reduce HBV mortality by an additional 10%-20% compared with following a HepB vaccination schedule without a birth dose. For this reason, a substantial number of countries in areas with intermediate or low hepatitis B endemicity have implemented newborn HepB vaccination.

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Progress in Introduction of Pneumococcal Conjugate Vaccine—Worldwide, 2000-2008

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1 figure, 1 table omitted

PNEUMOCOCCAL DISEASE IS A LEADING cause of childhood morbidity and mortality globally, causing an estimated 0.7-1.0 million deaths annually among children aged <5 years. A pneumococcal conjugate vaccine (PCV) that includes seven pneumococcal serotypes (PCV7) first became available in 2000. Studies in the United States have demonstrated that introduction of universal vaccination with PCV7 resulted in a 77% decrease in invasive pneumococcal disease among children aged <5 years and a 39% decrease in hospital admissions for pneumonia among children aged <2 years. A similar vaccine with two additional serotypes was highly efficacious against pneumonia and invasive disease in clinical trials in Africa and, in one trial, reduced all-cause mortality among children by 16%. Low-income countries, which account for >97% of pneumonia cases in children aged <5 years, will benefit most from introduction of PCV. This report summarizes the progress made in introducing PCV7 worldwide. As of August 2008, 26 countries offered PCV7 to all children as part of national immunization programs or had PCV7 in widespread use (i.e., with estimated national coverage >50%); however, none of these countries is a low-income or lower-middle-income country. The World Health Organization (WHO) and UNICEF have recognized the safety and effectiveness of PCVs and recommend that these vaccines for young children be included in national immunization programs. Overcoming the challenges to global introduction remains an urgent public health priority.

WHO recommends including PCV in national immunization programs (i.e., routine vaccination of all young children with PCV), particularly in countries where all-cause mortality among children aged <5 years is >50 per 1,000 live births or where >50,000 children die annually from any cause. In addition, because persons infected with human immunodeficiency virus (HIV) are up to 300 times more likely to have pneumococcal disease than those who are HIV negative, WHO recommends that countries with a high prevalence of HIV infection make the introduction of PCV a priority.

Only one PCV, the 7-valent formulation (PCV7), is currently licensed for use worldwide; new formulations of PCV (10-valent or 13-valent) are scheduled to become available in some countries within 2 years. The high cost of PCV7 has restricted the number of countries introducing the vaccine. In 2006, the GAVI Alliance (formerly known as the Global Alliance for Vaccines and Immunizations), an organization that aligns public and private resources to create global access to vaccines, made funding available through 2015 for PCV introduction in the 72 countries with the lowest gross national income per capita (<$1,000 per capita) in 2003. Some of the 193 countries that are WHO member states have made national decisions to provide vaccine to all children through their national immunization programs. Other countries have elected to offer PCV7 vaccine only to certain high-risk groups, such as children who are HIV positive or other immunocompromised or chronically ill persons.

To assess the current status of global PCV7 introduction, a database maintained by WHO was used to identify all countries that had introduced PCV7 by August 2008. This information was supplemented with data from other public and private sources, including the GAVI Alliance, vaccine manufacturers, and country press releases. Countries were characterized by their economic status using World Bank income classifications based on gross national income per capita. Countries also were categorized using three mortality or disease prevalence characteristics: (1) whether the country had a mortality rate >50 per 1,000 live births among children aged <5 years (one of the WHO PCV introduction criteria); (2) whether the prevalence of HIV infection in the country was >1% among adults aged 15-49 years, an indication of high HIV prevalence (another WHO PCV introduction criterion); and (3) whether >10% of deaths among children aged <5 years were attributed to pneumonia, an indicator of likely high childhood mortality from pneumococcal disease. Mortality data were obtained from the most recent statistics (from 2006) reported to the WHO Statistical Information System.† HIV prevalence data were obtained from the most recent statistics (from 2007) reported to UNAIDS.†

PCV7 was first introduced in 2000 in the United States. As of August 2008, PCV7 had been licensed in approximately 90 of 193 WHO member states. The vaccine had been introduced into the national childhood immunization programs as a vaccine for all children or was in widespread use in 26 (13%) member states.† The 26 countries included Australia, New Zealand, South Korea, and countries in Europe (15), the Americas (four), and the Middle East (four). Of these 26 countries, 18 have introduced the vaccine since 2006. Twenty-four of the 26 countries (92%) are high-income countries characterized by low childhood mortality and low prevalence of HIV infection.

Of the 72 countries that are eligible for funding from the GAVI Alliance
for PCV introduction, 59 (82%) have a mortality rate of >50 per 1,000 live births among children aged <5 years, 35 (49%) have >1% prevalence of HIV infection among adults aged 15-49 years, and 66 (92%) have >10% of deaths in children aged <5 years attributed to pneumonia. However, none of these countries had introduced PCV as of August 2008. During 2007-2008, GAVI received applications from 11 eligible countries; of these, eight countries (Central African Republic, Democratic Republic of Congo, Gambia, Guyana, Honduras, Kenya, Nicaragua, and Rwanda) have been approved for introduction of PCV into national immunization programs but have not yet introduced the vaccine.

**CDC Editorial Note:** This report indicates that, although progress is being made to introduce PCV globally, only 26 of 193 (14%) WHO member states have introduced PCV7 into their national immunization programs for all children or have PCV in widespread use, and these countries are primarily high-income countries with relatively few childhood deaths attributable to pneumococcal disease. Increasing the use of PCV worldwide, especially in the poorest countries, can make a substantial contribution toward achieving United Nations Millennium Development Goal 4, which seeks to reduce child mortality among children aged <5 years by two thirds by 2015.8 The global use of PCV will help prevent an estimated 5.4-7.7 million deaths among children by 2030.† The use of PCVs has been shown to be cost effective in preventing childhood mortality in GAVI-eligible countries.7

In 2003, the GAVI Alliance created the Pneumococcal Vaccines Accelerated Development and Introduction Plan (PneumoADIP) to work with GAVI-eligible countries to prove evidence of disease burden and vaccine effectiveness, to support evidence-driven policy-making, and to ensure a sustainable, affordable supply of vaccine. The decision of the GAVI Alliance in 2006 to support introduction of PCV in eligible countries was based on evidence generated by PneumoADIP and WHO.

To complement the financial support of the GAVI Alliance, a new mechanism called the Advanced Market Commitment (AMC) has been created. AMC is a binding contract offered by countries and private donors that guarantees vaccine makers a viable market for next-generation PCVs and ensures a sustainable and affordable supply of these vaccines for low-income countries. AMC offers access to nearly $1.5 billion in vaccine financing for the next 7-10 years. During this period, GAVI-eligible countries will be expected to pay a small co-payment for each dose of PCV (currently <$0.30 per dose), and under the terms of AMC, they are guaranteed a predictable, low price and access to supplies for up to 10 years after AMC funding is depleted.

Other challenges to PCV7 introduction in low-income countries include the logistics necessary to facilitate safe delivery of the vaccine. Vaccines other than PCV used in low-income countries are generally supplied in multidose vials that minimize cold-chain storage and transport volume. Current and planned PCVs require increases in cold-chain storage and transport capacity. In addition, PCV7 is available only in single-dose, prefilled glass syringes that are not automatically disabled, which leads to increased waste disposal and safety concerns associated with the potential reuse of syringes and needles.8

In countries introducing PCV, surveillance for diseases caused by pneumococcus is important to document the impact of vaccination on the burden of disease and on transmission patterns, including changes in the prevalence of pneumococcal serotypes. However, as noted in the WHO position statement on PCV, a country’s inability to conduct such surveillance should not be a barrier to introducing PCV. Although health officials in all countries should strive to build the capacity to conduct high-quality surveillance, this information might be most useful to the first countries to introduce the vaccine or those areas with special populations of interest (e.g., where a high prevalence of HIV infection exists).5

The slow introduction of hepatitis B vaccine worldwide, which occurred over a 20-year period, prompted recognition that financial and technical support are needed to facilitate more rapid introduction of new and underutilized vaccines.9 Similarly, nearly 2 decades after *Haemophilus influenzae* type b (Hib) conjugate vaccine became available, it remained underutilized among low-income countries. Beginning in 2005, the convergence of several factors facilitated introduction of Hib vaccine into GAVI-eligible countries; these factors included funding from the GAVI Alliance, technical support from WHO and its partners, a recommendation from WHO for global vaccination, and a guaranteed supply of vaccine.10 Several of these factors are now in place for the introduction of PCV. Additional strategies need to be developed to support introduction of PCV among middle-income, non-GAVI-eligible countries where donor support is lacking.

**REFERENCES**

10 Available.

†Four of the 193 WHO member states for which gross national income data were not reported (the Cook Islands, Nauru, Niue, and Tuvalu) were excluded from the income analysis.

†Available at http://www.who.int/whosis.

