problems of the uninsured, people in precarious social position, and the effects of stigma and discrimination;
 new ways are needed to overcome stigma
- Access to care for such populations (in practice only an estimated 10-15% of PWIDs in Albania attend clinics)
- Uncertainties remain about how to raise awareness (even date of World Hepatitis Day is problematic), increase
 knowledge, counter anti-vaccine lobbies and persuade politicians about the value of investments in prevention
 and control of viral hepatitis (from improvements in water and sanitation to prevention, especially measures for
 groups to whom the general public may be unsympathetic (e.g. PWIDs, MSM, CSWs, prisoners and migrants)
- Opportunities for vaccinating at-risk groups against hepatitis B

Issues and challenges (continued)

- Inadequacy or lack of resources across all sectors from prevention to treatment
- Lack of capacity, in particular in terms of diagnostics and reference laboratories
- Lack of staff, proper training example of dialysis units
- Collaboration between different units and disciplines, e.g. coordination of pre- and peri-natal care teams
- Potential for regional collaboration several examples of successful regional cooperation, especially in the health sector
- Hepatitis B vaccination policies: catch-up campaigns for adolescents in Albania but not in neighboring countries
- Cascade of care there are organizational issues, including the private and public sectors
- Linkage between screening /diagnostic services and referral to treatment centres is poor
- Issues about lack of use of HBIg for children born to HBsAg-positive mothers and need to prioritize screening; relatively higher prevalence of fulminant hepatitis; complications due to D3 genotype and precore mutant
- Monitoring of birth dose of hepatitis B vaccine and timing of vaccine administration
- Value of sharing ideas, experience, promoting common activities for better management of patients

Needs

- It is vital to improve data quality and comparability, including estimates of denominators for numbers in risk groups and numbers needing treatment and rates of seroprevalence, HCC and cirrhosis
- National strategies and action plans need to be costed, finalized, approved and implemented
- Estimates of cost-effectiveness and cost savings needed
- Case definitions need to be agreed, aligned (ideally with WHO's), accepted and used
- National surveys of seroprevalence (e.g. for hepatitis A antibodies in <15 year olds) and quality control of the immunization programmes (through seroprevalence or monitoring of disease); need for models to estimate impacts of different vaccination strategies
- Both surveillance systems and public health laboratory systems need to be evaluated, strengthened and standardized, with sustainable funding provided; further digitalization of the reporting system needed; the Biological and Behavioural Surveillance Study should be continued with reintroduction of testing for HBV markers
- Drinking water needs to be tested for viral pathogens (not just bacteria) such as hepatitis A virus, rotavirus and others, with a quality monitoring system.

Needs (continued)

- **Prevention:** greater action needed (e.g. to capitalize on the low rates of hepatitis C to prevent a worsening of the epidemic); better policies (e.g. fewer custodial sentences for drug offences and harm reduction measures, especially in prisons); infection control needs to be strengthened
- Treatment: need for:
 - coordination between disciplines in drafting clinical treatment guidelines;
 - prevention of mother-to child transmission priority should be given to use of HBIg and neonatal hepatitis B vaccine; guidelines on deciding whom to treat, with indicators (e.g. liver disease stage and genotype);
 - new or updated guidelines on management and treatment; better access;
 - a comprehensive package for management and follow-up;
 - Improving adherence to treatment;
 - setting up of outpatient clinics;
 - Introduction of new DAAs and support for treatment and determine duration of treatment, with monitoring of virological response and be aware of resistance

Needs (continued)

- Securing the blood supply: reduce and eliminate remunerated blood donors; recruit more new donors; prioritize diagnosis (including for haemoglobinopathies) and genotyping (including look back studies for HCV RNA in stored samples); introduce standard operating procedures, better donor selection/exclusion practices and better quality control measures (from history taking to laboratory procedures)
- Intersectoral and international **collaboration** (e.g. food and water sectors for hepatitis A prevention and control), sharing of resources with neighbouring countries e.g. reference laboratories, exchanging of experience; nationally create an independent oversight body
- Exploration of pooled purchasing (pros and cons), taking into account experiences (good and bad) – discussions being held at ministerial and WHO European Regional Office levels – and with national consensus;
- Need to capitalize on opportunities for international cooperation

Progress towards milestones and targets

- Immunization coverage is well advanced, with targets achieved
- Discussion about reaching 2018 milestones for prevention of mother-to-child transmission
- Blood safety: milestones implemented (Albania, Serbia and Macedonia) and progress made towards 2020 targets (no new paid donors since 2008 in Albania, and NAT testing in Macedonia but not yet or fully in other countries)
- Diagnosis: 2018 milestone too ambitious for Albania, and serious doubts about 2020 target
- Enhancing care and treatment: also serious doubts about feasibility of achieving 2020 targets - cost of DAAs a major constraint

Solutions: surveillance and data

- Albania will keep both its surveillance systems, and modernize and upgrade them
- Digitalization of reporting system (for all communicable diseases) is planned and Government and donor funding secured; implementation within three years
- Training materials for surveillance will be modified in terms of case definitions and extended to all communicable diseases by April 2017
- Albania has decided to align viral hepatitis case definitions with EU definitions and finalized by end-2016
- Laboratory capacity: strengthening will need a plan and assistance in its development:
- Water quality monitoring will continue to be improved (within three years)
- Registries exist: liver cancer (within the Institute of Public Health) links with viral hepatitis being developed; linkage and location of chronic hepatitis B and C registry under discussion (but that action is a priority)

Solutions

- Anti-HAV Ig serosurvey likely for 2017 but no funding for general population serosurveys for hepatitis A, B and C
- Need to monitor immunization programme through seroprevalence studies in under-15 year old population
- Prevention of perinatal hepatitis B
- Consensus was reached on the need for a step-wise approach to prevent perinatal transmission
- High coverage of neonatal dose and optimal timing of vaccination
 - offer HBsAg screening to pregnant women
 - if affordable, offer HBIg to exposed newborns
 - if funding available, treatment of pregnant women should be considered

Solutions (continued)

- Infection control: policy, standard operating procedures and putting IC units in place in hospitals will continue to be worked on
- Guidelines on infection control exist (and cover all settings including primary care) and must be implemented throughout the country, and the health ministry is developing a plan on infection control to strengthen that implementation
- Consideration of use of vaccination card as a prerequisite for HCWs to work; consider vaccination against hepatitis B of (para)medical staff and medical students
- **Global and national prevention strategies** exist for HIV and STIs and include prevention for PWIDs and other people at risk of viral hepatitis; prevention of sexual transmission needs to be included in national plans, and policy for follow-up of contacts of index cases for prevention and treatment also should be included in the national plan
- Continue to involve and support NGOs in reaching at-risk groups for prevention work; harm
 reduction activities supported for next three years by Global Fund with clear milestones for
 evaluation and commitment from health ministry to take over funding
- **Blood safety**: steps being take to meet milestones and targets, including NAT testing (from January 2017) and phasing out of remunerated blood donors
- Diagnosis: costing and modelling exercises will help health ministry to set priorities; WHO offering tools for all costing exercises

Solutions (continued)

 Albania has created a multidisciplinary platform chaired by the health ministry with a focal point within the Institute of Public Health; WHO has issued useful manual for the development and assessment of national hepatitis plans



 International guidelines for treatment need to be adapted to national circumstances and applied in a standardized way

Solutions (continued)

- Limited funds and the multiplicity of targets in the regional plan for elimination of viral hepatitis demand prioritization of application of existing funds
- Agreement was reached on the need for an evaluation of the effectiveness of implementation of the national plan for viral hepatitis; VHPB willing to participate