Increasing hepatitis B vaccine coverage rates by implementing an out-of-the-cold-chain strategy

Worldwide, as much as 15 percent of the population is chronically infected with the hepatitis B virus—a major cause of hepatitis B, an infection of the liver that can lead to death. The disease is a major cause of morbidity and mortality in Vietnam. PATH found that 18 percent of Vietnam’s Thanh Hoa Province residents had a current infection, and almost 80 percent of adults had evidence of previous exposure.

When mothers are chronic hepatitis B carriers, the rate of mother-to-child transmission is very high. To prevent this, a first dose of vaccine should be given as soon as possible after birth—ideally within 24 hours. WHO recommends a universal birth dose of hepatitis B vaccine for all newborns in high prevalence countries. This practice has proven highly effective in preventing 80-95 percent of cases of mother-to-child transmission.

Because the schedule of a hepatitis B vaccine birth dose is unique for Vietnam’s routine immunization program, PATH partnered with the National Expanded Program on Immunization (NEPI) to model a new strategy to increase coverage rates for the vaccine in Thanh Hoa Province. This collaboration aimed to achieve WHO’s target recommendation in high prevalence countries of more than 80 percent coverage in newborns within 24 hours of birth.

Challenges and opportunities

NEPI has achieved impressive immunization coverage levels—in some provinces, 96 percent of newborns are already receiving their first dose of hepatitis B vaccination within 24 hours of birth. Other provinces face particular challenges in achieving high coverage. Some regions cannot maintain the cold chain for vaccines because commune-level facilities lack refrigeration or sufficient budgets to continuously operate refrigerators. As a result, vaccines are not delivered to these centers. Health workers or family members must travel to higher-level health facilities at their own expense to access the hepatitis B vaccine birth dose.

Unlike most vaccines, hepatitis B is heat stable—in tropical climates the vaccine can be stored at room temperatures for up to a month without reducing effectiveness. At the same time, the vaccine is extremely sensitive to fluctuations within the cold chain—efficacy decreases or is lost when exposed to temperatures below 0°C.

A novel hepatitis B birth dose strategy

PATH and NEPI recently tested a new strategy. Single-dose vials of vaccine using vaccine vial monitors (indicators that change
color when the vial is exposed to heat over time) were collected by commune health center staff from district cold stores twice a month. The commune health centers received an appropriate supply of the vaccine based on the projected birth rates for the commune.

For commune health centers without refrigerators, the vaccine was kept outside the cold chain for up to two weeks. Infants born at centers received vaccinations onsite, and for the 20 percent of infants born at home (primarily in mountainous districts among ethnic minorities) midwives or parents notified the commune health worker and a home visit occurred the following day.

NEPI provided the hepatitis B vaccine to over 10,000 neonates during the study, including 3,000 hospital births using vaccine stored within the cold chain and over 7,000 home or commune health center births using vaccine stored out-of-the-cold-chain.

**Improved coverage without compromising safety**

In late 2005, PATH conducted an evaluation of the strategy using blood tests to confirm that vaccines kept out-of-the-cold-chain conferred effective protection. The evaluation documented an increase in the percent of infants vaccinated within 24 hours of birth and no decrease in immune response.

Before the project, only 45 percent of neonates received the hepatitis B vaccine within 72 hours of birth; after the study 83 percent received a dose within 24 hours, and 89 percent received it within 72 hours, with no significant difference in the coverage between hospital births and home or commune health center births.

PATH and NEPI found that those vaccinated with a birth dose of hepatitis B vaccine kept out-of-the-cold-chain demonstrated an immune response as strong as those using vaccine stored in the cold chain.

Immune response was tested by blood draws in 614 infants who had been vaccinated with hepatitis B vaccine in the cold chain and 352 vaccinated with vaccine kept out-of-the-cold-chain. The proportion of infants with protective levels of antibodies was found to be comparable in both groups—85.6 percent for in the cold chain and 91.7 percent for out-of-the-cold-chain.

**Community satisfaction**

Commune health staff reported positive feedback about the system noting they no longer needed to travel to the district store for vaccine each time a child is born, and more children received protection sooner after birth.

**Reaching WHO targets**

Because of Vietnam’s high rate of mother-to-child transmission of hepatitis B, administering a birth dose of vaccine within 24 hours is a crucial intervention.

According to NEPI data, the 2005 national coverage of hepatitis B vaccine birth dose was 62 percent within 24 hours, although the rate varied between provinces.

Implementing this strategy in four districts in Thanh Hoa achieved the WHO goal of more than 80 percent coverage of newborns vaccinated against hepatitis B within the first 24 hours after birth.

**Expanding a successful model**

During the project dissemination seminar, Ministry of Health representatives indicated a commitment to prioritize policy level discussions on this issue with the aim of creating an environment to allow national implementation of an out-of-the-cold-chain strategy for the provision of a birth dose of hepatitis B vaccine in rural and remote regions of the country.

**More information**

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