

# Summary of Key Points

**WHO Position Paper on Vaccines  
against Hepatitis E Virus(HEV)**

**May 2015**



**World Health  
Organization**

# Background

- **Hepatitis E Virus (HEV):** leading cause of acute viral hepatitis in developing countries.
- **Genotypes 1 and 2:**
  - Primarily infect humans, mainly male young adults
  - Annually cause 20.1 M infections, 3.4 M symptomatic cases, 70 000 deaths, 3000 stillbirths.
  - Genotype 1 is:
    - most prevalent;
    - widely found in Asia and Africa;
    - causes high mortality in pregnant women, and poor fetal outcomes
  - Genotype 2 cases in Mexico, Nigeria, Namibia
- **Genotypes 3 and 4:**
  - Primarily infect mammalian animals; occasional transmission to humans
  - Genotype 3 cases almost entirely in developing countries
  - Genotype 4 human cases mainly in mainland China and Taiwan



# Background

- **HEV transmission:**

- Sporadic disease in endemic countries.
- Periodic large epidemics due to contamination of water sources.
- Greatest disease burden in developing areas where clean water is scarce.

- **Treatment:**

- There are no WHO guidelines on treatment of Hepatitis E.
- Treatment is generally supportive.



# Vaccines

## ● HEV 239 Vaccine:

- Hecolin®
- Experimental vaccine at clinical trial stage in humans that has been developed and manufactured.
- Currently only licensed in China
- Licensed for use in people 16-65 years of age who are at high risk for HEV infection based on occupation/lifestyle
  - Those involved in animal husbandry, food handling, students, army personnel, young women, travellers



# Immunogenicity and Effectiveness

- Highly immunogenic
  - Almost all recipients seroconverted after 3 doses on a 0,1,6 month schedule.
- Efficacy rate:
  - High efficacy rate in healthy adults between 16-65 years of age in China, primarily against Genotype 4.
  - Limited data on protection against Genotype 1
  - No data on protection against Genotypes 2 and 3
  - However, there is data to show expected protection against all 4 genotypes.



# WHO Position

- Hepatitis E recognized as an important public health problem in developing countries
  - Especially among special populations: pregnant women, displaced individuals living in camps, outbreak situations.
- In the absence of sufficient information, the WHO does not:
  - make a recommendation on the introduction of the vaccine for routine use in national programmes in populations where epidemic and sporadic hepatitis E disease is common. However, national authorities may decide to use the vaccine based on the local epidemiology.
  - Recommend routine use of vaccine in the following groups in endemic areas:
    - Children below age of 16 years
    - Pregnant women
    - Patients with chronic liver disease
    - Patients on organ transplant wait lists
    - Travellers



# WHO Position

- In outbreak situations (high risk of Hep E) WHO recommends:
  - Considering use of HEV 239 vaccine to mitigate risk of Hep E outbreaks for high risk groups:
    - Pregnant women
    - Travellers
    - Health and humanitarian relief workers
  - Evaluate risk and benefit of vaccination on an individual basis
- To address information gaps WHO recommends:
  - Pre-emptive design of research protocol to study vaccine safety and immunogenicity in outbreak situations among high risk groups.



# Information Gaps

- Incidence and mortality of the Hep E disease in general and in special populations;
- Immunogenicity of HEV 239:
  - outside the 16-65 age range
  - in populations at higher risk for hep E disease
    - E.g. with pre-existing liver disease or immunosuppressive conditions
  - in pregnant women
  - after SC vs. ID administration
  - on an accelerated schedule.





# Information Gaps

- Efficacy of HEV 239:
  - against disease caused by genotypes 1, 2 and 3;
  - long term efficacy, duration of protection
  - with fewer than 3 doses or shorter intervals between doses;
  - need and timing of potential booster dose
- Effectiveness of HEV 239
- Cost effectiveness of vaccine programme in outbreak settings



**For more information on the WHO HEV  
position paper, please visit the WHO  
website:**

**[www.who.int/immunization/documents/  
positionpapers](http://www.who.int/immunization/documents/positionpapers)**



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