

Guidance on utilization of COVID-19 vaccines before the date of expiry

19 July 2021



EXP: XXX

WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication.

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WHO reference number: WHO/2019-nCoV/Vaccine_utilization/2021.1

Background

With an ongoing pandemic and a constrained vaccine supply context, it is essential to ensure that all COVID-19 vaccine doses are optimally utilized to protect those at the highest risk for severe disease and death. In such a situation, it is essential to minimize vaccine wastage. Due to the short shelf life, several countries have faced challenges with utilizing all available doses of vaccines before the expiry date. It is of utmost importance that countries ensure the utilization of all available vaccine doses.

Purpose of this document

This guidance note serves to enable countries to:

- closely monitor vaccine utilization with respect to expiry dates; and
- review options for accelerating vaccine utilization, thereby mitigating the risks of closed-vial wastage.

Detailed guidance on addressing the other underlying issues that contribute to low utilization are available in the World Health Organization (WHO) *COVID-19 vaccine introduction toolkit*.¹

This document, developed through a consultative process that included all six WHO regional offices as well as partner agencies supporting the rollout of COVID-19 vaccination, complements the guidance on *Considerations for optimizing the deployment of ChAdOx1-S [recombinant] vaccines in a time-limited constrained supply situation*.² It primarily applies to products with a short shelf life (6 months or shorter on arrival in the country).

Target audience

- national and subnational immunization managers;
- members of national coordination committees (or equivalent) for deployment and vaccination as part of the COVID-19 pandemic response; and
- international agencies, development partners and consultants supporting the rollout of COVID-19 vaccination.

Guiding principles

When making informed choices for enhancing the utilization of COVID-19 vaccines, national programmes should consider the following guiding principles:

- **Maintain focus on the primary objectives of COVID-19 vaccination in a supply-constrained situation:** In the early phases, when vaccine supplies are limited, the primary focus of vaccination should be to reduce the risk of death and severe disease among those most at risk, and to protect the health system and ensure the continued provision of other essential services.
- **Ensure equitable distribution:** All individuals in the priority target groups³ should have equal access to vaccination, irrespective of who they are, where they live, or their ability to pay.

¹ *COVID-19 vaccine introduction toolkit*. Geneva: World Health Organization; 2021 (COVID-19 vaccine introduction toolkit (who.int)).

² *Considerations for optimizing the deployment of ChAdOx1-S [recombinant] vaccines in a time-limited constrained supply situation*. Geneva: World Health Organization; 2021 (<https://www.who.int/publications/m/item/considerations-for-optimizing-deployment-of-astrazeneca-azd1222-and-sii-covishield-vaccines-in-a-time-limited-constrained-supply-situation>).

³ *WHO SAGE roadmap for prioritizing uses of COVID-19 vaccines in the context of limited supply*. Geneva: World Health Organization; 2020 (<https://www.who.int/publications/i/item/who-sage-roadmap-for-prioritizing-uses-of-covid-19-vaccines-in-the-context-of-limited-supply>).

Steps to ensure utilization of vaccine doses before the date of expiry

This section outlines a step-by-step approach and proposes a decision framework to support the planning and implementation of vaccination to ensure that vaccine doses are optimally utilized before reaching their expiry date. It is recognized that the reasons for slow utilization and the capacity or resources to implement different options will vary across countries. The process and the decision tree (Fig. 1) outlined in this document will support countries to arrive at feasible and practical solutions that are adapted to their context.

Step 1. Use monitoring data to estimate capacity to utilize vaccines before expiry

The objective of this step is to estimate whether available vaccine doses can be fully utilized at the current utilization rate at least 2 weeks before the expiry date (to allow a buffer period for unexpected delays). In this exercise, the assessment may be limited to products with a shelf life of 6 months or shorter.

The following monitoring indicators will be required. The level(s) at which the indicators are to be used will depend on the size and administrative structure of the country and the delegation of authority for decision-making.

- 1. Number and distribution of vaccination sites:** The total number of **functional sites**¹ and their geographical distribution (by district or equivalent administrative level and including both public and private service providers).
- 2. Number of sessions conducted at each vaccination site:** The frequency with which vaccination sessions are held at each site (i.e. daily, weekly, etc.).
- 3. Average number of vaccine doses administered per session at each site:** The average number of vaccine doses, ideally by vaccine type, administered per session (use the average for the past five sessions).
- 4. Vaccine stock levels:** The levels for each vaccine product at national, regional, district and health facility levels.
- 5. Expiry date of the available vaccine doses:** The date of vaccine expiry, by lot number and vaccine product.
- 6. Proportion of planned vaccinations administered during each session:** The number of vaccine doses administered per session as a proportion of the number of planned vaccinations at the session as per the microplan or session plan. This will provide an estimate of the uptake of vaccine at the site. An average of the last five vaccination sessions may be used.

Each of the following steps needs to be done separately for each vaccine product and each vaccine batch available in the country.

Step 1.1. Estimate the required utilization to consume all the doses 2 weeks before the expiry period

- 1.1.1. Calculate the number of days left before the expiry date based on the expiry date on the label and the current date.
In cases where only the month and year are mentioned, assume that the expiry date is the last day of the month.
- 1.1.2. Estimate the **required daily utilization rate**² to use up the vaccine 14 days before expiry using the following formula:
$$\text{Number of vaccine doses in stock} \div (\text{number of days left to expiry} - 14)$$
- 1.1.3. Estimate the required **weekly utilization rate** to use up the vaccine 14 days before expiry:
$$\text{Daily utilization rate} \times 7$$

¹ Sites where vaccination sessions are being conducted as per schedule.

² The daily utilization rate refers to the average daily utilization rate irrespective of the number of vaccination sessions being conducted per week. The adjustments for number of sessions held per week and number of vaccinations per session are made in Step 1.2. to compare the required weekly utilization and the current weekly utilization.

Step 1.2. Estimate the current weekly vaccine utilization

- 1.2.1. Calculate the weekly utilization of vaccines at each site using the following formula:

Average vaccinations administered per session (average of previous five sessions) × number of sessions conducted per week

- 1.2.2. Calculate the weekly utilization nationally:

Sum of the weekly utilization of vaccine doses at each site

Step 1.3. Estimate if there is a deficit in utilization

If the estimated weekly utilization rate required to use up the vaccine doses before expiry (from Step 1.1.) is equal to or lower than current weekly utilization (from Step 1.2.), continue to monitor the daily utilization rate at the district level, with weekly reporting and review at the national level to assess if any actions are required to accelerate utilization.

If the estimated weekly utilization rate required to use up the vaccine doses before expiry (from Step 1.1.) is greater than the calculated weekly utilization (from Step 1.2.) then move on to **Step 2** to explore the options for enhancing vaccine utilization.

The country case study provides a simple example for applying Steps 1.1. and 1.2. For the sake of simplicity, in the example, it is assumed that all the urban and rural sites are vaccinating at the same rate.

Step 2. Choose an appropriate strategy to enhance vaccine utilization

The reasons for slow utilization of vaccines are varied and contextual. Experience from countries with slow utilization of vaccines indicates the following common reasons:

- Vaccine rollout has been limited to certain geographic or administrative areas within the country and at an inadequate scale to ensure optimal utilization of vaccines.
- The number of vaccination sites is not enough to meet the target utilization rate.
- Vaccination sites are unable to meet their vaccination targets, due to inadequate planning and resources, sub-optimal implementation of delivery strategies, or vaccine hesitancy among priority target groups, e.g. health workers.

Several options are available to enhance vaccine utilization depending on the local context and the factors that may be contributing to sub-optimal vaccine utilization. Fig. 1 illustrates a decision tree approach to exploring the potential options for enhancing vaccine utilization and making appropriate choices. The choice of options should take the local reasons for low utilization into consideration.

Additional factors important in making informed choices

When multiple vaccine products or batches of vaccines are available in the country, the product or batch with the shortest shelf life should be used first unless there are logistical challenges in using the vaccines in certain geographies (e.g. availability of ultra-cold chain), interchangeability of vaccine products, or restrictions for the use of these products in any specific target group. This is consistent with the WHO recommendation of the earliest expiry first out (EEFO) principle and with good vaccine management practices.

If the vaccines administered in each session are lower than the number of vaccinations planned (as per the microplan and based on resource availability), then the potential causes of low uptake, including demand issues related to lack of trust in the vaccine, lack of access to vaccination sessions, or session timings, should be further explored. The WHO *COVID-19 vaccine introduction toolkit* provides further specific guidance on addressing some of the issues affecting vaccine uptake.¹

¹ *COVID-19 vaccine introduction toolkit*. Geneva: World Health Organization; 2021 (COVID-19 vaccine introduction toolkit (who.int)).

Country case study

On 1 March 2021, country X has a stock of 350 000 doses of vaccine with an expiry date of 30 July 2021.

The country currently has 80 vaccination sites, of which 20 are in urban areas and 60 in rural areas.

The urban sites conduct sessions 5 days a week and plan to administer 100 vaccinations during each session (as per the microplans).

The rural sites conduct sessions 2 days in a week and plan to administer 50 vaccinations during each session (as per the microplans).

The current average vaccinations administered each session at urban vaccination sites is 90 and at rural sites is 35.

Step 1.1. Estimation of required utilization rate

1.1.1. Number of days left before expiry of the vaccine = 152 days

1.1.2. Estimated required daily utilization rate = $350\,000 \div (152 - 14) = 350\,000 \div 138 = 2536$

1.1.3. Estimated required weekly utilization rate = $2536 \times 7 = 17\,752$

Step 1.2. Estimation of current weekly utilization rate

For simplicity, we are assuming that all urban and rural sites have similar utilization rates. Ideally, the utilization should be estimated per site and totalled up.

1.2.1. Average vaccinations administered in urban sites per week: $20 \times 90 \times 5 = 9000$

1.2.1. Average vaccinations administered in rural sites per week: $60 \times 2 \times 35 = 4200$

1.2.2. Total current average weekly utilization = $9000 + 4200 = 13\,200$

The current utilization rate is lower than the required utilization rate indicating the risk of vaccine doses being wasted.

If the planned utilization rates (as per the microplans) were achieved, then the weekly utilization would be:

Urban sites: $20 \times 100 \times 5 = 10\,000$

Rural sites: $60 \times 50 \times 2 = 6000$

Total weekly utilization = 16 000

Even if the vaccinations were administered as per the microplans, the weekly utilization would remain below the required utilization rate.

Hence, the country made the following strategic choices:

- Increase the number of urban sites to 30 to improve access to vaccination at more convenient locations.
- Increase the number of rural sites to 70 to improve access to vaccination at more convenient locations and increase the number of vaccination sessions to 3 times per week.
- Enhance communications and community engagement activities to improve uptake of vaccines in the priority target groups.

Based on the increase in the number of vaccination sites and the number of vaccination sessions in the rural sites, the utilization rate was expected to increase to 20 850 doses per week even if the average vaccinations administered at each session was unchanged, which would allow utilization of all doses 2 weeks before expiry.

In such instances, improving access by increasing the number of sessions at a site or adding sites at more convenient locations, extending the hours of service at each site, or changing the location of existing sites should be considered. All efforts to address vaccine hesitancy and generate demand should be made. Though it is difficult to predict the extent that efforts to implement delivery strategies to meet the needs of prioritized populations, engage trusted community leaders as champions of vaccination, or address vaccine hesitancy can accelerate vaccine utilization in the short term, such efforts will enable optimal uptake of vaccines in the long term.

To select between strategic approaches to accelerate utilization:

1. Map the effort and resources required to implement each option and the projected impact of that option.
2. Choose the options that have the optimal balance between feasibility (based on available resources) and accelerated vaccine utilization.

The following information may provide additional qualitative insights to help make informed choices:

- Session monitoring and/or supportive supervision reports may provide additional insights into the reasons for low utilization rates and should be taken into consideration.
- Information from any assessments on behavioural and social drivers¹ of vaccination uptake, including rapid assessments with prioritized populations, community representatives, or providers, will provide insights into the exact reasons for low uptake and inform additional measures required to improve uptake at each site.

The following guiding principles should also be kept in mind when making choices:

- When the chosen strategy requires an expansion of the target groups for vaccination to enhance utilization, it is important to ensure that the highest priority groups are vaccinated before moving to expanded targets. This will ensure that the principle of reducing mortality and severe morbidity and maintaining essential services is adhered to. Expansion to include all eligible adults may be considered when there is a high likelihood that vaccines will not be used before the expiry date, but only after ensuring that the highest priority groups who present themselves at a session are vaccinated.
- When making choices, ensure that the principle of equity is maintained and that vaccination services are accessible to the most vulnerable and underserved populations, including migrants, internally displaced persons and refugees.

Step 3. Estimate whether the choices made to accelerate utilization will result in consumption of the available vaccine doses before expiry

Once decisions on the strategic approach to accelerate vaccine utilization are made, but before implementation:

- Review the projected utilization based on the changes made using the planned vaccine administration rates and the formulae shown in **Step 1**.
- Assess whether the projected utilization rate is adequate to ensure consumption of all vaccine doses at least 2 weeks

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