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Infectious Disease > Hepatitis

HBV Treatment Fails to Meet Global Targets

— Only 5% of hepatitis B patients received antiviral therapy in 2016

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Only an estimated one in 20 patients with hepatitis B worldwide received antiviral therapy for their illness in 2016, a modeling study found.

Of the estimated 292 million people living with hepatitis B virus (HBV), there were 94 million individuals eligible for treatment, but only 4.8 million (5%) actually received it, reported The Polaris Observatory Collaborators.

Moreover, less than half of infants received timely birth dose vaccination, and less than 1% of mothers with a high viral load received antiviral therapy in 2016, the authors wrote in the *Lancet Gastroenterology & Hepatology*.

Reduction of hepatitis B in infants, via mother-to-child transmission, was characterized as important by the authors, because "most HBV infections in infants become chronic, which

is the leading source of new chronic HBV infections." Moreover, they cite the World Health Organization (WHO) Global Health Sector Strategy on Viral Hepatitis, which hopes to eliminate hepatitis B and hepatitis C worldwide by 2030. Targets for hepatitis B include:

- 90% global coverage of three-dose infant vaccination by 2020
- Timely birth dose vaccination in 50% of infants by 2020, and in 90% by 2030
- Prevalence in children age 5 years of 1% by 2020, and 0.1% by 2030
- Diagnosis of 90% of people infected with HBV by 2030
- Antiviral treatment of 80% of those diagnosed and eligible for treatment by 2030

The group cited recent estimates from the *Lancet* or the WHO, which estimated 248 million or 257 million individuals with HBV infection. But the authors added that "these reports were limited by their calculation of averages using a combination of robust and representative studies, studies done in different age groups, and studies done at different time points." They added that these were historical estimates that did not consider the effects of vaccination and efforts to prevent perinatal transmission of HBV.

Using a combination of data from prior studies as well as expert interviews, this group developed models for 120 countries, of which 78 used data approved by experts. They estimated that global prevalence of hepatitis B surface antigen (HbsAg) was 3.9% (95% uncertainty interval 3.4-4.6) or around 292 million infections (95% UI 251,513,000-341,114,000) in 2016.

However, only 29 million (10%) of the 292 million HbSAg-positive patients were diagnosed in 2016. An accompanying editorial by Geoffrey Dusheiko, MD, of King's College Hospital in London, and Kosh Agarwal, MD, of University College London, characterized these figures as "disconcerting," given that a diagnostic test for hepatitis B "has long been available."

"There is a need to raise awareness of HBV to the same level as that of HIV and a pressing prerequisite for inexpensive, innovative, point-of-care nucleic acid testing for HBV DNA

prerequisite for inexpensive, innovative, point-of-care nucleic acid testing for HBV DNA, paired with hepatitis C virus RNA and HIV RNA assays," the editorialists wrote. "The incidence of new chronic HBV infections will continue to increase unless appropriate prevention at birth is applied, and deaths will increase in unvaccinated adults unless large increases in screening and linkage to care are implemented."

The authors estimated that 1.8 million infections were in children age 5 years, with a prevalence of 1.4%. They added that while they estimated only 46% of infants received a timely birth-dose vaccination, 87% of infants younger than 1 year did receive the three-dose HBV vaccination schedule. Weighting by births of mothers with high viral loads, the authors found less than 1% received antiviral treatment in 2016.

Five countries -- China, India, Nigeria, Indonesia, and the Philippines -- accounted for more than half of hepatitis B infections worldwide, and five countries (Nigeria, India, Indonesia and the Democratic Republic of the Congo) accounted for more than half of estimated infections in children age 5 years.

Of note, the authors said that of the 16 countries with the greatest number of infected children, only China had timely-birth dose vaccine coverage of 90% or higher, while 10 of these countries had not yet introduced timely birth dose. They added that "these figures show the importance of robust prophylaxis schedules."

But they also said that the largest strides towards global elimination of HBV were in infant vaccination, with 94 of the modeled countries estimated to have met the 2020 target of 1% prevalence among children age 5, and 46 estimated to have met the 0.1% prevalence target for 2030.

Study limitations included that while it was available for 90% of the estimated number of infections globally, some countries where data was extrapolated had large populations, and some regions had only a few countries with data. In addition, while national estimates may be correct, there may be regional variations, as the study did not account for certain populations with a higher prevalence than the general population, such as immigrants, indigenous peoples and nations, people who inject drugs, and sex workers.

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Dusheiko and Agarwal disclosed relevant relationships with Gilead Sciences, BMS, Abbott Laboratories, Janssen, Transgene, Merck, and Vir Biotechnology.

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