NATIONAL DEPLOYMENT AND VACCINATION PLAN FOR COVID-19 VACCINE

ADDENDUM 1

National Immunization Advisory Committee approval: 02 November 2021
National Immunization Committee endorsement: 26 November 2021

Government of Nepal
Ministry of Health and Population
Department of Health Services
Kathmandu
Nepal

Government of Nepal
Ministry of Health & Population
Department of Health Service
Teku, Kathmandu

National Deployment and Vaccination Plan for COVID-19 Vaccine, Nepal

Addendum 1. NDVP update dated 02 November 2021

Nepal's National Deployment and Vaccination Plan for COVID-19 Vaccine (NDVP) has the strategy and plans to vaccinate 71.62% population of Nepal (≥ 15 years population; 21,756,763). The NDVP was submitted to WHO (COVID-19 platform) on 8 February 2021 and it was fully cleared by the Regional Review Committee to receive vaccines for both 3% and the remaining 17% out of the total targeted 20% of the population to be supported to Nepal by COVAX Facility through fully subsidized mechanism.

Nepal started the COVID-19 vaccination program on 27 January 2021 after receiving COVISHIELD / SII vaccine as grant support from the Government of India. So far, with the vaccines received from COVAX facility, donations and Government of Nepal's own procurement, Nepal has already delivered more than 15.9 million doses of COVID-19 vaccine using three different types of vaccines (COVISHIELD and AstraZeneca, Sinopharm BIBP, and Johnson & Johnson) and has been able to fully vaccinate 24% of its population.

With this achievement and the vaccines in expected pipeline, Nepal has already crossed Stage I and II, and reached Stage III (moderate vaccine availability, for 21–50% of national population) of the *WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supply*. The utilized and vaccines in expected pipeline (both COVAX and non-COVAX) are adequate to cover population more than initially envisaged in the NDVP. There are now vaccines available for use in the adolescent population (12 – 17 years of age; Pfizer BioNTech and Moderna vaccine which are based on mRNA platform). Further, other new vaccines maybe available soon for use in the younger population.

Based on the vaccine available that can be used for population ≥ 18 years of age so far, the target of vaccination achievement of the Government of Nepal is as follows:

1. By 17 October 2021 (end Ashwin 2078), vaccinate 33% of ≥ 18 years of age population (6,574,315)
    a. Status: already achieved.
2. By 14 January 2022 (end Poush 2078), vaccinate 66% of ≥ 18 years of age population (13,148,629)
    a. Status: as of 01 November 2021 (15 Kartik 2078), 44% vaccinated with first dose, and 36% fully vaccinated.
3. By 13 April 2022 (end Chaitra 2078), vaccinate 100% of the ≥ 18 years of age population (19,922,164).

Due to the vaccine availability and vaccination coverages being achieved progressively (and reaching Stage III of prioritization roadmap), it is now essential for the COVID-19 Vaccination

Program to plan for implementing vaccination for 12-17 years age population, as well as to initiate planning for resources requirement for the future anticipated target group vaccination.

Therefore, this addendum is prepared as an update of the NDVP. The core principle of COVID-19 vaccination program of Nepal is still to protect the vulnerable population and reduce mortality and morbidity due to COVID-19 as envisaged in the NDVP.

Updates in this Addendum:

1. Vaccination for 12-17 years age population of Nepal
2. Accelerating vaccination for population ≥ 18 years of age
3. Vaccination for pregnant population
4. Vaccination recognition for incoming travelers to Nepal
5. COVID-19 vaccine projection for future anticipated target groups

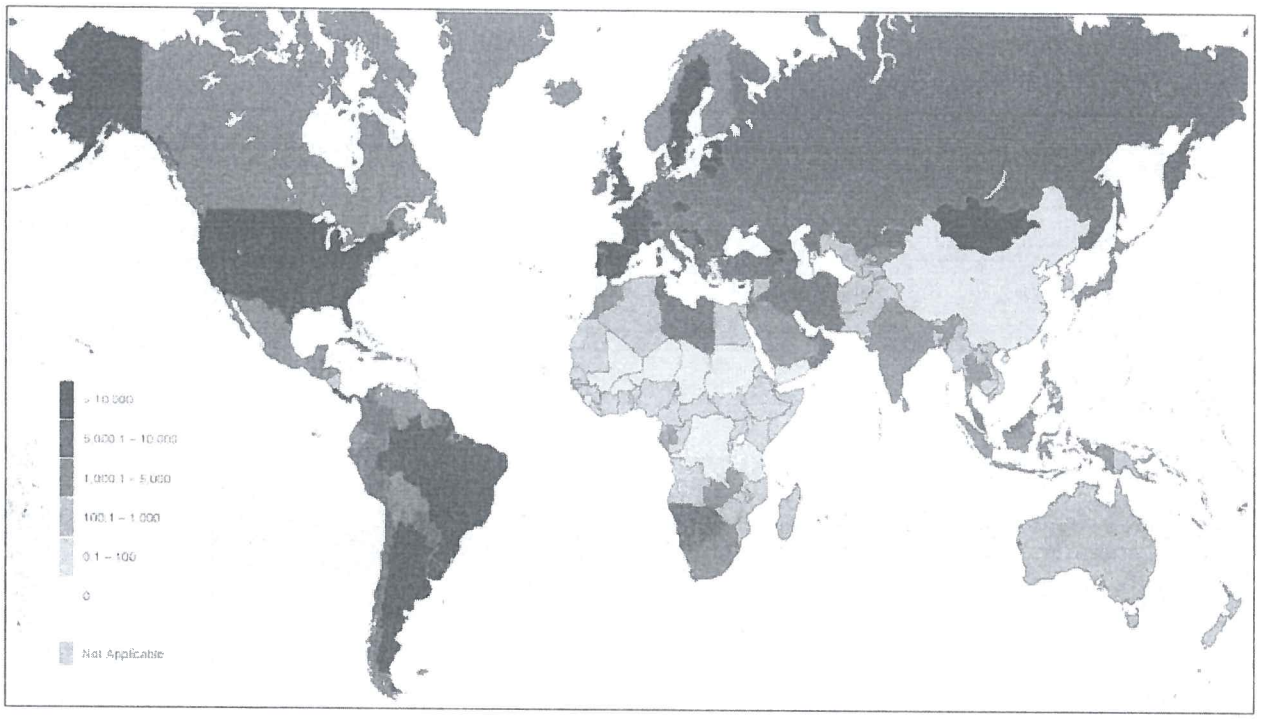
Note:

Based on the evolving epidemiological situation, country and program need, scientific developments and evidence availability, evidence and recommendation on need of extended primary series, booster doses and mix and match of vaccines, findings of the review of the COVID-19 vaccination program (mini-PIE and/or PIE, review), costing and resource needs, WHO SAGE recommendations, National Immunization Advisory Committee recommendations, etc., the NDVP will be further updated with additional Addendums when required.

COVID-19 Situation

As of November 2021, the COVID-19 pandemic caused by SARS-CoV-2 continues. Globally, as of 9:32am CET, 1 November 2021, there have been 246,357,468 confirmed cases of COVID-19, including 4,995,412 deaths (Fig 1). [1] This may be an under representation of true fatality of the COVID-19 pandemic, as the study by WHO suggests that the total number of global deaths attributable to the COVID-19 pandemic in 2020 is at least 3 million, representing 1.2 million more deaths than officially reported.[2] This is an underreporting by 40%.

Figure 1. Global map showing COVID-19 cases per 100,000 population by country[1]



In Nepal, as of 01 November 2021, a total 907,638 cases and 11, 416 deaths (CFR 1.4%) have been reported. A total of 792,277 cases have recovered, whereas there are 9318 active cases[3].

Since the start of the pandemic in Nepal in March 2020, Nepal has had two major waves of the pandemic (Fig. 2). The CFR of ≥ 1 in Wave 1, as noted in the NDVP, was from age 55 years and above. Among total cases combined in Wave 1 and Wave 2, and in Wave 2 alone, this has shifted down to 40 years of age and above (Fig. 3). This shows that the CFR is increasing in the younger age groups compared to initial 55 years age cut-off for high-risk population. Nepal has already started vaccination to the population below 40 years of age, with 22 out of 77 districts currently having ongoing vaccination for under 40 years population after

[1] WHO Coronavirus (COVID-19) Dashboard; https://covid19.who.int/

[2] The true death toll of COVID-19, Estimating global excess mortality; https://www.who.int/data/stories/the-true-death-toll-of-covid-19-estimating-global-excess-mortality

[3] Health sector response to COVID-19, SitRep #631, Ministry of Health and Population, Government of Nepal

having completed vaccination for above 40 years population. Therefore, it is essential now to plan simultaneously for 12-17 years age population vaccination.

Figure 2. Daily new positive and recovered COVID-19 cases in Nepal, Wave 1 and 2

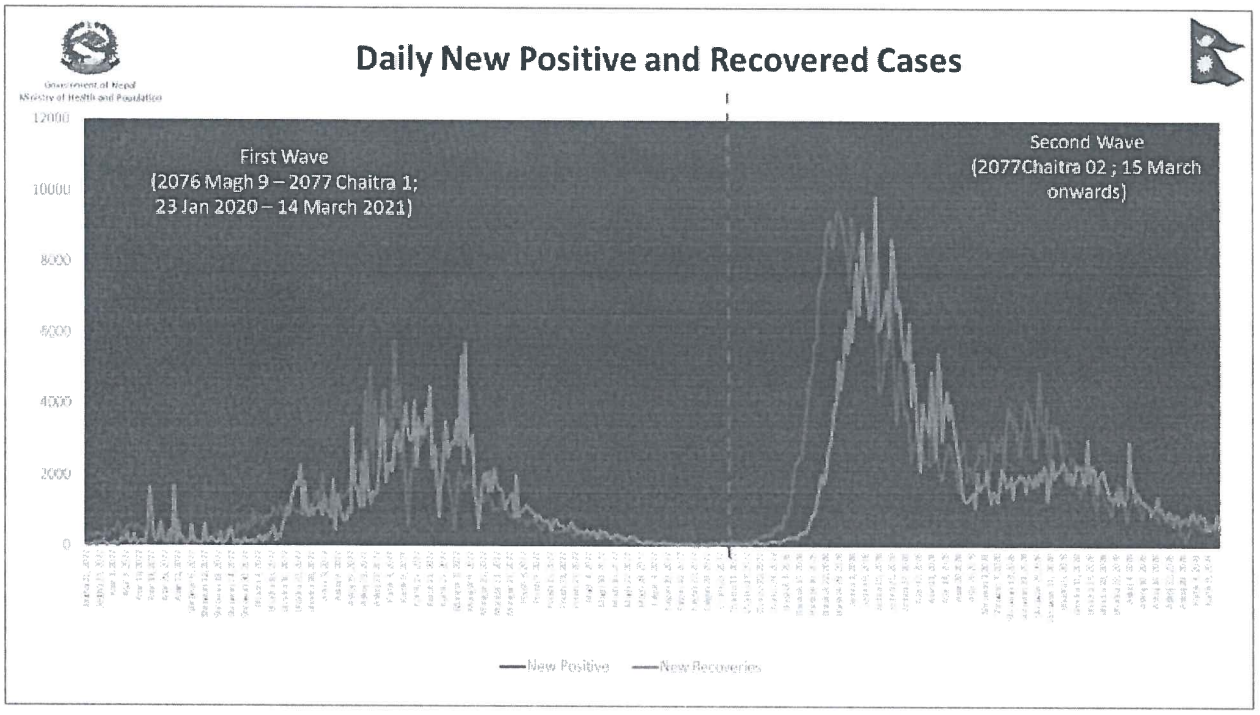
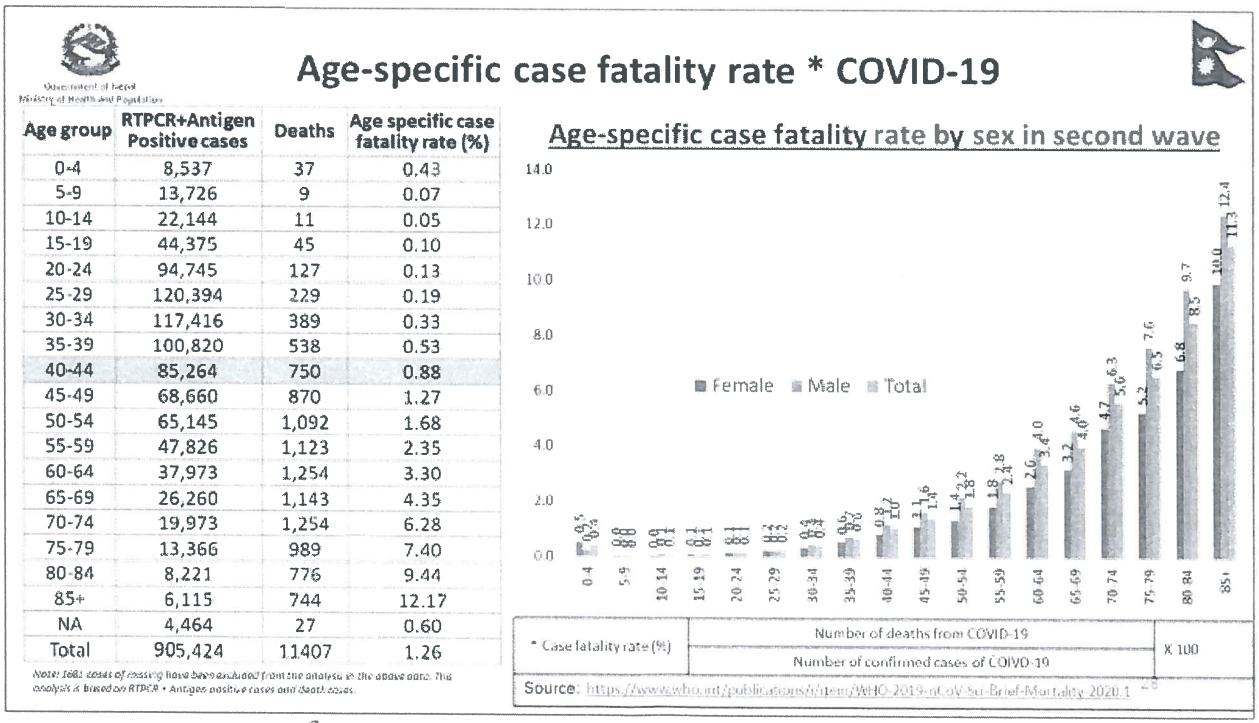


Figure 3. Age specific case fatality ratio of COVID-19 in Nepal, as of 31 October 2021



Age group	RTPCR+Antigen Positive cases	Deaths	Age specific case fatality rate (%)
0-4	8,537	37	0.43
5-9	13,726	9	0.07
10-14	22,144	11	0.05
15-19	44,375	45	0.10
20-24	94,745	127	0.13
25-29	120,394	229	0.19
30-34	117,416	389	0.33
35-39	100,820	538	0.53
40-44	85,264	750	0.88
45-49	68,660	870	1.27
50-54	65,145	1,092	1.68
55-59	47,826	1,123	2.35
60-64	37,973	1,254	3.30
65-69	26,260	1,143	4.35
70-74	19,973	1,254	6.28
75-79	13,366	989	7.40
80-84	8,221	776	9.44
85+	6,115	744	12.17
NA	4,464	27	0.60
Total	905,424	11407	1.26

Note: 168 cases of missing have been excluded from the analysis in the above data. The analysis is based on RTPCR + Antigen positive cases and death cases.

COVID-19 Vaccination Status

As of 28 October 2021, a total of 6,838,727,352 vaccine doses have been administered globally.[1]

Detail 1. COVID-19 vaccines with WHO EUL, as of 1 November 2021

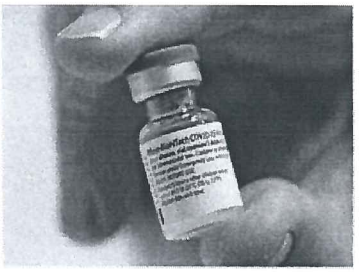
COVID-19 vaccines: WHO Emergency Use Listing (EUL)

- **31 Dec 2020**
  - BNT162b2 / Tozinameran – COVID-19 mRNA vaccine (nucleoside modified) – COMIRNATY®, **Pfizer/BioNTech**
- **15 Feb 2021**
  - **Two versions of the AstraZeneca/Oxford COVID-19 vaccine**, AZD1222 / COVID-19 Vaccine (ChAdOx1-S [recombinant]) produced by AstraZeneca-**SKBio** (Republic of Korea) and the **Serum Institute** of India (COVISHIELD™).
  - AZ/EU 16 April, AZ/MHLW (Japan) 9 July , AZ/TGA (Australia) 9 July 2021
- **12 Mar 2021**
  - **Janssen**–Cilag International NV (Belgium) COVID-19 Vaccine (Ad26.COV2-S [recombinant]), non-replicating Ad26 vectored vaccine encoding the S protein
- **30 Apr 2021**
  - COVID-19 mRNA Vaccine (nucleoside modified), **Moderna** Biotech
- **07 May 2021**
  - SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)], produced in Vero cells, **Sinopharm**, China
- **01 June 2021**
  - COVID-19 Vaccine (Vero Cell), Inactivated, **CoronaVac, Sinovac** Life Sciences Co., Ltd., China

NOTE: FOR THE EUL SITES OF EACH VACCINE WITH EUL, THE FOLLOWING LINK SHOULD BE VISITED

Information on COVID-19 vaccines WHO EUL available at:

https://extranet.who.int/pqweb/vaccines/vaccines-covid-19-vaccine-eul-issued

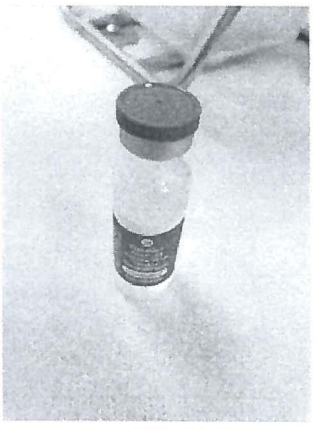


Pfizer-BioNTech COVID-19 vaccine

Detail 2. COVID-19 vaccine with EUA in Nepal, as of 1 November 2021

COVID-19 vaccines: NEPAL NRA EUA

- Drugs (3rd Amendment) Ordinance, 2077 (2020) was issued by the Rt. Hon'ble President upon recommendation of the Council of Ministers in Nov 2020 to amend the Drug Act 1978 (2035 BS) which now allows for EUA of vaccines and drugs in the context of the COVID-19 pandemic.
- DDA, Nepal's NRA has provided EUA for the following till date:
  - ChAdOx1 nCOV-19 Corona Virus Vaccine (Recombinant), **COVISHIELD** on 15 January 2021
  - SARS-CoV-2 Vaccine (Vero Cell), Inactivated, BIBP, **Sinopharm** on 17 February 2021
  - Whole Virion Inactivated Corona Virus Vaccine, (BBV152), **COVAXIN** on 19 March 2021
  - Gam-COVID-Vac Combination vector vaccine (**Sputnik V**) on 20 April 2021
  - COVID-19 vaccine (Vero Cell), Inactivated (**CoronaVac**) on 04 June 2021
  - **Astra Zeneca** AZD1222 and SK Biosciences on 30 June 2021; Japan and Australia manufacturing sites EUA added on 16 July 2021
  - COVID-19 Vaccine AD26COV2.S (Recombinant) by **Janssen** on 30 June 2021
  - **Pfizer-BioNTech** COVID-19 mRNA vaccine (COMIRNATY) on 09 September 2021
  - **Moderna** COVID-19 mRNA Vaccine on 15 September 2021



COVISHIELD™, SII

Six vaccines (including COVISHIELD and AstraZeneca/AZ as one) have received WHO emergency use listing (EUL) (Detail 1), and nine vaccines have received emergency use authorization (EUA) in Nepal (Detail 2) granted by the Department of Drug Administration, Ministry of Health and Population, Nepal. Out of these, 4 vaccines (COVISHIELD, AZ, Sinopharm BIBP, and Johnson & Johnson) have been used in Nepal, and currently Nepal is planning to implement Pfizer BioNTech vaccine starting from 14 November 2021 from the vaccine received from COVAX as dose-sharing donation from the US Government. The preparation and training (in-person training) to all levels and all 24 designated hospitals to provide the Pfizer BioNTech vaccine has been completed and the received vaccines have already been stored at ultra-low temperature (ULT) freezers at the Central Vaccine Store.

COVID-19 vaccination program of Nepal has so far administered 15.9 million doses fully vaccinating 24% of the total population (Detail 3). With the principle of leaving no one behind and protecting the vulnerable, Nepal has administered vaccines to high risk and vulnerable population including health care workers, elderly population, front-line workers, refugees, differently abled persons, staff and residents of elderly care homes, prisoners, as well the population of geographically very hard to reach areas.

Detail 3. COVID-19 vaccination coverage, Nepal, as of 1 November 2021.

COVID-19 vaccination coverage, 1 Nov 2021

Type of vaccine	1st dose	2nd dose	Total	Percentage
Covishield	1,940,094	524,659	2,464,753	15%
ChAdOx-1 Recombinant (AZ)	942,807	1,134,248	2,077,055	13%
Vero Cell, Sinopharm	5,787,123	4,050,881	9,838,004	62%
Johnson & Johnson	1,538,766		1,538,766	10%
Total	8,670,024	7,248,554	15,918,578	100%
Coverage on the current national target for vaccination (≥18 years)	44%	36%		
Coverage on total population	29%	24%		

Vaccination for 12-17 years age population of Nepal

Disease burden and vaccination coverage achievements have been discussed in the above section. With the achievement in COVID-19 vaccination coverage and the vaccines in

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expected pipeline, Nepal has already reached Stage III of the prioritization roadmap (moderate vaccine availability, for 21–50% of national population, Detail 4) of the *WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supply*. The utilized and vaccines in expected pipeline (both COVAX and non-COVAX) are adequate to cover population more than initially envisaged in the NDVP.

There are now vaccines available for use in adolescent population 12 – 17 years of age (Pfizer BioNTech and Moderna vaccine based on mRNA platform). Further, other new vaccines maybe available for use in younger population in the near future. Even though the COVID-19 Vaccination Program currently is in Stage III of the prioritization roadmap, some of the target populations recommended in Stage III such as the *remaining* teachers, essential workers, health care workers have already been vaccinated in Nepal. Therefore, while in Stage III, it is important to plan beyond Stage III. Of the 12-17 years age group, 15 years and above age group was already in the initial plan of the NDVP.

Pfizer BioNTech vaccine has already received EUA in Nepal for use in population 12 years and above. It is expected that Moderna vaccine will also receive EUA for use in population 12-17 years in Nepal (EUA for ≥ 18 years already received) based on WHO EUL.

Detail 4. WHO SAGE prioritization road map for COVID-19 vaccine use, Stage III[4]

Table 1. Epidemiological setting and vaccine supply scenarios, and recommendations for priority use of vaccines against COVID-19 in the context of limited supply[a,b]

(a) Epidemiological setting: community transmission – defined in Legend 2

Overall public health strategy for this epidemiological setting: Initial focus on direct reduction of morbidity and mortality, maintenance of most critical essential services and reciprocity. Expand for further reduction of mortality and morbidity and to contribute to reduction in transmission, to reduce disruption of social and economic functions. **(A1) (A2) (A3) (B1) (B2) (C1) (C2) (D1)** – labels explained in Legend 1

Vaccine supply scenario	Priority-use groups
Stage III (moderate vaccine availability, for 21–50% of national population)	• Seafarers and air crews who work on vessels that carry goods and no passengers, with special attention to seafarers who are stranded at sea and prevented from crossing international borders for crew change due to travel restrictions (S7) (A2) (A3) (B1) (C1) (D1) • Remaining teachers and school staff (A2) (A3) (B1) (C1) (C2) • Other essential workers outside health and education sectors (examples: police officers, municipal services, child-care providers, agriculture and food workers, transportation workers, government workers essential to critical functioning of the state not covered by other categories) (A2) (A3) (D1) • Personnel needed for vaccine production and other high-risk laboratory staff (A1) (A2) (A3) (D1) • Health workers at *low risk* of acquiring and transmitting infection, as defined in Annex 2 (A1) (A3) (D1) • Social/employment groups at *elevated risk* of acquiring and transmitting infection because they are unable to effectively physically distance (depending on country context, examples may include: people living or working in detention facilities, incarcerated people, dormitories, low-income people in dense urban neighbourhoods; military personnel living in tight quarters; and people working in certain occupations, such as mining and meat processing) (A1) (B1) (B2) (C1) (C2)

Legend 1: Value objectives applied to priority-use groups

A. Maximizing
(A1) Reduce deaths and disease burden from the COVID-19 pandemic
(A2) Reduce societal and economic disruption (other than through reducing deaths and disease burden)
(A3) Protect the continuing functioning of essential services, including health services

B. Equal respect
(B1) Treat the interests of all individuals and groups with equal consideration as allocation and priority-setting decisions are being made and implemented
(B2) Offer a meaningful opportunity to be vaccinated to all individuals and groups who qualify under prioritization criteria

C. Equity
(C1) Ensure that vaccine prioritization policy decisions taken and actions the vulnerabilities, risks and needs of groups who, because of underlying societal, geographical or biomedical factors, are at risk of experiencing a greater burden from the COVID-19 pandemic

D. Reciprocity
(C2) Develop the immunization delivery systems and infrastructure required to ensure that priority-use populations have access to COVID-19 vaccines, and that everyone in a priority-use group has equal access, particularly socially disadvantaged populations
(D1) Protect those who bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others, including health and other essential workers

Therefore, vaccination of 12-17 years adolescent population is planned in this Addendum which is to be implemented achieving high coverage in ≥ 18 years population.

[4] WHO SAGE roadmap for prioritizing uses of COVID-19 vaccines in the context of limited supply, 16 July 2021 update

Vaccine needs and vaccination strategy

The 12-17 years population is 3,425,409 (CBS data). Therefore, with two doses vaccination schedule with 5% wastage rate, the total vaccine doses required is 7,193,359.

At an estimated price of US$ 10 per dose, the estimated budget required for vaccine procurement only is up to US$ 71,933,590 (~US$ 72 Million) excluding operational costs.

Note:

- Pfizer BioNTech vaccine BNT162b2 price[5]: US$ 19.5 (USA) – US$ 23.15 (EC; also $14.7); African Union: US$6.75, Tunisia: US$ 7
- Moderna vaccine mRNA-1273 price[5]: US$ 15 (USA) – US$ 37 (HICs)
- COVAX price or direct procurement by Nepal could be lower (estimated US$ 10)

Vaccination delivery strategy would be as outlined in the NDVP and will include (but not limited to) based on need, health facilities (80% of the 5188 health facilities provide fixed site routine immunization), routine outreach immunization sites (~16,000 sites per month provide routine outreach immunization) and the vaccination campaign immunization sites (>30,000 sites). Since the 12-17 years adolescent population will be in schools, immunization session sites for this target population will largely be in schools, but other fixed and outreach sites will also be conducted to cover missed and out-of-school population.

Cold chain capacity requirement (ultra-cold chain and super-cold chain)

The Pfizer BioNTech COVID-19 vaccine [Tozinameran – COVID-19 mRNA vaccine (nucleoside modified) – COMIRNATY®] has a shelf-life of 9 months at storage temperature of - 90°C to - 60°C (ultra-cold chain).[6] Stability data have demonstrated that once removed from freezer, the undiluted vaccine can be stored for up to 31 days at 2 °C to 8 °C, prior to use. Within the 9 months shelf-life unopened vials may be stored and transported at -25 °C to -15 °C for a single period of up to 2 weeks.[6]

The Moderna COVID-19 vaccine [COVID-19 mRNA vaccine (nucleoside modified), also known as trade name 'Spikevax' in some countries] has a shelf-life of 7 months at storage temperature of -25 °C to -15 °C (super-cold chain). Within the 7 months of shelf life, the vaccine can be stored 30 days at 2-8°C.[7]

To limit logistics, cold-chain capacity and transport challenges, these vaccines will be stored at ultra-cold chain or super-cold chain (as applicable) only at central level (Central Vaccine Store). At sub-national level, the vaccine will be transported to and stored at 2-8°C. Based on program experience till now, the vaccine can be utilized within the given one-month period at

[5] COVID-19 Vaccine Market Dashboard, UNICEF; https://www.unicef.org/supply/covid-19-vaccine-market-dashboard

[6] WHO recommendation BioNTech Tozinameran – COVID-19 mRNA vaccine (nucleoside modified) – COMIRNATY®

[7] WHO recommendation Moderna COVID-19 mRNA Vaccine (nucleoside modified)

2-8°C. This will be ensured with continuous monitoring and phased supply to the sub-national level as per utilization and cold chain capacity.

Considering that only a maximum of 2 million doses should be received in one shipment based on vaccine availability, cold chain/logistics management aspect, the cold chain capacity needed is calculated as below. There will be adequate cold chain capacity to receive both these vaccines.

Table 1. Cold chain capacity requirement for receiving mRNA vaccines

Covid-19 vaccine	*Cold chain volume per dose (in secondary packaging)*	*Cold chain volume requirement for 2 million dose*	*Current status and plan*
Pfizer BioNTech	1.8 cm^3	3.6 m^3 (3600 L)	4 ULT freezers with each of 100 L gross volume already installed at CVS. Total gross volume 400 L. Can store 131,040 doses.[8] 7 ULT freezers each of 828 L gross volume is expected by end December 2021/early January 2022. Total gross volume of 5796 L. Can store 2,358,720 doses.[9] With these ULT freezers, up to 2,489,760 doses maximum can be stored
Moderna	4.30 cm^3	8.6 m^3 (8600 L)	Up to 25 m^3 space surge capacity available at central level (refer to NDVP for the calculations)

Accelerating vaccination for population ≥ 18 years of age

The COVID-19 Vaccination Program of Nepal has already vaccinated 44% with the first dose and 36% with second or full dose of the targeted ≥ 18 years of age population (as of 1 November 2021, Detail 3). Vaccination to high-risk and vulnerable groups have already been

[8] Calculation based on UNICEF-SD LTA ULT equipment list, Pfizer doses to be stored (6 doses per vial) in Model DW-86L100J ULT freezer (100 L gross internal volume)

[9] Calculation based on UNICEF-SD LTA ULT equipment list, Pfizer doses to be stored (6 doses per vial) in Model DW-86L828J ULT freezer (828 L gross internal volume)

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provided, and currently vaccine availability has improved compared to the first half of 2021. Because of this, there is currently no need to have a selected target group for vaccination as was done previously in the scenario of constrained vaccine availability. Further, three districts have already completed full immunization for ≥ 18 years of age population, and several municipalities and districts are in process to achieve this status. Therefore, to achieve highest coverage in a short time, the COVID-19 Vaccination Program of Nepal, based on the recommendation given by the National Immunization Advisory Committee, will provide vaccination to all remaining to be vaccinated ≥ 18 years of age population. Even though vaccination will be opened to all at and above 18 years of age, priority will be continued to be given (such as in session sites) to the higher age groups and vulnerable population (including pregnancy, *see section below on pregnancy*).

To accelerate vaccination to meet the vaccination targets, the following strategies will be adopted on top of the ongoing strategies:

- Based on local micro-planning, COVID-19 vaccination session sites will be increased to improve access to vaccination. Maximum of 7000 vaccination session sites have been utilized for COVID-19 vaccination. The session sites will be increased to match at least routine immunization sites (~16,000).
- Where feasible and required, COVID-19 vaccination delivery will be integrated with routine immunization sessions.
- In urban and highly populated areas, regular COVID-19 vaccination session sites will be conducted or continued (available on all days where/when required) through session sites at big/tertiary hospitals, medical schools, points/places in metropolitan/sub-metropolitan cities with high mobility, etc.
- Trusted public figures will be designated as COVID-19 vaccine ambassadors to promote vaccination coverage through increasing vaccine confidence in public.
- Collaboration with medical councils, societies, associations, and professional bodies will be done to advocate for COVID-19 vaccine status check as a standard medical practice (medical provider vaccine standardization). Those found to be unvaccinated will be provided or referred for vaccination after counselling.
- Mass media and social media will be further used aggressively to inform the public about vaccine availability and importance of COVID-19 vaccination. SMS text messages will be used to inform public about target population eligibility (≥ 18 years) and importance of vaccination.
- Reporting of vaccination achievement will be improved and capacity enhancement for recording and reporting will be done. Pre and post-vaccination digital registration will be encouraged.
- Advocate for and encourage employers, educational institutions, faith-based organizations, service providers, societies, associations (for e.g., transport associations), businesses, corporate houses, etc., to check vaccination status of its staff and members, and refer for vaccination if unvaccinated.

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Vaccination for pregnant population

Pregnant women with COVID-19 are more likely to have complications affecting both the pregnant women, fetus, and the new-born. Pregnant women are more likely than non-pregnant women of reproductive age to require ICU admission and mechanical ventilation if they have COVID-19. They are also more likely than pregnant women without COVID-19 to deliver preterm and more likely to have babies needing neonatal ICU. Pre-existing comorbidities, advance maternal age (≥ 35 years), and high body mass index (≥ 30 years) are risk factors for severe COVID-19 in pregnancy.[10]

Systematic review and meta-analysis[11] show that:

- The odds of admission to an ICU (2.13, 1.53 to 2.95; I2=71.2%), invasive ventilation (2.59, 2.28 to 2.94; I2=0%) and need for ECMO (2.02, 1.22 to 3.34; I2=0%) were higher in pregnant and recently pregnant than non-pregnant reproductive aged women.
- Compared to pregnant women without C-19, those with the disease had increased odds of maternal death (2.85, 1.08 to 7.52; I2=0%), of needing admission to the ICU (18.58, 7.53 to 45.82; I2=0%), and of preterm birth (1.47, 1.14 to 1.91; I2=18.6%)
- Increased maternal age (OR, 1.83, 1.27 to 2.63; I2=43.4%), high BMI (2.37, 1.83 to 3.07; I2=0%), any pre-existing maternal comorbidity (1.81, 1.49 to 2.20; I2=0%), chronic HTN (2.0, 1.14 to 3.48; I2=0%), pre-existing diabetes (2.12, 1.62 to 2.78; I2=0%), and pre-eclampsia (4.21, 1.27 to 14.0; I2=0%) were associated with severe C-19 in pregnancy
- The odds of admission to the neonatal ICU (4.89, 1.87 to 12.81, I2=96.2%) were higher in babies born to mothers with COVID-19 versus those without C-19.

WHO SAGE prioritization roadmap for COVID-19 vaccines[4] informs that for COVID-19 vaccination in pregnancy:

- DART studies in pregnant animals have been completed for all vaccines granted WHO EUL to date, and no harmful effects have been reported.
- The availability of data on the safety of COVID-19 vaccination in pregnancy varies by vaccine product.
- Post-introduction pharmacovigilance data on two mRNA vaccines have so far not identified any additional acute safety signals; the reactogenicity and adverse events profile by age group is like that reported in non-pregnant populations.
- Data on safety in pregnancy for other vaccine products are still being collected
- The VE of COVID-19 vaccines in pregnant women is expected to be comparable to that observed in non-pregnant women of the same age.

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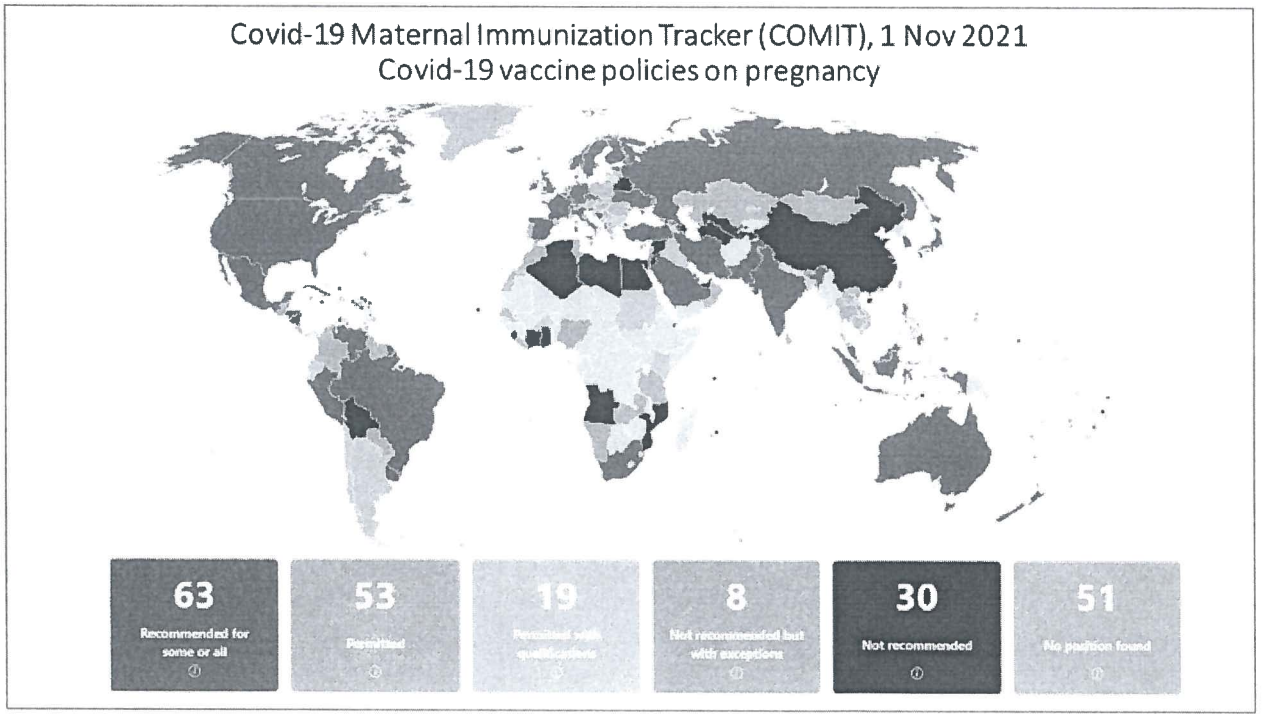
[10] Update on COVID-19 vaccination in pregnant and lactating women and children, WHO, 4 May 2021

[11] Allotey et al. BMJ 2020. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis

- Data from small studies have demonstrated that COVID-19 mRNA vaccines are immunogenic in pregnant women and that vaccine-elicited antibodies are transported in infant cord blood and breast milk, suggesting that the vaccines may give short-term early neonatal as well as maternal protection.
- Pregnant women are included in stage II of all epidemiological scenarios of the Prioritization Roadmap, as part of the "Groups with comorbidities or health states determined to be at significantly higher risk of severe disease or death".
- In many contexts, including the epidemiologic scenarios of both community transmission and sporadic cases or clusters of cases, these risks are likely to be greater than any theoretical risks posed by vaccination (the available evidence does not suggest any additional risks to date)
- WHO recommends that countries consult the section on pregnant women in the interim guidance documents for specific vaccine products when considering use of a vaccine during pregnancy.

Countries have different policy for COVID-19 vaccination in pregnancy, with more countries having an explicit recommendation that some or all pregnant women should receive the vaccine (most countries with this explicit recommendation are using the mRNA vaccines) (Fig. 4)

Figure 4. COVID-19 vaccine policies on pregnancy globally, as of 1 November 2021



Based on the evidence available, the National Immunization Advisory Committee, the committee mandated by the Immunization Act 2072 (2016) of Nepal, had recommended the following in its meeting on 26 May 2021.

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- NIAC recommended the use of COVID-19 vaccine in pregnant women when the benefits of vaccination to the pregnant woman outweigh the potential risks. Benefit risk assessment should be made on individual case to case basis and generally the risk factors listed as below can be considered.
- NIAC recommended considering pregnant women with increased maternal age (≥ 35 years), high body mass index (≥ 30), pre-existing maternal co-morbidity including chronic hypertension and diabetes, pregnancy specific disorders such as pre-eclampsia and gestational diabetes as high-risk group
- Similarly, if a pregnant woman belongs to a high-risk group by other criteria (e.g., health care professional), then she should be vaccinated.

Accordingly, the COVID-19 Vaccination Program of Nepal has been providing COVID-19 vaccine to high-risk pregnant women.

It is evident that all pregnancies have higher risk of adverse outcomes with COVID-19 compared to non-pregnant reproductive aged women. Therefore, the NIAC in its meeting on 2 November 2021 updated its recommendation as follows:

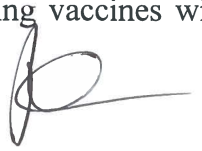
- NIAC reiterates its recommendation given on 26 May 2021 that pregnant women with high-risk condition should receive COVID-19 vaccine.
- Further, as any pregnancy with COVID-19 can have complications leading to morbidity and mortality, NIAC recommends that all pregnant women can receive COVID-19 vaccine.
    - The vaccine should preferably be given after first trimester where possible without posing additional risk due to delay of vaccination.
- Pregnant women should be given priority in COVID-19 vaccination sites and should be provided the vaccine without having to wait in queue.

Therefore, all pregnant women will be provided COVID-19 vaccine in Nepal.

Vaccination recognition for incoming travelers to Nepal

For incoming travelers to Nepal, Department of Immigration has issued Travel Management Order Notice which requires travelers to be fully vaccinated against COVID-19. Full immunization is defined as having received full doses (1 or 2 doses depending upon the vaccine) and that 14 days have passed since the last dose.

There is a need to have a standard for recognition of COVID-19 vaccine/vaccination certificate for incoming travelers to Nepal. National Immunization Advisory Committee in its meeting on 22 October 2021 has recommended for recognition of the following vaccines with full vaccination among incoming travelers:



All vaccines that have received WHO Emergency Use Listing

- Pfizer BioNTech – Comminate (Tozinameran)
- Serum Institute of India - Covishield
- AstraZeneca – Vaxzevria; AstraZeneca
- Janssen - Ad26.COV 2-S (Johnson & Johnson)
- Moderna - Spikevax
- Beijing CNBG - BBIBP-CorV (Sinopharm)
- Sinovac – CoronaVac
- Note: approved manufacturing sites are available at: https://extranet.who.int/pqweb/vaccines/covid-19-vaccines

All vaccines that have been granted Emergency Use Authorization (EUA) in Nepal by Department of Drug Administration

- Serum Institute of India - Covishield
- Beijing CNBG - BBIBP-CorV (Sinopharm)
- Bharat Biotech - COVAXIN
- Gamaleya - Gam-Covid-Vac (Sputnik V)
- Sinovac - CoronaVac
- AstraZeneca – Vaxzevria; AstraZeneca
- Janssen - Ad26.COV 2-S (Johnson & Johnson)
- Pfizer BioNTech – Comirnaty (Tozinameran)
- Moderna - Spikevax

Mutual recognition of vaccines: currently, vaccines that have received EUA in India, and mutual recognition with any country in the future

- Bharat - COVAXIN
- Gamaleya - Gam-Covid-Vac (Sputnik V)
- Janssen - Ad26.COV 2-S (Johnson & Johnson)
- Moderna - Spikevax
- Serum Institute of India - Covishield

Any vaccine recognized (EUA) in any of the 36 Stringent Regulatory Authority (SRA) countries

- AstraZeneca – Vaxzevria; AstraZeneca
- Beijing CNBG - BBIBP-CorV (Sinopharm)
- Gamaleya - Gam-Covid-Vac (Sputnik V)
- Janssen - Ad26.COV 2-S (Johnson & Johnson)
- Moderna – Spikevax
- Novavax – Covavax
- Pfizer BioNTech – Comirnaty (Tozinameran)

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- Serum Institute of India - Covishield
- Sinovac - CoronaVac

In summary, the following vaccines are recommended for recognition:

AstraZeneca – Vaxzevria; AstraZeneca, Beijing CNBG - BBIBP-CorV (Sinopharm), Gamaleya - Gam-Covid-Vac (Sputnik V), Janssen - Ad26.COV 2-S (Johnson & Johnson), Moderna – Spikevax, Novavax – Covavax, Pfizer BioNTech – Comirnaty (Tozinameran), Serum Institute of India – Covishield, Sinovac – CoronaVac, Bharat – COVAXIN

Any further vaccine fulfilling the above criteria in the future will automatically be added in the list. The above vaccines are recognized only if fully vaccinated. Other criteria as outlined in the current or future version of the Travel Management Order Notice will apply in addition to the vaccination recognition.

COVID-19 vaccine projection for future anticipated target groups

After completing vaccination for ≥ 18 years and 12-17 years age group, the COVID-19 Vaccination Program of Nepal will also need to plan for vaccinating younger age group (below 12 years of age) based on WHO EUL and vaccine authorization for such age groups in the future and after achieving very high coverage in the previous target groups. Further, based on evidence availability and recommendations as well as after achieving high coverage in previous target groups, extended vaccine doses in primary series and/or booster doses may be required for the vulnerable or high-risk targeted population, such as immunocompromised and elderly population.

WHO SAGE has provided interim recommendation that the primary vaccine series in moderately to severely immunocompromised persons should be extended to include an additional dose for all COVID-19 vaccines that have received WHO EUL.[12]

Currently, the anticipated future target groups are age group below 12 years of age, and target groups that may require additional dose of the vaccine. The vaccine requirement is given in the table below (Table 2). Estimated population at very high-risk taken is 13.45% (estimated figure taken from figures given in publication by Clark et al.[13]) of the total population.

As of 1 November 2021, Nepal has already received 20,180,930 doses of COVID-19 vaccines from different sources (Table 3). Nepal has procured 59% (12 million) of the total doses

[12] Interim recommendations for an extended primary series with an additional vaccine dose for COVID-19 vaccination in immunocompromised persons, WHO, 26 October 2021

[13] Clark, A., Jit, M., Warren-Gash, C., Guthrie, B., Wang, H. H., Mercer, S. W., ... & Jarvis, C. I. (2020). Global, regional, and national estimates of the population at increased risk of severe COVID-19 due to underlying health conditions in 2020: a modelling study. *The Lancet Global Health*, *8*(8), e1003-e1017.

received by the country. Other vaccines are supported from the COVAX Facility (18%) including AMC doses and dose-sharing, cost sharing through COVAX Facility (5%) and grant commodity support from different countries (18%).

Table 2. COVID-19 vaccine requirement with additional anticipated future target groups

Group	***Target population***	***Required doses for full dose*** *(including 5% wastage rate and assuming all vaccines have two doses schedule)*
≥18 years	19,922,165	41,836,547
12 to 17 years	3,425,408	7,193,357
2 to 11 years	5,816,636	12,214,936
Additional one dose for		
Front line health workers	112,690	118,325
Patient with chronic illness of 2-59 years (13.45% of total population)	3,925,386	4,121,656
≥60 years	2,652,258	2,784,871
Total	**35,854,543**	**68,269,692**

Table 3. COVID-19 vaccines received in Nepal, as of 1 November 2021

Vaccine sources	*Covishield/AZ*	*Sinopharm BIBP*	*Janssen (J&J)*	*Pfizer BioNTech*	*Total doses received*
COVAX Facility (AMC and dose-sharing)	1,962,740		1,534,850	100,620	3,598,210
COVAX Facility: Procurement (cost-sharing)		1,020,000			1,020,000
Grant support from countries	1,662,720	1,900,000			3,562,720
Government of Nepal Procurement	2,000,000	10,000,000			12,000,000
Total	**5,625,460**	**12,920,000**	**1,534,850**	**100,620**	**20,180,930**

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Government of Nepal has secured and is in process to acquire additional doses of COVID-19 vaccines to meet its priority to vaccinate all target population. A total of 39,884,060 doses of COVID-19 vaccine are in pipeline as shown below (Table 4) through various sources.

Table 4. COVID-19 vaccines in pipeline (expected), as of 1 November 2021

Vaccine sources	*Covishield/ AZ*	*Sinopharm BIBP*	*Janssen (J&J)*	*Pfizer*	*Moderna*	*Sinovac*	*Expected doses (pipeline)*
COVAX Facility: Commodity support	10,263,100	-	2,174,400	664560	1965600		15,067,660
COVAX Facility: Procurement (cost-sharing)		9,916,400			4000000		13,916,400
Grant support from countries		1,900,000				3,000,000	4,900,000
Government Procurement				6000000			6,000,000
Total	**10,263,100**	**11,816,400**	**2,174,400**	**6,664,560**	**5,965,600**	**3,000,000**	**39,884,060**

After receiving the expected vaccine doses in the pipeline by first quarter of 2022, the country will have a total of 60,064,990 doses of COVID-19 vaccine. The total doses required to vaccinate all target population including anticipated target in the future is 68,269,692 doses (Table 2). Thus, to secure vaccine to all targeted population, Nepal will require additional doses of 8,204,702. This calculation is included in this addendum to show vaccine requirements should the program implement vaccination to these future anticipated target groups based on recommendations.

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