

The Switch Series:

Preparing for an Unplanned Rotavirus Vaccine Product Switch in Ethiopia



Recommendations



Communicate early about suspected product shortages and anticipated switch requirements. Any vaccine product switch requires careful planning. A compulsory switch poses additional challenges in planning and implementation. Manufacturers and partners need to communicate to countries as soon as a future product shortages are suspected to allow adequate time for planning or leveraging resources to switch to other products. Manufacturers should regularly share supply availability information after a product switch so countries can anticipate and plan for any potential challenges post-switch.



Strengthen coordination and collaboration platforms. Having strong, functional coordination platforms and clear procedures for decision-making can make it easier to plan and implement a successful switch. It is critical to maintain these platforms so that when there is an emergency or unexpected change of plans, partners can mobilize quickly.



Leverage existing systems and look for opportunities for integration. Ideally, any product switch would be planned in advance and included within a country's immunization roadmap. In the case of an unplanned switch, expanded programmes on immunization (EPI) and ministries of health should consider opportunities to leverage and adapt existing systems (e.g., planning, reporting, etc.) and integrate switch activities into existing immunization plans as is possible. Leveraging resources and opportunities for training or tool updates aligned with planned product introductions and switches can increase efficiency.



Invest in health system strengthening to be prepared for the unexpected. A strong, resilient health system should be prepared to adapt and respond to anticipated and unanticipated challenges, such as a forced vaccine switch. Strengthening the health system building blocks (leadership and governance; service delivery; health system financing; health workforce, procurement, storage and distribution of medical products and vaccines, and technologies; and health information systems) will support immunization programs to better respond to and prevent challenges, such as those the Ethiopian Ministry of Health (MOH) faced with the compulsory Rotavirus vaccine switch.



Background

Ethiopia introduced the rotavirus vaccine (RVV) into the national immunization program in 2013 using ROTARIX, which has a two-dose schedule. In 2023, RVV coverage was estimated to be 73%. The government aims to achieve 95 percent coverage.^{1,2}

In July 2023, Gavi informed partners of manufacturer-related supply issues related to ROTARIX, made by GlaxoSmithKline. This product shortage began in late 2023 and persisted into 2024. As a result, Gavi identified a subset of countries requiring a vaccine product switch, including Ethiopia. The RVV product that was available for affected countries, ROTASIIL-Liquid (SII) (ROTASIIL), is a three-dose schedule, presented in two-dose vials.

The Ethiopian Ministry of Health (MOH) accepted the unplanned, compulsory RVV product switch in August 2023 because the remaining stock of ROTARIX was not sufficient to meet the population's needs for more than six months. Although it was anticipated to begin in December 2023, the first phase of the switch ultimately took place in March 2024. JSI, through a Gates Foundation-funded project, provided technical assistance to the MOH from August 2023 to April 2025 to support the switch process at national and subnational levels. This series of four case studies describes the preparation for and implementation of the RVV product switch. **This case study focuses on preparation for the product switch.**

¹<https://immunizationdata.who.int/global/wiise-detail-page/rotavirus-vaccination-coverage?CODE=ETH&ANTIGEN=ROTAC+ROTA1&YEAR=>

²National immunization evaluation research

Preparing for the RVV Product Switch

Good planning is essential for a successful vaccine product switch. In Ethiopia, the decision to switch was forced and agreed by the MOH after discussions with Gavi, WHO, and UNICEF, resulting in a tight timeframe for preparation that did not follow the country's usual planning process. Despite this, the MOH quickly mobilized partners and leveraged existing coordination platforms to move the switch process forward.

Table 1: Challenges and Opportunities in Preparing for RVV Switch

Factor	Challenges	Opportunities
Program Planning and Coordination	- The MOH anticipated having only three months to plan for the switch, which is significantly less time than the government typically takes to prepare for switch or introduction-related activities. - At the time of the RVV product switch, the MOH was planning to implement multiple activities as part of its multi-year immunization plan, including introducing the second dose of inactivated polio vaccine (IPV2), switching from a two-dose schedule to a single dose schedule for human papillomavirus (HPV) vaccine, implementing HPV multi-age cohort vaccination, conducting catch-up activities, and integrating COVID-19 vaccination into the routine immunization system	- Ethiopia has strong, functional immunization coordination platforms that enable quick and effective communication and collaboration across partners from national to sub-national levels. - The MOH could integrate RVV switch preparatory activities, such as health worker training, with other immunization activities, leveraging resources and creating efficiencies.
Delivery and Logistics	- ROTARIX and ROTASIIL have different presentations. Because of the adapter, the packaging system for ROTASIIL needed extra space. - OTASIIL packaging was changed from 50 vials per pack to 25 vials per pack to make distribution to health facilities easier. - Some regions in Ethiopia are affected by conflict, creating additional challenges to distribution.	- MOH could use existing well-built distribution and cold chain systems to deliver vaccines to health posts and prevent stockouts. - The MOH distributed medical supplies, including vaccines, to conflict-affected areas by military convoys and airlift.
Health Worker Readiness	- Health workers needed training on the new RVV product and to be prepared for the switch at the same time they were facing other competing priorities (planning for other vaccine introductions and switches, regular service delivery activities). - Because of time constraints, the TOT was implemented without the vaccine on-hand. - There were limited resources for activities like training for the RVV switch.	Because the RVV switch was happening at the same time as the HPV vaccine switch and IPV2 introduction, training for the three products could be integrated as one, streamlining activities and leveraging existing resources. However, the integrated training required additional time, posing challenges when it was cascaded to the facility level. When cascaded, the training was less standardized and elements such as videos could not be shown in facilities experiencing connectivity issues.
Reporting and Monitoring Tools	Reporting and monitoring tools like vaccination cards, tally sheets, and registration books did not account for a third dose of RVV, required with the product switch. Updating, printing, and distribution of these tools/updates to tools would not be time or cost effective.	As a temporary solution, health workers were instructed to record the third dose of RVV under the designated area after the second dose on vaccination cards. Similarly, in the tally book, health workers were instructed to add a separate row on the tally sheet and record the third dose in an empty shaded box under Rota in the vaccine register.

Lessons Learned

Optimized Coordination and Readiness Is an Important Baseline for the Switch

- Strong stakeholder coordination platforms and leadership enable better preparation. Clear direction and expectations must be communicated by leadership early.
- Adaptation and use of Readiness Assessment Tools (RAT) help assess program readiness, identify gaps, and prioritize actions to improve readiness at each level of the health system.
- Using data from RAT, immunization programs can identify program elements and geographies that need additional support. Regular weekly virtual meetings with regional health system structure enabled the MOH and RHBs to monitor progress and deliver targeted gap-filling orientation.

JSI worked with the MOH to develop and regularly update the RAT for the RVV switch and provided support to assess. The national immunization TWGs assessed the progress of readiness for the RVV switch process on a monthly basis. During the first three months of preparation, the overall national-level readiness reached 64% by the end of December 2023. **After providing tailored support at national level based on RAT scores, the national readiness level improved significantly, reaching over 92% before the commencement of the national-level switch.**

Adaptable Reporting and Monitoring Tools are Critical in Implementing a Switch

- Switching from ROTARIX to ROTASIIL brought significant change to the health system recording and reporting tools due to changing from a two-dose schedule to a three-dose schedule. When there is not enough time to make these changes, use of temporary solutions such as Ethiopia's Google Sheets Reporting System makes the forced switch operational within a short period of time.
- Tools like vaccination cards, tally sheets, and registration books can quickly become out-of-date and are costly and time consuming to update and distribute. Leverage what you have on hand, using open space on these tools for manual recording of new information or doses, although this can delay standardization in reporting.

JSI also supported the MOH to update reporting and monitoring tools for the new indicator, the third dose of RVV (Rota3). JSI helped the MOH in adapting a temporary reporting system, using Google Sheets, for woredas to report on Rota3. By June 2024, the MOH had updated DHIS2 to include Rota3 and IPV2. From July 2024, health facilities transitioned from reporting via the Google Sheet system to DHIS2. JSI provided support to facilities during this transition until all facilities started reporting into DHIS2. The MOH and its TWG instructed health workers to record Rota3 in open space on vaccination cards after the second dose and in free space on tally sheets and registration books.

Within the first four months of the switch, only 34% of health facilities were reporting administration of Rota3. **As of February 2025, about 98% of health facilities reported administration of Rota3, and as of March 2025, 100% of health facilities have switched to ROTASIIL and are reporting Rota3 through DHIS2.**

Integrated Training Ensures all Health Workers Have Necessary Information and Skills While Leveraging Available Resources

- Due to the forced nature of the switch, there was a budget shortage and limited time to prepare and conduct a specific training for RVV. Integrating RVV training into other immunization activities helps leverage resources and minimize time and travel required to hold separate training sessions for each vaccine, all while maintaining quality.
- To maintain training quality through the cascade, plan to integrate refresher training and demonstrations with follow-up visits, such as supportive supervision, post-training and throughout implementation. It is important to carve out time and resources for follow-up training and supportive supervision, as well as monitoring data to determine if and what additional and ongoing support is needed for health facilities during a switch.

JSI supported the MOH to conduct a training of trainers (TOT) at national and regional levels. This training was cascaded to local levels to ensure all health workers had the information and skills needed to implement the switch. The MOH integrated RVV training into other activities including HPV vaccination (multi-age cohort and single dose switch), COVID-19 vaccination, catch-up activities, and IPV2 introduction. **The MOH managed to provide training of trainers (TOT) for 73 trainers who conducted regional TOTs for 1,393 health workers and immunization focal points at regional level. Further cascade trainings were provided at woreda level for 57,566 health workers. The cascaded training took between two months in some regions to four months (Somali Region).**

Key Considerations

Based on the experience of the forced RVV switch in Ethiopia, below are key questions to consider when preparing for a switch:



Decision-making:

- Does the alternative product offer a comparative advantage or additional benefits to the existing product?
- Is the process of switching programmatically feasible in the current context?
- Are there opportunities for integration and/or schedule alignment with other planned programming?



Stakeholder engagement:

- Do coordination and collaboration platforms exist and are they functional?
- Are existing resources sufficient to implement the switch and/or can other resources be leveraged?
- Are there sufficient human resources to assign focal points at national and subnational levels?



Sustainability and resilience:

- Are existing planning, monitoring, and reporting systems functional and adaptable? Can they be sustained and easily updated in the short- and long-term?
- Is sufficient time built in for training and supportive supervision? How can on-the-job and refresher training and supportive supervision be integrated with other immunization activities?
- Are there any near or long-term concerns about the sustainability of vaccine supply?
- Is the health system resilient enough to withstand unforeseen events and be responsive to the needs and challenges of different contexts?