Two-dose measles vaccination schedules

S.R. Rosenthal\(^1\) & C.J. Clements\(^2\)

As measles continues to exact a high toll on infant mortality, particularly in developing countries, optimal strategies for the control of the disease are under discussion. As part of this debate, the place of 2-dose measles immunization schedules is reviewed regarding their potential as a strategy to improve measles control. To date, WHO has not recommended the use of a 2-dose schedule.

A number of industrialized countries have already adopted a 2-dose schedule, often choosing to administer measles vaccine in the same injection as mumps and rubella vaccines. However, at present not enough is known about such schedules in developing countries to make global recommendations. Further research should include randomized controlled trials of early 2-dose schedules to investigate both technical and epidemiological issues such as the effect of blunting immunity and the duration of antibody. Long-term safety should be determined through studies of adequate size. Programmes already using 2-dose schedules are encouraged to evaluate their impact on disease incidence, cost, vaccine usage, and effect on coverage.

Until further evaluation is complete, a high and timely coverage with one dose of measles vaccine in all areas remains the first priority for all immunization programmes.

Introduction

Since 1981, WHO’s Expanded Programme on Immunization (EPI) has recommended a single dose of measles vaccine at 9 months of age in countries where measles is a problem in the first year of life (1). Nine months was chosen as a compromise age between ensuring vaccine efficacy and preventing early measles cases (2). Vaccinating earlier than 9 months resulted in decreased vaccine efficacy owing to interference from passively acquired maternal antibody. Vaccinating later than 9 months was associated with higher vaccine efficacy, but resulted in many measles cases among children before they reached the age of vaccination. Based on data available to WHO as of April 1992, worldwide coverage of children with a single dose of measles vaccine before 1 year was 80%. With this level of coverage, WHO estimates that more than 89 million cases of measles and 1.6 million measles-associated deaths were prevented in 1991. However, an estimated 41 million cases of measles and 1 million measles-associated deaths occurred globally in 1991. Even in countries that have achieved high measles immunization coverage with one dose at 9 months, measles may occur among unimmunized persons and among those in whom the vaccine was ineffective.

Even with global coverage of measles vaccine around 80%, there remain many communities, districts and countries where immunization coverage is considerably lower. In these locations, WHO recommends that coverage for a single dose of measles vaccine be raised as quickly as possible to above the 80% level. This is the first priority for administration of measles vaccine in immunization programmes.

Driven by continuing high measles morbidity and mortality, in 1990, the World Health Assembly and the World Summit for Children adopted targets for very high levels of measles control. The summit declaration called for “a reduction by ninety-five per cent in measles deaths and a reduction by ninety percent in measles cases compared to pre-vaccination levels by 1995, as a major step to the global eradication of measles in the longer run.”\(^a\) Achieving these ambitious goals may require additional or alternative measles control strategies, such as campaign approaches or 2-dose schedules.

A major concern is the continued occurrence of measles cases in infants less than 9 months of age, particularly in densely populated African cities. Because measles case fatality rates are highest in the first year of life, and few cases occur before 6

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months of age, development of vaccines that are highly effective at 6 months of age is a high priority. In 1989, WHO recommended the use of high titre Edmonston-Zagreb (EZ) vaccine in such high-transmission settings (3); however, recent studies have suggested reduced survival in children receiving high-titre measles vaccines. As a result, high titre measles vaccines are no longer recommended for use in immunization programmes, requiring renewed efforts to obtain the best results from currently available vaccines (4).

It is anticipated that high coverage with a single dose of measles vaccine will produce a dramatic reduction in cases and deaths due to measles. High coverage levels (greater than 90%) have been shown in some countries to result in a 90% or greater reduction in disease incidence. The degree of impact depends on such variables as population density, vaccine efficacy under field use, and the distribution in the population of unimmunized individuals. EPI recognizes that there is no immunization schedule which is ideal for all situations, but each country should determine its own schedule to best fit its own needs.²

An alternative method for preventing early measles cases and later vaccine failures may be to give two doses of measles vaccine. Some early cases may be prevented by a dose of vaccine given at approximately 6 months of age. Vaccine failures would be reduced by a second dose given at approximately 12 months of age or later, when vaccine efficacy is higher. With the adoption of ambitious dis-


Alternative immunization schedules

Countries already using additional doses

Many countries routinely use more than one dose of measles vaccine in their immunization schedules (Table 1). Developing countries that use routine 2-dose schedules usually give the first dose early in life (6–9 months) and the second dose after maternal antibody has substantially waned (after 12 months) (Table 2). This schedule is intended to prevent cases in young infants and provide a high rate of protection in older children.

The USA and several countries in northern Europe have a policy for routine 2-dose measles schedules. These countries typically give the first dose at 12–18 months of age, and the second dose at school entry.

Regional and national elimination targets in developing countries are providing an opportunity to examine other vaccine delivery strategies using additional or later doses of measles vaccine. Brazil, Chile, Cuba, the English-speaking Caribbean, and Suriname have recently set measles elimination targets, and have given a dose of measles vaccine to all children aged 1–15 years during a mass campaign, regardless of prior immunization status. While these

<table>
<thead>
<tr>
<th>Table 1: Countries with routine immunization schedules which include more than one dose of measles vaccine, by WHO region</th>
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<tbody>
<tr>
<td>Africa</td>
</tr>
<tr>
<td>Lesotho</td>
</tr>
<tr>
<td>Cuba</td>
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<tr>
<td>USA</td>
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<td>Saudi Arabia</td>
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Table 2: Timing of measles vaccination in selected countries using routine 2-dose immunization schedules

<table>
<thead>
<tr>
<th>Country</th>
<th>First dose</th>
<th>Second dose</th>
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<tbody>
<tr>
<td>Bahrain</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>China</td>
<td>8</td>
<td>7 years</td>
</tr>
<tr>
<td>Iran</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>Lesotho</td>
<td>9</td>
<td>18</td>
</tr>
<tr>
<td>Maldives</td>
<td>9</td>
<td>4 years</td>
</tr>
<tr>
<td>Mongolia</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>Papua New Guinea</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Qatar</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>Saudi Arabia</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>Tunisia</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>United Arab Emirates</td>
<td>9</td>
<td>15</td>
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</tbody>
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Early 2-dose measles schedules

The optimal ages of administration of two doses of measles vaccine depend on both the local epidemiology of measles, and specific programme goals. Early 2-dose measles schedules may be more applicable for areas with high transmission rates in young infants. Typically, the first dose would be given at the age when infants first became susceptible, usually at 9 months, and the second dose 3–6 months later when maternal antibody has waned (Table 2). These 2-dose schedules are intended to serve two purposes:

— the first dose would be targeted to prevent measles cases and deaths that occur prior to the recommended age of immunization for 1-dose measles schedules;

— the second dose would be given at a time when maternal antibody had waned, thus decreasing the number of children who experience vaccine failure.

Since 1988, EPI has recommended an early 2-dose measles vaccine schedule for certain high-risk group where measles morbidity and mortality are high (5). These groups include infants in refugee camps, infants admitted to hospital, and those affected by disasters. In these situations, EPI has recommended that the minimum age for immunization may be lowered to 6 months, with the second dose of measles vaccine given as soon as possible after the child reaches 9 months of age, thereby reducing vaccine failures. Little information is available on evaluating early 2-dose schedules in these special situations, and WHO is at present not able to make any general policy recommendation in this special situation.

Two-dose schedules beginning between 6 and 9 months would be aimed primarily at protecting young infants and would potentially be most useful in countries with high age-specific attack rates in this age group. Little information is available to date, however, on the evaluation of such early 2-dose schedules.

Remme et al. (6) described how developing countries are likely to continue experiencing high attack rates in children below one year of age. They calculated age-specific attack rates in Kenya and in England and Wales prior to immunization programmes. For England and Wales during the period 1956–69 the age-specific attack rate was low for young children and increased substantially after one year of age, reaching a peak at school entry. Exposure before 12 months of age was relatively uncommon. In this population, a single dose of vaccine given at one year of age would protect infants throughout the period of high exposure.

In contrast, the age-specific attack rates in Kenya during the years 1976–82 were constant across all age groups. Young infants in Kenya had age-specific attack rates as high as schoolchildren in England and Wales. This was attributed by Remme to social and cultural characteristics of African communities where there are high birth rates and high contact rates among infants and children. Immunizing at 1 year of age would leave many infants below this age at risk for measles infection. Remme concluded that in high-transmission settings, such as Kenya, the age-specific incidence would always remain highest in the first year of life; even if the mean age should become equal to that for England, because of increased vaccination coverage, the proportion of cases in children less than 1 year of age would still be relatively high.

In some settings high coverage with one dose at 9 months of age may induce sufficient herd immunity to protect younger infants. However, despite moderate to high coverage with one dose of measles vaccine of children aged 9 months and older, infection in infants below 9 months remains a problem in some areas (7, 8). c d It is not yet clear whether coverage of 90% or more would interrupt transmission and

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provide herd protection for infants below 9 months of age in these settings. Nor is it clear whether that level of coverage could be achieved and sustained.

**Late 2-dose schedules**

Typically, the first dose of a late 2-dose schedule is given at 9–15 months of age and the second dose at school entry. Such 2-dose schedules are aimed at preventing cases in older vaccinated children not protected by the first dose (primary vaccine failure) or whose immunity has waned (secondary vaccine failure). There are only two reasons why older children remain susceptible to measles: failure to have been vaccinated and vaccine failure. As measles vaccine coverage rates increase, a greater percentage of susceptible persons will be unprotected because of vaccine failures rather than because they are not vaccinated. As an example, if vaccination coverage in all age groups was 100%, all cases would be due to vaccine failure. These cases could not be prevented using a 1-dose strategy. These late 2-dose schedules may be more appropriate for industrialized countries with good immunization coverage and where measles virus transmission among young infants is limited.

**Mathematical models of 2-dose schedules**

Several attempts have been made to model the effects of 2-dose measles schedules. All these models suggest a large benefit from 2-dose schedules. Hethcote suggested that when a measles vaccine has an efficacy of 95%, and coverage is more than 98%, one dose would be capable of interrupting transmission (9). When vaccine efficacy is lower than 93% (WHO assumes vaccine efficacy is 85% when given at 9 months of age), transmission could not be interrupted even with 100% coverage. With two doses (at 1 and 5 years of age), Hethcote predicted that coverage rates of 84% for the first dose and 80% for the second dose would be required to interrupt measles transmission. Nokes et al. (10) modeled doses given at 6 and 9 months of age. They predicted that such a policy would be of particular benefit to those populations with high rates of early measles cases. Markowitz & Orenstein showed that the elimination of measles in the USA was possible using a 2-dose schedule with lower levels of vaccine coverage than was currently being achieved with a 1-dose schedule (11).

One limitation of these models is the lack of information on the return rates for the second dose. For simplicity, return rates in these models have been assumed to be either entirely independent or entirely dependent on receiving the first dose. In reality, those receiving the "second" dose are likely to be a mixture of previously vaccinated and unvaccinated persons.

A linear model can attempt to account for the effects of age of vaccination on return rates and vaccine efficacy (Fig. 1). In this model, the first dose is given at 6 months of age (with 65% efficacy) and the second after 12 months of age (with 95% efficacy). The protection with the 2-dose schedule is compared with the protection induced by one dose given at 9 months of age (with 85% efficacy). After receiving the six-month dose, infants return for the twelve-month dose at a rate that is 90% of the underlying coverage rate. Those who did not receive a dose at 6 months return at a rate that is 50% of the underlying coverage rate.

The substantial benefit from 2-dose schedules predicted by previous models is also evident in the present model. It suggests that the increased benefit compared with a 1-dose schedule is greatest at moderate levels of coverage (40–70%); less benefit results at very low or very high levels of coverage. The protection from 100% coverage with one dose is comparable to 65% coverage with two doses. The global rate of coverage for one dose of measles vaccine is 80% which corresponds to a 68% rate of protection. With coverage of 80% for two doses, protection would be 92% which exceeds the 1995 target of 90%. The applicability of such modelling to field situations is not clear.

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**Fig. 1. Protection from 1- and 2-dose measles vaccination schedules.** Calculation of the percentage protection is based on the vaccine efficacy at age 6 months (65%), 9 months (85%) and 12 months (95%), the coverage rate, and the proportion of children unvaccinated by the first dose (or in whom the vaccine failed) who were vaccinated at the second immunization.
Use of 2-dose schedules in developing countries

Early experience. In 1978, three African countries, Kenya, Côte d'Ivoire, and Zaire instituted early 2-dose schedules (12–14). A first dose of measles vaccine was given at 6 months of age with a second dose at or after 9 months. However, of those children who received a first dose before 9 months of age, only 3–33% returned for a second dose. Because of these low return rates, 2-dose strategies were abandoned so as to concentrate on achieving high immunization coverage rates with one dose at 9 months. In countries with poor immunization services and weak health infrastructures, achieving high coverage with one dose of measles vaccine must remain the first priority.

Recent experience. With the continued development of EPI, some of the obstacles that existed in implementing 2-dose schedules in the 1970s may not exist in many countries today. For instance since 1985, a 2-dose schedule has been used in Tunisia where the immunization programme has a good infrastructure, well-trained staff, and a substantial degree of decentralization. The first dose is scheduled between 9 and 12 months of age. If a child receives the first dose during this period, he then receives a second dose 6 months later. If the first dose is given after 12 months of age, then a second dose is not given. In 1990, coverage for the first dose of measles vaccine in infants aged 9 to 12 months was 83%. Among those who received the first dose at this age, 96% received a second dose after the age of 12 months. Among those who did not receive the first dose at 9–12 months of age, 68% received a dose of measles vaccine at age 15–18 months. Overall, 80% received two doses and 91% received either two doses as recommended or one dose at 15–18 months of age.

In the United Arab Emirates a 2-dose schedule was instituted in 1985: the first dose of measles vaccine at 9 months of age, and a dose of measles, mumps and rubella (MMR) vaccine 6 months later. In 1991, coverage was estimated at 81% for the first dose, and 69% for the second.

These experiences suggest that countries with high immunization coverage and well-managed immunization programmes can successfully implement and sustain 2-dose measles schedules. However, the impact on disease by changing to a 2-dose strategy has not yet been evaluated adequately.

Efficacy

There have been no field trials evaluating the clinical efficacy of 2-dose measles schedules in developing countries. Several studies suggest that those infants who received measles immunization early in life have a lower antibody response to a subsequent dose of measles vaccine than those who were first immunized after the age of 12 months (15). It has been suggested that the presence of passively acquired antibody can interfere with a good response to the first dose. This may then result in a blunted antibody response to later doses given after maternal antibody has waned (16–19). Because measles protection is dependent on antibody levels and cell-mediated immunity, the clinical significance of blunted antibody response is not known.

High protection of infants younger than 9 months was demonstrated in Malawi refugee camps where the age of measles vaccination was lowered to 6 months with a second dose given after 9 months. Clinical vaccine efficacy in children aged 6 to 9 months was 93% during a measles outbreak (20). A second dose of measles vaccine for the Malawi refugees would probably also have benefited older children who were not immunized or were vaccine failures. In a study of an outbreak that occurred in the USA among children first immunized below 1 year of age, measles occurred in 36% of 55 infants who had not been revaccinated, but in none of 49 infants who had been revaccinated after 1 year of age (21).

Impact on vaccine supply

Two-dose schedules are likely to cost more than 1-dose schedules. However, the proportion of increase will be variable and indications are it would be less than double. The increased demand for vaccine would vary based on local demographics, coverage, size of vaccine vials used, and strategy for administration. Various options for administering vaccine include routine daily, weekly or monthly immunization sessions, mass campaigns, and immunizing at every contact to minimize missed opportunities, all of which have implications for vaccine wastage.

For a programme considering changing from a 1- to a 2-dose measles schedule, the following two examples illustrate the potential impact on vaccine needs.

(1) If a health clinic has a small number of children (less than 20) attending each immunization session, then a 1-dose measles schedule would mean that roughly one-fifth of attendees (1 to 4 children) would be present for the 9-months measles immunization. One 10-dose measles vial would be opened and 1 to 4 doses would be used to immunize these children. The unused doses remaining in the vial would be thrown away at the end of the session. If

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† Data from the Ministry of Health, United Arab Emirates, 1991.
the schedule is changed to two doses, then roughly twice as many children (2 to 8) would attend each session for a first or second dose and still one vial would be sufficient, with less wastage.

(2) In a clinic where large numbers of children (greater than 35) are attending each immunization session with a 1-dose schedule, then roughly 7 or more would receive the measles vaccine with low initial wastage. With a 2-dose schedule and about 14 children attending, the second dose of measles vaccine would not reduce the wastage. Depending on the number of children at each session, roughly 1.5 to 2 times the number of vaccine vials would be used up.

The vaccine requirements of clinics in Lesotho, which recently implemented a 2-dose measles schedule, appear to conform to the hypothesis described above.7 Health centres which had small numbers of children attending each session (because of small catchment populations and/or daily immunization sessions) found that they did not have to open any more measles vials during a session. While formerly they had experienced wastage rates of 70–80% with a 1-dose schedule, the second dose reduced this wastage. Health centers with large catchment populations and/or less frequent immunization sessions had more children attending each session; there was lower vaccine wastage even when the 2-dose schedule required more vials to be opened for giving the second dose.

In Lesotho, equipment for the cold chain and transportation, as well as fuel for sterilization, needles, syringes, and manpower hours needed were examined both before and after implementation of the 2-dose schedule. Health workers did not identify any increased need for equipment. Some clinics had required an upgrade from single-rack to double-rack sterilizers because of the increased needle/syringe usage. Existing cold-chain volume capacity in Lesotho was sufficient to accommodate the 2-dose measles vaccine schedule. It was estimated that even by doubling the amount of measles vaccine, the present cold-chain storage capacity in most countries would not be exceeded (Fig. 2).

**Incorporating 2-dose schedules into EPI**

In Lesotho, provision of an additional dose of measles vaccine did not result in the need for an additional immunization contact. However, many of the schedules shown in Table 2 would need amending if a second dose of measles vaccine were added.

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The most appropriate way of incorporating the second dose would depend on the specific local epidemiology of measles and the needs of the immunization programme. For example, high coverage using a 6- and 12-months schedule may have the advantage of preventing early measles deaths and may more easily achieve the 1995 measles case-reduction target; however, this schedule has the disadvantage of shifting one immunization contact and adding an additional one which is not already in the EPI schedule. A rational decision on which schedule a country should choose would depend on such considerations as the age at which measles cases are occurring, programme goals, logistics, training and management.

Separate strategies for urban and rural measles control have been proposed (22), the 2-dose schedule being adopted only in urban areas. If effective, the latter could reduce the measles virus reservoir in the cities and have a substantial impact in reducing the spread to rural areas.

Two-dose measles schedules could predictably contribute to further reducing the incidence of other EPI target diseases by allowing additional contacts for OPV and DPT supplemental or booster dose administration. The additional contact needed for a 2-dose schedule might usefully serve to administer other vaccines or other primary health care services such as micronutrient supplementation.

**Further research needs**

It is not clear at present whether 2-dose schedules have an advantage in developing countries over high coverage with one dose of measles vaccine at
Two-dose measles vaccination schedules

9 months of age. Research into this aspect is fraught with potential problems. Demonstration projects attempting to evaluate 2-dose schedules may record higher coverage and lower mortality by virtue of intense activity brought about by the researchers. Randomized controlled trials, while harder to conduct and more expensive than pilot projects, may be the only sound way to evaluate 2-dose schedules. Demonstration projects may only be able to address operational issues relating to the introduction of a second dose. Case-control trials will be needed to address technical and epidemiological issues such as efficacy, effect of blunting immunity, and duration of antibody. Long-term safety of two doses will need to be assessed through studies of adequate size.

Programmes already using 2-dose schedules should be encouraged to evaluate them for impact on the disease, cost, vaccine usage, and effect on coverage. Two important studies on safety and efficacy were proposed by Halsey in 1983 (23). The first study would attempt to evaluate the serological response and possible adverse effects of an early 2-dose schedule. Children in developing countries would be randomized to receive either measles vaccine in a single dose at 9 months of age or two doses at 6 and 9 months of age. Serological assessment by neutralization assay would be done in both groups prior to each immunization, at 4 to 6 weeks after each immunization, and at 2 years of age.

The second study suggested by Halsey was a field trial comparing an early 2-dose schedule with the currently recommended schedule of one dose at 9 months. These studies should be carried out in areas where measles attack rates are high in the first two years of life. Randomized controlled trials of adequate size will be needed to evaluate long-term safety, duration of antibody, and clinical efficacy.

Neither of these studies has been attempted since they were first proposed. Following studies in the USA in the early 1980s, Stetler et al. (15) suggested that serological studies of early immunization with the standard titre vaccine were unlikely to provide meaningful new information on efficacy, and more data on clinical protection were needed. In developing countries, studies of early 2-dose schedules were deemed less important following the initial reports of success of early immunization with one dose of the high titre Edmonston-Zagreb strain (14). With the withdrawal of WHO support for high titre vaccines (4), studies of the efficacy of 2-dose schedules should again be given high priority.

The third area of research is to identify the operational issues related to introducing 2-dose schedules. Among the important operational considerations are the drop-out rates between the two doses of measles vaccine, effect on coverage, cost, and vaccine usage. These can best be evaluated by a demonstration project in an area with high transmission rates such as in an urban setting in Africa.

Evaluation. WHO does not routinely collect reports on coverage with the second dose of measles vaccine in those countries that have implemented 2-dose schedules. Evaluation methodology, vaccination cards, reporting formats, and analysis software would need to be adapted and standardized to evaluate existing and future 2-dose schedules. The development of these methods would be an important contribution to the successful implementation of 2-dose schedules.

Acknowledgements

We thank Ms Karin Bergstrom, Mr James Cheyne, Dr Felicity CUTTS, Dr M. Grabowski, Dr Neal Halsey, Dr Robert Kim-Farley, and Dr Susan Robertson for their critiques and helpful suggestions. This work was supported by cooperative agreement DPE-5951-A-00-9033 between United States Agency for International Development, Office of Health and Johns Hopkins University Institute for International Programs (Dr Rosenthal).

Résumé

Schéma de vaccination antirougeoleuse en deux doses

Depuis 1984, le Programme élargi de vaccination (PEV) de l'OMS recommande la vaccination antirougeoleuse en une seule dose à l'âge de 9 mois, dans les pays où la rougeole pose un problème chez les enfants de moins d'un an. Le premier objectif des programmes de vaccination est d'amener la couverture par une dose de vaccin antirougeoleux à 80% ou davantage dans l'ensemble des districts et communautés. Comme il faudra améliorer encore la lutte antirougeoleuse pour atteindre l'objectif de réduction de la rougeole d'ici l'année 1995, il est nécessaire d'envisager de nouveaux moyens d'administration des vaccins antirougeoleux. Ces moyens consistent notamment en campagnes de vaccination et en utilisation de schémas en deux doses. Le présent article examine les connaissances actuelles sur ces schémas, leur application possible sur le terrain, et les recherches qui seraient nécessaires avant que l'on puisse formuler de nouvelles recommandations.

Actuellement, près de 40 pays utilisent plus d'une dose de vaccin antirougeoleux, selon divers protocoles de vaccination. Les schémas "pré-coces" en deux doses sont appliqués dans les
pays où le taux de transmission du virus rougeoleux sauvage est élevé chez les nourrissons de moins de 9 mois. La première dose est administrée à 6–8 mois et la deuxième 3 à 6 mois plus tard. Ces schémas visent à prévenir les cas de rougeole et les décès qui surviennent avant l’âge actuellement recommandé pour la vaccination, et en même temps à diminuer le nombre d’enfants chez qui on observe un échec de la vaccination en raison de la présence d’anticorps maternels antirougeoleux.

Les schémas en deux doses “tardifs” visent à prévenir les cas chez les enfants et les adultes qui deviennent sensibles à la rougeole à la suite d’un échec primaire ou secondaire de la vaccination. La première dose est administrée à l’âge de 9–15 mois et la deuxième dose à l’âge de scolarité. Ces schémas peuvent convenir pour les pays où la transmission du virus rougeoleux sauvage est rare chez les jeunes nourrissons.


Il existe divers autres schémas antirougeoleux en deux doses, mais on manque de données montrant lequel est le plus efficace, ou si ces schémas sont plus efficaces qu’une forte couverture par une seule dose. Le choix du schéma vaccinal reposera sur l’existence de données fiables de surveillance de la maladie, sur les objectifs des programmes et sur les moyens disponibles. Toutefois, avant de pouvoir formuler des recommandations, il est nécessaire de poursuivre l’évaluation des schémas en deux doses.

References