Summary of the WHO position on Rubella Vaccine- July 2020

This document replaces the WHO position paper on rubella vaccine published in the Weekly Epidemiological Record in July 2011. It incorporates the most recent developments in the field of rubella vaccines to provide updated guidance on the introduction and use of rubella-containing vaccines (RCVs) in national immunization schedules. It specifically updates guidance on co-administration of rubella vaccine with yellow fever (YF) vaccine and updates data and the WHO position on the control and elimination of rubella.

Background

Rubella is of public health importance because of the teratogenic potential of infections acquired during pregnancy. Rubella virus is generally recognized as the most common infectious cause of birth defects, accounting for an estimated 100 000 infants born with congenital rubella syndrome (CRS) each year worldwide. Infection with rubella virus within 12 days of conception and early pregnancy (usually within the first 8–10 weeks) may result in miscarriage, fetal death or CRS. For the rest of the population, rubella is an acute, usually mild viral infection transmitted by respiratory droplets, which affects susceptible children and adults worldwide.

A number of live, attenuated rubella vaccines are currently available. Most rubella vaccines are available in combination with other vaccine antigens such as measles, mumps and varicella (MR, MMR, MMRV, respectively) and also in a monovalent formulation.

WHO position

In light of the global burden of CRS, the proven efficacy, effectiveness and safety of RCVs and regional elimination goals, WHO recommends that countries introduce RCVs into their national immunization programmes. This recommendation includes the opportunity offered by accelerated measles elimination activities to achieve both goals. Countries that have not yet introduced RCV into their immunization programmes should do so if they can achieve a coverage level of 80% or greater, through either routine immunization or campaigns. While opportunities should not be missed, the decision to introduce rubella vaccine in combination with MCV needs careful consideration related to the sustainability of maintaining high RCV coverage into the future.

<u>Strategies for implementation</u>

Introduction of RCV into childhood immunization programmes implies a long-term commitment to achieving and maintaining sufficient immunization coverage to ensure sustained population immunity and thereby avoid a paradoxical epidemiological effect. Low coverage of rubella vaccination of infants and young children can reduce but not interrupt the circulation of rubella virus, ultimately resulting in increased susceptibility of women of reproductive age (WRA).

Countries that are planning to introduce RCVs should have $\geqslant$80% coverage with the first dose of measles vaccine during routine immunization and/or campaigns to demonstrate their ability to achieve these levels of RCV coverage and thereby avoid the previously mentioned paradoxical effect. RCV coverage that remains <80% over the long term is expected to shift infection to older ages, when the risk of CRS is highest. The recommended vaccination strategy is to begin with an MR vaccination campaign targeting both sexes and a wide age range (e.g. 9 months–15 years), based on

the susceptibility profile by birth cohort when possible, followed immediately by introduction of MR or MMR vaccine into the routine immunization programme. The campaign should target males as well as females in order to reduce the likelihood of creating immunity gaps. The first dose of RCV can be delivered at 9 or 12 months, depending on the level of measles virus transmission. RCV should be used in all subsequent follow-up campaigns. The precise target age for follow-up campaigns will depend on the country's susceptibility profile, operational feasibility and measles epidemiology.

WHO recommends that, in order to provide direct protection against rubella, all non-pregnant women of reproductive age who are not already vaccinated or who are seronegative for rubella receive 1 dose of RCV.

Rubella is less infectious than measles, and the effectiveness of 1 dose of RCV is $\geqslant$95%, even at the age of 9 months of age. Therefore, if high coverage is achieved, only 1 dose of RCV is required to achieve rubella elimination. For programmatic reasons, however, it is recommended that all countries implement a 2-dose RCV schedule with the same combined MCV vaccine for both doses. Administration of more than 1 dose of RCV is safe.

Outbreaks

During outbreaks of measles, RCVs may be administered to infants as young as 6 months as an off-label indication. Because of the possibility of lower levels of seroconversion, the dose administered at 6 months should not be counted as a valid first dose, and the child should be vaccinated with subsequent dose(s) of RCVs according to the national immunization schedule.

Co-administration

RCVs can be administered concurrently with inactivated vaccines. Live vaccines should be given either simultaneously or at least 4 weeks apart. An exception to this rule is oral poliovirus vaccine, which can be given at any time before, at the same time as or after RCV without interfering in the response to either vaccine. WHO recommends co-administration of RCV and YF vaccines. Although there may be immunological interference between the 2 vaccines when they are administered simultaneously, resulting in somewhat lower titres of rubella and YF antibodies, the seroconversion rates were found to be the same.

Precautions and contraindications

RCVs should not be given to anyone who has experienced a severe allergic reaction after a previous vaccine dose or vaccine component. It is recommended not to provide the vaccine to those with active TB or severe immunodeficiency (including individuals with symptomatic HIV infection, AIDS, congenital immune disorders, malignancies or aggressive immunosuppressive therapy).

Rubella vaccination should be avoided in pregnancy because of a theoretical (but never demonstrated) risk of teratogenic outcomes. Women planning a pregnancy are advised to avoid pregnancy for 1 month after rubella vaccination. Inadvertent vaccination with RCV during pregnancy is not an indication for terminating the pregnancy.

WHO recommends that people who receive blood products wait at least 3 months before vaccination with RCV, and, if possible, avoid administration of blood products for 2 weeks after vaccination.

Vaccination of health workers and travellers

Vaccination of health workers with RCV is recommended and documentation of immunity or vaccination with RCV should be required for health workers.

Rubella vaccine should be offered to all unvaccinated individuals independent of destination of travel (endemic or non-endemic country) to avoid individual risk of exposure to rubella virus as well as to reduce the risk of international spread.

Surveillance and monitoring

All countries should aim to establish preferably integrated, elimination-standard surveillance for measles and rubella. As rubella control progresses towards elimination, for which some regions have established targets, the sensitivity and specificity of surveillance systems must be increased. Therefore, WHO recommends strengthening integrated measles and rubella case-based surveillance of fever and rash and introduction of CRS surveillance.