UGANDA NATIONAL ACADEMY OF SCIENCES

Recommendation Report: The Use of the mRNA Moderna Vaccine in Uganda

Ratified Recommendation of the Interim Report submitted on September 02, 2021

By

UGANDA NATIONAL IMMUNISATION TECHNICAL ADVISORY GROUP (UNITAG)

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EXECUTIVE SUMMARY

The UNITAG recommends using the mRNA Moderna vaccine in Uganda because it is safe (the benefits outweigh the risks), efficacious, and has acceptable logistical and storage requirements in terms of the cold chain and administration, in line with available capacities in the country.

Vaccine efficacy: The mRNA-1273 Moderna vaccine is highly efficacious (94.1%) against symptomatic SARS-CoV-2 infection. The Vaccine is recommended for persons aged 18 years and above, particularly older persons without an upper limit of age and persons with comorbidities. A schedule of two doses (100 µg each, 0.5 ml each) should be given intramuscularly with an interval of up to 42 days between doses. The same product should be used for both doses, and no booster dose is needed.

Vaccination of specific populations: Healthcare workers involved in the vaccination process should conduct an individual risk-benefit assessment for very frail older persons with a life expectancy anticipated to be less than three (3) months. The mRNA-1273 Moderna use is not recommended in pregnancy until more data is available. However, in circumstances where the benefit of vaccinating a pregnant woman outweighs the potential vaccine risks, such as in health workers at high risk of exposure or women with significant comorbidities, vaccination may be considered. Breastfeeding women can be vaccinated if part of a risk group (healthcare workers, teachers, 50years and above or persons with comorbidities).

Vaccination logistics: Considering the fact that National Medical Stores has a net freezer capacity (L) is 12,200L to handle a maximum of 11,200L of three vaccine doses (nOPV, Moderna, and bOPV) with the same cold chain capacity of -15℃; there is adequate freezer capacity for the 647,080 doses of Moderna vaccine expected in the country.

Additional Considerations and recommendations regarding vaccine uptake

1. UNITAG recommends that the Ministry of Health/ UNEPI explore other methods of mobilizing the targeted high-risk groups (a targeted social mobilization strategy) to increase vaccination coverage before the country receives more vaccines as expected.
2. There is a need for the Ministry of Health to urgently address poor facilitation for health workers and mobilizers to be fully engaged in the vaccination process before the country receives more vaccines.
3. The Ministry of Health should develop appropriate behavioral communication messages in the five (5) regional local languages to ensure all Ugandans understand the intended message.

INTRODUCTION

The COVID-19 pandemic has caused significant global morbidity and mortality and social, educational, and economic disruptions. The World Health Organisation (WHO) recognizes an urgent global need for effective and safe vaccines and making them available at scale and equitably across all countries.

BACKGROUND

The Uganda National Immunisation Technical Advisory Group (UNITAG) received a request from the Ministry of Health to provide guidance on the selection of COVID-19 Vaccine (s) for Uganda in the event that the WHO approves more than one Vaccine. This recommendation aims to assist the Ministry of Health in planning for the use of the Moderna mRNA-1273 vaccine against COVID-19 in Uganda.

In response to this request, UNITAG developed its recommendations on vaccine selection based on the best available evidence, using scientific knowledge and practice criteria, particularly those peer-reviewed and approved by WHO. Out of the four WHO Emergency Use Licenced (EUL) vaccines, namely; (Vaxzevria fmr. Astra Zeneca vaccine (ChAdOx1 nCoV-19) and Janssen vaccine (Ad26.COV2-S [recombinant]), mRNA-1273 Moderna Vaccine and BNT162b2 Pfizer BioNTech vaccine, UNITAG recommended the Vaxzevria fmr. Astra Zeneca vaccine (ChAdOx1 nCoV-19) and Janssen vaccine (Ad26.COV2-S [recombinant]) for Uganda (UNITAG Recommendation on the Choice of COVID-19 Vaccines for Uganda, April 20, 2021).

Although the evidence showed that all vaccines are safe, effective, and efficacious against moderate and severe disease, hospitalization, and death, the mRNA-1273 Vaccine manufactured by Moderna was not recommended for use in Uganda because of a number of reasons, including;

i) high cost per dose of Vaccine and per person vaccinated, presenting as the highest of the four vaccines. i.e., the price per mRNA-1273 Moderna Vaccine dose cost between $15.0 and $37.0, and the cost per person vaccinated was between $30.0 and $74.0.

ii) ii) The cold chain temperature requirements of mRNA-1273 Moderna Vaccine were considered incompatible with the locally available cold chain system.

iii) iii) mRNA-1273 Moderna Vaccine not listed among vaccines on theCOVAX R&D Portfolio.

UNITAG revisited this recommendation following new developments and considerations in the vaccines profile globally and domestically as well as new evidence from preliminary literature review on the vaccines and ensured that consensus was arrived at through interdisciplinary dialogue among scientists, ethicists, and policymakers.

UNITAG recommended using mRNA Moderna vaccine in Uganda because it is safe (the benefits outweigh the risks), efficacious, and has acceptable logistical and storage requirements in terms of the cold chain and administration, in line with available capacities in the country.

Priority groups for covid-19 vaccine allocation should be maintained while allocating the mRNA Moderna to priority groups, including health care workers, teachers, 50+ year old, and 18+ year old with comorbidities.

CONCLUSIONS AND RECOMMENDATIONS

The following evidence was considered in developing updated conclusions and recommendations:

Upon being listed among vaccines on the COVAX R&D portfolio on May 3, 2021, following receipt of the WHO's Emergency Use Listing (EUL) on April 30, 2021, for use in individuals 18 years of age and older, the UNITAG reviewed the efficacy, safety, and logistical requirements data of the mRNA-1273 Moderna vaccine approved by WHO to determine its suitability for use in Uganda. https://www.gavi.org/news/media-room/gavi-signs-agreement-moderna-secure-doses-behalf-covax-facility

Moderna's mRNA-1273 COVID-19 Vaccine has been shown to be highly effective in preventing symptomatic COVID-19 following the phase 3 randomized, stratified, double-blind, placebo-controlled trial (Baden, et al., 2021).

a) **Vaccine Efficacy:**

The mRNA-1273 Moderna vaccine has been shown to have an efficacy of approximately 94% against symptomatic SARS-CoV-2 infection, based on a median follow-up of two months. The impact of variants of concern on vaccine effectiveness remains unknown to date, especially for the recently emerged Delta (B.1.617.2) variant. However, there is accumulating evidence that the Vaccine's protective effect against infection may wane over time. Therefore;

i) Vaccination is recommended for persons aged 18 years and above, particularly older persons without an upper limit of age and persons with comorbidities such as hypertension, diabetes, asthma, pulmonary, liver, and kidney disease, stable infections with HIV, Hepatitis C, and B virus.

ii) A schedule of two doses (100 µg each, 0.5 ml each) given intramuscularly with an interval of 28 days between the doses is recommended, with current data supporting an extension of up to 42 days between doses.

iii) The same product should be used for both doses, as there are no studies on interchangeability (mix and match) with other vaccines against COVID-19.

iv) There is currently no evidence on the need of a booster dose after the second dose; hence no booster dose is needed.

b) **Vaccination of specific populations:**

i) Vaccination is recommended for older persons without an upper age limit. Healthcare workers involved in the vaccination process should conduct an individual risk-benefitassessment for very frail older persons with a life expectancy anticipated to be less thanthree (3) months.

ii) Since mRNA-1273 is not a live vaccine, it does not enter the cell nucleus; hence, it is rapidly degraded. Animal studies have not shown toxicity to the fetus, but currently, no data on vaccine safety in pregnant women exists. Therefore, mRNA-1273 Moderna use isnot recommended in pregnancy until more data are available, except in circumstances where the benefit of vaccinating a pregnant woman outweighs the potential vaccine risks,such as in health workers at high risk of exposure or women with significant comorbidities.These can be included in stage II (limited vaccine availability, for 11–20% of national population) under groups with comorbidities or health states determined to be at significantly higher risk of severe disease or death.

iii) Breastfeeding women can be vaccinated if part of a risk group (healthcare workers, teachers, 50years and above or persons with comorbidities). Discontinuation of breastfeeding after vaccination is not recommended.

iv) The Vaccine can be offered to people living with HIV in accordance to the WHO Prioritization Roadmap (should be included in stage II (limited vaccine availability, for 11–20% of national population) under groups with comorbidities or health states, determined to be at significantly higher risk of severe disease or death.

c) **Vaccination logistics**

The mRNA-1273 Vaccine requires cold-chain distribution and storage conditions at -15 – to -25°C for unopened vial stored up to 7months; vials can be stored refrigerated at **2°C to 8°C** for a maximum of 30 days before the withdrawal of the first dose. According to a communication on the storage capacity at the National Medical Stores (NMS) to UNICEF as of September 9, 2021 (email communication from Dr. Eva Kabwongera), NMS Net freezer capacity (L) is 12,200L yet the projected maximum storage required to store vaccines (nOPV, Moderna and bOPV) at -15°C is 11,200L yet NMS Net freezer capacity (L) is 12,200L. The assumption is that doses for both rounds will not be delivered at the same time hence considered only quantities for the first dose campaign only (647,080 doses of Moderna vaccine). Moreover, considering that the oral polio vaccine is also stored at the same temperatures as the Moderna vaccine, – below 15°C, this will not be new technology in Uganda. From the volume analysis, there is adequate capacity (no potential risk to freezer capacity availability) since there is no possibility of receiving and storing the maximum indicated quantity for all three vaccines simultaneously.

ADDITIONAL CONSIDERATIONS

a) Vaccine Uptake in Uganda

UNITAG has also conducted some preliminary analysis of data available from phase one vaccination targeting high-risk groups in Uganda to consider increasing uptake of the vaccines among the priority groups and the general public as they become available.

The committee has considered factors such as population health disparities, individuals at higher risk because of healthstatus, occupation, or living conditions; and geographic distribution of active virus spread. In addition, the committee has considered how the population can be assured of equitable access to COVID-19 vaccines in Uganda and recommended strategies to mitigate vaccine hesitancy amongthe Ugandan public.

b) Evidence

The following observations have been noted:

Current evidence from the phase one COVID-19 vaccination targeting high-risk groups shows that Uganda has received 2, 024,280 doses of COVID-19 vaccines at 100% distribution rate. While more than half (68.0%) of these vaccines have been distributed to operational level, 71.0% have been administered as first dose and 29.0% as second dose (fully vaccinated). However, only 8.3% of the targeted high-risk groups have been fully vaccinated with the two doses and 20.4% with their first dose. In particular, only 12% of the elderly (50+ years), being the highest vaccination coverage by age group, have been vaccinated with the first dose. Cumulatively, only 1.8% of the overall target population (beyond phase one) has been fully vaccinated, leaving 4.5% awaiting their second dose. (Ministry of Health COVID-19 vaccination performance updates as of August 30, 2021).

According to the Government of Uganda's vaccine pipeline and proposed allocation strategy, more vaccines are expected, including a consignment of 647,080 doses of the Moderna vaccine from the United States of America. High priority groups awaiting the first dose (particularly teachers, health workers, 50+ year olds, and 18+ year olds with comorbidities) will be given first priority. Also, all districts will be considered, with higher doses allocated to 28 high burden districts and 14 citiesto cater for first and second doses. Yet, it is uncertain when the country would receive the next consignment/donation.

Prioritizing the most at risk of severe disease and death comes with benefits, including reducing risk of severe morbidity thus freeing up the health system and reducing mortality as the most critical indicators. Equitable distribution of the Moderna vaccine should aim at clearing the backlog of the high priority groups in the phase one category.

c) Recommendations

In addition to the above vaccine-specific recommendations, UNITAG made the following recommendations to increase vaccine uptake rates:

a) Revise mobilization strategy of high-risk groups; Given that only 8.3% of the targeted high-risk groups had been fully vaccinated and only 20.4%received their first dose, the UNITAG recommended that the Ministry of Health/ UNEPI explore other methods of mobilizing the targeted high-risk groups to increase vaccination coverage.

A targeted social mobilization strategy for the population, especially the high-risk groups, should be developed before the country receives more vaccines as expected.

b) The Ministry of Health should consider engaging religious and cultural groups in its mobilization efforts, through their leaders, with the assumption that majority of them will subscribe to it for the social good rather than the monetary reward.

c) UNITAG made an observation that in some areas, health workers and mobilizers were not fully engaged in the vaccination process because they are poorly facilitated. Therefore,there is a need for the Ministry of Health to urgently address this issue before the country receives more vaccines.

d) The Ministry should develop appropriate behavioral communication messages in the five (5) regional local languages to ensure all Ugandans understand the intended message.

Note: Although the individual and community health benefits of vaccination are now well understood by the population, demotivated healthcare workers due to insufficient facilitation/ allowance will continue to negatively impact vaccine uptake rates. This issue should be attended to and resolved before the country receives more vaccines.

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