

# WHO position paper on rubella vaccines

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## **Rubella and congenital rubella syndrom**

- Rubella is an acute, viral disease traditionally affecting children and young adults.
- Moderately infectious; incubation period 12–23 d
- The virus is transmitted by the respiratory route, replicates in nasopharynx and local lymph nodes; then spreads by viremia to different organs.
- Although usually a mild self-limited illness, rubella during early pregnancy may result in miscarriage, foetal death or congenital defects known as congenital rubella syndrome (CRS).

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### Congenital rubella syndrom (CRS)

- The period of highest risk of CRS (up to 90% of cases) is from just before conception and during the first 8–10 weeks of gestation.
- Foetal defects are rarely associated with maternal rubella after the 16th week of pregnancy. (Hearing defects up to week 20)
- Serious manifestations of CRS include meningoencephalitis, hepatosplenomegaly, hepatitis, and thrombocytopenia. Surviving infants may face developmental disabilities.

## Incidence of CRS

- Before introduction of rubella vaccine, the incidence of CRS varied from 0.1–0.2 per 1000 live births during endemic periods, and from 0.8–4 per 1000 live births during rubella epidemics.
- Large-scale rubella vaccination during the past decade has drastically reduced or practically eliminated rubella from many countries.

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### Available vaccines

- Most rubella vaccines are based on the live, attenuated RA 27/3 strain.
- Other attenuated rubella-vaccine strains include the Takahashi, Matsuura, TO-336, and BRD-2.
- Rubella-containing vaccines (RCVs) may be monovalent (rubella only) or combinations of rubella and measles vaccines (MR), rubella, measles and mumps (MMR), or rubella, measles, mumps and varicella (MMRV).
- The immune response to rubella antigens is not affected by the other vaccine components.

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## Immunogenicity and effectiveness

- In clinical trials, 95–100% of susceptible persons aged  $\geq 12$  months develop rubella antibodies after a single dose of the vaccine.
- In outbreak situations the effectiveness of different rubella vaccines has been estimated at 90–100%.
- RA 27/3-containing vaccines have eliminated rubella and CRS from the western hemisphere and in European countries with high vaccination coverage.

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### Administration and schedule

- RCVs are administered subcutaneously or intramuscularly, usually at age 12–15 months, but may be administered to children aged  $\geq 9$ –11 months and to older children, adolescents and adults.
- Although one dose of MR or MMR probably induces life-long protection against rubella, in most countries a second dose is offered at 15–18 months or 4–6 years, as indicated for protection against measles and mumps.

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### Adverse reactions

- Adverse reactions following vaccination with RCVs are mild, particularly in children.
- In susceptible adult women, transient arthralgia and arthritis have been reported in about 25% and 12% , respectively.
- No causal link has been demonstrated between RCVs and chronic joint disease, Crohn's disease, ulcerative colitis, or autism.
- No cases of CRS have been reported in more than 1000 susceptible women who unknowingly were vaccinated in early stages of pregnancy.

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## Precautions and contraindications

- Because of a theoretical, but never demonstrated teratogenic risk, rubella vaccination of pregnant women is not recommended, and pregnancies should be avoided for 1 month following rubella vaccination.
- Rubella vaccination is contraindicated for people with a history of an anaphylactic reaction to components of the vaccine and for persons suffering from severe immunodeficiency.

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### Vaccination strategies

- There are two general approaches to the use of rubella vaccine:
- *Strategy I*: Focus is on reducing CRS by immunizing adolescent girls and/or women of childbearing age
- *Strategy II*: Aims at interrupting rubella virus transmission and thereby eliminating rubella as well as CRS

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## Immunization strategies. I: Reducing CRS only

- For CRS reduction alone, adolescent and adult females should be vaccinated through either routine services or SIAs.
- This option will provide direct protection for women of childbearing age; however, the impact of this strategy is limited by the coverage achieved and the age groups targeted.
- In the absence of a programme that ensures vaccination of infants and young children, rubella will continue to circulate, resulting in exposure of pregnant women and the associated risk of CRS.

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## Immunization strategies. II: Rubella elimination

- For the elimination of rubella (and thereby CRS), the preferred approach is to begin with MR or MMR vaccine in a campaign targeting a wide range of ages, immediately followed by introduction of MR or MMR vaccine into the routine childhood programme.
- All subsequent follow-up campaigns should use MR or MMR vaccine.
- In addition, countries should make efforts to reach women of childbearing age by immunizing adolescent girls or women of childbearing age, or both, either through routine services or mass campaigns.

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## Synergy with measles programmes

- Measles-vaccine delivery strategies provide an opportunity for synergy and a platform for advancing rubella and CRS elimination.
- All countries that are providing 2 doses of measles vaccine using routine immunization or supplementary immunization activities (SIAs), should consider including RCVs in their immunization programme.
- Cost-benefit studies of rubella vaccination have shown that benefits outweigh costs and that rubella vaccination is economically justified, particularly when combined with measles vaccine

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## Importance of high vaccination coverage

- Sustained low coverage of rubella immunization in infants and young children can result in increased susceptibility among women that may increase the risk of CRS above levels during the prevaccine era (“paradoxical effect”).
- Hence, countries should achieve and maintain immunization coverage of  $\geq 80\%$  with at least one dose of an RCV delivered through routine services or regular SIAs.

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## Surveillance

- Assessment of the impact of rubella vaccination requires laboratory-supported surveillance for rubella and CRS.
- Vaccination coverage should be monitored by age and locality.
- Seroprevalence studies may be useful in monitoring susceptibility and determining the age groups for vaccination. Antenatal serological screening is a practical tool in this context.
- Field and laboratory surveillance for rubella should be fully integrated with measles in a single surveillance system.