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COMMENTARY

Hepatitis B vaccine birth dose in India: time to reconsider

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ABSTRACT

Viral hepatitis is increasingly being recognized as a public health problem in India with 96% of all hepatitis mortality attributed to hepatitis B and C combined. It has been recognized that hepatitis B vaccination has resulted in substantial reductions in the incidence of acute and chronic hepatitis B infections and carriage. Although coverage of third-dose hepatitis B vaccine has reached 86%, the birth-dose coverage was only 45% in 2015 despite high rates of institutional deliveries (79%). With the target set at 90% coverage of birth-dose hepatitis B vaccine by 2030, it is imperative to immediately incorporate WHO/SAGE recommendations of administering the hepatitis B vaccine birth dose until 7 d into the National Immunization Schedule (NIS).

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Introduction

Viral hepatitis is recognized as a major public health challenge that requires an immediate response.[1–4] Globally in 2015, 1.34 million deaths were due to viral hepatitis.[1,5] However, what is more alarming is that the number of deaths is in a rising trend.[1,5] Hepatitis B and C combined are responsible for 96% of all hepatitis mortality. Specific vaccine-induced protection for hepatitis B (HepB) is available and well proven in its effectiveness.[1]

Although wide variations in prevalence are found in the Pacific region, the burden of disease in India is not yet established due to a paucity of data.[1] India falls into the intermediate endemicity category of HepB.[6]

Combating viral hepatitis

Realizing the public health importance and to overcome the lapses, the World Hepatitis Day has been celebrated on 28 July since 2010. [7,8] The Government of India is committed to Sustainable Development Goal (SDG) 3; target 3.3 to combat hepatitis[9,10] and WHO Global Health Sector Strategy on Viral Hepatitis 2016–2021 which calls for the elimination of viral hepatitis as a public health threat by 2030[5,11] by increasing global coverage of the HepB vaccine birth dose to 50% by 2020 and to 90% by 2030, along with other approaches for preventing mother-to-child transmission.[12]

Vaccine coverage

Safe and effective vaccines for HepB have been available since 1982.[13] HepB vaccination has been associated with substantial reductions in the incidence of acute and chronic HepB infections/carriage, which will ultimately result in significant reductions in the incidence of cirrhosis and hepatocellular carcinoma.[13,14]

In 2015, global coverage with the three doses of HepB vaccine in infancy was 84%.[1,5,13] This has substantially reduced HBV transmission in the first 5 y of life, as reflected in the reduction in HBV prevalence among children to 1.3% and can potentially avert 4.8 million HepB-related deaths over a 10-y period.[7,13] However, coverage with the initial birth-dose is still low at 39%.[1,5,13] In India, the coverage of third-dose HepB vaccine has reached 86%. However, despite high rates of institutional deliveries (78.9%),[15] the birth-dose coverage was only 45% in 2015, with large variations across states.[7,16]

It is noteworthy that the HepB birth dose given any time before the first primary dose brings carriage rates from 6.2% down to 3.0% for those who received the first dose >7 d after birth, and to 1.4% if the first dose is received within 7 d of birth.[17]

Problem statement

India, the country with the second most chronic carriers in the world, has faults in health services that seems to be related to underperformance of birth-dose delivery.[14] It should be noted that one-third of infants perinatally acquire HBV from carrier mothers, while the remaining two-thirds acquire infection from household carriers (horizontal transmission) via service providers/medical errors and visitors; making receipt of the HepB birth dose imperative.[18]

The National Immunization Schedule (NIS)[19,20] and Indian Academy of Paediatrics (IAP)[21] recommend the HepB birth dose within 24 h of birth. The Health Management Information System (HMIS) of Government of India accepts the birth dose within 48 h as qualified, and manufacturers recommend this dose 'within discharge'.[7] However, as a result of adhering strictly to the NIS, in a few cases of unavoidable delay in India, birth doses are denied after 24 hr,[7] which has led to poor coverage for the HepB birth dose.

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A study conducted by Lahariya et al. to ascertain the reasons for low-reported coverage of HepB vaccine found that fear of vaccine wastage and poor knowledge of health-care workers were the main reasons for poor coverage of the birth dose.[14,22] Alexander et al. found that birth outside health facilities to be the main reason for low coverage of the HepB birth dose.[14,23] Being born outside a health facility and weakness of outreach vaccination service seem to be the most important factors related to underperformance of birth dose delivery. With the advent of the open vial policy,[24] fear of vaccine wastage is another issue, especially with HepB vaccine having a 25% wastage rate.

The way forward

The WHO Position Paper on Hepatitis B Vaccines, July 2017[13,25] has given recommendations stressing the importance of birth-dose vaccination for all infants as the most effective intervention for preventing HepB-associated disease worldwide. The recommendations also address target groups, appropriate schedules for vaccination and updated information on HepB vaccines, their storage, transport and deployment. The significant recommendations are to administer the birth dose of monovalent HepB vaccine ideally within 24 hr of birth. The birth dose can still be effective in preventing perinatal transmission if given within 7 d, particularly within 3 d, although somewhat less than if given within 24 hr and with declining effectiveness with each passing day. The Strategic Advisory Group of Experts (SAGE) recommends that all infants receive the birth dose during their first contact with health facilities at any time up to the time of the first primary dose. To accurately monitor the delivery of doses given within 24 h of birth, these doses should be recorded as a "timely birth dose" of HepB vaccine to differentiate them from birth doses given later ("late birth dose").

HepB vaccines may be co-administered at different anatomical sites with other vaccines – in particular, monovalent HepB vaccine can be co-administered with OPV and BCG at birth. It can be either a three-dose schedule of HepB vaccine with the first dose (monovalent) being given at birth and the second and third (monovalent or as part of a combined vaccine) given at the same time as the first and third doses of DTP-containing vaccine; or four doses, where a monovalent birth dose is followed by three (monovalent or combined vaccine) doses, usually given with other routine infant vaccines is appropriate. The interval between doses should be at least 4 weeks. There is no evidence to support the need for a booster dose. It can be given to low birth weight and premature infants. For these infants, the birth dose should not count as part of the primary three-dose series; the three doses of the standard primary series should be given according to NIS. It is for all children worldwide, and for all national programs.

SAGE on Immunization has given recommendations for births that occur outside of health facilities, which hinders timely administration of a birth dose since the vaccine should be kept in the cold chain and therefore may not be available at the birth site.

It has been recognized that HepB vaccines are thermostable for at least 4 weeks at temperatures of 37°C and 40–45°C, although the recommended storage temperature is 2–8°C.

SAGE strongly urges all the pre-qualified vaccine manufacturers of monovalent HepB vaccine pursue regulatory approval for Controlled Temperature Chain (CTC) as soon as possible, given the available evidence of compatibility with CTC requirements. In the meantime, SAGE supports countries that choose to pursue an out-of-cold-chain policy for a given monovalent HepB vaccine and strongly recommends that when doing so, countries should follow the current IPAC recommendations for out-of-cold-chain and CTC use of vaccines.[13,26]

Recommendation

With the National Viral Hepatitis Control Programme (NVHCP) being rolled out in India with a target to increase HepB birth-dose vaccination to >90%[1] it is of the utmost importance to incorporate SAGE recommendations for the HepB birth dose into the National vaccination schedule. All health-care workers should be informed and trained about the HepB birth dose schedule for administration up to 7 d after birth. HepB vaccine coverage can be improved if this knowledge will be disseminated among all health-care providers.

Disclosure of potential conflicts of interest

No potential conflict of interest was reported by the authors.

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