Part III Best practices and challenges

Chapter 3 The Health, Labor and Welfare Ministry (MHLW)

The Health, Labor and Welfare Ministry is a government organization in charge of measures under the Infectious Diseases Control Law and the Quarantine Act, and is at the center of the nation's system for managing infectious disease crises. It commands crisis management in the fields of public health, called "health crisis management," and develops the system to cope with infectious disease emergencies based on a set of internal rules and regulations.

By making use of its system, the health ministry acted quickly in the initial response to the outbreak of the novel coronavirus disease, conveying adequate notifications and holding communications with relevant authorities, and took various steps that served as the foundations for the "Japan model" in dealing with COVID-19. On the other hand, the ministry did not necessarily make prompt or appropriate decisions or response in terms of public communication and actions that involved other parties such as local governments, regional public health centers and public health institutes. An official of the ministry said such features of its COVID-19 response are symbolic of the ministry being "adept at fighting localized battles but weak in an all-out battle."

In this chapter, we review the health ministry's response to COVID-19 and examine the problems that must be overcome in preparing for the next big wave of novel coronavirus infections and any future onslaught of an even more deadly pandemic, as well as best practices that should be further reinforced.

1. Organization of the Health, Labor and Welfare Ministry

The Health, Labor and Welfare Ministry is a giant government organization with a 33,000-strong workforce and an annual budget of over \(\frac{4}{33}\) trillion. Along with the minister's secretariat and the office of the director-general for policy planning, coordination and evaluation, it has 11 bureaus and six departments. The ministry is responsible for policies that directly concern people's lives, such as medical care, health insurance, sanitation and labor issues, and plays important roles in setting the future direction of the nation with a rapidly aging and shrinking population.

Here, we focus on the schemes and tools at the ministry's disposal to deal with an infectious disease, and examine how they functioned in dealing with the COVID-19 crisis.

1.1. The infectious disease crisis response system of the health ministry

The Health, Labor and Welfare Ministry was created in the reorganization of central government bureaucracy in 2001, through the merger of the Health and Welfare Ministry and the Labor Ministry. At that time, the organizations of both the former Health and Welfare Ministry and the Labor Ministry were kept independent of each other. That structure is often blamed for the weakness in its system for making integrated ministry-wide decisions. Problems arising from divisions along old ministerial lines dating back before the merger still linger on, as Hideki Tarumi, head of the Office for Novel Coronavirus Disease Control at the Cabinet Secretariat, said in a news conference in September 2020 as he was newly appointed as the ministry's administrative vice minister.

The measures under the health ministry's jurisdiction to manage infectious disease crises are implemented by state bodies such as the National Institute of Infectious Diseases and quarantine stations, as well as regional public health centers and public health institutes under the control of prefectural and municipal governments.³ The ministry provides for unified standards and guidelines in the policy execution by the public health centers and public health institutes through notifications and clerical communications issued to those bodies.

At the center of the ministry's efforts to manage infectious disease crises is the Tuberculosis and Infectious Disease Control Division of its Health Service Bureau. All information concerning "health crisis management" measures under the ministry's jurisdiction is shared in a weekly conference organized by the Health Science Division of the minister's secretariat. Measures concerning the management of infectious disease crises are based on the implementation manual for an infectious disease health crisis. When a serious domestic impact is anticipated from an overseas outbreak of a grave infectious disease and emergency measures are deemed necessary, the ministry shifts into a crisis response mode, and sets up its headquarters and various working teams if necessary to deal with the crisis.

In response to the novel coronavirus disease, the Tuberculosis and Infectious Disease Control Division took charge of gathering information and building various response schemes at the beginning of 2020 and, after the first case of cross-border infection with the virus was confirmed on January 15, a conference of Yasuhiro Suzuki, chief medical and global health officer, and senior officials of the relevant bureaus and departments was organized to make decisions. From around January 20 – when the first case of human-to-human infection was confirmed in China – the ministry sped up its response to COVID-19, organizing a ministry-wide liaison conference (led by the head of the Health Service Bureau) on January 21 and setting up its headquarters for the COVID-19 response on January 28.

1.2. Limitations of administrative steps by way of notification

Based on the above-mentioned crisis response system, what tools did the health ministry possess in executing its policy measures?

From pre-World War II days, the nation's measures against infectious diseases were primarily targeted at containing the spread of tuberculosis. Health centers set up across the country under the Health Bureau of the former Health and Welfare Ministry took charge of tracking down and isolating infected patients. After the war, the new health center law put the public health centers under the control of prefectural governments. Unlike the health ministry of the prewar days, which had an organization known as the sanitation police equipped with the power to enforce isolation of infected patients, the infectious disease crisis control system of the Health, Labor and Welfare Ministry, based on the decentralized organizational structure, is bound by various restrictions.

As for the legal and organizational preparedness (as explained in Part III, Chapter 1), the ministry can take a variety of policy steps, such as designating medical institutions for dealing with infectious diseases and providing subsidies and assistance to measures against infectious diseases. However, it is the quarantine stations, public health centers, public health institutes and medical institutions across the country that are assumed to take the frontline roles in combating an infectious disease emergency when it breaks out. Under such a structure, the policy execution tools at the ministry's disposal are mainly notifications issued to local governments and medical institutions.

After it was disclosed in late December 2019 that a mass infection by an unknown pathogen causing pneumonia among the infected had broken out in Wuhan, China, the ministry issued the first notification concerning the novel coronavirus to relevant authorities on January 6, 2020 calling for alert and use of the system for surveillance of suspected cases. By the end of July, the ministry had issued a total of nearly 600 such notifications addressed to local governments and medical institutions.⁵ They numbered two to three a day on average, but as the infection spread in Japan in March, the ministry sometimes issued seven to eight notifications in a single day. Staff at public health centers and medical institutions were often kept busy responding to each of the large numbers of notifications issued in quick succession, according to an official at a local government.

Since instructions were given in one-way notifications, the health ministry had no means to confirm whether the instructions had in fact been carried out by the local authorities and medical institutions, to assess what effects the instructed measures have had, or to take sufficient follow-up steps. "Since January, we issued massive numbers of notifications to prefectural governments and medical institutions. But when we later asked doctors at local medical associations or officials of the local governments, it turned

out that our instructions were not always received in the way we had intended," said a senior official at the health ministry.

From January 23, the health ministry also issued a series of notifications to local governments "requesting" that they consolidate their regime for holding PCR and other tests for the novel coronavirus. However, local authorities and public health institutions did not necessarily act in accordance with notifications given in rapid succession. It has been reported that some public health centers were making judgments on who should get the PCR tests based on an old set of criteria on testing suspected cases — even after the criteria was amended in a notification from the health ministry.

Such problems with notification-based administrative measures are the result of a power structure in which the health ministry, which is empowered to craft policy measures for managing infectious disease crises, does not have local bodies on the frontline of battling infectious diseases (except for the quarantine stations) under its direct control. A senior official in the Cabinet Secretariat⁷ said the health ministry "lacks the power to execute" its policy measures.

1.3. Lessons from the past not fully learned

The health ministry's system for responding to an infectious disease crisis (as mentioned in 1.1.) is founded on past experience in dealing with infectious diseases. In particular, the novel influenza (A/H1N1) pandemic of 20098 prompted Japan to launch a large-scale operation to deal with the emergency, and the health ministry took various steps in response. A report by the government conference summing up its response to the novel influenza pandemic, compiled in June 2010, made a series of recommendations for strengthening the nation's crisis management system. That led to the enactment of the Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response. Further efforts were made in subsequent years to improve the ministry's functions for taking charge of the response to an infectious disease crisis, including the creation of a new position of chief medical and global health officer at the ministry, following the experience of dealing with the 2014 outbreak of the Ebola virus disease.

However, some of the problems highlighted in the 2010 report have since been left unaddressed. For example, proposals made in the report for consolidating the PCR and other testing system at public health institutes as well as the capacity of public health centers, or clarifying the division of roles between national and local governments (as detailed in Part II, Chapter 7, and Part III, Chapter 1), were not sufficiently put into action.

The 2010 report called for clarifying the decision-making process at the national level and the responsibilities of the parties involved, so as to build a system for making prompt decisions based on an accurate grasp of information from medical institutions and

local governments ("prompt and rational decision-making system"). It also proposed that the health ministry's divisions in charge of infectious disease crisis management should develop, promote and maintain personnel with both expert knowledge of infectious diseases and administrative capabilities ("strengthening the systems involved in infectious disease crisis management"). Has the health ministry acted in response to the report's recommendations – to consolidate the functions of its organization by placing staff well-versed in managing infectious disease emergencies at its core, so as to upgrade its capacity to play a central role in Japan's response to a future pandemic-class crisis? In this respect, the health ministry has not sufficiently put the proposals into action. Many of the staff at the ministry's headquarters responding to COVID-19 had not been properly trained for – much less had a practical experience of – managing an infectious disease crisis. One staff member even expressed frustration with having to deal with an unfamiliar crisis.⁹

1.4. A lack of industry policy in the regulatory body

The health ministry regulates the medical service system under the Medical Care Act, gives approval of drugs under the law on pharmaceuticals and medical devices, and defines health insurance coverage under the Health Insurance Act – implementing its policy measures by way of various regulations. The method serves its purpose of guaranteeing a minimum level of social security broadly to the public. But due to its lack of industrial policy perspectives – of developing related industries – the ministry fell behind in some aspects of the COVID-19 response.

This problem was particularly evident in its response to the shortage of masks and personal protective equipment in the early stages of the COVID-19 outbreak. From the beginning, Japan's total stockpile of such gear was far smaller than required. What is more, the nation relied on imports from China for a large portion of its supply of masks and other equipment. As imports from China were cut off and countries around the world competed with each other to secure those supplies, the health ministry could not get around to taking steps to launch domestic production of masks or securing new import routes. The "mask team" set up at the health ministry ended up asking for help from the Ministry of Economy, Trade and Industry.

The health ministry also lagged behind in efforts to promote development of COVID-19 vaccines and medicines, while many other countries proceeded with those efforts just as novel coronavirus infections continued to expand.

2. The health ministry's response to the novel coronavirus disease

How did the health ministry, based on its infectious disease crisis response system (as mentioned above in 1.), overcome difficulties in dealing with COVID-19? What problems hampered its efforts? In this section, we review several cases to assess the measures taken by the ministry.

2.1. Operation to repatriate Japanese from Wuhan

When China enforced the lockdown of Wuhan and Japan decided at the order of Prime Minister Abe to launch an operation to repatriate the Japanese stranded in the Chinese city, the health ministry took charge of the quarantine of returnees. Initially, the health ministry maintained that uniform isolation of returnees showing no symptoms was not necessary because there was supposed to be no risk of asymptomatic carriers transmitting the virus to others. However, the Prime Minister's Office, citing a growing public concern over the possibility of returnees from Wuhan spreading infections in Japan, urged the health ministry to isolate all of the returnees for two weeks upon their return. This was not necessarily a rational decision in light of the scientific knowledge about the new virus available at that point. But given that it was later discovered that asymptomatic carriers could infect others, the decision by the Prime Minister's Office turned out to be effective in containing the infection.

In the initial stage of the outbreak of an infectious disease crisis – when it is not yet known how virulent or contagious the virus is – it is naturally difficult to take perfect measures for the crisis, either scientifically or politically. However, the example of this decision by the Prime Minister's Office – its motivations aside – shows that in dealing with a crisis, you need to constantly follow the worst-possible scenario. Infectious disease crisis management led by the health ministry is founded on medical and public health "science." But at the same time, the very nature of the task of crisis management dictates that you need to always assume the worst-possible scenario in order to save people's lives and livelihood.

2.2. Response to the Diamond Princess case

2.2.1. Success of flexible manpower deployment and dispatch of commander to the front line

The first major challenge for the health ministry in the COVID-19 crisis was

dealing with the outbreak aboard the cruise ship Diamond Princess, which arrived at the Yokohama port on February 3. Initially, the Yokohama Quarantine Station was put in charge of the case, but the ministry realized the gravity of the situation when it was reported that 10 of the 31 passengers showing such symptoms as fever tested positive for the novel coronavirus in PCR tests.

Before the Diamond Princess entered the Yokohama port, Tokuaki Shobayashi, a technical official and licensed medical doctor who played a key role in the health ministry's response to the novel influenza pandemic in 2009, was called back from the Environment Ministry, to which he had been seconded, to deal with COVID-19. When the Diamond Princess case became a serious issue requiring a ministry-wide response, Shobayashi was dispatched to the Yokohama port, where he boarded the Diamond Princess to take charge of the government's on-site operation.

Since February 5 onward, Shobayashi took direct command of the operation aboard the Diamond Princess, asking the captain to get all passengers to keep to their individual cabin, sanitize their hands and wear masks. He also commanded the measures to prevent infection among the crew, holding training and drills for the crew with the cooperation of the National Institute of Infectious Diseases and related academic organizations. As a consequence, new infections aboard the ship thereafter were contained to a significant degree. This is an example of a flexible manpower deployment having an effect in dealing with a crisis.

2.2.2. Failure of crisis communication

The capacity for holding PCR tests was quite limited at that time, and tests had to be held bit by bit on each of the small groups of passengers and crew aboard the Diamond Princess. Results for people who tested positive were reported one by one each day, and the health ministry publicly released the results as they came in. As a consequence, announcements of the test results gave the wrong impression that more and more people were being infected aboard the cruise ship day by day – whereas in fact the number of new infections from February 5 onward was small. An official at the health ministry acknowledged that this was an example of a failure in the ministry's crisis communication. Also, the limited capacity for holding PCR tests was a result of the ministry's failure to implement the recommendations made in a government report summing up its experience with the 2009 novel influenza pandemic.

The health ministry was also unable to do much about disseminating information about its COVID-19 response to the international audience. When Dr. Kentaro Iwata, a professor of the Kobe University School of Medicine who briefly went aboard the Diamond Princess, posted a video on YouTube on February 18 criticizing the infection control measures taken aboard the cruise ship, the ministry came under fire from the

overseas media for its response to the Diamond Princess situation. Despite the international repercussion of the video message, the health ministry did not make an adequate rebuttal to Iwata's charges in concrete terms, such as by showing pictures of the inside of the ship, and the government was unable to give a timely explanation capable of winning the foreign media's understanding on the issue. A health ministry official noted that the ministry did not even pay much attention to how its actions were viewed overseas – or how to publicize its measures to an international audience. It appears that the ministry – mostly in charge of domestic affairs – was not sufficiently aware of the importance of crisis communication targeted abroad in dealing with a pandemic-class infectious disease crisis.

Furthermore, communication with the passengers aboard the Diamond Princess – half of whom were tourists from overseas – was less than adequate. Along with the fear of the infectious disease, the mental burden of being confined to their individual cabin for an extended period must have been greatly distressing for the passengers. As they had to stay in their rooms for days on, one passenger reportedly complained that he would rather jump into the sea. ¹⁰ The health ministry staff aboard the ship had particular trouble communicating with the non-Japanese passengers in English. That problem led some of the foreign passengers to individually get in touch with the media and politicians in their home countries and vent their frustration with the situation aboard the Diamond Princess, which caused further confusion in the operation on the ship.

Health minister Katsunobu Kato indicated that the government would take utmost care of people aboard the Diamond Princess, sending Gaku Hashimoto, state minister of health, labor and welfare, and Hanako Jimi, parliamentary vice health minister, aboard the ship beginning on February 10. However, it is undeniable that the crisis communication by the health ministry staff toward the foreign passengers was insufficient.

2.3. Seeking the help of experts

2.3.1. Setting up the advisory board

Dealing with an infectious disease crisis requires expert knowledge and experience in a variety of fields, including administrative governance, crisis management, related domestic and international laws, epidemiology, sequential SEIR (susceptible, exposed, infectious, recovered) model, clinical medicine, virology, bacteriology, vaccinology, pharmaceutical affairs and crisis communication. The health ministry has technical officers with medical licenses, and the chief medical and global health officer – a position ranked next to administrative vice minister – serves as the leader of those officers. However, the technical officers, including the chief medical and global health officer, are all staff members of the ministry's bureaucracy who must follow the

government's chain of command. Not all of the technical officers with a medical license are experts in infectious diseases. Therefore, when a crisis breaks out over an infectious disease of unknown pathogen, the health ministry needs the help of experts outside its organization to give expert advice from objective standpoints.

In dealing with the novel coronavirus disease, the health ministry began weighing the launch of a panel of experts in infectious diseases at an early stage of the outbreak – in late January – and its COVID-19 response headquarters on February 4 set up an advisory board of experts including Shigeru Omi, Nobuhiko Okabe and Hitoshi Oshitani, who had advised the government in the response to the novel influenza pandemic in 2009. The scheme was proposed by Tokuaki Shobayashi, who led the ministry's team dealing with the 2009 pandemic. The Expert Meeting on the Novel Coronavirus Disease Control set up as a body under the government's COVID-19 headquarters on February 14 effectively had the same number as the advisory board. In short, the health ministry's advisory board was converted¹¹ into the government's panel of experts.¹²

These experts and health ministry officials had built up mutual trust based on the experience of working together on a pandemic in the past. They engaged in active discussions, as the ministry officials basically respected the views of the experts but occasionally responded to proposals from the experts with counterproposals from the government's standpoint. The experience of dealing with an emergency in the past made the people involved better able to respond a new crisis and expedited their decision-making. "They are so much different from other people in the speed of making decisions or in predicting what could happen," a senior ministry official said of the experts tapped to advise the government. Due partly to its gigantic organization and to the wide range of interested parties in the social security field, the health ministry is often criticized as being "slow to respond" in normal times. He at in dealing with COVID-19, the ministry should take credit for acting promptly in its initial-phase response to the outbreak, making full use of its experience of the 2009 pandemic. The ministry did not use the experts as a nominal help but tapped their expertise for policy making in substance — a good example of the lessons learned from the 2009 emergency.

At the same time, there were problems in the relationship between the health ministry and the experts as well as in the crisis communication (as to be discussed in Part III, Chapter 5 and 6). In particular, the positioning of the experts making their own public statements was left vague, which caused some confusion in the health ministry's public communication about its COVID-19 response. Initially, the health ministry did not anticipate that the experts, tapped to give expert advice to the government on infectious disease control measures, would make their own statements to the public. But amid the tense situation of the pandemic, the experts could not wait for their advice to the government to be publicly released only after lengthy bureaucratic procedure of approval by the chief medical and global health officer, the vice minister and then the health minister, and they asked health minister Kato to allow them to speak directly to the public.

The health ministry maintained that the experts made the public statements based on their academic freedom as scholars in infectious diseases, and that the ministry had no powers to stop or control those statements. Still, the ministry allowed the experts to use its news conference room in releasing their own views as researchers. That contributed to a public misunderstanding about the nature of their statements – while the experts were giving their views in their capacity as researchers of infectious diseases, their statements were often mistaken as the official views of the health ministry or the Japanese government.

There were benefits to the experts making their own public statements, in that the experts themselves gave careful explanations and answered questions from the media about COVID-19. A member of the staff at the Prime Minister's Office acknowledged that the briefings given by the experts relieved the health ministry and the government of some of their burden of explaining to the public. Along with risk of the public misunderstanding the government's messages, however, this resulted in the experts themselves occasionally bearing the brunt of public criticism, possibly exposing them to some danger. Steps should have been taken to make a clear distinction between the government's official position and the statements made by individual experts.

2.3.2. Support by those who completed FETP and IDES programs

The active epidemiological investigation to track down infected patients is a task that belongs to public health centers. But in order to take an integrated government approach to track down people infected with the novel coronavirus, the government set up a "cluster taskforce" under the health ministry's COVID-19 headquarters on February 25. Measures to deal with infection clusters were taken in European and North American countries, but Japan's measures adopted a unique approach of focusing on identifying the origin of the clusters by retrospectively tracing the movement of the carriers to the source. The measures targeting the infection clusters were supported by officials who had completed the Field Epidemiology Training Program (FETP), which began in 1999 with the implementation of the Infectious Diseases Control Law, and the Infectious Disease Emergency Specialist (IDES) program launched by the health ministry in 2015.

According to the National Institute of Infectious Diseases, a total of 30 people who had either completed or were trained under the FETP program took part in the COVID-19 response (between February 25 and May 20). While playing a central role in the cluster taskforce, they were also dispatched to each prefecture to act as liaison from the health ministry to bridge national and local governments in combating COVID-19. A health ministry official also noted that officials who had completed the IDES program, with their experience at various domestic bodies related to crisis management, played useful roles in the operation of the Tuberculosis and Infectious Disease Control Division when its manpower was overwhelmed by the mission to repatriate Japanese stranded in

Wuhan and in the initial response to the COVID-19 outbreak, along with their contribution to the cluster taskforce.

Meanwhile, the number of people who can be trained under those programs remains far too small, given the need for such expert personnel in a nationwide response to a pandemic-class infectious disease crisis. Only several people are annually accepted into the FETP program, which has been ongoing for 20 years, and the IDES program is open to just some five people each year. South Korea, which experienced the MERS outbreak in 2015, has a total of more than 200 trainees under a program similar to FETP. The COVID-19 experience highlighted the need for expanding the FETP and IDES programs in Japan. As for the IDES, people who completed the program are required to cooperate with the health ministry's request for dispatch in the case of an infectious disease emergency.¹⁷ But in fact, they cannot always be mobilized promptly to deal with such a crisis because such a mission requires adjustments with the divisions to which they belong in normal times. How to secure those personnel with expertise for surge capacity in the case of an emergency is another issue under the system that must be resolved.

2.4. Various problems over testing

The problems over PCR and other tests were the most serious challenges that confronted the health ministry in its COVID-19 response. The problems continued to haunt the ministry throughout the crisis as 1) the testing capacity was absolutely lacking in the initial phase of the outbreak (from January to February); 2) the total capacity was increased as the infections expanded (from March to May) but the actual number of tests held did not increase much because the testing process was "clogged"; 3) the ministry maintained its strict criteria in holding the tests, even though it was aware of the risk of asymptomatic carriers infecting other people; and 4) even after tests were held in steady numbers beginning in May, the ministry was unable to clearly explain the purpose of the tests. As a result, the ministry could not dispel public suspicion that the required tests were not being held for the novel coronavirus.

2.4.1. Challenges during the initial phase of the outbreak (January to February): The absolute shortage in testing capacity

Even though the government report summing up its response to the 2009 novel influenza pandemic highlighted the need to boost the testing and analysis capacity of public health institutes, the nationwide capacity for giving PCR tests and processing the results was only about 300 cases a day as of January 2020. As a result, the ministry had to test the passengers and crew aboard the cruise ship Diamond Princess under the

constraints of such an extremely limited testing capacity.

During the initial phase of the outbreak (January to February), the greatest problem was the absolute shortage in testing capacity, due to scarce capacity at the public health institutes across the country. Owing to the problem, the health ministry had to narrow down the scope of people to be tested for the novel coronavirus, by introducing strict testing criteria. The problem was later eased by making use of the resources of private-sector testing companies.

2.4.2. Challenges during the expansion phase of domestic infections (from March to May): 1) the "clogged" testing regime

Even after testing capacity gradually increased as the government began to use the service of private-sector testing companies, the actual number of tests held did not increase. Just as the infection spread in Japan, large numbers of people were left unable to receive PCR tests even when their doctors said they needed to be tested, and the government came under severe public criticism. The problem also fueled international suspicion over Japan's COVID-19 response, and the U.S. Embassy in Tokyo issued a warning on April 1 urging Americans visiting Japan to return home, citing the shortage of tests performed in Japan.

Steps taken by the health ministry – including the introduction of tests covered by public health insurance on March 6 and the launch of local PCR test centers across the country starting on April 15 – did not lead to a fundamental solution of the issue. Prime Minister Shinzo Abe told a news conference on May 4 that the PCR testing system was "clogged," expressing frustration that the number of tests for the novel coronavirus was not increasing. A senior official in the Cabinet Secretariat recalled that the Prime Minister's Office, irritated with the situation, added pressure on the health ministry to hold more PCR tests.¹⁸

As mentioned in Part II, Chapter 7, the number of PCR and other tests for the novel coronavirus did not rise – even though the total capacity for such tests was gradually increased from March to May – because the testing regime was "clogged" by various factors including the manpower shortage at public health centers, the shortage of medical staff collecting specimens for the tests as well as the personal protective equipment needed for such work, and the additional workload at the public health centers and medical institutions due to the obsolete means of communication between them (by way of handwritten fax messages, and so on). The health ministry has no direct command over public health centers, public health institutes and medical institutions on the frontline of combating the infections. Therefore, even in a crisis situation that demands a prompt solution to the problems at hand, it took time for the health ministry to gather information about the work situation at those frontline bodies – including the "clogged" testing

procedure – and for those bodies to carry out the measures in line with the ministry's policy. "We realized that some things would not move forward, no matter how much budgetary allocation we set aside for them," a health ministry official said.

2.4.3. Challenges during the expansion phase of domestic infections (from March to May): 2) strict criteria for giving novel coronavirus tests

By around February 10 at the latest, the health ministry was aware – based on information from the advisory board and other sources – that asymptomatic carriers of the novel coronavirus could transmit the virus to other people. But the ministry would not publicly approve of giving PCR and other tests on people showing no symptoms – until it finally authorized testing such people in May when they were deemed by their doctors to need the tests and when they were identified as close contacts of infected patients.

Behind such an approach by the health ministry in the early phase of the outbreak was the absolute shortage of testing capacity. And when the number of tests did not rise, despite the gradual increase in overall capacity, due to the clogging of the testing system, the ministry had to keep tests to a minimum to avoid increasing the workload on staff in the frontline bodies. However, the fact that the ministry would not officially recognize the possibility of infections from asymptomatic carriers in order to limit the coverage of PCR tests – even when there was clear scientific knowledge of the risk of infection from carriers without symptoms – bred public suspicion over the ministry's policy on testing for the novel coronavirus, possibly undermining people's trust in the government's overall response to COVID-19.

2.4.4. The challenge from May onward: unclear purpose of testing

After coming under both domestic and international criticism, as well as pressure from the Prime Minister's Office, the health ministry managed to gradually increase the capacity for giving PCR and other tests¹⁹ for the novel coronavirus starting in May.²⁰ Even at that point, however, the health ministry was unable to summarize the government's purpose of such tests in an easily understandable manner, thus leaving the public in the dark as to for what purpose the tests were being given.

There are several forms of PCR tests held to serve different purposes as follows:

(1) Public health purpose:

Tests given for public health purposes – to gather information about the novel coronavirus, as well as to accommodate people found infected as a result of tests at

hospitals and other institutions, thus preventing the spread of the disease and securing the "safety" of society – are called administrative tests. Such tests are given mainly at the National Institute of Infectious Diseases and public health institutes at public expenses as part of the epidemiological surveillance called for under the Infectious Diseases Control Law.

(2) Clinical medicine purpose:

PCR and other tests given by medical institutions on the judgment of doctors from the clinical medicine purpose of providing appropriate medical care or preventing hospital-acquired infections are called "clinical tests." Initially, these tests were given as administrative tests as provided for by the Infectious Diseases Control Law, at the expense of the government and mainly by the National Institute of Infectious Diseases and public health institutes. After public health insurance coverage was extended to these tests, private-sector testing institutions began to conduct testing and analysis of the results, with 70 percent of the cost covered by health insurance and 30 percent by public expenses.

(3) Social and economic activities purposes

Private-sector companies or individuals can provide tests out of necessity for their social and economic activities or for their sense of security (to ease anxiety), according to their individual needs such as business activities (including taking overseas travel or holding entertainment events) or health control. PCR and other tests for these purposes are given at each party's own expenses and not covered by health insurance at private-sector testing institutions.

When issues with the PCR testing system gradually eased beginning in May and the question arose as to how far to extend the coverage of PCR tests to people showing no symptoms, differences in opinions within the government surfaced over the purpose of these tests. The Prime Minister's Office advocated broadly expanding the targets of PCR and other tests, in response to public opinion demanding that tests be made more widely available. But the health ministry was reluctant about expanding the target of PCR tests.

Both agreed that tests should be held for the purpose of public health. However, the Prime Minister's Office, while acknowledging that it was impossible to eradicate COVID-19 (or to reduce new infections to zero), took the position that the tests should be given for the purpose of reducing the risk of infection close to zero in order to secure a public sense of security over the disease. Meanwhile, the health ministry, from the viewpoint of securing "safety" through rational control of the infection risk and assuming that it was difficult to eradicate COVID-19, maintained a position close to "risk management" – that the purpose should be preventing an explosive spread of infection and managing infections at stable levels. The difference between the Prime Minister's Office and the health ministry was not a one-or-the-other choice but more a question of which was relatively closer to either's position. In any event, a gap has begun to emerge between the two parties over the purpose of the tests.

The health ministry was particularly guarded against introducing a scheme to make tests widely available to those who wished to be tested in order to ease public anxiety over COVID-19. A health ministry official compiled a document titled "About the argument that tests be made widely available to ease public concern" (listed among the reference materials at the end of this report) and distributed it to lawmakers and government officials in Nagatacho and Kasumigaseki to make the case against broadly expanding the target of the coronavirus tests. It is suspected that the health ministry, due to its bitter experience of an acute shortage in testing capacity in the early phase of the outbreak, was cautious toward easing the criteria for giving PCR tests to avoid coming under criticism again from people who could still not be tested even as it kept up its efforts to expand testing capacity.

It must be noted, however, that proponents of expanding the target of PCR tests, including the Prime Minister's Office, did not necessarily seek to make the tests available to all who wished to be tested so as to alleviate people's uneasiness. By distributing that sort of document to argue against broadening the target of the tests, the health ministry rather incurred more distrust from the proponents and, as a result, it had more trouble bridging the gap in approaches with the Prime Minister's Office, and thus was unable to clearly explain to the public the purpose of testing for the novel coronavirus. When, after the state of emergency was lifted in late May, calls grew from the business community for expanding the target of PCR tests for the purpose of "social and economic activities" and various proposals were made to Yasutoshi Nishimura, minister in charge of COVID-19 response, and the Prime Minister's Office, 21 the government was unable to clearly identify its purpose in giving the PCR tests, further deepening popular suspicion that the required tests for the virus were not being given.

Later, at the July 16 meeting of the government's Novel Coronavirus Infectious Disease Control Subcommittee, the "Basic ideas and strategy" of the subcommittee on the testing system was disclosed, finally clarifying the government's position that it would endeavor to secure the testing of people showing COVID-19 symptoms as well as others who, despite the lack of symptoms, had a high risk or pre-test probability of being infected (such as close contacts of infected patients). The subcommittee also noted that the government would not hold administrative tests on asymptomatic people with low risk or pre-test probability of infection, due to the risk of false negative or positive test results, but that such people might still take the tests at their own expense for "social and economic activities" purposes. It thus took the government roughly two months – after the problem of the "clogged" testing system began to be resolved in May – before it could clarify its strategy on testing for the novel coronavirus. That the health ministry was unable to the very end to sum up the testing strategy on its own was a serious problem as the ministry in charge of the government's infectious diseases crisis management.

3. Summary: Best practices and challenges

An official of the health ministry said the ministry was adept at localized campaigns but weak in an all-out battle.²² The ministry responded appropriately to the initial phase of the COVID-19 outbreak by utilizing the functions of its Tuberculosis and Infectious Disease Control Division, issuing an alert as early as January 6 calling for local authorities to use the system for surveillance of suspected cases, and promptly setting up its system to manage an infectious disease crisis, including the launch of an advisory board of experts in infectious diseases.

But the subsequent spread of domestic infections of the novel coronavirus exposed the limitations of its policy execution power, as the ministry had to rely on peacetime policy tools, such as one-way notifications to local authorities and medical institutions, even as the COVID-19 crisis deepened. Its preparedness against such a crisis in terms of training and strengthening personnel proved insufficient – a result of its failure to learn sufficiently from the lessons of past emergencies. The ministry faced various problems in waging an "all-out battle" against the crisis involving its sections other than the Tuberculosis and Infectious Disease Control Division as well as other organizations like the public health centers and public health institutes. It was unable to make full use of various in-house functions for better crisis communication and public relations operations. Its poor cooperation and information sharing with public health centers and public health institutes across the country resulted in the troubles it faced in increasing the capacity of PCR and other tests for the novel coronavirus.

Based on such a track record of its response to the COVID-19 crisis, this section explores the best practices and problems of the health ministry that should serve as lessons for the future.

3.1. Best practices

Despite the various constraints on its resources and operations, the health ministry somehow managed to respond to the crisis and achieved certain results. The most important of its best practices was that the ministry made full use of the human resources – including experts outside the organization – who had experienced dealing with the novel influenza pandemic of 2009.

The ministry put officials who had experience of the novel influenza pandemic at the center of its policy decision-making in responding to COVID-19 through flexible personnel deployment (including calling back an official who had been seconded to a different organization), and tapped experts of infectious diseases who shared the experience of the 2009 crisis again as advisers. When the ministry had to organize the

initial response team even though much about the novel coronavirus remained unknown at that point, the experience of people who had dealt with the novel influenza pandemic of the past enabled them to make predictions to a certain degree on the various problems that were likely to emerge, to make prompt judgments based on the predictions and to take steps ahead of time to contain the spread of the infection.

For example, when the capacity for PCR testing for the novel coronavirus was extremely scarce, the ministry set criteria to distinguish it from seasonal flu and other viruses, thus concentrating the limited testing capacity on patients with higher chances of infection with the new virus. Such a step was made possible by the experience of the 2009 crisis, and it was one example of the best practices carried out under various constraints. People with these experiences played key roles in putting up various ideas that made up the core of the "Japan model" and reflecting them in the policy measures for COVID-19.

This best practice tells the importance of organized efforts to build up and hand down the lessons and wisdom for managing infectious disease crises, in particular the tail risk of a pandemic-class crisis that could hit once in decades.

3.2. Issues

The health ministry made full use of the legacy of the 2009 pandemic to deal with the novel coronavirus crisis, but its COVID-19 response also exposed a variety of issues. In particular, the three following issues carry important lessons, and must be fixed as a priority to improve the nation's overall system for controlling infectious disease crisis with the health ministry at its center.

The first is the issue of governance, as symbolized by the troubles the ministry faced in fixing the "clogged" process for PCR and other tests. In dealing with an infectious disease crisis, the health ministry builds the strategy, while the measures are carried out, with the technical support of the National Institute of Infectious Diseases, by the quarantine stations, public health centers, public health institutes and medical institutions on the frontline of combating infections across the country. However, the health ministry does not have the power of direct command over these frontline bodies, except for the quarantine stations. Therefore, even in a crisis situation that demands prompt response, it takes time for the health ministry's strategy to be relayed to the frontline bodies throughout the nation, accepted and fully understood, and then put into action. The "clogging" of the PCR testing system was a structural issue that arose due to this weakness in the ministry's policy execution power – which is not necessarily an issue of the health ministry alone.

Speedy action is what is required most of all in responding to a crisis. To overcome these challenges, legislative measures will be needed to strengthen the health ministry's power of command over public health centers, public health institutes and

medical institutions in times of an infectious disease emergency, and to strengthen communication among the bodies involved.

The second issue is that the health ministry's strategy, relayed to the frontline bodies through the normal channel of administrative "notifications," did not effectively lead to action by those bodies as the notifications served little effect beyond formalities. As mentioned earlier, the health ministry has no power to directly execute the measures in line with its strategy, because it lacks the power of direct command over frontline bodies (except the quarantine stations) that implement the measures. Therefore, the ministry relies on such administrative tools as the notifications served to frontline bodies to prompt them to take action. In dealing with the COVID-19 crisis, the ministry issued enormous numbers of these notifications in quick succession, and public health centers and medical institutions were unable to process them all in their limited capacity and, as a consequence, there were cases in which the ministry's strategy was not relayed to the frontline bodies as intended, and thus was not translated into action by those bodies.

This issue was also caused by using peacetime decision-making and policy execution tools in responding to the crisis. To fix this problem, the ministry needs to build a system for mobilizing experts with experience in dealing with an infectious disease emergency as well as people trained under the FETP and IDES programs to each of the frontline bodies when a crisis breaks out, so that the ministry's strategy relayed through notifications is effectively put into action by those bodies. Such a system would be made smoother if the health ministry was also given power of command over frontline bodies in times of crisis. The government report that summed up its response to the 2009 novel influenza pandemic called for strengthening the system involved in infectious disease crisis management, including developing, promoting and keeping personnel with both expert knowledge in infectious diseases and administrative capabilities at the health ministry sections dealing with such a crisis. The FETP and IDES programs should be expanded in light of the lessons learned in the latest pandemic to put the recommendation into concrete practice.

The third issue is that the health ministry did not have adequate crisis communication functions in its system to manage infectious disease crises. In dealing with the outbreak aboard the Diamond Princess, the health ministry erred in the way it released information about the infection, giving a false impression to the public and to the rest of the world. In the first place, the ministry's crisis communication function in times of infectious disease emergencies was extremely poor, lacking an awareness of the necessity or importance of disseminating information to an international audience. As for the public statements made by members of the expert panel, the ministry failed to take enough steps to adjust or sort out their remarks in advance, which caused a misunderstanding that the experts' statements reflected the official position of the health ministry or the government. That was yet another indication of the ministry's poor awareness of the importance of crisis communication.

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The health ministry should learn from the lessons of these experience to consider building a new section with specially trained personnel to serve the crisis communication function, including communication to an international audience, as part of its system dealing with infectious disease crises.

Notes

- The Health, Labor and Welfare Ministry is a bureaucratic organization that handles a gigantic budget, but most of its work consists of distributing funds to the people, and the actual task of distribution is conducted via prefectural and municipal governments. Some of the ministry's "elite" bureaus, such as the Health Policy Bureau, in charge of developing the medical care system, and the Health Insurance Bureau, responsible for revisions to medical service fees, handle tasks that generate direct policy effects.
- 2. A health ministry official says that even though infectious disease control cannot be called a mainstream field in Japan's medical circles, the ministry works together with the limited numbers of experts and specialized institutions (such as the National Institute of Infectious Diseases and the National Center for Global Health and Medicine) to implement policy to combat infectious diseases.
- 3. Notification from the administrative vice health and welfare minister "Basic guideline on health crisis management" (Health and Welfare Ministry notification ko-No.1)
- The implementation manual for infectious disease health crisis management was devised on the basis
 of the Basic guideline on health crisis management.
 https://www.mhlw.go.jp/general/seido/kousei/kenkou/kansen/
- 5. The health ministry issued notifications to other parties, including pharmaceutical and medical device makers, organizations in the social welfare, employment and labor fields, nursing care providers, providers of welfare service for people with disabilities, and quarantine stations.
- 6. Interview with a senior health ministry official
- 7. Interview with a senior Cabinet Secretariat official
- A senior health ministry official said that the experience of the 2009 novel influenza pandemic spread
 the concept of infectious disease crisis management among regional public health centers and
 improved their awareness of the issue.
- 9. Interview with a health ministry official
- 10. The DPAT (disaster psychiatric assistance team) unit of the DMAT team is said to have addressed the problem, according to a senior health ministry official.
- 11. The health ministry's Tuberculosis and Infectious Disease Control Division and the "Office for influenza response" (later the "Office for COVID-19 control") of the Cabinet Secretariat were in charge of clerical support for the advisory board and the Expert Meeting on the Novel Coronavirus Disease Control, respectively.
- 12. Activities of the advisory board of the health ministry were suspended thereafter, but were resumed when the Expert Meeting on the Novel Coronavirus Disease Control was abolished.
- 13. Interview with a senior health ministry official
- 14. Interview with a senior METI official
- 15. When the expert panel submitted its opinions to the Prime Minister's Office and other ministries, health ministry staff were involved in drafting the documents and made adjustments for consistency with other policies and decisions. But the health ministry staff did not attend the news conferences given by the expert panel, and only the members of the expert panel engaged in questions and answers with media reporters.
- 16. Interview with a staff member in the Prime Minister's Office
- 17. The "post-program procedure" of the IDES program stipulates that the health minister can call on officials who have completed the program to cooperate in dealing with an infectious disease crisis in the case of such an emergency, including dispatch to the site of the crisis, and that the officials will cooperate in principle with such a mission.
 - https://www.mhlw.go.jp/seisakunitsuite/bunya/kenkou iryou/kenkou/ides/index.html

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- 18. Interview with a senior Cabinet Secretariat official
- 19. The PCR test refers to the reverse transcription polymerase chain reaction test (RT-PCR test), and "PCR and other tests" include other gene amplification tests and antigen tests.
- 20. The number of tests held in Japan was still far short of the target of 200,000 tests a day mentioned by Prime Minister Abe in his August 28 news conference, and as of the end of September 2020, it was unthinkable for Japan to hold nearly 1 million tests daily as was done in the United States.
- 21. One example is the proposal made by the COVID-19 conference of the Japan Business Federation (Keidanren) for "Re-accelerating economic activities compatible with the countermeasures for the novel coronavirus disease" (July 16, 2020) http://www.keidanren.or.jp/policy/2020/065_honbun.html.