Part II The Japanese government's response to COVID-19

Chapter 7
PCR and other tests

Against a background of growing public anxiety due to the spread of novel coronavirus infections, there were voices at home and abroad calling on the government to strengthen the PCR and other testing systems and expand the range of people covered by PCR tests. However, despite the government's efforts to strengthen the testing systems, including boosting the test analysis capacity and introducing administrative tests covered by health insurance, there were cases where the necessary tests could not be carried out, and Prime Minister Shinzo Abe expressed frustration that the PCR testing system was "clogged." In addition, the government did not initially carry out PCR tests for asymptomatic persons, and there were disagreements not only among the public but also within the government whether or not PCR tests for asymptomatic persons were "necessary testing" and what was the extent of "necessary testing."

This chapter clarifies how the government's policy on PCR and other tests changed from January to July 2020. Specifically, facts will be clarified on what the government did to strengthen PCR and other test systems and how the government defined and changed the scope of PCR and other tests.

1. Outline of PCR and other tests

1.1. Timeline of developments related to PCR tests

"Since February and March, the term PCR test, which in our laboratory is a technical term, has attracted so much interest as to have entered the public lexicon." As illustrated by the words of Hiroto Shinomiya, vice president of the Japan Association of Prefectural and Municipal Public Health Institutes, at a news conference held at the Japan National Press Club on August 7, 2020, public interest in PCR tests (polymerase chain reaction tests, which, together with other gene amplification tests and antigen tests, are referred to as "PCR and other tests") grew with the spread of COVID-infections. This was because there was no silver bullet for COVID-19, and while public anxiety spread, the PCR test was the only test method that could detect the novel coronavirus in the early stages of the domestic outbreak of the disease.

However, the number of PCR and other tests performed in Japan was small from the outset, and the pace of increase was subsequently slow. According to open data released by the Health, Labor and Welfare Ministry, the average number of PCR and

other tests performed per day for the previous seven days exceeded 1,000 on February 26, and 5,000 on April 7, and it was on July 9 that the number exceeded 10,000. In addition, the positive rate based on the results of PCR and other tests over the previous seven days exceeded 5% on March 29, reached 7.48% on April 12, and fell below 5% on April 25. As mentioned in Part I, Chapter 1, keeping the positive rate below 5% leads to suppressing an increase in the mortality rate, and it can be seen that from late March to mid-April, the increase in the number of PCR and other tests performed could not keep up with the increase in the demand for testing for the novel coronavirus.

As a result, since the end of March, many cases were reported in which people were kept on waiting to be tested, especially in metropolitan areas where the number of infected cases had increased rapidly. In some cases, PCR and other tests were not performed at the discretion of the public health center even though the doctor deemed it necessary.[1] It has been pointed out that a failure to diagnose early with PCR and other tests was partly to blame for some of the cases in which large numbers of people were infected in hospitals and nursing care facilities.[2] Therefore, there were growing calls for the government to strengthen the PCR testing system and expand the range of people covered by PCR and other tests. Kazunori Yamai, an opposition member of the Lower House (Constitutional Democratic Party of Japan), told the Budget Committee on February 25, "You say you have the capacity for 3,000 tests, but all we are seeing is 80 to 90 a day. It's not as if I'm saying anything extravagant, but they're doing more than 10,000 PCR tests in South Korea. I'm asking you to do the same as in other countries. I think it's a political decision here," criticizing the government for the small number of PCR tests performed in Japan.

In the international community, World Health Organization Director-General Tedros Adhanom Ghebreyesus emphasized the importance of PCR and other tests by stating at a news conference on March 16, "We have a simple message for all countries: test, test, test." The number of PCR and other tests conducted in Japan was significantly lower than the average of OECD countries.[3] The U.S. Embassy in Japan stated in a Health Alert issued on April 3 that "The Japanese government's decision to not test broadly makes it difficult to accurately assess the COVID-19 prevalence rate," urging Americans in Japan to return home promptly.

In response to severe criticism at home and abroad, Prime Minister Abe announced at a meeting of the government's COVID-19 response headquarters held on April 6 that he would "double the PCR testing system to 20,000 cases a day." However, despite the government's efforts to expand its domestic testing and analysis capabilities, the pace of increase in the number of PCR and other tests carried out was slow. The Prime Minister's Office is said to have been frustrated that the number of PCR tests performed did not increase, and pressured the health ministry to increase the number of PCR tests.[4] Irritated by the fact that the number of tests performed would not rise, Prime Minister Abe himself told a news conference on May 4, "I have always said that people will be able to take PCR tests if the doctors say they need to be tested, and we have tried consistently to increase the testing capacity, but even if we raise the capacity from 8,000

to 10,000 or 15,000, the actual number of tests performed is still at the 7,000 or 8,000 level, and I have repeatedly said where the testing system is clogged."

The problem of PCR and other testing system was gradually resolved by May. The average daily number of PCR and other tests performed for the previous seven days reached some 8,500 by April 28, the average positive rate for the previous seven days falling to 3.00% by May 3.

From June onward, the health ministry worked to strengthen the PCR testing system. The average daily number of PCR and other tests performed over the previous seven days reached about 14,000 by July 17, and the positive rate based on the results for the previous seven days fell to 0.52% on June 9.

Initially, the health ministry limited the coverage of PCR and other tests due to restrictions on the testing capacity, and did not carry out the tests for people showing no symptoms. The ministry also called on the public to consult with "returnee and contact persons consultation centers (novel coronavirus consultation centers)" according to certain standards, rather than immediately visiting a medical institution, if COVID-19 infection was suspected. As the strains on the PCR testing system were resolved, these standards were later relaxed and some asymptomatic persons were allowed to take PCR tests. However, regarding the extent to which PCR and other tests were permitted for asymptomatic persons, there were disagreements not only among the public but also within the government until the Novel Coronavirus Disease Control Subcommittee summed up a policy on PCR and other tests.

1.2. Purpose of PCR and other tests

Generally speaking, there were said to be the following three purposes of performing the PCR and other tests for the novel coronavirus.

The first was the public health purpose of preventing the spread of COVID-19 by isolating in hospitals people found to have been infected with the novel coronavirus as a result of the tests, along with collecting information on the disease. Such tests were mainly carried out by the National Institute of Infectious Diseases (NIID) and the public health institutes as administrative tests at public expenses after COVID-19 was specified as a designated infectious disease.

Second, tests were carried out at the discretion of the doctor because of the clinical medical need to provide appropriate medical care or prevent nosocomial infections in hospitals and the like. Such tests (clinical tests) were procedurally performed as administrative tests, and either carried out mainly by the NIID and public health institutes at full public cost,[5] or covered 70% by health insurance and 30% public expense when tests analysis was carried out mainly at private testing institutions.

Third, tests were carried out by private-sector companies and individuals out

of a necessity for socio-economic activities according to individual circumstances, such as the promotion of corporate activities (overseas travel, entertainment, etc.) or relief of personal anxiety. PCR and other tests for these purposes were carried out by private laboratories at the individual expense as medical care not covered by health insurance.

1.3. Outline of PCR and other testing process

The process for PCR and other tests mainly began when people who suspected COVID-19 infection contacted the novel coronavirus consultation centers. The consultation centers responded by telephone and made arrangements for those suspecting COVID-19 infections to visit the outpatient section for "returnees/contact persons" at hospitals. Initially, public health center staff were mainly in charge of consultations at the consultation enters. When a doctor diagnosed a patient with suspected case of COVID-19, the public health center, notified by the doctor, would arrange for further examination at the outpatient service at hospitals for those suspected of COVID-19.

Samples were collected at the hospital's outpatient service section from people suspected of COVID-19 infection for PCR and other tests as necessary. Contact information about the "returnees and contact persons" outpatient service was not disclosed to the public and people visited those facilities via the consultation centers, based on the lesson from what happened at the time of novel influenza (A/H1N1) epidemic of 2009 – when large numbers of people flooded the "fever outpatient" sections at hospitals and disrupted the operation of the outpatient services – and in order to prevent the spread of infection at those facilities.

Samples collected by the outpatient sections were transported to a testing and analysis institution according to the sample transportation manual established by the NIID,[6] and were subject to laboratory analysis.

The doctor diagnosed the patient based on PCR and other tests, and reported the patient diagnosed with COVID-19 (confirmed case) to the public health center. When the health center received a doctor's notification, it made a recommendation to the patient for hospitalization in a designated medical institution for infectious diseases or a request for recuperation at home. Since COVID-19 was the target infectious disease for the national epidemiological surveillance, the public health center initially entered the contents of the doctor's notification into the National Epidemiological Surveillance of Infectious Diseases (NESID) system.

2. Status of PCR and other tests in the early stages of the domestic epidemic (January-February 2020)

2.1. The shortage of PCR and other testing and analysis capacity and efforts to expand them

The main reason for the small number of PCR and other tests performed in the early stages of the domestic epidemic was the shortage of testing and analysis capacity. Initially, the laboratory analysis of PCR and other tests was carried out at the NIID and public health institutes, and as of February 12, the capacity was about 300 cases per day. For the background to the lack of preparedness in the testing and analysis system, see Part III, Chapter 1.

From the beginning, the Expert Meeting on the Novel Coronavirus Disease Control (expert panel) stressed the need to expand the PCR testing system. For example, at the February 10 meeting of the health ministry advisory board on COVID-19, it was pointed out, "The capacity of PCR tests will become a problem. The PCR capacity has to be raised somehow or other. That's the premise." At the expert panel meeting on February 24, the members also pointed out a lack of testing capacity for PCR and other tests, "Regarding the testing capacity at public health institutes nationwide, testing can't keep up in some areas, while there is still some leeway on a national basis."

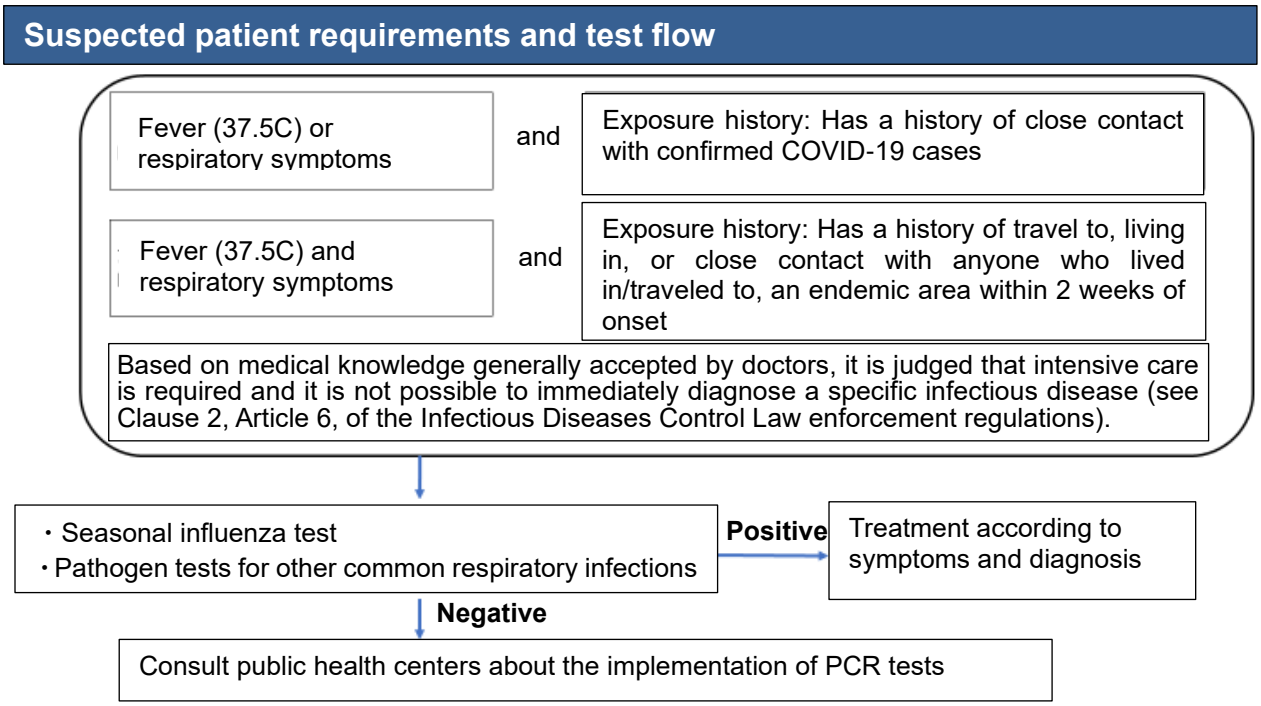
From the outset, the government had been working to expand testing and analysis capacity in response to these experts' suggestions. For example, the government's COVID-19 response headquarters on February 13 announced a policy to expand the testing system at the NIID and public health institutes. In addition, the government began efforts to expand testing and analysis capabilities at private testing institutions, announcing in mid-February that major private testing institutions would be entrusted with testing and analysis of samples for administrative tests. As a result of these efforts, on February 18, about 3,800 test and analysis capabilities were secured per day.

In this way, efforts to expand the PCR and other testing system in the early stages of the domestic epidemic were mainly aimed at expanding testing and analysis capabilities.

2.2 Limiting the standards for performing PCR and other tests

Based on the classification of the novel coronavirus disease as a designated infectious disease, the health ministry on February 3 revised the "standards for notification to prefectural governors for doctors and designated medical institution managers based on Clause 1, Article 12 and Clause 2, Article 14 of the Infectious Diseases Control Law" (notification standards), and established standards for running PCR and other tests as shown in the chart below. These standards were used when the coronavirus consultation centers, which were consulted by people who suspected COVID-19 infection, arranged for examination at "returnees/contact persons" outpatient services at hospitals.

In consideration of the shortage of the PCR and other testing and analysis capacity, these standards limited the scope of the tests in order to concentrate the testing resources on those who require hospitalization or treatment, such as those with severe symptoms. Suggested reasons for limiting the range of subjects for PCR and other tests were as follows: 1) it was necessary to efficiently use the limited resources under the restrictions on PCR and other test/analysis capacity; 2) attempting to detect all COVID-19 infections was not effective in the situation at the time when the pre-test probability (probable positive rate prior to testing) was not proven to be sufficiently high; and 3) there was concern that outpatient services at hospitals for "returnees and contact persons" would be flooded by those who suspected a COVID-19 infection. However, since it was deemed possible to avoid 3) through adjustments by the consultation centers, the main reason is believed to have been to use the limited testing/analysis capacity for people with higher pre-test probability.



(The endemic area as of Feb. 3, 2020 is China's Hubei Province)

Limiting the criteria for PCR and other tests also acted to suppress the number of people testing positive and avoid a collapse of the medical care system. Health, Labor and Welfare Minister Katsunobu Kato said that the government did not control the range of subjects for PCR and other tests in order to reduce the burden on the medical care system.[7] However, the health ministry advisory board, in response to the consultation from the ministry on February 6, indicated a negative view on carrying out PCR and other tests for asymptomatic persons on the grounds that hospitalization of asymptomatic carriers would increase the burden on designated medical institutions for

infectious diseases. Therefore, the possibility cannot be ruled out that the parties involved limited the criteria for conducting PCR and other tests in consideration of the burden on the medical care system at the time.

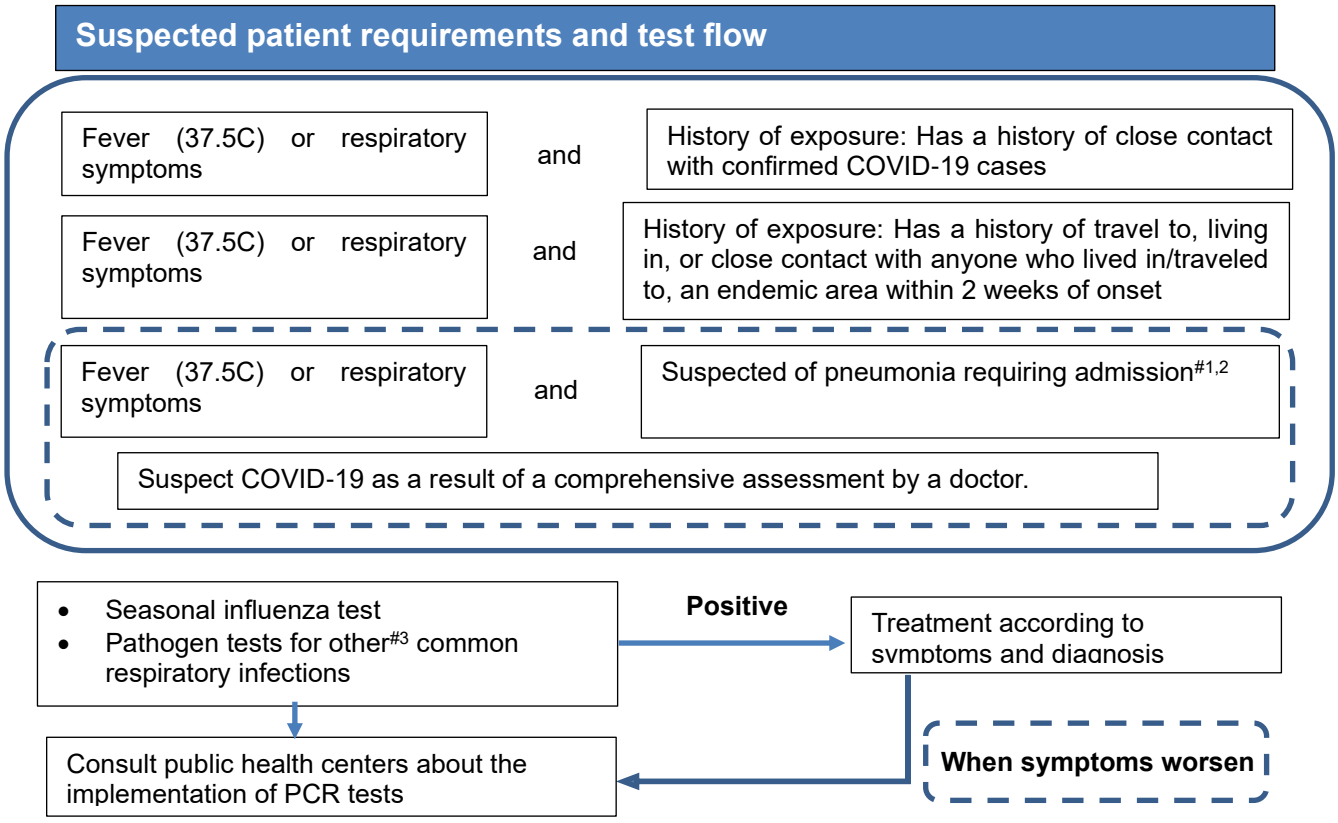
However, under such strict standards, patients with COVID-19 might not be included in the scope of PCR and other tests. First, for the second type mentioned in the chart, since the standards limited the endemic areas (although the areas were gradually expanded), there was a possibility that an infection chain by those who had not traveled or stayed in the endemic areas at the time could not be identified. Second, since the standards excluded asymptomatic persons for PCR and other tests, it was possible that the infection chain via asymptomatic carriers could not be detected.[8] In fact, on February 13, multiple sporadic cases occurred in Japan, and it was found that an infection chain not identified by the standards for PCR and other tests at the time was emerging in various parts of the country.

However, the health ministry was not unaware of the possibility of infection with COVID-19 from those who had not traveled or stayed in the endemic area,[9] and did not rule out tests for these people under the system. At the 2010 government conference wrapping up its response to the new-type influenza (A/H1N1) epidemic of the previous year, an opinion had been expressed that "Even if a medical institution wants to run a test, the public health center may refuse because (the patient has) no history of travel (to the endemic area). Wasn't it a problem that no arrangements were made for the public health centers to perform tests on suspected cases with no such travel history?" It was pointed out at the time that the requirements on the history of travel to or staying in an endemic area in the testing standards would restrict the coverage of testing.

The notification standard was subsequently revised in 2014 and, as for the outbreak of the Middle East Respiratory Syndrome (MERS), while requirements based on the exposure history in the area where the first case of MERS was confirmed were given, it stipulated that testing was "not necessarily limited to the following requirements," and it was possible to test those who had not traveled or stayed in endemic areas. Even in the recent measures against COVID-19, the notification standard as of February 3 said the testing was "not necessarily limited to the following requirements [Note: when specified in the above chart]." The health ministry requested local governments to flexibly run PCR and other tests based on the provisions of such standards in the notification issued on February 7 by the director of the Tuberculosis and Infectious Diseases Control Division of the Health Service Bureau. In the Q&A on the COVID-19 announced on February 11, the ministry's stance was "In light of the recent outbreaks in Japan and overseas, when doctors suspect a novel coronavirus infection, (without limiting the tests to people with travel history to the specified areas), tests will be given in consultation with the local government." In this way, the health ministry approved the implementation of PCR and other tests on persons who had not traveled or stayed in endemic areas even before the multiple sporadic cases occurred in Japan.

On the other hand, the health ministry did not adopt a policy of conducting PCR and other tests on asymptomatic individuals, although it was aware of the possibility of infection with COVID-19 from asymptomatic carriers at the time. The NIID recognized that asymptomatic carriers were infectious by February 7 at the latest after Chinese health officials announced on January 26 that they were infectious during the incubation period of the virus. However, in a document released on the same day, it quoted the WHO announcement as of February 1 and expressed its recognition that "transmission of the virus from asymptomatic carriers has been reported, but it is not the main route of infection." When on April 20 the NIID updated the active epidemiological investigation implementation guideline to add people who had been in contact with infected patients from two days before the onset date in the definition of "close contacts," the NIID maintained, in a Q&A released on April 22, that it "did not think the asymptomatic period is the main period of infection."

In the early stages of the domestic epidemic, the health ministry did not acknowledge that asymptomatic carriers of the virus were infectious. For example, the ministry asked members of the expert panel to delete a reference to the possibility of asymptomatic carriers infecting others when the panel issued its view on COVID-19 countermeasures on March 2.[10] The ministry maintained this stance up until members of the expert panel said on May 4 that "we have come to understand through evidence that there is an increased risk of people infected with the virus but asymptomatic infecting other people." However, given that at the advisory board meeting held on February 10, NIID chief Takashi Wakita, responding to the agenda document prepared by the health ministry that "infectivity is low in asymptomatic cases," pointed out that "the amount of virus does not change even for asymptomatic carriers," the health ministry and the NIID must have been aware, by February 10 at the latest, that asymptomatic carriers of the virus could not be said to be less infectious, and that the PCR testing criteria of February 3 might make it difficult to detect the infection chain from asymptomatic carriers. It is believed that the gist of discussion of the advisory board meeting on February 10 was posted on the health ministry's website between May 1 and 10.[11]



#1 Not limited to conventional intensive care and other similar treatments, but for persons suspected of having pneumonia requiring hospitalization.
#2 Consider proactively, especially for the elderly or those with underlying illness
#3 Depending on the medical condition and based on the results of rapid tests that give early results, consult with the health center even before results are available from time-consuming tests, such as culture tests.
*The dotted line indicates changes from February 3, 2020.
(The endemic area as of February 27, 2020 is Hubei and Zhejiang Provinces of China; Daegu and Cheongdo-gun, Gyeongsangbuk-do of South Korea)

Later, in light of the continuing increase in the number of COVID-19 patients, the health ministry, for doctors to make a definitive diagnosis necessary for treatment of pneumonia patients requiring hospitalization, eased the standard for clinical testing in the clerical notifications issued on February 17 and 27 and, as shown in the following chart, permitted PCR and other tests when a doctor deemed the test necessary for diagnosis.

Around this time, Prime Minister Abe viewed the strengthening of the PCR and other testing system as a means to ease public anxiety, along with protecting the people's lives and health. For example, at the fifth meeting of the government's COVID-19 response headquarters on February 5, Prime Minister Abe said, "Strengthening measures to prevent the spread of infection, such as enhancing and

expanding the testing system and consultation system is an urgent issue. (…) Please continue to work toward developing the systems and responding seriously to the public anxieties." Additionally, in the 10th meeting of the headquarters on February 16, he stated, "In order to alleviate public anxiety, the government will work more closely with local governments, etc., so that PCR tests for those suspected of being infected will be steadily carried out. (…) The government will work in cooperation with local governments in each region to prevent the spread of domestic infections and we will continue to strengthen significantly the testing system and make every effort to expand and strengthen the treatment and consultation systems. Please stay ahead of the curve in order to protect the lives and health of the people." At this point, the PCR test system was strained, and the number of cases being carried out was not nearly enough for the implementation level needed either for "the people's lives and health" or for eliminating "the public's anxiety." As the strain on the PCR and other testing systems was later resolved, the difference between the two sides became a significant issue.

2.3. Consultation/examination guideline

Based on discussions at the expert panel, the health ministry on February 17 announced a guide for consultation and examination for those suspecting infection with COVID-19. Specifically, "people who have cold symptoms or fever of 37.5 ° C or higher for four days or more" (two days for elderly people or people with underlying illness) or "strong fatigue (lethargy)" and "difficulty breathing (dyspnea)" were urged to consult with the "returnee/contact persons" consultation centers (novel coronavirus consultation centers).

Such a guide was meant to distinguish people with COVID-19 from influenza patients and formulated to ensure that patients with COVID-19 could receive the necessary medical care by concentrating limited PCR and other testing resources on those who might develop more severe symptoms. The PCR testing system was a series of processes starting from consultation with the novel coronavirus consultation centers. By not only limiting the implementation standards for PCR tests, but also restricting people consulting the coronavirus consultation centers, the subjects of the PCR and other tests will be limited. In light of the knowledge about COVID-19 at the time and the status of PCR and other testing systems, it was not necessarily inappropriate to set such a guideline.

3. The "clogged" PCR test system in the phase of infection expansion and enhancing PCR tests for some of the asymptomatic persons (March-May 2020)

3.1. Blockage in the PCR and other testing systems and efforts to eliminate it

As mentioned in the preceding Section 2.1., efforts to expand PCR and other testing systems in the early stage of the domestic epidemic were mainly aimed at expanding testing and analysis capacity. As of March 10, the domestic testing and analysis capacity was approximately 6,200 cases per day, and reached around 10,000 cases a day by April 1, as a result of the government's efforts to expand testing and analysis capacity and the expansion of capacity by private testing organizations. Although there was a nationwide shortage of test reagents that depended on overseas production from late April to early May, the bottleneck in testing and analysis capabilities was gradually resolved.

However, despite the expansion of testing and analysis capacity, the number of PCR and other tests did not increase. As a result, it became clear that multiple bottlenecks had occurred in the series of processes that comprised the PCR and other testing systems in areas other than the testing and analysis capacity. The government, led by the health ministry, was working to eliminate such bottlenecks in the PCR testing system (which Prime Minister Abe was "clogged") since March, and although the strains on the PCR system gradually disappeared by May, the pace of increase in the number of PCR and other tests was slow. It was thought that there were three main factors to this blockage, and the health ministry was working to resolve them.

(1) Insufficient staff at public health centers (consultation system, etc.)

The shortage of personnel at public health centers was a factor that caused a blockage in the entire PCR and other testing processes, including consultation at coronavirus consultation centers.[12] Public health centers were in charge of consultation, sample transportation, reporting, etc. in the PCR and other testing procedures, and the shortage of personnel had a large impact on the PCR and other testing systems. In the recent countermeasures against COVID-19, the health centers were in charge of operations related to PCR and other tests, active epidemiological investigations, and medical care system, and their workload increased as COVID-19 infections spread, making the manpower shortage even more apparent. As a result, there were delays in the regular duties of the health centers, such as health examinations for infants, suicide prevention, and measures for deterioration of physical and cognitive functions of elderly people. See Part III, Chapter 1 for the lack of preparedness in the public health center system.

In response, the health ministry first urged local governments to develop a support system and consider hiring part-time employees. However, it has been pointed

out that since prefectural governments' public health bureaus were operated independently from other departments, it was sometimes not possible to obtain support from other departments.[13] In addition, although there were cases where prefectures provided support to health centers when they were run by ordinance-designated cities or special wards,[14] it was deemed that the support was not always sufficient.[15]

Second, on March 11, the health ministry approved that all or part of the work of coronavirus consultation centers can be outsourced to parties with sufficient knowledge and understanding of the work. For example, it became possible to outsource the task to local medical associations and medical institutions.

Third, the health ministry extended health insurance coverage for clinical tests from March 6. As a result, when a doctor at a designated medical institution deemed it necessary, it became possible to collect a sample and commission a private laboratory to perform a test analysis without consulting the coronavirus consultation centers (or public health centers). However, the health insurance coverage of clinical tests did not immediately lead to an increase in the number of PCR and other tests performed, and it was not until April that the step began to have a major impact on the number of PCR and other tests run. One of the reasons behind this, it has been pointed out, was that in order to cover the out-of-the-pocket portion of the clinical test expenses with public funds,[16] the clinical tests covered by health insurance continued to be deemed as administrative tests.[17] Since the prefectural governments were to commission the designated medical institutions to perform the administrative test, the delay in concluding contracts with the medical institutions hampered the increase in the number of PCR and other tests. Since the health ministry also required prefectural governments to outsource the administrative tests to "medical institutions recognized by the prefectures as institutions with appropriate infection control measures" from the viewpoint of preventing nosocomial infections and quality control for administrative tests, not only did it take time for the prefectures to confirm that infection control measures had been taken, but it is also pointed out that because a requirement of the designated medical institution was that such a hospital can accept patients diagnosed with COVID-19, medical institutions did not apply for the designation.[18]

(2) Shortage of medical staff to collect samples (sample collection system)

It has been pointed out that the shortage of medical personnel responsible for PCR and other test sample collection was a factor that hampered sample collection.[19] However, we should be cautious about attributing the shortage of specimen collectors to medical personnel. The initial PCR tests using a swab inserted into the nose and the pharynx to wipe the fluid as a sample had a high risk of droplet infection at the time of sample collection. From the viewpoint of preventing the infection of the sample collector, personal protective equipment (PPE) was required for them, and the shortage of PPEs caused the blockage in sample collection.[20] In addition, providing medical care to patients with COVID-19 had a significant impact on the management of medical

institutions,[21] so it was difficult for the medical institutions to take charge of sample collection without support for their operations.

In response, the health ministry first set up regional outpatient/testing centers (commonly known as PCR centers) on April 15 as organs to intensively collect samples by authorizing prefectural governments to commission the operations of such bodies to local medical associations, which allowed doctors belonging to the local association to take charge of sample collection without significantly affecting the management of their own institutions. However, there was some criticism against the delay in establishing the regional outpatient/testing centers.[22]

Second, on April 27, as an exceptional and time-limited option, the health ministry allowed dentists to collect samples as required. However, it was pointed out that the number of PCR and other tests performed did not increase because prefectural governments were reluctant to conclude operational consignment contracts with dental associations regarding sample collection by dentists.[23]

Third, the procurement of PPEs will be dealt with separately in Part III, Chapter 4, but for example, in some regions the PPEs procured by prefectural governments were preferentially distributed to institutions responsible for sample collection in their outpatient services for people suspecting COVID-19 infection.[24]

As a result of these efforts, the number of people responsible for sample collection gradually increased. For example, the number of outpatient departments for "returnees and contact persons" was 843 as of March 1, but increased gradually to 1,268 as of May 1.

(3) Limitations of the conventional surveillance system under the Infectious Diseases Control Law (reporting system)

It is probable that the government's failure to grasp the results of PCR and other tests in a timely and accurate manner also contributed to the blockage in PCR and other tests for the purpose of public health.

As the number of positive cases increased, it became a burden for doctors to fill out the infection report by hand and send it by fax, and for the staff at public health centers to enter the contents of the report received by fax into the NESID system. In the first place, in the conventional surveillance system under the Infectious Diseases Control Law, it was not assumed that tests would be carried out in such large numbers. Therefore, it is said that the government could not grasp the results of PCR and other tests in a timely and accurate manner, and in some cases, information such as the positive rate was obtained one week after tests were conducted.[25] As a result, the health ministry could not grasp the status of the PCR tests already carried out in a timely and accurate manner, and it is thought that there were delays and errors in counting and reporting the number of tests and the number of positive cases, which caused a blockage. In response, the health ministry, regarding the number of PCR tests, was forced from

May 8 to change from compiling and releasing figures gathered through the surveillance system under the Infectious Diseases Control Law to tallying the numbers recorded and released on local government websites.

3.2. Relaxation of implementation criteria for PCR and other tests

From February 2020, the health ministry was aware that asymptomatic carriers of the novel coronavirus could infect other people, but decided not to adopt a policy of running PCR and other tests on asymptomatic persons. But after a peer-reviewed paper revealing that the novel coronavirus had the highest infectivity at the time of onset or before the onset was published in a major medical journal on April 15,[26] the ministry, as the strains on the testing system were eased in May, approved running PCR and other tests on asymptomatic persons if the doctor deemed it necessary or the persons were considered as close contacts of COVID-19 patients.

First, the NIID, based on the change in the definition of close contact in the WHO guidance,[27] revised on April 20 the definition of close contact for COVID-19 in the implementation guidelines for active epidemiological investigation, changing the starting date of contact with a COVID-19 patient from "the day of the onset of illness" to "two days prior to the onset date." However, the NIID maintained that "the asymptomatic period is not the major period of infection" in the Q & A regarding the change in the guideline's definition of close contacts released on April 22.

Later, on May 4, the expert panel said that it has "come to understand through evidence that there is an increased risk of people infected with the virus but asymptomatic infecting other people," indicating that there are cases where the novel coronavirus has been spread to other people by asymptomatic carriers or patients with mild symptoms. As mentioned in the preceding Section 2.2., the gist of discussions at the advisory board meeting on February 10 – when it was pointed out that the "amount of virus does not change for people who are asymptomatic but have the virus" – is believed to have been posted on the health ministry website around this time. The health ministry also announced on May 15 that even asymptomatic patients could take clinical tests covered by health insurance if the doctor deemed it necessary. In the active epidemiological survey implementation guidelines revised on May 29, the NIID decided to carry out PCR and other tests on all close contacts, including asymptomatic persons, as an initial screening from the viewpoint of promptly identifying positive persons.

In this way, the health ministry and the NIID came to approve the implementation of PCR and other tests on asymptomatic persons when a doctor deemed it necessary or when they fell under the definition of close contacts. Regarding such a change of position, a health ministry official said, "At the time, we were being pestered by the media all the time about asymptomatic carriers being possibly infectious, and I personally thought simply that it might be so, but to say that officially. … It would set

off a panic if you said 'they're asymptomatic but infecting other people' without any countermeasures in place. So, at what stage do you say it? If you were going to say it, how do you say that it's all right because we're taking such and such countermeasures … and the timing was very difficult. When going public with this, we checked everything about whether the public health centers could cope with it. So, we confirmed to some extent that the health centers could handle it even after we went public, so we thought it was a go, and we went public saying that the health ministry had changed its stance."[28] It is deemed that the health ministry maintained, even after February, that asymptomatic patients were not the main infection route because, by admitting that asymptomatic carriers were the main transmission route, it would be required to carry out PCR tests and active epidemiological surveys on asymptomatic people, and the ministry needed to avoid a situation where the workload of public health centers increased and put pressure on the PCR testing system.

3.3. Relaxing guidelines for consultation and examination

The guideline for consultation/examination called on people who either "have cold symptoms or a fever of 37.5 ° C or higher for four days or more" or "have strong fatigue (lethargy) or difficulty breathing (dyspnea)" to consult with the novel coronavirus consultation centers. However, the nature of the guidelines was misunderstood in some cases. For example, there were cases where the consultation center applied this guideline as a standard for arranging for examination at outpatient services at hospitals for people suspecting COVID-19 infection. The content of the guidelines was also misunderstood. For example, in some cases, it was rigorously interpreted that both of the conditions – cold symptoms or a fever of 37.5 ° C or higher for four days or more and strong fatigue (lethargy) or difficulty breathing (dyspnea) – had to be met. It is undeniable that misunderstandings about the guidelines for consultation and examination may have caused a blockage in PCR and other testing system. Health minister Kato also said, "It's just a guide. (…) But since what is written may not necessarily be accurately communicated, I think that this is a source for future reflection."[29] According to a health ministry official, there were only a few cases in which briefing sessions were given to prefectures and other parties when issuing notifications such as administrative communication on the measures against COVID-19.[30]

In response, the health ministry indicated on March 13 that even if the person did not meet the criteria for consultation/examination, adjustment for examination at outpatient services for people suspecting COVID-19 infection should be made flexibly based on the circumstances of the person in question. Furthermore, on March 22 it notified the prefectural government that people who either had "cold symptoms and a fever of 37.5 ° C or higher for four days or more" or "strong fatigue (lethargy) and difficulty breathing (dyspnea)" meet the guideline. Later, on May 8, the health ministry

significantly relaxed the "guidelines for consultation and examination" in light of the view expressed by the expert panel at its May 4 meeting about the risk of asymptomatic carriers of the virus infecting other people.

4. Further strengthening the testing systems and expanding test targets (June-July 2020)

4.1. Efforts to further strengthen the PCR and other test systems

The expert panel recommended that PCR and other testing systems be further strengthened in anticipation of the next stage of the spread of infections, and the health ministry worked to strengthen the testing systems as follows.

(1) Increasing the number of medical institutions to carry out clinical tests covered by health insurance (sample collection system)

In order to increase the number of designated medical institutions to carry out clinical tests covered by health insurance, the health ministry in May 2020 eased the standard for the "medical institutions recognized by prefectural governments as institutions with appropriate infection control measures" to which the prefectures can outsource the tests. The ministry said that it was now possible to commission the administrative tests for the novel coronavirus to medical institutions regardless of their size or outpatient service/hospitalization, so that clinics or hospitals with a small number of beds, as well as institutions that have no plans to provide outpatient service for people suspecting COVID-19 infection, can be entrusted to perform the tests. Coupled with the introduction of PCR tests using saliva – which carried lower risk of infection in sample collection – on June 2, the relaxed standard significantly increased the number of designated medical institutions – from 173 as of June 1 to 460 as of July 1 – and the total number of facilities collecting samples such as outpatient department of hospitals for people suspecting COVID-19 infection rose from 1,794 on June 1 to 2,192 on July 1.

(2) Introduction of new testing method (test analysis system)

In addition to the continuous efforts to boost the capacity for the nasal/pharyngeal swab PCR test and analysis, the approval of the antigen test (qualitative test) on May 13, the saliva PCR test on June 2, and the antigen test (quantitative test) on June 19, testing and analysis capacity was significantly enhanced as follows. Although antigen test (qualitative test) was inferior in sensitivity to PCR test and antigen test (quantitative test), the test time was short and testing was easy, and it is

easier to cope with the changes in test demand by stockpiling the test kits.

	As of April 1	As of May 15	As of July 1	As of August 7
PCR tests	10,000	22,000	31,000	52,000
Antigen tests (qualitative)	—	21,000	26,000	26,000
Antigen tests (quantitative)	—	—	—	8,000

(3) Introduction of HER-SYS to replace NESID (reporting system)

The health ministry developed a system for grasping and managing information on COVID-19 infections (Health Center Real-time Information-sharing System on COVID-19, HER-SYS) in order to reduce the workload on public health centers and speed up sharing and grasping of COVID-19 information. Unlike the NESID system, which collected and analyzed information only on the outbreak of infectious diseases, HER-SYS has the potential to immediately report and collect a wide range of information on COVID patients. See Part III, Chapter 4, for information on HER-SYS.

4.2. Building consensus on the scope of subjects of PCR and other tests

The health ministry relaxed the implementation standards for PCR and other tests in May 2020 as the strains on the testing system were gradually resolved, starting to allow some asymptomatic persons to take the tests. However, regarding the scope of PCR and other tests for asymptomatic individuals, opinion was divided between those calling for a greater scope of testing from the perspective of public sense of security and normalization of economic and social activities, and those who were cautious about expanding the scope of testing for the sake of efficient operation of the testing system, noting that widening the scope of PCR tests would have little effect on preventing infections. It seems that such disagreements existed not only among experts and medical professionals, but also within the government.

For example, the COVID-19 Medical Expert Meeting of the Japan Medical Association recommended using PCR and other tests for "socio-economic activities" and "basic data for policy making" in addition to the public health purpose of infection control and examination of patients. The "Urgent recommendations for normalizing economic and social activities through active infection prevention strategies," of which Keiichiro Kobayashi, chief researcher at the Tokyo Foundation for Policy Research, and Shinji Hirai, governor of Tottori Prefecture, were supporting members, recommended gradually expanding tests not only for "people with symptoms and close contacts" but for "facilities vulnerable to a cluster infection" and "tests to increase the sense of security in activities." The Prime Minister's Office is said to have actively supported

expanding the scope of people subject to PCR and other tests, such as considering regular tests on staff at nursing care facilities.[31]

On the other hand, many members of the Expert Meeting on the Novel Coronavirus Disease Control were cautious about expanding the scope of people taking the PCR and other tests. Some of them were concerned that making the tests more widely available would sharply increase the number of tests performed, possibly hampering the tests for people with serious symptoms. Based on a peer-reviewed paper published on a major medical journal, it was pointed out that the infection-suppressing effect of a wide range of PCR tests ("Mass testing of 5% of population per week") is weaker than behavioral change and contact confirmation.[32] The health ministry was also reluctant to expand the scope of people subject to PCR and other tests,[33] and in particular, there was a strong sense of caution against introducing a system that offered the tests widely to people who wished to be tested in order to alleviate public anxiety.

Around May, an official of the health ministry prepared a document entitled "Supplement: About the argument that tests should be widely given to people who wish to be tested in order to dispel their anxiety," explaining to members of the Diet the ministry's counterarguments. (The document is carried at the end of this report). Specifically, it pointed out that when tests were widely carried out, (1) a social loss would occur due to large numbers of people testing false positive (testing positive even though they are not infected),[34] causing a collapse of the medical care system and imposing restrictions on the movement and activities of people who are in fact negative; (2) people testing false negative (showing negative despite being infected)[35] could increase the risk of expanding infections by moving freely about and spreading the virus. Regarding the situation within the government at the time, an official of the Cabinet Secretariat recalled that there was an atmosphere where "heads could roll" if you expressed an opinion in favor of expanding the scope of people subject to PCR tests.[37]

It was the experts who played an important role in this situation where there were such disagreements inside and outside the government and the government did not appear to be trying to build a consensus. At the July 6 meeting of the Novel Coronavirus Disease Control Subcommittee, Shigeru Omi, chair of the subcommittee, submitted as a springboard for discussion, "Basic ideas and strategy for expanding the test system – how to balance infectious disease control and socio-economic activities?" The subcommittee later summarized "Basic ideas and strategy for the test system" at the meeting held on July 16 after discussions by members including Keiichiro Kobayashi and Shinji Hirai.

The "Basic ideas and strategy for the test system" was based on infection risk assessment and the pre-test probability for COVID-19, and after dividing test targets into 1) symptomatic persons; 2) asymptomatic persons (with high infection risk and pre-test probability); and 3) asymptomatic persons (with low risk of infection and pre-test probability), it took a position that for 1) and 2), PCR and other tests were to be carried out at public expense from the viewpoint of public health and clinical medicine, while for 3), PCR tests at public expense would not be widely performed, although tests

might be carried out at one's own expense from the perspective of socio-economic activities depending on individual circumstances such as engaging in corporate activities or easing personal anxiety.[38]

A senior official at the Cabinet Secretariat admitted that the government's policy on PCR and other tests was not strategic until the "Basic ideas and strategy for the test system" was put together. "Well, anyway, Japan's capacity concerning PCR tests was very limited at first, so the only way to allocate that limited capacity was to those who were likely to become seriously ill. In that sense, that was a kind of strategy, but we started in the range of testing to decide on the treatment policy for patients who had fever for a prolonged period and were likely to become seriously ill if they were left as was. I think the truth was that we could not even afford to build a strategy," the official said as he recalled the background to the lack of a strategy.[39]

However, the government was unable to formulate a strategy for PCR and other tests even after May, when the strain on the PCR testing systems was resolved, and the reason why there was no strategy for PCR tests should not be ascribed solely to the lack of preparedness in the testing systems. Six months had already passed since the start of PCR and other tests for COVID-19[40] when the "Basic ideas and strategy for the testing system" was compiled.

Notes

1. Interview with a public health center official
   Japan Medical Association, "JMA's response to the novel coronavirus" (Regarding the results of an investigation on "inappropriate cases" of PCR testing for novel coronavirus infection, press release, March 19, 2020) https://www.med.or.jp/nichiionline/article/009205.html
   Kobe city novel coronavirus control first response verification team, "Verification result report " (July 2020) https://www.city.kobe.lg.jp/a95474/kensho.html
2. Yuji Yuasa, "On resuming medical care," (Novel Coronavirus (32), Yuji Yuasa, director of Eiju General Hospital, Japan National Press Club news conference, Document 1, July 1, 2020) https://www.jnpc.or.jp/archive/conferences/35680/report
   Gunma Prefecture health and welfare department, "Verification report on outbreak of novel coronavirus infections at Fujiwaen home for the elderly"(July 2020)
3. OECD, Testing for COVID-19: A way to lift confinement restrictions (May 4, 2020), p.14 https://www.oecd.org/coronavirus/policy-responses/testing-for-covid-19-a-way-to-lift-confinement-restrictions-89756248 /
4. Interview with a senior Cabinet Secretariat official
5. Prior to the start of health insurance coverage, clinical tests were conducted at public expense as administrative tests, similar to tests for public health purposes.
   However, since the start of insurance coverage, most of the administrative tests for insurance coverage have been carried out at 70% medical insurance/30% public expense.
6. It was pointed out that the difficulty of transporting samples by the method specified in the sample transport manual was one of the reasons for the small number of PCR and other tests. Later, by updating the manual, the transport method was changed and the standards were relaxed.
7. Interview with Health, Labor and Welfare Minister Katsunobu Kato (September 8, 2020)
8. The third type in the chart (cases subject to suspected cases surveillance) was not limited by the endemic area, but since it was required that intensive care, etc. was necessary, it may have been possible that mildly ill persons who did not fall under the second type in the chart were not detected because they did not travel to or stay in an endemic area. In fact, at the Infectious Diseases

Subcommittee of the Health Science Council (35th meeting) held on January 24, 2020, Norio Omagari stated, "We have examined four patients at our outpatient department today who meet the definition of a suspected case [author's note: considered to mean fever (37.5 degrees or higher) and respiratory symptoms (regardless of the degree of respiratory symptoms)]. However, none of them met the definition of suspected cases surveillance."

9. At the Infectious Diseases Subcommittee of the Health Science Council (35th meeting) held on January 24, 2020, council member Komei Shirabe pointed out the possibility of COVID-19 infection by people who had not traveled or stayed in endemic areas.
10. Interview with a member of the Expert Meeting on the Novel Coronavirus Disease Control
11. The National Diet Library Internet Material Collection and Preservation Project is a page that collects and saves materials from the COVID-19 control advisory board on the Health, Labor and Welfare Ministry website (https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000121431_00093.html).
    A comparison of the data as of May 1 and that as of May 10, 2020 shows that the agenda of the advisory board's February 10 meeting was posted on the same page between May 1 to May 10.
    Takaji Wakita made a similar statement about the infectiousness of asymptomatic carriers at the 38th meeting of the Infectious Diseases Subcommittee of the Health Science Council held on February 18, and the minutes of that meeting were released on March 9, but this was because the minutes of the Infectious Diseases Subcommittee of the Health Science Council were to be published in principle according to the provisions of the Health Science Council management regulations. On the other hand, it was on July 14 when the operating guidelines were established for the publication of the agenda summary of the advisory board.
12. Interview with a senior health ministry official
13. Interview with a Prime Minister's Office staffer
14. Interviews with officials of a public health center and the Tokyo Metropolitan Government
15. Interview with a Prime Minister's Office staffer
16. Interview with health inister Kato (September 8, 2020)
17. Interview with Yoshitake Yokokura, honorary chairman of the Japan Medical Association (September 8, 2020)
18. Interviews with a public health center official, a senior health ministry official, and Keizo Takemi, an Upper House member of the Liberal Democratic Party
19. Interviews with a public health center official and a Prime Minister's Office staffer
20. Interview with health minister Kato (September 8, 2020); interview with a senior health ministry official
21. Japan Medical Association, "Impact of COVID-19 infection on hospital management – In the case of medical association hospitals" (July 8, 2020) http://dl.med.or.jp/dl-med/teireikaiken/20200708_2.pdf
22. Interview with a senior Cabinet Secretariat official
23. Interview with a senior Cabinet Secretariat official; Interview with a public health center official
24. Interview with a public health center official
25. Interview with a Prime Minister's Office staffer; interview with a local government official
26. He, X., Lau, E.H.Y., Wu, P. et al. Temporal dynamics in viral shedding and transmissibility of COVID-19. Nat Med. 2020; 26 (5): 672–5.
27. WHO, Global surveillance for COVID-19 caused by human infection with COVID-19 virus Interim guidance (March 20, 2020) https://apps.who.int/iris/handle/10665/331506
28. Interview with a health ministry official
29. Interview with health minister Kato (September 8, 2020)
30. Interviews with health ministry officials
31. Interview with a Prime Minister's Office staffer; interview with Yoshitake Yokokura, honorary chairman of the Japan Medical Association (September 8, 2020)
32. Adam J Kucharski, Petra Klepac, Andrew Conlan, Stephen M Kissler, Maria Tang, Hannah Fry, Julia Gog, John Edmunds, CMMID COVID-19 Working Group, et al. Effectiveness of isolation, testing, contact tracing and physical distancing on reducing transmission of SARSCoV-2 in different settings: a mathematical modeling study. Lancet Infect Dis 2020; published online June 16, 2020. https://doi.org/10.1016/S1473-3099 (20) 30457-6.

33. Interview with a senior health ministry official; interview with a senior Cabinet Secretariat official; interview with a senior health ministry official
34. The specificity of the PCR test is high and the false positive rate is low. There were views that the false positive rate was lower than 0.1%, given that there were no positives in Iwate Prefecture until July 29 and no positives were reported in 1,438 samples.
35. The sensitivity of the PCR test is 70%, and the false negative rate is said to be about 30%, considering that the virus may not be collected due to the amount of virus in the body or problems in the sample collection procedure.
36. Interview with a Cabinet Secretariat official. Although these points made by the health ministry may be a counterargument to the introduction of a system that allows all applicants to be widely tested for the purpose of relieving public anxiety, it was not that all proponents of expanding the scope of PCR and other tests were calling for such a system. Therefore, the health ministry's points could not be a valid counterargument to all claims calling for the active implementation of PCR and other tests. For example, from the standpoint of requesting PCR tests for inpatients and residents of elderly care facilities (including new inpatients and preoperative patients), it would still be necessary to conduct PCR and other tests even if false positives and false negatives would occur in some examinees. In view of this point, the above discussions do not seem to go anywhere and it can be said that the exact reason why health ministry officials were reluctant to expand the scope of people subject to PCR and other tests remains unclear.
37. Interview with a Cabinet Secretariat official
38. PCR and other tests for 1) and 2) correspond to tests for public health purposes or clinical tests, while tests for (3) correspond to tests for socio-economic activities.
39. Interview with a senior Cabinet Secretariat official
40. The National Institute of Infectious Diseases started testing domestic cases with the prototype PCR test method on January 14, completed the development of the conventional PCR test method on January 20, and completed the development of the real-time PCR test method on January 24.