Surveillance Guide for Vaccine-Preventable Diseases in the WHO South-East Asia Region

September 2023
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Introduction

Globally, rotavirus is the leading cause of severe gastroenteritis among infants and young children. In temperate climates, outbreaks of rotavirus diarrhoea occur during the winter months every year. In the tropics and subtropics, too, outbreaks occur during the cool dry months, but in general, rotaviruses are prevalent throughout the year. Since in low-income countries, children below 5 years of age get recurrent rotavirus infections and confirming the diagnosis requires special laboratory testing of faecal specimens, the identification of every case of rotavirus diarrhoea is neither necessary, nor practical. Yet, surveillance, together with laboratory support for the diagnosis of rotavirus, is necessary as rotavirus vaccination has been recommended in the Expanded Programme on Immunization in all countries.

Objectives

Surveillance for rotavirus gastroenteritis can have different objectives, depending on the stage of the roll-out of the rotavirus vaccine in the country. However, there are general objectives which are common to all.

For countries planning to introduce the rotavirus vaccine, the main objective is to generate information to facilitate and support the introduction of the vaccine.

For countries that have introduced the vaccine, the objectives are to:

- determine the epidemiology and burden of rotavirus hospitalizations;
- monitor the impact of vaccination on the reduction of morbidity and mortality from rotavirus disease over time;
- evaluate the effectiveness of the vaccine in field use;
- monitor the possible emergence of rotavirus strains; and
- identify population groups that might not be adequately covered by vaccination.

Types of surveillance

It is recommended that surveillance of rotavirus gastroenteritis be conducted through sentinel hospital units which have the capacity for providing laboratory confirmation. The global minimum standard for rotavirus surveillance is one sentinel site per country. Depending on the availability of personnel and laboratory resources, some countries may choose to have additional sentinel sites.
Selection criteria for sentinel surveillance sites

- The hospital should have demographically and geographically defined catchment populations.
- The hospital (in public or private sector) should be accessible and affordable to general public.
- It is widely used for the care of children under 5 years of age (hence likely to be representative of the target population).
- It should admit, on an average, a minimum of 100 children who are under 5 years of age and have diarrhoea (preferably about 250-500 before RVV introduction and 100 cases after RVV introduction) every year.
- The hospital should have the capacity to collect and store faecal samples.
- It should either have or is willing to build the capacity to conduct rotavirus screening through methods of rapid antigen detection (e.g., enzyme immune assay [EIA]), or should have a reliable system for transporting samples to a reference laboratory.
- The hospital should have the human and logistical resources necessary for establishing and sustaining the sentinel surveillance system.
- The hospital should be willing to make an institutional commitment to the conduct of rotavirus surveillance.

Types of surveillance

**Minimal surveillance:** The global minimum standard for rotavirus surveillance is one sentinel hospital per country that has the capacity for laboratory confirmation of cases. The sentinel site should conduct active, case-based surveillance.

**Enhanced surveillance:** Other than the minimum recommended requirements for active, case-based surveillance at sentinel hospitals, the following types of surveillance can be conducted to meet some of the surveillance objectives in certain settings.

- **Laboratory-based surveillance:** This can be initiated in countries where samples from cases of acute gastroenteritis are already collected and tested routinely for rotavirus. The rotavirus cases thus identified are reported to the public health authorities. Laboratory-based surveillance provides additional information on circulating strains of rotavirus and the general trends in the disease.
- **Population-based surveillance:** This involves the use of the sentinel surveillance protocol for all facilities within a defined geographical area with a known population. It allows for the calculation of the incidence of the disease in settings with one or multiple facilities in an area with a defined population.
- **Household-based surveillance/community clinics:** Using an adapted version of the hospital-based surveillance methodology (e.g., modifying the case definition
to include patients who are not hospitalized), the surveillance can be expanded to outpatient and non-hospital settings. This kind of surveillance will provide a more complete picture of the clinical spectrum of rotavirus disease in the community.

**Linkage to other surveillance platforms**

Rotavirus surveillance can be linked with other types of surveillance, as described below.

- Integrated Disease Surveillance and Response (IDSR) collects aggregate numbers of cases of diarrhoea with dehydration among children < 5 years of age. With the addition of laboratory testing, IDSR surveillance could meet some of the objectives of rotavirus surveillance.

- When stool samples are already being collected in a facility for surveillance of other diseases (such as polio), the existing systems for the collection, transport and virological laboratory testing of stool specimens could be leveraged for rotavirus surveillance.

- Rotavirus surveillance can be used to conduct global pediatric diarrhoea (GPD) surveillance. GPD surveillance (GPDS) monitors the burden of other enteric pathogens, such as enterotoxigenic Escherichia coli (ETEC), Shigella and norovirus, after modifying some components of the definitions of suspected and confirmed case, e.g., bloody diarrhoea might be included. In that case, these symptoms should be included in the CIF.

**Case detection**

**Definition of suspected case**

A suspected case refers to a child who is below 5 years of age and is admitted (to a hospital ward or emergency unit at a participating surveillance facility) for the treatment of acute (< 14 days) watery diarrhoea, defined as 3 or more loose or watery stools in a 24-hour period. Children with bloody diarrhoea and nosocomial infections are excluded.

**Signs and symptoms**

In a typical case, the onset of disease is abrupt and marked by:

- fever (up to one-third of infected children may have a temperature greater than 39°C (102°F).
- vomiting; followed by
- watery diarrhoea
Other associated signs and symptoms

The clinical spectrum of rotavirus disease is wide and the disease may:

- be asymptomatic
- cause self-limiting watery diarrhoea; or
- result in severe dehydrating diarrhoea with a fever and vomiting, causing electrolyte disturbances, shock, and death if rehydration is not provided.

Gastrointestinal symptoms normally resolve within 3–7 days but may last for up to 2–3 weeks. Although most patients recover completely, fatalities may occur in settings where timely access to rehydration is not available, mainly among children ≤ 1 year of age.

*Infants below 3 months of age:* The rates of rotavirus infection are relatively low in this group, probably because of passive maternal antibodies and possibly because of breastfeeding.

*Infants above 3 months of age:* The first infection after 3 months of age is generally the most severe. The gastrointestinal symptoms usually resolve in 3–7 days.

Date of onset of illness

The date of onset of rotavirus should be considered to be the date of the onset of diarrhoea.

Response to suspected case

A suspected case should be investigated by a surveillance officer. The responsibilities of the officer are described in Annex 2.

Within 48 hours

Surveillance staff in sentinel hospitals should screen cases of diarrhoea and identify those that meet the criteria of suspected cases. The staff should fill in case investigation forms for all cases meeting the definition of a suspected case. A stool specimen should be collected from the suspected cases within 48 hours of admission to avoid the detection of hospital-acquired pathogens. The detection of individual rotavirus cases does not require immediate notification to the public health authorities.

Investigation of suspected case

The investigation of suspected cases should be done by the trained health staff/clinician designated by the public health authority.
Case investigation form

A case investigation form should be filled in for every suspected case within 48 hours of reporting. (See Annex 3 for a sample case investigation form.)

Unique ID

A unique case identification (UID) number should be assigned to each suspected case. The number should begin with one or more three-letter combinations to designate the geographical location of the case, followed by the year and the case number. All communications and forms related to the case should cite the UID.

For example:
RVG – code for suspected rotavirus gastroenteritis
THA – country code
BKK – province code
BBN – district code
2022 – year of onset
001 – serial number of diphtheria case of the province
The UID would thus be RVG-THA-BKK-BBN-22-001.

Specimen collection

The collection and shipping of specimens are important steps in obtaining a diagnosis or confirmation of the disease from a laboratory.

Preferred specimen

The preferred specimen is whole stool, which should be collected within 48 hours of hospital admission (to avoid the detection of hospital-acquired infections).

Amount

About 5–10 mL should be collected in a sterile screw capped container with proper labels. A minimum of around 2–3 mL is required for basic confirmatory testing, and 3–4 mL or more may be needed for genotyping and additional testing. (It is advisable to avoid the use of rectal swabs or swabs placed in bacterial media, since these are not optimal for the detection or characterization of rotavirus.)
Storage

Stool specimens should be placed in sterile screw-top containers that are properly labelled.

At sentinel sites where EIA is not performed: The specimen should be stored at 2–8 °C till it is transferred to a laboratory for testing.

At sentinel sites / national laboratories performing EIA:

- For up to 1 month, samples should be stored at 4-8 °C for up to one month.
- For more than 1 month but under a year, samples should be stored at -20 °C. Freeze-thaw cycles should be avoided, where possible. If not possible, glycerol should be added to make a final concentration of 1–3% as this will minimize the harmful effects of repeated thawing and freezing.
- For prolonged storage for more than 1 year, samples should be stored at -70°C (the ability to characterize rotaviruses declines if a sample is stored at -20 °C for years).

If stool samples are to be tested for bacterial or parasitic pathogens by conventional methods, the specimens should be transported to the laboratory within 2 hours of collection and placed on appropriate media. They should then be stored at -20 °C or less until testing.

Laboratory testing

An aetiological diagnosis of rotavirus gastroenteritis requires laboratory confirmation. A range of diagnostic tests are commercially available.

- **Enzyme Immunoassays (EIA):** EIA for the detection of rotavirus antigen directly in stool specimens are in wide use. Some EIA kits are: Premier™ Rotaclone®, ProSpecT™ and RIDASCREEN®. The sensitivity of EIAs has been found to be 75–82% and their specificity, 100%. Thus, occasional false negatives are possible, particularly at lower viral loads, though the clinical significance of rotavirus at concentrations below the threshold of EIA detection is unclear.

- **Latex agglutination assay:** Rapid tests such as latex agglutination assays are simple-to-use immunochromatographic test strips but are less sensitive and often less specific than EIAs.

- **Reverse transcription-polymerase chain reaction (RT-PCR):** RT-PCR is used to characterize rotavirus strains and can identify both the G and P types. A subset of rotavirus-positive stools obtained from routine surveillance should be chosen for the characterization of strains. It is recommended that a minimum of 50–60 randomly selected specimens be genotyped from each country per
year. The randomly selected samples should be proportional to the age and seasonal distribution of the cases. If resources permit, the strains of all EIA-positive samples should be characterized. Only specimens >3 mL should be chosen to avoid running out of material. All non-typeable isolates should be sent to an appropriate reference laboratory for sequencing.

Classification of cases

Suspected case: This refers to a child who is below 5 years of age and is admitted (to a hospital ward or emergency unit at a participating surveillance facility) for the treatment of acute (< 14 days) watery diarrhoea, defined as 3 or more loose or watery stools in a 24-hour period. Children with bloody diarrhoea and nosocomial infections are excluded.

Confirmed case: This is a suspected case in whose stool the presence of rotavirus is demonstrated by means of an EIA or PCR-based methods.

Contact tracing

Contact tracing is not conducted routinely for rotavirus.

Clinical management

- Currently, no specific antiviral therapy is available against rotaviruses.
- Fluid replacement is important for preventing or treating dehydration.
  - Solutions of low-osmolarity oral rehydration salts (ORS) are more effective at replacing fluids than conventional ORS formulations.
  - If ORS are not available, appropriate fluids that are available in the home can be used.
- Zinc treatment reduces the duration and severity of diarrhoea episodes, the volume of stools, and the need for advanced medical care.
- Due importance should be given to continued feeding, including breastfeeding.

Country-specific guidelines or Integrated Management of Childhood Illness guidelines can be followed for the management of rotavirus.

Outbreak

Rotavirus is an endemic disease that does not usually occur in large-scale outbreaks that require intervention. Diarrhoea due to other causes, such as norovirus, cholera and ETEC,
can occur during outbreaks. These outbreaks might be detected by syndromic surveillance for diarrhoea, though sentinel surveillance is not an adequate way to detect outbreaks. Laboratory capacity developed for rotavirus surveillance can possibly be expanded to identify outbreaks of diarrhoea due to other causes.

**Special considerations**

- A previously available rotavirus vaccine was associated with an increased risk of intussusception. It will be important to conduct surveillance of intussusception in some countries to monitor the safety of rotavirus vaccines after they have been introduced, as described elsewhere (10). However, the lack of such surveillance should not be an impediment to the introduction of rotavirus vaccines.

- Sentinel surveillance sites used for rotavirus surveillance can also be considered for:
  - intussusception surveillance; and
  - surveillance for other enteric pathogens, including ETEC, *Shigella* and norovirus (vaccines for all of which are in the pipeline).

These special considerations would require modifications in the surveillance approach, including case definitions, the tests to be performed and case investigation forms.

**Data management**

**Reporting requirements**

- The number of rotavirus cases occurring each month should be reported to the ministry of health.

- If no cases of diarrhoea are identified at the sentinel site, this should be indicated specifically in the report (“zero reporting”).

- Aggregate reporting (numbers only) is sufficient for routine reporting even if case-based surveillance is conducted.

- There are no global reporting requirements for rotavirus.

**Unique ID**

A unique case identification number should be assigned to each suspected case, as explained earlier.
Recommended data elements

- Geographical information
- Demographics
- Clinical data
- Treatment
- Vaccination history
- Specimen collection details
- Laboratory data
- Outcome of case
- Date of discharge or death
  - Additional elements for case-based data
  - Clinical characteristics
  - Type of treatment
  - Laboratory investigations results

The sample case investigation form (Annex 3) provides details of the data elements.

Data analysis

The data should be periodically analysed to understand the characteristics of the disease and monitor the surveillance system. Since age distribution and seasonality are important in the epidemiology of rotavirus gastroenteritis, suspected and confirmed cases should be described according to the epidemiological week of the onset of diarrhoea and data must be consolidated monthly by the age of the affected children and the place where the cases occurred. It should also be established whether the case is an isolated occurrence, or an outbreak has occurred in a day-care centre, another institution, or the community.

- Minimal data analysis should comprise:
- Number of hospitalizations
- Number and percentages of diarrhoea-associated hospitalizations
  - numbers and percentages of diarrhoea-associated hospitalizations caused by rotavirus by age group (suggested: 0–2 months, 3–5 months, 6–8 months, 9–11 months, 12–17 months, 18–23 months, 24–59 months, and < 5 years).
  - numbers and percentages of hospitalizations due to diarrhoea and rotavirus diarrhoea by month of year.
  - number of deaths associated with rotavirus diarrhoea and in-hospital case fatality rate; and
Some surveillance settings require enhanced analyses, which should include the following.

- The clinical and epidemiological characteristics of cases must be described.
- The distribution of genotypes must be analysed.
- The seasonal trends must be examined, using weekly (if number of cases is sufficient) or monthly detection rates.
  - The peak of rotavirus activity should be defined as the 2 consecutive weeks (for weekly data) or the month (for monthly data) in which the greatest number of rotavirus cases was detected.
  - The onset of the rotavirus season is the week in which the number of rotavirus cases detected first exceeds the mean number of rotavirus cases detected per week for the entire year.
  - The duration of the rotavirus season is the number of weeks during which the number of cases detected exceeds the weekly mean.
- For population-based surveillance, the rates of hospitalization and deaths associated with diarrhoea and rotavirus per 1000 children < 5 years of age per year, in the surveillance population overall and by age group, must be recorded.
- The number of hospitalizations for all diarrhoea cases among children < 5 years of age may be gathered through logbooks or a review of hospitals’ administrative data.
- The percentage of total hospitalizations due to diarrhoea among children < 5 years of age may be gathered through logbooks or a review of hospitals’ administrative data.
- The distribution of hospitalizations due to diarrhoea by aetiology, including rotavirus diarrhoea may be noted if testing for other etiologist is conducted routinely.

**Using data for decision-making**

**Supporting vaccination strategies**
Rotavirus surveillance data are used primarily to support national vaccination strategies. Rotavirus is not targeted for global elimination or eradication.

**Evaluating impact of vaccines**
There are two principal ways of analysing surveillance data following the introduction of a rotavirus vaccine. The first is to measure the impact of the vaccine in terms of the reduction
in disease and evaluate the trends of the disease burden before and after the introduction of the vaccine. This is done by comparing the annual rates of rotavirus disease before and after the introduction of the vaccine, ideally when population-based surveillance data are available. If the surveillance population is relatively stable, counts of rotavirus cases or the proportion of rotavirus-positive cases by year can show a reduction in disease after the introduction of the vaccine. Second, it is possible to estimate the indirect effects of the introduction of the vaccine by monitoring for reductions in the rates of diarrhoea and rotavirus among unvaccinated children before and after the introduction of the vaccine.

**Evaluating vaccine effectiveness**

The effectiveness of a rotavirus vaccine can be estimated through test-negative, case–control studies. In these studies, which are often carried out in the setting of diarrhoea or rotavirus surveillance, confirmed cases of rotavirus gastroenteritis serve as the cases and confirmed rotavirus-negative gastroenteritis cases serve as the controls. This design is possible because of the high specificity of the rotavirus EIA test. It decreases the potential for selection biases since all children are prospectively enrolled prior to the confirmation of rotavirus infection or their vaccination status. However, considerable effort is needed to appropriately document the vaccination status of the enrolled children.
Indicators for surveillance performance

Table 9.1 gives the attributes that could be included in an evaluation of surveillance performance. It also shows the indicators, targets, and the formulas for calculation.

**Table 9.1: Indicators for surveillance performance**

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Indicator</th>
<th>Target</th>
<th>How to calculate</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completeness of reporting</td>
<td>Consistent reporting throughout the year</td>
<td>At least 10 months of reporting (including zero reporting)</td>
<td>Number of months of reporting per year</td>
<td>The ideal is 12 months; and confirmed zero reporting if no cases.</td>
</tr>
<tr>
<td>Enrolment of suspected cases</td>
<td>Proportion of eligible cases enrolled during the calendar year</td>
<td>80%</td>
<td>(Total number of children who met the case definition and were enrolled with a completed case report form and specimen collected total number of hospitalizations for acute watery diarrhoea among under-5 children eligible for enrolment)x 100</td>
<td></td>
</tr>
<tr>
<td>Case ascertainment</td>
<td>Minimum number of cases reported annually</td>
<td>≥ 80 cases of suspected diarrhoea /year</td>
<td>Number of diarrhoea cases reported per site per year</td>
<td>The ideal is ≥ 100 diarrhoea cases/year.</td>
</tr>
<tr>
<td>Specimen collection</td>
<td>Proportion of suspected cases with specimens collected within 2 days of admission</td>
<td>≥ 80%</td>
<td>(Number of suspected cases with specimen collected within 2 days of admission / number of suspected cases) x 100</td>
<td>The specimen is stool. ≥ 90% is ideal.</td>
</tr>
<tr>
<td>Completeness of laboratory testing</td>
<td>Proportion of specimens tested for rotavirus by EIA</td>
<td>≥ 80%</td>
<td>(Number of cases with specimens tested for rotavirus by EIA / number of cases with specimens collected) x 100</td>
<td>The ideal is ≥ 90%.</td>
</tr>
</tbody>
</table>

* There is no minimum number that should test positive since the number varies widely among countries and depends on the use of rotavirus vaccine.
Public health intervention

It is well established that to reduce diarrhoea in a community, one must improve hygiene and the water supply and ensure the safe disposal of wastewater. However, it has also become increasingly clear that measures being taken in these respects are not enough to reduce severe rotavirus gastroenteritis. The fact that the incidences of rotavirus disease are comparable in the developed and developing countries, which have widely different sanitation standards, is a definite indication that the disease cannot be controlled exclusively by such measures. The routine immunization of infants with a rotavirus vaccine is now considered the most effective public health intervention for population-wide rotavirus control.

Post-exposure vaccine prophylaxis is not recommended in response to an outbreak of rotavirus gastroenteritis.
Annex 1: Disease epidemiology

Background

Rotavirus is an RNA virus, of which 7 groups (labelled A to G) are known. Of these, group A causes most of the illness in humans, and has been classified into the G and P genotypes. G1P[8], G2P[4], G3P[8], G4P[8], G9P[8] and G12, in combination with P[6] or P[8], account for 90% of the genotypes that infect humans. The disease affects mostly infants between the ages of 3 months and a year.

Rotavirus gastroenteritis is the most common cause of severe diarrhoeal disease in infants and young children worldwide. A major reason for the occurrence of nearly all rotavirus deaths in the less developed countries – despite the fact that the disease is common in rich and poor countries alike – is the lack of timely access to health care. In addition, rotavirus can be more severe in low-income countries due to frequent concurrent infections, malnutrition and other factors. Year-round transmission due to climatic factors may also contribute to the much higher toll of the disease among children in low-income countries. In high-income countries/low-mortality countries, rotavirus accounted for 40–50% of hospital admissions due to diarrhoeal disease in the pre-rotavirus vaccine period.

Essential epidemiology

Infectious agent: Rotavirus belongs to the Reoviridae family.

Reservoir: The reservoir is the gastrointestinal tract and stool of infected humans. Although rotavirus infection occurs in many other mammals, the transmission of animal rotaviruses to humans is believed to be uncommon and probably does not lead to clinical illness.

Mode of transmission: Transmission is by the faecal–oral route, primarily through close person-to-person contact or indirectly via fomites (such as toys and other environmental surfaces contaminated by stool). The transmission of rotavirus through contaminated water or food appears to be uncommon. Rotavirus is highly communicable, its infectious dose being as small as < 100 virus particles.

Incubation period: The incubation period is short, usually less than 48 hours (range: 24–72 hours).

Duration of illness: The illness usually lasts for 3–7 days but may go on for 2–3 weeks.
**Period of communicability:** The disease is communicable from 2 days before the onset of diarrhoea to several days after the onset of symptoms, during the acute phase of the disease and later while virus shedding continues.

**Case fatality ratio:** In developing countries, rotavirus has a case fatality rate of approximately 2.5% among children who present to health facilities. It is difficult to estimate a case fatality ratio as it depends primarily on access to health services for rehydration.

**Vaccines**

The currently available rotavirus vaccines are live, oral, attenuated rotavirus strains of human and/or animal origin that replicate in the human intestine to elicit an immune response.

WHO has prequalified four vaccines: Rotarix, RotaTeq, Rotavac and Rotasig.

**Vaccine safety and precautions**

Each of the vaccines prequalified by WHO has a good safety profile. While rotavirus vaccines have been associated with intussusception, no other serious adverse event has been identified.

*Risk of intussusception*

One of the earliest vaccines, RotaShield (Wyeth-Lederle), was associated with intussusception. The recent Cochrane review of the four WHO prequalified rotavirus vaccines showed that in randomized controlled trials for each vaccine, there was no increase in the risk of intussusception after any dose.

**Disease burden in South-East Asia**

Building on the findings of the Global Burden of Disease Study 2016, models were used to estimate the burden of the disease in locations with sparse data. In 2016, rotavirus infection was responsible for an estimated 128 500 deaths (95% uncertainty interval [UI], 104 500–155 600) among children younger than 5 years of age throughout the world. South-East Asia accounted for 3765 of these deaths (95% UI, 2895–4789). Rotavirus infection was responsible for more than 29 million episodes of diarrhoea among children under 5 years of age in 2016 (95% UI, 21.19–41.49 million) in the Region, an incidence of 508 cases per 1000 population (95% UI, 21–41 million) (13).

In 2008, WHO launched the Global Rotavirus Surveillance Network. Its objectives are to generate local data for decision-making on the introduction and sustained use of rotavirus vaccines; assess and monitor the trends in the disease and the genotype distribution over time; develop a platform for studies on the effectiveness of vaccines; and highlight the value of surveillance data in general and in fund-raising and advocacy.
Annex 2: Responsibilities of a surveillance officer

The sentinel site surveillance officer’s responsibilities include the following.

**Data and specimen collection**

- Conduct a daily survey of the wards and maintain a diarrhoea log. This would help to identify children eligible for surveillance and facilitate their enrolment.
- Enroll eligible patients for surveillance. Ensure that a unique case ID is assigned to each enrolled patient, and a case investigation form filled (see Annex 3 for a sample case investigation form.) The unique IDs should be entered in the surveillance logbook.
- Ensure that the appropriate specimen is collected and sent to the laboratory for investigation.
- Track all cases whose samples are sent to the national or regional reference laboratory for genotyping and follow up to obtain results in a timely manner.
- Share the results with the sentinel surveillance hospital and with the Central data team so that they may be recorded in the database.
- Update the data logbook regularly to record follow-up visits, interactions with clinicians, nursing staff and laboratory personnel, etc.

**Data management**

The surveillance officer has the following functions related to data management:

- cleaning and validation of data;
- maintaining a back-up of the surveillance database; and
- analyzing core data variables epidemiologically, and sharing the results with the relevant stakeholders, including clinicians and staff at the sentinel hospital.

**Monitoring quality of data**

The surveillance officer should make a periodic review of the data collected to identify problems in the collection of data, enrolment of patients, or collection and handling of specimens. The following are a few useful examples of monitoring activities.

- If the number of children enrolled for surveillance from the sentinel surveillance hospital is less than 75% of the expected number for 2 consecutive months, it may indicate that the procedures for case-finding are inadequate.
- If < 15% of the children enrolled for surveillance test positive for rotavirus, it should raise a red flag. The following aspects need to be reviewed:
  - Is the surveillance system missing the youngest age groups?
- Is the quality of the stool collected poor and its volume insufficient to detect rotavirus? Are the handling procedures for stool specimens not optimal?
- Are the staff facing problems in using the enzyme immunoassay test kits?
- Are stools being tested in a timely manner?

### Annex 3: Case investigation form

<table>
<thead>
<tr>
<th>Case identification number:</th>
<th>RVGE <strong><strong><strong>/</strong></strong></strong><em><strong>/</strong></em><strong><strong><strong>/</strong>__/</strong></strong></th>
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<tbody>
<tr>
<td>Country code/ Province code/District code/ Year/Serial number</td>
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#### Patient information

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<tr>
<th>Name of health facility</th>
<th>Patient's name</th>
<th>Age in years / months</th>
</tr>
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<table>
<thead>
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<th>Date of birth</th>
<th>Sex</th>
<th>Male</th>
<th>Female</th>
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<table>
<thead>
<tr>
<th>Residential address</th>
<th>Street name</th>
<th>District/ province</th>
<th>Contact number (mobile)</th>
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<td>House no:</td>
<td>Village/ town/ city:</td>
<td>District/ province:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>State:</td>
<td>Zip code:</td>
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#### Clinical data

<table>
<thead>
<tr>
<th>Date of admission</th>
<th>Date of investigation</th>
<th>Date of onset of diarrhoea</th>
<th>Number of days of diarrhoea</th>
</tr>
</thead>
<tbody>
<tr>
<td>dd/mm/yyyy</td>
<td>dd/mm/yyyy</td>
<td>dd/mm/yyyy</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Maximum number of diarrhoea episodes in a 24-hour period at peak of illness</th>
<th>Fever: acute onset</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Maximum temperature recorded:</td>
<td>Yes</td>
<td>No</td>
<td>Unknown</td>
</tr>
<tr>
<td></td>
<td>Duration (in days)</td>
<td>Yes</td>
<td>No</td>
<td>Unknown</td>
</tr>
<tr>
<td></td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Maximum number of vomiting episodes in a 24-hour period at peak of illness</th>
<th>Dehydration</th>
<th>Yes</th>
<th>No</th>
<th>If yes, specify</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
<td>Unknown</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Maximum number of vomiting episodes in a 24-hour period at peak of illness</th>
<th>Dehydration</th>
<th>Yes</th>
<th>No</th>
<th>If yes, specify</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
<td>Unknown</td>
<td></td>
</tr>
</tbody>
</table>
## Treatment

<table>
<thead>
<tr>
<th>Rehydration therapy provided</th>
<th>Yes</th>
<th>No</th>
<th>Not known</th>
<th>Type of rehydration therapy provided</th>
<th>ORS</th>
<th>ORT</th>
<th>Intravenous fluids</th>
<th>Others</th>
<th>(Specify)</th>
<th>Unknown</th>
</tr>
</thead>
</table>

## Vaccination history

<table>
<thead>
<tr>
<th>Was rotavirus vaccine administered?</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Source of vaccination information</th>
<th>Vaccination card</th>
<th>Medical records</th>
<th>Maternal recall</th>
<th>Others</th>
<th>(Specify)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Rota vaccine (type)</th>
<th>Number of doses received</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>Unknown</th>
<th>Date of 1st dose</th>
<th>dd/mm/yyyy</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date of 2nd dose</th>
<th>dd/mm/yyyy</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date of 3rd dose</th>
<th>dd/mm/yyyy</th>
</tr>
</thead>
</table>

## Investigations

<table>
<thead>
<tr>
<th>Type of specimen collected</th>
<th>Stool</th>
<th>None</th>
<th>If stool collected, specimen ID</th>
<th>Type(s) of testing methodology</th>
<th>EIA</th>
<th>Rapid tests</th>
<th>Specify:</th>
<th>Latex agglutination test</th>
<th>Immuno-chromatographic test</th>
<th>RT-PCR</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date of specimen collection</th>
<th>dd/mm/yyyy</th>
<th>Type of laboratory where EIA was performed</th>
<th>Hospital laboratory</th>
<th>Private laboratory</th>
<th>National laboratory</th>
<th>Regional laboratory</th>
<th>Not known</th>
<th>Type of laboratory where GP was performed</th>
<th>Hospital laboratory</th>
<th>Private laboratory</th>
<th>National laboratory</th>
<th>Regional laboratory</th>
<th>Not known</th>
</tr>
</thead>
</table>

## Laboratory results

<table>
<thead>
<tr>
<th>Dates on which specimen(s) were received</th>
<th>dd/mm/yyyy</th>
<th>Dates on which specimen(s) were tested</th>
<th>dd/mm/yyyy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date(s) on which results were reported</td>
<td>dd/mm/yyyy</td>
<td>Laboratory results for each specimen</td>
<td>EIA</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>------------</td>
<td>--------------------------------------</td>
<td>-----</td>
</tr>
<tr>
<td>Classification of cases</td>
<td></td>
<td>Final classification</td>
<td></td>
</tr>
<tr>
<td>Outcome</td>
<td></td>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Referred / Transferred</td>
<td></td>
</tr>
<tr>
<td>Comments</td>
<td></td>
<td>Investigator's name:</td>
<td></td>
</tr>
</tbody>
</table>


**Further reading**


CONTRIBUTION

The document was produced under the strategic guidance of the Regional Director, Dr. Poonam Khetrapal Singh; Director, Programme Management Dr. Pem Namgyal, and Director CDS Dr. Suman Rijal WHO SEARO.

The entire process was overseen by Dr. Sunil Bahl, Coordinator, COVAX, Immunization and Vaccines Development.

Dr. Sudhir Khanal, IVD/CDS WHO SEARO, lead the coordination and development of the technical document together with Dr. Sudhir Joshi, IVD/CDS WHO SEARO. WHO Consultant Dr. Lalit Kant played a crucial role in updating the technical content of the document.

This document also benefited from the expert input of all the participants of the Regional workshop to review progress towards measles-rubella and other priority VPD surveillance and outbreak preparedness and response in WHO South-East Asia Region from 13-16 June 2022 in Dhaka, which included National EPI Programme Managers and VPD Surveillance Officers from Member States, as well as a number of WHO country office staff, UNICEF, and other external collaborators.

**WHO HQ staff:** Dr. Anindya Bose and Dr. Heidi Soeters reviewed the draft surveillance standard document and provided technical inputs.

**WHO-SEARO:** Dr. Jayantha Liyanage, Dr. Sigrun Roesel, Dr. Emmanuel Njambe, Dr. Lucky Sangal, Dr. Pankaj Bhatnagar, Ms. Uttara Aggarwal, Mr. Sharifuzzaman, Dr. Rajendra Bohara, Dr. Ariful Islam, Dr. Tanbir Islam, Dr. Subramanya Balakuntlam Pattabhiramaiah, Dr. Ratnesh Murugan, Dr. Stephen Chacko, Dr. Paba Palihawadana, Dr. Aishath Thimna Latheef, Dr. Balwinder Chawla, Dr. Khaing Khaing Gy, Dr. Vinod Bura, Dr. Rahul Pradhan, Dr. Pasang Rai, Dr. Preshila Samaraweera, Ms Aree Moungsookjareoun, Dr. Sudath Peiries

**UNICEF:** Christopher Gregory provided inputs as well as coordinated inputs from UNICEF team to the various sections of the document.

**US CDC:** Dr. Ahmed Kassem, Dr. Michelle Morales provided inputs to the various sections of the document and coordinated inputs from various teams within US CDC.