

UNITAG Interim Recommendation on COVID-19 Vaccine Allocation and Prioritisation

Top 3% of Population

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A. Executive Summary

On 3rd November 2020, the Uganda Ministry of Health made a request to the Uganda National Immunisation Technical Advisory Group (UNITAG) for advice on a) allocation framework and criteria to be used to prioritize COVID-19 vaccine recipients in the initial phase of vaccine scarce supply; b) vaccine selection in the event that more than one vaccine is prequalified and approved for use by WHO; c) what steps should be taken to mitigate vaccine hesitancy to COVID-19 vaccines especially among high priority groups and most appropriate methods for communication. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the virus responsible for the coronavirus disease of 2019 (COVID-19). First identified in Wuhan (Hubei, China) in December of 2019, it has since been declared a pandemic by the World Health Organization in March of 2020.

Uganda is a participant in the COVAX Facility, which is one of three pillars of the Access to COVID-19 Tools (ACT) Accelerator, brings together governments, global health organizations, manufacturers, scientists, private sector, civil society and philanthropy, with the aim of providing innovative and equitable access to COVID-19 diagnostics, treatments and vaccines. Although the ACT-Accelerator will speed up development and production, initial supplies of vaccines will be limited. The Strategic Advisory Group of Experts of the WHO has devised a generic roadmap for the initial allocation of the vaccine at the time when supplies will be limited and therefore countries need to contextualize it to their epidemiological situations.

Based on the WHO SAGE Values Framework, UNITAG adopted the following goals for COVID-19 Vaccine introduction to guide the allocation decisions:

Overall Goal: Promotion and protection of health, safety and wellbeing of population that is premised on the ethical principle of human wellbeing.

Short term (acute end of the pandemic) goals: To reduce death and severe disease from SAR-CoV-2 guided by the ethical principle of human wellbeing and the right to life and to protect the health system which aligns with the principle of reciprocity of Health Care Workers and human wellbeing as well as the protection of life for the sick.

Medium-term goal: To protect the continuing functioning of essential services, including health services in the midst of the epi/pandemic justified by the principle of human well-being.

Long term goal: To reduce societal and economic disruptions and reduce transmission of SARS-COV-2 justified by the principle of human wellbeing.

WHO SAGE using risk-based criteria and guided by a set of eight ethical value-principles, recommended that health care workers and older adults be prioritized in the top 10% of national populations, followed by people with high-risk co-morbidities, social demographic groups at higher risk of severe disease and death, health workers offering immunization services, and high priority teachers and school stuff in the top 11-20% of the population.

UNITAG reviewed Uganda specific epidemiological data on patients diagnosed with COVID-19, segregating them into those that were asymptomatic, presented with severe disease and those that died, and categorized by age, gender, residence and co-morbidity; and using that evidence and evidence in literature, contextualized the WHO SAGE vaccine prioritization and allocation framework as follows:

Top 3% (approx. 1.35 million out of a projected total population of 45 Million)

1a All Health Care Workers at front line health service delivery within a Health Facility because they are at very high risk of acquiring and transmitting infection.

This was based on the **value principles of reciprocity** (as they put their lives at risk to take care of the sick), and that of **human wellbeing**, as the sick need them for treatment and recovery.

Health Workers* were defined to include are both medical and auxiliary (other people within the HF that provide support services and whose work brings them into contact with patients e.g., cleaners, drivers, security guards, chefs, hospital chaplains, psychologists) workers and trainees in contact with patients within a Health Facility.

Health Facility* is inclusive of all Public Health facilities, Public Not For-Profit (PNFPs) facilities, and Private For-Profit facilities.

(*registered Health Facility and registered Health worker)

In event of very limited supplies (1-2%), the following should be prioritized in the list order:

i. Health Care Workers including trainees and auxiliary workers directly involved in treatment of COVID-19 patients,

ii. Health Care Workers who come into close contact with other patients (emergency care, inpatient services,)

iii. Health Care Workers who came into regular contact with patients (outpatient, immunisation) and Surveillance workers incl. contact tracers, Point of Entry workers

In event of extremely limited supplies (less than 1%), considerations of districts with highest case load should precede other districts.

1b Adult populations

Basing on the epidemiological data, adults aged 60yrs and over were found to be at highest risk of severe disease and death from COVID-19. UNITAG therefore recommended prioritizing all adults **aged 60yrs and over** for vaccination.

This was based on value-principles of human wellbeing, securing safety and health of all those mostly at high risk of morbidity and mortality, and mitigating vulnerability.

In event of very limited doses (< 1-2%) priority should be given those people with comorbidities (diabetes, hypertension, organ disease and other chronic illnesses) who should be considered in the following order:

- i. 60yrs+ who have more than one co-morbidity,
- ii. all below 60yrs but with multiple comorbidities,
- iii. all people with diabetes,
- iv. 60yrs+ with one comorbidity,
- v. 60yrs+ in districts with highest number of cases

UNITAG created a third category in this group

1c Essential workers

Other essential workers providing non health services in high-risk populations for example spiritual leaders, teachers, airline workers, prison warders, and key security forces. While at the time of this report, no occupation categorised epidemiological data had been availed to the committee, these groups were considered because the nature of their essential work brings them in contact with people who may be infected.

The value principles considered were: Human wellbeing, protection continuing function of essential services including the economy and social, and maximisation of benefit of vaccines with goal of saving the most lives.

Notes

It is to be noted that the recommended population groups **cover all people within Uganda**, including refugees and non-Ugandans living in Uganda under the value-principles of equal respect, and equity.

UNITAG reiterates that this is an **interim recommendation** based on evidence available to it at the time, and could be revised over time as the situation changes and in case of new evidence coming to light.

UNITAG also notes it concern for potential supply of **COVID-19 vaccine in the private sector** without a formal framework for Ministry of Health oversight, and recommends that a framework be drawn by the Ministry of Health to minimise any negative outcomes from such an exercise.

B. Introduction

On 3rd November 2020, the Uganda Ministry of Health made a request to the Uganda National Immunisation Technical Advisory Group for advice on a) allocation framework and criteria to be used to prioritize COVID-19 vaccine recipients in the initial phase of vaccine scarce supply; b) vaccine selection in the event that more than one vaccine is prequalified and approved for use by WHO; c) what steps should be taken to mitigate vaccine hesitancy to COVID-19 vaccines especially among high priority groups and most appropriate methods for communication. (Letter in Annex 1).

This report covers only the aspect of an allocation framework and prioritization of COVID-19 vaccine recipients during the initial phase for the top 3% of the population.

C. Methodology

In line with the UNITAG Internal Procedures Manual, the UNITAG Chair in consultation with the Secretariat formed a working group to develop a COVID-19 Vaccine allocation Recommendation Framework and gather relevant published and context specific information upon which conclusions and recommendations would be based by group consensus.

The Working Group Composition: The COVAX Working Group was co-chaired by a Physician and Pediatrician and comprised of some UNITAG members who included a health policy analyst, an epidemiologist, a sociologist, a bioethicist, vaccinologist and supported by liaison members from UNEPI, WHO and UNICEF. All members signed conflict of declaration and confidentiality forms and none had a significant conflict of interest.

Work Process: The working group met eight times to review the presented question from Ministry of Health, received presentations from Ministry of Health, WHO Africa region on SAGE guidance on prioritization roadmap for COVID-19 vaccines. The Secretariat then gathered peer reviewed data and information in addition to Uganda specific COVID-19 data that was provided by Ministry of Health. The Working group then developed draft conclusion and recommendations which were presented to the entire NITAG committee for review and consensus endorsement.

D. General Information on COVID-19

Cause, presentation, transmission, treatment and outcomes

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the virus responsible for the coronavirus disease of 2019 (COVID-19). First identified in Wuhan (Hubei, China) in December of 2019, it has since been declared a pandemic by the World Health Organization in March of 2020. Coronaviruses (CoV) are a large family of viruses that cause symptoms ranging from the common cold to more serious illnesses, e.g., the Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). This new virus and disease were unknown before the outbreak in Wuhan, China, in December 2019. COVID-19 infection remains mild in 80% of cases. (WHO, 2020) (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19), (Ministry of Health Uganda, 2020) https://www.health.go.ug/covid/faq/

The disease is transmitted by inhalation or contact with infected droplets and the incubation period ranges from 2 to 14 days. The symptoms are usually fever, cough, sore throat, breathlessness, fatigue, malaise among others. The disease is mild in most people; in some (usually the elderly and those with comorbidities), it may progress to pneumonia, acute respiratory distress syndrome (ARDS) and multi organ dysfunction. Many people are asymptomatic. The case fatality rate is

estimated to range from 2 to 3%. Diagnosis is by demonstration of the virus in respiratory secretions by special molecular tests. Common laboratory findings include normal/ low white cell counts with elevated C-reactive protein (CRP). The computerized tomographic chest scan is usually abnormal even in those with no symptoms or mild disease. Treatment is essentially supportive; role of antiviral agents is yet to be established. Prevention entails home isolation of suspected cases and those with mild illnesses and strict infection control measures at hospitals that include contact and droplet precautions.

(Singhal T. (2020). A Review of Coronavirus Disease-2019 (COVID-19). *Indian journal of pediatrics*, 87(4), 281–286. <u>https://doi.org/10.1007/s12098-020-03263-6</u>)

The WHO weekly epidemiological update dated 22nd December 2020 showed that 75 million reported cases and 1.6 million deaths had been reported globally since the start of the pandemic. By 27th December 2020, the WHO Africa Regional Office had recorded 2,618,932 cases and 61,829 deaths in the region (<u>https://who.maps.arcgis.com/apps/opsdashboard/</u>). In Uganda, as of 28th December 2020, there were 34, 281 reported cases, of which 250 had died and 11,450 had recovered (<u>https://covid19.gou.go.ug/index.html</u>).

COVID-19 Vaccines

There are three COVID-19 vaccines for which certain national regulatory authorities have authorized the use. None have yet received WHO EUL/PQ authorization an assessment on the Pfizer vaccine is expected by the end of December and for some other candidates soon thereafter.

Large studies of 5 vaccine candidates' efficacy and safety results, including these three (and for Moderna and AstraZeneca), have been publicly reported through press releases but only one (AstraZeneca) has published results in the peer reviewed literature. There are currently more than 50 COVID-19 vaccine candidates in trials. <u>https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines</u>

The COVAX Facility

COVAX is one of three pillars of the Access to COVID-19 Tools (ACT) Accelerator, which was launched in April by the World Health Organization (WHO), the European Commission and France in response to this pandemic. Bringing together governments, global health organizations, manufacturers, scientists, private sector, civil society and philanthropy, with the aim of providing innovative and equitable access to COVID-19 diagnostics, treatments and vaccines. The COVAX pillar is focused on the latter. The principal role of the COVAX Facility is to maximise the chances of people in participating countries getting access to COVID-19 vaccines as quickly, fairly and safely as possible. Coordinated by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO, COVAX achieves this by acting as a platform that will support the research, development and manufacturing of a wide range of COVID-19 vaccine candidates, and negotiate their pricing. All participating countries, regardless of income levels, will have equal access to these vaccines once they are developed. The initial aim is to have 2 billion doses available by the end of 2021, which should be enough to protect high risk and vulnerable people, as well as frontline healthcare workers. The Facility is working with manufacturers to provide investments and incentives to ensure that manufacturers are ready to produce the doses we need as soon as a vaccine is approved. The Facility will also use the collective purchasing power that comes from having so many countries participate in order to negotiate highly competitive prices from manufacturers that are then passed on to participants.

Uganda is part of the over 78 participating COVAX facility countries.

https://www.gavi.org/vaccineswork/covax-explained

Vaccine allocation on the COVAX Facility

Although the ACT-Accelerator will speed up development and production, initial supplies will be limited. If there is no international plan to manage vaccine distribution fairly, there will be hoarding in some places and life-threatening shortages in others. There will also be price spikes. WHO advises that once a vaccine(s) is shown to be safe and effective, and authorized for use, all countries receive doses in proportion to their population size, albeit initially in reduced quantities. This will enable every country to start by immunizing the highest priority populations. In the second phase, vaccines would continue to be deployed to all countries so that additional populations can be covered according to national priorities. Fair allocation of vaccines will occur in the following way:

An initial proportional allocation of doses to countries until all countries reach enough quantities to cover 20% of their population. Next will be a follow-up phase to expand coverage to other populations. If severe supply constraints persist, a weighted allocation approach would be adopted, taking account of a country's COVID threat and vulnerability.

https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccinesthrough-the-covax-facility

WHO/SAGE vaccine allocation framework

To guide the COVAX Facility allocation of COVID-19 vaccines between countries and individual countries allocation in the event of scarce supply, WHO's Strategic Advisory Group of Experts (SAGE) developed a Values Framework and Roadmap for COVID-19 Vaccines.

Figure 1 articulates the three-step process to guide decision making arising from the values framework to development of a prioritization roadmap to development of vaccine specific recommendations.

Figure 1 Three Step Process to guide decision making on COVID-19 Vaccines



The WHO/SAGE Values Framework outlines the overall goal, six key principles and their objectives as detailed in Table 1.

The WHO/SAGE roadmap uses the value principles to develop a listing of (unranked) about 20 different priority groups in accordance with vaccination objectives and their relevance to core principles. There are three epidemiological settings considered: community transmission, sporadic/cluster of cases, and no cases. Under each of the three settings, the roadmap provides for three vaccine supply scenarios: stage 1: very limited supply (1-10%), stage II limited supply (11-20%), and stage III Moderate supply (21-50%).

The initial focus is on direct reduction of morbidity and mortality, maintenance of most critical essential services and considering "reciprocity" (towards groups placed at disproportionate risks to mitigate the consequences of the pandemic).

Table 1WHO/SAGE Values Framework for COVID-19 Vaccines

Goal	COVID-19 vaccines must be a global public good. The overarching goal is for							
Statement	COVID-19 vaccines to contribute significantly to the equitable protection and							
	promotion of human well-being among all people of the world. Objectives							
Principles	Objectives							
Human	Reduce deaths and disease burden from the COVID-19 pandemic;							
well-being	Reduce societal and economic disruption by containing transmission, reducing severe							
	disease and death or combination of these strategies;							
	Protect the continuing functioning of essential services including health services.							
Equal	Treat the interests of all individuals and groups with equal consideration as allocation							
respect	and priority setting decisions are being taken and implemented.							
	Offer a meaningful opportunity to be vaccinated to all individuals and groups who							
	qualify under prioritization criteria.							
Global Ensure that vaccine allocation takes into account the special epidemic risks and need								
Equity	of all countries; particularly low- and middle-income countries;							
Ensure that all countries commit to meeting the needs of people living in countries the								
cannot secure vaccine for their populations on their own, particularly low- and middl								
	income countries.							
National	Ensure that vaccine prioritization within countries takes into account the							
Equity	vulnerabilities, risks and needs of groups who because of underlying societal,							
	geographic or biomedical factors are at risk of experiencing greater burdens from the							
	COVID-19 pandemic.							
	Develop the immunization delivery systems and infrastructure required to ensure							
	COVID-19 vaccines access to priority populations and take proactive action to ensure							
	equal access to everyone who qualifies under a priority group, particularly social							
Designed	Disadvantaged populations.							
Reciprocity	Protect mose who bear significant additional fisks and burdens of COVID-19 to							
Legitimacy	Engage all countries in a transparent consultation process for determining what							
Legitimacy	scientific public health and values criteria should be used to make decisions about							
	vaccine allocation between countries:							
	Employ best available scientific evidence, expertise and significant engagement with							
	relevant stakeholders for vaccine prioritization between various groups within each							
X	country, using transparent, accountable, unbiased processes, to engender deserved trust							
	in prioritization docisions							

Uganda is currently in the community transmission phase of the pandemic, and for this purpose, the community transmission scenario in the WHO/SAGE roadmap (Figure 2), was applied in this document. <u>https://www.health.go.ug/cause/update-on-covid-19-response-in-uganda-3/</u>).

Figure 2 WHO/SAGE roadmap for Prioritizing Use of COVID-19 Vaccines in the context of limited supply and Community Transmission epidemiologic setting scenario

https://www.who.int/news/item/16-09-2020-who-sage-values-framework-for-the-allocation-andprioritization-of-covid-19-vaccination

WHO SAGE ROADMAP FOR PRIORITIZING USE OF COVID-19 VACCINES IN THE CONTEXT OF LIMITED SUPPLY nt Endorsed by SAGE and published Oct 20, 2020. **PUBLIC HEALTH STRATEGY FOR THIS SETTING: EPIDEMIOLOGIC SETTING SCENARIO:** Ø Direct reduction of morbidity and mortality 1-COMMUNITY TRANSMISSION An intenance of most critical essential services and 'reciprocity'. 🔥 Expansion of reduction in transmission to further reduce disruption of social and economic functions. STAGE (II) STAGE (III) VERY LIMITED AVAILABILITY LIMITED VACCINE AVAILABILITY **MODERATE VACCINE AVAILABILITY** 88688888 88888888888 (for 1-10% nat. pop.) (for 11-20% nat. pop.) (for 21-50% nat. pop.) **PRIORITY GROUPS: PRIORITY GROUPS: PRIORITY GROUPS:** • Stage Ia (initial launch): · Older adults not covered in Stage I • Remaining teachers and school staff - Health workers at high to very high risk • Individuals with comorbidities or health states Other essential workers outside health and education sectors of acquiring and transmitting infection. determined to be at significantly higher risk Pregnant Women of severe disease or death • Stage Ib Health workers at low to moderate risk of acquiring and - Older adults defined by age-based risk Sociodemographic groups at significantly higher transmitting infection specific to country/region risk of severe disease or death Personnel needed for vaccine production and other high-risk Health workers engaged in immunization delivery lab staff High priority teachers and school staff Social/employment groups at elevated risk of acquiring and transmitting infection because they are unable to effectively physically distance

E. Presentation of Evidence (MOH Epidemiological data)

A sample of 7,233 COVID-19 positive cases seen in various COVID-19 treatment facilities and aggregated in the national COVID-19 database at the Ministry of Health was used as a representative of the population with COVID-19 to help understand further details and inform the UNITAG discussions, conclusions and recommendations.

1.0 Distribution of COVID-19 cases

1.1 Overall distribution of COVID-19 cases by age:

An analysis of the sample reveals that the majority of COVID-19 cases are in the age-groups 20-29, 30-39, 40-49 and 50-59. Given the Uganda population age distribution, the age groups 60-69, 70-79, and 80+ have a substantially smaller representation in the general population, hence the observed number of cases in these age-groups is substantial when relative age-group population sizes are considered.

Uganda National Immunisation Technical Advisory Group COVID-19 Vaccine Allocation Report 2021 Figure 3 General distribution of COVID-19 by age-group



Figure 4 Distribution of COVID-19 cases by Sex



As per the figure above, males make up close to one quarter of COVID-19 cases (73%), while females make up 27% of cases.

1.2 Geographical Distribution of COVID-19 Cases

To foster a better understanding of which districts have the highest burden, a map showing distribution and frequency of confirmed cases across the country was drawn.





According to the data, seven (7) districts had registered a high case load (between 500 and 13,396) namely; Kampala, Wakiso, Luwero, Gulu, Mbarara, Kasese and Masaka.

Thirty (30) districts with a moderate case load are; 1) Mityana, 2) Kassanda, 3) Kalungu, 4) Kyotera, 5) Mukono, 6) Buikwe, 7) Jinja, 8) Iganga, 9) Namutumba, 10) Tororo, 11) Busia, 12) Mbale, 13) Bulambuli, 14) Moroto, 15) Kitgum, 16) Pader, 17) Soroti, 18) Kalaki, 19) Lira, 20) Amuru, 21) Adjumani, 22) Moyp, 23) Arua, 24) Kiryandongo, 25) Hoima, 26) Kikuube, 27) Isingiro, 28) Kabarole, 29) Kabale, 30) Kisoro Districts with a mild number of cases are: 1) Kanungu, 2) Ntungamo, 3) Shema, 4) Buhweju, 5) Kazo, 6) Kamwenge, 7) Bundibugyo, 8) Kagadi, 9) Lyantonde, 10) Mpigi, 11) Kayunga, 12) Buvuma, 13) Mayuge, 14) Kibuku, 15) Bududa, 16) Amudat, 17) Dokolo, 10) Apac, 19) Abim, 20) Agago, 21) Lamwo, 22) Omoro, 23) Obongi, 24) Yumbe, 25) Koboko and 26) Nebbi.

The rest of the districts have very few cases.

Uganda National Immunisation Technical Advisory Group COVID-19 Vaccine Allocation Report 2021 2.0 Comparing the characteristics of symptomatic and asymptomatic patients

2.1 Proportion of COVID-19 positive people that are asymptomatic: 36.3 % of registered cases with COVID-19 are symptomatic while 63.7% are asymptomatic. It follows then that the majority of COVID-19 infected people (close to two thirds) do not show any symptoms.

2.2 Distribution of symptomatic people by age-group

The overall age distribution of symptomatic people mirrors that of the overall distribution of cases, with most symptomatic people being in the age-groups 20-29, 30-39, 40-49 and 50-59. However, as indicated before, the age-groups 60-69, 70-79, and 80-89 have a substantially smaller representation in the general population, hence the observed number of symptomatic cases is substantial if the relative age-group population sizes are considered. Across all age-groups, the asymptomatic individuals are more than the symptomatic ones.



Figure 6 Distribution of Symptomatic/Assymptomatic COVID-19 cases by age category

Does the percentage of symptomatic people change across age-groups? Further analysis was undertaken to determine whether the percentage of symptomatic people differed between the age-groups.



Figure 7 Percentage of symptomatic cases by age-group

The findings show that although the percentage of symptomatic people seems to increase gradually, especially in the age-groups 30-39, 40-49, 50-59 and peaking at 60-69, the differences in percentage of symptomatic people do not seem to be substantial.

2.3 Which socio-demographic characteristics are associated with being symptomatic?

A cross-analysis of socio-demographic variables with symptomatic/asymptomatic status was conducted in order to gain early insights on whether there are some factors associated with the likelihood of being symptomatic when one acquires COVID-19.

Variable	Category Asymptomatic		Symptomatic		Risk	p-value	
		No	%	No	%		
Sex	М	3,393	74.3	1,842	70.7	1.00	
	F	1,175	25.7	765	29.3	1.19	0.001*
Age group	<20	236	5.2	132	5.1	1.00	
	20-29	827	18.2	400	15.5	0.86	0.243
	30-39	1,286	28.3	715	27.6	0.99	0.960
	40-49	935	20.6	578	22.3	1.10	0.408
	50-59	607	13.3	367	14.2	1.08	0.541
	60-69	317	6.9	219	8.5	1.24	0.131
	70-79	193	4.3	96	3.7	0.89	0.479
	80+	145	3.2	80	3.1	0.98	0.938
Occupation	-		-	-	-	-	-
	-		-	-	-	-	-
Residence	Rural	904	19.8	706	27.1	1.00	
	Urban	3,664	80.2	1901	72.9	0.67	<0.001*
Comorbidities	None	3,896	85.3	2,128	81.6	1.0	
	One	570	12.5	421	16.2	1.35	<0.001*
	>One	102	2.2	58	2.2	1.04	0.809
\mathbf{O}							
Comorbidities disaggregated							
Diabetes	Ν	530	84.6	399	58.4	1.00	
	Y	96	15.3	68	14.6	0.94	0.723
Hypertension	Ν	406	64.6	297	63.7	1.00	
	Y	223	35.5	169	36.3	1.04	0.781
HIV	Ν	435	71.8	347	74.8	1.00	
	Y	171	28.2	117	28.2	0.87	0.273
Chronic respiratory disease	N	612	91.1	434	90.6	1.00	
	Y	60	8.9	45	9.4	1.06	0.704
Chronic organ disease	N	357	53.1	232	48.4	1.0	
(Heart, Kidney, Liver, Stroke)	Y	315	46.9	247	51.8	1.21	0.117
Other chronic diseases	Ν	357	53.1	274	57.2	1.00	
	Y	315	46.9	205	42.8	0.84	0.117
Obesity	N	-	-	-	-	1.0	-
	Y	-	-	-	-	-	-

Table 2: Socio-demographic factors associated with being symptomatic among people with COVID-19

District		-	-	-	-	1.0	-
		-	-	-	-	-	-
	etc.						

From the data, three main factors are associated with developing symptoms when one has COVID-19: 1) Sex, and 2) Rural urban residence, and 3) Presence of comorbidities.

The data shows that although a substantial majority of COVID-19 cases are males, females are 1.2 times more likely to show symptoms compared to males, and the difference is statistically significant (p<0.001).

- People in urban areas are 33% less likely to show symptoms compared to those in rural areas
- People with one co-morbidity are 35% more likely to show symptoms compared to those without a co-morbidity

3.0 Comparing the characteristics of people who develop severe disease and those who do not develop severe disease

3.1 What percentage of COVID-19 infected people develop severe disease? Among 7,280 cases involved in this analysis, 664 (i.e., 9.1%) developed severe disease while 6,616 (90.9%) did not develop severe disease.



Figure 8 Distribution of people who developed severe disease by age-group

- The age-groups most affected by severe disease are 1) 80+ (where <u>one quarter</u> of cases develop severe disease), 2) 70-79 (where about <u>1 in 6 people</u> develop severe disease) and 3) 60-69 (where about <u>1 in 6 people</u> develop severe disease). These age-groups are therefore at a substantially high risk compared to the other age groups.
- The age-group 50-59 appears to be the age-band where severe disease takes an upturn, rising sharply from 1 in 16 people developing severe disease in this age-group to one in 6 people in the next age-group. Attention should therefore also be paid to this group

• For the age-groups 40-49 and 30-39, 1 in 20 people develops severe disease.

3.2 Who is more likely to develop severe COVID-19?

A cross-analysis of socio-demographic variables with severe/non-severe disease status was conducted in order to gain deeper insights on factors associated with developing severe disease. The findings are summarized in the table below. Statistical significance is considered at p<0.05.

Table 3: Socio-demographic factors associated with progression to severe disease among people with COVID-19

Variable	Category	Non-severe		Severe disease		Risk	p-value
		disease No	%	No	%		
Sex	M	4 898	74.0	270	58.2	1.00	
Sex	F	1,718	25.9	194	41.8	2.05	<0.001*
	•	1), 10	2010			2.00	.0.001
Age-group	<20	360	5.5	5	1.1	1.00	
	20-29	1,180	17.9	40	8.8	2.40	0.060
	30-39	1,888	28.7	84	18.5	3.20	0.012
	40-49	1,411	21.4	73	16.1	3.70	0.005
	50-59	898	13.6	58	12.8	4.60	0.001*
	60-69	451	6.9	83	18.3	13.2	<0.001*
	70-79	228	3.5	57	12.6	18.0	<0.001*
	80+	166	2.5	54	11.9	23.4	<0.000*
Occupation -	-		-	-	-	-	-
-	-		-	-	-	-	-
Residence	Rural	5,099	77.1	377	81.2	1.0	
	Urban	1,517	22.9	87	18.8	1.29	0.038*
Comorbidities	None	5,661	85.1	276	59.5	1.0	
	One	881	13.3	102	21.9	2.37	<0.001*
	>One	74	1.1	86	18.5	23.8	<0.001*
Comorbidities disaggregated		4.00	405	~ ~			
Diabetes	N	100	10.5	64	48.9	1.0	.0.001 *
	Y	854	89.5	6/	48.6	8.16	<0.001*
Hypertension	N	312	32.8	/6	55.9	1.0	.0.000*
	Y	639	67.2	60 22	44.1	2.59	<0.000*
HIV	N	264	27.8	22	19.6	1.0	0.000
Changie vooringten diegeee	Ŷ		72.2	90	80.4 10.0	0.64	0.068
Chronic respiratory disease	N	85 970	8.9	20	10.6	1.U 1.210	0.451
Chronic organ disease (Heart	Y NI	870	91.1	100	89.4 64.4	1.218	0.451
Kidnov, Liver, Stroke)	N V	430	45.0 64.6	121	04.4 25.6	1.U 2.14	<0.001*
Alley, Liver, Suluke) Other chronic diseases	T NI	121	04.0 12.0	07 100	55.0 57.4	2.14 1.0	<0.001 ·
	IN V	410 5/15	42.9 57 1	80 100	37.4 12.6	1.0 1.70	<0 001 *
Obesity	N	J4J	27.1	00	42.0	1.79	VU.UU1
Obesity	V					1.0	
District	I					1.0	
						1.0	

Based on the available data, several factors were found to be associated with progression to severe disease among people with confirmed COVID-19 including: 1) Sex, 2) Age, 3) Rural-Urban Residence, 4) having co-morbidities and 5) type of comorbidity.

- i. Females are 2 times more likely to develop severe disease (p<0.001); however, because the number of affected males is 3 times the number of affected females, the overall case-load for severely ill males is more than that for females.
- ii. People aged 60 years and above have a very high risk of developing severe disease. Compared to the youngest age-group (less than 20 years), the risk of developing severe disease is 23 times higher for people aged 80 and above, 18 times higher for people aged 70-79, and 13 times higher for people aged 60-69.
- iii. People aged 30-59 carry moderate risk of developing severe disease. Compared to the youngest age-group (less than 20 years), the risk of developing severe disease is 4.6 times higher for people aged 50-59, 3.7 times higher for people aged 40-49, and 3.2 times higher for people aged 30-39
- iv. People resident in urban areas are 1.3 times more likely to develop severe disease compared to rural dwellers and the difference is statistically significant (p=0.038); however, since the vast majority of cases are from rural areas, the absolute number of people with severe disease is much higher for the rural areas compared to the urban
- v. People with one comorbidity are 2.4 times more likely to develop severe disease compared to those with no comorbidity and the difference is statistically significant (p<0.001). However, the most substantial departure is among people with more than one comorbidity who are 24 times more likely to develop severe disease compared to those with no co-morbidity
- vi. Sub-group analysis among people with co-morbidities shows that people with diabetes are at the highest risk (8 times higher than those without diabetes), followed by those with hypertension (2.6 times higher than those without hypertension), followed by those with organ disease (heart/liver/kidney) (2 times higher than those without organ disease), and followed by those with other non-specified chronic conditions (1.8 times higher than those without other chronic conditions)
- vii. People with HIV and those with chronic respiratory illnesses did not appear to be at higher risk among people with co-morbidities

4.0 Comparing the characteristics of COVID-19 cases who die and those who survive

4.1 What percentage of COVID-19 infected people die?

4.9 % of the COVID patients involved in this analysis died while 95.1% survived (i.e., a case-fatality rate of 4.9%) which is substantial compared to global trends. These findings also imply that since 9.1% of all COVID-19 infected people develop severe disease, the percentage of those who develop severe disease that die is 53.8%.

4.2 Percentage of those who die by age-group

Uganda National Immunisation Technical Advisory Group COVID-19 Vaccine Allocation Report 2021 Figure 9 shows the distribution of case-fatality rates by age-group.

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Uganda National Immunisation Technical Advisory Group COVID-19 Vaccine Allocation Report 2021 Figure 9 Case Fatality Rate per Age group

- i. The data shows an increasing trend in case fatality from 0.04% among people aged less than 20 years to 7.3% among those aged 80+
- ii. A substantial up-turn in case fatality is observed between the age-group 50-59 and 60-69, rising from 1.6% in the former age-group to 4.2% in the age-group 60-69, and continuing its steady rise from then on to 6.8% in the age-group 70-79 and 7.3% for those aged 80 and above.
- iii. Therefore, the age-groups above 60 years have a substantially higher case-fatality rate compared to the younger age-groups
- iv. Of note too, the age-group 50-59 has a case-fatality rate that is above 1%; the other younger age-groups have a case-fatality lower than 1

4.3 Who is more likely to die from COVID-19?

A cross-analysis of socio-demographic variables with survival of COVID-19 was conducted in order to gain deeper insights on factors associated with dying from COVID-19. The findings are summarized in the table below. Statistical significance is considered at p<0.05.

Variable	Category	Survived	1	Di	ed	Risk	p-value
		No	%	No	%		
Sex	Μ	4,956	73.9	185	53.8	1.00	
	F	1,743	26.0	159	46.2	2.44	<0.001*
Age-group	<20	358	5.4	3	0.9	1.00	
	20-29	1,190	17.9	12	3.6	1.20	0.78 <mark>0</mark>
	30-39	1,927	28.9	39	11.6	2.42	0.14 <mark>0</mark>
	40-49	1,451	21.8	38	11.3	3.12	0.06 <mark>0</mark>
	50-59	903	13.6	48	14.3	6.34	<0.001*
	60-69	451	6.8	72	21.5	19.05	<0.001*
	70-79	231	3.5	56	16.7	28.92	<0.001*
	80+	154	2.3	67	20.0	51.92	<0.001*

Table 4: Socio-demographic factors associated with death among people with COVID-19

	etc.						
Residence	Rural	1,500	22.4	38	11.1	1.0	
	Urban	5,199	77.6	306	88.9	2.32	<0.001*
Comorbidities	None	5,726	85.5	194	56.4	1.0	
	One	901	13.4	70	20.3	2.29	<0.000*
	>One	72	1.1	80	23.3	32.79	<0.000*
Comorbidities disaggregated							
Diabetes	Ν	874	89.8	34	36.9	1.0	
	Y	99	10.1	58	63.0	15.06	<0.001*
Hypertension	Ν	653	67.1	34	36.2	1.0	
	Y	320	32.9	60	63.4	3.63	<0.001*
HIV	Ν	713	73.3	47	68.1	1.0	
	Y	260	26.7	22	31.9	1.28	0.352
Chronic respiratory disease	Ν	889	91.4	131	87.3	1.0	
	Y	84	8.6	19	12.7	1.53	0.113
Chronic organ disease (Heart,	Ν	521	53.6	55	36.7	1.0	
Kidney, Liver, Stroke)	Y	452	46.5	95	63.3	1.99	<0.001*
Other chronic diseases	Ν	567	58.3	52	34.7	1.0	
	Y	406	41.7	98	65.3	2.63	<0.000*
Obesity	Ν						
	Y						
District			-				
	etc.						

The epidemiological picture for likelihood of dying from COVID-19 mirrors that for likelihood of developing severe disease.

Based on the available data, the factors found to be associated with death or survival among people with confirmed COVID-19 are: 1) Sex, 2) Age, 3) Rural-Urban Residence, 4) having co-morbidities and 5) type of comorbidity.

- Females are 2.4 times more likely to die (p<0.001) compared to males; however as noted before, because the number of affected males is 3 times the number of affected females, the overall deaths among males are more than those for females.
- People aged 60 years and above have a very high risk of dying from the disease. Compared to the youngest age-group (less than 20 years), the risk of dying from COVID-19 is 59 times higher for people aged 80+, 29 times higher for people aged 70-79, and 19 times higher for people aged 60-69.
- People aged 30-69 carry moderate risk of dying from the disease. Compared to the youngest agegroup (less than 20 years), the risk of dying from COVID-19 is 6.3 times higher for people aged 50-59, 3.9 times higher for people aged 40-49, and 2.4 times higher for people aged 30-39
- People resident in urban areas are 2.3 times more likely to die from COVID-19 compared to rural dwellers and the difference is statistically significant (p<0.001); however, since the larger majority of cases are from rural areas, the absolute number of people who die is much higher for the rural areas compared to the urban
- People with one comorbidity are 2.3 times more likely to die from COVID-19 compared to those with no comorbidity and the difference is statistically significant (p<0.001). However, the most

substantial departure is among people with more than one comorbidity who are 33 times more likely to die from COVID-19 compared to those with no co-morbidity

- Sub-group analysis among people with co-morbidities shows that people with diabetes are at the highest risk of dying from COVID-19 (15 times higher than those without diabetes), followed by those with hypertension (3.6 times higher than those without hypertension), followed by those with other non-specified chronic conditions (2.6 times higher than those without other chronic conditions), and followed by those with organ disease (heart/liver/kidney) (2 times higher than those without organ disease)
- People with HIV and those with chronic respiratory illnesses did not appear to be at higher risk of dying among people with co-morbidities

F. Conclusions and Recommendations

1.0 Uganda Specific goals for COVID-19 Vaccine Introduction

Overall Goal: Promotion and protection of health, safety and wellbeing of population that is premised on the ethical principle of human wellbeing.

Short term (acute end of the pandemic) goals: To reduce death and severe disease from SAR-CoV-2 guided by the ethical principle of human wellbeing and the right to life

To protect the health system which aligns with the principle of reciprocity of Health Care Workers and human wellbeing as well as the protection of life for the sick.

Medium-term goal: To protect the continuing functioning of essential services, including health services in the midst of the epi/pandemic justified by the principle of human well-being.

Long term goal: To reduce societal and economic disruptions and reduce transmission of SARS-COV-2 justified by the principle of human wellbeing.

2.0 Uganda specific Values Framework

The guiding values principles of Uganda COVID-19 Vaccine allocation framework, as suggested, adopts and tailors the WHO/SAGE values principles to the ethical challenges at hand in Uganda. Four additional values are included which are derived from the Uganda National Ethics Policy, Ministry of Health values, and UNESCO Bioethics Principles to which Uganda is member country.

The overall guiding value principles of the Uganda COVID-19 Vaccine allocation framework is contextualized to adopt WHO/SAGE value principles with additions of four ethical values as outlined on Table 5.

Value	Goal	Objectives	Application
Principle			
Stewardship	Maintain good governance and management of limited resources.	Ensure that the ethical challenges posed by public health action in SAR- CoV-2 response are addressed systematically and fairly by those who deliver the services at national, local and practice levels.	Provide financial, technical and social support to those involved in management of COVID- 19 challenges.
		Ensure that SAR-CoV-2 response mechanisms are applied in accountable and transparent manner.	Create mechanisms for dissuading corruption tendencies and provide a system for incentives and

Table 5 Additional Value Principles for Uganda COVID Vaccine allocation guidance

			reward for satisfactory work. Separate responsibilities for effective outcomes
		Ensure clear and effective communication of all policies and procedures for SAR-CoV-2 responses.	Create effective communication channels between and among health care providers.
Vulnerability	Equity in accessing vaccines by those in vulnerable conditions.	Prioritize the welfare of those in vulnerable conditions and high risk of SAR-CoV-2, such as the poor, children, prisoners, disabilities, co-morbidities, those in gender inequality; and, be inspired by retrospective analysis of epidemiological data in decision- making.	Identify persons in conditions of heightened susceptibility due to their conditions of vulnerability.
		Ensure inclusiveness in vaccine distribution and use.	Include persons in vulnerable conditions in dialogue regarding vaccine distribution and use.
Social	Build Trust	Ensure that community engagement	Develop community
responsibility	and Empower Community.	Ensure there are adequate communication platforms and tools to facilitate health authority communication with the public on vaccines	Develop adequate communication platforms and tools.
		Assure the public of openness.	Engage communities early enough in genuine dialogue.
		Assure the public of transparency.	Communicate to the public who is responsible
	nj,	Assure the public of accountability.	for decision-making and implementation at different levels; and how they can engage in dialogue regarding those
Scientific	Evidence	Public assurance that health and social	Put in place systems for
Integrity	Informed Decision Making	policies are based on solid scientific evidence, taking into account the uncertainties associated with pandemic outbreaks.	collecting, analysing, and disseminating scientific data.
		Counter false information in a timely manner.	Establish information systems for swift countering of false information.
		Ensure that major policy and health decisions are arrived at through interdisciplinary dialogue among scientists, ethicists, political actors, among others.	Establish interdisciplinary and pluralistic advisory committees.

Strengthen and ensure resilience of public health systems.	Provide adequate funding for strengthening public health systems
Ensure research complies with responsible research practices.	Support the accelerated review and approval of research protocols by ethics reviews committees.

2.0 Proposed Vaccine Prioritisation and Allocation groups

The proposed priority groups under stage 1 covers 3% of the population (approx. 1.35 million people based on a projected total population figure of 45 million people in Uganda). This group includes those at highest risk of exposure and transmission of COVID-19, and essential workers performing tasks crucial for socio-economic functioning and wellbeing.

2.1 Priority group 1a. Health workers

Top 3% (approx. 1.35 million out of a projected total population of 45 Million)

1a All Health Care Workers at front line health service delivery within a Health Facility because they are at very high risk of acquiring and transmitting infection.

This was based on the **value principles of reciprocity** (as they put their lives at risk to take care of the sick), and that of **human wellbeing**, as the sick need them for treatment and recovery.

Health Workers* were defined to include are both medical and auxiliary (other people within the HF that provide support services and whose work brings them into contact with patients e.g., cleaners, drivers, security guards, chefs, hospital chaplains, psychologists) workers and trainees in contact with patients within a Health Facility.

Health Facility* is inclusive of all Public Health facilities, Public Not For-Profit (PNFPs) facilities, and Private For-Profit facilities.

(*registered Health Facility and registered Health worker)

In event of very limited supplies (1-2%), the following should be prioritized in the list order:

i. Health Care Workers including trainees and auxiliary workers directly involved in treatment of COVID-19 patients,

ii. Health Care Workers who come into close contact with other patients (emergency care, inpatient services,)

iii. Health Care Workers who came into regular contact with patients (outpatient, immunisation) and Surveillance workers incl. contact tracers, Point of Entry workers

In event of extremely limited supplies (less than 1%), considerations of districts with highest case load should precede other districts.

Number Estimates of health workers in Uganda:

The respective excel sheets show the staffing levels for MoH, National Specialized Institutions, NRHs, RRHs, PNFP, GHs, HC IVs, HC IIIs, HC IIs, City Health Offices, Municipal Council Health Offices, Health Offices, Town Council Health Offices, Uganda Prison Services, Uganda Police Force, central level contract staff, decentralized contact staff and emergency staff recruited to combat the COVID 19 pandemic. (MoH 2020b, Human Resource Audit (unpublished))

Uganda National Immunisation Technical Advisory Group COVID-19 Vaccine Allocation Report 2021 Table 6 Number of registered health workers in Uganda

#	Type of Institution or Facility	No. of Facilities or Institutions	Approved No. of Staff	Existing No. of Staff	Vacant Positions	Excess Staff	% Filled	% Vacant
1	Ministry of Health	1	645	495	150	0	77	23
2	National Referral Hospitals	5	5294	3406	1888	0	64	36
3	Specialised Institutions	5	1970	1009	961	0	51	49
4	Regional Referral Hospital	14	5422	3748	1674	0	69	31
13	Medical Bureau (PNFP)	473	18203	15080	3123	0	83	17
5	City Health Office	7	42	55	7	10	131	0
6	District Health Office	135	1080	1204	0	124	111	0
7	General Hospital	44	8360	6285	2075	0	75	25
	HCIV	174	8352	7545	807	0	90	10
9	HCIII	1027	19513	15725	3788	0	81	19
8	HCII	1663	14967	8405	6562	0	56	44
11	Municipal Health Office	30	180	173	0	0	96	0
12	Town Council Health Office	100	300	153	147	0	51	49
	Total	3,678	84,328	63,283	21,182	134	75	25
	Contract Staff	No. of Staff						
1	COVID 19	546						
2	PEPFAR Central level	648						
2	PEPFAR Seconded (Decentralised)	172						
	Total	1,366						

Grand Total 85, 694

Source: Ministry of Health Human Resource Audit 2019/2020 report (unpublished).

1b Adult populations

Basing on the epidemiological data, adults aged 60yrs and over were found to be at highest risk of severe disease and death from COVID-19. UNITAG therefore recommended prioritizing all adults **aged 60yrs and over** for vaccination.

This was based on value-principles of human wellbeing, securing safety and health of all those mostly at high risk of morbidity and mortality, and mitigating vulnerability.

In event of very limited doses (< 1-2%) priority should be given those people with comorbidities (diabetes, hypertension, organ disease and other chronic illnesses) who should be considered in the following order:

i. 60yrs+ who have multiple co-morbidities,

- ii. all below 60yrs but with multiple comorbidities,
- iii. all people with diabetes (data shows it's a major high-risk comorbidity),
- iv. 60yrs+ with one comorbidity,
- v. 60yrs+ in districts with highest number of cases

Number Estimates: Prevalence of diabetes in Uganda is 1.4% (Bahendeka, S., et al., 2016).

Projections of 60 yrs+ in 2021 is approx. 1.6 mil (UBOS, 2019)

UNITAG created a third category in this group:

1c Essential workers

Other essential workers providing non health services in high-risk populations for example spiritual leaders, teachers, airline workers, prison warders, and key security forces. At the time of this report, no occupation categorised epidemiological data had been availed to the committee, and these groups were considered because the nature of their essential work brings them in contact with people who may be infected.

The value principles considered were: Human wellbeing, protection continuing function of essential services including the economy and social, and maximisation of benefit of vaccines with goal of saving the most lives.

Number estimates:

The number of **prison warders** is **9,146** as reported under vote 145 of prisons in the Ministry of Finance policy statement FY 2019/20. Under section 3: Staff recruitment and training. <u>https://budget.go.ug/sites/default/files/Sector%20Spending%20Agency%20Budgets%20and%20Pe</u> <u>rformance/2019-2020 VoteMPS 145 UgandaPrisons 3 29 20191 00 00PM.pdf</u>

The number of **teachers** at **pre-primary level** stands **23,699**, **primary level** teachers at **207,238** and **secondary school** teachers at **64,966** giving a **total** of **295,903**(MoES,2017). http://www.education.go.ug/wp-content/uploads/2019/08/Abstract-2017.pdf

Special Notes

It is to be noted that the recommended population groups **cover all people within Uganda**, including refugees and non-Ugandans living in Uganda under the value-principles of equal respect, and equity.

UNITAG also notes that this is an **interim recommendation** based on evidence available to it at the time, and could be revised over time as the situation changes and in case of new evidence coming to light.

UNITAG also notes it concern for potential supply of **COVID-19 vaccine in the private sector** without a formal framework for Ministry of Health oversight, and recommends that a framework be drawn by the Ministry of Health to minimise any negative outcomes from such an exercise.

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Annex

Ministry of Health Request for Advice letter

Telephone: General Lines: 256 - 417 - 712260 Permanent Secretary's Office: 256 - 417 - 712221

E-mail: <u>ps@health.go.ag</u> Website: <u>www.health.go.ug</u>

IN ANY CORRESPONDENCE ON THIS SUBJECT PLEASE QUOTE NO. ADM:105/309/23



Ministry of Health P. O. Box 7272 Plot 6, Lourdel

Wandegeya KAMPALA UGANDA

THE REPUBLIC OF UGANDA

3rd November, 2020

Dr. Nelson Sewankambo, Chairperson for NITAG, Uganda.

INTRODUCTION OF VACCINE(S) AGAINST SEVERE ACUTE RESPIRATORY SYNDROME CORONA VIRUS 2 (SARS-CoV-2)

In response to the coronavirus disease 2019 (COVID-19) pandemic and the societal disruptions it has brought, national governments and international community have invested in the development of safe and effective vaccines. Although subject to various uncertainties, mass vaccination against this novel coronavirus, offers the possibility of significantly reducing transmission and severe morbidity and mortality beyond what might be accomplished solely through nonpharmaceutical interventions, better diagnostic tests and improved therapies.

However, even if one or more safe and effective COVID-19 vaccines from those under development were to be prequalified and approved for use by WHO, they are unlikely to be available in amounts sufficient to vaccinate the entire population. In this context, scarce vaccines will need to be allocated in ways that reduce morbidity and mortality, and reduce SARS-CoV-2 transmission in order to control the pandemic.

This is therefore to request UNITAG to review contextually relevant evidence, and in light of global guidance and recommendations provided by WHO, and advice Ministry of Health on:

- a) An allocation framework and criteria to be used to prioritise vaccine recipients in the initial phase of the vaccine scarce supply
- b) Vaccine selection in the event that more than one vaccine is prequalified and approved for use by WHO
- c) What steps should be taken to mitigate vaccine hesitancy to COVID-19 vaccines, especially among high priority populations and most appropriate methods for communication

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Your advice within the next six weeks will be highly appreciated. The Ministry of Health will also appreciate to receive regular advice as new information comes in regarding COVID -19 vaccine candidates.

Yours Sincerely,

Dr. Henry G. Mwebesa DIRECTOR GENERAL HEALTH SERVICES

Cc: The Hon. Minister of Health

Cc: The Hon. Minister of Health for Primary Health care

Cc: The Hon. Minister of Health for General Duties

Cc: The Permanent Secretary, Ministry of Health

Cc: The Director Health Services, Clinical and Community

Cc: Commissioner Health Services, National Disease Control

Cc: The Program Manager, UNEPI