

Melbourne Statement on Prevention of Perinatal Transmission of Hepatitis B Virus

A Call for the Consideration of All Available Strategies

*Endorsed by participants in the WHO Consultation on
Best Practices and Tools for Preventing Perinatal Hepatitis B Virus Transmission
Melbourne, Australia - December 7th and 8th 2010*

Hepatitis B virus (HBV) infection is a major public health problem globally. Over 2 billion people have been infected with HBV worldwide, and up to 400 million people are chronically HBV-infected. HBV infection acquired early in life is a major cause of chronic liver disease, including cirrhosis, and the predominant cause of primary liver cancer worldwide, which is the 3rd most common cause of cancer death in humans. The hepatitis B virus is the 2nd most important known human carcinogen, after tobacco.

Hepatitis B vaccination starting at birth is highly effective at preventing chronic HBV infection and its subsequent burden of disease and death. The safety of hepatitis B vaccine has been amply demonstrated. A crucial aspect of hepatitis B vaccination strategies is the timely delivery of the birth dose - noting the strong evidence that first vaccination within 24 hours of birth has far greater efficacy in prevention of perinatal transmission than when the first vaccination is delayed. The critical importance of the timing of the hepatitis B vaccine birth dose is unique amongst childhood vaccines.

Universal infant hepatitis B vaccination is not only cost effective, but also cost saving to society regardless of whether the population prevalence is high, intermediate or low. The World Health Assembly resolution 63.18 provides us with the mandate to accelerate the implementation of this essential public health initiative.

Inequities in access to hepatitis B birth dose vaccination result in an increased burden of end stage liver disease, primary liver cancer and death in children and adults - increasing with age. Numerous barriers have been documented which must be overcome to ensure the inalienable right of all children worldwide to live free of the burden of chronic HBV infection. Disease prevention is of utmost importance because existing treatments cannot provide a permanent cure, and are limited by issues such as toxicity, antiviral resistance, relatively high cost and the need for long-term administration.

We must consider the potential value of all strategies to ensure the timely administration (within 24 hours of birth wherever possible) of the hepatitis B vaccine birth dose. Essential actions include:

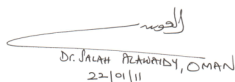
- Delivery of the hepatitis B vaccine birth dose can and should be implemented as part of an integrated package of maternal and newborn care.
- Securing expanded funding for programs designed to accelerate delivery of hepatitis B vaccine birth dose.
- Harnessing the momentum of The Decade of Vaccines can support hepatitis B vaccine birth dose delivery in various contexts, contributing to global elimination of HBV transmission.
- Prioritizing community and other communications aimed at increasing demand for birth dose vaccination as well as prioritizing the provision of information and support for parents at the time of vaccine delivery.

- Changing current GAVI policy in order to provide support for monovalent hepatitis B vaccine will facilitate provision of the birth dose among the poorest countries. Such support will lead to reduced morbidity and mortality due to hepatitis B, and represent a low cost way to support advances already made through GAVI's substantial investment in hepatitis B prevention.
- Increasing the proportion of facility-based childbirths, and ensuring every child born in a health care facility receives timely hepatitis B vaccine birth dose.
- For children born at home, ensuring the delivery of a package of maternal and neonatal health care, especially early postnatal care, which includes provision of the hepatitis B vaccine birth dose.
- Promoting the appropriate use of a Controlled Temperature Chain (CTC): that is where heat-stable vaccines can be transported and stored for limited periods at ambient temperature. The established heat stability of most WHO-pre-qualified hepatitis B vaccines makes a CTC feasible and provides an option for low-resource settings where cold chain is not available.
- Including heat stable vaccines with appropriate vaccine vial monitors (VVMs) amongst the options for countries that procure vaccines through United Nations systems would allow for flexibility in areas where CTC is required. This will also provide an incentive for manufacturers to assess and authorise their products for CTC use.
- Rigorously assessing presently available innovations in vaccine delivery. These include systems such as compact pre-filled auto-disable devices (CPAD) (such as Uniject™). If proven to be safe, convenient and affordable, then these devices must be funded, scaled up and deployed. The long delay between successful pilot studies and large scale implementation which has been observed previously will be measured in lives lost.
- Pursuing future innovations, with research and development funding directed towards attaining vaccines or vaccine delivery mechanisms that can be administered safely and effectively by a person with minimal training, preferably in a single dose, and with no residual sharp instrument requiring safe disposal. One example of the sort of technology that might be adapted for this purpose is microneedle patches.
- Addressing residual professional concerns around how vaccines can be safely provided at the time of birth.
- Building links with other programs, so that both birth dose vaccination and other aspects of early postnatal care for mother and baby can be strengthened and achieve true synergy. Good integration with maternal and neonatal care programs will ensure all essential childbirth care is included in the correct sequence, harmonise training and clinical standards, and provide systematic, supportive supervision – the most important contributor to effective scale-up.
- Coordinating hepatitis B birth dose vaccine delivery with other components of the Expanded Programme on Immunization (EPI) can provide mutual benefit, with evidence suggesting that the timely receipt of the hepatitis B vaccine birth dose is associated with improved uptake of other childhood vaccines.

In an increasingly connected world, with significant migration between regions of low and high hepatitis B prevalence, hepatitis B disease is now a trans-boundary issue, similar to polio and measles. A co-ordinated global effort to provide hepatitis B birth dose vaccination to all infants is urgently required. We call on the World Health Organization, all member nations, and non-government and community organizations to prioritize birth-dose vaccination in support of the elimination of transmission of hepatitis B worldwide.

From participants at the Consultation, Melbourne, December 2010

Signed:

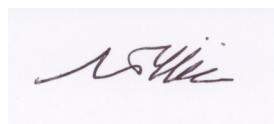


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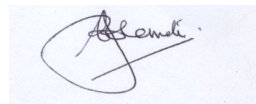
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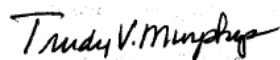
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