UGANDA NATIONAL ACADEMY OF SCIENCES

Uganda National Immunization Technical Advisory Group

Updated Recommendation on Pfizer-BioNTech vaccine

July 2021

1. Background

Pfizer BioNTech vaccine (BNT162b2) is an mRNA vaccine against COVID-19. A two-dose regimen of BNT162b2 given 21 days apart conferred 95% protection (95% CI 90.3–97.6%) 7 days post dose 2 against symptomatic SARS-CoV2- infection in persons aged 16 and above, based on a median follow-up of two months. Similar vaccine efficacy (generally 90 to 100%) was observed across subgroups, defined by age, sex, race, body mass index and comorbidities.

The vaccine received Emergency Use Listing from WHO on 8th January 2021. Since then, new evidence on vaccine performance and cold storage requirements has emerged, resulting in WHO issuing an update on to its EUL on 15TH June 2021.
(https://apps.who.int/iris/bitstream/handle/10665/341786/WHO-2019-nCoV-vaccines-SAGE-recommendation-BNT162b2-2021.2-eng.pdf?sequence=1)

2. Updated evidence

i. Vaccine efficacy/effectiveness

Post-introduction studies from Israel have shown high vaccine effectiveness from 7 days after dose 2 (with an inter-dose interval of 3 weeks): for documented infection 92% (95% CI 88–95%); for symptomatic COVID-19, 94% (95% CI 87–98%); for hospitalization 87% (95% CI 55–100%); and for severe disease, 92% (95% CI 75–100%).

A recent trial in **adolescents 12-15 years of age** showed a vaccine efficacy against symptomatic SARS-CoV-2 infection of 100% (95% CI 75–100%) from at least 7 days after dose two. Only limited safety data are available for this age group given the small sample size of the trial.

Post second dose studies showed that immunogenicity in terms of **neutralizing antibodies is increased** with a **longer inter-dose interval to 12 weeks** highlighting that extended inter-dose intervals will result in a good immune response, even in older adults.

Evidence on the **impact of variants of concern** other than Alpha on first and second dose vaccine effectiveness is only just emerging. Effectiveness after a single dose of vaccine against COVID-19 associated with Delta was lower than that against Alpha, whilst two dose effectiveness was similar for these two variants. Effectiveness was **notably lower after one dose** of vaccine **with Delta** cases **33.5%** (95%CI: 20.6 to 44.3) compared to Alpha cases 51.1% (95%CI: 47.3 to 54.7). With BNT162b2 **two dose effectiveness reduced** from 93.4% (95%CI: 90.4 to 95.5) with Alpha, **to 87.9%** (95%CI: 78.2 to 93.2) **with Delta**. (Ref. Bernal et al., 2021 preprint.
https://www.medrxiv.org/content/10.1101/2021.05.22.21257658v1.full)

ii. Inter-changeability with other vaccines

Preliminary results from a heterologous priming schedule where BNT162b2 was given as the second dose following a first dose of ChAdOx1- S [recombinant] vaccine showed a slightly increased but acceptable reactogenicity with superior or similar immunogenicity results, and an acceptable safety profile, thus supporting the use of such a heterologous priming schedule in settings where the second dose for the ChAdOx1-S [recombinant] vaccine is not available due to vaccine supply constraints or other concerns. (Refs: Bororbia et al., 2021
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3854768 and Hillus et al., 2021 medRxiv. 2021:2021.05.19.21257334. doi: 10.1101/2021.05.19.21257334)

iii. Vaccination logistics

The vaccine cab be stored at-90 °C to -60°C for six months, -25°C and -15°C for up to 2 weeks

The **storage period of the unopened thawed vial at 2–8 °C** (i.e. in a normal fridge after taking out of deep-freeze conditions) **is one month (31 days).**

3. Updated WHO EUL Recommendations

i. A Phase 3 trial in children aged 12-15 years showed high efficacy and good safety in this age group, leading to **an extension of the previous age indication from 16 years onwards down to age 12 onwards.**
The following statement was added: WHO recommends that countries should consider using BNT162b2 in children aged 12 to 15 only when high vaccine coverage with 2 doses has been achieved in the high priority groups as identified in the WHO Prioritization Roadmap. Children 12-15 years of age with comorbidities that put them at significantly higher risk of serious COVID-19 disease, alongside other high-risk groups, may be offered vaccination.

ii. Based on additional storage studies, **the storage period of the unopened thawed vial at 2–8 °C (i.e. in a normal fridge after taking out of deep-freeze conditions) has been extended from five days to one month (31 days).**
When assessing the feasibility of deploying BNT162b2, immunization programmes should consider the cold-chain requirements, the current minimum number of doses per shipment, the need to administer a whole batch of vaccine within a short time frame after removal from cold storage, and the need to ensure bundling with an adequate independent supply of the correct diluent.

4. UNITAG Considerations

Based on the updated evidence and WHO EUL revised recommendations, UNITAG reviewed the contextual country disease and Immunisation logistics, looking at the following evidence:

i. The **changing disease epidemiology**: anecdotal evidence from COVID-19 treatment units suggests that there has been a shift in the most affected age-groups, from older adults to much younger populations. Official GoU statistics show as follows:

Age Group (cases

Age Group	Cases (M+F)	Deaths (M+F)
0-9	(700+638)	(0+0)
10-19	(1,673+1,711)	(2+0)
20-29	(6,596+5,357)	(9+8)
30-39	(9,123+5,212)	(23+13)
40-49	(6,145+2,897)	(43+12)
50-59	(3,241+1,541)	(47+16)
60-69	(1,423+889)	(67+25)
70-79	(566+397)	(41+19)
80-89	(251+212)	(17+17)
90-99	(+23)	(3+1)

Ref: https://covid19.gou.go.ug/statistics.html updated 12/06/21

ii. The major circulating **variants of concern in Uganda** are:

B.1.617.1 (Indian)/ Kappa, B.1.617.2 (India)/Delta, B.1.351 (RSA)/ Beta, B.1.525 (Nigeria)/Eta, B.1.1.1.7 (UK)/ Alpha
Ref: Matthew Cotton (MRC/UVRI) May 2021 (unpublished)
https://twitter.com/mlcotten13/status/1399267387615109120

iii. The vaccine cold chain temp and space requirements versus **cold chain capacity in Uganda** stands as follows:
Vaccine packaging volumes:

1.8 cm3 (0.0018 L) per dose in secondary packaging
Carton holding 195 vials (1170 doses). Dimensions: 22.9 x 22.9 x 4.0 cm (2.1L)
Insulated box containing 5 secondary cartons with a total of 975 vials (5,850 doses). External Dimensions: 40 X 40 X 56 cm (89.6L)
Ancillary package containing syringes and needles provided free separately
Diluent sourced separately.
Ref: https://labeling.pfizer.com/ShowLabeling.aspx?id=14471&format=pdf

In country cold chain capacity

Central Vaccine Stores (-80^{o}C =120 L) (-20^{o} C = 5,476 L)
District Vaccine Stores (-80^{o}C = 0 L) (-20^{o} C = 86,884 L)
Health Facilities (-80^{o}C = 0 L) (-20^{o} C = 72,693 L)
Private Sector (Elsmed healthcare solutions, Kampala) -80^{o}C = 250 L available for leasing
Ref: UNEPI 2020. COVAX CCE Application- Consolidated Gavi Application Form, Nov 2020 (Unpublished)

iv. **Vaccine availability**:
500 million doses of Pfizer vaccine donated by US government to be delivered by June of next year, including 200 million to be delivered by the end of 2021 through COVAX facility and African Union.

Ref: https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/10/fact-sheet-president-biden-announces-historic-vaccine-donation-half-a-billion-pfizer-vaccines-to-the-worlds-lowest-income-nations/

v. **Vaccine demand, acceptability and uptake:** Uganda was allocated 3,024,000 doses of Astra-Zeneca vaccine by the COVAX Facility. 864,000 doses were delivered in March 2021, and an additional 100,000 doses donated by the Serum Institute of India. The delivery of additional doses of the vaccine was delayed due to supply constraints by the manufacturer.
As of 29th June, 955.158 doses had been administered, an uptake of 99.1%.

Ref: UNEPI, 2021, COVID-19 Vaccination Performance Updates, 1ST July 2021 ppt unpublished

5. UNITAG Conclusions:

Following the above review of evidence, UNITAG came to the following conclusions:

i. The Pfizer vaccine has been proven to be **safe for use in children 12years and over and in adults** as a 2-dose vaccine given 3 weeks apart**.**
ii. Two doses of Pfizer vaccine provide acceptable levels of **protection against the major circulating variants** of concern in Uganda.
iii. The updated vaccine **cold chain logistical requirements** of Pfizer BioNTech vaccine, particularly the ability to be stored at 2-8^{o}C for 31 days, put it **within the capabilities of Uganda's cold chain system, particularly in urban areas**.
iv. The **demand for COVID-19 vaccines in Uganda outstrips the available supply**. Pfizer vaccine supply can potentially be used to fill this gap.

6. UNITAG Recommendations

Following the above review of evidence and conclusions, UNITAG came to the following recommendations:

i. Pfizer BioNTech vaccine **(BNT162b2) should be introduced in Uganda** for use in persons aged 12 years and over.
ii. The Ministry of Health should **strengthen the laboratory and surveillance system** in Uganda to regularly monitor the circulating variants of concern among the population.
iii. The Ministry of Health should **strengthen the cold chain system particularly in urban areas**, in preparation for roll out of Pfizer vaccine. **Health workers should be adequately trained** in how to handle and administer this vaccine.
iv. The Ministry of Health should **ensure equity in vaccine distribution**, to ensure that all persons eligible for vaccination have access to vaccines. The UNITAG recommended framework for vaccination prioritization should be used in selecting eligible persons for vaccination.

Additional consideration

i. UNITAG in collaboration with Ministry of Health is working to review the updated disease epidemiology data, with a view of updating the vaccination prioritization recommendation based on updated evidence.