



Interim Advisory on the introduction of COVID-19 vaccine booster doses in Uganda November 25, 2021

BACKGROUND

On October 04, 2021, the World Health Organisation (WHO) issued an interim statement on booster doses for COVID-19 vaccination. According to WHO, a booster dose should be administered to a vaccinated population that has completed a primary vaccination series (currently one or two doses of COVID-19 vaccine depending on the product) but with a noticeable decline in immunity. The objective of a booster dose is to restore vaccine effectiveness when, with time, the immunity and clinical protection have fallen below a rate deemed sufficient in that population.

Following this recommendation, UNITAG - COVAX Working Group dedicated time to discuss the evidence to justify introducing booster doses in the Uganda National Expanded Program for Immunisation (UNEPI). The Working Group conducted some preliminary literature review on the issue globally, a preliminary analysis of data available from the phase one vaccination, and the accelerated mass vaccination campaigns (AMVCs) reports in Uganda and concluded that Uganda is not yet ready for booster doses. The Working Group's conclusion and recommendations were based on a decision-making framework outlined in this document, triggered by the need for evidence of decreased vaccine effectiveness against severe illness and/ or infection and benefit of safety and effectiveness of a booster dose in the Ugandan context. The Working Group continues to review emerging evidence on the need for and timing a booster dose for the currently available COVID-19 vaccines that have received WHO Emergency Use Listing (EUL).

SUMMARY OF EVIDENCE

Epidemiology and Burden of Disease

Following the second wave of Covid-19 in Uganda, UNITAG requested the Ministry of Health (MoH) Incident Management Team (IMT) for data on specific variables to guide the committee in conducting a substantive analysis of risk factors from April to August 2021 to see whether there was any change in the prioritisation considerations. The data provided enabled a descriptive analysis indicating that older age groups (50 years and above) were still at higher risk of getting infected. Moreover, the point of substantial increase in risk for infection seemed to have shifted to 30-year-olds, with people aged 30-49 years bearing a significant burden of the disease. In addition, there was a doubling of percentage cases among people aged 20 years and below, although their overall contribution to the caseload was still low compared to the older age groups. Nonetheless, the evidence suggested that the caseload was most likely to grow among this age group, recommending continual monitoring.

Since the data provided could not enable a detailed epidemiological assessment of the risk profile of new infections due to insufficient data on the specific variables from mild/moderate cases, the committee recommended that MoH establish sentinel surveillance sites. A minimum set of epidemiological variables at the sentinel sites, including background characteristics, comorbidities, disease-related characteristics, the spatial distribution of cases, vaccine-related



factors, and post-COVID factors such as long-term effects on discharged cases, would be monitored in addition to the already existing variables. Availability of this data would inform the epidemiology of breakthrough cases and disease severity by age, comorbidity and risk groups, exposure, type of vaccine and time since vaccination, and in the context of variants of concern (VOCs). In addition, this data would be beneficial for the Working Group to determine the need for boosters and make a fundamental recommendation.

While this recommendation was well received by the MoH and integrated into the already established National Integrated Sentinel Surveillance (NISS) Network, the integrated data collection has not been actualised yet. According to the NISS Framework implementation progress report, as of November 23, 2021, the Network would carry out site assessment in the last week of December 2021 and the first week of January 2022 to gather on-ground information that will guide the implementation of the different sentinel surveillance activities.

National Vaccine-Specific Data Requirements

According to the UNITAG recommendation report on the prioritisation of risk groups in Uganda as of October 07, 2021, MoH should collect vaccine-related factors among new COVID-19 cases previously not collected, including vaccination status (none, partial or full), date of last vaccination among the vaccinated, type of vaccine received, serious adverse events following immunisation, long term effects of COVID-19 following discharge at the sentinel sites. This data would provide evidence on vaccine efficacy, effectiveness, duration of protection of vaccines in the context of SARS-CoV-2 and VOCs from the national data.

Additionally, evidence from the AMVCs and COVID-19 vaccine uptake and rollout report as of December 09, 2021, indicated that over 2.2 million doses of vaccines administered were not yet captured in the Health Monitoring Information System (HMIS). Moreover, evidence from the Health Information Systems Program (HISP) Uganda confirmed that the figures captured in the system could be low due to underreporting following the substantial backlog in catching up on individual entries across the country. Furthermore, the lack of training and communication were some of the reasons reported to have contributed to the misreporting and under-reporting in the HISP. Indeed, supplemental evidence from immunological studies assessing neutralising antibodies over time and biomarkers of cellular immunity when possible is unavailable as national data is not yet sufficient to facilitate these studies.

Global Vaccine Supply

The Working Group could not access evidence on the global availability of vaccines because the WHO does not keep track of the number of available vaccine doses globally; hence, the number of doses available globally is currently unknown.

Vaccine Coverage among High Risk Groups

On April 20, 2021, UNITAG recommended that all healthcare workers, the elderly (all people aged 50yrs and above), all people of all ages with high risk-defining comorbidities including diabetes, hypertension, chronic organ disease (heart, kidney, liver, and stroke), other chronic conditions like cancer, TB, COPD, obesity, and essential non-health workers including teachers and security personnel be prioritised as high-risk groups in the initial phase of scarce



vaccine supply. According to the MoH/ EPI report on the COVID-19 vaccine rollout and uptake in Uganda, as of December 04, 2021, approximately 4.8 Million persons were prioritised as risk groups in Uganda. In particular, the program targeted 150,000 health workers alongside 250,000 security personnel, 550,000 teachers, 3,348,500 persons above 50 years and 500,000 persons with comorbidities.

Evidence on the COVID-19 vaccine coverage rates indicates that less than 20% (as recommended in the WHO and UNITAG prioritisation roadmap for phase one) of the Ugandan population aged 18 years and older have completed a primary COVID-19 vaccine series. According to the MoH/ EPI on the COVID-19 vaccine rollout and uptake in Uganda as of December 04, 2021, only 8% (1,723,077) of the target 22,000,000 people above 18 years have been fully vaccinated. While 21% (4,623,121) of the target population have received their first dose pending the second dose, 71% (15,620,000) have not been vaccinated at all. This means that most Ugandan population, especially among the high-risk groups, is still at risk of contracting the SARS-CoV-2 infection.

In particular, only 49.8% of the targeted health workers, 29.4% of security personnel, 28% of teachers, 5.4% of the elderly above 50 years and 2.9% of people with comorbidities had been fully vaccinated. While first dose uptake has improved among health workers, security personnel and the teachers with 96.7%, 64.6% and 70.3%, respectively, the elderly and people with comorbidities remain highly unprotected with 15.3% and 8.6% coverage rates, respectively.

Other Considerations for Booster dose Decision Making

Booster dose programs from other Countries

Evidence on the global COVID-19 vaccine booster and additional dose programs as of November 18, 2021, indicated that 81 countries had implemented the COVID-19 vaccine booster dose programs with 52 high-income countries (HICs). The evidence further highlighted that none of the low-income countries (LICs) had started booster dose programs as they struggled to reach their high priority groups. In addition, it was noted that most of the countries that had implemented booster doses in their programs started with the most vulnerable groups, including people on immunosuppressive treatment and the elderly.

WHO Values Framework

UNITAG is guided by a values framework based on principles that justify the committee's decisions. Guided by the principle of equity, the Working Group ensures decisions on vaccine prioritisation within Uganda take into account the vulnerabilities, risks and needs of the priority groups who, because of underlying societal, geographical or biomedical factors, are at risk of experiencing a greater burden from the COVID-19 pandemic. In addition, UNITAG recommended that MoH develop the immunisation delivery systems and infrastructure required to ensure that priority-use populations have access to COVID-19 vaccines and that everyone in a priority-use group has equal access, particularly socially disadvantaged populations.



Conclusion

Based on the preceding evidence, the COVAX Working Group concluded that Uganda is not yet ready for booster doses because of the following reasons:

- i. The available epidemiological data currently being collected is insufficient to enable a detailed epidemiological assessment of the risk profile of SARS-CoV-2 infection required to determine the need for booster doses in UNEPI.
- ii. The country is still behind in the primary series vaccination since only 10.4% (497,519) of the targeted 4.8M high-risk groups, and 8% of the national target of 22,000,000 people above 18years have been fully vaccinated.
- iii. Since most of the risk groups have not completed their primary series, there is no way to get adequate evidence on the effectiveness of the primary vaccination series.
- iv. Moreover, considering that there is still a huge (2.2M) backlog of vaccine-specific data that is not yet entered in the HISP, national vaccine-specific data remains insufficient to provide substantive evidence on vaccine efficacy, effectiveness, duration of protection of vaccines in the context of SARS-CoV-2 and VOCs required to make decisions regarding the need for a booster dose.
- v. Prioritising booster doses over breadth in the primary series coverage would be unethical as this undermines the principle of national equity.
- vi. Most countries that have rolled out boosters started with the most vulnerable groups, yet only 10.4% of Uganda's high risk/ vulnerable groups have so far received complete vaccination.

Recommendations

Following the above conclusions, the Working Group made the following recommendations:

- i. The MoH/ UNEPI should focus on achieving primary series vaccination targets before administering booster doses as fully vaccinated individuals have much lower SARS-CoV-2 hospitalisations, ICU admission, and mortality rates than unvaccinated individuals. In addition, the vaccinated are less likely to get infected, and therefore less likely to transmit the infection to others.
- ii. While the Working Group continues to monitor the evidence closely, MoH/ UNEPI should embark on a coordinated, evidence-informed approach to generate national data required for decision making.
- iii. MoH should invest in training data entrants at the district level and ensure adequate communication to avoid such backlogs in data entries, under and misreporting during data entry activities.