**Action Plan for the Rotavirus Vaccine Switch**

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# Introduction

## Rationale for Rotavirus Vaccine Switch

A rotavirus vaccine switch is needed due to current limits on vaccine supplies.

The available options were reviewed in June 2021. The first preference includes four different presentations, with two supplemental presentations as an emergency option (second preference) in the event the first is not available.

The National Immunisation Technical Advisory Group (NITAG) held a special session, in which the pertinence of the rotavirus vaccine switch was recognised and two options were proposed. The Inter-Agency Coordinating Committee (ICC) then approved liquid Rotasiil® in a single-dose plastic tube as the first preference, and liquid Rotavac® in a ten-dose tube as the second preference.

This switch provides the opportunity to save between 40% and 60% of the cost of co-financing the rotavirus vaccine switch and 60% to 70% of storage volume.

# Objectives

## Overall objective

To replace the Rotarix® vaccine with the Rotavac® vaccine in the routine immunisation schedule without compromising the rotavirus vaccine supply and demand.

## Specific objectives

* To inform healthcare personnel of the switch and the specificities of the Rotavac® vaccine and the implications of introducing it in the immunisation schedule to replace Rotarix
* To inform the community and parents of the rotavirus vaccine switch
* To make Rotavac® vaccine injection doses and supplies available to health facilities
* To monitor the performance of the rotavirus vaccine.

# Strategic aspects and planned activities

## Information and capacity building of the personnel in charge of immunisation

The personnel responsible for immunisation at various levels of the healthcare pyramid must be briefed on the conditions or requirements related to this switch. The various training aspects will be practical: immunisation and Adverse Events Following Immunisation (AEFI) surveillance and Adverse Events of Special Interest (AESI) and how they are managed. The goal of the “train the trainer” training is to update basic immunisation knowledge with special emphasis on the implications of the rota switch on day-to-day the practices of healthcare personnel in (i) interpersonal communication; (ii) stock management; (iii) data collection; (iv) AEFI surveillance; and (v) monitoring post-switch performance, especially the switch from two doses (for Rotarix®) to three doses (for Rotavac®).

Table 2: Healthcare personnel targeted by the briefing sessions.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Region | Number of HD | Number of AS | Number of EPI health facilities | National facilitators | Regional facilitators for 100 health districts | DMT members  | Health centre manager | Total participants |
| A | 10 | 79 | 174 | 1 | 5 | 20 | 79 | 105 |
| B | 32 | 298 | 1,181 | 2 | 16 | 64 | 298 | 380 |
| C | 15 | 114 | 230 | 1 | 8 | 30 | 114 | 153 |
| D | 32 | 298 | 362 | 2 | 16 | 64 | 298 | 380 |
| E | 24 | 189 | 602 | 2 | 12 | 48 | 189 | 251 |
| F | 15 | 146 | 256 | 1 | 8 | 30 | 146 | 185 |
| G | 20 | 234 | 317 | 1 | 10 | 40 | 234 | 285 |
| H | 20 | 235 | 601 | 1 | 10 | 40 | 235 | 286 |
| I | 10 | 104 | 196 | 1 | 5 | 20 | 104 | 130 |
| K | 19 | 117 | 225 | 1 | 10 | 38 | 117 | 166 |
| Total | 197 | 1,814 | 4,144 | 13 | 100 | 394 | 1,814 | 2,321 |

Ideally, the briefing session at the operational level should include all health facilities offering immunisation services throughout the country. Since the budget is limited, and all health facilities will be included, only health centre managers will participate in training at the district level. Health centre managers can take use meetings at another event, like polio immunisation campaigns, as an opportunity to brief healthcare personnel in charge of immunisation and distribute training media and posters.

Table 3: Briefing session participant and facilitator profiles

|  |  |  |
| --- | --- | --- |
| Level | Participant profiles | Facilitator profiles |
| Regional | * 10 National Technical Groups
* 197 Health District Heads (consisting of Physicians, Pharmacists and Healthcare Directors)
* 197 Health Bureau Heads (responsible for data management and monitoring HD micro plans)
* 100 Regional supervisors of immunisation activities to support briefing sessions at the health district level where the District Management Team lacks sufficient technical capability to do so.
 | * 13 National facilitators

Far North, Coastal and Central Regions will each have two sessions. |
| Health District | * 1814 Health centre managers
 | * 197 District Executive Teams
* 100 Regional supervisors of immunisation activities
 |

### Immunisation in Practice

“Train the trainer” training sessions will be conducted from the national
level to the operational level. Before training the trainers, a three-day workshop will be held to update (i) training modules on immunisation in practice; (ii) data collection and recording tools; (iii) communications media for the population and healthcare personnel; and (iv) practical guides for social mobilisers.

Preparatory meetings with regional managers will be held prior to training the trainers *online*. *Three (3) weekly meetings will be held before the first regional briefing session.*

**At the national level,** a one day workshop will be held to train the trainers who will in turn facilitate *management teams* at the regional level. *The national facilitator briefing session will consist of going through the entire agenda for the regional session and reviewing the specific tasks to be performed in the Regions by the national facilitators outside of those related to the rota switch. This session will be conducted online to also facilitate participation by coordinators of regional technical groups.*

***At the regional level****, the* district management teams *and the regional facilitators of District sessions will be briefed* by the national facilitators *during a two (2) day session*. *The first day will be devoted to general concepts, and the second day to information specific to the rota switch.*

*At the Health Districts level,* the health centre managers will be trained in each health district by the *district managers supported by* regional facilitators *in certain HDs requiring monitoring by the District Management Team.* The communications media, the updated data collection tools and the mobiliser guide will be distributed at this level.

A total of seven modules will be carried out:

* **EPI** **target diseases:** This module presents all EPI target diseases as well as the EPI immunisation schedule in effect, emphasising Rotavirus diarrhoea and the rotavirus vaccine.
* **The vaccine and the cold chain**: This module describes the composition of the cost chain, the equipment needed by the healthcare centres and how to use and maintain it. All EPI vaccines are presented, as well as their composition, safety profile and any side effects, the manner of preserving and transporting them, the administration timing, the number and volume of doses, and the administration route and method. The switch in presentation of the rotavirus vaccine, from a single-dose vial (Rotarix) to a ten-dose vial (Rotavac), will be emphasised. The multi-dose vial policy will be applied to the rotavirus vaccine. The actors will be instructed on the change in calculating the wastage rate, which will increase from 3% to 10%.
* **Injection Safety:** Injection safety relates to the methods that healthcare agents must use to inject vaccines in the safest manner possible, including oral administration of the vaccine.
* **Immunisation session scheduling**: This module involves the various immunisation strategies implemented in health facilities to meet targets.
* **Conducting immunisation sessions:** This module will include a description of the tasks that the healthcare agent must conduct on the day of the immunisation session to ensure its quality. It begins with the necessary preparation of the immunisation station and then details how to evaluate the immunisation status of mothers and infants. It also indicates the proper technique for administering each vaccine and how to communicate with the parents during and after the immunisation session, and how to close out the session.
* **Data Collection and Monitoring:** This module deals with how to collect and transmit data and how to monitor performance using the data itself. It also shows how to improve performance of the service by identifying and resolving problems, and incorporating the solutions made to the work plan.
* **Community cooperation**: This module explains how to make immunisation services attentive to the needs of the community and how to obtain community support.

### Management of any Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI)

Immunisation surveillance is a major challenge to ensure efficacy within the population and to identify any adverse effects that may not have been observed during clinical trials. It is even more important when using a new vaccine. Adverse Events Following Immunisation (AEFI) are medical events that may occur after and not necessarily linked to immunisation. These events are most often benign and rarely severe. An AEFI surveillance system has already been implemented in routine immunisation and SIA.

To ensure the effective use of Rotavac and guarantee its safety, AEFI and AESI capacity building for healthcare personnel will be conducted, especially detection, reporting, research, and treatment of AEFI cases indicated by the receiver. The training modules were designed for this purpose. This surveillance is essentially based upon the following aspects:

* Detection and Reporting: all AEFI cases reported to or detected by a healthcare provider working in the healthcare system will be reported as quickly as possible to the upper level using standard reporting forms (reporting sheet/investigation sheet) and also by completing the ODK form (pharmacovigilance-CM) online. All AEFIs that cause concern within the community or among healthcare personnel must be reported. The reporting path must be posted at all health facilities and AEFI management tools must be made available to personnel;
* Severe AEFIs must be investigated within 24 to 48 hours by the district management team. This will be conducted with the support of the region, and a report will be shared with the national level. An alert system for severe AEFIs was integrated for rapid response to severe cases. The pocket guide will be updated and also made available to them, as well as all related documentation (case definition, reporting and investigation sheets, inquiry, surveillance manual). An AEFI Expert Committee that is already in operation will determine whether or not there is a causal link between the severe AEFIs reported and the Rotavac vaccine;
* Inquiries concerning AEFIs resulting in fatalities (death): In the event of a death following immunisation, the field inquiry will be conducted immediately and a report will be completed within 24 hours. The case investigation will be conducted by a multi-disciplinary team. For this purpose, a public communication will be released to reassure the community. Samples will be taken during the investigation;
* Cluster AEFI investigation will first focus on determining whether an error in immunisation or a vaccine quality problem occurred;
* Laboratory sample analysis: If necessary, “routine” examinations will be conducted in appropriate laboratories authorised by the Ministry of Public Health;

Severe cases will be treated free of charge in public hospitals.

## Target community and child guardian information

### Context and current social environment

The current social context is marked by the proliferation of fake news and defiance with regard to immunisation. The health system is now addressing rumours that spread not only in traditional media but also through social networks and communities. Various studies conducted[[1]](#footnote-2) adequately demonstrate the need to implement mechanisms to improve knowledge, attitudes, and practices of the population with respect to immunisation. The distinguishing feature of these studies is that they highlight healthcare personnel as the new target of communication regarding immunisation. Since the switch from Rotarix to Rotavac may be a source of rumours, besides mass activities, the healthcare personnel should be at the centre of the communication strategy within the context of this switch.

### Planned communication activities

The communication activities will focus on healthcare personnel in charge of immunisation who are responsible for communicating with guardians of children. The briefing session for healthcare personnel will emphasise inter-personal communication techniques related to immunisation.

The following is planned, among other aspects:

* To draft and distribute a circular letter from the Ministry of Public Health containing all instructions addressed to all immunisation service managers on the rotavirus vaccine switch;
* To brief healthcare personnel on the Integrated Communication Plan (ICP) techniques during planned training sessions;
* To produce guides and flyers, including the new immunisation schedule, to be used by healthcare personnel and community actors;
* To plan and implement a post plan for the general public on various EPI digital platforms;
* To conduct a digital communication campaign in conjunction with Cameroonian bloggers on routine immunisation in general in which the new immunisation schedule including doses of Rotavac® will be publicised.

## Vaccine supply and stock management

### Organisation of the supply chain

The country’s supply chain is organised in four levels: national, regional, health district and health centre. Vaccine storage at each level requires cold chain equipment to be available. The vaccine supply will follow the customary path for routine vaccines. Purchasing the vaccine and transporting it to the ports of entry, which is the airport in this case, is handled by UNICEF because of its expertise in international pharmaceuticals purchasing. A memorandum of understanding was signed between the MoH and UNICEF. The carriers are selected by means of a negotiated procedure to pick up and deliver vaccines to national warehouses. The EPI has a database of customs and transit service providers for this purpose.

For transport, the CTG-EPI has a +2°C and +8°C refrigerated truck with a capacity of 20 m3 that transports vaccines and other immunisation consumables. The EPI uses Ministry of Public Health trucks to transport vaccines. In certain situations, delivery contracts are signed with private companies under the supervision of CTG-EPI monitors in order to ensure the safety of the cargo. In emergencies, packages of vaccines are transported to regions that have an airport. At the peripheral level, health districts are supplied according to needs at the regional warehouse, and health facilities do the same at district warehouses.

Biological products are destroyed according to the directives of the national waste management plan, under the responsibility of the Department of Health Promotion. Management of post-immunisation waste varies by type and is conducted according to Standard Operating Procedures (SOPs). Unusable vials are collected in appropriate packages according to the level and marked “For Destruction,” and are then transported from one level to another until they reach the identified destruction site.,

### Planned logistics activities for the switch

Doses of Rotavac® vaccine will be distributed to all Healthcare facilities that provide immunisation prior to the switch date to ensure availability during “train the trainer” briefing sessions and to facilitate Rotavac® immunisation data monitoring. All ten regions will be supplied by the national level at least one week prior to the regional briefing session. The districts will receive financial support for transport from the regional warehouses to the district warehouse and health facilities at least one week prior to the district level briefing session. Rotavac immunisation waste will be managed at each health facility providing immunisation, either by burning or incineration, as applicable, and then buried.

## Data management and performance monitoring

The data collection tools (immunisation tally and recording sheet) will be updated to take into account all changes caused by the switch, and all changes planned for the next three years in order to pool resources. Therefore, some of the updated tool production needs will be covered by the IPV-2 introduction grant, and another portion by integrating vitamin A supplementation, deworming and birth recording into EPI activities.

 The updated tools will allow data to be collected on children immunised with Rotavac®. These data will be entered into the DHIS2 and SMT no later than the fifth of each month. Immunisation coverage may be evaluated every month by triangulation with vaccine stock usage data.

# Activity timeline

Table 4: Rota switch activity timeline

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Activity** | **MANAGER (LEAD)** | **March** | **April** | **May** |
| **W1** | **W2** | **W3** | **W4** | **W1** | **W2** | **W3** | **W4** | **W1** | **W2** | **W3** | **W4** | **W5** |
| **Information and capacity building of the personnel in charge of immunisation** |
| Updating of training modules, tools, and communication materials |  |   |   |   |   |   |   |   |   |   |   |   |   |   |
|  Briefing for national supervisors |  |   |   |   |   |   |   |   |   |   |   |   |   |   |
|  Briefing for HD management teams |  |   |   |   |   |   |   |   |   |   |   |   |   |   |
|  Briefing for health centre managers |  |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **Target community and child guardian information** |
|  Production of communication guides, posters and materials |  |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   Distribution of communications materials in health facilities and the community |  |   |   |   |   |   |   |   |   |   |   |   |   |   |
|  Digital communication campaign on the new immunisation schedule |  |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **Vaccine supply and stock management**  |
|  Regional warehouse delivery |  |   |   |   |   |   |   |   |   |   |   |   |   |   |
|  Supplying Districts and Health Centres |  |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **Inventory of vaccines and injection materials**  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  Data management and performance monitoring |
|  Immunisation data review after the switch |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|  Data quality feedback to regions/health districts/health centres |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

# Budget

Making this switch requires an operational cost of $ 218,673 (not including programme management costs), distributed as follows:

Table 5: Rota switch budget overview

|  |  |  |  |
| --- | --- | --- | --- |
| ***Ref.*** | ***Activity*** |  ***Amount in USD***  |  |
| *1* | *Workshop for designing training modules , guides, and communication materials* | *6,441* |  |
| *2* | *Production and distribution of communication tools, guides, and materials* | *88,327* |  |
| *3* | *Briefing for national facilitators* | *-* |  |
| *4* | *Briefing for HD management teams at the regional level* | *57,233* |  |
| *5* | *Briefing for health centre managers*  | *40,318* |  |
| *6* | *Vaccine delivery to regional warehouses* | *5,755* |  |
| *7* | *Vaccine delivery to Health Districts and Centres* | *20,600* |  |
|  | ***TOTAL*** |  ***218,673***  |  |

# Monitoring-Evaluation framework

|   | Strategies | Intervention | Indicators | Verification source | Frequency |
| --- | --- | --- | --- | --- | --- |
| Overall objective: | **To replace the Rotarix with the Rotavac® vaccine in the routine immunisation schedule without compromising the rotavirus vaccine supply and demand.** |
| Specific Objectives (SO) | SO1: To inform healthcare personnel of the switch and the specificities of the Rotavac vaccine and the implications of introducing it in the immunisation schedule to replace Rotarix | Information and capacity building of the personnel in charge of immunisation | 1. Updating training modules, guides, communications materials, and data collection tools2. Training national supervisors3. Training HD management teams4. Training health centre managers | 1. Number of documents updated2. Number of national supervisors trained3. Number of regional and HD actors trained4. Number of health centre managers trained | Training reportsTraining completion certifications (as applicable) | Post-training |
| Management of Adverse Events Following Immunisation (AEFI) and Adverse Events of Special Interest (AESI) |
| SO2: To inform community and parents of the rotavirus vaccine switch | Community and child guardian information | 1. Drafting and distributing a press release on the rota switch2. Training healthcare personnel on ICP techniques3. Producing communications materials | 1. Number of press releases2. Number of healthcare personnel trained3. Number of materials produced | 1. Distribution reports2. Training workshop reports3. Materials produced | 1. Monthly2. Post-training3. Completion of production |
| SO3: To make Rotavac® vaccine injection doses and supplies available to health facilities | Vaccine supply and stock management | 1. Transporting vaccines from CTG-EPI to the regions2. Vaccine procurement from regions to health districts3. Vaccine procurement from health districts to health centres | 1. Number of regions supplied2. Number of health districts with Rotavac vaccines3. Number of health centres that received the Rotavac vaccine | Delivery reports | Post-delivery |
| SO4: To monitor the rotavirus vaccine performance | Data management and performance monitoring | Monitoring data transmission in the DHIS2 | Rotavac wastage rate (10%) | DHIS2 | Monthly |

1. Study on the reasons for refusing immunisation during SIA (MoH/EPI February 2021). Study on population acceptability and logistics to the introduction of the COVID-19 vaccine in Cameroon (MoH/EPI April 2021) [↑](#footnote-ref-2)