Prevention and control of viral hepatitis virus in Spain: Lessons learnt and the way forward

Madrid, November 23-24, 2006

Preliminary meeting conclusions

Objectives of the meeting

- Update of the epidemiological situation on viral hepatitis in Spain
- Overview of surveillance systems for infectious diseases with emphasis on hepatitis viruses and adverse events following vaccination in Spain
- Overview of the research activities on viral hepatitis in Spain
- Evaluation of current prevention and control measures on viral hepatitis in Spain
- Lessons learnt from the experience in Spain: successes, problems and barriers to overcome

Sequence of conclusions presentation

- Organization of health care system in Spain
- Surveillance systems
- Diagnostic tools and epidemiology of viral hepatitis
- Vaccination policies for hepatitis A&B
- Lessons learnt and challenges

Organization of health care system in Spain

- The Spanish National Health System:
  - Is based on public funding with universal free health services
  - is divided between State and Autonomous Community (AC) Health Departments (devolution)
  - is coordinated by the Inter-Territorial Board
  - the inter-Territorial Board makes recommendations (national consensus) but the ACs make decisions regarding health policies and vaccines procurement
  - MOH national consensus guarantees equal minimum health care standards;
  - Health care budget is allocated per capita to each AC. Individual ACs may decide on additional priorities within the budget.

Hepatitis epidemiological surveillance in Spain

- 3 main information systems (since 1995):
  - Statutory notification by GPs for Hep A&B. However, 5-10 times underreporting observed for Hep A in Catalonia
  - Microbiological information: Hep A, B&C (25% reporting coverage)
  - Outbreak reporting: Hep A, B&C
- Complementary systems:
  - Hospital discharge
  - Mortality surveillance
  - Seroepidemiological surveys
  - Special registries

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Hepatitis outbreak investigation in Spain

- Outbreak investigation is part of national surveillance and a specific training program has been in place for 10 years
- Objectives:
  - Assess & confirm magnitude of outbreak
  - Identify source/vehicles
  - Identify risk factors/source of transmission

$\Rightarrow$ Recommended control measures: improved hygiene, enhanced surveillance, enhanced international cooperation

$\Rightarrow$general recommendation to use vaccines but ACs make the decision

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Molecular epidemiology of Hep A & E in Spain

- HAV detected in sewage, rivers & occasionally shellfish
- Most HAV isolates are of genotype 1A & 1B
- 6 HEV strains isolated from serum samples of patients with acute HEV (4 autochtonous & 1 imported; 1989-2003)
- Identification of HEV-RNA in 44% of sewage samples from Barcelona (genotype 3)
- Anti-HEV(IgG) antibodies identified in 19% of pigs in Catalonia (genotype 3)
- HEV virus strains detected in pigs could also be a source of infection for humans
- Both HAV and HEV isolates occasionally identified in the same sewage samples

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Diagnosis of Hepatitis B

- Safety testing of blood donations in Spain includes compulsory HBsAg assay and of secondary importance anti-HBc Ab and ALT.
- Nucleic acid testing (NAT) technology is used in 80% of blood donations
- Yield of HBV identification using NAT-technology ranges from 1:98.000 in the window phase and 1:24.000 in silent HBsAg-negative samples
- Certain HBsAg mutants may be missed by some serological assay in blood donation testing
- HBsAg mutants have been detected in HBsAg carriers but do not cause a measurable threat to the current vaccination policy

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Epidemiology of Hepatitis A & E in Spain

HAV

- Low endemicity with low rates of disease and very low mortality
- High % of <30-yr-olds not protected (<5% of 5-14yr-olds seropositive in Catalonia)
- High degree of detection of HAV in environment (tested in Catalonia)
- 2005: decreased incidence since 1997 but rise between 2002-2005 possibly due to immigration (study in Catalonia)
- In 2 communities (Melilla and Ceuta) with exceptionally high incidence rate initially, a significant decline of HAV incidence was demonstrated following implementation of immunization

HEV

- Anti-HEV prevalence is 7.3% in Catalonia, compared to 3-20% in industrialized countries
- similar HEV strains found in sewage samples and swine indicate that swine might be a reservoir for HEV in Spain

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Hepatitis A outbreaks in Spain

- 1996-2003: 375 outbreaks; 2881 cases (107 outbreaks in Catalonia)
- Characteristics:
  - 15% foodborne (50%water/50% shellfish)
  - 70% direct transmission
  - significant number of cases in schools;
  - control measures reported for 235 outbreaks

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Epidemiology of Hepatitis B in Spain

- Progressive decline in incidence of acute Hepatitis B in all Spain between 1997-2005 (47.3% fall)

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Hepatitis C epidemiology in Spain

- HCV prevalence ranges from 1.5-2.5% in the general population of Spain (number of new infections dropped rapidly between 1996-2005)
- Up-to-date molecular tools are used for diagnosis of hepatitis C in Spain.
- In Spain, drug addiction is the most prevalent risk factor for HCV infection
- HCV prevalence is high in hemodialysed patients but Universal precaution and isolation measures have lead to the decrease of HCV infections
- Routes of transmission include IVDA, nosocomial infection, sexual transmission and vertical transmission
- Approximately 1/3 of HIV patients are co-infected with HCV

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Hepatitis Vaccination policy in Spain

- Spanish National Immunization (NIS) guidelines are generally implemented in all ACs

- Recommended vaccines are free of charge and paid by ACs (HBV recommended for the entire country and HAV in 3 regions and high-risk groups)
- Most vaccines are given by paediatricians or in schools
- Some ACs provide additional vaccines (e.g. Hep A)

Hep A Vaccination in Spain

- 1993-1997: high risk-group vaccination (reviewed in 2004)
- 1998: Routine adolescent vaccination in Catalonia (combined Hep A/B vaccine, with estimated 98% effectiveness in 2005)
- 2000:Routine vaccination of children <2yrs in Ceuta and Melilla (based on epidemiology)

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Hep B Vaccination in Spain

- 1983: high risk-group vaccination
- 1990: extended high risk-group list, including newborns of HBsAg+ mothers (reviewed again in 2004)
- 1992: efforts toward adolescent vaccination programmes
- 1996: adolescent (12-13yrs) vaccination in all ACs + newborn vaccination in some ACs
- 2003: infant vaccination in all ACs (now unified to 2,4,6-month schedule)+passive/active vaccination of newborns to HBsAg+mothers on 0,1,6-month schedule
- 2003: adolescent vaccination continued until children immunized reach adolescence
- 2005: >95% vaccination coverage for primary series in all ACs

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Lessons learnt

- Preventive measures have led to a significant decrease in the incidence of Hepatitis A, B and C infections
- Up-to-date molecular tools are being used in Spain for identification of source of infection in nosocomial outbreaks
- Need to include HEV-RNA testing in investigation of acute/fulminant non-A,non-B, and non-C hepatitis, even in the absence of travel history
- HCV-positive cirrhosis of the liver has become a major cause for morbidity and mortality in HIV-positive patients
- Presence of a large cohort of HIV patients co-infected with HCV is expected to have an impact on the demand of health resources for clinical care

Challenges

- Strengthening of surveillance and reporting system for viral hepatitis;
  - Ensuring timely and complete case based reporting for all variables including laboratory confirmation
  - Analyzing data to define high risk groups and using for policy decisions and actions to further strengthen prevention and control efforts
- Sustaining immunization programme high performance and prioritizing high risk groups, including immigrants
- Data on the different therapeutic modalities used in Spain for treatment of HBV, HCV and co-infected patients, utilization and response rates were not presented