

SECTOR ASSESSMENT (SUMMARY): VACCINES

A. Sector Road Map

1. Sector Performance, Problems, and Opportunities

1. Nepal has made significant gains in improving its health outcomes over the past two decades. Between 2000 and 2018, average life expectancy increased from 62 to 70.5 years; under-5 mortality rate decreased from 81.1 to 32.2 per 1,000 live births.¹ This can be attributed to Nepal's noteworthy success in routine immunization through its National Immunization Program (NIP). Full vaccination coverage² among infants aged 12-23 months increased from 65.6% in 2001 to 77.8% as of 2016.³ Coverage has remained high as of 2019 for routine vaccines.⁴ Furthermore, Nepal has been declared polio-free since 2010, has eliminated maternal and neonatal tetanus and reduced the burden of Japanese Encephalitis (JE) through successful introduction of the JE vaccine in its regular immunization schedule in 2006.⁵

2. **Improved basic vaccination coverage is the result of a strong national immunization program.** The National Immunization Program (NIP) of Nepal, initiated in 1977 as part of the Expanded Immunization Program (EPI), is one of the government's high-priority programs in the health sector. The NIP provides nationwide routine vaccinations against 11 pathogens for children, with an immunization schedule covering the first 24 months, with a further increase in the number of antigens provided to children aged 6 to 11 years over the past decade.⁶ The NIP has been lauded as one of the country's most successful public health campaigns with several milestones (para 1). In 2014, Nepal became the first Global Alliance for Vaccine and Immunization (GAVI) eligible country in the world to introduce the Inactivated Polio Vaccine.⁷ Through strategies such as community-level actors' participation and periodic intensification of immunization outreach, the program has expanded its services in all districts. In 2012, the "Reaching Every Child" initiative was launched which targeted full immunization for all villages, municipalities, and districts. To date, 18 districts and 1,800 village development committees have been declared as fully immunized.⁸ The NIP has successfully adapted its existing health infrastructure to integrate new vaccines. For example, Nepal utilized resources that were designed for polio and measles vaccinations to implement vaccinations for JE. Vaccines under the NIP are administered free-of-charge.

3. **A new immunization law further signals the government's commitment to improve services and finance vaccines.** In 2016, Nepal approved the National Immunization Act which aims to improve oversight, set higher standards for vaccine testing and use, and supports

¹ Organization for Economic Cooperation and Development (OECD)/WHO. 2020. *Health at a Glance: Asia/Pacific 2020: Measuring Progress towards Universal Health Coverage*, OECD Publishing. Paris.

² Full vaccination refers to having received the following vaccines: one dose of the Bacille Calmette Guérin (BCG) vaccine, three doses of combination vaccine including diphtheria, pertussis and tetanus (DTP3), three doses of oral polio vaccines (OPV), and a first dose of Measles-Rubella (MR) vaccine by the first 12 months.

³ Kiran Acharya, Yuba Raj Paudel and Dinesh Dharel. "The trend of full vaccination coverage in infants and inequalities by wealth quintile and maternal education: analysis from four recent demographic and health surveys in Nepal". *BMC Public Health* (2019) 19:1673

⁴ Bacillus Calmette-Guérin (BCG) vaccine (96%), diphtheria, tetanus toxoids, and pertussis (DTP3) vaccine (93%), and measles and rubella (MCV1) vaccine (92%). Official government estimates reported.

⁵ World Health Organization. 2019. [Nepal: WHO and UNICEF estimates of immunization coverage: 2019 revision](#). Geneva.

⁶ <https://www.path.org/articles/four-barriers-nepal-overcame-introduce-je-vaccines/> WHO. Factsheet 2019 Nepal – Expanded Program on Immunization.

⁷ WHO. 2018. Nepal–WHO Country Cooperation Strategy (CCS), 2018–2022.

⁸ PAHO. 2014. [Strengthening Immunization in Nepal: Introducing the Inactivated Polio Vaccine \(IPV\) and Beyond](#).

transition towards financial independence for vaccine purchases. Currently, Nepal relies on GAVI to fund up to 70 percent of its vaccine purchases. However, once the country graduates from a low-income status by 2022, it will not be eligible for GAVI support. The new immunization law establishes two channels for financing the national immunization program through mandatory government budget allocation for the National Immunization Fund and through supplementary contributions from domestic private partners.

4. Despite the gains in vaccination coverage and subsequent declines in mortality, some gaps remain. While aggregate coverage for routine basic immunization coverage is 77.8%, disparities exist by administrative and geographic regions, income and other socioeconomic factors. Coverage is significantly lower in Province 2 where only 65.2% of infants have received all basic vaccinations (compared to 92.7% in Gandaki Province). Routine immunization is also lower in Terai (71.3%) and mountain (74.1%) zones compared to the hilly region (88%). Data from the Demographic and Health Survey (DHS)⁹ also reveal the need to expand targeting and coverage beyond households in the poorest income groups. Children from households in the middle wealth quintile had lowest immunization coverage (70.9%) as opposed to those from the bottom two quintiles (76.6%-77.2%) and the top two quintiles (81.6%-84.8%). Parental education is also an important factor; immunization rates were lower among children of fathers without education (63.5%) and mothers without education (67.8%). This is a critical issue for the country where nearly a third of the adult population is not literate.¹⁰

5. Despite increase in childhood immunization and remarkable control of a number of vaccine-preventable diseases, some communicable diseases are still prevalent. While mortality due to communicable diseases has decreased over the past decade (32% of all deaths in 2000), they accounted for 18% of all deaths in 2017.¹¹ Prevalence of tuberculosis is high at 416 cases per 100,000.¹² Climate-related factors combined with poor hygiene and sanitation practices further increase vulnerability to infectious diseases.¹³ While prevalence of hepatitis B and C are low, the country faces sporadic outbreaks of hepatitis E during the rainy season. A dengue outbreak in 2019 has been linked to unexpectedly early monsoon rains.

6. The COVID-19 pandemic added to risks of communicable diseases and other negative long-term health outcomes. Initial measures to contain spread of COVID-19 had deleterious effects on routine immunization and related health outcomes. A measles outbreak with at least two confirmed fatalities was reported in five districts in April 2020 threatening to reverse gains made in reducing incidence.¹⁴ This coincided with suspension of all routine vaccinations until June 2020, including a national Rubella-Measles campaign with UNICEF that had targeted over 3 million children nationwide.¹⁵ Out of over 650,000 children in need of

⁹ MOHP. 2016. *2016 Demographic and Health survey*. Kathmandu.

¹⁰ The World Bank. 2019. Literacy rate, adult total (% of people ages 15 and above) – Nepal. <https://data.worldbank.org/indicator/SE.ADT.LITR.ZS?locations=NP>. (Accessed 13 May 2021).

¹¹ WHO. 2018. Nepal–WHO Country Cooperation Strategy (CCS), 2018–2022.

¹² WHO. 2020. Nepal National TB Prevalence Survey Brief.

¹³ Saleem Shaikh. 3 November 2020. “Nepal exposed to climate-sensitive disease outbreaks”. SciDevNet. <https://www.scidev.net/asia-pacific/news/nepal-exposed-to-climate-sensitive-disease-outbreaks/>. Accessed 13 May 2021

¹⁴ Shiva Upreti. 12 May 2020. “Meanwhile, a measles outbreak in Nepal”. Nepali Times.

<https://www.nepalitimes.com/here-now/meanwhile-a-measles-outbreak-in-nepal/>. Accessed on 13 May 2021.

¹⁵ UNICEF. 2020. *Resuming routine immunization*. <https://www.unicef.org/rosa/stories/resuming-routine-immunization>.

Measles-Rubella vaccines every year, about 120,000 children have missed their inoculations.¹⁶ Health campaigns such as distribution of Vitamin A drops and deworming tablets, and community-based nutrition programs for early detection and treatment of malnourished children have also been affected which could have adverse long-term public health impacts.¹⁷

7. Regulatory requirements for vaccine introduction and pharmacovigilance are in place. Vaccine safety, efficacy and quality control are managed by the Department of Drug Administration (DDA), Nepal's National Regulatory Authority. In order to facilitate timely inoculations against COVID-19, the Government of Nepal (GON) issued the Drugs (Third Amendment) Ordinance 2077 B.S. (2020 A.D.) on 18 November 2020 that amends the Drug Act 2035 B.S. to allow for emergency use authorization (EUA) of vaccines. According to the ordinance, GON will issue EUA within 15 working days and issue import licenses from the appropriate authority within 5 working days after the vaccine is offered by COVAX. The expedited mechanism for licensing and approval is also applicable to COVID-19 vaccines supplied through non-COVAX mechanism, if DDA finds them suitable. As of 13 May 2021, DDA has provided emergency use authorization to 4 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 Sputnik V vaccine manufactured by Gamaleya Research Institute of Epidemiology and Microbiology.¹⁸ Other vaccines such as Janssen and Novovax remain under consideration. Through the Council of Ministers' decision on 4 January 2021, the provision to provide required indemnification to the manufacturer, distributor and donor is in place. DDA also has the authority to waive lot release testing based on the review of summary protocols of the vaccine. Close coordination and collaboration among the customs department, cargo handlers in Tribhuvan International Airport, DDA and NIP are in place to minimize delays in distribution.

8. Nepal has a functional surveillance system for detecting, reporting, and investigating adverse event following immunization (AEFI). Serious AEFI cases are investigated, classified, and addressed per national and global AEFI guidelines.¹⁹ The National AEFI Investigation Committee, mandated by the National Immunization Law 2016, is responsible for causality assessment.²⁰ Health workers are trained on AEFI yearly during training for vaccinations. For reporting of AEFI during COVID-19 vaccinations, GON plans to adopt the existing reporting system for Measles and Rubella vaccinations. GON will also adapt guidelines for AEFI surveillance to align with the WHO guidelines on COVID-19 vaccine safety surveillance. Case-

¹⁶ Arjun Poudel. 29 April 2020. "Measles outbreaks reported in five districts including in Kathmandu and Lalitpur in last one month". *The Kathmandu Post*. <https://kathmandupost.com/national/2020/04/29/measles-outbreaks-reported-in-five-districts-including-in-kathmandu-and-lalitpur-in-last-one-month>

¹⁷ Sharmistha Sharma & Jeevan Bhatta. Public health challenges during the COVID-19 outbreak in Nepal: a commentary. *Journal of Health Research* 34(4).

¹⁸ Department of Drug Administration. 2021. [Regarding the permission for Emergency Use Authorization of Covid-19 Vaccine \(AstraZeneca\)](#). 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 \(COVAXIN\)](#). Kathmandu; Department of Drug Administration. 2021. [EUA \(Emergency Use Authorization\) for SPUTNIK-V - COVID-19 Vaccine](#). Kathmandu.

¹⁹ Ministry of Health and Population, Nepal, World Health Organization, Nepal. Adverse Event Following Immunization, National Immunization Program, Program Guideline, Nepal; 2011; and WHO. 2016. Global Manual on surveillance of adverse events following immunization, 2016 update.

²⁰ R. Pradhan et al. 2020. *Vaccine safety surveillance informs public health policy beyond immunization: A case series on bleeding following vaccination, Nepal, 2016-2018*. <https://www.sciencedirect.com/science/article/pii/S0264410X20309531>

based AEFI reporting, with particular attention to the brand name of the vaccine and the manufacturer along with details such as batch numbers and documentation of dates, will be included. Currently, the AEFI reporting and investigation are done manually at vaccination sites with low accuracy and poor timeliness. There is a need to establish a digital AEFI reporting system or integrate AEFI reporting function into the existing vaccination-related IT systems and extend them to facility level 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.

9. **Vaccine storage and delivery system.** The logistics for vaccines is managed by the Logistics Management Section under the Management Division of the Department of Health Services (DoHS). 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 comprising 2 central level, 6 provincial level and 77 district level stores. There are around 5,188 health facilities (health centres and health posts) across the country which are considered the lowest supply chain level and the service delivery points for providing immunization sessions against COVID-19. More than 80% of all health facilities are already providing fixed site routine immunization every month. According to the National Deployment and Vaccination Plan (NDVP), the existing cold chain capacity at all levels is considered adequate. An arrangement has also been made to use government cold chain space outside the immunization system in case of a surge or whenever needed. Vaccines transported via air are transported via refrigerator van to the central vaccine store in Kathmandu while vaccines transported via land (from India) are stored at the second central vaccine store in Pathlaiya in the central Terai region. Vaccines are transported from central to provincial stores that are responsible for delivering the vaccines to district level vaccine 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 level which will only be initiated in advance based on anticipated vaccine arrival.

10. GON has expanded the existing vaccine storage capacity to accommodate both COVID-19 vaccines and vaccines for routine immunization. GON is augmenting federal and provincial store capacity by adding 10 walk-in coolers through the GAVI-supported cold chain equipment (CCE) optimization program. The ultra-cold chain space expansion has also been planned through GAVI CCE support while required coolers and freezers will be procured by UNICEF through GAVI's CCE optimization platform. 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 district-level stores or health facilities using trucks and containers. 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 at all provincial vaccine stores and at some of the districts vaccine stores and health facilities. Service level vaccine usage aggregated data are collected through the integrated health management information system (IHMS). Used and stock of vaccines at vaccination centers are regularly updated at local level in the IHMS.

11. **Vaccination sites.** Vaccinations in Nepal are administered in health facilities (at the provincial, district and local levels), outreach immunization sites and session sites at the ward level in the case of mass immunization campaigns. Designated private hospitals also provide immunization services under the NIP. Out of the 5,188 health facilities in the country, over 80% provide routine immunization services. Each government health facility has 3-5 outreach immunization sites covering their catchment area. The health facilities and outreach sites provide over 16,000 immunization sessions per month. These sites will be utilized for COVID-19

vaccinations as well. In addition, session sites used in recent nationwide Measles-Rubella Vaccine Supplemental Immunization Activity will also be utilized. On average this modality has 10 session sites in each ward of a metropolitan and sub-metropolitan city, 8 session sites in each ward of urban municipality, and 6 session sites in each ward of rural municipality and can accommodate up to 48,000 vaccination booths.

12. **Tracking vaccine administration.** The Ministry of Health and Population (MOHP) issues paper-based Child Health Cards (CHC) to record and track immunizations. To date, paper-based vaccine cards are being used to track administration of COVID-19 as well. The vaccination card includes information such as the batch number and 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. This poses challenges as retention rate of vaccination cards for routine immunization is very low. According the 2016 DHS, only 52% of children had retained their vaccination cards.²¹ In 20xx, GON has launched the COVID-19 Immunization Management Unit Nepal Software System or IMU, a real-time reporting software for COVID-19 case investigation and contact tracing which is currently being further strengthened to enable real-time reporting of individual level vaccination data. There is an opportunity to further utilize this tool for use in registration, recording and vaccine administration.

13. **Medical waste management.** MOHP has legislation, policy and guidelines for healthcare waste management (HCWM) in place for treatment and disposal of infectious waste from health care facilities. GON plans to 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, GON has developed a work plan for medical waste management at health facility level and at COVID-19 vaccination centers. Both injection safety and waste care management will be part of the training for vaccinators and associated frontline health workers. HCWM will be a budgeted activity for COVID- 19 vaccine delivery for all levels. Each health facility will manage waste according to aforementioned legislation, policy and guidelines, and should coordinate with respective municipality office if capacity does not exist within the health facility.

14. **Demand side barriers to vaccinations could result in low coverage.** Vaccination efforts in Nepal face challenges related to lack of awareness about the need for immunization and barriers such as proximity to vaccination sites and high transport costs particularly for those living in remote areas. While vaccine hesitancy has not been identified as a widespread challenge in the case of routine immunization, reports of hesitancy for COVID-19 vaccines have emerged.²²

15. **A concerted effort has been initiated to combat misinformation against COVID-19 vaccine and raise awareness.** Nepal's health system including the NIP has solid experience in mobilizing female community health volunteer (FCHVs) to raise awareness about the benefits of immunization among other essential health services at village and community levels. FCHVs will be mobilized to combat misinformation about COVID-19 vaccines. Training will be conducted for FCHVs to equip them with adequate communication skills and appropriate vaccine-related message. To date, MOHP has initiated various vaccine communication activities. Around 20 video public service announcements regarding COVID-19 vaccine safety have been developed and widely disseminated through various government platforms. A hotline for COVID-19 vaccine is

²¹ MOHP. 2019. *Factors affecting vaccination coverage and retention of vaccination cards in Nepal*. Kathmandu?

²² Sonia Awale. 2021. [Why is there vaccine hesitancy in Nepal?](#) *Nepali Times*. 10 February.

also fully operational. In addition, GON has developed a partnership with mass media platforms at the federal, provincial, and local levels for regular dissemination of key messages surrounding vaccine need and safety.

2. Government's Sector Strategy

16. **Government's COVID-19 Vaccination Allocation Plan.**²³ MOHP has developed a National Deployment and Vaccination Plan for COVID-19 Vaccines (NDVP) to guide for planning, preparation, implementation and monitoring of the COVID-19 vaccination program. The NDVP provides prioritization criteria for vaccination and guides the country's vaccination allocation plan. It also presents the country's plans to deploy potential COVID-19 vaccines, implement and monitor the nation-wide mass COVID-19 vaccination, and outline the country's medical waste management plan to manage incremental immunization waste due to the COVID-19 vaccination. The plan has been approved by the government and submitted to WHO for fulfilling the requirement of accessing free COVID-19 vaccines through the COVAX facility. GON plans to vaccinate 71.62% of its population above 15 years of age. The NDVP prioritizes 6.07 million people under the first two phases of vaccinations. The government's prioritization of vaccine access is consistent with the WHO Strategic Advisory Group of Experts on Immunization's recommendations as it first protects health workers, public officers, older people and people at high risk.²⁴

B. ADB Experience and Assistance Program

17. In May 2020, ADB approved a \$250 million loan to alleviate the impact of COVID-19 pandemic on public health, livelihoods, and the economy.²⁵ In June 2020, ADB approved a \$3 million grant to GON to support procurement of food, water, logistics and other support to improve quarantine facilities and effectively manage inflow of returning migrants in border areas.²⁶

²³ Country National Vaccination Allocation Plan (accessible from the list of linked documents in Appendix 2 of the report and recommendation of the President).

²⁴ WHO Strategic Advisory Group of Experts on Immunization. [COVID-19 materials](#) (accessed 26 December 2020).

²⁵ ADB. [Nepal: COVID-19 Active Response and Expenditure Support Program](#). Manila.

²⁶ ADB. [Nepal: COVID-19 Emergency Response](#). Manila.