VACCINE NEEDS ASSESSMENT

A. Background

1. Nepal has set a target of inoculating 71.62% of its population (21,756,763 individuals) against the coronavirus disease (COVID-19) to reduce transmission of the disease and expedite recovery from the pandemic's impact. The first case of COVID-19 in Nepal was identified on 27 January 2020 and a total of 591,494 cases have been confirmed and 7,990 people have died from the virus as of 7 June 2021.[1] The immunization campaign in the country started on 27 January 2021. As of 7 June 2021, roughly 2,113,080 individuals have been administered the first dose of the COVID vaccine and 691,494 have received the second dose (footnote 1). A COVID-19 Vaccine Advisory Group of Experts was established by the Government of Nepal (the government) for regularly assessing its vaccination needs and developing vaccine deployment plan. With support from the World Health Organization (WHO), the United Nations' Children's Fund (UNICEF) and the World Bank, the COVID-19 Vaccine Advisory Group of Experts has prepared a vaccine needs assessment using the COVID-19 Vaccine Country Readiness Assessment Tool, which is a WHO-developed tool for countries to self-assess vaccines readiness against key milestones and identify gaps. Areas of focus include logistics, service delivery, pharmacovigilance, advocacy and communication, monitoring and evaluation, and budget. The needs assessment serves as the basis for the National Deployment and Vaccination Plan (NDVP) which has been developed and regularly updated by the government and submitted to WHO to meet the requirement of accessing COVID-19 vaccines through the COVID-19 Vaccines Global Access (COVAX).[2]

2. According to the assessment, there is a high level of readiness in terms of vaccination objective and target setting, planning and coordination, regulatory, service delivery, cold chain and logistics, training and human resource, and demand generation and communication. The government is working towards strengthening aspects relating to vaccine waste management and vaccine safety, pharmacovigilance, program supervision, monitoring and evaluation. Detailed findings in the assessment and corresponding solutions proposed in the NDVP regarding country's vaccination readiness are summarized below:

B. Population Prioritization and Vaccination Targets

3. **Current status**. The Government of Nepal has developed a prioritization strategy for vaccine deployment based on the values framework and road map for vaccine prioritization guidance developed by the Strategic Advisory Group of Experts on Immunization (SAGE) of the WHO as well as the country context and disease epidemiology in Nepal.[3] According to the strategy, the phased plan with identified priority groups and approximate target populations has been mapped out in the NDVP by the government's National COVID-19 Vaccine Advisory Committee (COVAC), which has been endorsed by the Council of Ministers of Nepal. The allocation plan has a strong focus on ensuring equity in vaccination and has been developed to cover the entire population above 15 years of age without segregation of marginalized or

---

[1] Government of Nepal, Ministry of Health and Population, Situation Report: Health Sector Response to COVID 19 Coronavirus COVID-19 dashboard (accessed 8 June 2021).

[2] Government of Nepal. 2021. *National Deployment and Vaccination Plan for COVID-19 Vaccine*. Kathmandu (the NDVP is in annex 2 of the Country National Vaccination Prioritization and Allocation Plan which is accessible from the list of linked documents in Appendix 2 of the report and recommendation of the President).

[3] WHO. 2020. WHO SAGE roadmap for prioritizing uses of COVID-19 vaccines in the context of limited supply. Geneva; and WHO. 2020. WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination. Geneva.

vulnerable population groups or remote geographies and hard to reach areas. Table 1 shows the government's prioritization plan for the COVID-19 vaccination program.

Table 1: Prioritization of COVID-19 Vaccine Access

Phase	Target Group	Approximate Target No. (% of total population)
1	Frontline workers of the health and social sector, which includes: – Health care workers, including hospital or health facility staff – Sanitation, garbage, or waste management collectors and drivers – Ambulance and mortuary van driver and helper – Volunteers and security staff deployed in immunization centers – Workers directly involved in dead body management – Female community health volunteers – Health workers and staff working in an international point of entries – Elderly and their caretakers at old age homes – Prisoners and security staff in prisons	911,342 (3%)
2A	All elderly ≥ 55 years of age	3,733,463 (12.29%)
2B	Persons with comorbidities in 40–54 years age group[a]	1,117,912 (3.68%)
2C	Migrant workers and refugees with comorbidities[b]	312,894 (1%)
The above prioritization (Phase 1, 2A, 2B, 2C) covers 20% of the population = Total 6,075,611		
3A	Remaining 40–54 years: 2,901,104 (9.55%)	
3B	Remaining 15–39 years: 12,780,048 (42.07%)[c]	
The above prioritization (Phase 3A, 3B) covers 51.62% of the population = Total 15,681,152[d]		
Total target group for COVID-19 vaccination: 71.62% of the population = Total 21,756,763[e]		

COVID-19 = coronavirus disease.

[a] Identifying target groups with comorbidity is very challenging in Nepal, especially there is currently no mechanism to identify younger populations with comorbidities. Therefore, the government only targets people with comorbidity above 40 years age as it assumes that most people with comorbidities fall under this age group. Self-declaration is required for people under 40 with comorbidity.

[b] All adult migrants and refugees with comorbidity irrespective of their age shall be included in this category.

[c] Although the National Deployment and Vaccination Plan mentioned a lower age cut-off of 15 years, the plan also included a footnote that the lower age limit may be revised based on available vaccine age recommendation, and the vaccine guidelines clarify that the lower age limit will be 18.

[d] Based on epidemiological need and the available number of doses in each tranche, the above phases/prioritization can be clubbed or further divided.

[e] Pregnant, lactating mothers and children below a specific year (as per the available vaccine's age cut-off) will not be given the COVID-19 vaccine unless there is a specific recommendation for the available vaccines based on the risk-benefit situation analysis.

Source: Ministry of Health and Population.

4. The prioritization of beneficiaries for COVID-19 vaccination may be further updated based on various factors, including:

(i) Evolving epidemiological situation of COVID-19 in the country.

(ii) Number of vaccine doses that would be available at each time, for which the prioritization or the phases may need to be further broken down or clubbed based on dose availability.

(a) Within the 'occupational' targeted group, those with a higher risk of exposure due to their work and involved with higher risk or vulnerable group and principle of reciprocity will be applied if fewer vaccine doses are available in one tranche.

(b) Within the targeted group by age, since epidemiological data shows a higher case of fatality rate as age increases, those in the higher age groups will be prioritized if fewer vaccine doses are available in one tranche.

(iii) Type of vaccine available including its safety, efficacy, and possible allergic reaction to vaccine or any of its components, such as for special population (e.g., pregnant) and age groups (e.g., children and adolescents, elderly).

5. **Remaining steps.** The government will review and further update its prioritization plan according to the epidemiological situation in the country and the dynamics of global vaccine supply. The target population might also be further modified from time to time as per the latest scientific recommendations from WHO.

C. Planning and Coordination

6. **Current status**. The government has formed a well-structured planning and coordination mechanism for COVID-19 vaccination which is highly integrated into its existing immunization mechanism. The COVAC has been established to oversee all aspects of COVID-19 vaccine introduction in Nepal including regulatory guidance on vaccine access, vaccine selection, equitable distribution of vaccine, procurement, financing, delivery mechanisms, prioritization of population groups, vaccine safety surveillance, communication, media response, etc. This committee consists of experts on immunization, researchers and representatives from National Immunization Advisory Committee (NIAC), WHO and UNICEF.

7. The implementation of the COVID-19 vaccination program has been tasked to the National Immunization Programme (NIP), which is a well-established program in the Ministry of Health and Population (MOHP) with an extensive experience in carrying out vaccination campaigns such as for Polio, Tetanus, and Measles-Rubella. The NIP reached the entire population above one year of age during the Japanese Encephalitis vaccine campaigns in targeted endemic districts. It also conducted a nationwide vaccination campaign during the COVID-19 pandemic in 2020.

8. In order to support the resource mobilization and implementation of vaccination, a federal COVID-19 vaccine coordination committee chaired by the Secretary of Health, and a facilitation committee chaired by Secretary of Finance were also established. These committees will support the NIP to better coordinate with concerned ministries and all levels of local governments for the implementation of vaccination. Corresponding coordination committees and taskforces at all levels of local governments have also been formed to facilitate the implementation of COVID-19 vaccination program at each level. The roles and responsibilities of all working groups, committees and task forces are clearly defined for effective functioning and clear budget outlays have also been earmarked for each level.

9. **Remaining steps**. There is a need to identify and plan for the national vaccine procurement and deployment approach, including costs of items, due diligence mechanisms and ensuring regulatory compliance. The government is still planning and procuring waste management supplies and equipment for appropriate implementation of waste management protocols.

D. Regulatory

10. **Current status**. All required regulatory preparedness is in place for appropriate COVID-19 vaccine use in Nepal. Drugs (Third Amendment) Ordinance (2020) has been issued by the Right Honorable President, Bidya Devi Bhandari upon recommendation of The Council of

Ministers on 18 November 2020 to amend the Drug Act 1978, which now allows for emergency use authorization of vaccines and drugs in the context of the COVID-19 pandemic. According to the ordinance, the government will ensure the issuance of emergency use authorization of vaccine within 15 working days and issue import licenses from the appropriate authority within five working days after the vaccine is offered by the COVAX. The expedited mechanism for licensing and approval is also applicable to COVID-19 vaccines supplied through non-COVAX mechanism, if the Department of Drug Administration (DDA) Nepal's National Regulatory Authority, finds them suitable. DDA also has the authority to wave lot release testing based on the review of summary protocols of supplied vaccine. Close coordination and collaboration among the customs department, cargo handlers in Tribhuvan International Airport, DDA and NIP are in place to ensure that vaccines will be released from airport custom without any unnecessary delays.

11. The vaccine selection in Nepal is based on the Cabinet's four-point directives: (i) efficacy and safety, (ii) availability, (iii) compatibility with local logistics, and (iv) affordability. The identified approach of vaccine procurement includes through COVAX, through UNICEF and other UN agencies, through diplomatic channels and government-to-government support, and direct purchase from manufacturers. Considering the current global supply shortage, vaccine coverage will be slower than anticipated if the vaccine supply continues to be disrupted.

12. As of 13 May 2021, DDA has provided emergency use authorization to four vaccines, namely, AstraZeneca vaccine manufactured by both Serum Institute of India and S K Bioscience, Sinopharm vaccine manufactured by Beijing Bio-Institute of Biological Products, COVAXIN vaccine manufactured by Bharat Biotech International Limited and Spuntik V vaccine manufactured by Gamaleya Research Institute of Epidemiology and Microbiology.[4] Other vaccines such as Janssen and Novovax remain under consideration. Through the decision of The Council of Ministers on 4 January 2021, the provision to provide required indemnification to the manufacturer, distributor and development partners are in place.

13. **Remaining steps.** All required regulatory preparatory works have been done by the government.

E. Funding

14. **Current status**. The government, with the support of the World Bank Group, WHO, UNICEF and Gavi, the Vaccine Alliance (GAVI), has developed a cost estimation for implementing its COVID-19 vaccination program to vaccinate up to 71. 62% of its population in the absence of confirmed information on specific vaccine candidates, their characteristics, quantities and timing of availability. The proposed estimated cost of COVID-19 vaccine was initially $7 per doses, which is also the estimated unit cost adopted by the COVAX and the World Bank in their respective support to Nepal's COVID-19 vaccination program. However, as the current global vaccine supply is very limited with many uncertainties, the price of most promising candidate vaccines has become much higher than the cost at the time the estimation was made. Therefore, as advised by the government, Asian Development Bank (ADB) is using $10 per doses as the updated estimated unit cost of vaccines in addition to those covered by COVAX and the World Bank financing. With respect to the operational cost, a per capita operational cost of $2 per person for

[4] Department of Drug Administration. 2021. *Regarding the permission for Emergency Use Authorization of Covid-19 Vaccine (COVISHIELD)*. Kathmandu; Department of Drug Administration. 2021. *EUA of covid 19 vaccine (Vero cell), inactivated manufactured by BIBP(under Sinopharm)*. Kathmandu; Department of Drug Administration. 2021. *Regarding the permission for Emergency Use Authorization of Covid-19 Vaccine (COVAXIN)*; and Department of Drug Administration. 2021. *EUA (Emergency Use Authorization) for SPUTNIK-V - COVID-19 Vaccine*. Kathmandu.

the initial 20% of population vaccinated using vaccines from COVAX and $1 per person for rest of target population is proposed.

15. Based on the above assumption, the estimated total cost of the country's COVID-19 vaccination program is $452.85 million, which comprises $425 million for vaccine procurement and $27.8 million for operational costs.

16. Nepal has joined the COVAX Advance Market Commitment countries to secure COVID-19 vaccine(s) for 20% of the population. The cost of these vaccines is fully subsidized by the COVAX. As of 5 May 2021, the government has procured 2 million doses of COVID-19 vaccines that cover 2.79% of its population from the Serum Insititute of India and has allocated $5.27 million for operational costs of the vaccination program. The government has also received 1.1 million doses of free vaccines from the Government of India and 1.8 million doses of free vaccines from the Government of the People's Republic of China as gifts. Both donations cover the vaccines required for 4.04% of total population. The World Bank approved the additional financing for its COVID-19 Emergency Response and Health Systems Preparedness Project on 18 March 2021, which provides $62.6 million financial support to procure vaccines for 12.47% of population and $10.9 million for operational cost. In addition, ADB is also proposing $165 million financial support to procure vaccines for 22.3% of population. The estimated remaining funding gap of the government's COVID-19 vaccination program is $83.41 million which comprises of $71.747 million for procurement of vaccines for the remaining 10.01% of population and $11.666 million for operational costs. Table 2 summarizes the sources of funding of COVID-19 vaccine program and the remaining funding gap.

Table 2: Sources of COVID-19 Vaccine Procurement

A. Vaccine Procurement				
Financing Sources		**Target Population Size** (individual)	**Vaccine Requirement**[a] (number of doses)	**Vaccine cost**[b] ($)
Total vaccine financing requirement (i)	**71.62%**	**21,756,763**	**51,345,960**	**425,015,694**
COVAX (ii)	**20%**	**6,075,611**	**14,338,442**	**100,369,094 (Free)**
Other Sources				
Government of Nepal- procurement	2.79%	847,458	2,000,000	8,000,000 (government's own resources)
Government of India -donation	1.53%	466,102	1,100,000	4,400,000 (Free)
Government of the People's Republic of China - donation	2.51%	762,712	1,800,000	18,000,000 (Free)
World Bank	12.47%	3,789,346	8,942,857	62,600,000
ADB	22.30%	6,775,424	15,990,000	159,900,000
Total of Other Sources Including ADB (iii)	**41.61%**	**12,641,041**	**29,832,857**	**252,900,000**
Remaining Gap for Vaccine	**10.01%**	**3,040,110**	**7,174,660**	**71,746,600**

Procurement (i-[ii+iii])%				

B. Operational Cost	
Financing Sources	**Amount ($)**
Total operational cost requirement (iv)	27,832,374
Government of Nepal (v)	5,266,021
The World Bank (vi)	10,900,000
Remaining Gap for Operational Cost (iv-[v+vi])	**11,666,353**

ADB = Asian Development Bank, COVAX = COVID-19 Vaccines Global Access Facility.
[a] Vaccine requirement is computed as 2 doses per person + 15% wastage.
[b] Cost of vaccines by financing source: (i) World Bank and COVAX: $7 per dose; (ii) Government of Nepal and Government of India: $4 per dose; and (iii) ADB and other sources: $10 per dose.
Sources: Consultation with development partners and the Government and National Deployment and Vaccination Plan for COVID-19 Vaccination and Ministry of Health and Population.

17. **Remaining steps.** Given the allocation scenario, the government needs to mobilize its own domestic resources or explore financing support from other development partners to fulfill the remaining $83.41 million financing gap for both vaccine procurement and operational cost.

F. Service Delivery

18. **Current status**. The government has developed its COVID-19 vaccine delivery strategies as well as implementation arrangements for vaccination to reach identified target groups. Considering the supply constraint of vaccines, vaccination will be conducted in a phased manner from the highest priority groups to less vulnerable groups based on vaccine availability. The first phase will target frontline workers of the health and social sectors. All elderlies above age 55, mid-age people with severe comorbidities and migrant laborers and refugees with comorbidities are considered target population of the second phase vaccination. If vaccine availability increased, the first and second phases may occur simultaneously. Anyone in the general population above age 18 who did not receive a vaccine during the two phases will be vaccinated in the third phase.

19. According to NDVP, frontline health workers and social sectors directly involved with COVID-19 work will be vaccinated through their occupational setting in the health institutions, and the rest of the target population will be vaccinated through a community-based static and outreach booth approach. Vaccination sites have already been identified and are ready for immunization deployment as per need. These sites are as follows:

(i) **Health facilities:** Nepal has 5,188 health facilities, out of which >80% are providing fixed site routine immunization throughout the country every month. This includes all government health facilities at provincial level, district level, and local level health facilities. Further, designated private hospitals also provide immunization services through the National Immunization Program.

(ii) **Routine outreach immunization sites:** Each government health facility has 3 – 5 outreach immunization sites providing immunization sessions routinely covering their catchment area. These outreach sites along with the health facility sites amounts to total of >16,000 immunization sessions per month.

(iii) **Vaccination campaign immunization sites:** To cover a large number of populations within a short time within geographical reach, the sessions used in mass immunization campaigns, such as in recent nationwide Measles-Rubella Vaccine Supplemental Immunization Activity, have been identified. On average this modality has 10 session sites in each ward of a metropolitan and sub-metropolitan city, eight session sites in each ward of urban municipality, and six

session sites in each ward of rural municipality and can amount up to 48,000 booths.

20. Currently, there are over 3,000 active immunization sites. The further expansion in the number of sites depends on the supply status of COVID-19 vaccines. More than 8,000 trained vaccinators in Nepal who conduct regular immunization session are being mobilized for COVID-19 vaccination campaign.

21. On the spot registration and identity verification of beneficiaries is being conducted at vaccination centers by a trained worker / volunteer. A vaccination card is signed and issued by the vaccinator to individuals who receive their first dose. The card includes information such as the batch number and the type of vaccine, the name of vaccinator and the date and place of vaccination. It is signed again after the individual receives the second dose of the vaccine. The government has developed an online COVID-19 vaccine system to allow pre-registration of vaccination, creation of a unique digital ID with a QR code, time-slot designation, vaccination follow-up and notification. The system was launched on 12 May 2021.

22. Detailed vaccination booth arrangement has been developed. The protocols for infection prevention and control measures including adequate personal protection equipment to minimize exposure risk during immunization sessions are also updated to address the challenge of vaccinating mass population during severe pandemic.

23. **Remaining steps**. The government is working on the development of protocols regarding consent to vaccinations, process for agreeing to or refusing to be vaccinated, and measures to protect those that refuse to be vaccinated.

G. Cold Chain and Logistics

24. **Current status**. The logistics of COVID-19 vaccines is led by the Logistics Management Section of the Management Division of Department of Health Services (DOHS) with support from UNICEF and WHO. A National Vaccine Logistics Working Group with clear terms of reference to coordinate the deployment of COVID-19 vaccines and ancillary products is functional.

25. After the vaccines from manufacturer are delivered to Tribhuvan International Airport, a refrigerator van will transport the vaccines to the central vaccine store (CVS) in Kathmandu and stored vaccines in walk in cooler/freezer rooms. The other central store in Pathlaiya, which is adjoining the India border, will store vaccines and immunization supplies (e.g., syringes, safety boxes, cold chain equipment and other dry goods) from manufacturers in India via land. Nepal has a fully operational vaccine cold chain system across the country supported by various development partners including UNICEF and WHO. There are 85 vaccine stores across the country, two of them are at central level, six are at provincial level and 77 are at district level. As Province 2 and Karnali Province do not have a provincial vaccine store, vaccines for these two provinces are delivered from the provincial stores in Province 1 and Lumbini Province, respectively.[5] The lowest supply chain level is health facilities and health posts (para. 19) which serve as sub-store/local level government service delivery points that provides immunization sessions against COVID-19.

[5] Nepal has seven provinces. As of June 2021, two provinces, Province 1 and Province 2 are awaiting a decision on their names, and are referred to by their respective number.

26. Vaccines will be transported by refrigerator vans from CVS to provincial stores within a week of arrival at CVS. Provincial vaccine stores have their own refrigerator vans which are responsible for vaccine delivery from provincial vaccine stores to district vaccine stores and from district vaccine stores to vaccination sites according to the distribution plan. Syringes, safety boxes, and ancillaries for COVID-19 vaccines will be distributed separately from vaccines from central warehouse to provincial stores and from provincial stores to vaccination to district-level stores. Special arrangement will be made for transportation of COVID-19 vaccine below district level based on the micro planning at the health facility and local levels which will only be initiated in advance based on anticipated vaccine arrival.

27. Currently, the country can maintain a stock of 4 million doses, that is, 7.85% of total required COVID-19 vaccine doses at one point of time. Since the type of COVID-19 vaccine to be deployed in the country was unknown, the government assessed its cold chain capacity under two varying scenarios: cold chain capacity for vaccines to be stored between 2–8°C and for vaccines to be stored at –25°C. According to the assessment, there is a need to expand the cold chain space (both at 2–8 °C and –25°C) at central and provincial levels to accommodate both routine vaccines and the COVID-19 vaccine. The government has developed two cold chain expansion plans to fulfill the gap of cold chain capacity at 2–8°C and –25°C, respectively. Two walk-in-coolers at central vaccine stores and eight walk-in-coolers for provincial vaccine stores have been deployed with support of UNICEF and GAVI to provide sufficient cold spaces at 2–8°C. Two walk-in-coolers at central vaccine stores and seven walk-in-freezers for provincial vaccine stores are proposed in the cold chain expansion plans for cold spaces at –25°C. The capacity for vaccines requiring ultra-cold chain facility is not currently available in the immunization system of Nepal. The ultra-cold chain space expansion has been planned through GAVI-funded cold chain equipment (GAVI CCE) support and required coolers and freezers shall be procured by UNICEF through GAVI CCE Optimization Platform (May to June 2021). There is adequate storage capacity at district and sub center levels.

28. Nepal has a special category of trained health workers called Cold Chain Officer / Assistant available at central, provincial and each district in the country. These officials are experienced in safe vaccine logistics, have successfully supported in various nationwide campaigns and will be leveraged for COVID-19 vaccine deployment.

29. A well-established Electronic Logistic Management Information System (e-LMIS) is used to manage, track and monitor the delivery and deployment of COVID-19 vaccines, which is fully functional at all provincial vaccine stores and at some of the districts vaccine stores and health facilities. The quantity of COVID-19 vaccines received from the manufacturer through air shipment at Tribhuvan International Airport are entered into e-LMIS right after landed. Vaccines are recorded in the e-LMIS system to get real-time information on stock and consumption patterns. First expiry first out principle is followed when managing the stock of vaccines. Paper-based recording and reporting is still maintained at all levels. The MOHP is coordinating with Ministry of Home Affairs for the security of the vaccines and staff deployed for COVID-19 vaccination. The Management Division of DOHS, Provincial Health Logistic Management Centers, Health Officers and local governments are working closely with security officials to ensure security of vaccines across the supply chain at their respective levels as well as the personnel deployed.

30. For service level usage data (aggregate data), the integrated health management information system (IHMIS) under the Management Division of DOHS is used. Used and stock vaccines at vaccination centers are regularly updated at local level in the IHMIS.

31. **Remaining steps**. The monitoring and reporting of cold chain temperature has not yet been digitalized. Government is still working on disseminating the delivery and acceptance protocols, ensuring monitoring arrangements are in place, and identifying supervisory focal points at each facility. The e-LMIS is in the process of being extended to local level in order to capture service level data (recording of used and unused vials) and support real-time monitoring of stock and utilization. The government is also establishing security arrangements to ensure the integrity of COVID-19 vaccines and ancillary products throughout the supply chain. Further, there is a potential to introduce a barcode/QR scanner to track the COVID-19 vaccines.

H. Vaccine Waste Management

32. **Current status**. The Nepal government has legislation, policy and guidelines for health care waste management (HCWM) in place for treatment and disposal of infectious waste from health care facilities. The NDVP indicates that the government will manage COVID-19 immunization medical waste during the implementation of the vaccination done in accordance with (i) National Immunization Injection Safety Policy, (ii) Health Care Waste Management Guideline in the context of COVID-19 emergency, and (iii) National Health Care Waste Management Standards and Operating Procedures. For COVID-19 vaccine delivery, both injection safety and waste care management will be part of the training to vaccinators and associated frontline health workers. HCWM is a budgeted activity for COVID- 19 vaccine delivery for all levels. Each health facility will manage waste according to legislation, policy and guidelines, and should coordinate with respective municipality office if capacity does not exist within the health facility.

33. While policies and regulations for managing COVID-19 medical waste are in place, the compliance of frontline health workers at health facilities remains challenging. The government and private hospitals and nursing homes in the local areas usually do not possess equipment for proper treatment and disposal of medical waste and often mix medical waste with municipal waste and dump them openly in river or forest area.

34. The government has developed a work plan for medical waste management at health facility level and at COVID-19 vaccination centers. A total of $6.956 million is estimated for the work plan implementation covering existing as well as future immunization and other HCWM within three years (April 2021 to December 2023). The implementation responsibility of the work plan lies with the Family Welfare Division of DOHS. There are 141 hospitals identified for COVID-19 immunization. Of these, some level of logistics & facilities, and system of HCWM are established in 45 hospitals (32%) and no HCWM system exists in the remaining 94 hospitals (68%). The government and development partners are supporting HCWM in these 141 hospitals. Based on the interim plan, waste from vaccination centers in Kathmandu Valley will be transported to a suitable hospital near an autoclave facility. A technical working group has been established with government and development partners support to coordinate and steer HCWM activities at federal, provincial & local levels.

35. **Remaining steps.** Availability and capacity for waste management at health facility level may be reviewed. Training of relevant personnel needs to be conducted and robust monitoring systems need to be put in place to ensure compliance with necessary protocols. Further, requirement and scope for engaging third-party service providers for waste management may be reviewed.

I. Vaccine Safety and Pharmacovigilance

36. **Current status**. A functional adverse event following immunization (AEFI) surveillance system is already in place to detect, report, investigate, and analyze serious AEFI during any immunization program in Nepal. Health workers are trained on AEFI in all vaccination trainings yearly. However, as the adverse events of most of the COVID-19 vaccines are not yet clearly and completely identified due to the expedited vaccine development process, the existing surveillance system's capacity to identify, report, investigate, analyze and determine the cause and respond to COVID-19 vaccination-related adverse events need to be further strengthened to better understand the safety profile of possible vaccines.

37. The government has made necessary adjustments in existing forms and formats of the AEFI surveillance system to accommodate COVID-19 vaccine safety surveillance as per WHO guideline. The existing National AEFI Investigation Committee has been activated with adequate information and orientation to the members on the COVID-19 vaccine. The existing reporting system for measles and rubella campaign will be used with necessary adaptation for COVID-19 vaccination. The government will be responsible for all indemnity costs of serious AEFI cases regardless of the source of vaccine.

38. For COVAX procured vaccines, vaccine manufacturers receive an indemnity for all damages relating to or arising from the use and administration of the vaccine within the jurisdiction of the country. The indemnification would not apply if an injury associated with the Approved Vaccine resulted from:

(i) Willful misconduct of the manufacturer; or
(ii) A defect in the Approved Vaccine due to non-compliance with, for example, terms of the marketing authorization; or
(iii) Failure to comply with good manufacturing practices.

39. The Council of Ministers in Nepal decided on 4 January 2021 to provide indemnification to manufacturer, distributor, and development partners in case of occurrence of AEFI for COVID-19 vaccination.

40. **Remaining steps**. Additional training on AEFI surveillance of health workers are required, given that adverse events of most COVID-19 vaccines are not yet clearly and completely identified. Currently, reporting and investigation of AEFI are done manually at vaccination sites with low accuracy and poor timeliness. Establishing a digital AEFI reporting system or integrating AEFI reporting function into the existing e-LMIS and extending it to facility level might be a solution to improve the accuracy and timeliness of AEFI surveillance system through enabling real-time reporting of AEFI cases and tracking of details of vaccine that causes each case of AEFI including the brand name, the manufacturer and the batch number.

J. Training and Human Resource

41. **Current Status**. As COVID-19 vaccination is targeting a significant number of adult population rather than children who are the main target of most routine immunization programs, it is required to deploy a high number of trained human resources to conduct mass adult COVID-19 vaccination program across the country. The government has developed a training plan for key groups of participants that will be involved in the COVID-19 vaccine introduction. Major content of the training includes the introduction of vaccine characteristics, cold chain maintenance (especially for Cold Chain Officers/Assistants who belong to a special category of trained health

workers that look after cold chain logistics for vaccination), management of vaccination booth, recording and reporting of vaccination status, AEFI management, social mobilization, and biomedical waste management. All training for COVID-19 are developed and conducted at federal, provincial, district and local levels following cascaded modality. Regular virtual training from central level core technical team is provided to all levels regularly.

42. In order to conduct training in a timely and efficient manner, training of trainers have been conducted at federal, provincial, and district levels and training of female community health volunteers will be conducted in communities. Currently, there are around 15,000 frontline health workers trained on the COVID-19 vaccine administration. The government is also mobilizing over 50,000 female community health volunteers and 40,000 male volunteers to assist vaccinators in vaccination sites.

43. **Remaining steps.** All required preparatory works on training and human resource mobilization have been done by the government. Further, training will be provided as the vaccination campaign expands.

K. Demand Generation and Communication

44. **Current status**. The objectives of the government's communication and social mobilization activities for the COVID-19 vaccination program are (i) providing timely, accurate, and focused messages on vaccine availability date, safety, timeline, and phased approach; (ii) improving understanding and acceptance of the importance of phased and prioritization of vaccine administration; (iii) creating public demand and confidence on efficacy and effectiveness of new COVID-19 vaccine; (iv) timely addressing rumors, misinformation and vaccine hesitancy among the public; (v) continuing the practice of public health safety measures during and after the vaccination; and (vi) fostering collaboration with other line ministries, private sectors and formal networks for demand management, vaccine deployment, and administration.

45. The proposed objectives will be achieved through integrated advocacy, digital and mainstream media mobilization, and mobilization of community volunteers, influencers, and frontline workers. Vaccine task teams at provincial and local levels adapt, plan, implement, monitor, and report all communication and social mobilization activities based on guidance from the federal level. At the household and community levels, female community health volunteers have been capacitated and mobilized to disseminate the timely and appropriate vaccine risk communication messages. Community, religious and political leaders and other celebrities are also being leveraged to improve willingness towards vaccination among communities and for vaccine uptake as per the plan. Training materials and messages have been endorsed by the National Immunization Advisory Committee for further adaptation and dissemination at the provincial and local levels.

46. To date, the government has initiated various vaccine communication activities to improve the vaccine awareness of public. Around 20 public service announcement videos regarding COVID-19 vaccine safety were developed by MOHP and widely disseminated through various government platforms. Hotline for COVID-19 vaccine is also fully operational. Frequently asked questions on COVID-19 vaccine are already developed and disseminated widely through various platforms. Various webinars on COVID-19 vaccines have been conducted.

47. In addition, the government also partnered with the mass media at the federal, provincial, and local levels for regular engagement to amplify key messages and leveraging existing broadcast platforms for effective COVID-19 vaccine communication. The Ministry of Health leads

the government's media crisis hub with support from UNICEF and WHO for media monitoring and responding to misinformation. This also includes social listening using technology and collaborative approaches.

48. **Remaining steps**. The measures for managing hearsays and false information, monitoring social media and assessing behavioral and social data are under development. Continued engagement with local leaders is important to disseminate accurate information and mobilize communities for increased uptake of vaccines.

L. Program Supervision, and Monitoring and Evaluation

49. **Current status**. The government has developed a surveillance and monitoring framework for COVID-19 vaccine. Measures for data protection and appropriate data governance regulation is in place to ensure the legitimate, appropriate and proportionate use and processing of data on COVID-19 vaccination. The supervision will be done at three stages: (i) assessing the readiness for vaccination at pre-vaccination stage; (ii) monitoring the vaccination activities, progress and support in vaccination activities during the vaccination: and (iii) assessing the performance and lesson learned at post-vaccination stage. Supervision and monitoring will take place in all three levels of the government.

50. The existing e-LMIS will be used for monitoring and tracking the logistic status of COVID-19 vaccines across the country. Vaccination-related data are currently collected through two information systems: the heath management information system and the COVID-19 Immunization Management Unit Nepal Software System (IMU). The IMU is used to record patient vaccination data and IHMIS provides aggregated reports on the daily number of immunization sessions conducted, the number of immunizations and vials consumed, and AEFI cases (serious or non-serious). Data on number of beneficiaries who received first and second doses of vaccine, doses of vaccine given, cases of AEFI observed are collected by data collectors at local levels from vaccination sites and inputted to IHMIS in an aggregated manner daily. Currently, data are received from all 753 municipalities everyday including from all remote areas. After each vaccination session is finished, vaccinators need to check the stocks of vaccine, safe box and other consumables and record it accordingly in the IHMIS. Vaccinators also need to summarize detailed individual data of beneficiaries who received vaccines in each site and upload it to IMU no later than three days after the completion of the vaccination session.

51. Evaluation of COVID-19 vaccination will be carried out after the first and second phase of the vaccination. The Nepal Health Research Council in collaboration with development partners and research organizations will carry out the evaluation activities. Evaluation methodology will be worked out focusing on program performance, vaccine uptake and safety, and cohort analysis for effectiveness.

52. **Remaining steps**. The government should further strengthen the existing IMU system to enable real-time reporting of individual level vaccination data. The government may also extend the e-LMIS to local levels or even vaccination sites to enable more timely and accurate tracking of COVID-19 vaccines. The government is also working on linking e-LMIS, heath management information system, and IMU through application programming interface to enable better monitoring and tracking of AEFI and biomedical waste management. Additionally, the management information systems for monitoring medical waste management at facility level and supporting digital AEFI reporting need to be developed.