Measles and Rubella Initiative Outbreak Response Fund Application
Standard Operating Procedures

This update of the M&RI ORF Standard Operating Procedures (SOPs) includes the following modifications:

1. To encourage countries to submit applications for ORF support early in the evolution of the outbreak in order to effectively stop measles virus transmission before it becomes more widespread, M&RI will monitor indicators of timeliness of outbreak response immunization in accordance with Immunization Agenda 2030 guidelines;

2. To accelerate the process to receive support, M&RI has removed requirements for advance notification when requesting ORF support and has established a limited timeframe to evaluate the application for ORF support and to provide feedback or issue a decision letter;

3. To more comprehensively address outbreak response linked to timely and efficient use of vaccine, M&RI will allow for greater flexibility in areas of support on an exceptional basis and with adequate justification;

4. To reduce the likelihood of requested additional information or clarifications from M&RI, the SOPs provide greater detail regarding the key data elements and analysis recommended when investigating measles outbreaks and preparing reports, plans and budgets;

5. To maximize use of outbreak investigations and their follow up to strengthen immunization systems, M&RI requests countries to include findings from root cause analyses and, based on these, plans to improve routine immunization, surveillance and outbreak preparedness in the required post-outbreak report.

A. Background

The Measles and Rubella Initiative (M&RI) has provided funding through an outbreak response fund (ORF) since 2012 to support bundled vaccine and operational costs for measles and rubella outbreak response immunization (ORI), with Gavi supporting up to a total of US$10 million per year for Gavi-eligible countries.

The purpose of national measles and measles-rubella SIAs is to prevent virus transmission by efficiently achieving high levels of population immunity when routine immunization is unable to do so, and to interrupt virus transmission nationwide when there is ongoing circulation. The purpose of ORI is to reduce measles/rubella morbidity and mortality and prevent further spread of the outbreak by interrupting measles virus transmission locally. World Health Organization (WHO) recommendations for measles outbreak response\(^1\) include two phases of ORI:

1) initial rapid ORI in the affected areas that includes social mobilization and communication, and selectively targets unvaccinated and under-vaccinated children 6-59 months old (or older age groups, depending on the age distribution of cases)

2) if phase 1 fails to stop the outbreak, subsequent ORI on a larger scale targeting children, usually non-selectively, based on outbreak epidemiology, immunity gaps and risk of virus transmission and spread

Experience has shown that applications for the measles and rubella ORF often address the second response phase and are submitted long after the outbreak’s onset when the geographic extent of transmission moves well beyond its initial boundaries, leading to requests to fund relatively large scale, non-selective campaigns. In addition, the epidemiologic analyses from the outbreak investigation reports submitted with the applications do not always discriminate sufficiently between measles and non-measles cases and/or do not always justify the geographic scale of the proposed response or targeted age groups, leading to delays in ORF awards until such discrepancies are clarified or corrected. For these reasons, M&RI has modified its guidelines for ORF applications as noted above.

B. Eligibility and application requirements

All Gavi-eligible countries that have a lab-confirmed measles or rubella outbreak of public health importance AND cannot respond to the outbreak fast enough with in-country funding (e.g., domestic outbreak response funds or donor funding) are eligible to request ORF support for outbreak response immunization that includes: a) bundled vaccine alone; b) bundled vaccine and operational costs (including root cause analyses) up to $0.65 per child; or c) operational costs alone up to $0.65 per child. M&RI will consider funding other or additional approaches to outbreak response, linked to timely and efficient use of vaccine, within the $0.65 per child limit to prevent further measles virus transmission on an exceptional basis and with adequate justification. M&RI will consider supplementing the $0.65 per child operational costs on an exceptional basis for countries faced with fragility, emergencies, disasters or refugee situations.

The M&RI will also consider applications from non-Gavi eligible countries for technical assistance for outbreak investigations and immunization response based on availability of M&RI funding from non-Gavi sources.

M&RI will review the merits of the proposed interventions and budget and may request from the country additional information or analysis before deciding to fully fund, partially fund, or not fund at all. Countries may need to supplement M&RI ORF with other funding sources. ORF support will not be provided retroactively for completed immunization activities except under exceptional circumstances.

A request for M&RI ORF should include five components:

1. A completed request form (Annex 1);
2. A report of the outbreak and any interventions already undertaken, including

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2 A standard protocol and sample questionnaires for conducting a measles outbreak root cause analysis is available from M&RI upon request
a. a description of how the outbreak started and evolved, initial identification of the proximate and underlying (root) causes of the outbreak and reasons for its continuation until the present;

b. a table with the number of reported suspected cases, and among these the number that were lab-confirmed, epidemiologically linked, \(^3\) clinically compatible and discarded, by district; \(^2\) the rash onset date of the first reported suspected case and first lab-confirmed case in each district should also be included, as well as the date that the outbreak was confirmed in the district;

c. an estimate of the true number of measles (and rubella) cases, by district and province
   i. the preferred method to determine the estimated number of true measles and rubella cases is to multiply the total number of epi-linked and clinically compatible cases in each affected district by the district-specific laboratory-confirmation rate \(^5\) and adding this result to the number of lab-confirmed cases for each district; the total estimated number of true cases during the outbreak would be the sum of estimated true cases per district (see example in annex 2);

d. attack rates of 1) lab-confirmed, epi-linked and compatible cases and 2) estimated true cases, by district and age group (see example in annex 2);

e. separate, detailed descriptive epidemiologic analyses of lab confirmed, epidemiologically linked and clinically compatible cases that address the following descriptive epidemiologic categories:
   i. Time: epidemic curves, with bars stacked by
      1. classification status (i.e., lab-confirmed, epi-linked, clinically compatible, discarded) and
      2. location (i.e., district or province, or village if the outbreak is geographically limited); two separate epidemic curves may be presented for
         a. lab confirmed and epi-linked cases only and
         b. lab confirmed, epi-linked and clinically compatible cases
   ii. Place: tables and spot map or pattern map of where (i.e., in which village or district) cases were infected, by classification status;
   iii. Person:
      1. tables and/or bar charts of age, age group, vaccination status, \(^6\) and sex for
         a. lab-confirmed and epi-linked cases only and

\(^3\) The report should indicate what criteria were used to classify cases as epidemiologically linked;
\(^4\) Specimens for lab confirmation should be collected from at least 5-10 suspected reported cases per district and tested at a WHO-accredited laboratory; if the outbreak has continued for greater than 2 – 3 months in the same district, specimens from at least 5-10 additional cases should be collected prospectively every 2-3 months
\(^5\) The laboratory confirmation rate is the number of IgM+, IgM equivocal and PCR+ cases divided by the total number of suspected cases tested serologically
\(^6\) A stacked bar chart describing cases by year of age stacked by vaccination status is a convenient way to illustrate age distribution and vaccination status in a single graphic; ideally, two stacked bar charts should be provided – one for lab-confirmed and epi-linked cases; a second for lab confirmed, epi-linked and clinically compatible cases
b. lab confirmed, epi-linked and clinically compatible cases;

2. tables with number of deaths and case fatality rates by age group and sex

Tables and bar charts of cases by year of age are the most important “person” data to justify the proposed target age for ORI; case fatality rates may help determine if case management is adequate; vaccination status and sex are important to better understand the proximate and root causes of the outbreak. The report should state if any substantial differences exist in age distribution, vaccination status, sex or case fatality rates in any district and if so, to provide those data by district

f. Results of contact tracing, if conducted;

g. A description of any immunization activities conducted previously in response to the outbreak, including target number by age group, number vaccinated and impact;

i. NB: If any immunization activities were already conducted in response to the outbreak, separate analyses should be provided of the number of cases, by classification status, estimated magnitude of the outbreak, and descriptive epidemiology (i.e., items a, b and c above), by district, among suspected cases with rash onset before the immunization activity and 3 weeks or more after the activity was completed;

3. Risk assessment of the potential for spread of the outbreak that includes, at a minimum, estimates of population immunity nationally and in the affected and surrounding districts or areas, by birth cohort/year of age, relying on past administrative and survey data of routine and supplementary immunization activities;

4. A plan of action describing the planned outbreak response activities including:

a. Identification of the target areas, age-groups and number of persons to be vaccinated;

b. Operational plans, including at a minimum, dates of the outbreak response, vaccine and logistics needs and transport, human resource requirements, training, social mobilization and communication activities and dates, supervision and monitoring (including rapid convenience monitoring or rapid coverage assessments), AEFI management and waste disposal;

c. Post campaign evaluation of the outbreak response, if planned;

d. Plans for a root-cause analysis of the outbreak, if not already conducted, that address potential reasons for immunity gaps, deficiencies in surveillance performance, and delays and/or ineffective outbreak preparedness and response;

e. A detailed, line item budget with unit costs for the proposed activities;

5. An official letter (cover letter) of request for ORF that includes a written commitment from the MOH that government will provide the human resources required for planning and implementing the vaccination activity, including sufficient staff working at health facilities

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7 Countries are not encouraged to use the limited operational support funds to conduct a post-campaign coverage survey (PCCS); rather, these funds should be used for rapid convenience monitoring/rapid coverage assessments that would potentially be followed by mopping up activities. A PCCS would be indicated for very large-scale ORI activities.
and outreach sites in the targeted areas. In situations where there is no acting government, WHO and/or UNICEF may provide a letter in consultation with the relevant local authorities.

M&RI can provide technical assistance with outbreak related investigations, planning, monitoring, coverage surveys and root cause analyses. Detailed guidance and examples of tables and charts for many of the above proposed analyses in section B2 and B3 are provided in annexes 1 and 2, respectively.

C. Reporting

Any recipient of ORF support is required to submit to the M&RI within 2 months of completion of the vaccination activity:

1. a technical report on the outbreak response activities and outcomes;
2. if operational costs are awarded, a statement of expenditures of awarded funds;
3. a report of the root-cause analysis and, based on the analysis, planned activities to strengthen routine immunization, surveillance and outbreak preparedness to prevent and/or rapidly stop future outbreaks. These plans may be considered for future Gavi Health Systems Strengthening or other donor/partner funding.

D. Management and decision making for ORF requests

In-country responsibilities: the WHO and UNICEF country offices are responsible for reviewing and endorsing ORF requests and accompanying documents. As such, countries are encouraged to work with their WHO and UNICEF country office counterparts in preparing and submitting applications and supporting documents for ORF to expedite WHO and UNICEF endorsement. Other relevant partners should also be encouraged to participate. After endorsement, the WHO and UNICEF country offices will submit the application forms and documents to the WHO and UNICEF Regional Offices (and in the WHO African Region, simultaneously to the sub-regional Inter-country Support Team (IST)) for Regional Office comment, feedback and, ultimately, endorsement.

Regional Office/IST responsibilities: The Regional Offices (and ISTs) will review and provide feedback to the country if any revisions are needed; otherwise, the Regional Offices will endorse the application and supporting documents and forward these to WHO/HQ and UNICEF HQ.

WHO/HQ responsibilities: WHO/HQ will summarize the applications and supporting documents and share the summary with supporting documents with all members of the M&RI Program Implementation Working Group (PIWG).

PIWG responsibilities: the PIWG will review, analyse and discuss the application and will either request clarifications or additional information from the country or recommend full, partial, or no funding to the M&RI Management Team (MT). PIWG recommendations to the MT, as well as MT decisions, will be based on a simple majority vote (one vote from each agency) to fully fund, partially fund, not fund, or request additional information and clarification from the country.

Figure: ORF application process

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8 Responsibilities for reviewing and endorsing ORF applications may be delegated to a proposed M&RI Outbreak Response Working Group (ORWG) in the future.
ORF application review, decision and feedback will be accomplished as soon as possible and no later than 10 working days following receipt at WHO HQ. The M&RI will monitor and evaluate on an annual basis the ORF processes and outcomes and make needed changes to the SOPs to maximize effective, efficient and timely deployment of bundled vaccine and funds. Partners and national counterparts also are encouraged to provide feedback to the M&RI regarding ORF processes and decisions.

In accordance with Immunization Agenda 2030 guidance, M&RI will monitor timeliness of outbreak response immunization as well as M&RI response to ORF requests using the following indicators:

1. Intervals between the date of laboratory confirmation of the outbreak, by district, and date the complete ORF application is received by WHO/HQ;

2. Interval between the date the ORF application is received by WHO/HQ and either
   a. the date of the PIWG response to the country for additional information or, if the PIWG recommends approval,
   b. the date the M&RI decision letter is sent to the country;

Interval between the date the M&RI decision letter is sent to the country and the date that outbreak response immunization activities begin.