Socialist Republic of Vietnam
Ministry of Health

Detailed Design Study for Cho Ray Vietnam-Japan Friendship Hospital Development Project (Phase II)

Study and Analysis on the Strengthening of Infectious Diseases Control in Vietnam

Final Report

October 2022

Japan International Cooperation Agency (JICA)

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List of Abbreviations

ACPHEED	ASEAN Centre of Public Health Emergencies and Emerging Diseases
ADB	Asian Development Bank
AMR	Antimicrobial Resistance
APSED	Asia Pacific Strategy for Emerging Diseases
ASEAN	Association of Southeast Asian Nations
ASTT	Administration of Science, Technology, and Training
ARV	Anti-retrovirus
BSL	Bio Safety Level
CDC	Centers for Disease Control and Prevention
COVAX	COVID-19 Global Vaccine Access
COVID-19	Coronavirus disease of 2019
CR-VJH	Cho Ray Vietnam –Japan Friendship Hospital
DOHA	Direction Office for Healthcare Activities
DWH	Data Warehouse
DX	Digital Transformation
EHAD	Electronic Health Administration Department
EOC	Emergency Operations Center
EPI	the Expanded Program on Immunization
EQA	External Quality Assessment
FETP	Field Epidemiology Training Program
GDPM	General Department of Preventive Medicine
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
HHTP	Hoa Lac Hi Tech Park
HR	Human Resources
ICT	Information and Communications Technology
IHR	International Health Regulations
IMPE	Institute of Malariology Parasitology and Entomology (Quy Nhon)
IPV	Inactivated Polio Vaccine
ISO	International Organization for Standardization
JEE	Joint External Evaluation
MERS	Middle East Respiratory Syndrome
mRNA	Messenger Ribonucleic acid
NCD	Non-Communicable Disease
NE Institutes	Four national institutes as the core center for epidemiology, microbiology, and immunology: NIHE, PINT, TIHE, PIHCMC
NICVB	National Institute for Control of Vaccine and Biologicals

NIHE	National Institute of Hygiene and Epidemiology
NIMPE	National Institute of Malariology, Parasitology and Entomology
NIN	National Institute of Nutrition
NIOEH	National Institute of Occupational and Environmental Health
ODA	Official Development Assistance
OHR	Organization & Human Resources Department (under Vietnam MOH)
PCPM	Provincial Center for Preventive Medicine
PHEOC	Public Health Emergency Operations Centre
PINT	Pasteur Institute in Nha Trang
PIHCMC	Pasteur Institute in Ho Chi Minh City
R&D	Research & Development
RT-PCR	Reverse Transcription Polymerase Chain Reaction
SARS	Severe Acute Respiratory Syndrome
SOP	Standard Operating Procedure
STEP	Special Terms for Economic Partnership
TIHE	Tay Nguyen Institute of Hygiene and Epidemiology
VIBC	Vietnam International Biomedical Center
VND	Vietnam Dong
WHO	World Health Organization
WPRO	World Health Organization Western Pacific Regional Office

1. Study Outline

1.1 Study Background

An unprecedented pandemic of novel coronavirus infection (hereinafter referred to as “COVID-19”) occurred during the implementation of the detailed design study of the Cho Ray Viet Nam-Japan Friendship Hospital Development Project. In Vietnam, a cumulative total of 10,743,448 confirmed cases and 43,084 deaths from COVID-19 were reported to WHO from January 3, 2020 to June 27, 2022. Cho Ray Hospital, as the base hospital in the southern region, is playing a leading role in the fight against COVID-19 and other infectious diseases that may occur in the future. While providing conventional medical services even during the recent coronavirus outbreak, the hospital has been taking various measures such as dispatching treatment support teams for the first, second, and third waves of outbreaks in the northern and central regions, including Binh Phuoc, Hai Duong, Bac Giang, and Danang City and providing online training for medical staff at regional hospitals on the diagnosis, treatment, and prevention of COVID-19. However, in light of the current situation, there is a need for further strengthening of functions and collaboration with other medical institutions and institutes, such as the National Institute of Hygiene and Epidemiology (NIHE).

The government of the Socialist Republic of Vietnam (hereinafter referred to as “GOV”) has positioned four national institutes of epidemiology (hereinafter referred to as “NE Institutes”) including NIHE as the core center for epidemiology, microbiology, and immunology. They are expected to spearhead the fight against infectious diseases in Vietnam and to lead the Provincial Center for Preventive Medicine (hereinafter referred to as “PCPM”). With regard to countermeasures against COVID-19, NIHE under GOV has taken the lead in building and expanding a nationwide COVID-19 testing network and is also working with medical facilities. The recent experience with the COVID-19 pandemic, which far exceeded the world's expectations, has required NIHE to further strengthen its capacity to become a research center of excellence, especially for more sophisticated research that meets international standards. In November 2021 Japan-Vietnam summit meeting, it was declared that the two countries would work closely together to develop a COVID-19 vaccine and treatment, as well as other measures to combat this infectious disease. At the meeting between the Minister of Health and JICA's senior vice president, concrete needs were expressed for the construction of Vietnam International Biomedical Center (hereinafter referred to as “VIBC”) for R&D of vaccines, and for the expansion of support for base hospitals, including Cho Ray Hospital.

While this project includes the detailed design of Cho Ray Hospital, in order to maximize the functions and effectiveness of the hospital to provide appropriate preventive, laboratory, diagnostic, and treatment services, it is necessary to strengthen cooperation with other medical institutions and laboratories and clarify the division of roles, taking into consideration the overall health care system in Vietnam for infected patients. In addition, GOV is currently in the process of materializing a Central CDC concept that "completes the organization of preventive medicine units at the provincial and central levels into disease control centers through the merger and integration of units performing similar

functions," which details still need to be confirmed. VIBC is expected to function in strengthening preventive medicine and infectious disease control in the CDC concept.

Furthermore, in order to strengthen NIHE's functions, facilities and equipment will be developed in Hoa Lac district to expand research and training functions, and the remaining three NE Institutes will be strengthened to reduce the burden on NIHE. Since PIHCMC is currently developing a BSL3 laboratory under a technical cooperation project, GOV requested JICA's cooperation in strengthening the remaining two NE Institutes (TIHE, PINT)

1.1.1 Purpose of the Survey

In order to maximize the functions and effects of Cho Ray Hospital in order to appropriately provide preventive medicine, examination, diagnosis, and treatment services, in light of the current status of response to COVID-19, it is necessary to develop a detailed design based on the strengthening of cooperation with other medical institutions and research institutes and the clarification of the division of roles, with a view to the health care system of Vietnam as a whole that responds to infectious diseases.

For this reason, in this survey, in order to design a facility that can further promote cooperation between Cho Ray Vietnam-Japan Friendship Hospital (hereinafter referred to as "CRVJH") and other medical and research facilities, not only to collect information on the current state of health policy and infectious disease control in Vietnam, the current state of infectious disease research and development, testing at core laboratories related to infectious disease control, the state of ICT system construction for infectious disease prevention, the current state of vaccine manufacturing systems, but also to examine the necessary functions and roles of CRVJH related to infectious disease control and the possibility of cooperation with related organizations, and finally to consider and to propose related project proposals that contribute to strengthening measures against infectious diseases at CRVJH based on the results of various information gathered.

1.1.2 Survey Overview

The outline of this survey ("Study and Analysis on the Strengthening of Infectious Diseases Control in Vietnam") is as follows.

(1) Collecting, analyzing, and sorting out issues related to Vietnam's health policy and infectious disease research and development system
   a) Confirmation of the GOV's health policies and systems, ICT systems, and confirmation of the content and implementation status of reform policies (5-Year plan) related to the health sector
   b) Analysis of the current situation and issues related to infectious disease control and confirmation of improvement policies
   c) Confirmation of organization and jurisdiction of relevant ministries and agencies related to infectious diseases
   d) Confirmation of infectious disease research and development system
   e) Confirmation of the current situation and issues related to human resources for research and development of infectious diseases (deployment status, training system, etc.)

(2) Collection and analysis of information on infectious disease research and development & testing at NE Institutes (NIHE/PINT/TIHE/PIHCMC)

a) Confirmation of current functions, management system (organization), budget, status of facilities/equipment, research and development, inspections of each institution, and arrangement of issues
b) Confirmation of other donors' support for each institution
c) Confirmation and analysis of future function expansion plans and Master Plans of each institution: Confirmation and analysis of future directionality of policies for strengthening functions, management systems, personnel allocation, research and development plans, financial plans, network improvement projects between research facilities

(3) Collection and analysis of information on ICT system construction between hospitals and research institutes
a) Confirmation of the current situation and plans for building ICT systems between hospitals and research institutes in Vietnam
b) Confirmation of existing projects and projects not yet started in the plan
c) Examination of the possibility of building an ICT system between hospitals and research institutes that will be required in the future

(4) Confirmation and analysis of needs related to strengthening the vaccine manufacturing system
a) Confirmation of the current situation and plans related to the vaccine manufacturing system in Vietnam
b) Confirmation of existing projects and projects not yet started in the plan
c) Examination of the possibility of building a vaccine manufacturing system that will be required in the future

(5) Examination and analysis of necessary functions and roles of CRVJH related to infectious disease control based on the above

(6) Examination of related project proposals that contribute to strengthening measures against infectious diseases in CRVJH

1.1.3 Site area

Throughout Vietnam (Hanoi, Nha Trang, Dak Lak, and Ho Chi Minh City are assumed)

1.1.4 Counterpart agencies

MOH of Vietnam

2. Current State of Health Policy and Infectious Disease Control

2.1 Health Policies and Systems of the Government

2.1.1 National development policy

The "Five-Year Socio-Economic Development Plan 2021-2025," a national development policy in Vietnam, calls for "ensuring rapid and sustainable economic growth on the basis of enhancing macroeconomic stability, advancing science, technology and innovation, and maximizing Vietnam's potential and superiority" as a "General objectives," and identifies the economy, society, and the environment as "Major targets." Among them, the social targets include "Average life expectancy is about 74.5 years, of which healthy life expectancy is at least 67 years" and "10 doctors per 10,000 population and 30 beds."

12 main tasks and solutions to achieve the above main targets are identified. Of these, descriptions related to health care are included in 3.1 and 3.8. Specific descriptions are as follows, and the underlined sections are descriptions concerning infectious diseases.

(3.1) Focusing on achieving both COVID-19 management and socio-economic recovery and development goals, prioritize public health, safety and social protection according to the actual situation and specific conditions of the particular local jurisdiction. Based on a proactive, energetic, flexible and creative frontline approach, take drastic prevention and control measures against COVID-19 , apply technology radically and effectively, promote a comprehensive and effective vaccination strategy, organize a public COVID-19 vaccination program and by the end of 2021/early 2022, commit to achieving mass immunity.

(3.8) Shift the focus of population policy from family planning to population and development. Strong and comprehensive reform and improvement of the quality of medical and health services provided to the people, ensuring social security, and striving to achieve 80% or more of the people's satisfaction with medical services by 2025. To promote preventive medicine, promote health, prevent and manage infectious diseases and non-infectious diseases, and ensure health, safety and security. Develop a network of satellite hospitals and focus on the development of school and school health. Develop a model for family medicine by encouraging public-private partnerships, private investment, and provision of online consultation and treatment services. Develop traditional medicine in collaboration with modern medicine. Strongly promote research and production of vaccines, drugs for diseases, and medical devices. Implement a roadmap for universal health insurance.

2.1.2 Health Sector Reform Policy (Five-Year Plan)

The "Five-Year Plan for Protecting the People's Health, Care and Improvement 2021-2025,"[1] a Five-Year Plan for the Health Sector, sets as its overall goal "The situation of infectious diseases in the world

[1] As of September 2022, still awaiting final approval. According to MOH, the draft that was prepared at the end of 2020 is currently undergoing major revisions to combat the spread of the novel coronavirus. The draft will be completed in 2022 and will be submitted to the National Assembly in Autumn 2023

has become more complicated in recent years, environmental pollution and climate change have caused many new diseases, especially the new coronavirus epidemic has become increasingly complex, and its negative impact on all aspects of socioeconomic activity has become longer and cannot be adequately evaluated. As Vietnam is located in the world trade area which is the most complex in terms of international trade, migrant labor, tourism and so on, the risk of disease transmission is high." The Five-Year Plan also sets as its overall goal "The development of a health care system that is fair, equitable, of high quality, efficient, sustainable and internationally integrated; that all citizens have adequate access to health care management; that citizens have access to health care services that contribute to improving their physical and mental health, capabilities, life expectancy and standard of living." The Five-Year Plan sets as its specific goal of infectious diseases: "Ensuring and improving health safety and the effectiveness of disease prevention and management," "Develop pharmaceutical raw materials, the pharmaceutical industry and medical equipment, and ensure sufficient medicines, vaccines and medical equipment at reasonable prices to meet the public's disease prevention and treatment needs".

With regard to infectious diseases, during the previous Five-Year Plan period, Vietnam has prevented pandemics by preventing outbreaks of infectious diseases in the country and controlling the influx of Ebola, MERS-CoV, and other infectious diseases that occurred in other countries in the region in a timely manner. In addition, effective prevention, detection, isolation, and treatment of COVID-19 have reduced local transmission. On the other hand, it has been noted that the lack of a special procurement mechanism in the event of a public health emergency has made it difficult to procure medicines, consumables, equipment, chemicals, and biologicals on short notice and on demand during an emergency such as, for example, an outbreak of a new type of coronavirus infection, resulting in price fluctuations.

Therefore, the current Five-Year Plan newly aims to meet domestic demand, for example, by acquiring vaccine production technology in the country, while continuing to implement drastic solutions to prevent and control novel coronavirus infections.

Specific solutions for infectious diseases include the following.

- Fundamental solutions for preventing and controlling infectious diseases, especially COVID-19, should continue to be implemented. Ensure health and safety, strengthen and enhance the effectiveness of disease prevention and control, and prevent major outbreaks.
- Improve the capability of the testing and testing system for drugs, vaccines, biological agents and medical devices.
- Adequate resources will be invested to acquire the next generation vaccine production technology and multiple integrated vaccines to meet the demand and export of the national expanded program on immunization. Encourage companies to produce investments, pharmaceuticals, vaccines, biological products, medical devices, and consumables, and enter the regional and global pharmaceutical value chain.

The list of large-scale investment programs and projects includes the following for infectious diseases:

- Initial stage of Export-Import Bank of Korea loan project for investment in CDCs at the central and local levels. (ODA project)
- Central and local CDC investment: 1.4 trillion VND (National budget project)
- Vaccine production project: 400 billion VND (National budget project)

2.1.3 Party Resolution No. 20 and Government Resolution No. 139

Party Resolution No. 20, which came into effect in 2017, states that improving prevention and response for infectious diseases associated with health reforms at the grass-roots level should include improving prevention and control of infectious diseases and avoiding the outbreak of a wide range of epidemics, responding quickly to emergencies, mobilizing domestic resources to help prevent and combat HIV/AIDS, tuberculosis and malaria, strengthening the immunization system, and increasing the number of immunizations under the expanded immunization program according to the budget.

In order to accelerate the development of the pharmaceutical and medical device sectors, it is stated that: to improve the research and production capacity of pharmaceuticals and vaccines; to invest sufficient resources in acquiring the production skills of next-generation vaccines and combined vaccines; to meet the domestic immunization expansion program demand and promote exports; and to encourage companies to invest in the production of pharmaceuticals, vaccines, biology, medical devices and consumables and to deepen their involvement in the regional and global pharmaceutical value chain.

Furthermore, for the development of human resources (hereinafter referred to as “HR”) and health science and technology, the following measures should be introduced: improving research capacity in health science and technology, pharmacy and biomedicine; promoting the application and transfer of advanced technologies; training health professionals in medical equipment; ensuring that health professionals are properly treated; determining initial salary scales commensurate with training time; and introducing incentives that are attractive enough to motivate qualified personnel to work in grassroots medicine, remote and isolated areas, border regions and islands. The aim is to introduce incentives that are attractive enough to motivate qualified personnel to work in grassroots medicine, remote and isolated areas, border areas and islands, and in fields such as preventive medicine, forensic medicine, psychiatry, tuberculosis and leprosy.

Also, the government's action plan for the implementation of the party's resolution No. 20 was enacted in 2017, Government Resolution No. 139. Regarding the role of MOH in strengthening epidemic control in parallel with community health reform, the followings are listed.

- Develop and implement programs and projects for health security, timely response to emergencies, especially recent outbreaks, and implement measures to strengthen and streamline epidemic prevention and to prevent pandemics from occurring.
- Develop and submit to the government a road map to increase the number of vaccines used in the Expanded Program on Immunization within the budget.

In addition, the role of MOH in strengthening the development of pharmaceutical and medical device sectors is to improve the research and production capacity of pharmaceuticals and vaccines, utilize next-

generation combined vaccine production technologies, meet the demand for domestic immunization expansion plans, establish a system for export, and make sufficient investments.

These are the bases of the Five-Year Plan for the Health Sector (awaiting final approval).

2.1.4 Infectious Disease Prevention and Control Act

The Infectious Disease Prevention and Control Act was enforced in 2007. The national policy on prevention and control of infectious diseases, ensuring biosafety in testing, use of vaccines and biological products for disease prevention, and practices for preventing infectious diseases are in place.[2]

Article 5 of the law lists the following as the national policy for the prevention and control of infectious diseases.

- Prioritize and support preventive medicine training
- Prioritize capacity building of HR and systems for monitoring infectious diseases and investment in research and production of vaccines and biopharmaceuticals
- Supporting and encouraging scientific research, exchange and training of experts, and technology transfer on prevention and control of infectious diseases
- Supporting health-care visits for infected persons in the workplace and other health-care providers as needed
- Support compensation for the killing of infectious disease-carrying cattle and poultry in accordance with the law
- Mobilize funds, technology and labor from society as a whole to prevent and combat infectious diseases
- Expand cooperation with international organizations, regions and countries in the world in the prevention and control of infectious diseases

Laboratories must meet the biosafety requirements for their level, and may perform the testing within their expertise after obtaining a certificate of compliance with the biosafety standard from the national health agency. Laboratories' workers are also obligated to protect themselves from infection.

In addition, the principles, voluntary and mandatory use of vaccines and medical biologics for disease prevention, as well as the responsibilities of the State (securing funding), the Minister of Health (promulgation of the list of infectious diseases for which use is mandatory, organization of EPI implementation, etc.) and health centers (immunization and use) are defined.

2.2 Analysis of the Current Status and Challenges Concerning Infectious Disease Control and Policy for Improvement

2.2.1 Health Indicators and Disease Structure

Table 2-1 shows the major health indicators in Vietnam. Life expectancy has increased by 2 years in 20 years, which is not a large increase compared to neighboring countries. Fertility rates have remained

[2] Revisions are currently underway, and some are invalid.

flat, while maternal mortality, under-five mortality, and underweight rates have declined significantly. Immunization rates have remained generally unchanged and have been relatively high for the past 20 years.

Table 2-1 Key Health Indicators

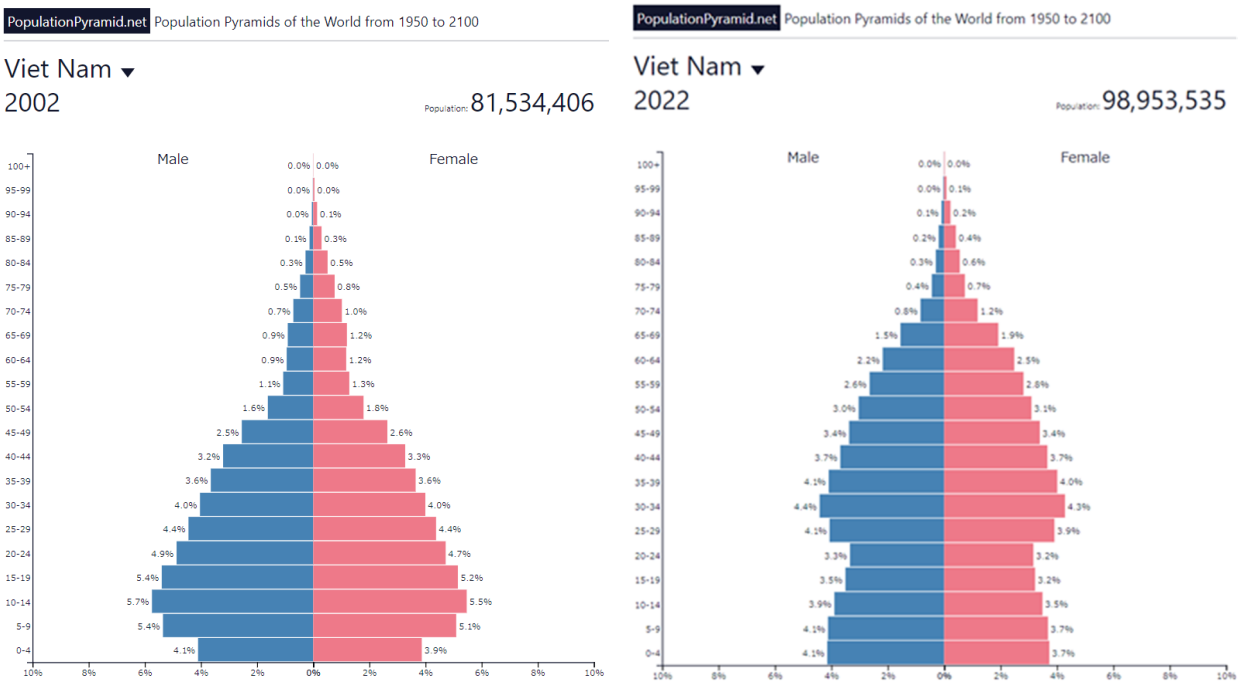
Indicator	Year 2000	Year 2020
Life expectancy at birth	73	75
Birth rate per woman	2.0	2.0
Adolescent fertility rate per 1,000 women aged 15-19	29	26
Contraceptive prevalence rate (all methods) among married women aged 19-45	74	77
Deliveries by skilled health personnel (as a percentage of total births)	59	N/A
Under-five mortality rate per 1,000 live births	30	21
Percentage of children under five who are underweight and weight by age	26.7	13.4
Immunization: measles (percentage of children aged 12-23 months)	97	97
Immunization: BCG*	98	95.37
Immunization: First Mixture of Three Doses*	96.9	96.29
Immunization: hepatitis B (within 24 hours of birth)*	97	82.19
Immunization: third polio*	96	79.89
Immunization: tetanus (second or later)*	89.8	87.82
Maternal mortality ratio per 100,000 live births, model estimate	68	43(2017)
HIV prevalence among persons aged 15-49 (per 1,000 uninfected people aged 15-49)	0.4	0.1

* WHO Immunization Data Portal

Source: World Development Indicators: Vietnam | Data (worldbank.org)

As Figure 2-1 shows, the population of Vietnam increased by 21.4% in 20 years from 81.53 million in 2002 to 98.95 million in 2022. In addition, the shape of the population pyramid had already become bell-shaped in 2002, but in 2022 there was a large decline in the number of people in their teens and twenties, and the shape of the population pyramid has changed to a longer bell-shaped shape. The average life expectancy of children born in 2020 is 80 years for women and 71 years for men[3] [4].

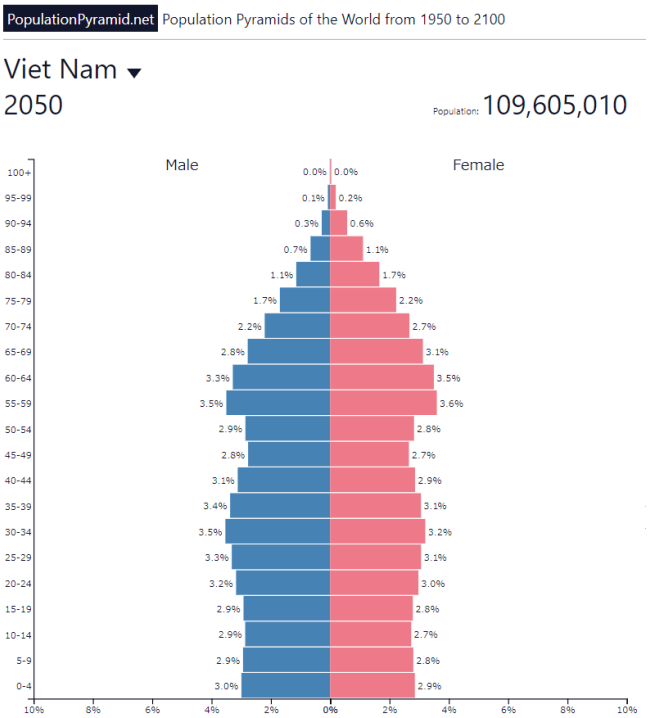
[3] Institute for Health Metrics and Evaluation, IHME:https://vizhub.healthdata.org/gbd-compare/
[4] https://data.worldbank.org/indicator/SP.DYN.LE00.FE.IN?locations=VN



Source: Population by age-group: https://www.populationpyramid.net/

Figure 2-1 Population Pyramids in 2002 and 202221

Moreover, as shown in Figure 2-2, the projected pyramid in 2050 is closer to the bell-shaped shape, and the number of elderly people aged 65 or older is expected to steadily shift to an aging society, as the percentage will increase from 8.4% (2022) to 20.5% (2050) of the total population. In addition, the percentage of children under 15 years of age has decreased from 23% (2022) to 17.2% (2050), and it is expected that the birthrate will continue to decline.

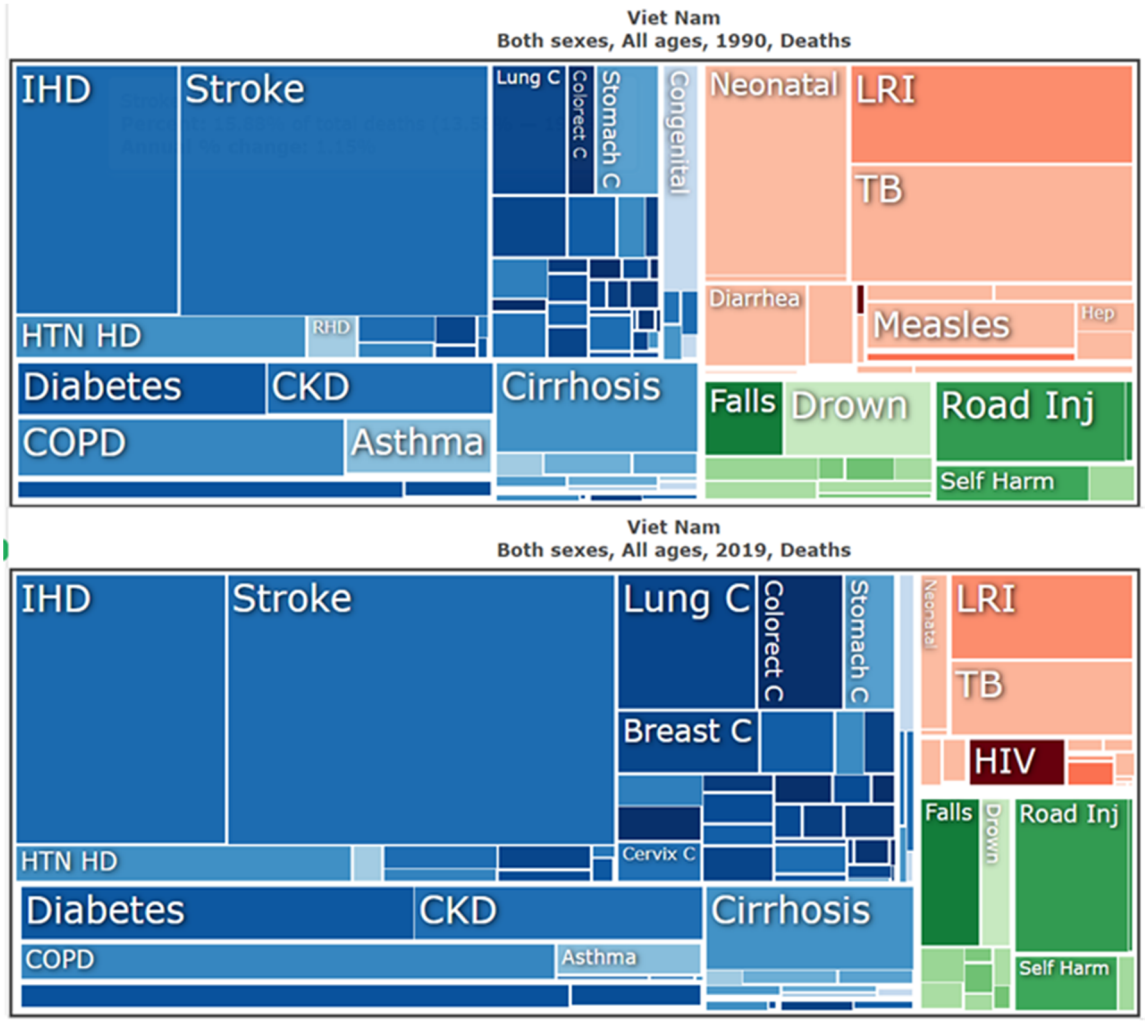


Source: Population by age-group: https://www.populationpyramid.net/

Figure 2-2 Population Pyramid in 205022

2.2.2 Mortality status

In 2019, cerebrovascular disease (21.5%), ischemic heart disease (11.8%), diabetes (4.7%), and chronic obstructive pulmonary disease (4.5%) were the leading causes of death among the population as a whole. Moreover, the proportion of non-communicable diseases (hereinafter referred to as "NCD") in the disease structure in Vietnam has increased over time compared to infectious diseases. As shown in Figure 2-3, when deaths are broadly divided into three groups according to the International Classification of Diseases: NCD, infectious diseases/maternal and child diseases/nutrition-related diseases, and trauma, the proportion of deaths due to NCD was more than twice than that due to infectious diseases/maternal and child diseases/nutrition-related diseases in 1990 (61.2% and 27.7%, respectively). In 2019, the proportion of deaths due to NCD was almost eight times that due to infectious diseases/maternal and child diseases/nutrition-related diseases (80.4% and 9.9%, respectively). Table 2-2 shows the 10 major causes of death.[5]



Source: Institute for Health Metrics and Evaluation. GBD compare. https://vizhub.healthdata.org/gbd-compare/

Figure 2-3 Three-Group Mortality Rates in 1990 and 2019

[5] Institute for Health Metrics and Evaluation, IHME:https://vizhub.healthdata.org/gbd-compare/

Table 2-2 Ten Major Causes of Death (2009 and 2019)

Ranking	2009	2019
1	Cerebrovascular disease	Cerebrovascular disease
2	Ischemic heart disease	Ischemic heart disease
3	Traffic accidents	Diabetes mellitus
4	Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease
5	Tuberculosis	Lung cancer
6	Lower respiratory infectious disease	Traffic accidents
7	Diabetes mellitus	Cirrhosis
8	Lung cancer	Chronic kidney disease
9	Cirrhosis	Lower respiratory infectious disease
10	Hypertensive heart disease	Alzheimer's disease

Source: Vietnam | Institute for Health Metrics and Evaluation (healthdata.org)

2.2.3 Current Status and Challenges of Infectious Diseases

(1) Trends of infectious diseases in Vietnam

As mentioned above, the burden of infectious diseases has greatly decreased in Vietnam. One of the achievements of the Five-Year Health Sector Plan from 2016 to 2020 is that "regional health facility networks have been strengthened, preventive hygiene has been improved, dangerous diseases have been prevented, and no pandemic has occurred. During this period in particular, Vietnam has actively implemented measures to prevent and control COVID-I9 epidemics, and thus far epidemics have been fundamentally controlled." Specifically, it is mentioned that "The incidence and mortality of most infections is declining year by year. Tuberculosis, malaria and measles are under control and achieving the global target. HIV/AIDS prevalence in the region has been reduced to less than 0.3%, and new infections have been declining continuously for five years. The rates of drug addicts receiving methadone replacement therapy and HIV/AIDS infected persons receiving antiretroviral therapy (ARV) are increasing." On the other hand, the Five-Year Health Sector Plan points out that "endemic diseases such as dengue fever, hand-foot-and-mouth disease, measles, and diphtheria are still at high risk levels, and vaccination coverage is low in some regions and ethnic groups, especially among migrant workers." With regard to COVID-19, since May 2021, the Delta strain has been invaded and the epidemic has spread, and effective vaccination strategies have been inadequate. Even if social isolation measures are applied nationwide, the epidemic cannot be brought to an end. In October of the same year, the government switched to a relaxation policy for with-corona.

(2) Current Status of Infectious Disease Control in Vietnam

Vietnam has a history of successful pandemic control. It was the first country in the world to control the 2003 outbreak of severe acute respiratory syndrome (SARS). In response to the SARS outbreak, the government increased its investment in public health infrastructure and established a national public health surveillance system centered on NIHE. NIHE, PIHCMC, PINT, and TIHE have been managing preparedness for various infectious diseases by conducting exercises and training on avian influenza,

measles, Ebola, the Middle East Respiratory Syndrome (MARS), and deer fever. Since 2016, hospitals have been required to report notifiable infections to the central database within 24 hours, allowing MOH to track epidemiological information from all over the country. In addition, the "event-based" monitoring program has been implemented since 2018. These efforts helped control the epidemic up to the third wave of COVID-19. However, as noted above, it was difficult to prevent the spread of highly infectious Delta strains.

(3) Analysis of Challenges Related to Infectious Disease Control

As noted above, Vietnam has been strengthening the infectious disease control system including the establishment of a nationwide public health surveillance system, and a Joint External Evaluation (JEE) of IHR conducted from October 28 to November 4, 2016, points out that Vietnam has made significant progress in meeting the core IHR capacity requirements. Specifically, 52% of the evaluation items were rated "capacity has been developed", 31% were rated "capacity is limited", and 17% were rated "capacity has been demonstrated". Particularly highly evaluated were coordination skills, communication and advocacy, zoonoses, real-time surveillance, and immunization. The results are shown in Table 2-3.[6]

[6] This assessment was designed to use the IHR JEE tool to evaluate 19 technical items and to reflect them in the multi-year national action plan of ASPED III.

Table 2-3 JEE results

Capacities	Indicators	Score
National legislation, policy and financing	P 1.1 Legislation, laws, regulations, administrative requirements, policies or other government instruments in place are sufficient for implementation of IHR (2005)	3
	P 1.2 The state can demonstrate that it has adjusted and aligned its domestic legislation, policies and administrative arrangements to enable compliance with the IHR (2005)	3
IHR coordination, communication and advocacy	P 2.1 A functional mechanism is established for the coordination and integration of relevant sectors in the implementation of IHR (2005)	4
Antimicrobial resistance	P 3.1 Antimicrobial resistance (AMR) detection	2
	P 3.2 Surveillance of infections caused by AMR pathogens	2
	P 3.3 Health care associated infection prevention and control programmes	3
	P 3.4 Antimicrobial stewardship activities	2
Zoonotic disease	P 4.1 Surveillance systems in place for priority zoonotic diseases/pathogens	4
	P 4.2 Veterinary or animal health workforce	4
	P 4.3 Mechanisms for responding to zoonoses and potential zoonoses are established and functional	3
Food safety	P 5.1 Mechanisms are established and functioning for detecting and responding to foodborne disease and food contamination	3
Biosafety and biosecurity	P 6.1 Whole-of-government biosafety and biosecurity system is in place for human, animal and agriculture facilities	3
	P 6.2 Biosafety and biosecurity training and practices	3
Immunization	P 7.1 Vaccine coverage (measles) as part of national programme	4
	P 7.2 National vaccine access and delivery	4
National laboratory system	D 1.1 Laboratory testing for detection of priority diseases	3
	D 1.2 Specimen referral and transport system	3
	D 1.3 Effective modern point of care and laboratory based diagnostics	3
	D 1.4 Laboratory quality system	3
Real-time surveillance	D 2.1 Indicator and event based surveillance systems	4
	D 2.2 Inter-operable, interconnected, electronic real-time reporting system	3
	D 2.3 Analysis of surveillance data	3
	D 2.4 Syndromic surveillance systems	4
Reporting	D 3.1 System for efficient reporting to WHO, FAO and OIE	3
	D 3.2 Reporting network and protocols in country	2
Workforce development	D 4.1 Human resources are available to implement IHR core capacity requirements	3
	D 4.2 Field epidemiology training programme or other applied epidemiology training programme in place	4
	D 4.3 Workforce strategy	3
Preparedness	R 1.1 Multi-hazard national public health emergency preparedness and response plan is developed and implemented	2
	R 1.2 Priority public health risks and resources are mapped and utilized	2
Emergency response operations	R.2.1 Capacity to activate emergency operations	2
	R.2.2 Emergency operations centre operating procedures and plans	3
	R.2.3 Emergency operations programme	3
	R.2.4 Case management procedures are implemented for IHR relevant hazards	3
Linking public health and security authorities	R.3.1 Public healthy and security authorities, (e.g. law enforcement, border control, customs) are linked during a suspect or confirmed biological event	2
Medical countermeasures and personnel deployment	R.4.1 System is in place for sending and receiving medical countermeasures during a public health emergency	2
	R.4.2 System is in place for sending and receiving health personnel during a public health emergency	2
Risk communication	R.5.1 Risk communication systems (plans, mechanisms, etc.)	3
	R.5.2 Internal and partner communication and coordination	3
	R.5.3 Public communication	3
	R.5.4 Communication engagement with affected communities	2
	R.5.5 Dynamic listening and rumour management	3
Points of entry	PoE. 1 Routine capacities are established at points of entry	3
	PoE. 2 Effective public health response at points of entry	2
Chemical events	CE. 1 Mechanisms are established and functioning for detecting and responding to chemical events or emergencies	2
	CE. 2 Enabling environment is in place for management of chemical events	2
Radiation emergencies	RE.1 Mechanisms are established and functioning for detecting and responding to radiological and nuclear emergencies	3
	RE. 2 Enabling environment is in place for management of radiation emergencies	2

Source: Joint External Evaluation of IHR Core Capacities of Viet Nam, Mission Report: 28 October – 4 November 2016

The scores are viewed as follows.

Table 2-4 Color Scoring System of the JEE Tool

Score	Status	Color
1	No capacity	Red
2	Limited capacity	Yellow
3	Developed capacity	Yellow
4	Demonstrated capacity	Green
5	Sustainable capacity	Green

Source: Health Sciences 2017 Vol. 66 No. 4 p.387-394

(4) Policy for improving measures against infectious diseases

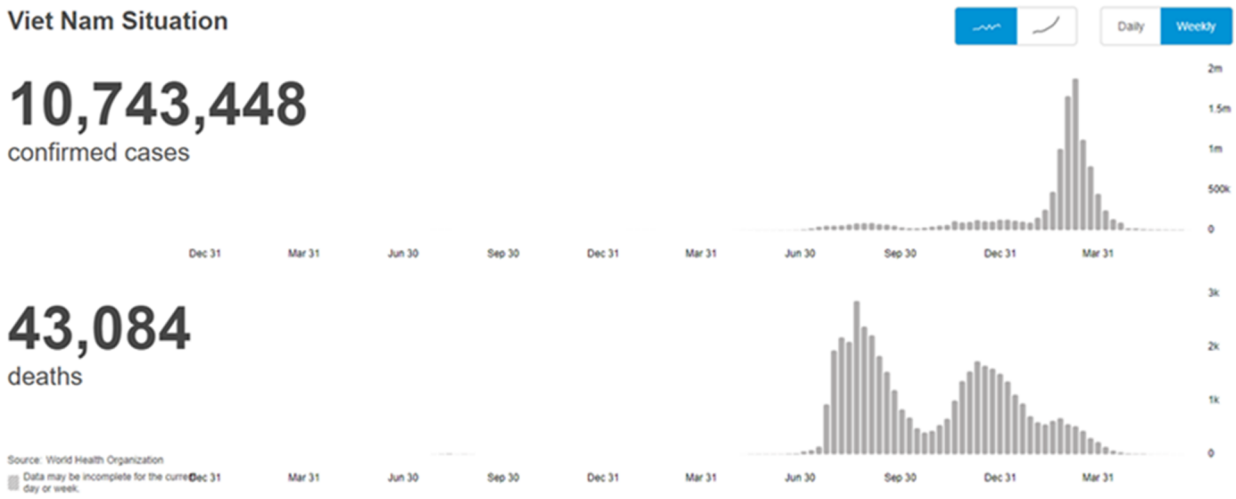
As mentioned above, Vietnam has generally taken firm measures against infectious diseases, and the following recommendations were made as a result of the JEE in 2016.

- Formulation of a national action plan over several years. Vietnam has a strong legal and regulatory framework, but compliance and consistency with IHR (2005) and other national obligations should be ensured by reviewing and clarifying from time to time the legal mandate and the responsibilities of those involved in health and security.
- Support for health security plans and procedures should be strengthened by guidance from the National Integrated Risk Assessment for Threats and Hazards, development, documentation and finalization of national guidelines, and standard operating procedures (SOPs) (e.g. Public Health Emergency Operations Centre (PHEOC) Handbook).
- Strengthening multisectoral coordination and information exchange at the national level should be improved through formal and informal information systems.
- Review national strategies for human resource development, including the deployment of public health personnel and initial & current education.
- Strategic investments in sustainable health security need to be promoted.

Based on these recommendations and under the latest Five-Year Plan for the Health Sector, the Five-Year Plan of preventive medicine will be drafted by each responsible department.

2.2.4 Current status of the new coronavirus infection

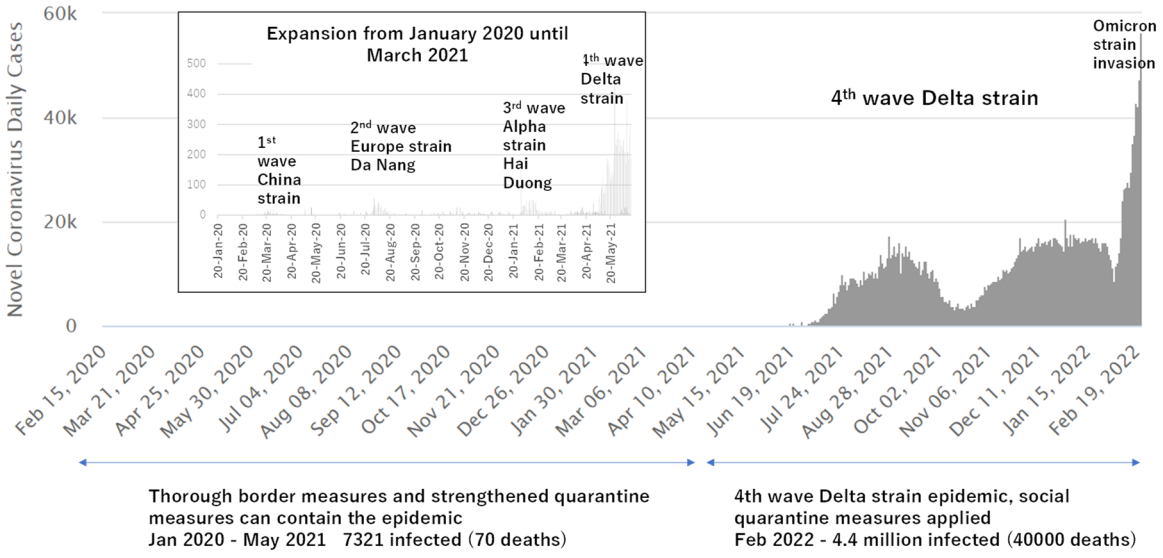
In Vietnam, a cumulative total of 10,743,448 confirmed cases and 43,084 deaths of the COVID-19 cases were reported to the WHO between January 3, 2020, and June 27, 2022.



Source: WHO Coronavirus (COVID-19) Dashboard

Figure 2-4 Transition of COVID-19s and deaths in Vietnam (as of June 27, 2022)

Figure 2-5 shows the relationship between the number of patients and epidemic strains in Vietnam. The rise in the number of deaths was caused by the invasion of Delta variant and the spread of the epidemic, and the bimodality was attributed to the first nationwide lockdown, but it could not be suppressed, and the rise was again due to the relaxation of regulations.

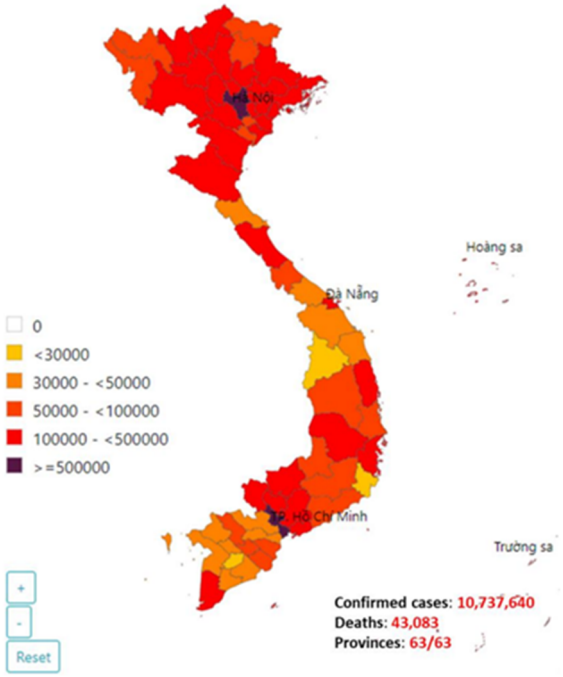


Source: prepared by JST

Figure 2-5 Relationship between the number of patients in Vietnam and epidemic strains (as of February 2022)

The cumulative total of infections from April 27, 2021 to June 21, 2022 by region is shown in Figure 2-6: Hanoi City (1,603,941 cases, 1,224 deaths), Ho Chi Minh City (609,838 cases, 20,475 deaths), Nghe An Province (485,295 cases, 145 deaths), and Bac Giang Province (387,682 cases, 92 deaths). When the infection spread, cities and provinces had been promoting activities to minimize deaths caused by COVID-19 by suspending the operation of bars, karaoke, etc. as public health and social measures, promoting vaccination, strengthening communication, and improving the management of home isolation of asymptomatic and mildly ill patients. However, the infection has settled down since the

autumn of 2021, and the number of infected increased sharply for about four months after the Tet holidays. In addition, since Vietnam resumed tourism on March 15, 2022, it is expected that community infections caused mainly by the Omicron strain will continue.[7]



Source: MOH, WHO COVID-19 Situation Report #94

Figure 2-6 Infection Status by Region

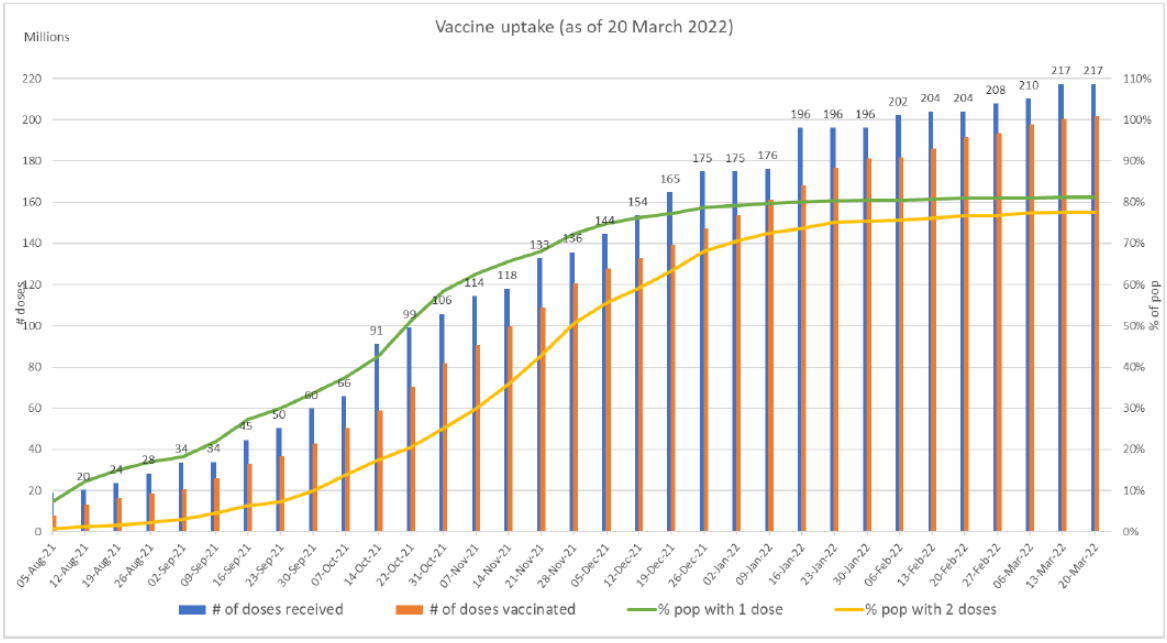
Currently, there are 42 provincial CDCs in Vietnam that have laboratories using the RT-PCR method for the COVID-19, and there are 374 laboratories which can provide the same testing (154 in the northern region, 39 in the central coastal region, 7 in the central highland region, and 174 in the southern region).[8]

On 17 March 2022, the government announced Resolution 38 updating the policy of the COVID-19 Prevention and Control Program for 2022-2023. The goal of the resolution is to promote: 1) effective control of the pandemic; 2) control of disease transmission; 3) maximum protection of people; 4) minimization of morbidity and mortality; and 5) socio-economic recovery and development. It also focuses on setting clear targets for vaccination and mortality and on coordinating public health and social behavior measures.[9]

As of 20 March 2022, COVID-19 vaccines that arrived in Vietnam totaled to 217,469,996 times, comprising 61,731,300 doses from COVAX, 32,265,800 doses from other countries, and 123,472,896 doses from bilateral sources. As of 20 March, 79,696,647 persons aged 12 years or older (approximately 81.1% of the total population) had received the first vaccination and 76,190,406 persons aged 12 years or older (approximately 77.6% of the total population) had received the second vaccination. 14,650,864

7 WHO (2022) COVID-19 Situation Report #85, Ministry of Health, Vietnam
8 WHO (2022) COVID-19 Situation Report #85, Ministry of Health, Vietnam
9 WHO (2022) COVID-19 Situation Report #85, Ministry of Health, Vietnam

immunocompromised and high-risk persons received boosters and 29,793,984 fully vaccinated persons (30.3% of the total population).[10]

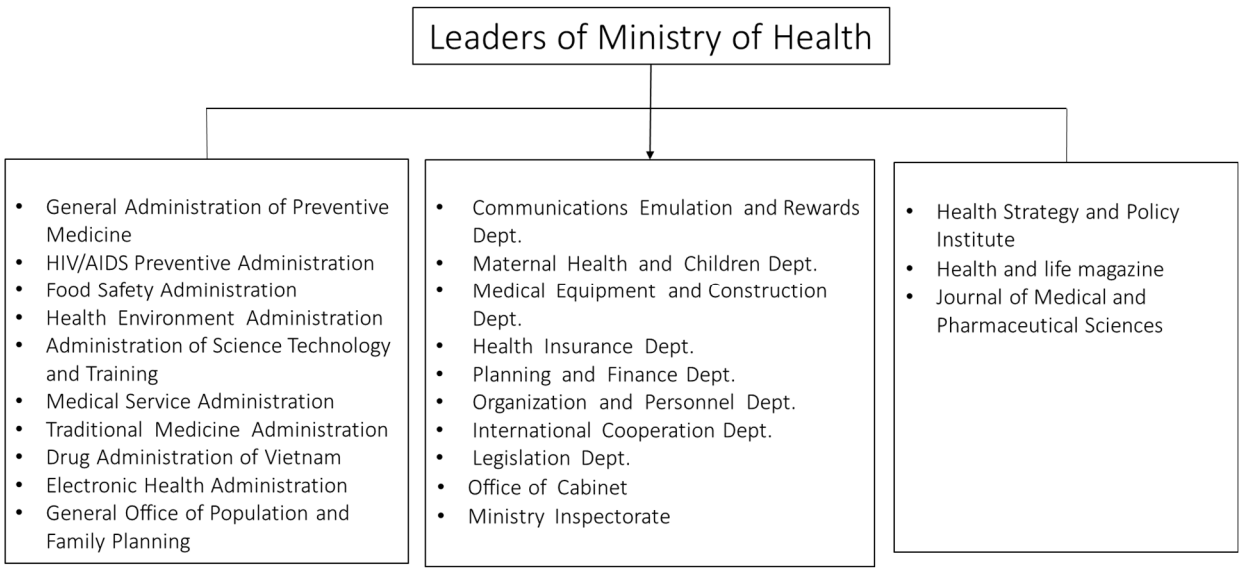


Source: MOH, WHO COVID-19 Situation Report #85

Figure 2-7 Changes in Vaccine Usage and Vaccination Rate per Population

2.3 Organizations and Responsibilities of Relevant Ministries and Agencies Related to Infectious Diseases

The organizational chart of MOH is as follows:



Source: prepared by JST

Figure 2-8 Organizational chart of MOH

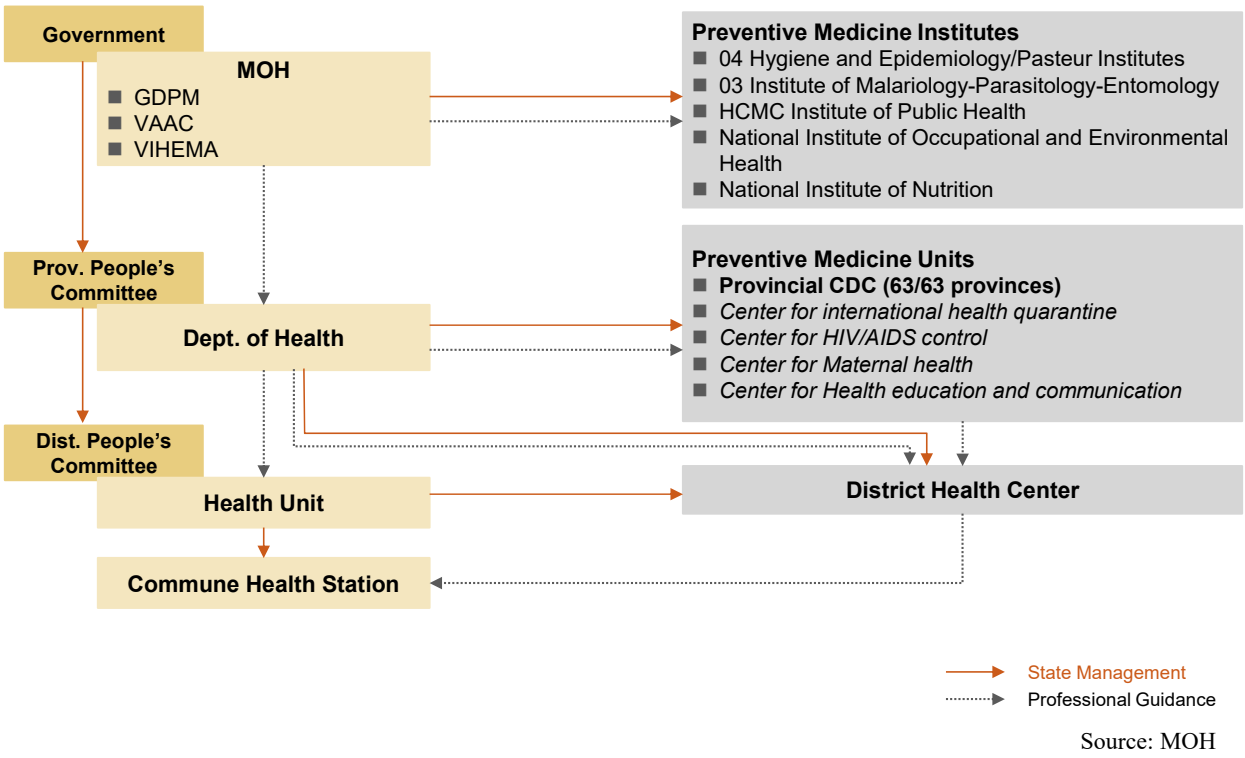
[10] WHO (2022) COVID-19 Situation Report #85, Ministry of Health, Vietnam

The Organization & Human Resources Department (hereinafter referred to as "OHR") and the General Department of Preventive Medicine (hereinafter referred to as "GDPM") of MOH are leading the reorganization of the preventive health sector and are in charge of formulating the master plan and development plan of the health system in Vietnam, in accordance with Resolution No. 20/NQ-TW. In particular, The OHR is in charge of overall coordination and review of organizational matters, while the GDPM is in charge of technical matters. Administration of Science, Technology, and Training (hereinafter referred to as "ASTT") is responsible for vaccine development, research, and production.

With regard to infectious diseases, Article 6 of the Law on Prevention and Control of Infectious Diseases defines the state management agencies in charge of prevention and control of infectious diseases as follows.

- GOV shall exercise unified national control over the prevention and control of infectious diseases throughout the country.
- MOH, on behalf of GOV, is responsible for the national management of prevention and control of infectious diseases throughout the country.
- Each ministry and provincial-level agency shall, within the scope of its duties and authority, work with MOH to carry out the national management of infectious disease prevention and control.
- People's committees at all levels of government shall carry out state management of infectious disease prevention and control in accordance with the decentralization of government.

The relationship between the ministries and agencies involved in infectious diseases as prepared by MOH is shown in the figure below.



Source: MOH

Figure 2-9 Diagram of Relationships between Ministries and Agencies Related to Infectious Diseases

2.4 R&D System for Infectious Diseases

One of the achievements from 2016 to 2020 in this Five-Year Plan for the Health Sector is that "the capacity of research facilities for epidemiology and microbiology, and advanced technology centers are being strengthened. Many scientific research plans, themes, and projects are being deployed, effectively used for diagnostics, treatment, drug materials, pharmaceutical manufacturing, and vaccines, and are internationally recognized." As shown in the diagram in Figure 2-9, the Institute of Preventive Medicine at the central level (NIHE, PIHCMC, TIHE, PINT), NIMPE (parasites, malaria, insects), NIOEH (occupational and environmental), and NIN (nutrition and food safety) HCMC Public Health Institute are the main players. Specifics are listed in the table below.

Table 2-5 Primary Preventive Medicine Functions Matrix

No.	Institute	Com. Disease Control	NCD Control	Occupational and Environment	Nutrition and Food safety	Materal and Child health
1.	NIHE	X	X			X
2.	NIOEH			X		
3.	NIN				X	X
5.	Pasteur HCMC	X	X			
6.	Public Health Institute HCMC		X	X	X	
4.	TIHE	X	X	X	X	
7.	Pasteur Nha Trang	X	X	X	X	
8.	NIMPE	X				
9.	IMPE Quy Nhon	X				
10.	IMPE HCMC	X				

Source: MOH

The status of research implementation at the Preventive Medicine Institutes is discussed later.

In the current Five-Year Plan for the Health Sector, one of the outcomes for 2016-2020 is "The capacity of the epidemiology and microbiology research facilities and the advanced technology centers have been strengthened. Many scientific research programs, themes, and projects have been developed and are effectively used for diagnosis, treatment, drug materials, drug production, vaccines, etc., and are internationally recognized".

2.5 Current Status and Challenges Concerning HR for R&D of Infectious Diseases (Assignments, Training System, etc.)

Although the previous paragraph mentioned the international recognition of the competence of epidemiology and microbiology research facilities, as discussed below, there is a need for human resource development in each institution. Prime Minister's Decision No. 376/QD-TTg emphasizes the development of quality personnel involved in the research and manufacture of pharmaceuticals and pharmaceutical raw materials, and aims to provide specialized training in vaccine and medical biologics production, bioequivalence research, and clinical trials in university pharmacy training programs.

At present, there are ten training schools for physicians in preventive medicine and 13 training schools for public health graduates throughout the country. Many graduate every year, but the reputation and treatment in the field of preventive medicine is lower than in other fields, so there are many who change jobs.

Meanwhile, in 2007, MOH, in cooperation with WHO and the CDC of the United States, initiated the Field Epidemiology Professional Training Program (FETP) and trained 900 field epidemiologists between 2007 and 2021. Currently, the basic three-month course, the intermediate nine-month course, and the advanced twelve-month course are implemented, and a total of 200-240 persons are trained annually in the NIHE, TIHE, PINT, and PINHCM.

2.6 Central CDC Concept

GOV stated that the organization and operation of public service providers face many challenges and in 2017, in the Resolution No. 19-NQ/TW, the Government set reforming the organizational and management structure of public service providers and improving their quality and efficiency as one of the top priority tasks and urgent and sustainable tasks to be undertaken by the Party Executive Committee[11]. With regard to the health sector, the resolution also called for the quick completion of the conversion from central and provincial preventive health centers into centers for epidemic control and prevention at same levels based upon acquisition of entities and organizations serving same functions and integration.

The Central CDC concept is now taking shape, with several government resolutions issued between October 2017 and March 2022. First, Resolution No. 19-NQ/TW, dated October 24, 2017, to "complete the organization of provincial and central level preventive medicine units into Centers for Disease Control through the merger and consolidation of units performing similar functions," and Resolution No. 20-NQ/TW, dated October 25, 2017, to "continue the organization of preventive medicine centers and units at the provincial and central levels, to create a unified system of disease control centers at all levels, and to connect them to the global disease control network". Further, in Resolution No. 139/NQ-CP dated December 31 of the same year and in Resolution No. 08/NQ-CP dated January 24, 2018, "to formulate a proposal to reorganize the central level preventive medicine units into a central disease control center." In Notice 347/TB-BYT dated March 23, 2021, former Minister of Health Nguyen Tan Long concluded, "In the near future, two campuses will be established in the north and south to organize research institutions." Furthermore, Government Resolution No. 38/NQ-CP dated March 17, 2022

[11] The resolution points out "the organization and operation of public service providers are still facing unsolved issues, shortcomings and challenges. Many legislative documents concerning public service providers are not promulgated on time or not timely amended. The renovation of organizational structure of public service providers is in slow progress. The planning for public service provider network is done based upon administrative units but fails to focus on sectors, fields, regional characteristics and reality. Inefficient and poor organizational structure with poor internal management of public service providers has resulted in low-quality services. State budget has spent too much on public service providers while some of them suffer losses or waste their funding. Public officials and public employees fail to be structured logically and show low productivity. The financial autonomy mechanism is inflexible and non-transparent; service charges fail to be converted to services prices and the roadmap to adjustment to public service price is not prepared timely. Private sector involvement in public service provision is still in slow progress. State management shows limitation on its effect and efficiency. There are still shortcomings in inspection, audit, supervision and handling of violations regarding operation of public service providers."

(Program for Prevention and Control of COVID-19) states that "the establishment of a Central CDC and local CDCs in socio-economic regions shall be accelerated."

In response to the above government resolutions, MOH is in the process of reviewing the CDC models of other countries, including the United States, China, Taiwan, South Korea, and Canada[12].

OHR and GDPM are drafting plans for the establishment of the Central CDC concept, and around October 2022, they will obtain input from relevant institutions, and submit the plan to the Prime Minister in December of the same year.

According to OHR, the plans and progress regarding the Central CDC are as follows:

[Organization of the Central CDC]

- The Central CDC will integrate the central level preventive medicine institutes (NIHE, TIHE, etc. (sanitary epidemiology), NIMPE (parasites, malaria, insects), NIOEH (occupational and environmental), NIN (nutrition and food safety), etc.).
- The Central CDC will be established in Hanoi, and the NIHE is expected to serve as the Central CDC Headquarters. However, since it is difficult to relocate NIHE to the Central CDC headquarters, VABIOTECH is considered to be moved off site to strengthen its research function. On the other hand, GDPM is of the opinion that the Central CDC has so many functions that the NIHE cannot assume them.

[Functions of the Central CDC]

- The Central CDC is expected to provide technical notifications and guidance to the provincial CDCs, provide testing based on technologies that cannot be handled by the provincial CDCs, manage national data on infectious diseases, and serve as an emergency operations center (EOC).
- Vaccine R&D and manufacturing are also part of the Central CDC concept, but it is assumed that R&D and manufacturing will be separated as functions.

[Regional branches]

- In regions where there are no laboratories that can serve as branch centers (e.g., South-Central and Mekong Delta), provincial CDCs are planned to be upgraded and established as branch centers, and in addition to NIHE, PINT, TIHE, and PIHCMC, Son La Provincial CDC (Northwest), Nghe An Provincial CDC (Northeast), and Can Tho City (Mekong Delta dept.) CDC are candidates. The following are the candidates for the CDC The level of laboratories, etc. will be considered according to the functions of each laboratory and the content of testing.
- In the Central Highlands region, the probability of emerging infectious disease outbreaks is higher than in urban areas, and MOH's management of the region is weak. In the region, more efforts will be made not only for prevention of infectious diseases, but also for treatment based

[12] Since the U.S. CDC does not have a CDC for each state, Vietnam will refer to the Chinese version of the CDC. (Hearing from the OHR on April 26)

on the national hospital to be established in Dak Lak Province.

- As of April 2022, integration into regional CDCs is proceeding ahead of schedule, including the purchase of equipment.

Furthermore, the United States, Germany ($275 million), and ADB ($100 million) have been approached to provide funding for the Central CDC concept, and Korea has committed to provide $450-475 million to fund the construction of the Central CDC.

In terms of the region, the establishment of the ASEAN Center for Public Health Emergencies and Emerging Infectious Diseases (ACPHEED) was approved at the ASEAN Health Ministers' Meeting in May 2022; ACPHEED will have three pillars: surveillance and detection, response, and risk management, and will be established in Vietnam, Thailand[13]. The relationship with the Central CDC concept in Vietnam needs to be closely monitored.

VIBC plays the most central role in the CDC concept consisting of the Central CDC and seven regional CDCs, and as a core base for preventive medicine and infectious disease control, is expected to have 1) vaccine research and manufacturing, including clinical trial function, 2) international research center for infectious diseases, 3) Central CDC Headquarters, and 4) testing/surveillance functions. The establishment of VIBC will contribute to the improvement of R&D and vaccine manufacturing functions for infectious disease control in Vietnam, and eventually to the establishment of a resilient health system.

[13] ASEAN aims to develop global vaccine passport - Politics & Laws - Vietnam News | Politics, Business, Economy, Society, Life, Sports - VietNam News

3. Current Status of the R&D, Testing of Infectious Diseases in NE institutes

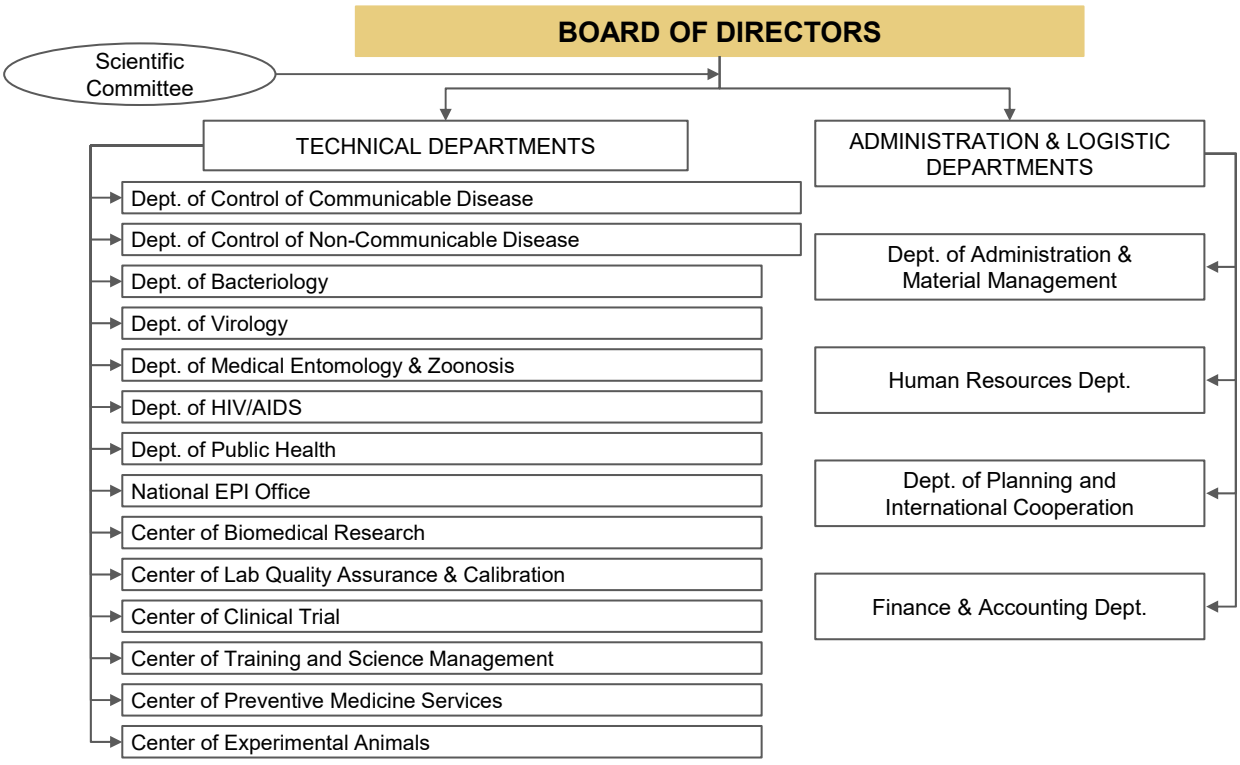
3.1 Analysis of Current Status, Challenges, and Future Direction of NIHE

3.1.1 Current situation

Established in 1926 as the Hanoi Pasteur Institute, it became the Vietnamese Institute of Microbiology in 1961 and the National Institute of Hygiene and Epidemiology in 1998. National institutions responsible for organizing, guiding and implementing national preventive medicine and public health practices and programs. Its main functions include prevention and control of infectious diseases, Non-Communicable Disease (NCDs), public health emergencies, scientific research, preventive medicine and public health training, networking, and international cooperation on preventive medicine and public health. As of April 2022, the NIHE has 339 staff members.

Major strategies include building advanced research capacity and prioritizing R&D in order to become an excellent research center in Vietnam that meets international standards, applying research results for community health interventions and transfer of technologies and products, and becoming a national laboratory responsible for quality control of international standards and quality control.

The organization chart of NIHE is shown below.



Source: NIHE

Figure 3-1 Organization Chart of NIHE

NIHE also has 14 technical departments.

- Dept. of Control of Communicable Disease: Trend, Risk Assessment, Interventions for Disease Prevention and Control, Application of IT in Data Management, Analysis and Interpretation for Early and Prompt Response to Public Health Problems
- Dept. of Control of Non-Communicable Disease: Surveillance of NCD (NCDs); Establishment and update of databases on NCDs and risk factors; Analysis and identification of trends in NCDs and risk factors for effective interventions; Public health interventions for NCDs and risk factors; Health management of the elderly; and Health promotion.
- Dept. of Bacteriology: Improvement of laboratory performance, surveillance, prevention and control, and application of state-of-the-art technologies for the detection of pathogens of emerging and re-emerging infectious diseases and zoonotic diseases.
- Dept. of Virology: Diagnosis, monitoring, and research of viruses that infect humans. There are arbovirus laboratories, enterovirus laboratories, hepatitis laboratories, influenza laboratories, national influenza centers, zoonotic laboratories, rabies laboratories, respiratory laboratories, ultrastructural laboratories, and nanotechnology laboratories.
- Dept. of Medical Entomology and Zoonosis: Organizations, guidance, implementation and research of activities related to the monitoring and control of sanitary insects and zoonoses, and studies and proposals for national standards and regulations related to the monitoring and control of vectors and zoonoses
- Dept. of HIV/AIDS: HIV/AIDS testing and counselling, Scientific Research, Training and International Cooperation Organization, Guidance, Implementation and Supervision, HIV/AIDS Epidemiology, Serology Surveillance and HIV/AIDS Program Monitoring and Assessment
- Dept. of Public Health: Investigation of community health problems and health risk factors, implementation of monitoring and evaluation, implementation of interventions to promote community health, including maternal and child health and adolescent health, development and implementation of communication and health education in the community, policy recommendations and awareness raising on preventive medicine.
- National EPI Office: Coordinating activities of the Expanded Program on Immunization nationwide; Implementing immunization safety and disease surveillance; Establishing and maintaining partnerships with international agencies, governmental agencies and non-governmental organizations for mobilizing resources.
- Center of Biomedical Research: Early detection and identification of new pathogens and emerging/re-emerging infections; optimization of laboratory diagnostic methods for outbreaks; study of infectious diseases and NCD cell, molecule, and genetic pathogenesis; elucidation of superstructural and histoimmunological characteristics of microbial pathogens; integration of bioinformatics data, such as epidemiology, biology, and microbiology, and development of mathematical models for epidemic prediction and drug discovery; development of new methods for diagnosing, preventing, and treating human diseases;

development of preventive and therapeutic vaccines and biological products using biotechnology; and strengthening of nanomedicine research.

- Center of Lab Quality Assurance and Calibration: Training on quality control, biosafety, biosecurity laws and regulations, guidelines, Standard Operating Procedures (SOPs), quality assessment of reagents and laboratory equipment, quality control, calibration, and biosafety biosecurity.
- Center of Clinical Trial: Implementation of clinical trials of vaccines, biological products, and pharmaceutical products; investigation of directions for research, development, production, and use; and implementation of development of vaccines, biological products, and pharmaceutical products in laboratories.
- Center of Training and Scientific Management: Master's, Master's, and Medical Student Training, Testing, Immunization, Biosafety, Issuance of Professional Training and Certificates, Training and Re-training for staff of Provincial Preventive Medicine Centers (PCPM) and regional laboratories, Scientific conferences and workshops on preventive medicine and public health.
- Center of Preventive Medicine Services: Organizing the provision of preventive services for NCD, community health care, screening, and outpatient care; Testing and management of common diseases; Providing consultation services and immunizations; Distributing and supplying vaccines and antisera; Providing testing services; Quality assurance for testing; Preventing and eradicating vectors; Providing verification, modification, and calibration of medical devices and services; Providing pharmaceuticals, functional foods, nutritional products.
- Center of Experimental Animals: Research and supply of laboratory animals required for vaccine production

NIHE has 10 facilities. These include the 14 technical departments mentioned above, 34 units, 22 laboratories with advanced equipment, Emergency Operation Center (established in the Infectious Diseases Management Department) connected to the EOC network in Japan and overseas, Biosafety Laboratory Level 2 (BSL-2), and Level 3 (BSL-3). 55 ISO certification technologies and ISO 9001-2008 (Quality Management System) have been acquired.

NIHE has a high laboratory management capability and a SOP for BSL3. On the other hand, the budget for maintenance and maintenance is not sufficient, and only a few million yen for the necessary amount of 20 million yen can be secured. By stopping operation for 24 hours and introducing idling mode, clogging of HEPA filter is slowed down. In BSL3, fumigation in the laboratory is conducted for about a week with formalin in the room, but in BSL2, only the safety cabinet is conducted.

3.1.2 Identified challenges

Challenges pointed out included aging facilities, lack of animal laboratories, inability to conduct clinical trials because of inadequate laboratory standards, absence of biologics manufacturing facilities, and inadequate maintenance and maintenance budgets. In addition, problems such as a failure of the

autoclave at both doors of the BSL3 laboratory, and the fact that the specimens at the influenza center were not barcoded and there were concerns about human errors in matching the ID number with the specimens, were confirmed.

The Deputy Director stated that the BSL4 laboratory, which is unlikely to be comparable to the maintenance of the BSL3 laboratories under the current circumstances where it is difficult to procure the cost of maintenance and management of the BSL3 laboratories, are not only unnecessary for NIHE, but may also be hindered, and that he intends to ask Nagasaki University's Institute of Tropical Medicine and the National Institute of Infectious Diseases, which have BSL4 laboratories, for emergency situations that require testing. This is why he wishes collaboration with these institutes. In addition, the Head of Laboratory Quality Assurance and Calibration Center believes that JICA's support for the action plan for preventive medicine is desirable.

3.1.3 Analysis and consideration of future direction

NIHE is expected to play a major role in: 1) nationwide supervision of preventive medicine activities and public health activities and health programs in Vietnam; 2) scientific research on infectious diseases (including control of emerging and reemerging infections, vaccine development research and clinical trials); 3) training and guidance of preventive medicine networks (including strengthening of laboratory and diagnostic capacity); 4) provision of preventive medicine and public health services; and 5) international cooperation in preventive medicine and public health in collaboration with international organizations such as the World Health Organization (WHO), including core functions such as international research and training.

Now that NIHE has experienced a COVID-19 pandemic that far exceeds the world's expectations, it needs to be empowered to become an excellent center of research, especially for more advanced research that meets international standards. In the future, there is a growing need to promote sound collaborative research with many international organizations, universities, and companies in Japan and overseas, transfer new diagnostic technologies, and conduct R&D of highly accurate diagnostic and therapeutic drugs. To prepare for a new pandemic, the country must become a comprehensive training facility for improving health systems. To this end, Japan will provide training and refresher training on experimental techniques and field epidemiology by expanding its doctoral education program and HR development program, such as refresher training, and introducing an internship system with international organizations.

MOH has positioned VIBC as a part of the Central CDC concept, and NIHE is expected to play a central role in VIBC's R&D on infectious diseases control. It is planned to expand the current NIHE laboratory and research capabilities and become the core for infectious disease surveillance throughout Vietnam, including BSL3+ laboratories. In the future, it is expected to become a specialized outbreak control and outbreak prediction station capable of supporting the whole of Vietnam and neighboring countries, as well as a driving force for Vietnam's host activities in ACPHEED.

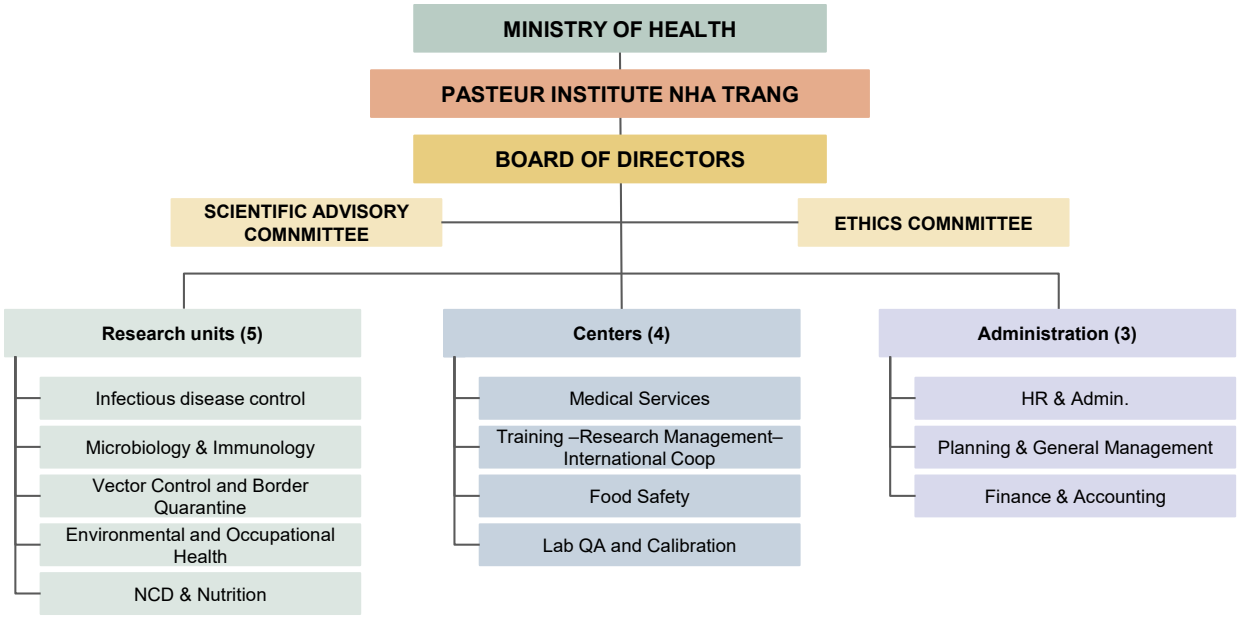
3.2 Summary of PINT's Current Status and Challenges

3.2.1 Current situation

PINT was founded in 1895 by Dr. Alexandre Yersin, then at the Pasteur Institute in France, and has been responsible for preventive medicine in central Vietnam. It covers 12.3 million people and covers 37% of the region in the mountains and islands, making it difficult to manage preventive care in some areas. A total of 157 employees are employed.

PINT operations include infectious diseases, NCD, food hygiene, environmental and occupational health, health services, and scientific research and training.

The organization chart of the PINT is shown below.



Source: PINT

Figure 3-2 PINT Organization Chart31

There are three facilities: Main Campus, Branch 2 (Training Center), and Branch 3.

Main Campus has a research and administration building. There are six laboratories and nine laboratories, all in operation. The Department of Microbiology and Immunology also includes a laboratory at Nagasaki University's Institute of Tropical Medicine. There are other laboratories, Food Safety Analysis Centers, and Medical Service Centers. Because PINT is self-supporting, medical service centers provide paid blood tests and vaccinations. Although there is a budget allocation from MOH for activities, it has been reduced year by year.

In the wake of the Corona devastation, PINT provided technical guidance and support (HR development, strengthening of inspection capacity, support for inspection, etc.) to the CDC at 11 locations in the Chubu region. As a result, the number of District Medicine Centers that can accommodate the COVID-19 test was 42.

3.2.2 Challenges

The following challenges and needs were identified in the field survey.

- The PINT is located near the sea, and measures against salt damage should be considered.
- There is a need for developing HR for preventive medicine in the Chubu region, including PINT staff, measures against infectious diseases and NCD, AMR research, and long-term HR development. Therefore, Japan requests support from JICA.
- BSL3 is required because some research activities require BSL3, biobanks are in place, and the central region has geographical and epidemiological characteristics that predispose to the spread of emerging and re-emerging infections. However, it is preferable to use the laboratory as a BSL2 function.

3.2.3 Analysis and consideration of future direction

The central region includes mountainous areas and islands, which account for 37% of the jurisdictional area and include areas where preventive medical management is difficult. In addition, the geographical and epidemiological characteristics of the region make it susceptible to emerging and reemerging infectious diseases. Moreover, the future development of the region as one of the leading tourist resorts in Southeast Asia will increase the risk of imported infectious diseases. In this context, PINT plays a leadership role for 11 provincial CDCs. While the roles of the four core laboratories, including PINT, and the provincial CDCs in the Central CDC concept have not been finalized at this time, their importance in the national laboratory network and their leadership role for the provincial CDCs will increase further. In addition, the response to a pandemic such as COVID-19 should be decentralized to PINT, TIHE, and PIHCMC, rather than centralized to NIHE.

Based on these factors, further human resource development and strengthening of research capacity through BSL3 development are desirable. On the other hand, in order to secure maintenance costs under a self-financing system, consideration should be given to making it compact and usable as BSL2, as well as to expanding fee-based services.

3.3 Summary of TIHE's Current Status and Challenges

3.3.1 Current situation

TIHE is responsible for the four central highlands provinces (five provinces are responsible for nutrition and food safety) and functions almost the same as PINT. Approximately 150 staff members are employed in 12 departments in total.

The main functions of the division are as follows.

- Infectious Diseases Control Division: Vaccination, surveillance, disease prevention, human resource development in CDC in each ministry
- Vector control and quarantine departments: Dengue, plague, etc. Since TIHE is close to Cambodia and Laos, it also handles border quarantine operations.

- Occupational diseases and NCD sector: grasp of the working environment, guidance for improvement of the working environment for each company, management and guidance on occupational diseases to check the health condition of workers, activities to prevent NCD, etc.
- Environmental Health, School Health and Nutrition: The Central Highlands region has many ethnic minorities and many malnourished children. School Education and Nutrition Guidance for Children
- Microorganisms: Five groups (respiratory infection, blood infection, bacterial infection, vector infection, etc.) conduct virus culture, serological research, etc. Ten laboratories, all BSL2. SOPs are prepared by TIHE
- Training centers provide training programs to researchers and others in each province of CDC. Cooperation with universities in the Chubu Highlands region
- Food Safety Centre: The Central Highlands region uses large amounts of pesticides for crops. Responding to pesticide and food poisoning
- Service Centers: Providing Public Health Services

TIHE is not fully independent because of the low income level of the population in the jurisdiction area and the small size of the population, which makes it impossible to monetize the paid service. TIHE itself will be responsible for 30% of the budget by 2025, but the current level is around 20%. The remuneration and research expenses of the staff are allocated by the government.

3.3.2 Challenges

Field surveys confirmed that TIHE has the following support needs:

- Human Resource Development for TIHE Staff: Since TIHE is located in a remote area, there are few opportunities to collaborate with other organizations. Technical guidance and EQA guidance such as dengue are also required when introducing next-generation sequencers.
- BSL3 laboratory maintenance: TIHE is an agency that handles high-risk pathogens (rickettsia, hantavirus, plague) and requires BSL3 for culture and isolation. Technical assistance related to BSL3 is also required.
- ABSL3: There is a need to raise animals that live in the central highlands and can be used for experiments such as influenza.
- HR development for the competent ministry CDC. TIHE has limited training due to budgetary issues.

3.3.3 Analysis and consideration of future direction

The Central Plateau region, where TIHE is located, includes areas where human living areas and wildlife habitat areas intersect and zoonotic diseases occur. This makes TIHE handle high-risk pathogens. As previously mentioned, while the roles of the four core laboratories including TIHE and the provincial CDCs in the Central CDC concept have not been finalized at this time, their importance in the national laboratory network and their leadership role for the provincial CDCs will be further

enhanced. In addition, the response to a pandemic such as COVID-19 should be decentralized to PINT, TIHE, and PIHCMC, rather than centralized to NIHE.

Based on the above, further human resource development and strengthening of pathogen testing and research capacity through BSL3 development will be further required in the future. At the same time, consideration should be given to the fact that it is difficult for TIHE to be fully self-financing due to the small population size in the region.

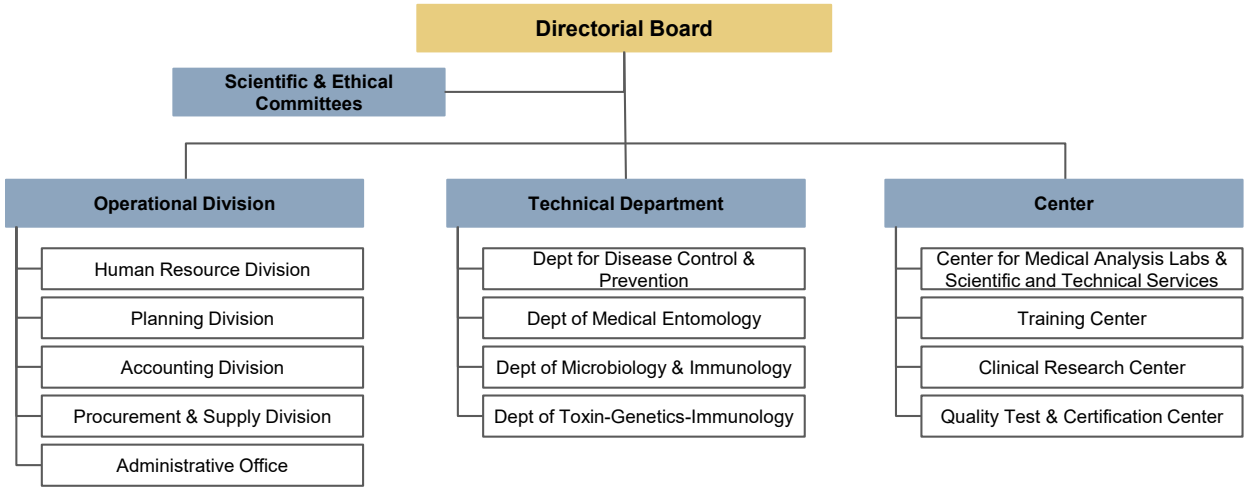
3.4 Summary of PIHCMC's Current Status and Challenges

3.4.1 Current situation

Established in 1891 with the support of the Paris Pasteur Institute by the French government, it was renamed NIHE Ho Chi Minh in 1971 and PIHCM in 1977.

PIHCMC supervises the southern part of Vietnam, provides guidance for a total of 20 provincial CDCs, and cooperates with medical facilities such as provincial general hospitals. It also provides MOH with policy advice, short-and long-term training on public health in the southern region, preventive medicine, various public health services, and international cooperation. There are about 330 staff members.

The organization chart of PIHCMC is shown below.



Source: PIHCMC

Figure 3-3 PIHCMC Organizational Chart

The functions of PIHCMC include the following.

- Provision of policy advice on public health in the southern region to MOH
- Technical guidance and technology transfer to CDC in 20 provinces in the south
- Implementation of short-and long-term training
- Provision of preventive medicine and public health services
- International cooperation
- PIHCMC laboratories conform to WHO standards and have acquired ISO 15185 certification.

- Pathogens handled by the microbial immunity department are viruses transmitted by mosquitoes (dengue, deer fever, etc.), gastrointestinal viruses (polio, rota, etc.), and respiratory viruses (COVID-19, etc.). High-risk pathogens are tested with PIHCMC.
- Only Phase 3 of the vaccine has been studied in clinical trials. Ongoing clinical trials are COVID-19 vaccine (two vaccines overseas and in Japan), but in the past, clinical trials have been conducted for hand-foot-and-mouth disease and dengue fever vaccine.
- The Department of Parasites and Insects is conducting research on infectious diseases transmitted by mosquitoes and on insecticides. In addition, laboratory animals are kept and managed.
- Since the installation of Mobile BSL3, no referral to NIHE has been made. Referral from CDC to PIHCMC is supported for a fee.
- Until 2020, the government allocated approximately ¥100 million per year, but from the same year, the budget has shifted to self-supporting accounting, and personnel salaries, fuel, and other expenses are to be borne independently. The government allocates 50 million yen per year for food safety, preventive medical services, and surveillance activities. Applications for the purchase of goods are filed with the government and, if approved, a budget is allocated. At the end of 2021, the BSL3 laboratory, which was developed with JICA's support, will be put into operation. However, the cost of operation (fuel and inspection, etc.) will be 1 billion VND/ month (about 500,000 yen) and must be borne independently. Therefore, efficient and effective operation is required. Sources of income include testing services, sales of insecticides, and paid vaccination services.

3.4.2 Challenges

The PIHCMC support needs identified in the field survey included the following:

- To enhance the breeding ability and quality control of laboratory animals
- Strengthening the Confirmation Diagnostic Network
- Human Resource Development
- Equipment maintenance for the BSL3 laboratory and HR development for operation staff
- Standardization of biobanks
- Epidemiological surveillance, specialized training and seminars, and academic exchanges
- Establishment of a multi-laboratory center including infectious and non-communicable disease laboratories to integrate dispersed functions

3.4.3 Analysis and consideration of future direction

The PIHCMC has jurisdiction over southern Vietnam and provides policy advice to MOH on public health in the southern region, placing it in an important position alongside the NIHE. Since the introduction of mobile BSL3, the PIHCMC has been autonomously responding to COVID-19, including isolation, without referring to the NIHE, but it is important to further strengthen the definitive diagnosis network. In addition, there is an intention to develop a multi-laboratory center that integrates dispersed laboratory functions.

As mentioned above, the role of PIHCMC in the Central CDC concept has not been finalized at this time, but its role in the southern region is expected to increase in importance through the strengthening of the confirmed diagnosis network and the multi-testing center. In addition, the response to a pandemic such as COVID-19 should be distributed among PINT, TIHE, and PIHCMC, rather than concentrated in NIHE.

3.5 Assistance from other Donors

3.5.1 NIHE

- JICA provided grant aid to develop four BSL3 laboratories
- JICA implements the "Project on Strengthening Laboratory Functions and Collaboration to Improve the Capacity to Prevent and Respond to Infectious Diseases"
- Nagasaki University set up a next-generation sequencer in the university's laboratory.
- The Irish government will develop the IVVI (Ireland Vietnam Blood-borne Virus Initiative) to promote research projects on blood-borne infectious diseases.
- USCDC establishes on-site laboratories for microbiological research

3.5.2 PINT

- Laboratory maintenance with support from the French government (free)
- Nagasaki University Laboratory is located in the Microbiology and Immunology Laboratory.
- Collaboration with USCDC, WHO, Pasteur Institute, Nagasaki University, Osaka University, NCGM, Australia, Taiwan University, Shionogi, Chinese pharmaceutical companies, etc.

3.5.3 TIHE

- US CDC may collaborate in avian influenza surveillance and research
- CDC and WHO plan to support HR development in the United States
- WHO and UNICEF support NCD
- Planned International Collaboration Projects with Taiwanese University

3.5.4 PIHCMC

- Establishment of Emergency Response Center and data warehouse (DWH) with support from USCDC. Data confirmed in each region for a specific infectious disease are entered into the system, tested and analyzed by each laboratory, and the results are returned to the sampling facility.
- 3,500 m^2 inspection area development with support from the U.S. Department of Defense
- JICA provides mobile BSL3 laboratories and installation BSL3 laboratories
- JICA implements the "Project on Strengthening Laboratory Functions and Collaboration to Improve the Capacity to Prevent and Respond to Infectious Diseases"
- Collaboration with France and other Pasteur institutes, the U.S. CDC, the U.S. Department of Defense (DTRA), Nagasaki University, National Institute of Infectious Diseases (NIID), WHO, etc.

4. Current Status of Constructing ICT Systems for Infectious Diseases Prevention

4.1 Current Status of ICT System in Vietnam

As a result of the efforts from 2016 to 2020 described in the current Five-Year Health Sector Plan (2021-2025), "The health statistical standards system is designed to monitor and assess gender inequality, assess inequality in access to health care, and monitor SDGs indicators, and includes 70 basic criteria classified by gender, region, and ethnicity." In addition, MOH is proceeding with the construction of a system for collecting medical statistics in Vietnam, stating that "a medical statistics reporting system is in place to ensure that the system is implemented nationwide."

In addition, according to the Five-Year Plan for the Health Sector, MOH is also developing policies and regulations concerning the application of medical information technology. Specifically, documents such as decisions and notices are issued for a wide range of items, including electronic medical information, hospital computerization standards, telemedicine practice, rules for providing medical care in the Internet environment, and rules for extracting and transferring electronic data for management and payment of medical examination and treatment costs covered by health insurance. In addition, medical information and connectivity are standardized in Vietnam based on the HL7 standard, and guidelines for ICT utilization in preventive medical facilities are being developed. The following is a partial extract of the major provisions related to medical ICT in Vietnam.

Table 4-1 Medical ICT-related provisions in Vietnam (excerpts from major provisions)

No.	Year of publication	Issuing authority	Title
No.3582/QD-BHXH	2006/12/26	VSS	Notice of Decision on Issuance of Information Technology Activity Management Rules in the Medical Insurance System
No.1313/QD-BYT	2013/04/22	MOH	Notice of Decision on Outpatient Guide
No.53/2014/TT-BYT	2014/12/29	MOH	Notice of Requirements for Providing Online Medical Services
No.1456/QĐ-BHXH	2015/12/01	VSS	Notice of Decision on Medical Insurance Review Procedures
No.54/2015/TT-BYT	2015/12/28	MOH	Notification on Reporting of Infectious Diseases and Infectious Diseases and Tax Return Information
No.445/QĐ-BYT	2016/02/05	MOH	Decision Notice on IT Utilization and Development Plan 2016-2020
No.5004/QĐ-BYT	2016/09/19	MOH	Notice of Decision on Approval of a General Architecture Model for a Health Insurance Medical Information System
No.4210/QĐ-BYT	2017/09/20	MOH	Notice of Decision on Standards and Format of Output Data Used for Management, Evaluation, and Payment of Insurance Services
No.48/2017/TT-BYT	2017/12/28	MOH	Directive on the electronic data transfer rules used to manage and pay health care costs
No.49/2017/TT-BYT	2017/12/28	MOH	Remote Care Notification

No.	Year of publication	Issuing authority	Title
No.5454/QĐ-BYT	2018/09/10	MOH	Notice of Decision on Issuance of Implementation Plan for Electronic Medical Statistics
No.46/2018/TT-BYT	2018/12/28	MOH	Notification on the provision of electronic medical records
No.4888/QD-BYT	2019/10/18	MOH	Decision Notice on Smart Healthcare Information Technology Development and Application Scheme Implementation for 2019-2025
No.5349/QD-BYT	2019/11/12	MOH	Notice of Approval Decision on Electronic Medical Record Introduction Plan
No. 6085/QD-BYT	2019/12/30	MOH	Notice of Decision on Problem of MOH E-Government Ver. 2.0
No.749/QD-TTg	2020/06/03	Government	Decision Notice on National DX Implementation Programs to 2025 and Orientation to 2030
No.2628/QD-BYT	2020/06/22	MOH	Decision Notification of Approval of Remote Care Schemes from 2020 to 2025
No.5316/QD -BYT	2020/12/22	MOH	Decision Notice on Medical DX Conversion to 2025 and Orientation Approval to 2030
No.43/2021/ND-CP	2021/03/31	Government	Laws and regulations in the National Insurance Database
No.5969/QD-BYT	2021/12/31	MOH	Notice of Decision on Approval of the MOH Information Technology Utilization Plan for 2021-2025

Source: prepared by JST

The Electronic Health Administration Department (hereinafter referred to as “EHAD”) within MOH is responsible for the planning, implementation, and management of medical ICT in Vietnam in general. EHAD, like "Ministry of Health e-Government 2.0" (decision: No. 6085/QD-BYT), formulates ICT and DX plans for the entire health sector in Vietnam, and develops and manages various regulations and guidelines for implementation [14].

On the other hand, ICT planning and implementation in the health sector as well as in the subsectors such as prevention and treatment can be planned and implemented not by EHAD but by the departments in charge of each subsector within MOH. As a result, ICT planning and implementation in the field of infectious disease prevention will be handled not by EHAD but by the GDPM, which is under the jurisdiction of MOH in the field of infectious disease prevention. When the department responsible for each subsector develops its own ICT plan, the department is required to consult with EHAD beforehand regarding the concept of the plan and the details of the plan, and to coordinate the plan after having the plan reviewed by EHAD [14].

4.2 Current Status of Constructing ICT Systems for Infectious Diseases Prevention

This survey aims to "strengthen the infectious disease control system in Vietnam by strengthening the research functions related to epidemiology, microbiology, and immunology and strengthening the network of laboratory diagnostics in Vietnam." In consideration of this survey, the current status of the

[14] Based on interviews with EHAD as of April 2022

establishment of ICT systems in Vietnam, particularly in the field of infectious disease prevention, is summarized from the following viewpoints.

- Collaboration with the National Database (establishment of infrastructure for linking relevant data, such as reporting of cases and cases of infectious diseases, and reporting of vaccination records)
- Collaboration in laboratory referrals between medical facilities and laboratories (request and implementation of tests related to infectious diseases, and establishment of infrastructure for sharing related data)

4.2.1 Linking with national databases

MOH has established a medical statistics reporting system for infectious diseases, and is building a data linkage system to identify the number of cases of specific infectious diseases and their communities. MOH has mandatory reporting of infectious diseases, reporting formats, and reporting information to the relevant facilities in Vietnam based on Notification No. 37 (37/2021/TT-BYT) issued by MOH and Notification No. 54 (54/2015/TT-BYT) issued by MOH.

As the basis for this reporting system, MOH has introduced a dedicated reporting system for specific infectious diseases for which reporting is required. The system is a web-based system in which individual medical and laboratory facilities access the reporting system from Web-accessible terminals within the facility and report by inputting the necessary information.

In addition, the vaccination record of COVID-19 also has a dedicated reporting system, which has been introduced for specific diseases and vaccines, etc. for which reporting is mandatory.

In addition, international organizations and donor countries are also supporting the establishment of data linkage infrastructure for medical statistical reports on infectious diseases. USCDC worked with GDPM to support the introduction of DWH as a system platform to enhance the collection and surveillance of epidemiological statistics on specific infectious diseases. In addition, the German government has been conducting feasibility studies for the formulation of grant-in-aid projects of 15 million for the purpose of constructing a data network for infectious disease control and constructing an AI infectious disease prediction system using the collected data.[15]

4.2.2 Laboratory referrals between hospitals and laboratories

Tests that cannot be handled by the medical institution may be requested by the medical institution to the laboratory and may be performed at the laboratory. In addition, tests that cannot be handled by local laboratories are referred to the CDC or NE Institutes for information on specimens and patients suspected of having infectious diseases.

Since the scope of ICT adoption and diffusion is limited in this type of inspection referral system and no data linkage infrastructure has been established between facilities, it is common to use an analogous

[15] Based on hearings with the GDPM as of April 2022

system. According to the interviews with NIHE and PIHCMC, when specimens are transported from the medical institution to the testing institution, printed hardcopy or spreadsheet software files containing basic information (name, sex, blood type, address, etc.) on patients suspected of having an infection and identification information (ID number, etc.) linking the patient to the specimen are sent from the medical institution.

In addition, barcode operation is not performed for specimens, and only the identification information that is attached voluntarily by the medical institution is used to link specimens with patient information. In response to this voluntary information, the laboratory performs the test by assigning a unique ID number to manage the internal test process. When returning the examination results to the medical institution, the printed hardcopy containing the examination results or spreadsheet software files are sent to the medical institution.

4.3 Challenges in Constructing ICT systems for Infectious Diseases Prevention

As mentioned above, MOH is promoting ICT in the health sector. However, in the Five-Year Plan for the Health Sector, it is pointed out that the following problems remain after the efforts from 2016 to 2020.

- Most statistical indicators are collected through periodic reports, and some data are not collected in a timely manner and are not accurate. This has limited the use of collected data.
- Information as a result of health services activities is not yet available as evidence to determine which areas require innovation or improvement.
- There is no necessary basis for systematically and uniformly connecting IT applications and utilizing information for information coordination, management, planning and statistical forecasting.
- The lack of coordination between health information systems and the lack of uniformity in some reporting statistical areas within the health sector system as a whole make it difficult to coordinate among systems and to integrate report data.

Although the above-mentioned problem is a generalization of the problem of ICT adoption and diffusion in the health sector in Vietnam, it could be replaced as a major problem in the construction of ICT systems in the prevention of infectious diseases covered by this survey.

In addition, the problems identified by the survey team through the interviews with EHAD, GDPM, and the NE institutes are as follows.

(1) Problem Recognition from EHAD

- EHAD does not have a clear picture of the ICT plans in each sub-sector, their implementation status, the content of the system, the maintenance and management organization, and the budget.
- Departments in charge of sub-sectors within MOH and donors in each country are working together individually without EHAD to introduce the system. However, as a result, various individual systems have been inadequately established, and the overall integration and

coordination has become issues. The data is managed separately by each system under the jurisdiction of each department and stored without being integrated or utilized. According to interviews with EHAD, there are cases in which about 37 systems are installed at one facility in some provinces of CDC, and each system is not integrated or coordinated.[16]

- There are several related laws and regulations on which the case reporting system is based, including MOH Notice No. 37/2021/TT-BYT and MOH Notification No. 54/2017/TT-BYT, but each law/regulation is not related to the other. Therefore, it is necessary to report the same content in multiple systems for some cases. Due to this, operations in medical facilities and testing facilities are duplicated, and the burden on the facilities is increasing.

(2) Recognition of Problems from GDPM

- Due to the lack of data coordination between medical facilities, laboratories, MOH could not correspond to rapid and efficient implementation of tests and data coordination at the time of the COVID-19 outbreak and the spread of infection. In particular, the need to consolidate records and data on the number of COVID-19 patients, test results, the number of vaccinations, patient accommodation facilities, etc. was recognized.

(3) Recognition of problems from the NE Institutes (NIHE, PINT, PIHCMC, TIHE)

- NIHE, PINT, and TIHE did not identify any specific ICT issues. On the other hand, PIHCMC pointed out the need to systematize a series of procedures, including collection of test samples from local medical facilities and testing facilities including sample collection facilities, efficient collection and management of patient information and data on affected areas, implementation of tests, and automatic return of test results to each facility.

In addition, the concerns identified by the survey team through the field survey are described as follows.

(1) Insufficient budget and maintenance & management organizations

- In some cases, the system developed by the donor etc. is operated by the donor budget for a period of one to two years after the introduction of the system. However, since the budget has been lost thereafter, it is difficult to allocate the necessary budget and human resources when maintaining and managing the system at the expense of the Vietnamese government. In some cases, it is difficult to maintain the system operation.
- EHAD may not be able to grasp the overall picture and status of the systems installed in the sub-sector, and the maintenance and management organization for each system may be ambiguous.

(2) Shortage of ICT personnel at the National Institute of Epidemiology

- When interviews were conducted with individual institutes, there were many cases in which even major national epidemiological institutes did not have specialized departments or

[16] In April 2022, the ICT bureau conducted a verbal interview with the ICT bureau to confirm the contents of the informal questionnaire survey conducted by the ICT bureau to the CDC.

human resources capable of planning, procuring, and maintaining systems and equipment in the facilities. Only PINT had an ICT department in which only about three ICT personnel belong.

In light of the above, the main challenges related to the establishment of ICT systems for infectious diseases prevention in Vietnam envisaged by the survey team through the field survey are generalized and summarized as follows.

(1) Strengthening Governance of ICT Sectors within MOH
(2) Consolidating ICT-related laws and regulations
(3) Integrating systems and establishing data collaboration infrastructure between Facilities
(4) Securing ICT-related costs and strengthening the maintenance and management organizations
(5) Securing ICT human resources

4.4 Establishment Plan of ICT System for Infectious Diseases Prevention

In the Five-Year Plan for the Health Sector, MOH has set the following policy objectives in relation to the establishment of ICT systems in the health sector.

(1) Based on Prime Minister's Decision 749/QD-TTg of 3 June 2020, the National Digital Transformation Program will be implemented towards 2030, focusing on the following tasks by 2025:

- Development of remote medicine platforms to reduce the burden on health-care facilities, reduce direct contact between populations, and reduce the risk of infection
- DX promotion in the health sector, etc.

(2) Aim to build health management and disease prevention systems based on digital technology.

- Application of integrated digital technology to medical facilities and testing facilities that contribute to operational reforms, reduction of burdens, improvement of medical care quality, use of electronic medical records to overcome the need for paper medical records, payment of medical expenses, development of smart hospitals, etc.
- Building a smart health management platform based on digital technology by integrating information and data and constructing a national health database

(3) Aim to establish and implement a master project on the application of information technology to the health sector.

- Application of Information Technology in Activities of Commune Health Centers
- Developing, managing, and monitoring individual patient health records and electronic medical records in conjunction with other management information and data, such as medical history covered by health insurance, immunization history, control of infectious and non-infectious diseases, and management of some core information (e.g., development and improvement of database inventory information, mortality monitoring and cause of death analysis)

(4) Maintain health records of the public and persons with disabilities.

- Integrate health insurance contribution and payment data with social insurance data, national ID code, and medical facility code to ensure consistency across the country

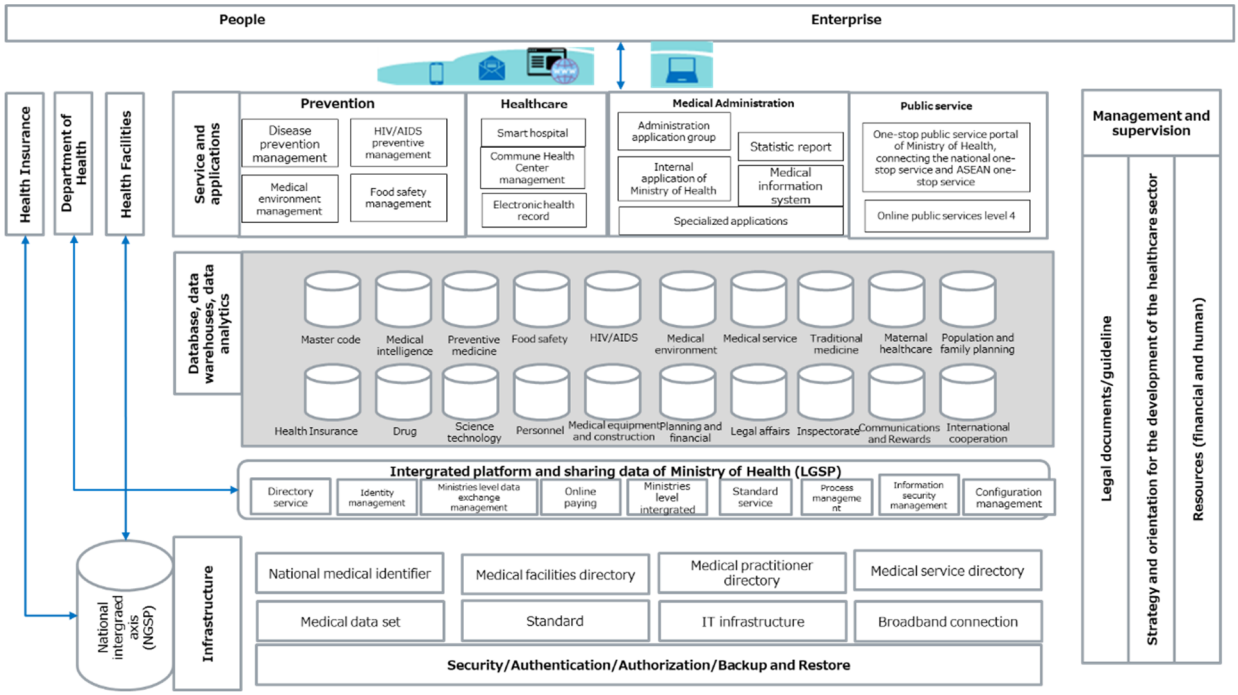
(5) Complete a network of laboratories and pharmacies.

- Nationwide Control of Drug Distribution Based on Country/Region of Manufacture, Price and Prescription of Drugs Received/Shipped

(6) Application of information technology to disseminate knowledge on disease prevention, treatment and promotion of health.

- Application of artificial intelligence in healthcare
- Improving public and patient access to health and medical information

In addition, MOH advocates MOH electronic government version 2.0 (MOH decision No. 6085/QD-BYT dated 20 Dec 2019). MOH's e-Government Ver. 2.0 aims to establish a comprehensive framework for the development and application of information technology in the health sector in order to optimize the health information system in Vietnam and to enhance the interoperability between the systems. In addition, effective use of the health information system is aimed at helping to formulate health strategies for the public. MOH's electronic government version 2.0 framework envisages the development of a comprehensive linkage infrastructure as a digital architecture, ranging from the infrastructure for data collection at the lower layer to the utilization of data at the upper layer. It also stipulates the data to be handled by each sub-sector, including the prevention of infectious diseases, and serves as a guideline for the government to establish a national database in Vietnam.



Source: MOH Decision No. 6085/QD-BYT dated 30 Dec 2019

Figure 4-1 E-Government Ver. MOH Construction diagram of 2.0

4.5 Confirmation of Past and Pending Projects

In the Five-Year Plan for the Health Sector, the following projects are considered to be related to the establishment of ICT systems for the prevention of infectious diseases. However, the details of the project are not clearly stated. All are in the planning stage, and the progress is unknown. It is also unclear whether the term "network" refers to a system or a data linkage via an ICT system.

- Plan for the National Network of Healthcare Facilities for 2021-2030, Vision to 2045
- Planning of network of medical facilities for medical treatment and testing

In addition to the above-mentioned projects, the results of interviews with the GDPM and EHAD in the field survey confirmed that the following projects have been implemented in the past one to two years and will be implemented.

(1) Construction of DWH for specific diseases by CDC in the United States

The Bureau of Preventive Services and the CDC of the United States have introduced DWH as a system platform to help strengthen the collection and surveillance of epidemiological statistics on specific infectious diseases. According to the interview with the ICT Department, the DWH is not linked to the database of the entire MOH managed by the ICT Department, and the DWH is managed as a separate system.

(2) Preparation of an AI analysis system contributing to the prevention of infectious diseases through grant aid from the German government

As of April 2022, the GDPM and the Government of Germany are conducting feasibility studies toward the formulation of grant aid projects, with the aim of constructing a data network for countermeasures against infectious diseases and constructing an AI infectious disease prediction system based on the collected data. The project will be worth 15 million euros.

4.6 Possibility of Constructing ICT Systems for Infectious Diseases Prevention in the Future

Of the issues generalized in "4.3 Challenges in Constructing ICT systems for Infectious Diseases Prevention", the only issues that can be expected to be solved through the construction of ICT systems are "(3) Integrating systems and establishing data collaboration infrastructure between Facilities". Therefore, the possibility of the construction of ICT systems is summarized in (3).

4.6.1 System Integration and Data Collaboration between Facilities

Efficient and effective data collection from medical facilities and testing and research facilities including the commune level, integration and aggregation of collected big data, construction of data coordination infrastructure to enable storage, analysis and utilization, and coordination with national databases, etc. are required.

At present, individual systems are managed in a decentralized manner and are often not integrated or coordinated. Therefore, it is necessary to consider the introduction of interfaces to enable the

coordination of such individual systems, the possibility of integration through the introduction of common systems, and the replacement of such systems with systems that can be coordinated based on standard specifications. In addition, it will be necessary to develop the system with a view to linking it with the national database for the entire health sector promoted by EHAD.

With regard to the establishment of a foundation for efficient and effective data collection and the establishment of effective operations, it is important to review and reorganize the relevant laws and regulations, develop standard specifications for data coordination, unify the reporting format and platform, and develop the necessary infrastructure such as terminals and the Internet environment at each facility, based on an overview of the purpose and importance of data collection and utilization throughout MOH.

GDPM has begun a specific project to develop infrastructure for system integration and data coordination between facilities. GDPM, in response to a hearing conducted by a survey team, stated that "records such as the number of COVID-19 patients, test results, the number of vaccinations, and detention facilities are managed in a decentralized manner, and it was recognized that there was a need to integrate them." GDPM recognized that there were problems with data linkage between different systems. Based on the learn from the spread of COVID-19 infection, GDPM seems to be in demand for efficient and effective inter-facility data coordination during the spread of infectious diseases, as well as infrastructure development that enables effective countermeasures to be studied and implemented based on the prediction of the outbreak of infectious diseases.

In response to this demand, GDPM has been working with the Government of German to conduct feasibility studies for the construction of a system with the aim of introducing an infectious disease prediction system that makes it possible to predict the occurrence of infectious diseases in regions using AI. The development of AI by a research institute in Germany, the development of other software aspects by Viettel, and related materials and equipment by Vietnamese government are planned. The AI Infectious Diseases Prediction System was originally planned to be used to predict the incidence of COVID-19 infections. According to an interview with GDPM as of April 2022, the system is intended to be used not only for COVID-19 but also for other infectious diseases.

On the other hand, in the utilization of data for the purpose of AI analysis, one of the important factors is how effective primary data can be collected. For effective primary data collection, it is essential to establish a data linkage infrastructure, as described above, for individual systems within MOH or for systems to be introduced in the future. On the other hand, according to the interview with EHAD, although EHAD did not understand the overall picture of the AI Infectious Diseases Prediction System or the progress of the plan, it was pointed out that the development of the AI Infectious Diseases Prediction System might not include the establishment of a data linkage base. It is necessary to confirm with the relevant parties including EHAD whether the planned AI Infectious Diseases Prediction System is effective in fulfilling its purpose.

5. Current Status of Vaccine Production System

5.1 Current Vaccine Production System

The current Five-Year Health Sector Plan states that "the quality of pharmaceuticals is strictly and comprehensively controlled at all stages of production, storage, distribution, wholesaling and retailing. The national vaccine production facilities provide 10 of the 11 vaccines in the Expanded Program of Immunization." On the other hand, the following limitation is pointed out: "The pharmaceutical industry in Vietnam is a domestic dispensing industry based on imported raw materials, and production of raw materials (pharmaceutical products and excipients) is very small. R&D investment is very small, and research and production of the latest formulations, such as controlled-release formulations, targeted formulations, multi-component formulations, and multicomponent vaccines, has not been conducted yet."[17]

Vietnam has a vaccine management system (NRA=National Regulatory Authority) that corresponds to level 3 of the WHO List of Stringent Regulatory Authorities. The Pharmaceutical Affairs Management Bureau is responsible for the management of imported vaccines and has marketing license (licensing) and GMP review functions. Quality testing and licensing of domestic vaccines are the responsibility of NICVB. The Bureau of Preventive Services manages the entire vaccine, and EPI programs administered by NIHE are responsible for vaccination.

Currently, there are four vaccine production facilities under MOH in Vietnam, which supply the EPI program as well as the fee-based vaccine market.

Table 5-1 Vaccine production facilities under MOH

Name	Year of establishment	Number of employees	Manufacturing facilities	Japan's assistance	Assistance from other donors
Vietnam's first vaccine herbal medicines manufacturer (VABIOTECH)	2000	240	Two vaccine production and vaccination centres	Transfer of Vaccine Manufacturing Technicians for Japanese Encephalitis (Osaka Osaka-Osaka Biken)	Production Facility Development with South Korean Loan
Vaccine Biologics Research and Manufacturing Center (POLYVAC)	1994	140	3 sites: measles-rubella combined vaccine production facility, polio-vaccine and rota vaccine production facility, and monkey island	Polio Transfer of vaccine production technology (Polio Institute) and measles-rubella combined vaccine production technology (JICA grant and technical cooperation project)	
Vaccine Biologics Laboratory (IVAC)	1978	252	2 sites: vaccine production facilities and serum production and animal breeding centers		UNICEF, WHO, Hungary and the Netherlands
Darat Pasteur Vaccine Company (DAVAC)	1936	130	Production of typhoid fever vaccine and production of microbial preparations and functional foods	None	UNICEF, Cuba, India, etc.

Source: prepared by JST

[17] In Directive 38, a list of infectious diseases, ranges, and mandatory vaccines and biologicals is established.

The table below summarizes domestic vaccines produced by domestic vaccine manufacturing facilities and imported and sold vaccines.

Table 5-2 Domestic Vaccines and Import and Sales Vaccines

MANUFACTURERS AND FACILITIES	MANUFACTURED VACCINES AND BIOLOGICALS		IMPORTED AND SOLD VACCINES
	VACCINE	BIOLOGICS	
Vaccine Manufacturing Company (VABIOTECH)	• ORAL CHOLERA VACCINE • JAPANESE ENCEPHALITIS • HEPATITIS B • HEPATITIS A		• MENINGOCOCCI (VA-MENGOC-BC) • MEASLES RUBELLA MUMPS VACCINE (MMR) • CHICKEN POX VACCINE
VACCINE BIOLOGICS RESEARCH AND MANUFACTURING CENTER (POLYVAC)	• MEASLES-RUBELLA VACCINE (MR) • MEASLES SINGLE VACCINE (M) • ROTAVIRUS VACCINE • LIVE ORAL POLIOMYELITIS VACCINE	• CULTURE MEDIUM • SPF RABBITS • EXPERIMENTAL MONKEYS	• IPV
VACCINE BIOLOGICS LABORATORY (IVAC)	• TETANUS DIPHTHERIA VACCINE (TD) • ADSORBED TETANUS VACCINE • DIPHTHERIA-PERTUSSIS-TETANUS VACCINE (DTP) • BCG vaccine	• TETANUS ANTITOXIN SERUM • ANTIRABIES SERUM • ANTI-NAJAKAUSSIA VENOM SERUM • ANTI-SILOXANE HAB VENOM SERUM	
DARAT PASTEUR VACCINE COMPANY (DAVAC)	• TYPHOID VACCINE		

Source: prepared by JST

The table below summarizes the status of development and production of COVID-19 vaccines by state-owned enterprises, organizations under MOH, and private companies.

Table 5-3 Status of development and production of COVID-19 vaccines by state-owned enterprises, organizations under MOH, and private companies

Organization Name	Self-developed vaccine		Cooperation with foreign countries		Imported vaccines
	Vaccine name	Status	Cooperating company	Status	
VABIOTECH		The development was discontinued due to death of the monkey inoculated preclinically.	Angels and clinical trial cooperation (manufacturing technical support)	Nondisclosure agreement concluded but no progress made at present	None
			Cooperation in clinical trials with Shionogi Pharmaceutical (manufacturing technology support)	Supporting the implementation of phase III vaccine trials by Shionogi. Currently being conducted in the northern mountainous region (via AIC). The medical institution in charge of clinical trials is the Military Medical University.	None
			Fill Russian Sputnik V with VABIOTECH	The vaccine was to be used in Vietnam and imported back to Russia, but there has been no progress since the first refilling was successful in November 2021.	None
POLYVAC		Stopped in a laboratory study	WHO established the COVID-19 Vaccine Manufacturing Technology Transfer Centre in South Africa to provide access to corona vaccines in lower middle-income countries, and asked the Vietnam Ministry of Health to recommend a vaccine production facility. The Ministry of Health recommended IVAC and POLYVAC, but the WHO only selected POLYVAC. POLYVAC dispatched staff to South Africa to learn mRNA vaccine production techniques.		Cuban product Vaccine imports
IVAC	COVIVAC	The Phase 2 of the study was completed, but Phase 3 non-vaccinated patients could not be recruited and the study was discontinued.	HIPRA vaccine	Phase 2 of the vaccine developed by Ipra Pharmaceutical Co., Ltd. was conducted in Vietnam, but the clinical trial was discontinued due to the inability to recruit unvaccinated persons.	None
DAVAC	Request from the Cuban government for transfer of corona vaccine production technology, but no progress				
VINBIOCARE (Private)	Received transfer of ARCT-154 vaccine manufacturing technology from Arcturus Therapeutics, USA, from Phase 1 of the clinical trial in Vietnam. Phase III 3B started in Bac Nin Province in October 2021. The institution responsible for clinical trials is Hanoi Medical University. The plant is under construction at Hoa Lac High Tech Park.				
NANOGEN (Private)	NANOCOVAX	The clinical trial went through to phase 3 and the results were compiled and submitted to the Ethics Committee, but was not approved due to remaining doubts about the protective effect and other issues.			

Source: prepared by JST

As of March 2022, 9 vaccines for which emergency licenses have been granted by the Vietnamese national regulatory authorities are AstraZeneca, Pfizer, Moderna, Johnson & Johnson, Sinopharm BIBP, Spotonic V, Hayat-Vax COVID-19 (Sinopharm's manufacturing site), Abdala, and Cobaxin (Barat Biotech International, India).[18]

5.2 Plan for Strengthening the Vaccine Production System

In the Five-Year Health Sector Plan, one of the main responsibilities of MOH is to "strengthen the production and supply of pharmaceuticals and medical devices and food safety management" and to this end, to "invest sufficient resources to acquire the next generation vaccine production technology and multiple integrated vaccines, basically meet the domestic immunization expansion plan demand and aim for export. Encourage the production of corporate investments, pharmaceuticals, vaccines, biological products, medical devices and consumables, and enter the regional and global pharmaceutical value chain." It is also planning a national budget vaccine production project (with a budget of 400 billion VND).

Prime Minister's decision No. The 376/QD-TTg "Approval of the Program for the Development of the Pharmaceutical Industry and Domestic International Raw Materials by 2030 with a View to 2045" sets out the overall goal of "developing the domestic pharmaceutical industry into a high-level industry in the World Health Organization (WHO) category, ranking among the top three ASEAN countries, and contributing to the appropriate and prompt supply of high-quality, safe, effective, and inexpensive pharmaceutical products. Developing domestic raw materials and their products into competitive high-quality, high-value products in the domestic and international markets."

Specifically, the Government of Japan will take the following measures.

[18] WHO (2022) COVID-19 Situation Report #85, Ministry of Health, Vietnam

- Applying special incentives as required by law: to invest in the construction and implementation of the Center for Bioequivalence Studies and Clinical Trials, the Center for High-tech and Medicinal Products and Traditional Medicinal Products, and the National Center for Seed Research in Genetic and Medicinal Materials.
- Mobilize all domestic and international resources to invest in products from domestic pharmaceutical production, franchised pharmaceutical production, technology transfer, vaccines, medical-biological products, and pharmaceutical raw materials. Focus on investing in and developing pharmaceutical chemistry programs to reduce dependence on imported raw materials and produce domestic pharmaceutical raw materials.
- To conduct research, development, and production of mixed vaccines in at least two national science and technology issues in the national budget in three years and at least five ministerial-level science and technology issues in the development of the domestic pharmaceutical industry in one year.
- Focus on the development of HR involved in research and manufacturing of pharmaceuticals and raw materials for pharmaceuticals, and provide specialized education on manufacturing of vaccines and ethical biologics, bioequivalence research, clinical trials, etc. in the course of training university pharmacists.

In Prime Minister's decision No.1657 "Approval of the National Priority Science and Technology Program for the Production of Human Vaccine Research and Development Plan for 2030", the following targets are set as the program targets.

- To conduct R&D of manufacturing technologies and to respond to emerging infectious diseases, the Government will enhance and strengthen the capacity of domestic companies and institutions in the field of vaccine production and research.
- 100% of domestically produced vaccines will reach international standards, a vaccination expansion program and other vaccines will be secured, and Vietnam vaccines will be gradually introduced to the international market.
- Ten vaccine production technologies will be acquired by 2015, and at least three vaccines will be produced. Fifteen vaccine production technologies will be acquired by 2030, and at least five vaccines will be produced.

Specific initiatives include research and application of new, advanced, and traditional technologies, and preferential adoption of mRNA, recombinant protein, and viral vector technologies to facilitate production of COVID-19 vaccines, cancer prevention vaccines, mixed vaccines, and other vaccines to meet disease prevention and management needs.

5.3 Past and Pending Projects

Aforementioned Prime Minister's Decision No. The 376/QD-TTg "Approval of the Program for the Development of the Pharmaceutical Industry and International Domestic Raw Materials by 2030 with a View to 2045" contains a list of major projects calling for investment, including "Projects for the Production of Biotechnological Combined Vaccines and Infectious Diseases Vaccines (including

COVID-19)" and "Projects for the Establishment of Bioequivalence Testing Centers and Clinical Trials Centers", but as of June 2022, no progress has been made.

5.4 Possibility of Constructing a Vaccine Production System in the Future

Interviews with the Drug Administration, the ASTT and vaccine manufacturers confirmed that POLYVAC has high production capacity and is trusted due to past Japanese assistance, and that there are high expectations for Japanese assistance in strengthening the vaccine manufacturing system.

In particular, the following support needs were identified.

- Prime Minister's Decision No. 376 priorities facilities for the production of five- and six-vaccine combinations. Currently, single vaccines are the mainstay, and research, development and production of mixed vaccines is the way forward; POLYVAC is considering R&D of an inactivated polio vaccine (IPV vaccine), which would also include a six-vaccine combination.
- The Prime Minister's Decision No. 1657 specifies the expansion of human vaccine production capacity by 2030, with priority given to mRNA technology, coronavirus vaccines and vaccines for cancer prevention. mRNA vaccine technology transfer (human resource development and provision of technical materials, etc.) supported by WHO (POLYVAC has been). mRNA technology would enable research, development and production of next-generation vaccines other than COVID-19.
- The EPI program has produced 11 vaccines with support from Japan, South Korea and WHO, but as some of the needs have not yet been met, remaining vaccines from the EPI program are given top priority. The Vietnamese national policy has been confirmed that all vaccines in the EPI program are to be produced domestically; IPV vaccines are currently imported in the EPI program. MOH is also considering the addition of rotaviruses and other vaccines to the EPI program, as POLYVAC has been researching, developing and producing rotaviruses on its own and new vaccine production facilities are needed to increase production and ensure high quality.
- Strengthen the functions of the National Biomedical Research and Vaccine Institute by integrating the four vaccine manufacturing institutes and developing a National Biomedical Research and Vaccine Institute, which will contribute to the R&D of EPI vaccines, combination vaccines and next-generation vaccines. and production of EPI vaccines, combination vaccines and next-generation vaccines. However, OHR is currently considering whether to organize the roles of the institutes or merge them into one, and even if the four institutes are merged, it will only be for administration and will not bring the facilities together; in addition, the same institute will have vaccine research, development and production It should be noted that the manufacturing and evaluation departments need to be operated separately, as having the functions of vaccine research, development and manufacturing and the functions of clinical trials could lead to conflicts of interest. It was noted that there is no problem to incorporate the clinical trials and vaccine research, development and manufacturing functions of the NIHE adjacent to the VIBC.

5.5 Support for the Vaccine Production Facilities by Development Partners

5.5.1 POLYVAC

- JICA supported oral polio vaccine (OPV) facility with filling machines, culture rooms, and quality control (QC) equipment.
- JICA supported Measles Vaccine Production Facilities (MVPF) (Grant Aid), and Kitasato Institute transferred the technology.
- JICA implemented a measles vaccine technical assistance project and a combined measles and rubella vaccine technical assistance project.
- JICA, WHO, and the Developing Countries Vaccine Manufacturers' Network (DCVMN) developed human resources.
- WHO supported mRNA vaccine (made by Moderna) technology transfer.

5.5.2 IVAC

- WHO and PATH (an international non-profit global health organization based in Seattle) provide Good Manufacturing Practices (GMP) technical guidance.
- WHO established influenza vaccine production facilities and wastewater treatment systems.
- Since IVAC was originally a part of the Dalat Pasteur Institute, it received support from UNICEF in the 1980s for the production of DPT vaccine, and in the 1990s received equipment for the freeze-dried BCG vaccine production. In addition, in order to expand the quantity and quality of DPT and TT vaccines to be supplied to Vietnam's EPI, Hungary and the Netherlands provided equipment and technical assistance.
- Collaboration with Niigata University (vaccine R&D for COVID-19) secured Japanese government budget for equipment procurement for vaccine research and testing building, as well as online technical guidance to staff.

5.5.3 VABIOTECH

- In the 1980s, many children in Vietnam contracted Japanese encephalitis and the need for a vaccine increased, but it could not be manufactured in Vietnam. A Japanese expert who was on a business trip to NIHE at that time made a request for technology transfer to the Research Institute for Microbial Diseases, Osaka University through GOV, and dispatched the Director of the Department of Virology and other staff, who were not independent from the Virus Department of NIHE, to Osaka University in Japan,
- Construction of a factory with loan from South Korea
- Cooperation with AnGes in clinical trials for the R&D of coronavirus vaccine, but no progress was made.
- Cooperation with Shionogi in clinical trials for coronavirus vaccine R&D
- Filled with Russian-made Sputnik V (coronavirus vaccine)

5.5.4 DAVAC

- DAVAC was founded in 1936 as the Dalat Pasteur Institute at the suggestion of Dr. Alexandre Yersin. In 1975, it began manufacturing vaccines and pharmaceuticals for the Indochina Peninsula. In 1986, UNICEF provided support for the production of DPT vaccine, Cuba for the production of HBV and Hib vaccines, and India for the production of rabies vaccine (Abhayrab).

6. Consideration of the Functions and Roles of Cho Ray Vietnam-Japan Friendship Hospital (CR-VJH) related to Measures against Infectious Diseases

6.1 Role of the Existing Cho Ray Hospital during the Pandemic

The existing Cho Ray Hospital provides general medical services in the southern region of Vietnam and plays a central role in transferring technology to local hospitals, providing guidance, and developing HR.

Since February 2020, during the outbreak of COVID-19 in Vietnam, Cho Ray Hospital has not only provided traditional medical services, but also carried out the following activities:

- Dispatched treatment support teams for the 1st, 2nd and 3rd waves in the northern and central regions such as Vinh Phuc, Hai Duong, Bac Giang and Da Nang.
- Conducted online training on COVID-19 diagnosis, treatment and prevention for medical staff of local hospitals.
- When the number of infected people in Ho Chi Minh City increased rapidly after May 2021, a 1,000-bed ICU hospital was operated for COVID-19 treatment established in July 2021 at a cancer hospital under the Ho Chi Minh City Health Department. The hospital's medical staff is not limited to Cho Ray Hospital, but consists of various hospitals in the northern, central and southern regions, targeting the most severe corona patients such as ventilator installation and ECMO in Ho Chi Minh City.
- Utilized the existing hospital as a vaccination facility for COVID-19 vaccine for Ho Chi Minh City citizens.
- As a member of the treatment team of the National Medical Advisory Committee for the Novel Coronavirus, CRVJH created treatment guidelines for COVID-19 patients and participated in serious patient conferences.
- Provided an online consultation service for patients with other diseases than corona who cannot access hospitals due to the rapid increase in infected people in Ho Chi Minh City.

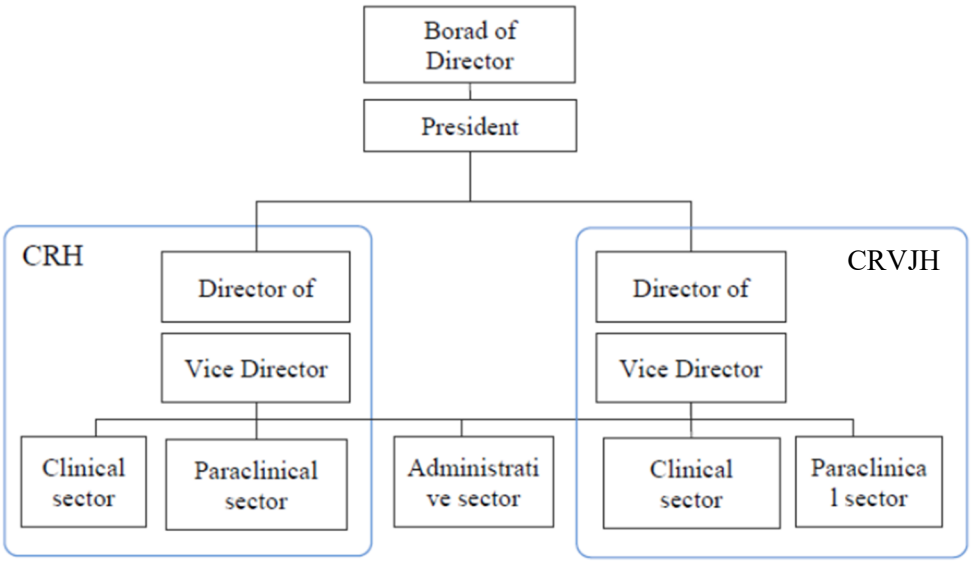
From July 2021 to February 2022, a total of 5,006 severe COVID-19 patients were treated.

In January 2022, an examination room for the aftereffects of the COVID-19 infection was opened in the existing hospital, and medical services such as mental examinations, nutrition and rehabilitation interventions are provided to those affected.

6.2 Infectious Disease Measures Expected from CRVJH

For the normal operation of Cho Ray Hospital (CRH) and CRVJH, the plan is to form an independent hospital organization, appoint a director and other top management at each facility, and operate under an individual organizational system. In addition, in order to improve the efficiency of operation and management, regarding unification of operations between hospitals (establish a headquarters function, consolidate operations such as regional cooperation/DOHA, general planning, personnel and labor

affairs, and goods management, so that Cho Ray Hospital can comprehensively manage both, there was an opinion at the design stage that it is possible to unify the management of goods, but it is difficult to manage personnel and labor.



Source: JST

Figure 6-1 Joined Management of CRH and CRVJH

CRVJH consists of three sectors: the clinical sector, the paraclinical sector , and the administrative sector.

Table 6-1 CRVJH Sectors and Departments

	Departments *At this stage, the unit of work is shown, and organization names such as departments and departments will be coordinated with the hospital in the future.
Administrative sector	Quality Control Department, Administration Department, General Planning Department, Medical Information Department, Personnel and Labor Department, Education and Research Center, Finance and Accounting Department, Nursing Management Department, Administration Department, Social Affairs Department, Merchandise Management Department, Medical Device Management Department
Clinical sector	Emergency department, intensive care center, day care center, medical examination center, Rehabilitation Department, Nutrition Department, Surgery Department, Brain Surgery, Gastroenterological Surgery, Hepatobiliary-Pancreatic Surgery, Urology, Orthopedic Surgery, Otorhinolaryngology, Ophthalmology, Thoracic Surgery, Vascular Surgery, Burn/Plastic Surgery, Respiratory Medicine, Gastroenterology , Neurology, Nephrology, **Tropical Diseases and Infectious Diseases**, Dialysis, Endocrinology, Hematology, Cardiovascular Surgery, Cardiovascular Catheterization
Paraclinical sector	Department of Pharmacy, Department of Infection Control, Department of Clinical Laboratory (microbiology, biochemistry, molecular biology, blood test, pathology), ultrasound, endoscope

Source: JST

The existing Cho Ray Hospital, as the main hospital, has substantial resources in terms of HR, facilities, and financial resources, so it will play a central role even in the event of a pandemic. However, it is considered essential to enhance certain infectious disease treatment functions in CRVJH.

CRVJH will have an infection control department in the subclinical department, and microbiological and molecular biological tests in the clinical department. In addition, on the 8th floor, a department of tropical diseases and infectious diseases (26 beds) and an operating room (2 rooms, class 10,000) are planned for operations on patients with infectious diseases and those who may have them. In the department plan, the policy is to shorten the stay time in the outpatient as much as possible and isolate patients with suspected infectious diseases by the following measures.

1. Early triage through interviews
2. Encouragement to wear a mask
3. Classification of flow line
4. Guidance of infected patients to the waiting room
5. Priority medical care

The CRVJH design already includes the following as evidence-based measures against infectious diseases in Japan.

1. Supporting Standard Precaution: Installation of hand washing in various places and in appropriate locations, arrangement of clean preparation room and dirty preparation room, etc.
2. Operating Room Unit in Single Corridor: Functional Structure with Improved Operating Method
3. Febrile outpatient treatment: A simple compartment with direct access from outside.

In addition, the following measures can be taken based on the current knowledge of corona countermeasures.

1. Planning of staff station ward as a room rather than an open system
2. Securing a space where infected outpatients and wards can be installed externally
3. Since the number of elevators on the ward is large, it is possible to use one of the elevators exclusively for infectious diseases.

6.3 Support for Clinical Research at CRVJH

As feedback from this survey is basically different in function from the hospital (CRVJH) in the survey subjects, the possibility of accepting the clinical research will be examined at CRVJH because of the need for the development of clinical research, clinical trials, and clinical trial facilities for biologics (vaccines, testing and in-vitro diagnostics, etc.) in Vietnam. Required facilities include the following:

1. Hospital beds (assumed to be internal medicine wards, including work spaces)
2. Examination room (assumed to be outpatient)
3. Counseling Room (assuming outpatient)
4. Record Storage + Reading Space (assumed for some warehouses)

Basically, it is possible to divert facilities already included in the design. However, partial design changes are possible if there is a request to consolidate the above 3. Counseling room and 4. Records Storage + Reading Space.

6.4 Cooperation with Other Medical and Research Institutions

The scope of ICT implementation is limited in the data linkage for infectious disease control among medical institutions, testing and research institutions, and MOH, and the referral system for specimens and patients, the data exchange infrastructure between these institutions has not been constructed. Even during the outbreak and spread of COVID-19, the importance of integrating records and data e.g. the number of infectious disease patients, test results, vaccination numbers, patient accommodation facilities, etc., was recognized, as rapid and efficient test implementation and data linkage were not possible. As one of the main policies, efforts are being made to strengthen networks using ICT, such as the development of telemedicine platforms aimed at reducing the burden on medical institutions, reducing direct contact between groups, and reducing the risk of infection.

It is also important to smoothly share information with other medical institutions (e.g. secondary medical institutions in the region) and infectious disease research institutions that have requested clinical research and clinical trials. In terms of supporting these, CRVJH's ICT environment and enhanced meeting and training functions are also included in this design.

In terms of supporting these, CRVJH's ICT environment and enhanced meeting and training functions are also included in this design.

7. Consideration of Contributing Projects to Strengthening CR-JVH's Measures against Infectious Diseases

7.1 International Biomedical Center Project Proposal

In this study, to respond to the request of GOV, the results of "Consideration of the Functions and Roles of Cho Ray Vietnam-Japan Friendship Hospital (CR-VJH) related to Measures against Infectious Diseases" described in Chapter 6 and the 5-year (2021-2025) plan of MOH (draft), important A to E action plans related to infectious disease control and project proposals that could contribute to the strengthening of infectious disease control subject to Japan's support and assistance were sorted out at the start of this survey.

Action plan related to infectious disease control:

A. National Strategy for the Protection, Care and Improvement of People's Health Vision 2020-2030/2040
B. Establishment of disease prevention agencies (drug, vaccine and food testing and inspection agencies at central and local levels)
C. Research and manufacturing of next-generation vaccines, including combination vaccines
D. Building a National Network of Medical Facilities 2021-2030, Vision 2045 for Building a Medical Facility Network for Diagnosis and Treatment
E. Development of Pharmaceutical Industry 2020-2030, Vision 2045

Cooperation project proposals assumed at the start of this survey:

Project a. Development of facilities for infectious disease control (research, testing, diagnosis): above A and B are related
Project b. BSL-3 laboratory development project at a regional key infectious disease research institute: above A and B are related
Project c. ICT system development within MOH: A, B and D above are related
Project d. Development of facilities for manufacturing next-generation vaccines: A, B, C, and E above are related

As a conclusion of this survey, the following cooperation project proposal was proposed to the Vietnam side in May 2022.

1. The above "Project a. Development of facilities for infectious disease control" and "Project d. Development of facilities for manufacturing next-generation vaccines" will be constructed in HHTP as VIBC under Yen loan. In the future, part of the functions will be built on the existing NIHE site in Hanoi city.

2. In Project b, the development of BSL3 laboratories will be carried out with Grant Aid for the key infectious disease research institutes in Nha Trang (PINT) and Buon Ma Thuot (TIHE). Refurbishment of existing facilities and provision of equipment for PINT, whereas construction of new facilities for TIHE.

As it has already been decided that support from Germany will be provided for the development of the ICT system within MOH, Project c which give ICT support from Japan will not be provided this time.

7.1.1 Proposed Project Outline

1. Project Name: ODA Loan Project (Vietnam International Biomedical Center Development Project)
2. Project Objectives: This project aims to improve R&D of infectious diseases control and vaccine production capabilities by establishing the International Biomedical Center in the Hoa Lac Hi-tech Park, Hanoi City, Vietnam, thereby contributing to the construction of a strong health system in Vietnam.
3. Nature of operations
   A. nternational Biomedical Center Development Project for Research on Infectious Diseases (one site: International Competitive Bidding)
      A1. Facility construction work
      A2. Equipment Procurement
   B. International Biomedical Center Development Project for Next-Generation Vaccine Production (one site: International Competitive Bidding)
      B1. Facility construction work
      B2. Equipment Procurement
   C. Human Resource Development for Infectious Diseases Control
   D. Consulting services (basic design, detailed design, tender assistance, construction supervision, equipment procurement support, facility maintenance support, etc.)

7.1.2 Estimated size and estimated cost of the target project

A. Development of International Biomedical Center for Research on Infectious Diseases: 24,000 m^2
B. Development of International Biomedical Center for Next-Generation Vaccine Production: 9,000 m^2
C. HR development for infectious disease control R & D: 30 people in total
D. Consulting services: Services related to A through B above

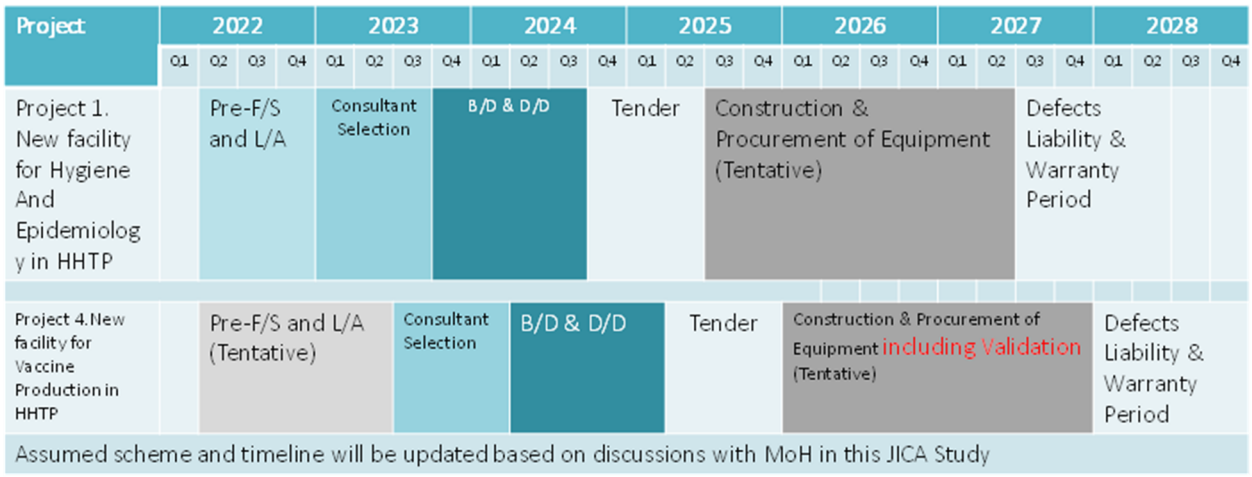
7.1.3 Implementation structure of the relevant project

1. Borrower: The Government of the Socialist Republic of Vietnam by the Ministry of Finance of the Social Republic of Vietnam
2. Guarantor: None
3. Project Implementation Organization: MOH
4. Project executing agency: Central Project Management Unit (PMU) in MOH

7.1.4 Organization of related superiors' plans in Vietnam

1. Five-Year Socio-Economic Development Plan 2021-2025
2. Five-Year Plan for Protection, Care and Improvement of Human Health 2021-2025[19]
3. Prime Minister's decision No. 376/QD-TTg (Approval of the Program for the Development of the Pharmaceutical Industry and International Domestic Raw Materials by 2030 with a view to 2045)
4. Action Plan of the MOH for Implementation of the Sustainable Development Agenda 2030
5. Prime Minister's decision No. 1657 "Approval of the National Priority Science and Technology Program for the Production of Human Vaccine Research and Development Plan for 2030"

7.1.5 Proposed Project Implementation Schedule



Note: In the healthcare sector, the warranty period for equipment (Warranty Period) is three to five years in some cases.

7.1.6 Proposed operational effectiveness index

A. International Biomedical Center for Research on Infectious Diseases Development Project
   - Number of Biologics Research Projects in VIBC
   - Number of international joint research projects in VIBC
   - Number of Vaccine Clinical Research Projects in VIBC
   - Number of published papers in VIBC
   - National Laboratory System score of IHR capacity (limited to research capacity)

B. International Biomedical Center Development Project for Next-Generation Vaccine Production
   - Vaccination rate of the target disease (percentage of the population who have completed vaccination)
   - Number of vaccines (doses) manufactured (according to WHO-GMP standards)

[19] As of September 2022, still waiting for final approval.

7.2 BSL3 Lab Development Project at the Regional Institute of Infectious Diseases

7.2.1 Proposed Project Outline

1. Project Name: National Institute of Infectious Diseases in Central Vietnam (PINT, TIHE) BSL3 Development Project
2. Project Objectives: This project aims to improve research, development, and surveillance functions for measures against infectious diseases by establishing BSL3 at the National Institute of Infectious Diseases in central Vietnam (PINT, TIHE) where there is the risk of emerging and re-emerging infectious diseases and imported infectious diseases, thereby contributing to the establishment of a robust preventive medical system in Vietnam.
3. Nature of operations
   A. TIHE's BSL3 Development Project (BSL3: 3 laboratories, BSL2: 3 laboratories)
      A1. Facility construction work
      A2. Equipment Procurement
      Three BSL3 laboratories (newly built), one each for testing and diagnosis of highly pathogenic viruses, bacteria, and vector-borne pathogens, will be constructed. In addition, one BSL2 laboratory will be newly constructed as a basic laboratory corresponding to the BSL3 laboratory, for a total of three laboratories.
   B. PINT's BSL3 development project (BSL3: 1 laboratory, BSL2: 1 laboratory)
      B1. Facility construction work
      B2. Equipment Procurement
      One BSL3 laboratory (to be renovated from an existing facility) is assumed to be used for testing, diagnosis, or research of highly pathogenic viruses or bacteria. In addition, one BSL2 laboratory (to be renovated) is assumed as a basic laboratory.
   C. BSL-3 operation and maintenance
   D. Consulting services (basic design, detailed design, tender assistance, construction management, equipment procurement support, facility maintenance support, etc.)

7.2.2 Estimated size of the projects

A. TIHE's new BSL3 development project (newly built): 2,000 m^2
B. PINT BSL-3 Rehabilitation and Upgrading Project (to be renovated): 200 m^2
C. Soft Components: BSL3 operation and maintenance
D. Consulting services: Services related to A through C above

7.2.3 Implementation Agencies

① Recipient: The Government of the Socialist Republic of Viet Nam represented by the Ministry of Health of the Socialist Republic of Viet Nam

② Project Implementation & Responsible Organization: MOH

③ Project Implementation Agency: Department of Preventive Medicine, MOH (GDPM)

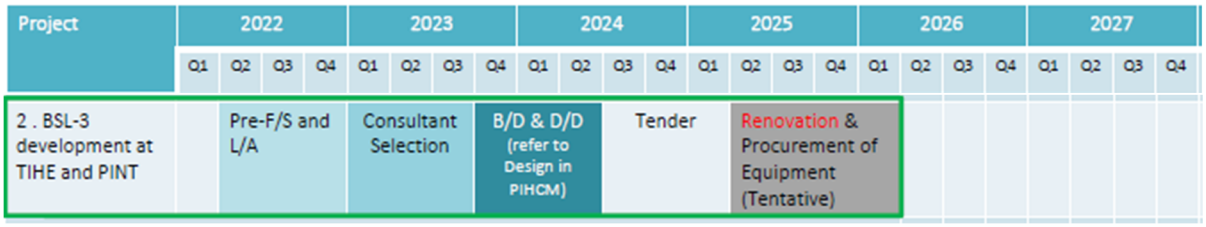
7.2.4 Relevant National Plan in Vietnam

(1) Five-Year Socio-Economic Development Plan 2021-2025

(2) Five-Year Plan for Protection, Care and Improvement of Human Health 2021-2025[20]

(3) Action Plan of the Ministry of Health for Implementation of the Sustainable Development Agenda 2030

7.2.5 Project Implementation Schedule



7.2.6 Operational Effectiveness Indicator

A. TIHE's BSL3 development project

- BSL3 containment laboratory training completed
- Introduction of diagnostic methods required for the use of BSL3 containment laboratories
- Number of research projects using BSL3 containment laboratories
- Biosafety &Biosecurity and Surveillance scores of IHR capacity (limited to research capacity)

B. PINT's BSL3 development project

- BSL3 containment laboratory training completed
- Introduction of diagnostic methods required for the use of BSL3 containment laboratories
- Number of research projects using BSL3 containment laboratories
- Biosafety &Biosecurity and Surveillance scores of IHR capacity (limited to research capacity)

[20] As of September 2022, still waiting for final approval.

【Annexes】

1. JICA Study Team Members
2. Site Survey Schedule
3. List of Counterparts
4. List of Reference and Documents Received

1. JICA Study Team Members

No.	Name	Assignment	Company
1	Teruyasu EZURE	Collection and analysis of information on core laboratories for epidemiological research①	Oriental Consultants Global Co., Ltd.
2	Aiko KOISHI	Collection and analysis of information on core laboratories for epidemiological research②	Oriental Consultants Global Co., Ltd.
3	Shohei ISHIKAWA	Collection and analysis of information on core laboratories for epidemiological research③ (concurrent with: Bidding Document 1)	Oriental Consultants Global Co., Ltd.
4	Dai FUJITA	Collection and analysis of information on core laboratories for epidemiological research④	Oriental Consultants Global Co., Ltd. (Subcontract: International Total Engineering Corporation)
5	Jun HAYATSU	Collection and analysis of information on core laboratories for epidemiological research⑤ (concurrent with: Structure Design)	Azusa Sekkei Co., Ltd.
6	Ado KAMAGATA	Collection and analysis of information on core laboratories for epidemiological research⑥	Oriental Consultants Global Co., Ltd. (Subcontract: System Planning Corporation)
7	Asuka TODA/ Haruhisa ISHIKAWA	Collection and analysis of information on core laboratories for epidemiological research⑦	Oriental Consultants Global Co., Ltd.
8	Tatsuya MATSUOKA	Information collection and analysis for constructing ICT systems	Oriental Consultants Global Co., Ltd. (Subcontract: International Total Engineering Corporation)
9	Masashi TATSUMI	Information collection, analysis, and sorting out issues related to health policy and infectious disease R&D system①	Oriental Consultants Global Co., Ltd. (Subcontract: Individual)
10	Keigo ANDO	Collection and analysis of information on core laboratories for epidemiological research⑧ (concurrent with: Environment Impact Assessment)	Oriental Consultants Global Co., Ltd.
11	Ritsuko YAMAGATA	Confirmation of needs for strengthening the vaccine manufacturing system	Oriental Consultants Global Co., Ltd. (Subcontract: Mitsubishi UFJ Research & Consulting Co., Ltd.)
12	Futoshi HASEBE	Information collection, analysis, and sorting out issues related to health policy and infectious disease R&D system②	Oriental Consultants Global Co., Ltd. (Subcontract: Nagasaki University)
13	Junichi MOCHIZUKI	Collection and analysis of information on core laboratories for epidemiological research⑨	Azusa Sekkei Co., Ltd.
14	Tomoo NITTA	Collection and analysis of information on core laboratories for epidemiological research⑩	Oriental Consultants Global Co., Ltd. (Subcontract: Himawari Design Ltd.)
15	PUJI Nata Djaja	Information collection, analysis, and sorting out issues related to health policy and infectious disease R&D system③	Oriental Consultants Global Co., Ltd.

2. Site Survey Schedule

＜1st Site Survey＞ 10th April 2022 to 27th May 2022

No	Date	Day	Activity
1	4/10	Sun	Moving day (Narita → Hanoi)
2	4/11	Mon	Organizing documents, team meeting
3	4/12	Tue	Site visit to NIHE-JICA project、meeting with JICA office
4	4/13	Wed	Meeting with GDPM
5	4/14	Thu	Site visit to NIHE
6	4/15	Fri	Site visit to POLYVAC
7	4/16	Sat	Organizing documents, team meeting
8	4/17	Sun	Moving day (Hanoi → Nha Trang)
9	4/18	Mon	Survey visit to PINT,IVAC
10	4/19	Tue	Moving day (Nha Trang → Ho Chi Minh City)
11	4/20	Wed	Survey visit to PIHCMC
12	4/21	Thu	Organizing documents, team meeting
13	4/22	Fri	Moving day (Ho Chi Minh City → Buon Ma Thuit), site visit to TIHE
14	4/23	Sat	Moving day (Buon Ma Thuot → Hanoi)
15	4/24	Sun	Organizing documents, team meeting
16	4/25	Mon	Online meeting with JICA, Meeting with ASTT
17	4/26	Tue	Meeting with MOH Organization & Human Resources Department (OHR), Electronic Health Administration Department (EHAD)
18	4/27	Wed	Meeting with Tri Viet (company)
19	4/28	Thu	Online meeting with JICA、Official meeting with GDPM
20	4/29	Fri	Organizing documents, team meeting
21	4/30	Sat	Organizing documents, team meeting
22	5/1	Sun	Organizing documents, team meeting
23	5/2	Mon	Organizing documents, team meeting
24	5/3	Tue	Organizing documents, team meeting

25	5/4	Wed	Organizing documents, team meeting
26	5/5	Thu	Meeting with JICA Hanoi Office
27	5/6	Fri	Meeting with MOH Drug Administration of Vietnam
28	5/7	Sat	Organizing documents, team meeting
29	5/8	Sun	Organizing documents, team meeting
30	5/9	Mon	Organizing documents, team meeting
31	5/10	Tue	Meeting with GDPM
32	5/11	Wed	Site visit to NIHE Animal (rat) Laboratory
33	5/12	Thu	Organizing documents, team meeting
34	5/13	Fri	Organizing documents, team meeting
35	5/14	Sat	Organizing documents, team meeting
36	5/15	Sun	Organizing documents, team meeting
37	5/16	Mon	Organizing documents, team meeting
38	5/17	Tue	Presentation to POLYVAC
39	5/18	Wed	Organizing documents, team meeting
40	5/19	Thu	Organizing documents, team meeting
41	5/20	Fri	Organizing documents, team meeting
42	5/21	Sat	Organizing documents, team meeting
43	5/22	Sun	Organizing documents, team meeting
44	5/23	Mon	Hearing to POLYVAC
45	5/24	Tue	Organizing documents, team meeting
46	5/25	Wed	Site visit to VABIOTECH
47	5/26	Thu	Organizing documents, team meeting
48	5/27	Fri	Moving day (Hanoi → Narita)

3. List of Counterparts

From Vietnam

Ministry of Health (MOH), General Department of Preventive Medicine (GDPM)

Mr. Hoang Minh DUC PhD.	Vice Director
Mr. Tran Huu Quang MD	Head of Division
Mr. Phi Van KIEN MD	Senior Officer
Mr. Trinh Xuan TUNG MD	Senior Officer
Mr. Vu Thanh TU MD	Officer

National Institute of Hygiene and Epidemiology (NIHE)

Ms, Le Thi Quynh MAI. MD. PhD.	Vice Director
Mr. Tran Nhu DUONG MD. PhD	Vice Director
Mr. Nguyen Thanh THUY MD. PhD	Center of Laboratory Quality Assurance and Calibration
Ms. Nguyen Le Khanh HANG MD. PhD	Virus Department
Ms. Nguyen Thi Minh	International Cooperation Department
Ms. Nguyen Dieu Chi Mai	International Cooperation Department

Pasteur Institute in Ho Chi Minh City (PIHCMC)

Mr. Nguyen Vu TRUNG MD. PhD	Director
Ms. Cao Minh THANG MD.PhD	Head of Department of Microbiology and Immunology
Ms.Tran Thi Luu Nguyen HUONG	Head of Planning Department
Ms. Nguyen Thi Thu PHUONG	Staff, Planning Department
Ms. Nguyen Thi Yen NHI	Department of Microbiology and Immunology
Mr. Nguyen Hoang Anh	Department of Microbiology and Immunology
Le Huong Trang	Staff, Planning Department

Pasteur Institute in Nha Trang (PINT)

Mr. Do Thai Hung, MD, MPH, PhD	Director
Ms. Le Ho Phuong NGA MD	Vice Director
Ms. Nguyen Thi Hai BINH MD	
Mr. Hoang Tien THANH MD	Infectious Disease Control and Prevention Department
Ms. Ngo Le Minh TAM MD	Director of Center for Laboratory Quality Assurance and Calibration
Ms. Huynh Kim MAI MD	Department of Microbiology and Immunology
Mr. Phan Vu TIEN MD	Director of Medical Service Center
Ms. Dao Thi Van KHANH	Center for Food Safety in Central Viet Nam

Tay Nguyen Institute of Hygiene and Epidemiology (TIHE)

Mr. Vien Chinh Chien	Director
Mr. Bui Khanh Toan	Vice Director
Ms. Nguyen Thi Thu Ha	Vice Head, Microbiology Department
Ms. Ly Thi Thuy Toang	Staff
Ms. Tran Tuong Vi	Staff

POLYVAC

Mr. Nguyen Dang HIEN MD.PhD	Director
Ms. Nguyen Thuy HUONG MD. PhD	Vice Director
Ms. Ngo Thu HUONG MD. PhD	Vice Director
Pham Thi Phuong Thao	Head of Q.A Department
Nguyen Dang Anh	Head of Technical Department
NGUYEN Thi Hai Thanh	Head of General Affair

IVAC

Mr. Duong Huu Thai PhD	Director
Mr. Nguyen Xuan Nghia MBA	Vice Director
Ms. Vu Thi Hong DUNG MD	Head of Personnel Department
Ms. Pham Thi Bich HONG	Staff

VABIOTECH

Mr. Anh TUAN M D .PhD	Director
Ms. Hai	In charge of Animal Breeding

ASTT (Administration of Science, Technology, and Training)

Mr. Nguyen Ngo Quang MD. PhD	Vice Director
Mr. Hoan Hoa SON	Head of Division
Mr. Le HIEU	Senior Officer

Organization & Human Resources Department (OHR)

Mr. Nguyen Hong SON	Director
Ms. Tran Thi THOA	Senior Officer
Ms. Do Thi Phuong THAO	Senior Officer

Electronic Health Administration Department (EHAD)

Mr. Nguyen Van VIET	Vice Director
Ms. Nguyen Thanh MAI	Head of Database Division
Mr. HIEU	Officer

Drug Administration of Vietnam

Mr. Ta Manh HUNG	Vice Director
Mr. Nguyen Van VIEN	Head of Quality Department
Ms. HIEN	Senior Officer

JICA & Vietnam's Ministy of Health

Mr. SHOBAYASHI Tokuaki	Health Policy Adviser
Ms. NGUYEN THI THU NGOC	Assistant for Health Policy Adviser

JICA・NIHE

Mr. KAI Masanori	Chief Advisor
Mr. HASHIMOTO Ken	Project Expert
Ms. TANAKA Chiho	Project Coordinator

Tri Viet (company)

Mr. Nguyen Minh HIEU	Director
Mr. Dang Anh MINH	Vice Director
Mr. Pham Quoc TRONG	Engineer
Mr. Pham Tuan DIEN	Engineer

From Japan

JICA Vietnam Office

Mr. TANAKA Akihisa	Senior Representative
Ms. TAKASHIMA Kyoko	Senior Project Formulation Advisor (predecessor)
Ms. YAMASHITA Yukiko	Senior Project Formulation Advisor (successor)
Mr. BUI THANH TRUNG	Senior Program Officer

JICA HQ

Mr. YAMAMOTO Kenichi	Senior Advisor/ PPP Expert
Ms. FURUTA Ayano	Human Development Dept. Health Group 2

4. List of Reference and Documents Received

No	Title	Source
1	FIVE-YEAR SOCIO-ECONOMIC DEVELOPMENT PLAN DURING THE 2021 – 2025	https://english.luatvietnam.vn/official-gazette.html
2	No. 03/2007/QH12: LAW ON PREVENTION AND CONTROL OF INFECTIOUS DISEASES	https://english.luatvietnam.vn/official-gazette.html
3	Party Resolution No.20 on Enhancing Public Health Protection in the New Situation	https://english.luatvietnam.vn/official-gazette.html
4	The Resolution No. 20/NQ-TW dated October 25, 2017 of the Central Committee on enhancement of citizens' health protection, improvement, and care in new situation	https://english.luatvietnam.vn/official-gazette.html
5	DECISION No. 376/QD-TTg: Approving the Program on development the pharmaceutical industry and domestically produced medicinal materials to 2030, with a vision to 2045	MOH
6	Decision by the Ministry of Health on establishment of action plan for drug development strategy	MOH
7	NATIONAL ACTION PLAN: FOR THE IMPLEMENTATION OF THE 2030 SUSTAINABLE DEVELOPMENT AGENDA	MOH
8	DECISION No: 153/2006/QD-TTg: APPROVING THE MASTER PLAN ON DEVELOPMENT OF VIETNAM'S HEALTHCARE SYSTEM UP TO 2010 WITH A VISION TO 202	MOH
9	CIRCULAR No. 38/2017/TT-BYT: INTRODUCING LISTS OF INFECTIOUS DISEASES, SCOPE AND RECIPIENTS OF COMPULSORY VACCINES AND BIOLOGICALS	MOH
10	DECREE No. 103/2016/ND-CP: ON BIOSAFETY IN LABORATORIES	MOH
11	CIRCULAR No. 41/2016/TT-BYT: LIST OF INFECTIOUS MICROORGANISMS SORTED BY THREAT CATEGORY AND BIOSAFETY LEVEL SUITABLE FOR THEIR TESTING METHODS	MOH
12	CIRCULAR No: 37/2017/TT-BYT: ON BIOSAFETY IN LABORATORIES	MOH
13	DECISION No: 1657/QĐ-TTg: APPROVING KEY NATIONAL SCIENCE AND TECHNOLOGY PROGRAM "RESEARCH FOR MANUFACTURING VACCINE FOR HUMAN USE BY 2030"	MOH
14	DECISION No. 749/QD-TTg: INTRODUCING PROGRAM FOR NATIONAL DIGITAL TRANSFORMATION BY 2025 WITH ORIENTATIONS TOWARDS 2030	MOH
15	Ministry of Health Decree No.5969 : ICT Application Plan 2021-2025	MOH
16	Presentation slides from POLYVAC	POLYVAC

17	Presentation slides from IVAC	IVAC
18	Presentation slides from PINT	PINT
19	BSL3 Layout of PINT	PINT
20	Presentation slides from PIHCMC	PIHCMC
21	Presentation slides from NIHE	NIHE