UNITAG Recommendation on the Choice of COVID-19 Vaccines for Uganda

April 20, 2021

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1 INTRODUCTION AND BACKGROUND

1.1 National COVID-19 Response

The Coronavirus disease 2019 (COVID-19), caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) was declared a pandemic by the World Health Organization (WHO) on March 11, 2020. The disease first manifested in Wuhan China in December 2019. **On March 21, 2020, Uganda reported her first case of COVID-19**, which was imported. Subsequently, more predominantly imported cases were detected. The government responded by issuing guidelines to curb the spread: **closure of schools**, religious places, non–essential businesses, entertainment places, the stoppage of public transport, **social distancing**, border-points testing, **wearing face masks**, **hand washing/sanitizing**, and **staying home–stay safe campaigns** (The State House of Uganda, 2020). These measures effectively slowed down the virus's spread to enable the health system to prepare better to respond to the pandemic (Minstry of Health, 2020).

However, these **interventions were unable to prevent the country from progressing to community transmission** by September 2020 (Ministry of Health Uganda, 2020), with a peak in infections observed in week 50 of 2020, with a weekly reported number of new cases hitting 4,566 people (Figure 1). The **negative impacts of the control measures** on human rights (Barugahare, et al., 2020), **livelihoods**, and the **economy** (UNDP Uganda, 2020) as well as the moderate number of new infections following two rapid surveys, informed the government to ease lock-down measures in a phased approach (Kodowa, 2020). **A modelling study** (Mugisha, et al., 2021) showed that for Uganda to have a safe **return to full activity may not be possible until an effective vaccine** and possibly a drug are found, and used massively.

Ministry of Health developed a **COVID-19 vaccine deployment plan** with the goal to: *"Prevent and reduce severe COVID-19 disease and deaths, sustain national health system response and restore health and productivity of the Ugandan societies and the economy*". However, Government needed guidance on the most appropriate vaccine(s) to use in Uganda in order to achieve these goals.

1.2 Ministry of Health guidance request to UNITAG.

The **Ministry of Health requested UNITAG to provide guidance on selection of COVID-19 Vaccine(s)** for Uganda in the event that **WHO approves more than one vaccine**. (Full request letter attached as Annex 1).

1.3 Global vaccine landscape

From the onset of the WHO pandemic declaration on 30th January 2020, global efforts to develop safe and effective vaccines against COVID-19 immediately kicked into high gear. As of March 05, 2021, the World Health Organisation had recorded **79 vaccines under clinical development and 182 under pre-clinical development.** Of these, four have reached Phase 4, i.e., one viral vector non replicating vaccine, one inactivated virus vaccine, and two messenger ribonucleic acid (mRNA) vaccines. 12 vaccines were at phase 3; two protein subunits, three viral vector, one deoxyribonucleic acid (DNA), and five inactivated virus vaccines (WHO, 2021).

1.4 COVID-19 Vaccines approved by WHO

As of 6th April 2021, **four COVID-19 vaccines had received WHO Emergency Use Listing** (EUL) by the WHO: Two **mRNA vaccines**: **Pfizer-BioNTech and Moderna, and two viral vector vaccines: Vaxzevria (formerly AstraZeneca), and Janssen.** See Table 1 for summary details on these vaccines.

2 UNITAG METHODOLOGY

Following the Internal Procedures Manual of UNITAG, a COVAX **working group was formed composed of diverse specialists** in medicine, paediatrics, public health, epidemiology, immunology, social sciences, co-opted experts in bioethics and behavioural sciences, as well as representatives from the Scientific Advisory Committee of the Ministry of Health. (Working Group Terms of reference attached as Annex 2).

In **conformity** with the **ethical principles** of **legitimacy, trust, and scientific integrity**, UNITAG developed it recommendations on vaccine selection basing on the **best available evidence**, using **criteria of scientific knowledge and practice**, particularly those that have been peer-reviewed and approved by WHO. They ensured that consensus was arrived at through **interdisciplinary dialogue** among scientists, ethicists and policy makers.

The working group held **weekly meetings and deliberated on evidence** presented to it by local and international experts in the field. They also developed a recommendation framework that outlined questions that needed to be addressed by credible evidence to guide their considerations in developing conclusions and recommendations. **Topics covered** included **disease, vaccine characteristics, programmatic considerations, policy issues and economic considerations**. The detailed recommendation framework attached as Annex 3.

3 EVIDENCE CONSIDERATIONS

This section summarises the evidence considered by UNITAG in developing its conclusions and recommendations.

3.1 DISEASE CONSIDERATIONS

Under disease considerations, the committee sought to understand the impact of COVID-19 disease on the Ugandan population, in terms of **disease morbidity and mortality**, potential for **pandemic spread**, **treatment options and related costs**.

3.1.1 Global, regional and national disease morbidity and mortality.

COVID-19 is a novel, infectious and potentially fatal disease and has the ability to spread rapidly among the population. it was declared as a pandemic by the WHO on 11th March 2020. **Globally**, as of, 5 April 2021, there have **been 131,020,967 confirmed cases of COVID-19, including 2,850,521 deaths**, reported to WHO. Of the confirmed cases, **3,126,037 were in Africa, with 78,369 deaths** (World Health Organisation, 2021). In **Uganda**, as of 17th April 2021, there have been **41,396 confirmed cases of COVID-19 with 338 deaths**, reported to WHO (World Health Organisation, 2021). **The case fatality ratio varies from 0-30%** with risk increasing with age (World Health Organisation, 2020).

Symptoms vary from **moderate to severe respiratory infection, accompanied by fever, coughing breathing difficulties, and new loss of smell and taste. Seniors** and people with **pre-existing chronic illnesses** seem more vulnerable and at risk of complications. The COVID-19 infection is transmitted by people carrying the virus. The disease can be **spread from person to person through respiratory droplets** expelled from the nose or mouth when a person coughs or sneezes. There is **no specific treatment** at this time, although research is ongoing. The treatment is mainly symptomatic. (Ministry of Health Uganda, 2021).

Figure 1 shows the trend of COVID-19 infections, deaths, and recoveries in Uganda as of April 17, 2021 (Ministry of Health Uganda, 2021).

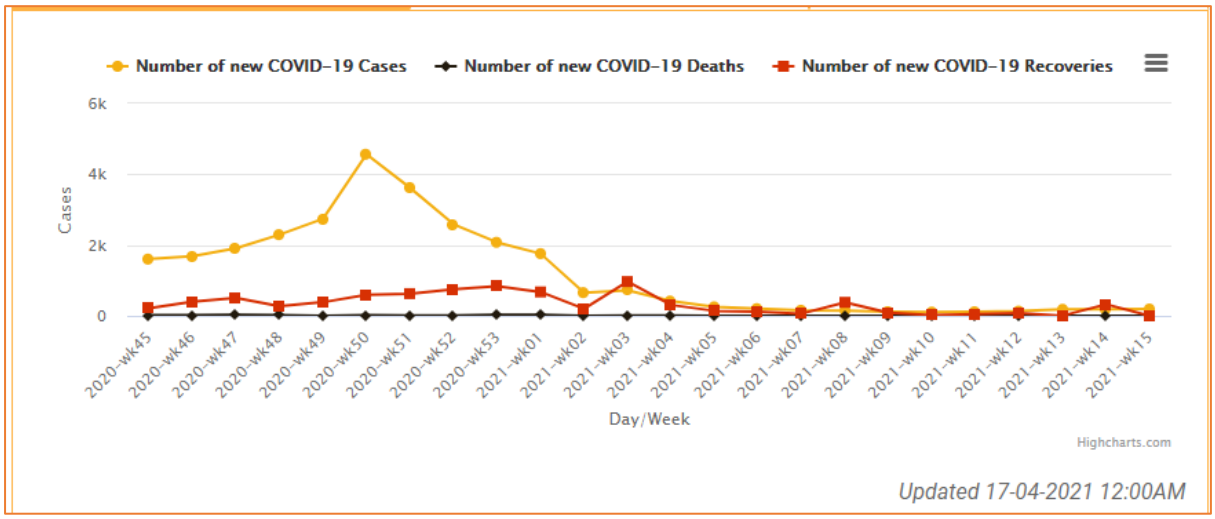


Figure 1 Number of COVID-19 new cases, new deaths, and recoveries

Source COVID-19 Response Info Hub: https://covid19.gou.go.ug/statistics.html accessed 20th April, 2021.

Variants: The **A.23.1 sub-lineage** is observed to be the **major virus lineage now observed** in the Kampala region in Uganda. This sub-lineage is reported to encode multiple spike proteins, nsp6 (non-structural protein), ORF8 and ORF9 (open reading frames 8 and 9) protein changes. Some of these replacements are predicted to be functionally similar to those observed in lineage B variants of concern (VOCs). (Bugembe, et al., 2021). Towards The end of March 2021, Government had confirmed that Uganda had registered a **few Covid-19 cases with the South African strain B1 351 and Nigerian variant B.1.525** (Daily Monitor Newspaper, 2021).

3.1.2 Cost of disease, impact on healthcare in Uganda

On 31 March 2020, **government**, through the parliament of Uganda approved **284 billion Ugandan shillings** (UGX) **to cater for the government's response to the COVID-19 pandemic** of Shs 104.1 billion would be used by the health ministry (Parliament of the Republic of Uganda, 2020).

H.E. the President also established a **National Response Fund** for COVID-19 to collect **private contributions**. The purpose of this initiative is to raise UGX **170 billion (US$45 million)** to purchase test kits, PPE, and vehicles, as well as provide relief to the most vulnerable. **As of May 2020, 21 billion shillings had been raised** (Office of the Prime Minister, 2020)

The Ministry of reported that it **cost USD 65 per person** to carry out a **PCR test for COVID-19** (Ministry of Health, 2020). As of June 2020, the MOH and health development partners had purchased and placed orders for **USD$ 36 million** worth of test kits (Federica, et al., 2020).

On an **individual and household level**, anecdotal evidence suggests that **Government spends Shs 22 million per recovered patient** of COVID-19 hospitalised for a fortnight, and **in the private sector**, treatment of a **mild case of COVID-19 cost Shs. 1.5 per da**y and **Shs 3-5 million per day for critical cases** (Daily Monitor Newspaper, 2020).

On 11th February 2021, Parliament passed a supplementary budget of **Shs 18.5 billion** in deposit payment for purchase of 18 million doses of **COVID-19 vaccines** to immunise 9 million Ugandans at highest risk (Parliament of Uganda, 2021).

The COVID-19 response also **negatively impacted healthcare services for other diseases**. The measures taken by the Ugandan government intended to combat the spread of COVID-19 **disrupted the supply chain and healthcare service delivery system** as all efforts were focused on COVID-19. Sharp declines were observed on Outpatient visits, ANC visits, facility births, as well as immunisation coverages (Ministry of Health-CEHS, 2020). Patients with **chronic conditions**, such as HIV/AIDS, Cancer, Sickle Cell Disease, Tuberculosis, and Epilepsy, had difficulties in **adherence to medication** as they were not able to get their refills, while others could not afford to buy medication due to a lack of income (Komoga, 2020).

COVID-19 has also had a **severe impact on business and the national economy**. A Uganda **business climate survey** done in May 2020 (Lakuma, et al., 2020) found that COVID-19 pandemic and subsequent lockdown has **reduced business activity by more than 50 percentage points**. Overall, **76% of the businesses reported to have reduced the size of the workforce**. **Nationally**, by August 2020, preliminary estimates indicated that **economic growth slowed to 3.1** percent during FY2019/20 **down from pre-pandemic projections of 6.0 percent** (Muhakanizi, 2020). This was attributed to loss of income associated with taxes, foreign direct investment, remittances, and tourism.

3.2 VACCINE CHARACTERISTICS

The UNITAG reviewed the **vaccine constitution**, **efficacy, safety and logistical requirements** data of COVID-19 vaccines approved by WHO to determine those most suited to the Ugandan context.

3.2.1 Vaccine constitution: mode of work and formulation

- **What are the formulations and presentations available for the different types of vaccines with an emergency authorization from WHO or a proven stringent NRA?**

3.2.1.1 mRNA-1273 Moderna Vaccine

Moderna's mRNA-1273 COVID-19 **vaccine is a lipid nanoparticle (LNP)-encapsulated mRNA vaccine expressing the prefusion-stabilized spike glycoprotein. The vaccine contains a synthetic mRNA (single-stranded, 5'-capped) encoding the prefusion-stabilized spike glycoprotein (S) of SARS-CoV-2 virus.**

It comes as a white to off white dispersion (Ph: 7.0 – 8.0) **ready for use once thawed**. This vaccine comes in a **multidose vial which contains 10 doses of 0.5 ML**. One dose (0.5 ML) contains 100 micrograms of messenger RNA (mRNA) (embedded in SM-102 lipid

nanoparticles). Single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.

Other excipients include: Lipid SM-102, Cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000 DMG), Tromethamol, Tromethamol hydrochloride, Acetic acid, Sodium acetate trihydrate, sucrose, and Water for injections

Ref: European Medicines Agency Report/product formulation: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-moderna-epar-product-information_en.pdf

3.2.1.2 BNT162b2 Pfizer BioNTech vaccine

The Pfizer–BioNTech COVID-19 vaccine, BNT162b2, is an **mRNA vaccine encoding a P2 mutant spike protein (PS 2) and formulated as an RNA–lipid nanoparticle (LNP) of nucleoside-modified MRNA (modRNA**). BNT162b2 **elicits a blunted innate immune sensor activating capacity and thus augments antigen expression**. Encapsulation into LNPs allows transfection of the mRNA into host cells after intramuscular (IM) injection. During mixing of the RNA and the dissolved lipids, the lipids form the nanoparticles encapsulating the RNA. After injection, the LNPs are taken up by the cells, and the RNA is released into the cytosol, where it is translated into the encoded viral protein. **The mRNA is rapidly degraded intracellularly**, while the **resulting peptides are presented at the cell surface, triggering a specific humoral T-cell-mediated immune response with activity against the spike protein.**

This vaccine comes in a **multidose vial and must be diluted before use**. **One vial (0.45 ML) contains 6 doses of 0.3 ML after dilution. 1 dose (0.3 ML) contains 30 micrograms of COVID-19 mRNA Vaccine** (embedded in lipid nanoparticles). Other excipients include: ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159), 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC), Cholesterol, Potassium chloride, Potassium dihydrogen phosphate, Sodium chloride 10, Disodium phosphate dihydrate, Sucrose, Water for injections.

Ref: European Medicines Agency Report/product formulation: https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf

3.2.1.3 Vaxzevria fmr. Astra Zeneca (ChAdOx1 nCoV-19)

AZD1222 vaccine is a **monovalent vaccine composed of a single recombinant, replication-deficient chimpanzee adenovirus vector encoding the full-length SARS CoV-2 spike glycoprotein gene SARS-CoV-2 (ChAdOx1-S (recombinant)**. **Adenoviruses are non-encapsulated, icosahedral particles (virions), and contain a single copy of the double-stranded DNA genome.** The expression cassette for the SARS-CoV-2 spike protein fused to the tissue plasminogen activator leader sequence uses a modified human cytomegalovirus promoter and a bovine growth hormone polyadenylation sequence.

One dose (0.5mL) contains chimpanzee Adenovirus encoding the SARS-CoV-2 Spike glycoprotein ChAdOxl-S*, not less than $2.5x10^8$ infectious unit. *Produced by recombinant DNA technology. This product contains genetically modified organisms (GMOs). The other excipients are L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80(E 433), sucrose, disodium edetate(dihydrate), water for injections.

Presentation of the AstraZeneca Vaccine

i. **8-dose vial 4 mL of suspension**. Each vial contains 8 doses of 0.5 mL. Pack sizes of 10 multidose vials
ii. **10-dose vial 5 mL of suspension**. Each vial contains 10 doses of 0.5 mL. Pack sizes of 10 multidose vials.

Ref: European Medicines Agency Report/ Product Formulation: https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca#product-information-section

3.2.1.4 Janssen vaccine (Ad26.COV2-S [recombinant])

The Janssen COVID-19 Vaccine is **a replication-incompetent adenovirus type 26 (Ad26)-vectored monovalent vaccine encoding the SARS-CoV-2 spike (S) protein from the Wuhan-Hu-1 isolate (GenBank accession number MN908947), stabilized in its prefusion conformation. The vector cannot replicate in human cells because the E1 gene was deleted** from the genome. This cell line is derived from a single human primary cell, obtained in 1985 from fetal retina tissue (at 18 weeks of gestation adhering to the Dutch laws that were in effect) . The Ad26 vector expressing the S protein is grown in PER.C6G TetR cell line, in media containing amino acids and no animal-derived proteins.

One vial (2.5 ML) contains 5 doses of vaccine. The Ad26.COV2.S is supplied as a colourless to slightly yellow, clear to very opalescent sterile **liquid suspension for injection**. Each dose contains not less than 8.92 Log10 Infectious Units (Inf.U) and not less than 2.5 x 1010 VP. Each dose contains Ad26.COV2.S Active Sodium chloride, Citric acid monohydrate, Trisodium citrate dihydrate, Polysorbate-80, 2-hydroxypropyl-β-cyclodextrin (HBCD), Ethanol, Sodium hydroxide, Hydrochloric acid and Water for injections. 0.5ML single dose, no dilution required.

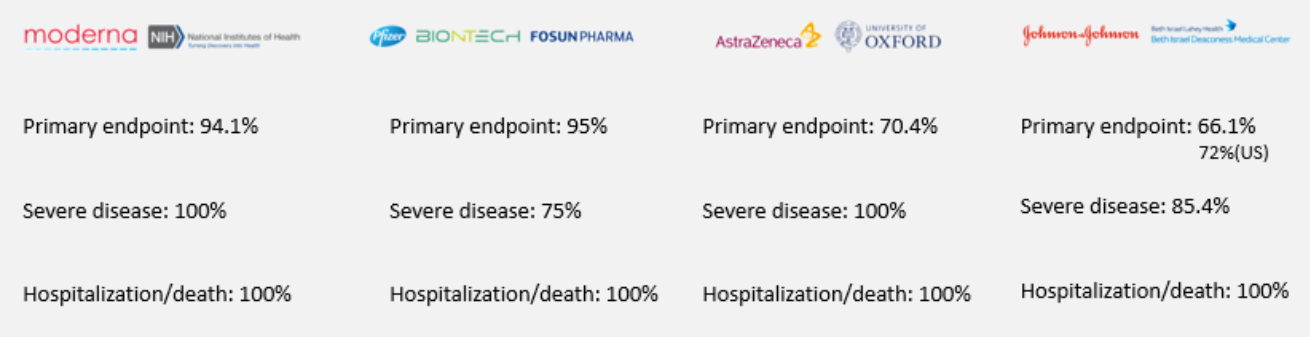
Ref: European Medicines Agency Report. https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-janssen-epar-public-assessment-report_en.pdf

3.2.2 Efficacy

What Is the efficacy of the COVID-19 vaccine against moderate and severe disease, hospitalisation and death?

The figure 1 below summarises the efficacy of the four WHO EUL approved vaccines.

Figure 2 Efficacy of COVID-19 vaccines against moderate, severe disease, hospitalization/death



Ref: Thomas Cherian (WHO) Presentation 30/03.2021 titled **Interim Recommendations for the Janssen COVID-19 vaccine**citing: Baden et al. NEJM, 2021; FDA Briefing Document, Dec 10, 2020; Voysey et al. Lancet, 2021; FDA Briefing Document, Feb 26, 2021

3.2.2.1 mRNA-1273 Moderna Vaccine

Phase 3 results were obtained from a trial that enrolled 30,420 volunteers **18 years and over** who were randomly assigned in a 1:1 ratio to receive either vaccine or placebo, **2 doses, 28 days apart.** Symptomatic Covid-19 illness was confirmed in 185 participants in the placebo group (56.5 per 1000 person-years; 95% confidence interval [CI], 48.7 to 65.3) and in 11 participants in the mRNA-1273 group (3.3 per 1000 person-years; 95% CI, 1.7 to 6.0); **vaccine efficacy was 94.1% (95% CI, 89.3 to 96.8%; P<0.001).** Efficacy was **similar across key secondary analyses**, including assessment **14 days after the first dose**, analyses that **included participants** who had evidence of SARS-CoV-2 infection at baseline, and analyses in participants **65 years of age or older**. Severe Covid-19 occurred in 30 participants, with one fatality; all 30 were in the placebo group. (Baden, et al., 2021).

Studies on the impact of the **UK mutation variant B.1.1.7** on Moderna vaccine efficacy showed a 2-fold reduction in neutralization titres, but considering that neutralization titres increase by approximately 10-fold after the second dose, **data suggests that the variant will have minimal impact on vaccine efficacy** in people who receive both doses of vaccine. (Shen, et al., 2021).
South Africa variant – **efficacy unknown**, trial of a modified version of vaccine to target B.1.351 variant awaiting approval from regulators.

3.2.2.2 BNT162b2 Pfizer BioNTech vaccine

Method: Phase 3 results from a multinational trial that enrolled a total of 43,548 participants (**16 years and over**) of whom 43,448 received injections, **2 doses, 21 days apart**: 21,720 with BNT162b2 and 21,728 with placebo.

Results: There were 8 cases of Covid-19 with onset at least 7 days after the second dose among participants assigned to receive BNT162b2 and 162 cases among those assigned to placebo; BNT162b2 was **95% effective in preventing Covid-19** (cconfidence interval, 90.3 to 97.6). **Similar vaccine efficacy** (generally 90 to 100%) was observed **across subgroups** defined by age, sex, race, ethnicity, baseline body-mass index, and the presence of co-

existing conditions. Among 10 cases of severe Covid-19 with onset after the first dose, 9 occurred in placebo recipients and 1 in a BNT162b2 recipient (Polack FP et al, 2020)

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Method: A test negative case control design to compare the rate of vaccination in symptomatic people who tested positive for COVID-19 with those who tested negative. **Compared hospital admissions and death rates in people in their 80's** who were vaccinated at least two weeks previously with those who were not vaccinated.
Findings: Study showed that **protection after two doses of the Pfizer vaccine increased to 85-90% and protection against symptomatic COVID-19 after a single dose of the Pfizer vaccine reached 61% (95 confidence interval 51% to 69%) from 28 to 34 days after vaccination**.
Ref: Lacobucci G, BMJ. 2021.372, https://doi.org/10.1136/bmj.n612
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3.2.2.3 ChAdOx1 nCoV-19 (AZD1222) (Vaxzevria formerly AstraZeneca)

Method: Three single-blind randomised controlled trials of the Astrazeneca vaccine-one phase ½ study in the UK (COV001), one phase 2/3 study in the UK (COV002), and a phase 3 study in Brazil (COV003)-and one double-blind phase ½ study in South Africa (COV005).

Findings: Study findings reveal **overall vaccine efficacy after 14 days being 66.7%** whereas vaccine efficacy **after single dose of vaccine from day 22 to 90 after vaccination was 76%.**

Study showed that **protection did not wane during this initial 3-month period.** Similarly, **antibody levels were maintained during this period with minimal waning by day 90**. In the participants who received two standard doses, **after second dose, efficacy was higher in those with a longer prime-boost interval (≥12 weeks) at 81.3% than in those with a short interval at 55.1% (<6 weeks).**

Ref: Voysey et al, Lancet. 2021. 397(10277)881-891. https://doi.org/10.1016/s0140-6736(21)00432-3

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Method: Analysis of data from four ongoing blinded randomised controlled trials done across UK, Brazil and South Africa to evaluate safety and efficacy of the ChAdOxl nCov-19 vaccine.

Findings: The study found ChAdOx1 nCov-19 to have an acceptable safety profile and efficacious against symptomatic COVID-19 in the interim analysis of ongoing clinical trials. **In participants who received two standard doses, vaccine efficacy was 62.1% while participants who received a low dose followed by a standard dose, efficacy was 90.0%.**

Ref: Voysey et al, Lancet.2021,397(10269).99-111. https://doi.org/10.1016/s0140-6736(20)32661-1

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Method: A test negative case control design to compare the rate of vaccination in symptomatic people who tested positive for COVID-19 with those who tested negative. **Compared hospital admissions and death rates in people in their 80's who were vaccinated at least two weeks previously with those who were not vaccinated.**

Findings: The study showed that **among people aged 70 and over,** protection against symptomatic COVID-19 after a single dose of the Pfizer vaccine reached 61% (95% confidence interval 51% to 69%) from 28 to 34 days after vaccination then plateaued. Protection **after a single dose of the Oxford Astra-Zeneca vaccine reached 60% (95% CI 41% to 73%) from 28 to 34 days and increased to 73% (95% CI 27% to 90%) from day 35 onwards.**
Ref: Lacobucci G, BMJ. 2021.372, https://doi.org/10.1136/bmj.n612
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Method: Commentary
Findings: citing a pre-print paper under review at Lancet, a single standard dose provided **76% protection overall against symptomatic COVID-19** in the first 90 days. Efficacy reached **82.4% (95% CI 62.7% to 91.7%) after a second dose given 12 weeks+ apart.** If doses were given less than 6 weeks apart, the efficacy was only 54.9% (95% CI 32.7% to 69.7%). The analyses suggest that it is the **dosing interval and not the dosing level** which has the **greatest impact on the efficacy of the vaccine**.
Ref. Jacqui Wise BMJ 2021;372:n326, https://www.bmj.com/content/372/bmj.n326
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Efficacy against variants: Preliminary analyses have shown a slightly reduced vaccine effectiveness of AZD1222 against **B1.1.1.7** in the V002 trial in the **United Kingdom** which is associated with **only a limited reduction in neutralizing antibody**. Preliminary analyses from the Phase ½a trial (COV005) in **South Africa** indicate **marked reduction in vaccine effectiveness against mild and moderate disease due to B 1.351** based on a small sample size and substantial loss of neutralizing antibody activity. This study was designed to assess efficacy against disease of any severity, but the small sample size **did not allow a specific assessment of vaccine efficacy against severe COVID-19. Indirect evidence is compatible with protection against severe COVID-19**; however, this remains to be demonstrated in ongoing clinical trials and post-implementation evaluations.
Ref: Madhi et al 2021 NJEM https://www.nejm.org/doi/full/10.1056/NEJMoa2102214

3.2.2.4 Janssen vaccine (Ad26.COV2-S [recombinant])

Method: An ongoing, multicentre, randomized, double-blind, placebo-controlled phase 3 study to assess the efficacy, safety and immunogenicity of a **single dose** (5×1010 vp) of Ad26.COV2.S for the prevention of COVID-19 **in adults aged 18 years and older**. The study is being conducted in **Argentina, Brazil, Chile, Colombia, Mexico, Peru, South Africa and the USA.** A total of 44 325 participants were randomized, of whom 43 783 were given either Ad26.COV2.S or placebo. The study was well balanced among subgroups with regard to age, comorbidities, sex, region, race, and ethnicity. The time of **study enrolment coincided with a marked increase of incidence of COVID-19 and the emergence of new SARS-CoV-2 variants**, which were emerging in some of the countries where the study was being conducted. Efficacy results were based on the primary analysis, which included 19 630 participants who received the vaccine and 19 691 participants who received placebo.

Findings: A single dose of Ad26.COV2.S protected against moderate to severe/critical COVID-19 in adults **≥18 years of age**, including adults ≥60 years of age, with an **efficacy that was consistent across age groups** but with **some variability across countries**. Vaccine **efficacy against first occurrence of moderate to severe/critical COVID-19**, including non-centrally confirmed cases**, was 66.9% (95% CI 59.0- 73.4), 14 days after vaccination, and 66.1% (55.0-74.8%) 28 days after vaccination.**

Efficacy against COVID-19 hospitalization: In the per protocol analysis set, **14 days or more after vaccination**, there were 2 COVID-19-related hospitalizations in the vaccinated group and 29 in the placebo group **(VE 93.1%, 95%CI 72.74–99.20%).** In the per-protocol analysis set, **28 days or more after vaccination**, there were no COVID-19-related hospitalizations in the vaccinated group and 16 in the placebo group **(VE 100%, 95%CI 74.26–100.00%).**

Efficacy against deaths related to COVID-19: There were **no COVID-19-related deaths in the Ad26.COV2.S group** and 6 COVID-19-related deaths in the placebo group.
Vaccine impact on symptom severity A post-hoc analysis found that the **participants with moderate COVID-19 who received Ad26.COV2.S most frequently reported 4 to 6 symptoms, while participants in the placebo group reported 7 to 9 symptoms.**

Efficacy against asymptomatic infections Among 2650 individuals for whom day 71 results were available, 50 in the placebo group had evidence of an asymptomatic or undetected infection versus 18 in the Ad26.COV2.S group (**VE 65.5%, 95%CI 39.91–81.08%).** A sensitivity analysis, which removed all participants who had had symptoms at any time since screening prior to the SARSCoV-2 N IgG positive result, found 10 and 37 seroconversions in the vaccinated and placebo group, respectively (**VE 74.2%, 95%CI 47.13–88.57%).**

Onset of efficacy after a single dose: The onset of VE against moderate to severe/critical COVID-19 was observed at 14 days after vaccination; efficacy persisted for the duration of follow-up (median 58 days). The onset of efficacy against severe/critical COVID-19 **was observed at 7 days after vaccination, with a clear trend of increasing VE that persisted for the duration of follow-up (median 58 days).**

Efficacy against new variants of concern: In the USA, VE against moderate to severe/critical COVID-19 and against severe/critical COVID-19 was consistent with the global VE findings. In **South Africa**, where the 20H/501Y.V2 variant (**B.1.351 lineage**) was the predominant strain (96.3% of sequenced cases thus far), high efficacy was observed **against severe/critical COVID-19 (81.7%, 95%CI 46.2– 95.4% at least 28 days after vaccination) and robust VE was observed for moderate to severe/critical COVID-19 (64.0%, 95%CI 41.2–78.7% at least 28 days after vaccination)**. In **Brazil**, where a **variant from the P.2 lineage** was the predominant strain (70.7% of sequenced cases thus far), **VE estimates were similar to the USA and South Africa.**

Ref: Background document to the WHO Interim recommendations for use of Ad26.COV2.S (COVID-19) vaccine. https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Ad26.COV2.S-background-2021.1

Table 1. Summary description of COVID-19 vaccines authorized for emergency use by WHO

Vaccine	Pfizer-BioNTech (BNT162b)	Moderna (mRNA-1273)	Vaxzevria fmr. Astra Zeneca (ChAdOx1 nCoV-19)	Janssen Janssen vaccine (Ad26.COV2-S [recombinant])
Type of vaccine COVID-19	mRNA	mRNA	VVnr	VVnr
Authorized ages for use	16 years of age and older	18 years of age and older	18 years of age and older	18 years of age and older
Dose	0.3 ML (30 mcg of mRNA)	0.5 ML (100 mcg of mRNA)	0.5 ML (5×10^{10} viral particles)	0.5 ML
Schedule	2 Doses, 21 days apart	2 Doses, 28 days apart	2 doses, 8-12 weeks apart	Single dose**
Route of administration	IM	IM	IM	IM
Nature of the antigen	Prefusion spike protein	Prefusion spike protein	Adenovirus Spike glycoprotein	Adenoviral vector 26 spike glycoprotein
Adjuvant (if present)	None	None	None	None
Primary storage requirements pre-puncture	-80°C to -60°C[a]	-25°C to -15°C [a,b]	(2°C to 8°C) [a,d]	-25°C to -15°C , 2°C to 8°C[a,b]
Storage requirements pre-puncture [a]	120 hours (5 days) at +2°C to +8°C AND/OR 2 hours up to +25°C	30 days at +2°C to +8°C AND/OR 12 hours at +8°C to +25°C	6 months when stored in a refrigerator (2°C to 8°C)	24 months at -25°C to -15°C 3 months at 2°C to 8°C
Diluent	Yes	No	No	No
Usage limit post-puncture	6 hours at +2°C to +25°C[c]	6 hours at +2°C to +25°C	48 hours at (2°C – 8°C) 6 hours up to 30°C	6 hours +2°C to +25°C[c]
Price per dose*	$6.75 - $19.50	$15 - $37	$2.06 - $13.27	$8.50 - $10.0
Formats available	Multi-dose vial (5 doses), preservative-free	Multi-dose vial (10 doses), preservative-free	Multi-dose vial (8 & 10 doses) preservative free	Multi-dose vial (2.5 ML) contains 5 doses preservative free

Abbreviations: IM: intramuscular; mRNA: messenger ribonucleic acid; VVnr: Viral Vector non replicating

a Protected from light during storage

b Do not store on dry ice or below -40ºC

c After dilution, the vaccine must be used within 6 hours

d Do not freeze.

*Source: UNICEF COVID-19 Vaccine Market Dashboard https://www.unicef.org/supply/covid-19-vaccine-market-dashboard

**ongoing studies on need for a booster dose

Table 2 Summary table of vaccine efficacy and safety: www.bmj.com/content/bmj/372/bmj.n597.full.pdf

Vaccine	Doses	Efficacy against symptomatic disease	Efficacy against variants		Reported effectiveness from mass rollout	Safety profile from Phase III trials
			B.1.1.7 (UK)	B1.351(RSA)		
Moderna	2	94.5%	Unknown	Unknown	TBC	Solicited adverse events at injection site occurred more in vaccine group than placebo. Serious adverse events were rare, with incidence similar in the two groups.
Pfizer and BioNTech	2	95%	Unknown	Uknown	Reduced symptomatic cases by 94%, hospital admissions by 87% and sever COVID-19 by 92% in Israel.	27% reported adverse events in vaccine group vs. 12% in placebo. This was mainly due to transient reactogenicity e.g. injection site pain. Few people in either group had severe or serious adverse events.
Vaxzevria fmr AstraZeneca	2 (12 weeks apart)	82.4%	74.6%	21.9%	In Scotland, risk of hospital admission for COVID-19 fell by up to 94% four weeks after first doses administered	Serious adverse events in 79 in vaccine group and 89 in control.
Janssen	1	66.9% (mod- to severe disease)	70.7%	81.7% (mod- to severe disease)	TBC	More serious adverse events in placebo than vaccine group. Most solicited Aes were grade 1 or 2 in severity and were transient in nature. No grade 4 (serious) solicited Aes were reported during the study

Note: trials were conducted at different times, in different settings and with different end point assessments, therefore, head-to-head comparisons of efficacy data is not possible

3.2.3 Safety Profile

What is the safety profile of the vaccine across population groups by age, comorbidities, pregnant and lactating women?

3.2.3.1 mRNA-1273 Moderna Vaccine

Method: Review

Findings: Study showed that Pfizer and Moderna COVID-19 vaccines can cause **mild adverse effects** after the first or second doses, **including pain, redness or swelling at the site of vaccine shot, fever, fatigue, headache, muscle pain, nausea, vomiting, itching, chills and joint pain and can also rarely cause anaphylactic shock.** The occurrence of adverse effects is reported to be lower in the Pfizer/BioNTech vaccine compared to the Moderna vaccine.

Ref: *Meo S et al, Eur Rev Med Pharmacol Sci.2021.25(3):1663-1669. https://doi.org/10.26355/eurrev_202102_24877*

- **What are the specific ages/populations for which the safety profile was not established in phase 3 clinical trials of COVID-19 vaccines?**

  Exclusion Criteria:

  Is **acutely ill or febrile 72 hours prior** to or at Screening. Fever is defined as a body temperature ≥38.0°Celsius/100.4°Fahrenheit. Is pregnant or breastfeeding. Known **history of SARS-CoV-2 infection**. **Prior administration of** an investigational **coronavirus** (SARS-CoV, Middle East Respiratory Syndrome [MERS]-CoV) **vaccine** or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19. Known or suspected **allergy or history of anaphylaxis, urticaria, or other significant adverse reaction to the vaccine or its excipients**. **Bleeding disorder** considered a contraindication to intramuscular injection or phlebotomy. **Immunosuppressive or immunodeficient state, including human immunodeficiency virus (HIV)** infection, asplenia, and recurrent severe infections. Has **received systemic immunosuppressants** or immune-modifying drugs **for >14 days in total within 6 months prior** to Screening (for corticosteroids ≥20 milligram (mg)/day of prednisone equivalent). Has received **systemic immunoglobulins or blood products within 3 months** prior to the day of Screening.

  Ref: Moderna vaccine phase III clinical trial protocol.
  https://clinicaltrials.gov/ct2/show/NCT04470427?term=vaccine&cond=covid-19&draw=5

3.2.3.2 BNT162b2 Pfizer BioNTech vaccine

Method: Review of phase 2/3 Clinical trial data.

Findings: Safety data from 37 586 participants ≥16 years of age randomized 1:1 to vaccine or placebo with a median of 2 months of follow-up after the second dose suggested a **favourable safety profile**. Reactogenicity symptoms, defined as solicited **local injection site or systemic reactions during the seven days after vaccination, were frequent and mostly mild to moderate**. **Reactogenicity and adverse events (Aes) were generally milder and less frequent in the older group (≥55 years of age) than the younger group (18–55 years of age) and tended to be more frequent and severe after the second dose.** Reactogenicity was mostly mild to moderate and short-lived for both age groups (**median onset was 0–2 days after either dose for a median duration of 1–2 day**s). **Severe adverse reactions occurred in 0.0–4.6% of participants**. The incidence rates of

serious adverse events (SAEs), deaths, and discontinuation due to SAEs were low and **comparable for the vaccine and placebo groups**. The most **common solicited adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%)**. The mean duration of pain at the injection site after dose 2 was 2.5 days (range 1 to 36 days), redness 2.6 days (range 1 to 34 days), and swelling 2.3 days (range 1 to 34 days).

Ref: WHO, 2021. https://www.who.int/publications/i/item/background-document-on-mRNA-vaccine-bnt162b2-(pfizer-biontech)-against-covid-19

Safety in older adults
Method: Review of clinical trial data
Findings: Overall, the vaccine, given as a two-dose regimen at one of three doses (10 µg, 20 µg, 30 µg) **was tolerated well in two age groups: 18–55 years and 65–85 years**. Local and systemic adverse events were generally mild and were more frequent in the two higher dose groups. **Systemic adverse events were generally milder in the older age group.**
Article: WHO. 2021. https://www.who.int/publications/i/item/background-document-on-mRNA-vaccine-bnt162b2-(pfizer-biontech)-against-covid-19

- **What are the specific ages/populations for which the safety profile was not established in phase 3 clinical trials of COVID-19 vaccines?**

PfizerBioNTech phase 3 exclusion criteria;

Excluded categories: Individuals with **history of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis**) to any component of the study intervention(s), receipt of medications intended to prevent COVID 19, **previous clinical** (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) **diagnosis of COVID 19**, **immunocompromised individuals with known or suspected immunodeficiency**, as determined by history and/or laboratory/physical examination, **bleeding diathesis** or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection, **women who are pregnant or breastfeeding**, previous vaccination with any coronavirus vaccine. **Individuals who receive treatment with immunosuppressive therapy, including cytotoxic agents or systemic corticosteroids, e.g., for cancer or an autoimmune disease**, or planned receipt throughout the study, rreceipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study, participation in other studies involving study intervention within 28 days prior to study entry through and including 6 months after the last dose of study intervention, with the exception of interventional studies for prevention of COVID 19, which are prohibited throughout study participation, 15accinat participation in other studies involving study intervention containing lipid nanoparticles.

Ref: Pfizer BioNTech phase III clinical trial protocol. https://clinicaltrials.gov/ct2/show/NCT04368728?term=vaccine&cond=covid-19&draw=3

3.2.3.3 Vaxzevria fmr. Astra Zeneca (ChAdOx1 nCoV-19)

Method: Interim analysis of pooled data from four clinical trials conducted in United Kingdom, Brazil and South Africa. Safety data were available for 23 745 participants aged 18 years and older. Of these, 12 021 subjects received at least one dose of the vaccine, and 8266 received two doses. At the time of analysis, the median follow-up time after dose 1 was 105 days in the AZD1222 group and 104 days in the control group.

Results: The **majority of the adverse reactions were mild to moderate in severity and usually resolved within a few days of vaccination**. Adverse reactions reported after the second dose were milder and less frequent than after the first dose. The **most frequently reported adverse reactions were injection site tenderness (63.7%), injection site pain (54.2%), headache (52.6%), fatigue (53.1%), myalgia (44.0%), malaise (44.2%), pyrexia (including feverishness (33.6%) and fever >38 °C (7.9%)), chills (31.9%), arthralgia (26.4%) and nausea (21.9%).** The incidence of subjects with at least one solicited local or systemic event after any vaccination was highest on day 1 following vaccination, decreasing to 4% and 13%, respectively, by day 7. The **most common systemic solicited adverse events (Aes) on day 7 were fatigue, headache and malaise. Very common (≥10% of subjects) included; headache, nausea, myalgia, arthralgia, injection site tenderness, injection site pain, injection site warmth, injection site pruritus, fatigue, malaise, feverishness, chills.** Most common (1–10% of subjects) were injection site swelling, injection site erythema, fever ≥ 38 °C.
Ref: WHO. 2021. *https://www.who.int/publications/i/item/background-document-on-the-azd1222-vaccine-against-covid-19-developed-by-oxford-university-and-astrazeneca*

- **What are the specific ages/populations for which the safety profile was not established in phase 3 clinical trials of COVID-19 vaccines?**

Excluded categories: Individuals with confirmed or suspected immunosuppressive or immunodeficient state, asplenia; recurrent severe infections and chronic use (more than 14 days) of immunosuppressant medication within the past 6 months except topical steroids or short term oral steroids(course lasting ≤14 days), history of allergic disease or reactions likely to be exacerbated by any component of chA0x1 nCoV-19 or MenACWY or paracetamol, any history of angioedema, any **history of anaphylaxis, pregnancy, lactation** or willingness/intention to become pregnant during the study, **current diagnosis of or treatment for cancer** (except basal cell carcimona of the skin or cervical carcimona in situ), history of serious psychiatric condition likely to affect participation in the study, **bleeding disorder** (for example factor deficiency, coagulopathy or platelet disorder) or prior history of significant bleeding or bruising following IM injections or venepuncture and suspected or known current **alcohol or drug dependency**, **Severe and/or uncontrolled cardiovascular disease, respiratory disease, gastrointestinal disease, liver disease, renal disease, endocrine disorder and neurological illness** (mild/moderate well controlled morbidities are allowed), **History of laboratory confirmed COVID-19**, Sero positive for SARS-CoV2 antibodies before enrolment, New onset of fever for a cough of shortness of breath or anosmia/ageusia since February 2020, unless seronegative for SARS-CoV-2 antibodies at screening, **Continuous use of anticoagulants such as coumarins and related anticoagulants (i.e warfarin) or novel oral anticoagulants (i.e apixaban, rivaroxaban, dabigatran and edoxaban), Any other significant disease, disorder** or finding which may significantly increase the risk to the volunteer because of participation in the study affect the ability of the volunteer to participate in the study or impair interpretation of the study data.
Ref: *Vaxzevria fmr. Astra Zeneca (ChAdOx1 nCoV-19) vaccine phase 3 trial exclusion criteria, https://doi.org/10.1186/ISRCTN89951424*

What serious AEFIs have been reported using this vaccine globally and in Uganda?

By mid March, 2021, vaccination against COVID-19 using the ChAdOx1 nCoV-19 (AZD1222) vaccine from Oxford–AstraZeneca was paused in a number of European countries (Denmark, Norway, Iceland, Austria, Estonia, Lithuania, Luxembourg, Italy, and Latvia) due to reports of **thromboembolic events** in vaccinated individuals. According to **the European Medicines Agency (EMA)'s safety Committee**, which carried out an in-depth review of 62 cases of cerebral venous sinus thrombosis and 24 cases of splanchnic vein thrombosis reported in the EU drug safety database (EudraVigilance) as of 22 March 2021, 18 of which were fatal, **unusual blood clots with low blood platelets should be listed as very rare side effects of Vaxzevria** (formerly COVID-19 Vaccine AstraZeneca). The committee noted that the blood clots occurred in veins in the brain (cerebral venous sinus thrombosis, CVST) and the abdomen (splanchnic vein thrombosis) and in arteries, together with low levels of blood platelets and sometimes bleeding. So far, **most of the cases** reported have occurred in **women under 60 years** of age within 2 weeks of vaccination. Based on the currently available evidence, specific risk factors have not been confirmed.

Ref: European Medicines Agency, 2021. https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood

The WHO Global Vaccine Safety Committee also reviewed the data related to the thromboembolic events and concluded that the **available data do not suggest any overall increase in clotting conditions** such as deep venous thrombosis or pulmonary embolism following administration of COVID-19 vaccines. Reported rates of thromboembolic events after COVID-19 vaccines are in line with the expected number of diagnoses of these conditions. They noted that **a causal relationship between these rare events has not been established** at this time.

Ref: WHO, GVSC, 2021. https://www.who.int/news/item/19-03-2021-statement-of-the-who-global-advisory-committee-on-vaccine-safety-(gacvs)-covid-19-subcommittee-on-safety-signals-related-to-the-astrazeneca-covid-19-vaccine

In Uganda, as of 25th March 2021, **45 AEFIs** had been reported, of which **five (5) were serious** with **two (2) deaths**. The serious AEFIs have been assessed by the National AEFI committee and no direct causal relationship with the vaccine had been found.
Ref. UNEPI (MOH), 2021. Nationa Covid-19 VD Plan-23-03-performance v.2 (ppt. unpublished)

3.2.3.4 Janssen vaccine (Ad26.COV2-S [recombinant])

Findings: Most adverse events occurred **1 to 2 days following vaccination, were mild to moderate in severity and usually resolved within 1 to 2 days**. Observed events were **generally milder and less frequently reported in older adults (≥60 years)** than in younger adults. **Very common (≥1/10): Headache, nausea, myalgia, pain at the injection site, fatigue Common (≥1/100 to <1/10): Swelling or redness at the injection site, chills, arthralgia, cough, fever (≥38 °C). Uncommon (≥1/1 000 to <1/100): Rash, muscle weakness, arm or leg pain, feeling weak and generally unwell, sneezing, sore throat, back pain, tremor, hyperhidrosis (abnormal sweating). Rare (≥1/10 000 to < 1/1 000): Allergic reaction, hives. Not known** (cannot be estimated from available data): Severe allergic reaction (**anaphylaxis**).

Ref: Janssen Ad26.COV2-S [recombinant], WHO COVID-19 vaccine explainer.
https://www.who.int/publications/m/item/janssen-ad26.cov2-s-recombinant-covid-19-vaccine

- **What are the specific ages/populations for which the safety profile was not established in phase 3 clinical trials of COVID-19 vaccines?**

  Phase 3 trial exclusion criteria

  Participant has a **clinically significant acute illness** (this does not include minor illnesses such as diarrhea or mild upper respiratory tract infection) or temperature greater than or equal to (>=) 38.0 degree Celsius (100.4-degree Fahrenheit) within 24 hours prior to the planned first dose of study vaccine; randomization at a later date is permitted at the discretion of the investigator and after consultation with the sponsor

  Participant received or **plans to receive: (a) licensed live attenuated vaccines** – within 28 days before or after planned administration of study vaccine; and (b) **other licensed (not live) vaccines** – within 14 days before or after planned administration of study vaccine. Participant **previously received a coronavirus vaccine**

  Participant **received an investigational drug** (including investigational drugs for prophylaxis of COVID-19) within 30 days or used an invasive investigational medical device within 30 days or received investigational immunoglobulin (Ig) or monoclonal antibodies within 3 months, or received convalescent serum for COVID-19 treatment within 4 months or **received an investigational vaccine** (including investigational Adenoviral-vectored vaccines) within 6 months before the planned administration of the first dose of study vaccine or is currently enrolled or plans to participate in another investigational study during the course of this study.

  Ref: Janssen phase III trial protocol
  https://clinicaltrials.gov/ct2/show/NCT04505722?term=NCT04505722&draw=2&rank=1

3.2.4 Dosage, route of administration, preparation requirements

3.2.4.1 mRNA-1273 Moderna Vaccine

The vaccine should be administered **intramuscularly**. The preferred site is the **deltoid muscle of the upper arm. 2 dose regimen, 0,5 ML each, 21 days apart**. The vaccine **comes ready to use once thawed**. Do not shake or dilute. Swirl the vial gently after thawing and before each withdrawal.

Ref: European Medicines Agency Report/product formulation:
https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-moderna-epar-product-information_en.pdf

3.2.4.2 BNT162b2 Pfizer BioNTech vaccine

The vaccine should be administered **intramuscularly** in a **2-dose regimen, 0.3 ML each, 28 days apart**. The preferred site is the **deltoid muscle of the upper arm**. This is a multidose vial and **must be thawed and diluted before use**. **One vial (0.45 ML) contains 6 doses of 0.3 ML after dilution**. After dilution, vials contain six doses of 0.3 ML of vaccine. In order to extract six doses from a single vial, **low dead-volume syringes and/or needles should be used**. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle: **Each dose must contain 0.3 ML of vaccine**.

Ref: European Medicines Agency Report/product formulation: https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf

3.2.4.3 Vaxzevria fmr. Astra Zeneca (ChAdOx1 nCoV-19)

The vaccine should be administered **intramuscularly**. The preferred site is the **deltoid muscle of the er arm**. The vaccine is administered intramuscularly (IM) in **two doses** of **0.5 mL per dose**, (2.5×10^8 infectious units) **given between 4 and 12 weeks apart**. The finished product is presented as a **multidose suspension ready for use.**

Ref. European Medicines Agenct Report: https://www.ema.europa.eu/en/documents/assessment-report/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-public-assessment-report_en.pdf

3.2.4.4 Janssen vaccine (Ad26.COV2-S [recombinant])

Ad26.COV2.S is administered intramuscularly as a **single dose regimen of 0.5 mL** (5x1010 vp, corresponding to not less than 8.92 log10 infectious units). Trials ongoing on the need for a booster dose After **visual inspection, and gentle swirling of the vial, vaccine is ready for use**.

Ref: European Medicines Agency Report. https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-janssen-epar-public-assessment-report_en.pdf

3.3 ECONOMIC CONSIDERATIONS

What is the known cost of administering the SARS COV2 vaccine per person vaccinated?

3.3.1 Cost per dose of vaccine and per person 19accinated

Vaccine	Price per dose*	Per person vaccinated
Pfizer-BioNTech (BNT162b)	$6.75 - $19.50	$13.5 -$ 39.0
Moderna (mRNA-1273)	$15.0 - $37.0	$30.0 - $74.0
Vaxzevria fmr. Astra Zeneca (ChAdOx1 nCoV-19)	$2.06 - $13.27	$4.12 - $ 26.54
Janssen vaccine (Ad26.COV2-S [recombinant])	$8.50-$10.0	$8.50 - $10.

Ref: Source: UNICEF COVID-19 Vaccine Market Dashboard https://www.unicef.org/supply/covid-19-vaccine-market-dashboard

3.3.2 Availability of funding for vaccine (COVAX, AU, GOU)

At least 1.3 billion donor-funded doses will be made available to 92 economies eligible for the **Gavi COVAX AMC, targeting up to 20% population** coverage by the end of the year. Uganda is a beneficiary of the COVAX facility.

Ref: WHO, 2020. https://www.who.int/news/item/18-12-2020-covax-announces-additional-deals-to-access-promising-covid-19-vaccine-candidates-plans-global-rollout-starting-q1-2021.

The **African Union has secured a provisional 270 million COVID-19 vaccine** doses for Africa through its COVID-19 **African Vaccine Acquisition Task Team** (AVATT), the Africa Medical Supplies Platform (AMSP), on behalf of the Africa Centres for Disease Control and Prevention (Africa CDC), through a **COVID-19 vaccines pre-order programme for all African Union Member States**. The **African Export-Import Bank** (Afreximbank) will

facilitate payments by providing advance procurement commitment guarantees of up to US$2 billion to the manufacturers on behalf of the Member States. AVATT has secured a provisional 270 million COVID-19 vaccines doses from Pfizer, Johnson & Johnson and AstraZeneca

Ref: African Union, Jan 2021. https://africacdc.org/news-item/amsp-opens-covid-19-vaccines-pre-orders-for-55-african-union-member-states/

3.3.2.1 mRNA-1273 Moderna Vaccine

Moderna is not listed among vaccines on the COVAX Portfolio.

3.3.2.2 BNT162b2 Pfizer BioNTech vaccine

Pfizer BioNTech is not listed among the vaccines on the COVAX Portfolio.

3.3.2.3 Vaxzevria fmr. Astra Zeneca (ChAdOx1 nCoV-19)

Uganda has been allocated 3,024,000* free doses under the COVAX facility, with the first batch of 864,000 doses delivered. Uganda also received 100,000 doses free from the Serum Institute of India.

Ref. *Gavi distribution list https://www.gavi.org/sites/default/files/covid/covax/COVAX-Interim-Distribution-Forecast.pdf

3.3.2.4 Janssen vaccine (Ad26.COV2-S [recombinant])

The **COVAX Facility has booked 500 million doses** of the vaccine. Currently no allocation has been made to Uganda of the Janssen Vaccine. Uganda is one of the beneficiaries of the COVAX Facility.

Janssen Pharmaceutica NV has agreed with the African Vaccine Acquisition Trust (AVAT) to make up to 220 million doses of its single-shot COVID-19 vaccine available to African Union (AU)'s 55 member states. Delivery of the vaccine is expected to **begin in the third quarter of 2021**. Additionally, under the terms of the agreement, AVAT has the option to order an additional 180 million doses, for a combined total of up to 400 million doses through 2022.

3.4 STRATEGIC AND PROGRAMMATIC CONSIDERATIONS

3.4.1 Cold chain requirements

What are the cold chain requirements of the vaccines viz a vis the country's cold chain capacity?

- **What are the additional cold chain requirements for the deployment of SARS COV2 vaccine in the country?**

3.4.1.1 In-country cold chain capacity.

UNEPI estimates that a total of **271,117 L space is required for COVID-19 vaccine storage**. An assessment was conducted in November 2020 to find out available in country capacity and found the following:
In country **ultra-cold chain (-80 °C) space in public sector is only available at the central vaccine store with a space of 120 L.**
Available storage for -20 °C in public sector is 5,476 L at CVS, 86,884 L at DVS, and 72,693 L at HF.
Available vs required 2 to 8 °C storage was estimates at 58,796 L vs.55,428 L at CVS, **19,390 L vs 55,428 L at DVS** and **266,720 L vs 55,428** L at HF. The storage gap at CVS was hoped to be filled with the **planned installation of drive-in cold rooms.**
A total of 13 cold rooms with storage capacity 10 cm^3 each had been earmarked for procurement to support newly created cities in the country.

Ref: MoH Nov 2020. Application Form for COVAX Cold chain Equipment (CCE) Support to GAVI. COVAX CCE Support Application. Consolidated Application Form.pdf (Unpublished).

3.4.1.2 mRNA-1273 Moderna Vaccine

Temperature requirements: Unopened vial **can be stored for 7 months at -25ºC to -15ºC**. The unopened vaccine **may be stored refrigerated at 2°C to 8°C, protected from light, for maximum 30 days**. Once thawed the vaccine should not be re-frozen. **The unopened vaccine may be stored at 8°C to 25°C up to 12 hours** after removal from refrigerated conditions. **Punctured Vial**: Chemical and physical in-use stability has been demonstrated for **6 hours at 2°C to 25ºC after initial puncture**. Store in the original carton to protect from light. Do not store on dry ice or below -40ºC.

Ref: European Medicines Agency Report/product formulation: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-moderna-epar-product-information_en.pdf

Packaging: A carton of Moderna vaccine contains ten multiple dose vials. **Each vial contains ten doses.** A case includes 12 cartons, or a total of 120 vials providing 1,200 doses. A shipping pallet may include up to 129 cases. The dimensions of a carton of vaccines are 5.5" x 2.2" x 2.5" = 13.9 x 5.6 x 6.35 cm (0.49L).

Ref: www.modernatx.com/covid19vaccine-eua/providers/storage-handling

3.4.1.3 BNT162b2 Pfizer BioNTech vaccine

Temperature requirements: This vaccine **requires an ultra-low-temperature freezer for storage up to 6 months (-80°C to -60°C). Temperature-controlled thermal shippers using dry ice** to maintain the recommended temperature of –70 °C ± 10 °C for up to 10 days will be needed for transportation. There are three options for storage of the Pfizer BioNTech vaccine;

i. Ultra-low-temperature freezers, which are commercially available and can extend shelf-life for up to six months.
ii. Refrigeration units, which are commonly available in hospitals: the **vaccine can be stored for five days in such refrigerators at 2–8 °C.**
iii. The Pfizer thermal shippers in which doses arrive can be refilled with dry ice and used as temporary storage units for up to 15 days. After the 15 days, the vials may be transferred to refrigerated storage at 2–8 °C for an additional five days, giving a total storage time of 20 days. Once thawed and stored at 2–8 °C, the vials may not be refrozen or stored in frozen condition.

Ref: European Medicines Agency Report/product formulation: https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf

Packaging: Each multiple dose vial contains a volume of 0.45 ML supplied as a **frozen suspension**. Each vial must be thawed and diluted prior to administration. The vial contents must be diluted using 1.8 ML of 0.9% sodium chloride injection, USP (not provided). **The diluent is not packaged with the vaccine, and must be sourced separately.**

Ref: Pfizer BioNTech EUA factsheet www.fda.gov/media/144413/download

The **cool boxes used to transport the vaccines are 39.8 cm sq** and insulated by a dry ice pod or liner inserted around five trays of vaccine doses. **Each tray, which is 23.1 cm sq. carries 1,000 doses**. These boxes are then made up into a pallet and placed in an insulated pallet shipper.

Ref Thomas Cullen. www.ti-insight.com/briefs/pfizers-new-vaccine-undelines-the-importance-of-packaging/

3.4.1.4 Vaxzevria fmr. Astra Zeneca (ChAdOx1 nCoV-19)

Temperature requirements: Store in a refrigerator **(2°C – 8°C) for 6 months**. Do not freeze and keep vials in outer carton in order to protect from light. Chemical and physical in-use stability have been demonstrated from the time of vial opening (**first needle puncture) to administration for no more than 48 hours in a refrigerator (2°C – 8°C).** Within this time period the **product may be kept and used at temperatures up to 30°C for a single period of up to 6 hours**. After this time period, the product must be discarded. Do not return it to the refrigerator.

Ref: WHO. 2021. *https://www.who.int/publications/i/item/background-document-on-the-azd1222-vaccine-against-covid-19-developed-by-oxford-university-and-astrazeneca*

Packaging: Each vial contains ten doses. A carton (13.2 x 5.7 x 5.0 cm) holds 10 vials (100 doses). 24 secondary packaged cartons containing 10 vials per carton (2400 doses) occupy a space of 24.8 x 28.8 x 18.0 cm (12.86 L)

Ref. WHO. www.extranet.who.int/pqweb/vaccines/covid-19-vaccine-chadox1-s-recombinant

3.4.1.5 Janssen vaccine (Ad26.COV2-S [recombinant])

Temperature requirements: Frozen unopened vaccine vial can be stored in a in freezer at -25 and -15 °C for 24 months. **Thawed unopened** vaccine vial can be stored in a refrigerator at **+2 to +8 °C** once removed from the freezer, for a single period of **up to 3 months**. **Thawed opened vial** (after first puncture) can be **stored at +2 to +8 °C: up to 6 hours** after the first dose has been withdrawn.

Ref: European Medicines Agency Report. https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-janssen-epar-public-assessment-report_en.pdf

Packaging: The vaccine is supplied in a carton of 10 multi dose vials. Each vial contains 5 doses and each dose 0.5mL. Each carton is 9.3 x 3.8 x 5.4 cm. Cartons are shipped in cases, 48 cartons per case. Each case is 38.9 x 24.3 x 12.1 cm. (11.44L)

Ref: JanssenMD. www.janssenmd.com/janssen-covid19-vaccine/product-propertie/how-supplied/dimenssions/

3.4.2 Availability of supply

What is the global supply availability of the vaccine compared to Uganda's demand?

Uganda targets to vaccinate **49.6 per cent of the population**, which is about **21,936,011**, in a phased manner. Each phase is intended to cover 20% of the population.

Ref: MOH 2021. COVID-19 Vaccine Deployment Plan (Unpublished) cited by WHO Uganda. https://www.afro.who.int/news/uganda-receives-864000-doses-covid-19-vaccines

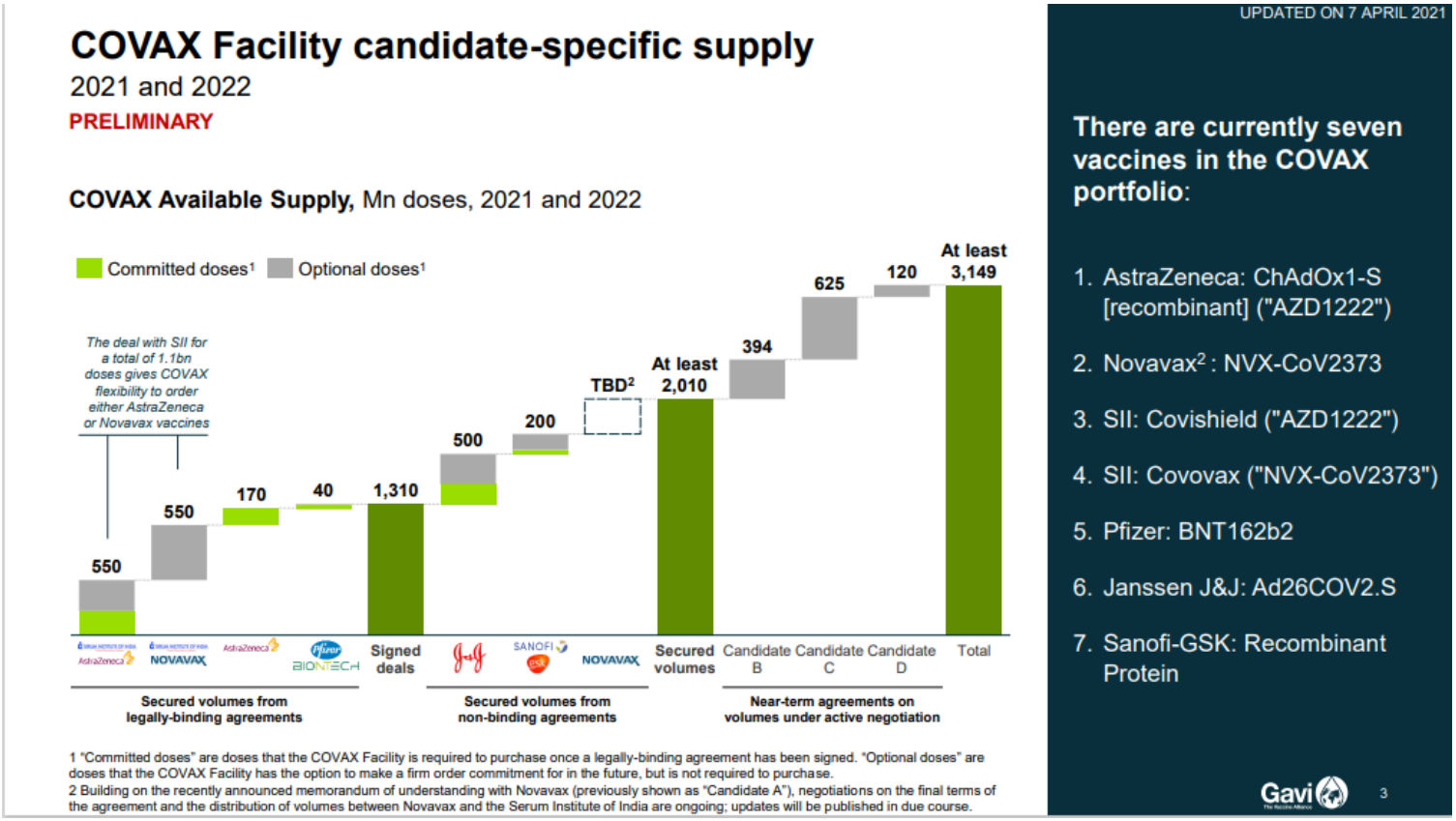
Figure 3 shows the COVAX Facility supply forecast for 2021/2022 Update April 7, 2021.

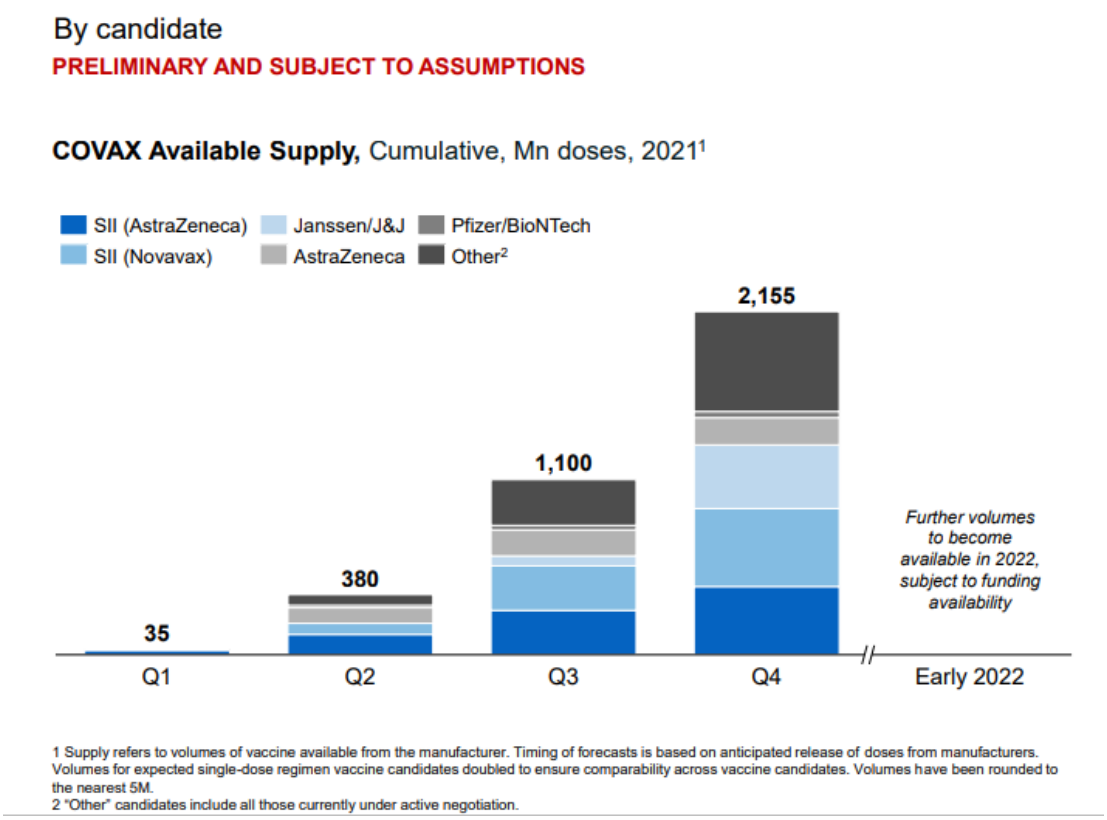
3.4.2.1 mRNA-1273 Moderna Vaccine

This vaccine is currently **not available on the COVAX Facility** portfolio. The European Medicines agency on 26 March 2021 announced approval of new manufacturing site and scaled-up processes for Moderna's COVID-19 vaccine aimed at increasing vaccine manufacturing capacity and supply.

Ref: European Medicines Agency 2021: https://www.ema.europa.eu/en/news/increase-vaccine-manufacturing-capacity-supply-covid-19-vaccines-astrazeneca-biontechpfizer-moderna

Figure 3 COVAX Supply forecast 2021-2022





Ref: Gavi, April 2021. https://www.gavi.org/sites/default/files/covid/covax/COVAX%20Supply%20Forecast.pdf

3.4.2.2 BNT162b2 Pfizer BioNTech vaccine

COVAX Facility has a commitment for supply of **40 million doses of** Pfizer BioNTech vaccine. There are currently 3 approved manufacturing sites for the vaccine in its market authorisation, with a fourth site recently approved by EMA.

Ref: European Medicines Agency 2021: https://www.ema.europa.eu/en/news/increase-vaccine-manufacturing-capacity-supply-covid-19-vaccines-astrazeneca-biontechpfizer-moderna

On 11 February, UNICEF announced the signing of an agreement with Pfizer for the supply of the Pfizer-BioNTech COVID-19 Vaccine through 2021. This supply agreement allows UNICEF to procure up to 40 million doses that have been secured under the COVAX Facility's Advance Purchase Agreement (APA) with Pfizer/BioNTech to be available throughout 2021.

Ref: UNCIEF, Feb, 2021. https://www.unicef.org/press-releases/unicef-signs-supply-agreement-pfizerbiontech-covid-19-vaccine

3.4.2.3 Vaxzevria fmr. Astra Zeneca (ChAdOx1 nCoV-19)

COVAX Facility has secured commitment for a total of **720 million doses** of the Vaxzevria fmr. Astra Zeneca vaccine. **UNICEF and AstraZeneca** signed a long-term agreement for the supply of COVID-19 Vaccine AstraZeneca on behalf of the COVAX Facility.The supply agreement will enable access to **170 million doses secured under the COVAX Facility's Advance Purchase Agreement (APA) with AstraZeneca**, which will be available throughout 2021 for around 85 countries.

Ref: UNICEF, Feb. 2021. https://reliefweb.int/report/world/unicef-signs-covid-19-vaccine-supply-agreement-astrazeneca

The COVAX facility has allocated 3,552,000 doses of the Vaxzevria fmr. AstraZeneca vaccine to Uganda for the period of January – June 2021, of which 864,000 doses have been delivered. The remaining 2,688,000 doses are expected by June 2021. The **Serum Institute of India donated 100,000 doses** of vaccine to Uganda and have been delivered.

Ref. Gavi 2021. COVAX Vaccine roll out Uganda. https://www.gavi.org/covax-vaccine-roll-out/uganda

3.4.2.4 Janssen vaccine (Ad26.COV2-S [recombinant])

COVAX Facility has a commitment of supply for 500 million doses of Janssen Vaccine. Uganda has not been allocated Janssen vaccine by COVAX Facility.

Janssen Pharmaceutica NV has agreed with the **African Vaccine Acquisition Trust (AVAT) to make up to 220 million doses** of its single-shot COVID-19 vaccine available to African Union (AU)'s 55 member states. Delivery of the vaccine is expected to **begin in the third quarter of 2021**. Additionally, under the terms of the agreement, AVAT has the **option to order an additional 180 million doses**, for a combined total of up to 400 million doses through 2022.

Ref: https://www.afreximbank.com/africa-signs-historic-agreement-with-johnson-johnson-for-400-million-doses-of-covid-19-vaccines/

3.4.3 Acceptability

What is the perception of the public and health workers of on COVID-19 disease, and prevention measures?

In Uganda, a number of Knowledge Attitude and Practice (KAP) studies were conducted in the country ahead of introduction of COVID-19 Vaccines. Overall, **most respondents surveyed were knowledgeable about the COVID-19 disease**, and were generally willing to follow recommended prevention measures, with no gender disparities. **Knowledge gaps** were identified among **drivers, business entrepreneurs, and security personnel.** The most **common sources of information** were **Radios, Health workers, TVs and social media platforms.**

Refs: UVRI Feb 2021. A survey to evaluate the willingness-to-participate in COVID-19 vaccine trials among a population of Health Care Workers (HCWs) in Uganda (Unpublished).

Olum Ronald et.al. April 2020. Perspective of Medical Students on the COVID-19 Pandemic: Survey of Nine Medical Schools in Uganda. http://publichealth.jmir.org/2020/2/e19847/

Olum Ronald et. al., April 2020. Coronavirus Disease-2019: Knowledge, Attitude, and Practices of Health Care Workers at Makerere University Teaching Hospitals, Uganda. https://www.frontiersin.org/articles/10.3389/fpubh.2020.00181/full

Twinamasiko Nelson et. al. Feb 2021. Assessing Knowledge, Attitudes and Practices Towards COVID-19 Public Health Preventive Measures Among Patients at Mulago National Referral Hospital. https://doi.org/10.2147/RMHP.S287379

Okello Gerald et. al., Dec 2020. Findings of a Cross-Sectional Survey on Knowledge, Attitudes, and Practices about COVID-19 in Uganda: Implications for Public Health Prevention and Control Measures. https://doi.org/10.1155/2020/5917378

Ground Truth Solutions, May 2020. COVID-19 insight from refugee community leaders: Uganda.

Sebuufu Robinson et al. Knowledge, Attitude, and Self-Reported Practice Toward Measures for Prevention of the Spread of COVID-19 Among Ugandans: A Nationwide Online Cross-Sectional Survey.

What is the perception of the public and health workers of on COVID-19 vaccines?

A vaccine **acceptance survey** carried out in **15 countries across Africa** showed **willingness** to take COVID-19 vaccines varied from **94% in Ethiopia to 59% in Democratic Republic of the Congo**. Overall, **vaccine safety was the leading concern**; 25% of respondents believed that a COVID-19 vaccine would be unsafe and 18% believed that vaccines generally were not safe. Respondents who were **older, those who knew someone who has tested positive for COVID-19, and those living in rural areas were more likely to take a COVID-19 vaccine** than younger people, those who have not seen COVID-19 affect anyone, and those living in urban settings. **Reasons for vaccine refusal** included **a belief that COVID-19 does not exist, or its threat is exaggerated**. **Misinformation circulating in the media** was **responsible for a lot of mistrust** and suspicion around COVID-19 vaccines on the continent: The survey found that many respondents believed that **COVID-19 was a planned event by foreign actors**, that people in Africa were being using as **guinea pigs in vaccine trials**, and that the spread of **COVID-19 was linked to 5G technology**.

Ref: Udani Samarasekera. Lancet. March 2021. https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00082-7/fulltext

In Uganda, a joint Makerere University School of Public Health and UNICER Rapid survey (Jan 2021) found that **majority of the HW's 294 (81.2%) were willing to take the vaccine**, believed the vaccines were safe (64%) and effective (67%). The **biggest concerns were safety of the vaccines, authenticity and fear of side effects**.

An online poll conducted by UNCIEF in Feb 2021 on the U Report Platform found that **53% of respondents** reported they **would take the vaccine without hesitation**, **36%** wanted to **wait and see**, and **11% would not take the vaccine**. Those **35 years and over were most willing to be vaccinated**.

Ref: UNICEF 2021. COVAX: What People Think About the Covid-19 Vaccine Poll Analysis Results – February 2021. https://uganda.ureport.in/opinion/4857/

What has been the uptake of COVID-19 in Uganda?

Uganda started rolling out the Vaxzevria fmr. Astra Zenaca vaccine on 10th March 2021, targeting health workers, all persons aged 50 years and above, teachers, security forces and people aged 18 years + with comorbidities. As of **April 06, 2021, 141, 697 people had been vaccinated**, but performance was below 20% for all target groups (Figure 4).

Figure 4 Coverage of target populations with first dose of vaccine as at April 06, 2021

Priority groups (Individual)	Target	No. Vaccinated with 1st Dose	Performance
Health workers (Ind)	150,000	19,958	13.3%
Security (Agg+Ind)	250,000	42,183	16.9%
Teachers (Ind)	550,000	5,296	1.0%
Elderly (>50yrs)	3,438,000	9,155	0.3%
People with Co-morbidities (Ind)		718	
Others (Ind)		3,278	

MoH staff reported that there were **programmatic challenges with the roll out**, including delays in vaccine deliveries, shortages of vaccination cards, poor and uncoordinated communication, and lack of funds for communication, lack of equipment for quick data capture and untimely delivery of funds for payment of implementing staff at the service delivery points.

Ref: Personal Communication, Dr Immaculate Ampaire SMO, UNEPI contact: ampaire7@yahoo.co.uk

While no studies are available on acceptability of specific COVID-19 Vaccines in Uganda, **the concerns about the thromboembolic events related to Vaxzevria fmr. Astrazeneca** vaccine were related **to psychological anxiety around individual acceptance** of the vaccine in countries where it was temporarily suspended.

A four-country poll conducted in United Kingdom, France, Germany and Spain, following the temporary suspensions showed **an overall increase in mistrust of the Astra Zeneca Vaccine** with **more than half** the people surveyed **believing the vaccine is unsafe**. The only country surveyed where **confidence in the vaccine remained high** was in the **United Kingdom**. Roughly three-quarters of those polled locally still believed the vaccine was safe, although that figure also represented a **slight decline** on when people were polled last month.

Ref. Micheal B Peterson et al. March 2021. https://psyarxiv.com/uh4y6

Mark Scott. March 2021. https://www.politico.eu/article/trust-oxford-astrazeneca-coronavirus-vaccine-wanes-europe-survey/

Recent reports out of the USA indicate similar concerns about **thromboembolic incidents linked to the Janssen vaccine**, which are under review by the European Medicines Agency.

Ref: https://www.pharmaceutical-technology.com/news/ema-review-jj-vaccine/

3.5 GLOBAL AND REGIONAL POLICY CONSIDERATIONS

Do the vaccines have WHO approval for use?

3.5.1.1 mRNA-1273 Moderna Vaccine

WHO approved the vaccine for emergency use in people aged 16 years and older.

Ref. WHO, 2021. https://www.who.int/publications/i/item/interim-recommendations-for-use-of-the-moderna-mRNA-1273-vaccine-against-covid-19

3.5.1.2 BNT162b2 Pfizer BioNTech vaccine

WHO approved the vaccine for emergency use in people aged 16 years and older.

Ref: WHO, 2021. https://extranet.who.int/pqweb/sites/default/files/documents/TAG-EUL_PublicReport_Pfizer_31DEC20.pdf

3.5.1.3 Vaxzevria fmr. Astra Zeneca (ChAdOx1 nCoV-19)

WHO approved the vaccine for emergency use in people 18 aged 18 years and older.

Ref: WHO, 2021. https://extranet.who.int/pqweb/sites/default/files/documents/AZD1222_TAG_REPORT_EUL%20vaccine_FEB2021_v2.pdf

3.5.1.4 Janssen vaccine (Ad26.COV2-S [recombinant])

WHO approved the vaccine for emergency use for people aged 18 years and older.

Ref: WHO, 2021.

What COVID-19 vaccines are being used in the African and East African region?

Africa: Through the COVAX Facility, **16.6 million vaccine doses** – mainly **AstraZeneca** – have been delivered to 27 African countries.

Ref. WHO, AFRO. https://www.afro.who.int/news/africas-covid-19-vaccination-gains-pace-nearly-7-million-doses-given

Kenya is rolling out the Vaxzevria fmr. Astra Zeneca vaccine. So far, 1.02 million doses of the Astra Zeneca-Oxford COVID-19 vaccine have been received from the COVAX vaccine.They were delivered on Wednesday March 3, 2021.

Ref: WHO Kenya. https://www.afro.who.int/news/kenya-receives-covid-19-vaccines-and-launches-landmark-national-campaign

On 3 March, Rwanda received 240 000 doses of the AstraZeneca vaccines through the COVAX Facility. Rwanda also received 102 960 doses of the Pfizer-BioNTech vaccines. India also supplied Rwanda with 50 000 doses of AstraZeneca vaccine doses. Rwanda plans to vaccinate 30% of the population by the end of 2021 and 60% by the end of 2022. Rwanda has now exhausted its initial vaccine supplies and expects 200 000 more doses via the COVAX Facility.

Ref: GAVI, 2021. https://www.gavi.org/vaccineswork/rolling-out-covid-19-vaccines-rwanda

4 CONCLUSIONS

i. Do we need a vaccine against COVID-19 in Uganda?

Yes. COVID-19 is a disease of significant importance in Uganda, given **the high incidence of infection, high case fatality ratio particularly for the elderly and persons with comorbidities**, the **negative impact on the health care system and the economy**, and its **potential for pandemic spread**. There is **currently no curative treatment** for the disease and the **alternative control measures** of mask wearing, social distancing and hand hygiene are not **sufficient to effectively control** the spread of the virus.

ii. Are the vaccine(s) available safe and efficacious?

Yes. All vaccines have an **efficacy rate of over 50% in all population groups**, including **efficacy against severe disease, hospitalisation and death** caused by currently known variants in the country. All vaccine available under WHO Emergency Use Listing **have acceptable safety profiles**. The **adverse events following immunisation are mostly mild and moderate, and self-resolving within 1-2 days**. The **benefit of using the vaccines outweighs the risks**.

iii. Can we afford the vaccine in terms of vaccine and consumables cost, cold chain requirements, and human resource to administer?

Uganda's cold chain capacity is currently well suited to manage two of the four WHO approved vaccines, i.e., **Vaxzevria fmr. Astra Zeneca (ChAdOx1 nCoV-19) and Janssen vaccine (Ad26.COV2-S [recombinant]).** These two vaccines **can be stored at refrigerator temperatures of +2°C to + 8°C for at least 3 months**. The **ultra-cold chain temperature requirements of mRNA-1273 Moderna Vaccine and vaccine** make them **incompatible** with the locally available cold chain system. The preparation and administration **requirements for BNT162b2 Pfizer BioNTech vaccine including thawing, dilution and use of low dead syringes of 0.3mL are incompatible with the human resource knowledge in the country**. All considered vaccines **except Moderna** are **available on the COVAX and African Union AVAT funding platforms. Vaxzevria fmr. Astra Zeneca (ChAdOx1 nCoV-19) and Janssen vaccine (Ad26.COV2-S [recombinant])** are the **cheapest** of the four vaccines when considering **vaccine price per fully immunised person. BNT162b2 Pfizer BioNTech, Vaxzevria fmr. Astra Zeneca (ChAdOx1 nCoV-19), and Janssen vaccine (Ad26.COV2-S [recombinant])** and are **available for free to cover 20% of the country's population on the COVAX facility**, of which Uganda is a beneficiary. Government, through Parliament has also passed **UGX 18.5 billion** to privately procure vaccines.

iv. Is the vaccine available, and acceptable to the Ugandan population?

Uganda has **so far received 964,000 doses of Vaxzevria fmr. Astra Zeneca** (ChAdOx1 nCoV-19) vaccine with a **commitment of 3,024,00 from the COVAX Facility**, with an option to change the selected vaccine requests. **UNICEF** has **secured supply** of **40 million dosses of Pfizer BioNTech vaccine, 140 million doses of Vaxzevria fmr. AstraZeneca vaccine and 500 million doses of Janssen vaccine** on behalf of the COVAX facility. **African Union has secured supply of 200 million doses of Janssen Vaccine**. Vaccine availability is expected to pick up in the third quarter of 2021, and substantially increase thereafter.

The available evidence suggests that **all COVID-19 vaccines are generally acceptable to the Ugandan population**, provided they are **assured the vaccines are safe and efficacious**. The **difficulties in accessing accurate information about the vaccines and the programmatic challenges in easing access to the vaccines contribute to observed low uptake rates.**

5 RECOMMENDATIONS

5.1 Vaccine selection recommendation

UNITAG recommends the Vaxzevria fmr. Astra Zeneca vaccine (ChAdOx1 nCoV-19) and Janssen vaccine (Ad26.COV2-S [recombinant]) for Uganda out of the four WHO Emergency Use Licenced (EUL) vaccines because they are safe (the benefits outweigh the risks) and efficacious, and have acceptable logistical and storage requirements in terms of the cold chain and administration; in line with available capacities in the country.

UNITAG will continue to study emerging evidence on the two recommended vaccines, as well as other vaccines as they receive approval from WHO.

5.2 Additional Considerations regarding vaccine selection

1. UNITAG recommends that government should not commit to buying many doses of vaccines from one source or any one company because information about the vaccines is rapidly changing, and prices are likely to go down as more different products come on board.
2. UNITAG recommends that procuring of vaccines be made through established channels such as UNICEF and African Union because of advantages related to price and quality. Procurement of additional Vaxzevria fmr. Astra Zeneca (ChAdOx1 nCoV-19) vaccines by the government outside the free COVAX allocation should still be made through the COVAX facility (and UNICEF) because of its advantages, including the opt-out option if the country later chooses to go for a different vaccine.
3. UNITAG recommends that future Vaccine selection decisions be based on lessons learned from vaccine experiences within the country's context. Therefore, the rollout should be combined with related studies on topics such as vaccine acceptability, safety, and immunogenicity within our population.
4. UNITAG recommends an overall coordinated mechanism to decide on new vaccines to be introduced in the country be set up.

5.3 Recommendations on promoting vaccine acceptability

i. The government, through Ministry of Health, should urgently commit funds to implement a community-based strategy for creating immunization awareness and promote vaccine acceptability across the country. The

strategy development mechanism should identify where the expertise in health promotion lies and who should develop and implement the strategy.

ii. UNEPI and Implementing Partners should come together and devise means of improving access to vaccines and overcoming programmatic bottlenecks to vaccine roll out at the community level.

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