INTRODUCING RUBELLA VACCINE INTO NATIONAL IMMUNIZATION PROGRAMMES

A STEP-BY-STEP GUIDE
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## Abbreviations

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<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AEFI</td>
<td>adverse event following immunization</td>
</tr>
<tr>
<td>CCL</td>
<td>cold chain and logistics</td>
</tr>
<tr>
<td>cMYP</td>
<td>comprehensive multiyear plans for immunization</td>
</tr>
<tr>
<td>CRI</td>
<td>congenital rubella infection</td>
</tr>
<tr>
<td>CRS</td>
<td>congenital rubella syndrome</td>
</tr>
<tr>
<td>CSO</td>
<td>civil society organizations</td>
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<tr>
<td>EPI</td>
<td>Expanded Programme on Immunization</td>
</tr>
<tr>
<td>FBO</td>
<td>faith based organizations</td>
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<tr>
<td>Gavi</td>
<td>Gavi, The Vaccine Alliance</td>
</tr>
<tr>
<td>ICC</td>
<td>Inter-Agency Coordinating Committee</td>
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<tr>
<td>MCV</td>
<td>measles-containing vaccine</td>
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<tr>
<td>MCV1</td>
<td>first dose of MCV</td>
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<tr>
<td>MCV2</td>
<td>second dose of MCV</td>
</tr>
<tr>
<td>MMR</td>
<td>measles-mumps-rubella vaccine</td>
</tr>
<tr>
<td>MR</td>
<td>measles-rubella vaccine</td>
</tr>
<tr>
<td>MRCV</td>
<td>measles and rubella containing vaccine</td>
</tr>
<tr>
<td>NGO</td>
<td>non-governmental organizations</td>
</tr>
<tr>
<td>RCV</td>
<td>rubella-containing vaccine</td>
</tr>
<tr>
<td>RCV1</td>
<td>first dose of RCV</td>
</tr>
<tr>
<td>RCV2</td>
<td>second dose of RCV</td>
</tr>
<tr>
<td>RV</td>
<td>rubella virus</td>
</tr>
<tr>
<td>SAGE</td>
<td>Strategic Advisory Group of Experts on Immunization</td>
</tr>
<tr>
<td>SIA</td>
<td>supplementary immunization activity</td>
</tr>
<tr>
<td>SOP</td>
<td>standard operating procedure</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
</tr>
<tr>
<td>WRA</td>
<td>women of reproductive age</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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About this guide

This document is intended for use by national immunization programme managers and immunization partners involved in operational support.

General guidance about planning the introduction of a vaccine into a national immunization programme is provided in the document “Principles and considerations for adding a vaccine to a national immunization programme: from decision to implementation and monitoring” published by WHO in 2014.

The specific objectives of this document are:

- To guide the policy discussions and operational aspects of the introduction of rubella containing vaccine (RCV) into the national immunization programme.
- To provide technical guidance, up-to-date references on global policy, technical justification, strategic issues and laboratory guidelines related to the introduction and provision of rubella containing vaccine (RCV) in the national immunization programme.

Introduction

The Global Vaccine Action Plan (GVAP) was endorsed by the 194 Member States of the World Health Assembly in May 2012. One of the indicators included in the GVAP is that measles and rubella would be eliminated in at least five WHO regions by 2020.

This integrated vision of "a world without measles, rubella or congenital rubella syndrome ( CRS)" is supported by WHO, UNICEF and other partners in the Global Measles and Rubella Strategic Plan 2012–2020. All the six WHO regions have established measles elimination goals, two regions have rubella elimination goals. In April 2015, the region of the Americas has been certified as eliminating endemic rubella and CRS.

The Measles and Rubella Initiative (M&RI) is a global partnership committed to ensuring that no child dies from measles or is born with CRS. Since 2001, the Initiative has supported 80 countries to deliver more than 1.1 billion doses of measles vaccine, helped to raise measles vaccination coverage to 84% globally, and reduced measles deaths by 71%.

Since 2011, WHO has recommended that countries should make use of their accelerated measles control and elimination activities to also tackle the problem of rubella and CRS.

There are many ways that measles vaccine delivery strategies provide an opportunity for synergy and a platform for addressing rubella and CRS:

• Switching to the use of a combination measles and rubella containing vaccine (MRCV);

• Conducting wide-age range MRCV vaccine supplementary immunization activities;

• Strengthening immunization systems and implementing strategies to achieve and maintain high immunization coverage of both measles and rubella vaccines;

• Adding/augmenting rubella laboratory testing, case/outbreak investigation and reporting into the existing measles case-based surveillance system and establishing CRS surveillance.

While opportunities should not be missed, the decision to introduce rubella vaccine in combination with measles vaccine as MRCV needs careful consideration.

It requires long-term commitment and financing to achieve and maintain sufficient RCV immunization coverage (at least 80%, through routine services or regular SIAs, or both) to ensure a sustained reduction in the incidence of CRS, and ultimately the elimination of rubella and CRS. Lower coverage may postpone exposure to the virus until later into child-bearing years, increasing the risk of exposure during pregnancy, thereby paradoxically increasing the risk of CRS.

This guide summarizes the relevant policy recommendations and technical issues, and provides a “step-by-step” process to assist countries to assess their state of readiness to introduce RCV and to put in place the needed strategies for success.

Figure 1. Measles and rubella elimination goals, 2014, by WHO Regions
Important WHO recommendations for rubella containing vaccines (RCV)¹

1. Countries should take the opportunity offered by accelerated measles control and elimination activities to introduce RCVs. Measles vaccine delivery strategies provide an opportunity for synergy and a platform for advancing rubella and CRS elimination.

2. Countries that have not yet introduced rubella vaccine, and are providing 2 doses of measles vaccine using routine immunization or SIAs, or both, should consider including RCVs in their immunization programme.

3. Countries planning to introduce RCVs should review the epidemiology of rubella, including the susceptibility profile of the population; assess the burden of CRS; and establish rubella and CRS prevention as a public health priority. Cost–benefit studies are not needed in every country before rubella vaccination is implemented; results from studies in countries with similar sociodemographic circumstances can be informative.

4. For the elimination of rubella and CRS, the preferred approach is to begin with MRCV in a campaign targeting a wide range of ages (typically 9 or 12 months to <15 years of age) that is followed immediately by the introduction of MRCV into the routine programme.

5. To avoid the potential of an increased risk of CRS, countries should achieve and maintain immunization coverage of 80% or greater with at least 1 dose of an RCV delivered through routine services or regular SIAs, or both. Because rubella vaccine is provided as MRCV and measles elimination needs >95% coverage, the coverage aimed for should be >95%.

6. Because the effectiveness of 1 dose of an RCV is ≥95% even at 9 months of age, the first dose of measles containing vaccine (MCV) at 9 or 12 months age should be MRCV. An additional reason is the higher coverage of MCV1 compared to MCV2. For programmatic reasons, it is easier to implement a 2-dose schedule of RCVs using the same combined MRCV for both doses.

¹ Based on the WHO position paper on rubella – http://www.who.int/entity/wer/2011/wer8629.pdf
Additional strategies to fill immunity gaps in older age groups, e.g. women of reproductive age (WRA), adolescents >15 years of age and adult men may be needed.

Immunity gaps in health workers should be filled by immunizing unprotected health workers.

Vaccination of pregnant women with RCV should be avoided in principle. It should be noted that no cases of CRS have been reported in more than 1000 susceptible women who were unknowingly vaccinated against rubella in early stages of pregnancy.\(^1\)\(^2\) Screening tests to exclude pregnant women are not required. Rubella vaccination of unknowingly pregnant women is not an indication for abortion.

In all stages of rubella control rubella surveillance should be integrated with the measles surveillance system. Susceptibility or immunity to rubella can be ascertained only by serological tests. Seroprevalence studies may be useful in monitoring susceptibility. Antenatal serological screening is a practical tool for surveillance in this context.

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The diseases — rubella and congenital rubella syndrome (CRS)

Rubella (also called German Measles)

Clinical presentation

- An acute, usually mild illness accompanied by rash that commonly occurs during childhood or early adult life. Rubella results in few complications apart from the serious consequences of in utero infection.

- The average incubation period is 18 days with a range of 12 to 23 days.

- During the first week after exposure, there are usually no symptoms.

- During the second week after exposure, there may be early signs of illness consisting of low-grade fever (<39.0°C), malaise, runny nose and mild conjunctivitis. These symptoms are more common in adults. Swelling of the lymph nodes behind the ears, back of neck near the skull, and neck are characteristic and typically precede the rash by 5 to 10 days. Children usually develop few or no symptoms.

- At the end of the incubation period, a flat, bumpy, red (maculopapular) rash appears on the face and neck. The rubella rash occurs in 50%–80% of rubella-infected persons and is often misclassified as measles or scarlet fever.
Introducing Rubella Vaccine into National Immunization Programmes

- Starting on the face and neck the rash of rubella progresses down the body. The rash may be itchy and usually lasts between one and three days. It is fainter than measles rash and doesn’t coalesce, and it may be difficult to detect, particularly on pigmented skin.

- Transient joint symptoms (e.g. arthritis, arthralgias) may occur in up to 70% of adult women with rubella. They usually begin within one week after rash onset and typically last for 3–10 days, although occasionally they may last for up to one month.

- Postinfectious encephalitis occurs in approximately 1/6000 rubella cases, but occasionally higher incidences have been reported.

Infectiousness

Persons with rubella are most infectious just prior to and just after the rash has erupted.

### Table 1. Features of some of the diseases causing febrile illness with generalized rash

<table>
<thead>
<tr>
<th>Disease</th>
<th>Rubella</th>
<th>Measles</th>
<th>Dengue fever&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Erythema infectiousum&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Roseola infantum&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Causative agent</td>
<td>Rubella virus</td>
<td>Measles virus</td>
<td>Dengue virus</td>
<td>Parvo virus B19</td>
<td>human herpes virus 6</td>
</tr>
<tr>
<td>Incubation period (days)</td>
<td>14–23</td>
<td>7–18</td>
<td>2–12</td>
<td>4–20</td>
<td>10</td>
</tr>
<tr>
<td>Fever</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Rash</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Conjunctivitis</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Coryza</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Joint symptoms (especially adult women)</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes (especially adults)</td>
<td>No</td>
</tr>
<tr>
<td>Postauricular adenopathy</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Diagnostic test</td>
<td>IgM</td>
<td>IgM</td>
<td>IgM</td>
<td>IgM</td>
<td>IgM</td>
</tr>
<tr>
<td>Result of infection during pregnancy – stillbirth: birth defects:</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes&lt;sup&gt;d&lt;/sup&gt;</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Vaccine-preventable</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

<sup>a</sup> Vaccines against dengue are under development.

<sup>b</sup> Also known as fifth disease.

<sup>c</sup> Also known as sixth disease, or exanthema subbitum.

<sup>d</sup> Three fetal deaths reported following onset of dengue fever in mothers between weeks 17 and 24 of pregnancy (Carles et al. 1999).

Transmission of rubella
Rubella virus (RV) is transmitted through person-to-person contact or through droplets shed in the respiratory secretions of infected persons.

Clinical and laboratory diagnosis
The clinical diagnosis of rubella is unreliable as it is one of many diseases that present with rash and fever (Table 1).

Congenital rubella syndrome (CRS)
Of serious concern are the effects that rubella can have when a susceptible pregnant woman becomes infected, especially during the first trimester, which can result in miscarriages, stillbirths, therapeutic abortions, congenital rubella infection (CRI) without birth defects and congenital rubella syndrome (CRS), a constellation of birth defects that often includes blindness, deafness, mental retardation, and congenital heart defects.

- When primary rubella infection occurs in a pregnant woman, the virus can infect the placenta and fetus.

- The risk of congenital infection is related to the gestational age at the time of maternal infection. When pregnant women are infected with rubella during the first 11 weeks of pregnancy, up to 90% of liveborn infants may have CRS. After 11 weeks the rate of CRS declines until 17–18 weeks of gestation when hearing impairment is a rare consequence.

Newborn with CRS
• After 18 weeks of gestation, the risk of CRS is low.

• The most common defects of CRS are hearing impairment / deafness, eye defects (cataracts, congenital glaucoma or pigmentary retinopathy), and cardiac defects.

• Other clinical manifestations may include microcephaly, developmental delay or mental retardation, purple discolorations on the skin (purpura), meningoencephalitis, enlarged liver and spleen (hepatosplenomegaly), low birth weight and radiolucent bone disease.

• In some cases of rubella infection during pregnancy, particularly after the first twenty weeks, the foetus can be infected but not develop the signs and symptoms of CRS. These infants are termed as having congenital rubella infection (CRI) only. They do shed rubella virus and should be followed up for virus shedding.

**IMPORTANT:** All congenitally infected infants, including those without clinical manifestations of CRS, may shed RV from body secretions until one year of age and, for infants with CRS, in some instances even up to 27 months. Such infants are infectious, and rubella outbreaks have occurred among health workers caring for infants with CRS. It is necessary to ensure that persons in contact with these infants (e.g. health workers, family members) are immune to rubella either through vaccination or natural infection.
Decision-making at country level

What should be the process?

It is important to have a systematic and transparent process for making a decision about introducing rubella vaccine into the national immunization programme. Ideally, the national immunization technical advisory group (NITAG\(^1\)) or an equivalent independent advisory body should be requested to undertake a rigorous review of the evidence and make an independent recommendation to the national government.

NITAG members should have a broad health perspective to ensure that the impact of rubella vaccine (or any other new vaccine) on the immunization programme and the overall health system is considered. Unlike a completely new vaccine, rubella containing vaccine is combined with measles vaccine as MR (or MMR) and can be easily integrated into the system.

The NITAG committee and its members must be perceived as objective, independent and not representing a particular interest group. The independence of the NITAG and its reliance on evidence-based decision-making reinforces the credibility of the decision, helps to resist pressure from interest groups and enhances the ability to secure government and/or donor funding for the vaccine introduction. NITAGs function best when they are supported by a secretariat or technical sub-committee to collect and synthesize the evidence.\(^2\)

Subsequently, the Inter-agency Coordinating Committee (ICC)\(^3\) will serve to coordinate partner activities and funding for the immunization programme. As with other decisions pertaining to the national immunization schedule, the national government takes the decision to introduce (or not to introduce) rubella vaccine.

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1. NITAGs should consist of national experts in a broad range of disciplines — such as senior paediatricians, immunization and vaccine experts, epidemiologists, public health experts, health economists, health systems experts and social scientists — who are capable of analysing the different types of scientific evidence and issues that should be considered in making an informed decision.

2. More information and references on NITAGs can be found at: http://www.who.int/immunization/sage/national_advisory_committees/en/

3. A committee made up of representatives of the Ministry of Health (MOH), WHO, UNICEF, and other domestic and external partners to improve coordination among partners for the support of the national immunization programme.
Introducing Rubella Vaccine into National Immunization Programmes

**Key reading**

A generic guide for countries explaining the principles and issues to be considered when introducing a new vaccine into a national immunization programme. It describes the process and latest references and tools/checklists for:

- vaccine decision-making
- economic analyses
- developing an introduction plan
- cold chain
- integrated disease control and health promotion
- vaccine safety
- communications
- monitoring

Importantly, this guide highlights ways to use the opportunity of adding a new vaccine to strengthen immunization and health systems.

**What information is needed?**

In the absence of rubella vaccination, rubella is an universal disease that occurs in all populations with CRS as a consequence of rubella in pregnancy.

The basic questions to be answered are:

1) What is the epidemiology and burden of rubella and CRS;

2) What is the susceptibility profile of the population; and

3) Can the immunization programme ensure high coverage? As rubella vaccine is delivered in combination with measles vaccine in the form of MRCV, the coverage aimed for should be >95% which is needed for measles elimination.

The sources of information to answer these questions are case based measles and rubella surveillance data, coverage data of MCV1, rubella serosurveys, CRS surveillance data and/or retrospective CRS studies. If data from a country are not available, data from neighbouring countries should be used. In addition, the coverage for two doses of MCV (in routine) and SIAs for children or for wider age groups should be analysed to ascertain whether the immunization programme can achieve and maintain adequate levels of protection.
How to introduce rubella vaccine?

There are **six strategies** to introduce RCV. These can be implemented in phases.

**Initial phase**

1. Wide age range immunization campaigns/SIAs
2. Introduction of RCV into the routine immunization schedule as MRCV. Both MCV doses should be in combination with rubella vaccine, however, it is important that at least MCV1 should be MRCV
3. Surveillance for rubella, integrated with measles surveillance

**Subsequent phase**

4. Follow-up MRCV SIAs to maintain high (> 95%) coverage, as RCV is combined with MCV
5. Fill the immunity gaps in older population
   a. SIAs in >15 years age group (both males and females), if these groups are susceptible
   b. Immunization of WRA through routine immunization
   c. Immunization of health workers
6. CRS surveillance

**The first step in the preferred approach** to introduce RCV into the routine childhood immunization programme **is a wide-age immunization campaign** (typically 9–12 months to <15 years of age, both males and females)\(^1\) using MRCV. This is often termed the ‘catch-up campaign’. The rationale for starting with a wide-age campaign is to ensure that a shift in the incidence of the age distribution of cases to older age groups, such as young adults, does not occur. If high vaccination coverage is achieved in the catch-up campaign and high coverage of MRCV is sustained through routine childhood immunization, the transmission of rubella virus will be interrupted leading to the elimination of both rubella disease and CRS.

\(^1\) The precise target population for the SIA will depend on the country’s susceptibility profile, cultural acceptability and operational feasibility.
2 The second step is the rapid introduction of MRCV into the routine immunization programme following the catch-up MRCV campaign. This should be done within six months of the campaign. The reason is to protect children who were born after the catch-up campaign or were too young to be vaccinated in the catch-up campaign. These children would get their first MRCV dose through the routine immunization programme.

3 The third step is the initiation or strengthening of surveillance for rubella. Rubella surveillance should always be integrated with measles surveillance. Specimens obtained from suspect cases of measles or rubella should be tested for both.

REMEMBER: As rubella vaccine is delivered in combination with measles vaccine, the coverage aimed for should be >95%, the level which is needed for measles elimination.

In the subsequent phase the programme will need to implement the following:

4 Follow-up MRCV campaigns will be needed if the coverage achieved in the initial catch-up campaign and the routine immunization programme is below 95%, to avoid the accumulation of susceptibles and possible outbreaks of rubella and subsequent infants born with CRS. Typically follow-up campaigns target children from 9 (or 12) months to <5 years old. The timing and frequency of follow-up campaigns are driven by immunity to measles. This depends on the coverage of MCV achieved in the routine immunization programme and in SIAs.

5 a. Immunization of older age groups (both women and men) will be needed depending on the epidemiology of rubella transmission to fill the immunity gaps in age groups >15 years of age. The rubella virus circulates among people, both men and women, who are older than the cohorts vaccinated and have not had the disease. Large rubella outbreaks in adolescent and young adult males with subsequent occurrence of CRS cases have been experienced in several countries where the target group for SIAs had included women of reproductive age but not men. Cases of CRS may continue to occur as long as the circulation of rubella virus continues. Depending on the age-specific fertility rates in a country and the susceptibility of the older non-vaccinated population, the time period until elimination of CRS would vary. If the non-vaccinated older population has very low levels of susceptibility then elimination may occur shortly after the introduction of the rubella vaccine, however, if susceptibility is high, then the period may be longer.
b. In addition to the introduction of MRCV into the routine childhood immunization programme, to provide individual protection for women of reproductive age (WRA), it is possible to target WRA through routine immunization strategies that minimize the likelihood of vaccinating pregnant women. Countries can vaccinate women at premarital screening, provide postpartum vaccination and vaccinate at the time of other contacts with the health system. In countries that do not have these services, WRA can be vaccinated at the time when their infants come for their first vaccinations. The contact for human papillomavirus (HPV) vaccination for young adolescent girls (9–13 years) is another opportunity to check if they have received MRCV, and to provide it if they have not. When immunization is targeted only at adolescent girls or WRA, the epidemiology of rubella and circulation of rubella virus remain largely unaffected. With such an approach, the incidence of CRS declines linearly with increasing levels of coverage. However, elimination of CRS is unlikely to be achieved with this strategy alone as it would require every susceptible woman to be effectively immunized.

c. Health workers come in contact with pregnant women regularly, and because they may deliver babies, or be involved in the care of infants born with CRS or congenital rubella infection (CRI) (who can continue to shed rubella virus for a long period of time) it is important that health workers are vaccinated.1,2 This is to prevent them transmitting rubella, particularly to pregnant women who are not protected by vaccination or prior disease. Outbreaks of rubella have been caused by unvaccinated health workers in medical facilities. These can have serious consequences including pregnancy terminations, disruption of hospital routine, absenteeism from work, expensive containment measures, negative publicity and possible litigation. In these outbreaks, transmission occurred from health workers to susceptible co-workers and patients, as well as from patients to health workers and other patients. Strategies to vaccinate health workers include (i) making it mandatory for employment; (ii) providing free or subsidized cost vaccination to all health workers; (iii) offering serological testing to all employees and free or subsidized cost vaccination to those health workers who lack immunity; and (iv) counselling and education about the benefits of vaccination to new employees.

Surveillance for CRS should be established before or as soon as possible after the introduction of MRCV. It does not have to be in place prior to MRCV introduction. See Annex 2 and Annex 4 for details on how to set up surveillance for CRS and investigation of rubella outbreaks.

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1 Immunization of Health-Care Workers, Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC), available at http://www.cdc.gov/mmwr/PDF/RR/RR4618.pdf

Before introducing RCV, you should:

1) Review the epidemiology of rubella, including the susceptibility profile of the population; and assess the burden of CRS. The sources of this information are case based measles and rubella surveillance data, rubella serosurveys, CRS surveillance data and/or retrospective CRS studies;

2) Plan to ensure high coverage. To introduce RCV, MCV1 coverage must be >80% through routine and/or SIAs; however, as rubella vaccine is delivered in combination with measles vaccine as MR (or MMR), the targeted coverage should be the same as for measles elimination, i.e. >95%.

Once data have been reviewed indicate that rubella vaccination is epidemiologically warranted, you should:

1) Define your goal and the time frame for achieving it, depending on the burden of CRS and available resources;

2) Obtain strong political commitment for the elimination of rubella and CRS;

3) Establish rubella and CRS prevention as a public health priority;

4) Make a long term commitment to achieving and maintaining uniformly high immunization coverage (>95%) through routine immunization and SIAs;

5) Ensure sustainable financing for both the immunization and surveillance activities.
Planning

What policies must be in place?

It is a prerequisite for MRCV introduction that health workers have clear policy guidance and knowledge of the rubella and measles strategy that the country is implementing. As part of the planning process for the introduction of MRCV, the existence and implementation status of the following policy issues should be reviewed:

• **Rubella vaccination**, although scheduled to be given at 9 or 12 months of age (together with MCV1), vaccination should not be limited to infants less than 12 months of age. Many children come late for vaccination but they need to complete the immunization schedule no matter how old they are.

• Irrespective of the strategy or age given, **any MR (or MMR) dose given should be recorded** on a child’s immunization card and in the health facility register.

• Children should be **screened for their vaccination history at the time of school entry**, and those lacking evidence of receipt of MRCV should be provided the missing vaccinations by referring them to the nearest health facility. Other missed vaccine doses should be administered at that time.

• Depending on each country’s policy, **WRA should be screened for and offered rubella vaccination** when they come in contact with the health system. Policy should be developed to support the recommended strategy or strategies (e.g. vaccinate at premarital screening, postpartum, or when mothers bring infants for vaccination services).

• **Health workers**¹ (including students who have contact with patients), **should be immune to measles and rubella. They should be vaccinated** with RCV and proof of vaccination should be made mandatory before employment (or acceptance as a student).

If, as recommended, school entry and nursery/day-care screening for measles and rubella vaccination is to be established the appropriate agencies concerned (e.g. the Ministry of Education) will need to be involved.

To implement post-partum rubella vaccination of WRA it will be necessary to work with mid-wives, trained delivery attendants, and maternity nurses and partners.

¹ All persons involved in patient care such as health care professionals, residents, students, laboratory staff, as well as persons in public health such as field workers, epidemiologists, laboratory staff and community health workers.
and programmes concerned with implementing the Every Newborn Action Plan\(^1\). This also is a chance to promote and improve the coverage of the birth dose of Hepatitis B, OPV and BCG for infants.

**What is the best age to administer RCV?**

Rubella vaccine should be given as MRCV vaccine and should be administered with the first dose of measles containing vaccine. The age of administering MCV1 depends on a country’s immunization schedule. All unvaccinated older children, regardless of age, should be offered MRCV whenever the child comes into contact with health services. This instruction should be clearly reflected in the EPI policy and guidance documents, supervision and training of health workers, in the forecasting of vaccine needs and in the vaccination monitoring tools (e.g. a column for recording doses given to children >12 months of age).

As this is a simple replacement of measles-only vaccine by MR (or MMR), there are few programmatic implications in terms of procurement, storage, distribution and use at the service delivery end-point. The training needs for the health workers related to implementing childhood rubella vaccination are minimal – comprising mainly of information about the switch to a combination vaccine that includes a rubella vaccine component and the key communication messages. The storage requirements, storage space required, transport methods, mode of use and the precautions to be observed remain identical as for measles-only vaccine.

Unlike measles vaccine, which has lower seroconversion rates when administered to children before 12 months of age (hence the need for two doses of measles vaccine), nearly all children (>95%) seroconvert after receiving just one dose of rubella vaccine, even at 9 months of age. Given this, and because it is less infectious than measles, rubella can be eliminated with just one dose of RCV if high coverage is achieved.

For programmatic reasons, to avoid the complication of managing two different presentations of MCV in the supply chain (monovalent measles and MRCV) it is recommended that countries that are implementing a routine 2-dose schedule for MCV use the same combined MRCV vaccine for both doses.

Implementing a two-dose childhood schedule for MRCV is safe and the advantages outweigh the $0.30 cost increase per dose (at UNICEF prices for

\(^1\) [http://www.everynewborn.org/every-newborn-action-plan/](http://www.everynewborn.org/every-newborn-action-plan/)
2014, in 10-dose vials) between the cost of monovalent measles\(^1\) vaccine and MR\(^2\) combination vaccine:

- Vaccine procurement, logistics and monitoring/recording are simplified
- Vaccine wastage is decreased
- Rubella vaccination coverage is increased by reaching children who missed their first MR dose, or failed to seroconvert after receiving one dose.

**REMEMBER:** For countries implementing a routine 2-dose measles vaccination schedule, when introducing RCV, WHO recommends using combined **MRCV vaccine for both doses.**

### What is the estimated target number of children for RCV?

The number of target children for MRCV is exactly the same as that currently targeted for MCV1 (and MCV2 if following a 2-dose schedule). The only thing that changes is the form of the vaccine, that is MR or MMR instead of monovalent measles vaccine.

For the first dose:

**Estimated MRCV target population (9–12 months) = Children surviving until 1 year (12 months) of age**

For the second dose:

**Estimated MRCV target population (15–18 months) = Children surviving until 1 year (12 months) of age**

If MCV2 is currently given at school entry (5–6 years of age):

**Estimated MRCV target population (5–6 years) = Children surviving until 5 years (60 months) of age**

In practice, estimates of population by single year of age are frequently difficult to obtain. The number of live births can be used to approximate the number of children in annual cohorts under 5 years of age. For annual cohorts between 5–10 years of age, the number can be estimated by using the number of children surviving until 5 years of age, which is often available from the national statistical office or the United Nations Population Division\(^3\).

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Introducing Rubella Vaccine into National Immunization Programmes

What plans need to be made or revised?

The plan for introducing RCV should not be a standalone document. It should be fully integrated with the measles elimination plan, as the diseases have similar clinical appearances in children and the rubella vaccine is to be administered as a combined measles and rubella containing vaccine (MRCV). As countries prepare to introduce RCV into their national immunization programme, each country will need to update their comprehensive multi-year plan (cMYP) and develop a plan of action for rubella control/elimination and CRS prevention/elimination. Step-by-step guidance is provided in the document “WHO/UNICEF Guidelines for developing a comprehensive multi-year plan (cMYP)” available at the WHO website.¹

The cMYP outlines the national goals, objectives and strategies usually for five years based upon situational analyses. It encompasses all aspects of the immunization programme and highlights synergies between various vaccine initiatives (e.g., polio eradication, measles elimination, maternal and neonatal tetanus elimination) so that duplication is avoided and separate plans do not need to be developed. The cMYP also includes costing and financing assessments that are linked to the country’s planning cycles. For every year of the cMYP, a detailed annual plan of action should be prepared.

The plan for rubella elimination and CRS prevention should describe the different components: epidemiological situation of rubella and CRS; comprehensive vaccination strategies; surveillance activities; cold chain capacity; communication strategies; monitoring and evaluation; and budget and financing. It should discuss the linkages to the current schedule of measles vaccination including the measles second dose. The plan should also describe how high RCV coverage will be maintained through either routine immunization or routine immunization and SIAs, and the additional efforts that will be made to vaccinate WRA and health workers.

Although the introduction of RCV by switching from monovalent measles vaccine to MRCV is less complex than adding a stand-alone new vaccine, it is still useful to refer to the checklists and tools contained in the WHO guide “Principles and considerations for adding a new vaccine to a national immunization programme: From decision to implementation and monitoring” (see box in the section ‘Decision-making at country level’). In particular, Annex 3 (Instructions and template for a new vaccine introduction plan) and Annex 4 (Instructions for a new vaccine introduction checklist, activity list and timeline) of that document would be useful. The main document and both these annexes can be downloaded².

How much will it cost to introduce RCV?

Adding RCV will have cost implications beyond the increase in vaccine costs (see box below). Therefore, the immunization programme budget and financing plan would need to be updated using WHO’s “**Immunization costing and financing: A tool and user guide for comprehensive Multi-Year Planning (cMYP)**”\(^1\). This tool enables countries to estimate the costs, the amount of financing needed and the funding gap of their immunization programme to meet their coverage goals (which should be >95% because it is combined with measles vaccine) for rubella vaccine. Gavi requires that all recipient countries prepare a cMYP and update it whenever applying for funding support. All countries, whether Gavi eligible or not, would greatly benefit from preparing and actively using a detailed budget.

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### Possible costs to include when estimating the funding needs for RCV introduction

**Initial phase:**
- Cost of conducting a wide-age range (9 months–15 years) MR catch-up vaccination campaign
- Increased cost of MR vaccine (about USD 0.30 more/dose at 2014 prices)\(^2,3\)
- Development of an effective communication strategy and social mobilization activities/materials for RCV introduction and the switch to MRCV
- Training of all relevant health workers at all levels, including refresher training
- Expansion of cold chain and dry storage capacities and strengthening vaccine transport systems due to the expanded target age group of MRCV campaigns’ after systems
- Strengthening rubella case-based surveillance
- Revision and printing of child health/vaccination cards, immunization tally sheets, registers, forms, stock management tools, guidelines and procedures including AEFI (in the short term, as MR (or MMR) will replace MCV and follow the existing measles vaccination schedule it may be possible to make these changes by hand until stocks are used up and need to be reprinted).

**Subsequent phase:**
- Procurement of additional vaccine
  - For follow-up campaigns (9 or 12m – 59m) to maintain >95% coverage
  - For campaigns in >15 years age groups to fill in immunity gaps
  - For vaccinating WRA and health workers
  - For routine immunization
- Establishing CRS surveillance.

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Opportunities for the integration of MR delivery with other vaccinations and health services

To improve the efficiency of the health care delivery system it is practical to consider if the administration of MR can be combined with other vaccinations or the delivery of other health services. When given as MR vaccine, the introduction of rubella vaccine is already fully integrated with measles elimination activities. The decision to introduce MR into the national immunization schedule presents opportunities to link with other programmes and interventions. Some of these may be entirely new to the immunization programme. The possibilities include:

- Routine MR second dose given at 1–6 years can be integrated with the delivery of a DTP booster; this opportunity can also be integrated with the distribution of long-lasting insecticide treated nets (LLIN) for malaria control;
- If pneumococcal conjugate vaccine (PCV) is administered using the “2+1” schedule (two doses before 6 months of age), MR can be administered with PCV3 at 9–15 months of age;
- Provision of MR vaccination to WRA as part of premarital counselling or HIV/AIDS screening;
- Post-partum rubella vaccination of mothers with MR at the time when their infants receive HepB birth dose and BCG, together with essential newborn care package;
- MR vaccination of non-pregnant mothers when they bring their infants for vaccination;
- School-based vaccination of boys and girls with MR at the time of HPV vaccination of girls (9–13 years) or with Td/TT immunizations (this may also provide an opportunity to include other adolescent health services or health education). Because these interventions are school based, collaboration with the Ministry of Education and school teachers will be important;
- Integration with Vitamin A supplementation in areas where vitamin A deficiency is a public health problem (Vitamin A is given every 6 months to children 6–59 months old);
- Integration with deworming which is recommended every year for children 12–59 months and adolescents in areas with high burden of worms;
- For retrospective CRS searches, it would be appropriate to engage with the national deafness prevention programme and with civil society organizations (CSOs or NGOs) active in the area of caring for deaf children.
Vaccine management issues for rubella vaccination

What rubella vaccine presentations are available?

The rubella vaccine comes in combination presentations as measles-rubella (MR) or measles-mumps-rubella (MMR) and as monovalent rubella vaccine\(^1\) (not available through UNICEF). MR vaccine procured through UNICEF comes in 10 dose vials, and the volume of the presentation is the same as for 10 dose measles vaccine. MR vaccine is supplied as freeze-dried (lyophilized) and needs to be reconstituted with the diluent provided. The diluent is specific for the vaccine supplied by a manufacturer and cannot be interchanged.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Presentation</th>
<th>Packed volume per dose (cm(^3)/dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measles-Rubella (MR)</td>
<td>10-dose vial</td>
<td>2.611</td>
</tr>
<tr>
<td>Measles (M)</td>
<td>10-dose vial</td>
<td>2.611</td>
</tr>
<tr>
<td>Measles-Mumps-Rubella (MMR)</td>
<td>1-dose vial</td>
<td>26.11</td>
</tr>
<tr>
<td></td>
<td>2-dose vial</td>
<td>13.1</td>
</tr>
<tr>
<td></td>
<td>5-dose vial</td>
<td>5.22</td>
</tr>
<tr>
<td></td>
<td>10-dose vial</td>
<td>2.611</td>
</tr>
</tbody>
</table>

NB: Measles and MR vaccines are prequalified in 1-, 2-, 5- and 10-dose vials, however currently only 10-dose vials are available through UNICEF procurement. Measles and MR in 10-dose vials supplied through UNICEF have similar packed volumes. UNICEF does not supply monovalent rubella vaccine.

How to forecast and calculate vaccine supply needed for RCV?

The introduction of rubella vaccine in combination as MRCV means \textbf{that the number of doses needed remains the same as that presently forecasted for measles vaccine}. If the introduction of MRCV is used as an opportunity to begin a routine 2-dose schedule for measles vaccination, then more vaccine will be required (the requirement will double if the targeted coverage for the second dose is the same as for the first).

\(^1\) Using monovalent rubella vaccine is not recommended because of the measles elimination goals in all regions.
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Target population size = surviving infants\(^1\);
Estimated coverage = even though to introduce RCV it should achieve >80\% coverage, because it is combined with measles, the coverage must be higher (>95\%) for measles elimination;
Number of doses = 1 or 2 depending on the national immunization schedule;
Wastage factor = Use national data or see Table 3.

It will also be necessary to forecast the vaccine supply required to vaccinate WRA\(^2\) (including postpartum vaccination) and health workers.

There is a high wastage rate with measles and measles-rubella combination vaccines, frequently ranging from 45–60\%. The multi-dose vial policy (MDVP)\(^3\) requires that multi-dose vials of MRCV should be discarded at the end of the immunization session, or within six hours of opening, whichever comes first. For the handling of specific vaccines please consult each individual vaccine product sheet.\(^4\) Introducing a 2-dose schedule for childhood vaccination with MRCV may actually reduce the wastage rate, because some of the doses will be administered as MCV2 using vaccine that would otherwise have been discarded using a 1-dose schedule. Similarly, if the strategy of vaccinating non-pregnant mothers at the time they bring their infants for vaccination is adopted, this too would be likely to decrease wastage. vaccinating health workers may also decrease wastage.

It is estimated that switching from a 1-dose to a 2-dose schedule may reduce current measles vaccine wastage rates by almost 40\%. However, vaccine wastage should be monitored at all levels and the data should be used for forecasting future supply needs. This includes monitoring the needs for diluent and injection supplies (bundling).

As an approximate guide, the estimated wastage rates for 1 and 2-dose MR schedules and different vaccine vial presentations are provided in Table 3.

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1. It is more accurate to use surviving infants. But estimates of surviving infants are more difficult to obtain and the number of live births serves as a good surrogate.
2. If post-partum contacts and contacts at the time of immunization of their infants are used to deliver RCV to WRA, the target may be assumed as 3% of the total population per year for rough calculations, more accurate estimates are possible if the country’s birth rate is used.
3. Multi-dose vial policy: Once measles (or MR) vaccine has been reconstituted, the vial must be discarded at the end of the immunization session or within six hours of opening, whichever comes first. Available at http://www.who.int/immunization/documents/general/WHO_IVB_14.07/en/
4. Consult each individual vaccine product sheet at the WHO prequalification website, referencing the description “Handling of opened multi-dose vials”.

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### Table 3. Estimated wastage rates for 1 and 2-dose MR schedules

<table>
<thead>
<tr>
<th>Vial size of MR</th>
<th>For 1 dose schedule</th>
<th>For 2 dose schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Estimated wastage rate</td>
<td>Estimated wastage factor</td>
</tr>
<tr>
<td>Single dose(^a)</td>
<td>&lt;5%</td>
<td>1.05</td>
</tr>
<tr>
<td>5 doses/vial(^a)</td>
<td>30–40%</td>
<td>1.43–1.67</td>
</tr>
<tr>
<td>10 doses/vial</td>
<td>45–60%</td>
<td>1.82–2.50</td>
</tr>
</tbody>
</table>

\(^a\) Not available through UNICEF.

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### What cold chain capacity will be required to introduce RCV?

The introduction of any new vaccine, including a switch to MRCV, offers a good opportunity to critically review the cold chain and logistics (CCL) system and to improve its performance. It is recommended that countries conduct an Effective Vaccine Management (EVM)\(^1\) assessment and develop a CCL improvement plan. Cold chain challenges are expected for campaigns in particular, but can also arise in case of a change in vial size or the decision to introduce a 2-dose schedule. For each vaccine storage site, an assessment is needed to ensure that sufficient capacity is available. If the space available is insufficient, a decision needs to be taken whether additional equipment is required or alternative mechanisms can be used. This decision can be taken in the context of other planned new vaccine introductions or campaigns that will be implemented over the next few years, as well as the need for cold chain for other health commodities such as rapid diagnostic tests or temperature sensitive drugs. The CCL improvement plan needs to be developed at least one year before the introduction of a new vaccine or campaign, to allow for expansion of the cold chain as required, including ordering and installation of cold chain equipment.

Fortunately, the commonly used 10-dose MR vaccine presentation is similar in terms of packed volume to 10-dose measles-only vaccine (see Table 2). If the vial size does not change, the introduction of rubella as combination vaccine (MR) in the routine immunization programme is a simple vial swap, replacing the existing measles vaccine in the cold chain and logistics system.

As the introduction of MRCV must be accompanied by efforts to vaccinate WRA and health workers, this may also impact on cold chain capacity requirement. It is important to note that the cold chain capacity required for a 2-dose MRCV schedule may already exist – that is, depending on the national situation, it may not always be necessary to expand the cold chain to introduce 2-doses of MRCV. Programme managers are advised to use the Excel-based *WHO Vaccine Volume*

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*Calculator 2012* in order to precisely determine the specific cold chain capacity needs for introducing MR (or MMR) into their national immunization schedule.

For all the new implementation strategies (e.g. introducing a 2-dose schedule of MCV, vaccinating WRA and health workers) adequate dry storage will also need to be available to accommodate the additional injection materials, such as syringes (including reconstitution syringes) and safety boxes. Waste management plans that describe the ultimate destruction of the increased volume of used needles and syringes will also need to be updated.

**REMEMBER:** It is recommended to introduce MRCV into the routine childhood vaccination programme *immediately* after conducting a wide-age range MRCV vaccination campaign.

### Cold chain and MR campaigns

For MR campaigns, the logistical challenges are identical to measles-only vaccination campaigns. The wide age-range, or catch-up campaigns pose an extra burden on the cold chain system and cold chain capacity needs to be carefully reviewed in the early planning stage of the campaign, allowing sufficient time to expand the cold chain as required.

The calculation of the storage and transport needs for MR vaccination campaigns is based on the known maximum volume for the presentation that is planned to be used.

- The required cold chain storage needs = total vaccine required X packed volume per dose
- The total vaccine required = target population X expected vaccine wastage factor X expected coverage X proportion of buffer stock desired
- Vaccine wastage rate for campaigns are significantly lower and may be as low as 5% to 10%.
- Number of vaccine carriers = minimum two per vaccination team
- Daily icepack requirement = number of vaccine carriers X 4 X number of renewals of icepacks per day
- Cold boxes as required to transport vaccines to health centres and for storage at places with no cold chain equipment for short periods of time
- Refrigerated trucks as required for transport of large quantities of vaccines

Fast cold chain option/strategy can be put in place in some areas to complement the lack of permanent cold storage capacity. Passive containers (cold boxes, vaccines carriers and coolant packs) will be used to store vaccine for short periods during campaign, where necessary. This strategy will rely on frequent distribution of vaccine using reliable transportation.

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What are the storage requirements for MRCV?

MRCV should be kept between +2°C and +8°C. The diluent should be kept in the refrigerator, cold box or vaccine carrier starting the night before use (or for at least 60 minutes before use) to ensure a temperature of less than +8°C. Reconstituted vaccine should be kept on a reconditioned icepack or in a hole in a foam pad. The reconstituted vaccine should be discarded after six hours or at the end of the immunization session, whatever comes earlier. It does not contain a preservative and is therefore subject to microbial contamination. **Only the diluent supplied with the vaccine by the manufacturer should be used to reconstitute the vaccine – this must be emphasized during training and supervision. Diluents of different vaccines – monovalent measles, MR and MMR – should not be interchanged.**

The reconstituted vaccine is less stable than the dry powder and loses its efficacy fairly quickly, depending on the temperature of the solution. Reconstituted measles and MR vaccines quickly lose their potency at room temperatures; at 22°C to 25°C they suffer approximately 50% loss in potency in one hour. In addition, measles and MR vaccines are UV light sensitive and should be protected from light. It is therefore extremely important to keep reconstituted vaccine cool and protected from sunlight.

What impact does RCV introduction have on waste management?

The impact of introduction of MRCV on waste management will be small if the vial size and schedule (one or two doses) remains the same. Provision will need to be made for disposing of waste from the additional routine vaccination of WRA and health workers, but this is likely to be small in volume and regular.

Regardless, it will be necessary to verify that the current waste management system is adequate and can cope with any expected increase in volume. **Strengthening of vaccine/healthcare waste management should be planned for within the cMYP and vaccine introduction plan1.**

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Advocacy, communication and social mobilization

Communications

A communication plan should be developed prior to the introduction of any new vaccine and the introduction of RCV is no exception. Ample time should be allocated for the assessment of community response and readiness to accept the new vaccine, to identify any potential sources of resistance and/or opposition, to analyse other causes of low coverage and to address these concern and to prepare a range of programmatic responses to the issues that are identified.

Preparatory activities should include the establishment of a communication committee, coordination and definition of roles among partners and other potential allies and collection of available research and information required to ensure the development of an evidence-based communication plan. For a detailed discussion of communication issues for rubella immunization refer to the section on communications (Annex 1). If countries know that vaccine refusal will not be an issue, they should move forward quickly to introduce RCV.

Key communication messages

- Rubella vaccine is safe for children and adults and has been used for many years in many countries;
- It prevents birth defects (common ones are hearing impairment, cataracts and heart defects) associated with rubella infection during pregnancy;
- No harmful effects have been observed when administered to pregnant women;
- It is usually given in combination with measles vaccine as MR.
Implementation

Training

Before the introduction of RCV into the national programme, health workers will need to be trained. The training will be different for SIAs and for routine introduction. For introduction into the routine programme, the necessary background information, operational issues and hands-on practice can be covered in a well-planned one-day training session. This can be done as part of any regular annual or refresher training since the surveillance and vaccination of rubella is integrated with measles. To prepare for a SIA, a special training would need to be organized to ensure a high quality SIA. Annex 4 of the document "Principles and considerations for adding a vaccine to a national immunization programme: from decision to implementation and monitoring" provides a checklist for the introduction of a new vaccine, including considerations for training.

Training materials need to be prepared (or translated) in the appropriate local language and in sufficient quantities. Summarized reference materials and job aids should be developed and provided to the participants so that they have information to refer to and share with others they work with when they return to their post.

**REMEMBER:** MR vaccine should always be reconstituted using the diluent provided by the manufacturer to avoid severe adverse events after the incorrect use of other drugs as diluent. This should be emphasized during training. It may also be useful to provide pictures of the MR vaccine and the diluent to all health workers.

Studies suggest that for more effective learning interactive and hands-on training like field visits, showing videos of correct practices, small group discussions, demonstrations and skills practice is generally more successful than passive classroom lectures.

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Training topics should include the following:

- Brief overview of the measles and rubella control or elimination strategies and goals, and the rationale for introducing MR into the national programme including understanding the burden of rubella and CRS;
- Importance of surveillance, case definitions and how to identify, diagnose and report cases of rubella and CRS;
- Review of relevant policies;
- Rubella in pregnancy – the importance of following up these women, the care and handling of babies born with CRS;
- Key messages/materials for communities and mothers/caregivers about MR, and the social mobilization efforts that will be needed to ensure that high coverage is achieved in both routine immunization and SIAs;
- Clarification of the vaccination schedule for routine immunization if a two-dose schedule is being introduced. For example, guidance on screening and what to do with children who have already received one dose of monovalent measles vaccine and are eligible for a second dose: would it be MR? How to record it?
- AEFI – how to detect, how to investigate, how to respond, how to report;
- Instruction and practice on how to administer MR, including schedule, reconstitution and dosage, storage and handling of the vaccine and diluent, vaccine vial monitors (VVMs), co-administration with other vaccines, safe injection practices and waste disposal;
- Avoiding errors related to the use of wrong diluent;
- Record keeping and reporting of doses administered, including calculation of coverage, drop-out rate and use of the monitoring chart;
- Stock management of MR vaccine supplies, including how to forecast supplies and wastage rates;
- Microplanning to ensure that all communities (especially the hard to reach) have access to vaccination services;
- The importance of vaccinating health workers themselves receiving MR vaccination and how they can obtain it;
- Interpersonal communication skills, as rubella vaccination is new for the community health workers, they need to know how to relay the message about rubella to the community.
School entry screening

A very high proportion of children, even in poor neighbourhoods enrol in primary schools. An excellent opportunity to ensure high coverage with RCV and MCV is school entry screening. This affords the opportunity to administer missing immunizations. If a child has not received her/his MCV2, a dose of MRCV should be provided, if she/he has not received any measles vaccine earlier, two doses of MRCV should be given, at least one month apart. Other missing immunizations should also be provided, as needed by the child and in accordance with the national immunization schedule. The child should be referred to the nearest health facility for receiving the missing doses. If many children have missing doses, it may be possible to arrange a team from the nearest health facility to come to the school and provide the necessary vaccinations.

School entry screening also provides a means of estimating coverage in the cohort entering primary school. The cohort of children entering primary school (5, 6 or 7-year olds) can be screened and the coverage of RCV in the 5, 6 or 7 year old cohort can be estimated.

Collaboration with the Ministry of Education and private doctors will be essential for screening the vaccination history of children at school entry, and administering any missed doses.

Consent

Where the capacity exists a school or health facility nurse may vaccinate undervaccinated or unvaccinated children in the school itself. School children often do not have the age – legally – to provide consent and are mostly not accompanied by their parents. Therefore, informed consent for vaccination needs to be obtained from the parents or caregivers.

The way to obtain informed consent depends on the national regulations. Firstly, parents and children should be adequately informed about the characteristics, benefits and potential risk of adverse events related to measles and rubella vaccinations. Subsequently, in countries where this is the norm, written consent can be provided using a consent form. Otherwise, verbal or implied consent procedures can be used. It is good practice to allow older children to indicate their agreement with the vaccination (assent). Irrespective of which procedure is followed, it is more efficient to adopt “opt-out” protocols that require those parents or children who do not want the vaccination to indicate so. It should be noted that written consent procedures require additional advance planning.

For further guidance please refer to “Considerations regarding consent in vaccinating children and adolescents between 6 and 17 years old” (WHO/IVB/14.04), available at http://www.who.int/immunization/programmes_systems/policies_strategies/consent_note/en/
Supplementary Immunization Activities

Supplementary Immunization Activities (SIAs or mass immunization campaigns) are an important part of rubella and measles control/elimination plans. The initial wide age range SIA aims to greatly reduce rubella virus transmission, thereby protecting WRA from rubella infection and the risk of CRS.

Vaccination of WRA and health workers

Please see sections on immunizing WRA and health workers on pages 9 and 11.

1 A separate guide on SIAs focusing on MR campaigns is currently under development by WHO. When published, this guide will provide details on SIA planning, implementation, monitoring and evaluation. In the interim, a short description of aspects specific to SIAs is provided at Annex 6.
Monitoring and evaluation

Measuring routine RCV coverage

Routine childhood coverage

By 2014, 140 of 194 (72%) WHO member states had introduced RCV either as MR or MMR in their national immunization programmes. Coverage of RCV is reported by member states in the joint reporting form (JRF) to WHO and UNICEF.1

The existing tally sheets used to record the vaccines given during an immunization session will need to be modified to include RCV. Spaces on the tally sheets currently used to record the first and second doses of measles can be replaced with spaces for MRCV1 and MRCV2. The vaccination cards (and other home based records), the clinic immunization register, reporting and summary forms will also need to be modified to include RCV. There should also be provision to record doses given to older children and adults.

In the absence of reliable administrative data on coverage, estimates of coverage can be obtained through coverage evaluation surveys (CES) using the standard 30 cluster sampling technique for defined geographical areas e.g. a district. For larger areas e.g. a province or a country, a specially designed survey with the help of a statistician should be used. In addition there are other survey methods that may be employed to evaluate coverage e.g. simple or stratified random sampling, household surveys, etc. For details on the 30 cluster survey methodology, refer to the WHO Immunization coverage cluster survey: reference manual.2

EPI Programme Reviews are usually undertaken every 3–5 years and should be adapted to include RCV once it has been introduced. All surveys (e.g. EPI, Demographic and Health Survey (DHS), Multiple Indicator Cluster Survey (MICS), etc.) should include the estimation of RCV wherever it is part of the national schedule.

Post-introduction evaluations (PIE) are carried out a year after the introduction of new vaccines. The post-introduction evaluation (PIE) tool3 provides a systematic method for evaluating the impact of the introduction of a vaccine on the existing

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1 WHO-UNICEF estimates of rubella vaccine coverage are not available so far. Additional information, such as the type of vaccine used and the age groups targeted for routine administration, need to be incorporated in the JRF to help the generation of these estimates.
2 http://apps.who.int/iris/bitstream/10665/69087/1/WHO_IVB_04.23.pdf (WHO/IVB/04.23)
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immunization system in a country. The PIE tool is designed for immunization managers in countries that have introduced a new or underutilized vaccine. WHO recommends that all countries which have introduced a new vaccine conduct a PIE.

Coverage in women of reproductive age

Estimating coverage among WRA is challenging. In some countries that have conducted mass campaigns among adults, coverage can be calculated either from administrative reports or by doing coverage surveys. For vaccine administered through the routine system, countries may have registers for women of reproductive age, so coverage can be calculated; however, in countries that do not have registers, coverage surveys may be the only way to estimate the coverage of RCV in WRA. In addition, serosurveys among women attending health facilities like ante-natal clinics can be used to estimate protection against rubella.
Surveillance

Rubella surveillance is integrated with measles surveillance

Rubella surveillance must be integrated with measles case-based surveillance. Countries may initially identify rubella cases through testing of sera that were negative for measles. As countries establish rubella control/elimination goals, the surveillance system may be modified to either fever and rash, or if a health worker suspects measles or rubella.

Rubella surveillance includes two components:

- **Surveillance for rubella cases** should be based on individual reporting of cases with collection of specimens for laboratory confirmation together with outbreak confirmation and investigation.

- **CRS surveillance** (at sentinel sites, investigation of outbreaks) will need to be established before or as soon as possible after RCV is introduced in the routine immunization programme in order to document the impact of the vaccination programme in reducing the incidence of CRS.

Rubella case definitions

**Suspected rubella case:** Any patient of any age in whom a health worker suspects rubella. A health worker should suspect rubella when a patient presents with: fever, maculopapular rash and cervical, suboccipital or postauricular adenopathy or arthralgia/arthritis.

**Clinically compatible case:** A case with maculopapular (non-vesicular) rash and fever (if measured) and one of arthritis/arthralgia or lymphadenopathy, for which no adequate clinical specimen was taken and which has not been linked epidemiologically to a laboratory-confirmed case of rubella or another laboratory-confirmed communicable disease.

**Laboratory-confirmed rubella case:** Because of the difficulty of clinical diagnosis of rubella, laboratory confirmation is recommended. A laboratory-confirmed case is a suspected case with a positive blood test for rubella either by IgM positive, at least fourfold rise in titre of IgG or rubella virus or RNA detected.

**Epidemiologically confirmed rubella case:** A suspected case of rubella that has not been confirmed by a laboratory but was geographically and temporally related with dates of rash onset occurring within 12–23 days of exposure to a laboratory-confirmed case or, in the event of a chain of transmission, to another epidemiologically confirmed rubella case.
When a suspected rubella case is identified, it should be reported to the surveillance officer. As rubella surveillance is integrated with measles surveillance, all suspected cases of measles and rubella should be investigated. However, irrespective of the stage of control or elimination, all pregnant women presenting with rash illness (suspected rubella) as well as those with history of exposure to a person with rash illness should be investigated (see the section below on investigation of pregnant women). Once notified, epidemiological investigation including laboratory testing should be conducted for suspected cases of measles and rubella. In most countries introducing RCV, sera will be taken and tested for measles IgM first and then for rubella IgM if negative for measles IgM.

**Figure 2. Classification of measles and rubella cases**

*May also lab confirm by fourfold rise in IgG in acute and convalescent phase specimens of sera or PCR*
**Investigation of pregnant women either exposed to or with suspected rubella**

Pregnant women are the group of greatest concern for rubella. Pregnant women known to have been exposed to rubella should be tested (see Figure 3) and followed until delivery to assess the outcome of their pregnancies. Pregnant women found to be susceptible should be vaccinated after delivery.

a. Depending on the laboratory testing facilities available, all pregnant women with suspected febrile rash illness or suspected rubella, should be tested for rubella-specific IgM.

b. If rubella IgG testing is available, pregnant women with suspected febrile rash illness or suspected rubella should be tested for both IgG and IgM.

c. If the result of the blood specimen is positive for rubella-specific IgM, the patient should be counselled accordingly and followed up. If the incidence of rubella is low or near elimination settings particular care should be taken when rubella IgM is detected in a pregnant woman with no history of illness or contact with a rubella-like illness. Additional laboratory evaluation should be conducted (as highlighted in Figure below).

d. If the result of the blood specimen is negative for rubella-specific IgM and the first blood specimen was taken in the first five days after rash onset (and rubella specific IgG is negative, if tested), a second blood specimen should be obtained and tested for rubella-specific IgM (and for IgG, if available).

e. If the result of the blood specimen is negative for rubella-specific IgM and the rubella-specific IgG is positive within 5 days after rash onset, the patient should be considered immune to rubella.
Figure 3. Serologic evaluation of pregnant women exposed to rubella

- **IgM and IgG at the time of first visit (save sera)**
  - **IgM+ / IgG+**: Acute infection or false IgM positive
  - **IgM+ / IgG-**: Collect 2nd serum 5–10 days later. IgM, IgG and avidity testing to be conducted
    - **High avidity, no rise in IgG titers (tested together with first serum)**: Likely false positive
    - **Low avidity, rise in IgG titers (tested together with first serum)**: Acute infection
      - Discuss options for pregnancy outcome

  - **IgM- / IgG-**: Repeat IgM / IgG 6 weeks if risk of exposure continues to exist (test concurrently with first specimen)
  - **IgM- / IgG+**: Negative

Figure 4. Case-based rash and fever or suspected rubella surveillance for pregnant women, case notification chart

- **Rash and fever**
  - **If suspected or confirmed rubella, case will be included in pregnancy registry and before time of delivery, information will be provided**

- **Investigates and takes blood sample**
  - **Public Health Programme, department level**
  - **Ministry of Health, national level**
    - **Department of Epidemiology**
    - **Measles/Rubella Laboratory**

- **Protocols for evaluation of infant and infection control**

- **Maternity hospital**
Figure 4 highlights the investigation of a pregnant woman suspected of rubella. How the suspected pregnant woman is worked up will vary by country, however, a pregnant with confirmed rubella must be followed up until the end of her pregnancy. For all laboratory-confirmed cases of rubella infection during pregnancy, the patient’s name and other relevant information should be entered into a rubella pregnancy register. Counselling and medical follow-up must be assured. The potential outcomes include: miscarriage, termination, still birth, fetal death, infant born with either CRS or congenital rubella infection (CRI) or a normal infant (see Figure 5).

**Figure 5. Follow-up for pregnant women with confirmed rubella infection during pregnancy**

![Diagram](image)

Pregnancy outcomes should be recorded to fully understand the impact of rubella in pregnancy. For pregnant women delivering at a health facility, the health facility must be notified prior to delivery to ensure that the infant should be isolated and evaluated for signs/symptoms of CRS including laboratory testing.

**CRS surveillance**

**Rationale for CRS Surveillance**

Surveillance for CRS is often implemented prior to the introduction of RCV to document the burden of CRS. However, if it has not been established prior to RCV introduction, CRS surveillance should be put in place as soon as possible after RCV introduction to monitor the effectiveness of rubella vaccination programmes, to detect and isolate affected infants rapidly and to reduce the consequences of the disease on infants and their families through early provision of appropriate medical care. CRS surveillance allows for detection of infants with clinically apparent manifestations and can be standardized for regional and global reporting and comparison purposes. Countries should develop a CRS surveillance
system that captures the majority of infants with suspected CRS. If there is no surveillance in place, countries may opt to first establish CRS surveillance at a few sentinel sites, then broaden the surveillance network and add additional sites. Countries may also implement CRS surveillance associated with a rubella outbreak.

Rapid identification of infants with CRS is necessary to ensure that appropriate testing can be conducted and the infant entered into the CRS surveillance system. Detection of infants with CRS is necessary to ensure infection control and prevent further spread, as infants with CRS may shed virus for up to 1 year. Immediate diagnosis of CRS also facilitates early intervention for specific defects.

The following section provides a comprehensive framework for developing and monitoring high-quality CRS surveillance.

**CRS: Case definitions and Laboratory criteria for confirmation**

**Table 4. CRS case definitions and laboratory criteria for confirmation**

<table>
<thead>
<tr>
<th>CRS case definition</th>
<th>Definition</th>
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<tbody>
<tr>
<td><strong>Case category</strong></td>
<td></td>
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<tr>
<td><strong>Suspected CRS case</strong></td>
<td>Any infant less than one year of age in whom a health worker suspects CRS. A health worker should suspect CRS when an infant aged 0–11 months presents with heart disease and/or suspicion of hearing impairment and/or one or more of the following eye signs: white pupil (cataract), or larger eye ball (congenital glaucoma) or pigmentary retinopathy. A health worker should also suspect CRS when an infant’s mother has a history of suspected or confirmed rubella during pregnancy, even when the infant shows no signs of CRS.</td>
</tr>
<tr>
<td><strong>Clinically confirmed CRS case</strong></td>
<td>An infant in whom a qualified physician detects at least two of the complications listed in group (a) below, or one in group (a) and one in group (b): (a) Cataract(s), congenital glaucoma, congenital heart disease, hearing impairment, pigmentary retinopathy; (b) Purpura, splenomegaly, microcephaly, developmental delay, meningoencephalitis, radiolucent bone disease, jaundice that begins within 24 hours after birth.</td>
</tr>
</tbody>
</table>

**Laboratory confirmed CRS case:** An infant who is a suspected case (with 1 condition from cataract(s), congenital glaucoma, congenital heart disease, hearing impairment, pigmentary retinopathy) and meets the laboratory criteria for CRS laboratory confirmation.

**Congenital rubella infection (CRI):** An infant who does not have group (a) clinical signs of CRS but who meets the laboratory criteria for CRS is classified as having congenital rubella infection (CRI).
Criteria for laboratory confirmation of CRS

- Rubella IgM antibody detected, or
- Sustained rubella IgG antibody level as determined on at least two occasions between 6 and 12 months of age in the absence of receipt of rubella vaccine, or
- Rubella virus detection (e.g., nucleic acid detection by RT-PCR or rubella virus isolation) in an appropriate clinical sample (best results come from throat swabs, but nasal swabs, blood, urine, or cerebrospinal fluid specimens are also acceptable).

Efforts should be made to obtain clinical specimens for serology as well as viral identification from infants at the time of the initial investigation. Infants with congenital rubella infection, even without clinical features of CRS will usually be positive for rubella-specific IgM at or shortly after birth. Although IgM antibodies may persist for up to 1 year, about 50% of CRS cases are IgM negative at 6 months of life, depending on test sensitivity. Because IgM may not be detectable in some infants tested shortly after birth, IgM negative infants with suspected CRS should be retested at one month of age or shortly thereafter. Laboratory confirmation of CRS in an infant aged over six months should not rely on the IgM test alone if the result is negative. In such cases, serial IgG testing should also be included to check for a sustained level of antibody over several months.

Algorithm for testing infants

Figure 6. Testing infants <6 months of age

*Every effort should be made to obtain a blood sample of adequate size (1ml) and that is kept cool during transport.*
Infants with congenital rubella infection (CRI) and congenital rubella syndrome (CRS) should also be tested for rubella virus shedding through virus isolation techniques. Congenitally infected infants may shed and transmit rubella virus for up to one year of age and be the source of rubella outbreaks. Therefore, it is important to continue testing the infant for virus throughout the first year of life so that infection control measures can continue until virus shedding stops. This has to be confirmed by two negative results of viral testing of specimens obtained one month apart from infants at least 3 months of age.

All countries need a CRS surveillance system that has the ability to capture the majority of infants with suspected CRS within the country. Routine surveillance for CRS should focus on identifying infants less than 1 year of age, although some defects associated with CRS surveillance may not be detectable until children are older. The most common congenital defects related to CRS are cataracts, heart defects, and hearing impairment. These are the primary conditions under CRS surveillance. These conditions are most likely to be seen at secondary and tertiary health care facilities, which should be included as sentinel sites for CRS surveillance.
The following steps should be implemented to establish CRS surveillance:

1. Identify national CRS surveillance coordinators responsible for epidemiologic and laboratory components of the system.
2. Determine the health care facilities at which infants with CRS are likely to be seen and enrol them as sentinel surveillance sites; identify a CRS surveillance coordinator at each facility, or group of facilities.
3. Conduct initial and refresher trainings for participating sites
4. Initiate CRS surveillance activities
5. Conduct surveillance quality assessment and monitoring
6. Expand CRS surveillance and include other sites, as appropriate
7. Analyse CRS surveillance data on an annual basis, or more frequently if necessary
8. Provide periodic feedback to all stakeholders involved in the CRS surveillance system.

Other approaches to identify CRS cases

Rubella in pregnancy registries
Rubella in pregnancy registry can be used for follow-up of pregnant women exposed to rubella and their pregnancy outcome(s), as well as for identification of CRS cases. Rubella in pregnancy registries should be maintained at the local level so that comprehensive follow-up of pregnant women can occur, and infants born with CRS can be identified and diagnosed immediately and receive early interventions for any associated defects. The registry should include maternal contact and demographic data and pregnancy outcome (e.g. miscarriage, still birth, termination, infant with CRS, etc.). The infants identified as CRS should be included in the CRS surveillance.

Retrospective searches for CRS Cases
Retrospective searches allow for a rapid identification of infants with CRS by reviewing medical records of infants with defects or signs consistent with CRS. Retrospective searches can help determine a baseline for the burden of CRS in a country. However, a limitation of this approach is that retrospectively identified cases usually lack laboratory confirmation.

A retrospective search systematically reviews available data in places where infants with CRS may be cared for such as tertiary hospitals or specialty clinics. Retrospective studies can be used to provide baseline data for measuring the impact of rubella vaccination programs, to monitor the sensitivity of the surveillance system and finally for the documentation of elimination of CRS. To identify possible cases of CRS, a review of medical records (discharge, hospital
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or clinic) of infants should be conducted in facilities where children who have structural manifestations or birth defects consistent with congenital rubella syndrome are likely to be seen.

Another type of retrospective study is the examination of deaf children’s eyes for CRS associated eye findings such as pigmentary retinopathy to estimate the proportion of children infected in utero with rubella. All children who meet the inclusion criteria (who are deaf) will have their eyes examined. Using a data collection questionnaire, the information will include the demographics of the child, results of examination and any other clinical signs and symptoms associated with CRS. If the medical records are available, data will be extracted from these. Data collected will be entered in EPI-info or another appropriate database.

**Laboratory surveillance**

**Serological testing**

Clinical diagnosis of rubella is unreliable, therefore, cases should be laboratory confirmed. Virus detection and serologic testing can be used to confirm acute or recent rubella infection. Serologic tests can also be used to screen for rubella immunity.

**Diagnosis of rubella**

**Rubella IgM testing**

Detection of rubella-specific immunoglobulin M (IgM) in serum is the standard test for the rapid laboratory diagnosis of rubella. IgM testing is most commonly performed using commercial enzyme immunoassay (EIA) kits. A number of commercially available IgM assays are available for rubella use. Rubella-specific IgM can usually be detected 4–30 days after onset of illness, and often for longer. Sera should be collected as early as possible after onset of illness. However, IgM antibodies may not be detectable before day 5 after rash onset. In case of a rubella IgM-negative result in specimens taken before day 5, serologic testing should be repeated on a specimen collected after day 5.

**Rubella IgG testing**

Detection of a significant rise in specific IgG in serum samples collected during the acute and convalescent phases, can be used to confirm infection. To use IgG testing for diagnosis, the first serum should be obtained as soon as possible after onset of illness and the second serum sample should be collected about 7–21 days after the first specimen. In most rubella cases, rubella IgG is detectable by 8 days after rash onset. Tests for IgG antibody should be conducted on both acute-and convalescent-phase specimens at the same time with the same test usually using the EIA kits. IgG assays can also be useful for classification of sporadic cases of IgM positive or equivocal results in elimination phase countries.
Rubella avidity testing
Assays for IgG avidity are useful to distinguish the difference between recent and past rubella infections. Low avidity is associated with recent primary rubella infection, whereas high avidity is associated with past infection or reinfection. Avidity tests are not routine tests and should be performed in reference laboratories.

Seroprevalence studies
Seroprevalence studies conducted in support of rubella control/elimination activities typically use the quantitative detection by EIA of IgG in a single serum sample. (See Annex 3 for further information.)

Viral detection
To detect rubella virus, two different techniques can be used: isolation of rubella virus and detection of rubella virus using RT-PCR, including real time assays. Rubella virus can be detected from nasal, throat, urine, blood, and cerebrospinal fluid specimens from persons with rubella. The best results come from throat swabs. Cerebrospinal fluid specimens should be reserved for persons with suspected rubella encephalitis. Efforts should be made to obtain clinical specimens for virus detection from all rubella case-patients at the time of the initial investigation. Virus may usually be detected from 1 week before to 1 week after rash onset. However, maximum viral shedding occurs up to day 4 after rash onset.

Unlike persons with rubella, infants with CRS may shed virus for a prolonged period. Infants with CRS should be considered infectious until two cultures of clinical specimens obtained 1 month apart after the infant is older than 3 months of age are negative for rubella virus.

Reverse transcription polymerase chain reaction (RT-PCR)
Real-time RT-PCR and RT-PCR can be used to detect rubella virus and has been extensively evaluated for its usefulness in detecting rubella virus in clinical specimens.

Molecular surveillance
Molecular surveillance is recommended because it provides important epidemiologic information to track the epidemiology of rubella. By comparing virus sequences obtained from new case-patients with other virus sequences, the origin of particular virus types in this country can be tracked. Furthermore, this information may be required for documenting the achievement and maintenance of the elimination of endemic transmission. In addition, genotyping methods are available to distinguish wild-type rubella virus from vaccine virus.
Annexes

Annex 1. Communications for measles-rubella vaccination

Many countries have inter-agency coordination committees (ICC) to oversee the planning, implementation and coordination of immunization. A communication sub-committee should be formed under the oversight of the ICC, to enhance the planning and implementation of communication activities. The introduction of MR vaccine should be included in the regular work of this sub-committee to oversee the national, state and district level planning and implementation of activities. This sub-committee plays an essential role in the development and testing of key messages, advocacy, behaviour and social change communication, social mobilization and training materials. The sub-committee should also oversee national, state and district capacity building activities to ensure consistency and coherence in the delivery of communication interventions.

Advocacy, social mobilization and media engagement

**Advocacy strategies** promote effective policies, political commitment and increased resources to enable sustainable financing of vaccines and immunization services. It is a key component to gain, influence and maintain the support and participation of opinion leaders and decision-makers for the immunization programme.

**Social mobilization strategies** ensure that the key actors, mass media and community level organizations work together to promote immunization, particularly through community participation and ownership. The objective of social mobilization is to ensure adequate awareness in the community so that eligible people seek out and accept the immunization services.

**Media engagement** of traditional and news media is necessary to influence the general population’s perceptions related to vaccination as well as their attitudes towards vaccination. Therefore, media engagement is required to improve the health literacy of media professionals and raise their awareness about the risks and threats posed by measles and rubella. These interventions would be helpful for the media to convey correct and appropriate messages related to immunization. Media engagement as well as effective and timely information from government and the medical profession is also critical to deal with AEFIs\(^1\).

Once an AEFI has occurred, the response should include at least the following elements: effective coordination between the Ministry of Health, the ICC and

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\(^1\) For a complete discussion on setting-up AEFI surveillance, the investigation of AEFI, causality assessment and on how to respond to serious AEFI, including communication, refer to the "Global Manual on Surveillance of Adverse Events Following Immunization" available at http://www.who.int/vaccine_safety/publications/aefi_surveillance/en/
other high officials; providing the parents and caregivers with factual and clear information; reassure the public that necessary measures are being taken; communicate the results of the investigation to programme managers at all levels; broadcast an official statement about the event on radio and television and publish a statement in newspapers; repeat the message as necessary to dispel fears and reassure the public about the safety of vaccines.

Using social media and the internet can be cost-effective tools to promote positive attitudes towards vaccination. Possible approaches include: interactive websites, online discussion groups, involvement of influential bloggers, use of social networks and resources, dissemination of text (SMS) messages, etc. However, use of social media must recognize the important challenges such as inequities in internet access and use and difficulties in reaching some target audiences for MR vaccination.

1. Communication planning
A communication plan should be developed. This is to help coordinate, implement, monitor and evaluate communication interventions to contribute to generate demand for MR vaccine and to promote community engagement and mobilization.

A good communication plan would ensure that:

- Communities and families are well informed and motivated to demand MR immunization services;
- Health workers have a solid understanding of MR vaccine and the diseases it prevents and the required inter-personal communication skills to improve quality of communication to raise demand for the vaccine;
- Organizations and media are mobilized around common MR immunization activities and goals;
- Political commitment and resources needed are in place.

The steps to set up a communication plan for MR vaccine introduction should include:

- The starting point for planning communication activities for the introduction of MR vaccine should be a situation analysis. This may involve rapid assessment of the knowledge and attitudes of the community to identify and foresee barriers that may have an impact on immunization acceptance. The results of these assessments about public familiarity with measles, rubella and CRS; cultural beliefs about these diseases and the perceived risks of vaccination, both among parents and health providers provide the evidence on which the communication plan should be based.
Introducing Rubella Vaccine into National Immunization Programmes

- Map the communities, especially those hard to reach, to ensure that underserved populations who are often missed by routine vaccination are provided access to the new vaccine.

- Review available human, material and financial resources for communication activities for MR vaccine introduction at all levels.

2. Set objectives

- Analyse the factors underlying the behavioural problems: immunization systems related reasons/factors, communication and information related reasons/factors, family characteristics related reasons/factors, parental attitudes and knowledge.

- Formulate communication objectives and measurable targets to address factors underlying main behavioural problems with particular focus on the individual or groups that communication activities will target as well as the specific purpose, i.e. what is expected from this individual or group as a result of the communications interventions.
  - Some examples of the MR vaccination programme objectives are:
    - Contribute to increased and sustained immunization coverage.
    - Contribute to countries reaching at least 95% national vaccination coverage with two doses of MR.
    - Contribute to the elimination of measles and rubella.
  - Some examples of the communication objectives to achieve the above programme objectives are:
    - Increase the general understanding of the risks linked to measles, rubella and congenital rubella syndrome.
    - Increase the number of people who know how to prevent measles, rubella and congenital rubella syndrome
    - Increase the number of people who know the main causes of babies born deaf and/or blind.
    - Increase levels of reassurance among people who are pro-vaccination so as to ensure that those who currently immunize their children continue to do so.
    - Change misperceptions regarding the necessity of MR vaccination including the elimination of uninformed perceptions about the risks of the vaccine.

3. Determine strategies and activities

- On the basis of results from the previous steps, select key communication strategies (advocacy, social mobilization and behaviour and social change communication) and develop their components for each participant group.
• Communication activities specifying media to be used, message content and support materials.
  ▪ Media channels can include ‘traditional’ channels, such as leaflets/brochures, posters, TV or radio commercials, or ‘new media’ such as blogs and social networking.
  ▪ Messages should:
    – Stress that MR vaccination is the most effective way to prevent potential complications or death from measles, rubella and CRS. The most common presentation of CRS is babies born deaf or blind or with heart defects.
    – Address public concern regarding vaccine safety and stress that the vaccine can be given even to children who have a minor illness, disability or are malnourished.
    – Strengthen the importance of the second dose of MCV.
  ▪ Support materials: Deciding on which types of materials are to be produced as part of the communication activities depends on budget, target audiences and the level of detail to be conveyed. A mix of different materials is usually preferred. These may include: letters or invitations to targeted individuals, disease factsheets and frequently asked questions (printed or online), brochures, leaflets and posters, advertisements, TV and radio spots; and educational materials to be used in local health literacy programmes.

• Training and capacity-building plan and community involvement activities.
  ▪ Social mobilization activities should be planned so as to enlist all feasible support from various groups, institutions, organizations etc. These may include health committees, religious and community groups, faith based organizations (FBO), NGOs, civic society groups like youth and women’s organizations.

• Establish a budget.

4. Determine communication indicators
• Impact indicators would be defined in terms of reduction in refusal and noncompliance and increases in children vaccinated by antigen and fully vaccinated as appropriate for their age.
• Outcome indicators would allow measuring the extent to which communication objectives have been met.
• Process indicators would allow to measure implementation of planned activities

Indicators of communication effectiveness can include a number of indicators which could measure change in attitude towards MR vaccination, health literacy levels, changes in vaccination uptake and observation of vaccination schedules.
They might address reasons for no vaccination, sources of information, knowledge about adverse events and side effects following MR vaccination.

### Examples of questions to assess communication effectiveness during SIAs/campaigns

#### Questions for vaccinator:
1. Reasons for non-vaccination. Why the person was not vaccinated?
   - ☐ Refused; if so, why did they refuse
   - ☐ Was sick
   - ☐ Not informed about the campaign
   - ☐ Other

2. Against what illness was the person vaccinated during this campaign
   - ☐ Measles
   - ☐ Rubella
   - ☐ Measles and rubella
   - ☐ Other illness
   - ☐ Do not know

#### Questions for beneficiary:
3. Were you informed of the measles and rubella vaccination campaign?
   - ☐ Yes   ☐ No

4. If yes, how did you obtain the information?
   - ☐ Vaccination team
   - ☐ Radio
   - ☐ TV
   - ☐ Mobilizers
   - ☐ Religious leader
   - ☐ Health worker
   - ☐ Neighbour
   - ☐ Other

#### Question about AEFI (to beneficiary and provider):
5. Do you know anyone who got sick as a result of the vaccine?
   - ☐ Yes   ☐ No
5. Develop an action plan for implementation and monitoring

- Draw up an implementation plan of action and format for data collection activities with timeframe.
  - Surveys and field studies can be effective tools for measuring perceptions, attitudes, values, health literacy levels and behaviour at the beginning, during, and after the completion of the health communication interventions.
  - When designing such a study, indicators should be developed and built into the communication plan. Particular focus should be given to measurable activities.

- Develop monitoring indicators and decide on periodicity for monitoring.
  - Effective monitoring helps determine:
    - If all planned activities were fully implemented on time;
    - if all hard-to-reach groups are being reached;
    - if appropriate channels are being utilized;
    - which channels are most effective at reaching the various participant groups;
    - the impact of communication interventions on the participant groups’ knowledge, attitudes and practices;
    - the need for and nature of actions that should be implemented to enable continuous improvement of results.

6. Monitor and assess effectiveness of communication activities

- Use indicators for evaluation.
  - Evaluation will compare the actual outputs, outcome and impact of communication interventions with those that were planned, and determine the extent to which and how communication efforts have influenced the quality and utilization of immunization services. It should be based on analysis of results from output, outcome and impact indicators, as well as on other external factors that might have influenced programme implementation.

- Make recommendations based on the results of evaluation.
  - Evaluation helps communication managers to account for investments made, to refine strategies, and identify and correct flaws, and to ensure the most effective allocation of communication financial resources for the vaccination programme.
Annex 2. Steps to establish a CRS Surveillance System

1. Identify national CRS surveillance coordinators responsible for epidemiologic and laboratory components of the system.

a) The epidemiologic coordinator oversees:
   - Development of a protocol for CRS surveillance
   - Development of necessary training materials
   - Training on the CRS surveillance system
   - Monitoring of surveillance performance and data quality
   - Adequacy of collection and transportation of specimens for laboratory testing
   - Maintenance of the CRS surveillance database
   - Coordination with laboratory activities, to ensure linkage of laboratory and epidemiologic data
   - Coordination of activities with national measles and rubella elimination programme in country, including reporting to WHO
   - Feedback on CRS surveillance to health workers, participating facilities and relevant public health authorities.

b) The laboratory coordinator oversees:
   - Adequacy of the laboratory testing, standard operating procedures (SOPs), necessary accreditations and an ongoing quality assurance programme
   - Interpretation and reporting of test results for CRS
   - Monitoring duration of virus shedding by CRS cases
   - Coordination with epidemiological activities, to ensure linkage of laboratory and epidemiologic data
   - Laboratory related training

2. Determine facilities at which infants with CRS are most likely to be seen.

   - The facilities at which infants with most common defects associated with CRS – cataracts, heart defects or hearing impairment, as well as infants with maternal history of rubella during pregnancy are likely to be seen should be included in the CRS surveillance system. As these defects are most likely to be evaluated and treated at secondary and tertiary care facilities, adequate sentinel surveillance for CRS can be conducted at these facilities, without including primary health care providers and facilities in the CRS surveillance system. This will help to avoid overwhelming general health care providers by having to identify, report, and follow-up on cases of CRS.

1 Additional details can be found in ‘Guidelines for surveillance of congenital rubella syndrome and Rubella – Field test version, May 1999’ (WHO/V&B/99.22) available by request at http://apps.who.int/iris/handle/10665/68104
• The types of facilities/providers most likely to evaluate and treat infants with CRS:
  - Secondary care providers/facilities, particularly ophthalmologists, cardiologists, audiologists, neonatologists
  - Tertiary care facilities, particularly those that provide surgical services for the eyes, ears and heart
  - Specialty care centres (e.g. Children’s Hospitals; Centres for Hearing and Blindness)
  - Obstetric centres or private clinics involved in care of pregnant women with rubella

• If providers and facilities included in the CRS surveillance system capture the majority of infants with suspected CRS within a country, the CRS surveillance system can be considered adequate.

• It is recommended that countries with newly established CRS surveillance systems pilot test their system with a few facilities to ensure adequacy of developed protocols and SOPs. Protocols may then be updated with feedback from the piloted sites.

• Responsibilities of local surveillance coordinators at sentinel sites include to:
  - Ensure adherence to the national protocol and SOPs for CRS surveillance
  - Assist as needed in training health workers at the respective facilities
  - Ensure collection of clinical and epidemiologic data and completion of case investigation forms
  - Ensure appropriate collection and transportation of specimens with and ensuring that laboratory data can be linked to clinical and epidemiologic information
  - Maintain a line listing of suspected CRS cases in the assigned facilities
  - Provide periodic feedback to health workers
  - Maintain contact with the national coordinator regarding identification and follow-up of suspected cases of CRS identified in the area

3. Conduct initial and refresher trainings for participating providers.

• Trainings for the providers from the sentinel facilities participating in CRS surveillance activities should be conducted on an annual basis.

• Trainings should include information regarding clinical features of CRS, evaluation of infants with suspected CRS, appropriate laboratory testing of suspected cases, follow-up of CRS cases, the importance of completing case investigation forms, infection control measures to prevent rubella virus spread from infants with CRS, and reporting cases in a timely manner.

4. Initiate CRS surveillance activities.

• Reporting of suspected CRS cases should be initiated once the coordinator and participating sites have been identified and participating providers have been trained in SOPs for CRS surveillance.
5. Conduct surveillance quality assessment and monitoring.

- Surveillance quality assessments need to be conducted at the sentinel sites at least every 6 months to assess completeness of CRS surveillance at the site
  - This should be done by review of hospital records by the site level coordinator to identify any missed cases.
  - Missed cases can be identified by comparing the list of reported CRS cases with the list of all cases that meet the entry criteria for CRS surveillance (i.e. criteria for suspected CRS case). The proportion of missed cases at a sentinel site can be assessed as the percent of missed cases identified by the coordinator, among all cases that meet the CRS surveillance entry criteria (total of both reported and unreported cases).
  - Similarly, the proportion of suspected CRS cases that have been reported but have not been tested by laboratory can be assessed as the percent of reported cases without laboratory testing among all reported suspected CRS cases (both tested and not tested).

- Monitoring surveillance data quality. CRS surveillance case reports should be assessed for any missing variables. If records are incomplete, the findings should be discussed with providers at the site and the need for completeness of data and case reporting should be emphasized.

6. Expand CRS surveillance and include other sites, as appropriate.

In countries that have conducted limited pilot testing of CRS surveillance systems or in countries where assessments have shown that the majority of infants within the country are not included in CRS surveillance, the surveillance should be expanded to include more sites, with the ultimate goal of establishing sentinel site surveillance that captures the majority of infants in the country.

7. Analyse the CRS surveillance data on an annual basis, or more frequently if necessary. Epidemiologic variables that should be assessed include:

- Number of cases reported throughout time frame assessed (e.g. year)
- Case classification status
- Geographic location of CRS cases within country
- Whether or not cases were clustered and/or associated with rubella outbreaks
- Maternal characteristics (age, race/ethnicity, country of birth)
- Location of maternal exposure to rubella.

8. Provide feedback to stakeholders involved in the CRS surveillance system.

Feedback should include information on the status of the epidemiology of CRS, including, if necessary any updates and recommendations for improvements.
Annex 3. An introduction to seroprevalence surveys

Surveillance programmes for rubella, based on an understanding of a country’s unique epidemiology and operational needs, provide essential information to control and eliminate the disease and prevent the devastating consequences of CRS. Components of a rubella surveillance programme include timely identification of disease and thorough case investigation; assessment of data to insure that indicators are being met; and timely feedback to local, national and international public health stakeholders. Information from high-quality surveillance reveals areas where the immunization programme needs strengthening and where targeted vaccination activities are appropriate.

In some instances, serosurveys can be an important complement to surveillance activities. Serosurveys are defined as the collection of serologic specimens from a population over a specified period of time to measure immunity status. Appropriately interpreted data from well-designed and well-implemented serosurveys can provide reliable evidence about the immunity profile of the population surveyed. Serosurveys may also provide valuable evidence documenting disease control and elimination.

Historically, rubella serosurveys have been conducted in diverse settings and populations, using different methods, and the results interpreted to guide a variety of activities. For example, results of a serosurvey were used to determine a baseline rubella vaccination strategy in Kyrgyzstan: After a rubella outbreak was identified there in 2001, a serosurvey was conducted among women aged 15–39 years. Testing for rubella-specific IgG antibodies revealed significantly higher susceptibility among women >25 years of age. After considering all available information, including other surveillance data, rubella vaccination of women aged <35 years and selective vaccination of older women who were planning on becoming pregnant was recommended.

Serosurveys are also used to document susceptibility among particular cohorts of individuals. For example, although coverage with a rubella-containing vaccine may be high overall, there could be geographic areas with large numbers of vaccine refusers and large cohorts of persons who have never been vaccinated. Rubella continues to occur in such areas. Serosurveys show susceptibility among women of reproductive age, vaccine refusers, as well as in other cohorts such as health workers and among populations with limited access to health care.

If conducted appropriately and used in conjunction with other surveillance data, serosurveys may provide countries with key information to target strategies to reduce susceptibility levels so that interruption of disease transmission and

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1 This annex is only an introduction to serosurveys for rubella, a detailed guide on the methodology and interpretation of serosurveys is under development by WHO (expected in 2015), some additional details can be found in ‘Guidance on conducting serosurveys in support of measles and rubella elimination in the WHO European Region’ available at http://www.euro.who.int/__data/assets/pdf_file/0011/236648/Guidance-on-conducting-serosurveys-in-support-of-measles-and-rubella-elimination-in-the-WHO-European-Region.pdf
consequent elimination is possible. Serosurveys can be used to help develop the most complete information on a population’s rubella susceptibility profile given one of 3 typical scenarios that precede elimination.

1) If the epidemiologic evidence reveals disease among persons targeted for vaccination (usually as a result of suboptimal coverage), serosurveys can provide information on where to target enhanced vaccination efforts. In addition, vaccination recommendations may have changed over time, leaving some cohorts of males, females or both susceptible to disease. For example, large-scale rubella outbreaks among males have been documented in countries where rubella vaccine was historically targeted only to adolescent females to prevent CRS. To eliminate disease, countries must ensure that both sexes have high immunity levels to rubella, acquired either through vaccination or natural infection.

2) If a country’s vaccination programme did not cover persons who are now adults, serosurveys can provide information on immunity levels among adults to determine if disease is likely to circulate among them.

3) If the epidemiology of disease indicates an age shift from children to persons in their teens or twenties (posing a higher risk for CRS), serosurveys can provide information on immunity levels to guide targeted vaccination efforts.

Application of serosurvey findings:
These questions should be considered when applying serosurvey results:
• Do results indicate that additional vaccination strategies are necessary to achieve control and elimination goals?
• What policy actions are necessary to enable action based on the findings?
• What, if any, additional studies are needed as a result of this assessment?
• What additional efforts are needed to reach the goal
Annex 4. Rubella outbreak investigation and response

The intensity of rubella outbreak investigations and outbreak response will vary by regions and countries. Here are some basic steps for a rubella outbreak investigation.

- Confirm the diagnosis;
- Conduct case investigations and vaccinate susceptible contacts;
- Enhance active and passive surveillance measures;
- Implement rubella control measures;
- Develop a plan for preventing future rubella outbreaks.

The steps of an outbreak response are:

a. Confirm the diagnosis through laboratory testing

b. Determine if an outbreak is happening

c. Establish a response team

d. Enhance active and passive rubella surveillance to increase case detection
   i. Active rubella surveillance is established including laboratory confirmation
   ii. Health workers are alerted about the rubella outbreak including instructions on where to report suspected cases
   iii. A pregnancy registry is established to document all pregnancy outcomes.
       These may include abortions (spontaneous and therapeutic), fetal deaths, CRS cases and infants with congenital rubella infection

e. Conduct case investigation and vaccinate susceptibles
   i. Ensure staff understand how to do case investigation and contact training including what information is needed for pregnant women and the required follow-up

f. Implement rubella control measures
   i. Control measures will depend on the situation in the country
   ii. Ensure immunity of health workers (vaccinate or IgG testing)
   iii. Implement infection control practices in hospitals and clinics
   iv. Isolate persons that are contagious for up to 7 days after rash onset
   v. Depending on the status of rubella elimination, implement vaccination strategies either to contacts or to targeted groups or implement nationwide SIAs.

1 Additional details can be found in ‘Guidelines for measles and rubella outbreak investigation and response in the WHO European Region’ available at http://www.euro.who.int/__data/assets/pdf_file/0003/217164/OutbreakGuidelines-updated.pdf

2 This will vary by country. If vaccine supply is limited, ensure immunity among HCWs. At second level of priority – ensure immunity around contacts of susceptible pregnant women, particularly in early pregnancy.
g. Establish or strengthen CRS surveillance: Active CRS surveillance should be established or strengthened in maternity hospitals, paediatric hospitals, neonatal intensive care units and amongst specialists who treat infants with cardiac, hearing or eye problems. Hospital located in the area where the outbreak is occurring should be prioritized.

h. Develop a plan for the prevention of future rubella outbreaks which should include plans for integrated measles and rubella surveillance, CRS surveillance, routine immunization with MR vaccine and periodic SIAs as needed.
Annex 5. Frequently Asked Questions (FAQs)

1. What is RCV administration?
It is the administration of a dose of rubella containing vaccine (RCV) to a child, usually at the same time that the child receives MCV, as a combination vaccine.

2. When should RCV be given?
At 9 – 12 months of age along with measles vaccine. In countries with a two-dose MCV and RCV schedule, the minimum interval between two doses of RCV is 1 month. It is recommended that countries develop a policy to screen children at school entry to verify that the children have received the recommended number (one or two) doses of RCV vaccine and vaccinate any child missing any dose.

3. Why is a RCV needed?
Providing routine RCV to children reduces the number of susceptible children and the risk of rubella transmission and occurrence of CRS. RCV should be given with all doses of MCV as MR (or MMR) vaccine recommended in the country’s immunization schedule.

4. Who should receive RCV?
Any child who is receiving MCV should get RCV. A second dose of RCV should be given in countries providing two doses of MCV. In addition, health workers and susceptible individuals should also receive RCV.

5. Is RCV limited only to young children? What about teenagers and adults?
The age of vaccination depends on the schedule of measles vaccination in a country. Teenagers and adults should also receive RCV if they do not have documented history of rubella vaccination or disease. Since rubella occurs predominantly in children and adolescents, they are the priority targets for vaccination.

6. How is RCV administered?
The vaccine is commonly administered as a combination vaccine (MR or MMR) at the time of measles vaccination. The vaccine is diluted with the accompanying diluent and administered by sub-cutaneous injection.

7. Is it safe to have two doses of rubella vaccine? Is there any risk of overdosing?
Yes, it is safe and there is no risk of overdosing. In fact, two doses would ensure that the very small proportion of children who did not seroconvert after one dose would acquire immunity.
8. Do other countries give rubella vaccine? Do they use the same vaccine?
Many countries (137 countries reported giving RCV to WHO and UNICEF in 2013) have introduced RCV into their national immunization schedules. The vaccine commonly given is in combination with measles (MR).

9. Will the MR campaigns (SIAs) stop now that there is MR in the routine immunization schedule?
The decision to stop SIAs is based on many considerations like the coverage of the recommended number of doses of MR, the duration for which that coverage has been achieved continuously, the incidence and age group of rubella cases, etc. Stopping SIAs is a serious decision, prior to which a careful review should be conducted by a national committee to evaluate the potential risks and benefits of relying solely on routine immunization. Among other things, it is suggested that the committee should consider routine subnational and SIA coverage of MR, the expected rate of accumulation of susceptibles without SIAs, rubella epidemiology and the performance of the surveillance system.

10. Can I ignore the next SIA if my child has already received the recommended number of doses of rubella vaccine?
The purpose of SIAs is not only individual protection of your child but may also be the elimination of disease. So it will be best not to ignore the SIA if your child is within the age group targeted by the SIA.

11. What will happen if my child starts school and they have not received rubella vaccine?
Your child should get his recommended number of doses of RCV as soon as possible. If a country follows a 2-dose schedule, the minimum interval between the doses is one month. There is no maximum interval.

12. As part of a campaign among adults, even though we have asked women to state whether or not they are pregnant, we subsequently identify women who were pregnant at the time of vaccination.
No cases of CRS have been reported in almost 3000 susceptible women who were unknowingly vaccinated against rubella in early stages of pregnancy. However, because of a theoretical, but never demonstrated teratogenic risk, rubella vaccination of pregnant women should be avoided in principle. Although women should be asked about the possibility of early pregnancy prior to rubella vaccination, screening tests to exclude pregnant women are not required. Rubella vaccination of unknowingly pregnant women is not an indication for abortion.
Annex 6. Supplementary Immunization Activities (SIAs)\(^1\)

Introduction

SIAs are complementary to routine immunization. SIA planning should incorporate activities that strengthen routine immunization and surveillance systems, with a detailed budget and identification of responsible persons at all levels for planning and implementing the activities.

The SIA microplan establishes a timeline that indicates the timing of critical activities. This timeline will enable authorities and technical agencies to monitor the progress of preparations and implementation of the SIA. The microplan indicates the types of posts to be used during the SIA: (1) permanent – fixed immunization posts, (2) temporary – fixed or outreach immunization posts and (3) mobile immunization posts. The type of post employed in an area depends on the health infrastructure and population density of that area.

During SIAs, all children in the target age group and geographic area are eligible to receive a dose of measles-rubella vaccine irrespective of past immunization history or history of clinical measles or rubella. Strategies should be developed and deployed to overcome barriers to reaching previously unreached populations. Areas with high disease burden, such as areas which have had measles or rubella outbreaks, other vaccine preventable disease outbreaks, have poor sanitary conditions or migrant and/or marginalized populations, should be targeted for special efforts.

The duration of a campaign (SIA) depends on the number of health workers; available transportation; and other factors. Time should be taken to ensure proper planning to ensure quality. Preferably, a measles-rubella campaign should be conducted over a period of 7 days up to a month. In cases of logistical constraints one alternative is to conduct a rolling campaign, phasing large geographical areas over a longer period of time.

The best time to schedule MR SIAs is during the low transmission season, as determined from local experience and review of epidemiological data. Factors such as seasonal accessibility and important events such as planting, harvesting, religious, traditional and political events, school openings and examinations etc. need to be considered.

SIAs are a good platform to deliver other interventions that create synergy, such as delivering vitamin A, deworming tables, other immunization antigens, insecticide treated bed-nets and other interventions. Keys to successful integration include compatibility between interventions, adequate support for additional services and rapid uptake of linked interventions. Care needs to be

\(^1\) This annex is only an introduction SIAs, a detailed guide on the methodology and monitoring of SIAs is under development by WHO (expected in 2015).
taken to avoid any negative effect of integrating services on the performance of the SIA (e.g. overburdened staff, unequal resource allocation and logistical difficulties).

**Characteristics of successful measles-rubella SIAs**

- Part of an integrated disease control/elimination framework;
- Country ownership;
- Buy-in from political leaders and other stakeholders;
- Bottom-up planning;
- Active community participation;
- Good micro-planning to ensure smooth implementation with no disruption of supplies;
- Adequately monitored and documented;
- Administrative coverage of > 95% achieved in all districts;
- No remaining large pockets of unvaccinated children;
- Very low proportion of missed children especially in hard-to-reach areas
- National level administrative coverage validated through coverage surveys;
- Minimal wastage of inputs (vaccines, devices, human resources);
- AEFIIs are monitored and well managed;
- Ability to forge and strengthen local partnerships beyond the SIAs;
- No harm to the health workers or to community, through appropriate immunization waste disposal.

Macroplanning at the national level helps to secure high level political commitment and ownership, to develop realistic budget estimates, to mobilize resources, to obtain commitments from key partners, to order vaccines, cold chain equipment and related supplies on time. The national level planning process has to include a thorough review of previous performance in order to identify good local practices that have been associated with successful outcomes in the past. The plan needs to ensure that these good practices will be strengthened.

**Microplanning**

Microplanning is a bottom-up approach to planning with the participation of local leaders and health centre officials, often carried out at district level. This exercise should come up with valid and realistic estimates of resource needs based on target population and realities on the ground with regard to existing and locally available resources: human resources, cold chain equipment, transport, waste management issues, per-diem to health workers and involvement of community leaders. The involvement of other ministries like the Ministry of Education, NGOs,
faith based organizations (FBOs), civil society groups and other stakeholders at the planning stage helps to pool resources that normally may not be accessible. During this exercise special attention should be given to address barriers to reach underserved populations.

**Vaccine and supplies**

The microplan should indicate the number of doses of vaccines, AD syringes, reconstitution syringes and safety boxes that will be required. In general, a wastage rate of 10% (wastage multiplication factor of 1.11) is adequate for SIAs when the target population is accurately estimated. All items need to be ordered six months ahead of the SIA dates to allow for vaccine production and release, shipment by sea of the injection devices, clearance at ports and inland distribution.

**Vaccination teams**

The programme needs to estimate the composition and number of teams required to implement the campaign. The success of mass campaigns depends in large part on there being enough trained teams on the ground. Vaccination teams comprise of vaccinators and volunteers. Vaccinators are health workers trained in injection techniques and vaccination, their responsibilities include reconstitution of vaccine, administration of vaccine, safe disposal of waste, response to adverse events, final summary and reporting of the number of children vaccinated and supervision of volunteers. Health workers from hospitals and other health facilities should be drawn carefully to ensure minimal disruption of routine and essential services. Volunteers are responsible for crowd control, screening of children, recording and tallying, mobilizing the community and identifying unvaccinated children in the eligible age group.

Depending on the setting, each vaccination team can vaccinate between 100 and 400 children per day. In some rural and sparsely populated areas, the population density might make it difficult to reach even 100 children a day. One of the advantages of bottom up microplanning is that these ground realities can be recognized and planned for.

**Injection safety and waste disposal**

Standard procedures for injection safety and waste disposal need to be followed during SIAs, as during any immunization activity. At the service delivery post, needles should not be recapped. Used syringes and needles should be discarded into the safety boxes provided. At the end of each day of immunization, each team will bring back or send their ¾ filled safety boxes to designated health facilities for incineration. If incinerators are not available, plans should be drawn up to store the filled safety boxes for subsequent collection and incineration at a centralized location. Any other waste should not be put into the safety boxes. Instead, other waste should be disposed of in bins and incinerated along with
the safety boxes. As large quantities of waste are produced during SIAs, special measures need to be planned for to ensure adequate waste management. This includes drawing up an inventory of functioning incinerators, means of transportation and the frequency of transport from the vaccination posts to the incinerators, estimation of the incineration capacity per installation and programming of the waste incineration. In some countries other procedures are followed e.g. using hub or needle cutters to separate the needles from the syringes and privatization of the collection and disposal of wastes.

**Prevention of adverse events following immunization (AEFI)**

The microplan should describe measures to avoid programmatic errors leading to AEFI and adequately address the issue of AEFI management. Health worker training is critical, as well as adequate supplies to ensure safe injections at all times. This includes the provision of adequate quantity of diluents. AEFI management kits should be available at the vaccination posts. Vaccinators should be trained in the use of the AEFI kits. During the campaign, the AEFI committees need to be functional. A crisis communication plan needs to be developed and disseminated to streamline communications in case a serious AEFI occurs. This is to assure the public that the event is adequately taken care of.

**Supervision**

Intensive supervision is necessary to ensure quality of implementation of SIAs. Supervisors should be identified at each level to guide and support personnel for quality implementation of the campaign. Supervisors should be given refresher training in order to re-orient them on key skills and activities required to conduct effective supportive supervision for the measles and rubella SIAs. In addition, an adequate monitoring system needs to be set up to measure the quality of the campaign and to address possible gaps before the campaign ends.

**Monitoring of campaign coverage**

Real time coverage data should be collected at all levels, enabling rapid data transmission from local levels to control rooms at intermediate and national levels. Tally sheets should be carefully designed to collect all essential information while not being too long so as to be impractical. Critical elements should include the identification of the neighbourhood and the age group of the children or adults vaccinated.
Intra-campaign local level SIA campaign quality monitoring is intended to immediately address whatever operational issues may be preventing universal coverage of the targeted population. **Whereas monitoring of campaign quality is usually conducted during a vaccination session, coverage assessment is conducted after completion of vaccination activities in the area to be monitored.** Timely monitoring has the advantage of limiting potential recall bias and the disappearance of finger markings (if done). Unvaccinated individuals should either be vaccinated during the monitoring activity or asked to go to the nearest immunization site. When several unvaccinated persons are identified, vaccination teams should be re-deployed to review the entire area and vaccinate any left out persons. This requires flexibility in SIA tactical operations including vaccination team management and vaccine, cold chain and logistics resource allocation.

**Intra campaign monitoring**

Measles and rubella SIA campaign quality monitoring at the local level is usually conducted through rapid coverage monitoring (RCM), sometimes also referred to as rapid coverage assessments (RCAs). Sampled populations usually include those at highest risk for being missed during SIAs as well as convenience “grab” samples in markets, transit points, and other places. As such, RCM does not use representative sampling and is not a scientifically valid means of measuring or generalizing overall campaign coverage.

**Post-campaign assessment**

One method of SIA coverage assessment is lot quality assurance sampling (LQAS), which is based on a representative sample of the target population that is obtained through simple random sampling (SRS) or cluster sampling. LQAS results in a binary classification (pass or fail) of a given lot rather than an estimate of coverage. However, data from multiple lots may be combined in a manner similar to those from a stratified sample to determine vaccination coverage point estimates with confidence intervals for larger areas.

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**SIA coverage monitoring serves several important purposes. These include:**

- identifying local areas with inadequate coverage early on, allowing corrective actions to be taken;
- providing a separate independent assessment to validate administratively reported coverage, particularly when denominators are uncertain; and
- Determining reasons at the local level for failing to vaccinate the target population to improve follow up.
Another method of coverage assessment is the coverage survey, which is based on a representative sample through cluster or stratified-cluster sampling. The coverage survey provides a quantitative point estimate with confidence intervals of overall coverage in the area surveyed.