SECTOR ASSESSMENT (SUMMARY): VACCINES

1. Sector Performance, Problems and Opportunities

1. The Department of Health (DOH) confirmed local transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 or coronavirus) that causes COVID-19 on 7 March 2020. Global pandemics in the past 100 years, e.g., 1918, 1957, 1968, 2009 pandemics¹ have shown that non-pharmaceutical interventions (NPIs) and community mitigation are the primary strategies (individuals, households and communities) in the immediate short-term prevention and preparedness phases of the disaster. Without the vaccine for COVID-19, NPI measures are key for "persons and communities to slow down the spread of the virus including personal protective measures for everyday use and pandemic use, community measures to increase social distancing and environmental measures, such as surface-cleaning measures, to reduce the transfer of viruses."² Equally important, efforts to strengthen the health system, surveillance and service delivery capacity are non -negotiable to meet essential health services and critical care needs of the population from COVID-19 related illnesses and other causes.

2. Global COVID-19 cases have reached 85.1 million and 1.8 million deaths as of 4 January 2021. The US has the greatest number of cases and deaths at 20.6 million and 0.351 million, followed by India (10.3 million cases, 0.149 death), Brazil (7.7 million cases, 0.196 million deaths. The Philippines has recorded its first case of COVID-19 on 30 January 2020 and now has recorded 0.521 million confirmed cases and 10,600 deaths as of 29 January 2021. It currently has a doubling time of 22.90 days and a halving time of 101.32 days since the first local transmission was recorded in March 2020 (Figure 1). The crude fatality rate stands at 2.03%. The Philippines now the second number of reported cases in Southeast Asia, after Indonesia (0.765 million cases, 0.227 million deaths). ³

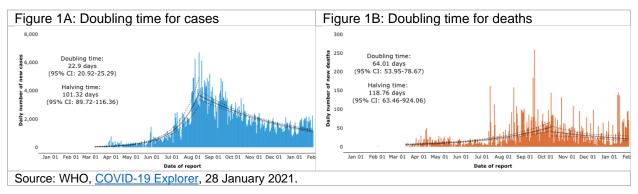


Figure 1: Doubling time for Cases and Deaths in Philippines

3. The government imposed enhanced community quarantine (EQC or known as hard lockdown) measure initially in NCR and nearby regions but was subsequently expanded nationwide, after the Department of Health confirmed local transmission in March 2020. Subsequently, it moved to modified ECQ and general community quarantine (GCQ) measures–

¹ B. Jester, T. Uyeki, and D. Jernigan. Readiness for Responding to a Severe Pandemic 100 Years After 1918, *American Journal of Epidemiology*, Volume 187, Issue 12, December 2018, Pages 2596–2602, <u>https://doi.org/10.1093/aje/kwy165</u>.

 ² N. Qualls et al. Community mitigation guidelines to prevent pandemic influenza - United States, 2017. MMWR Recomm Rep. 2017;66(1):1–34. DOI: <u>http://dx.doi.org/10.15585/mmwr.rr6601a1</u>.

³ John Hopkin University & Medicine. Coronavirus Resource Center. Data as of 4 January 2021. Accessible at <u>https://coronavirus.jhu.edu/map.html</u>.

supposedly to ease restrictions including mobility of persons-to restart economic activities in starting June 2020. Coronavirus infection rate was at its highest from July to October 2020. During this period, COVID-19 dedicated isolation facilities, intensive care unit (ICUs), and ward beds were, on average, at 50% occupancy nationally. NCR, which makes up 36% of the country's GDP, was the most affected region with isolation at 70%, ICU at 75%, and ward occupancy at 79%.⁴ In August 2020, medical associations appealed for a "timeout" and sought a stricter lockdown, i.e., MECQ, in NCR while they revisit and refine the country's strategies to contain the spread of the virus. The medical frontline workers have experienced fatigue, anxiety and even depression as a result of the pandemic.⁵ At the time, 5,008 health workers have been infected by COVID-19, 38 of them died. Of those, 1100 are physicians and 1734 are nurses.⁶

4. Since the first case of COVID-19 in the Philippines in January 2020, the government has enhanced its capacities in testing, tracing, isolating, and treating COVID-19 cases. It has accredited 184 laboratories for COVID-19 testing, increased PPE supply to its different health facilities, and deployed around 46,000 contact tracers in various regions of the country.⁷ This approach, together with NPI,⁸ has helped to reduce the spread of coronavirus in the country. The weekly increases in new COVID-19 cases were reduced from a peak of 23,019 new cases during 6–12 August 2020 to 9,203 new cases during 17–23 December 2020. Daily positivity rate was also reduced from 12.7% on 1 August 2020 to 6.5% on 29 December 2020.⁹ These downward trends are due to NPIs such as localized modified enhanced community quarantines (MECQ) from time to time, and extending general community quarantine (GCQ) all over the country; implementing strict social distancing, and imposing mandatory use of masks and face shields in public places; and increased testing and isolation measures. However, the risk of rapid spikes in new cases similar to trends seen in Europe, the United States, and other countries, remains.

5. **Top cases and deaths by region.** As of 3 February 2021, a total 530,118 confirmed cases and 10,942 deaths have been recorded in the Philippines. Table 1 indicates the top regions in terms of cases and deaths. The NCR represents 42.0% and 36.6% out of the total cases and deaths. DOH has estimated. The WHO situates the country at *Stage 2, localized community transmission with some geographic areas showing higher transmission intensity and indicators of widespread community transmission.* There is evidence of increasing trend in number and higher transmission in Region III, IV-A (CALABARZON), and NCR.¹⁰

| Top Regions | Cases | | Top Regions | Death | |
|-----------------------------|---------|-------|---------------------------------|--------|-------|
| | Number | % | | Number | % |
| Philippines | 530,118 | | Philippines | 10,942 | |
| NCR | 222,820 | 42.0% | NCR | 4,338 | 39.6% |
| Region IV-A (CALABARZON) | 93,691 | 17.7% | Region VII - Central Visayas | 1,460 | 13.3% |
| Region III - Central Luzon | 35,551 | 6.7% | Region IV-A | 1,316 | 12.0% |

 Table 1: Top Cases and Deaths, By Region (as of 3 February 2020)

⁴ DOH. <u>COVID-19 Tracker</u> and <u>COVID-19 daily case bulletin</u> (accessed on 29 December 2020).

⁵ H. Bania, J. Joaquin. <u>COVID-19: The need to heed distress calls of healthcare workers.</u> *Journal of Public Health,* Volume 42, Issue 4, December 2020.

⁶ S. Tomacruz. <u>PH health workers infected with corona virus reach 5008</u>. *Rappler*. 3 August 2020.

⁷ World Health Organization. 2020. <u>COVID-19 in the Philippines Situation Report 62</u>. Manila.

⁸ NPIs include social distancing measures, face mask and face shield policies, bans on public gatherings, school and workplace closures, transport and travel restrictions, enforcement of large-scale quarantines including stay-at-home and work-at-home orders, and national lockdowns.

⁹ DOH. <u>COVID-19 Tracker</u> (accessed on 31 December 2020).

¹⁰ World Health Organization. <u>WHO Situation Report #68.</u> 12 January 2021.

| Top Regions | Cases | | Top Regions | Death | |
|----------------------|--------|------|----------------------|-------|------|
| Region VII - Central | 30,906 | 5.8% | Region III - Central | 865 | 7.9% |
| Visayas | | | Luzon | | |
| Region VI-Western | 24,617 | 4.6% | Region VI-Western | 653 | 6.0% |
| Visayas | | | Visayas | | |

Source of basic data: DOH. COVID-19 Tracker.

6. Countries and pharmaceutical companies are on high gear to develop vaccines for COVID-19. An international platform for equitable access and distribution has been set-up, i.e., COVID-19 Vaccines Global Access (COVAX) facility. Like most developing member countries (DMCs), the Philippines is not able to develop a vaccine for coronavirus in the short- to medium-term. Therefore, the government will have to initially access vaccine through the COVAX facility and bilateral arrangements with countries and pharmaceutical companies. It can also participate in any alternative regional pooling mechanism that may be organized. However, access to and delivery of COVID-19 vaccines in the Philippines will be confronted with key constraints and challenges.

7. **Development problem and key constraints.** The core development problem is inequitable access to quality health services including safe and effective COVID-19 vaccines and routine immunization, which perpetuates poor health outcomes, poverty, and inequality. The major constraints are: (i) inadequate supply of and delivery system for safe and effective COVID-19 vaccines to cover vulnerable population; (ii) weak health financing framework and fragmented service delivery systems including surveillance to detect and swiftly respond to public health threats, immunization and COVID-19 vaccine delivery program; (iii) inadequate supply and unreliable delivery of essential health services and goods including vaccines; and (iv) weak governance and accountability at the national and subnational levels including monitoring and evaluation for health (Problem Tree for Vaccines in Annex 1).

8. The critical constraints of the Philippine health system and the operational capacity of its National Immunization Program (NIP) will impinge on the government's COVID-19 vaccine program once available in the global market. The Philippine government will have to consider the following policy and capacity issues: (i) weak enabling policy and regulatory framework to set policy objective/s, criteria and alternatives for the selection and access COVID-19 vaccine/s, target population/ group, institutional arrangements and financing; (ii) low capacity of National Immunization program (NIP) and vaccine readiness¹¹ that constrain procurement and delivery system for COVID-19 vaccines; (iii) limited capacity of multi-level cold chain system; and (iv) pharmaceutical companies race to develop, seek approval for use of safe and effective COVID-19 vaccines in the immunization coverage performance, multiple new and underutilized vaccines in the immunization package. This has resulted in variable national immunization schedule and removal of some vaccines.¹² It is instructive to assess the institutional arrangements for and state of NIP prior to the pandemic to inform support for coronavirus vaccine delivery.

2. NIP institutional arrangements and implications for COVID-19 vaccination

9. **Legal framework.** The Philippines compulsory basic immunization for infants and children below 8 years old can be traced to Presidential Decree No. 996 of 1976, which was amended by

¹¹ DOH leads the conduct of COVID-19 Vaccine Introduction Readiness Assessment Tool (VIRAT) of UNICEF and WHO. It also integrates elements of the World Bank's Vaccine Readiness Assessment Framework (VRAF).

¹² Coe, M., Gergen, J.; and Ileana Vilcu. 2017. Philippines Country Brief: Sustainable Immunization Financing in Asia Pacific. Washington, DC: ThinkWell.

Republic Act No. 7846 in 1994. Building on earlier legislations, the Mandatory Infants and Children Immunization Act of 2011¹³ provides for the coverage of basic immunization of vaccinepreventable diseases as follows: Tuberculosis; Diphtheria, tetanus and pertussis; Poliomyelitis; Measles; Mumps; Rubella or German measles; Hepatitis-B; H. Influenza type B (HIB); and such other types as may be determined by the Secretary of Health in a department circular. These will be given for free at any government hospital or health center to infants and children up to five (5) years of age. The expanded immunization program is included in the annual appropriations for DOH. The Act likewise mandates the Philippine Health Insurance Corporation (PHIC) to include basic immunization services among its benefit packages.

10. **Weak policy and regulatory framework.** At the central level, there has been a weak policy and regulatory framework due to lack of–or perhaps limited capacity of National Immunization Committee–National Immunization and Technical Advisory Group (NITAG) or a health technology assessment body to provide guidance and make informed decisions on NIP (footnote 7). The 2019 UHC law established Health Technology Assessment Council (HTAC) attached to DOST (transition from DOH in 5 years) to perform NITAG role on vaccines.

Lack of coordination between central and local governments weaken NIP. The DOH 11. procures vaccines as well as finances campaigns, updates cold chain, and trains health workers, as needed. With the devolved health system and service delivery under the Local Government Code of 1991, the local government units (LGUs) cover all operational expenses for local health facilities to deliver immunization services. The NIP gets funded from sin taxes revenues (e.g., 42% in 2015) as well as taxes on sugar-sweetened beverages earmarked for health. PhilHealth's engagement, is still limited, i.e., birth related immunization; the legal framework provides for immunization financing (para. 6). There is overlapping role between central and local governments in financing for birth doses of vaccines through reimbursement of infant care package. Central and local relations have led to communications and collaboration issues resulting in low coverage performance. There is weak flow of information, i.e., vertical programs and feedback mechanism, making the immunization program inefficient. Further, there is lack of accountability between central and local authorities on immunization delivery. Apparently, there is a "push" from central level instead of "pull" system for immunization with limited data and information exchange on local needs, which affect stock levels and supply chain.

12. Effective Vaccine Management (EVM) Assessment. In 2017, WHO and UNICEF in collaboration with DOH conducted an EVM assessment looking into four (4) levels of vaccine supply chain, i.e., primary, subnational, lower distribution and service point levels. It also looked into the nine (9) criteria for vaccine management: vaccine and commodity arrival procedures; storage temperatures; cold and dry storage capacity; building, equipment and transport; maintenance; stock management; effective distribution, good management practices; and information and supportive management functions.¹⁴ The assessment identified the following gaps: (i) space storage at the Research Institute for Tropical Medicine (RITM) functioning at only 3-month stock levels due to space constraints; (ii) unrealistic forecast of target population, which affect stocks management and distribution; (iii) limited stock management system, particularly below regional stores; (iv) outdated cold chain manual and standard operating procedures for health workers including systems, temperature monitoring procedures, supervision and training; (v) reverse distribution policy below regional stores leading to lack of accountability on supply chain at level levels; (vi) ineffective wastage management system; (vii) unavailable temperature monitoring devices; (vii) lack of data/ information and management system to support EVM

¹³ Republic Act No. 10152. Accessible at <u>https://www.officialgazette.gov.ph/2011/06/21/republic-act-no-10152/</u>.

¹⁴ WHO and UNICEF. 2017. Republic of the Philippines EVM [Effective Vaccine Management Assessment]

supervision, evidenced-based decision making, e.g., rational stocks planning, and distribution.

3. Operational challenges of NIP

13. Key operational challenges of NIP identified are: (i) vaccine hesitancy; (ii) complacency and lack of communication of vaccination campaign; (iii) change in lifestyle and working conditions among parents, where they skip and unable to attend to or prioritize the immunization needs of their children; (iv) limited access, i.e., local health centers, lack of staff/ health workers, and/or vaccine supply/stock; and (v) lack of monitoring of materials delivery.¹⁵ Moreover, there has been a low, declining coverage, and untimely delivery of immunization. COVID-19 disruptions threaten routine immunization coverage to decline further in 2020 (para. 15).

14. Addressing vaccine hesitancy and concerns on vaccine safety. The Philippines has recorded outbreaks of vaccine-preventable diseases in 2018-2019 including measles, dengue, and polio. It continues to suffer from a bit of vaccine hesitancy which is attributed in part to how the introduction of a dengue vaccine ("Dengvaxia") was managed in 2017. Consequently, the Vaccine Confidence Project found "dramatic drop in vaccine confidence from 93% in 2015 to 32% in 2018. Over the same period, those who strongly agree that vaccines are "safe" dropped from 82% to 21%, while confidence on vaccine "effectiveness" dropped from 82% to 22%.¹⁶ The DOH has recognized the needs to address concerns on the safety of COVID-19 vaccines and has introduced Vaccine Experts Panels, and strengthened communications, safety surveillance, and engagements with doctors and health professionals to help address safety concerns.

15. **Low, declining immunization coverage and untimely delivery of immunization.** Consequently, UNICEF observes a generally low childhood immunization rates in the Philippines.¹⁷ Even before the "Dengvaxia" vaccine anxiety, immunization data suggest declining and significant drop (and fluctuations) of routine immunization coverage rates from 88.1% in 2013 to 71.5% in 2015, and down to 67.0% in 2018-2019.¹⁸ Empirical work finds that: (i) immunization for specific vaccines and basic vaccination has been unstable in the past two decades; (ii) "only 38 to 65% of immunized children had timely administration per recommended age of the national immunization schedule...," ("among children immunized with all 8 vaccines considered in the study, only 11% had timely basic vaccination"(p.19).¹⁹ These contribute to incidence of vaccine-preventable diseases such as rubella, measles, and the resurgence of polio with 17 confirmed cases in 2019. As a consequence of COVID-19 pandemic, UNICEF estimates that some 2 million Filipino children will miss out routine vaccination in 2020 due to COVID-19.²⁰ DOH's expanded immunization program coverage rates range from 22% to 27% as of 31 May 2020.

4. Preparing for COVID-19 vaccine access and delivery

16. **COVID-19 vaccine policy criteria and alternatives.** As the government awaits quality, safe and effective coronavirus vaccine/s, policy criteria and alternatives have to be laid out for its decision-makers. These include (i) target vaccination level; (ii) prioritization, e.g., medical practitioners, elderly and those with pre-existing medical problems, and how to identify target

¹⁵ Based on discussions with WHO and UNICEF on 15 and 16 September 2020.

¹⁶ Larson, HJ., Hartiga-Go, K., and de Figueiredo. 2019. Vaccine confidence plummets in the Philippines following dengue vaccine scare: why it matters to pandemic preparedness, Human Vaccines & Immunotherapeutics, 15:3, 625-627, DOI: <u>10.1080/21645515.2018.1522468.</u>

¹⁷ NEDA and UNICEF. 2018. *Situation Analysis of Children in the Philippines.* Manila.

¹⁸ WHO and UNICEF. 2020. Estimates of national immunization coverage. 2019 revision. 6 July 2020.

¹⁹ Ulep, V.G.; and Uy, J. 2019. Too early, too late: timeliness of child vaccination in the Philippines. Discussion Paper Series NO. 2019-21. Philippine Institute for Development Studies: Quezon City.

²⁰ UNICEF. <u>2 million Filipino children may miss out on vaccinations in 2020 amidst COVID-19</u>.

groups; and (iii) public finance and level of state financing (and local governments') to be made available to cover for the entire or a percentage of the population (e.g., 20%, 60% to 70%).

17. **Constraints to swiftly procure and deliver COVID-19 vaccine/s.** Any COVID-19 vaccine will be confronted with institutional constraints of the country's health system on the one hand, and the national immunization program on the other. The fragmented health system and service delivery at the national, subnational and local levels is a fundamental constraint, which the 2019 Universal Health Care law (UHC), the Fourmula One Plus for Health strategy, and the National Objectives for Health 2017-2022 seek to address prior to COVID-19. The UHC law effectively poses a legal barrier that can potentially delay the acquisition of COVID-19 rather than swiftly; that is, regulating purchase of *drugs and medicines including vaccines which have undergone Phase IV clinical trial, systematic review and meta-analysis to be used for any population-based intervention.* Consequently, the Bayanihan 2 law adopted on 11 September 2020 has relaxed the required Phase IV trials for COVID-19 until 19 March 2021.²¹

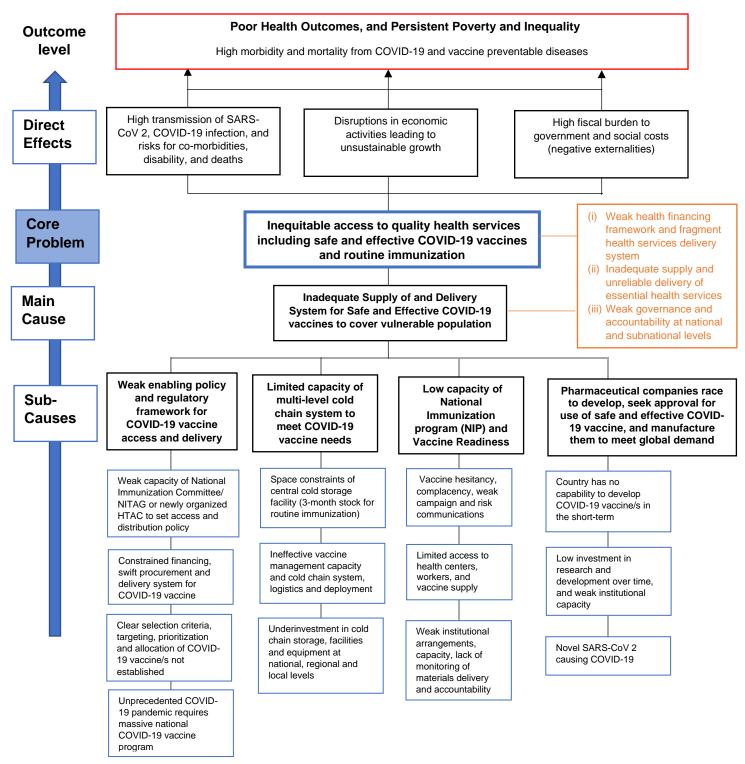
18. **Cold Chain System: storage, logistics, training.** Vaccines are delicate pharmaceutical products that require a stable and controlled temperature (e.g., 2 to 8 degree Celsius) from manufacturing, cross-country shipment, in-country distribution, central and subnational/ local storage until injection to target individuals. Except for Sinovac (+2 to +8°C), front-runners of coronavirus vaccine development require below zero ultra-low cold storage: Pfizer (-70 to-80°C), Moderna (-20 °C), Gamaleya (-16 °C). The country's cold chain system and storage limited capacity (with 3-month stock levels) will further be strained when the COVID-19 vaccine/s start to be procured and supplied, i.e., coronavirus vaccines and immunization stocks. (para. 12).

5. Conclusion

19. In conclusion, the Philippine health system including NIP operates under a multi-level government structure. On the whole, the government's policy framework and plan for COVID-19 vaccines are still evolving. It requires institutional and capacity development support to ensure access to safe and effective vaccines as well as their efficient delivery to target population. The issues and challenges of COVID-19 vaccine access and NIP will have to be addressed at different levels: policy and regulatory framework, institutional and financing arrangements including funds flow, service delivery, monitoring and accountability. PhilHealth can consider expanding its benefit package for vaccines. The institutional capacity of newly created HTAC needs to be developed – its policy autonomy (e.g., authority, decision-making processes, prioritization, resources), systems and procedures, research and development, governance and accountability. Finally, the readiness and capability of the delivery system for vaccines need to be strengthened.

²¹ Republic of the Philippines. <u>Republic Act No. 11494</u>. 11 September 2020.

Annex 1: Problem Tree for COVID-19 Vaccines Delivery and National Immunization Program



COVID-19 = coronavirus disease, HTAC = Health Technology Assessment Council, NITAG = National Immunization and Technical Advisory Group, SARS-CoV 2 = severe acute respiratory syndrome coronavirus 2.