Pneumococcus

Program Management

Although infection with pneumococci accounts for a substantial proportion of the estimated 2 million deaths from pneumonia occurring in children, the use of pneumococcal vaccine should be seen as complementary to the use of other pneumonia-control measures, including appropriate case management and the reduction of exposure to known risk factors, such as indoor pollutants, tobacco smoke, premature weaning and nutritional deficiencies.

Vaccine Handling

(PCV-7) does not tolerate freezing and should be stored at 2-8 °C.

The only currently licensed pneumococcal conjugate vaccine, a 7-valent vaccine produced by Wyeth, is formulated with aluminum adjuvant, is a liquid, and should be protected from freezing as for other aluminum adjuvanted vaccines. For long term storage it should be stored at 2-8°C.
**Pneumococcus**

### Schedule

Consistent with WHO’s position on new vaccines, PCV-7 (7-serotype conjugate pneumococcal vaccine) can be easily integrated into routine vaccination schedules, and it may be administered at the same time, though at a different site, as other vaccines in infant immunization programmes, including DTP, hepatitis B, Hib and polio vaccines. Routine immunization with PCV-7 should be initiated before the age of 6 months to maximize the benefits of the vaccine and may start as early as 6 weeks of age.

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

Clinical efficacy has been demonstrated in 2 schedules (for PCV-7, the 7-serotype conjugate pneumococcal vaccine): a 6-week, 10-week, 14-week schedule and a 2-month, 4-month, 6-month schedule, which was followed by a booster dose at 12-15 months of age. Further information on the cost effectiveness of other potential schedules (for example, using different numbers of doses or different intervals between doses, and with and without boosters) should be obtained. Other schedules (such as 2 doses in a primary series plus a booster dose) are being used in some countries, whose experiences may be important as GAVI-supported countries begin introducing PCV-7 or review its use. Although a late dose (around the first birthday) may be challenging operationally for GAVI-eligible countries, there may be suitable opportunities when a dose of PCV-7 could be given, such as at the same time as measles vaccination. Countries should evaluate this information once it is available and select the most appropriate schedule based on the anticipated impact, cost effectiveness and programmatic feasibility.

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

The 23-valent (pneumococcal) vaccine is primarily designed for use in older children and adults who are at high risk for pneumococcal disease. It is not licensed for use in children aged <2 years.

Pneumococcal conjugate vaccine for childhood immunization (WHO position paper)

27 June 2008
PCV-7 (7-valent polysaccharide–protein conjugate pneumococcal) vaccine is highly immunogenic in all age groups, but it is currently licensed for use only in children aged <5 years, including infants aged <12 months.

Trials in several developing countries have demonstrated the efficacy of a 3-dose schedule for infants without a subsequent booster dose. This schedule is compatible with the schedules of national immunization programmes in many developing countries. The benefit of administering an additional dose in the second year of life requires further investigation in these settings. Similarly, consideration of alternative PCV-7 vaccination schedules - including delaying the administration of a third dose so it may be given along with measles vaccination or in the second year of life - should be guided by future research findings.

When the vaccine is first introduced into routine childhood immunization programmes a single catch-up dose of PCV-7 may be given to previously unvaccinated children aged 12-24 months and to children aged 2-5 years who are at high risk.

When PCV-7 is first introduced into routine childhood immunization programmes, maximum individual and community-level protection can be achieved by also providing a single catch-up dose of the vaccine to previously unvaccinated children who are aged 12-24 months and to children aged 2-5 years who are considered to be at high risk.
The primary series of PCV-7 consists of 3 intramuscular doses administered to infants at intervals of at least 4 weeks, starting at the age of 6 weeks or later.

Vaccination at the age of 6 weeks, 10 weeks and 14 weeks in infants in developing countries is as immunogenic as vaccination at 2 months, 4 months and 6 months in industrialized countries. A booster dose administered after 12 months of age may improve the immune response and may especially affect pneumococcal nasopharyngeal carriage. Some industrialized countries have adopted a schedule based on delivering 2 doses during infancy (for example, at 2 months and 4 months) and a third dose at 12-13 months.

To maximize the benefits of the vaccine, routine immunization with PCV-7 should be initiated before 6 months of age and may start as early as 6 weeks of age.

There are 2 schedules that have proven clinical efficacy: a 6 week–10 week–14 week series and a 2 month–4 month–6 month series; this latter series is followed by a booster dose at 12–15 months of age.

Countries should evaluate information on impact and scheduling once it is available and select the most appropriate schedule based on anticipated impact, cost effectiveness and programmatic feasibility.

The polyvalent PS (polysaccharide) vaccine (against Streptococcus pneumoniae) is recommended for healthy people over 65 years of age, particularly those living in institutions. Randomized controlled trials in healthy elderly people in industrialized countries have, however, failed to show a beneficial effect of the vaccine, so that recommendation for its use in the elderly is based on data from observational studies showing a significant protective effect against invasive (bacteraemic) pneumococcal disease, but not pneumonia.
(P)oor immunogenicity of polysaccharide (pneumococcal) vaccines in early childhood precludes the use of the 23-valent pneumococcal vaccine in the high-risk group of children under 2 years of age.

The duration of protection following immunization with the 23-valent polysaccharide vaccine is estimated at 5 years, or more, in healthy adults. However, the duration may be considerably shorter in some high-risk groups for pneumococcal disease. Revaccination using the polysaccharide vaccine is not routinely recommended.

A single dose of the 23-valent polysaccharide vaccine is recommended for selected groups above 2 years of age at increased risk of pneumococcal disease. These groups include the healthy elderly (over 65 years of age), particularly those living in institutions.

The polyvalent polysaccharide vaccine is recommended for selected groups above 2 years of age with increased risk of pneumococcal disease. Such groups include the healthy elderly (over 65 years old), particularly those living in institutions, patients suffering from chronic organ failure, diabetes, nephrotic syndrome and certain immunodeficiencies, particularly those with functional or anatomical asplenia.

Recent meta-analyses on the efficacy and effectiveness of the pneumococcal polysaccharide vaccine have raised doubts about the benefit of the vaccine in the elderly population. However, these vaccines continue to be recommended for this group based on evidence from observational studies that show a beneficial effect against pneumococcal disease associated with bacteraemia.
Pneumococcus

Vaccine Administration

Consistent with WHO’s position on new vaccines, PCV-7 (7-serotype conjugate pneumococcal vaccine) can be easily integrated into routine vaccination schedules, and it may be administered at the same time, though at a different site, as other vaccines in infant immunization programmes, including DTP, hepatitis B, Hib and polio vaccines. Routine immunization with PCV-7 should be initiated before the age of 6 months to maximize the benefits of the vaccine and may start as early as 6 weeks of age.

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

PCV-7 should not be mixed in the same syringe with other vaccines.

The vaccine may be administered concomitantly with other vaccines in the Expanded Programme on Immunization provided that separate syringes and sites of injection are used.

(Page 103) - (PCV-7) may be administered concurrently with, though at a different site from, other vaccines in infant immunization programmes, including DTP, hepatitis B, H. influenzae type b and polio vaccines.

Contraindications

The only contraindication to PCV-7 immunization is a severe hypersensitivity reaction to a previous dose of the vaccine.
**Pneumococcus**

There are no absolute contraindications to vaccination with pneumococcal polysaccharide vaccine except for an anaphylactic reaction to the previous dose.

_Pneumococcal vaccines (WHO position paper)_

**Surveillance of Vaccine Preventable Disease**

Countrieres are encouraged to conduct appropriate surveillance for pneumococcal invasive disease in order to establish a baseline and to monitor the impact of vaccination, including the occurrence and magnitude of replacement disease.

_Consclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006_
**Pneumococcus**

Countries are encouraged to conduct appropriate surveillance for pneumococcal disease in order to establish a baseline measurement of disease and to monitor the impact of vaccination. This is particularly important in those developing countries that will be among the first to introduce the vaccine and in countries with a high prevalence of HIV infection or other conditions known to increase the risk of pneumococcal disease.

Changes in the incidence of disease due to non-vaccine serotypes after vaccine introduction need to be evaluated carefully to determine whether they are attributable to the vaccine or to natural temporal changes in serotypes. The replacement phenomenon should be carefully monitored especially in developing countries that have higher rates of nasopharyngeal carriage and disease burden.

**Research**

Clinical efficacy has been demonstrated in 2 schedules (for PCV-7, the 7-serotype conjugate pneumococcal vaccine): a 6-week, 10-week, 14-week schedule and a 2-month, 4-month, 6-month schedule, which was followed by a booster dose at 12-15 months of age. Further information on the cost effectiveness of other potential schedules (for example, using different numbers of doses or different intervals between doses, and with and without boosters) should be obtained. Other schedules (such as 2 doses in a primary series plus a booster dose) are being used in some countries, whose experiences may be important as GAVI-supported countries begin introducing PCV-7 or review its use. Although a late dose (around the first birthday) may be challenging operationally for GAVI-eligible countries, there may be suitable opportunities when a dose of PCV-7 could be given, such as at the same time as measles vaccination. Countries should evaluate this information once it is available and select the most appropriate schedule based on the anticipated impact, cost effectiveness and programmatic feasibility.
Introduction of Vaccines

SAGE considers that including pneumococcal conjugate vaccine in national immunization programmes should be a priority and supports the introduction of the currently licensed PCV-7 vaccine. This recommendation is based on epidemiological data and vaccine-impact data from a number of different settings.

Countries with mortality among children under the age of 5 years of >50 deaths/1000 births, or with >50,000 annual deaths among children, should make the introduction of PCV-7 a high priority for their immunization programmes.

The incidence of preventable disease (that is, the product of the proportion of severe disease caused by vaccine serotypes and the rate of pneumococcal disease) should be used to anticipate the likely impact of pneumococcal conjugate vaccine. Where country-specific estimates of the incidence of preventable pneumococcal disease are not available, they may be approximated using data from epidemiologically similar populations.

The burden of pneumococcal disease is substantially higher among individuals infected with HIV. Since pneumococcal conjugate vaccines have been shown to be safe and efficacious in HIV-infected children, SAGE recommends introducing PCV-7 in countries where HIV is a significant cause of mortality and it encourages evaluation of the impact of vaccination among the HIV-infected population.

Populations with a high prevalence of other underlying conditions that increase the risk of pneumococcal disease, such as sickle-cell disease, should also be targeted for vaccination.
The risk of serious pneumococcal disease remains high throughout childhood. When vaccine is introduced, maximum individual protection and community-level protection can be achieved by also vaccinating children aged 1 year to 5 years with a single dose. Countries should determine the feasibility of reaching such children and, where possible, implement strategies for vaccinating this population within the first year of vaccine introduction.

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

When other formulations of pneumococcal vaccine that are appropriate for infant immunization become available, countries using PCV-7 should assess the value of switching to one of these formulations.

Recognizing the heavy burden of pneumococcal disease occurring in young children and the safety and efficacy of PCV-7 in this age group, WHO considers that it should be a priority to include this vaccine in national immunization programmes, particularly in countries where mortality among children aged <5 years is >50/1000 live births or where >50 000 children die annually.

WHO considers that pneumococcal conjugate vaccine should be a priority for inclusion in national childhood immunization programmes. Countries with mortality among children aged <5 years of >50 deaths/1000 births or with more than 50 000 children’s deaths annually should make the introduction of PCV-7 a high priority for their immunization programmes.
The burden of pneumococcal disease is substantially higher among individuals who are infected with HIV. Since pneumococcal conjugate vaccines have been shown to be safe and efficacious when used in children infected with HIV, WHO recommends that countries with a high prevalence of HIV prioritize the introduction of PCV-7. Furthermore, populations with a high prevalence of other underlying conditions that increase the risk of pneumococcal disease, such as sickle-cell disease, should also be targeted for vaccination.

Once pneumococcal vaccines offering broader serotype coverage become available, countries using PCV-7 should assess whether it would be helpful to switch to these vaccines. This assessment should be based on the distribution of serotypes causing invasive pneumococcal disease in the affected population and the likely additional benefit to be gained from broadening the spectrum of vaccine serotypes. The introduction of pneumococcal conjugate vaccines with broader coverage will be facilitated if PCV-7 is already in use.