

An overview of the reclassification of COVID-19 of the Infectious Diseases Control Law in Japan

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Abstract: Japan's responses to COVID-19 have been conducted based on the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (the Infectious Diseases Control Law) and the Act on Special Measures against Novel Influenza, *etc.* (the Act on Special Measures), as COVID-19 is classified as the category of "the Novel Influenza *etc.*" under the Infectious Diseases Control Law. The government's Novel Coronavirus Response Headquarters decided to reclassify COVID-19 as a Category V infectious disease under the Infectious Diseases Control Law in May 2023 since the disease has become less lethal. Accordingly, the countermeasures such as surveillance and medical care are going to be reviewed, and COVID-19 prevention actions will depend on personal choices (Prior to the review in May, mask usage will be changed from 13 March). However, this does not mean that infection control measures are no longer necessary; it is recommended that such measures be taken in certain settings in order to prevent the elderly and those who at a high risk of severe illness from being infected, even after the disease is classified as Category V.

Keywords: COVID-19, the Infectious Diseases Control Law, the Act on Special Measures

Introduction

In December 2019, multiple outbreaks of pneumonia of an unknown cause were reported in the City of Wuhan, Hubei Province, People's Republic of China (1), and this was later determined to be the novel coronavirus disease 2019 (COVID-19). The first case in Japan was confirmed on January 15, 2020 (2). As for the legal position of COVID-19, it had been specified as "the Designated Infectious Disease" since February 1, 2020 based on the enforcement of the Cabinet Order for the determination of Designated Infectious Diseases according to the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 1998, hereinafter referred to as "the Infectious Diseases Control Law"), and then it has been defined as "the Novel Influenza *etc.*" since February 13, 2021 under the same law due to a law amendment. Measures have been implemented based on the Infectious Diseases Control Law and the Act on Special Measures against Novel Influenza, *etc.* (Act No. 31 of 2012, hereinafter referred to as "the Act on Special Measures") (Figure 1) (3). On January 27, 2023, approximately three years after the first reported case in Japan, the government's Novel Coronavirus Response Headquarters decided that COVID-19 will be classified as a Category V infectious disease starting on May 8, 2023 under the Infectious

Diseases Control Law.

This article describes the legal framework regarding COVID-19 response, namely the Infectious Diseases Control Law and the Act on Special Measures, and outlines the reclassification of the category of the disease under the Infectious Diseases Control Law.

Legal significance of COVID-19 under the Infectious Diseases Control Law and the Act on Special Measures

The Infectious Diseases Control Law is to provide necessary measures concerning the prevention of infectious diseases and medical care for patients with infectious diseases in order to prevent outbreaks and the spread of infectious diseases, to thereby improve and promote public health (4). Under the Infectious Diseases Control Law, the term "infectious disease" refers to Category I Infectious Diseases, Category II Infectious Diseases, Category III Infectious Diseases, Category IV Infectious Diseases, Category V Infectious Diseases, Novel Influenza *etc.*, Designated Infectious Diseases, or New Infectious Diseases; measures that can be taken for each category are stipulated in advance. As mentioned earlier, COVID-19 has been defined as "the Novel Influenza *etc.*" under the Infectious Diseases Control Law.

Main measures, supports, and systems currently being implemented as countermeasures against the novel coronavirus infectious disease (Provisional translation)

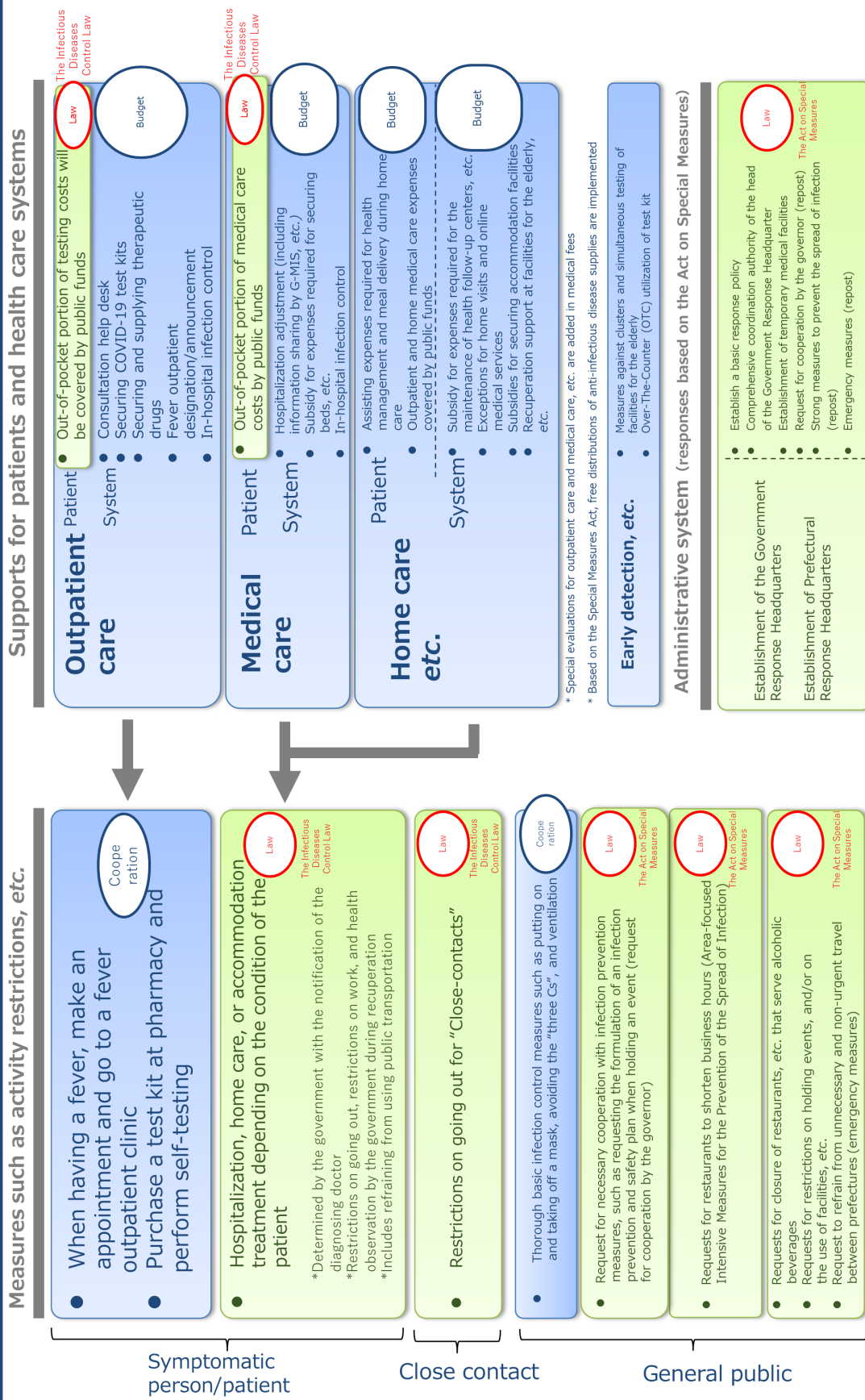


Figure 1. Main measures, supports, and systems currently being implemented as countermeasures against COVID-19 (the 110th Novel Coronavirus Infection Control Advisory Board, Document 4, Ministry of Health, Labour and Welfare).

The Act on Special Measures stipulates a system for a prompt initial response and comprehensive countermeasures to be taken throughout the economy and society in a unified manner, and its aims are to protect the lives and health of people and minimize the impact on the lives of the people and the national economy (5). Novel Influenza *etc.*, Designated Infectious Diseases, and New Infectious Diseases under the Infectious Diseases Control Law are defined as "Novel Influenza *etc.*" in the Act on Special Measures; it stipulates countermeasures such as "Measures under the State of Emergency" and "Area-Focused Intensive Measures for Prevention of the Spread of Infection", as well as requests for cooperation from local residents. In response to COVID-19, requests were made to refrain from leaving home and to restrict the use of facilities including schools as emergency measures were based on the provisions of the Act on Special Measures (Article 45).

Except in cases where Novel Influenza is recognized to be less than or as severe as seasonal influenza, The government's Response Headquarters headed by the Prime Minister will be established based on Article 20 of the Act on Special Measures. The government's Response Headquarters must hear the opinions of "the Council for the Promotion of Countermeasures against Novel Influenza *etc.*" and formulates the Basic Policies for the Disease Control. Based on this policy, measures against novel influenza *etc.* will be implemented in prefectures. According to Article 21 of the Act on Special Measures, the government's Response Headquarters will be abolished "when the disease is clearly equal to or less severe than seasonal influenza" or "when it is no longer considered as a Novel Influenza *etc.*". In other words, when COVID-19 is classified as Category V from a "Novel Influenza *etc.*" according to classification review under the Infectious Diseases Control Law, responses based on the Act on Special Measures, including The government's Novel Coronavirus Response Headquarters and the Basic Policies for Novel Coronavirus Disease Control, will be abolished.

Previous discussions on reclassification of COVID-19 under the Infectious Diseases Control Law

Since November 2022, the Novel Coronavirus Infection Control Advisory Board (ADB), organized by the Ministry of Health, Labour and Welfare has discussed the reclassification of the disease under the Infectious Diseases Control Law (6). On December 1, 2022, based on the response to COVID-19 and preparing for future outbreaks and the spread of infectious diseases that might seriously impact the lives and health of people, the Infectious Diseases Control Law was enacted with amendments to enhance outpatient and inpatient medical care. These changes also seek to allocate medical personnel and infectious disease supplies, to strengthen the system of public health centers and

testing, and to improve the information infrastructure. Moreover, an amendment was added in the process of deliberating the law, stating that the "classification of COVID-19 in the Infectious Diseases Control Law will be promptly reviewed". Based on the discussion and this reviewed provisions, the Infectious Disease Subcommittee of the Health and Welfare Science Council also held deliberations, and their opinion was compiled as "the status of COVID-19 in the Infectious Diseases Control Law" on January 27, 2023 (7). The conclusions of this report were as follows. Although the severity of COVID-19 has decreased, compared to the early stage of the pandemic, the number of individuals infected with the Omicron strain has increased due to the variant's high transmissibility. Attention needs to be paid to the burden on the medical care system and the increase in the number of deaths, and attention must be paid to the possibility of a new variant emerging in the future. Nevertheless, allowing restrictions on private rights in a uniform manner is not appropriate since these restrictions should be kept to a minimum, and specially for many patients with mild symptoms. COVID-19 is not considered to "have a serious impact on the lives and health of the public", so the current situation is no longer commensurate with the restrictions on private rights under the Infectious Diseases Control Law. Therefore, COVID-19 should now be reclassified as a Category V infectious disease since it does not correspond to a Novel Influenza *etc.* Since the changes in the classification and various measures will have major impacts on people's living, these changes should be implemented after approximately three months of preparation. If the scientific circumstances change in the future, such as the emergence of novel variants with significantly different pathogenicity from Omicron, then this policy would need to be immediately reviewed.

Based on these discussions, The government's Novel Coronavirus Response Headquarters that held on the same day decided on the "Policy for Changing the Status of the Novel Coronavirus Infection under the Infectious Diseases Control Law" (8). This policy indicated that, unless there are special circumstances such as the emergence of a variant with significantly different pathogenicity from the Omicron, COVID-19 does not correspond to a Novel Influenza *etc.* under the Infectious Diseases Control Law and thus will be reclassified as a Category V infectious disease starting on May 8, 2023. However, the decision was also made to hear the opinions of the Infectious Diseases Subcommittee of the Health and Welfare Science Council again before the change, and that implementation would take place after final confirmation of changing the classification at the planned time.

Future outlook

Along with the change in the classification of COVID-19

under the Infectious Diseases Control Law, there will be a revision of the policies and measures implemented thus far. The details of the revision were indicated in the aforementioned Decision of The government's Novel Coronavirus Response Headquarters (8). Filing of notification of outbreaks of COVID-19 based on the Infectious Diseases Control Law will be discontinued, and there will be a shift from notifiable disease surveillance to the monitoring of infection trends by sentinel surveillance with designated medical facilities, with continued genome surveillance. The decision was also made to announce a specific policy regarding public financial support for medical care of patients and a medical care system for COVID-19 by approximately early March 2023. Vaccination will continue to be implemented under the Immunization Act (Act No. 68 of 1948) regardless of the change in COVID-19's status under the Infectious Diseases Control Law.

The government's Novel Coronavirus Response Headquarters indicated that effective indoor ventilation and hand hygiene will be still recommended, while mask usage will require further deliberation from the perspective of respect of personal choice, certain recommended settings of mask usage that should be publicized by the government, and trends and situation of COVID-19, then the result should be released at an early date with information of the timing of revision of mask policy. At the 115th and 116th ADB, future infection control measures were discussed, and also mask wear was reviewed on February 10, 2023 at the subcommittee on the basic response policy under the Council for the Promotion of Countermeasures against Novel Influenza (32nd meeting) (9). Based on this discussion, The government's Novel Response Headquarters made a decision regarding the "Revised view of mask usage" on the same day (10). The decision indicated that the current recommendation to wear a mask indoors will be changed, and that personal choices should be respected, leaving the wearing of a mask up to the individual, instead of guided by the Government's decision as a uniform rule. Given a preparatory period, the review is set to take effect starting on March 13, 2023, and from April 1 for schools. For graduation ceremonies in schools to be held before April 1, the suggestion was made that children and students could attend ceremonies without wearing a mask from the perspective of event's educational significance. As for the certain recommended settings of mask usage that should be publicized by the government, following settings were demonstrated: When in medical institutions, when visiting medical institutions and nursing homes where people at high risk of more severe disease lives, crowded settings such as crowded commuter trains and buses (excluding those that permit seating for all passengers, such as Shinkansen, commuter liner, highway bus, charter bus *etc.*), when people at high risk of severe illness during the spread of infection

go to crowded places. The "Industry Guidelines", which are compiled by industry groups voluntarily for infection control measures, will be abolished due to the transition to a Category V infectious disease. As individuals and business implement voluntary infection control measures, the Government will continue to support the efforts of individuals and businesses by providing necessary information, even after the change in COVID-19's status under the Infectious Diseases Control Law.

Based on these measures, preparations for the transition will be made at each site until May 8, 2023 when COVID-19 will be reclassified as a Category V infectious disease. (*The revised policy regarding public financial support for medical care of patients and a medical care system for COVID-19 was released on March 10, 2023.)

Conclusion

Due to the change in the classification of COVID-19 under the Infectious Diseases Control Law, infection control measures that have been implemented based on this law and the Act on Special Measures will be reviewed. However, this does not mean that infection control itself will become unnecessary; rather, continuing to ensure the cooperation of the public with infection countermeasures is essential while obtaining their assent. Necessary infection control measures should be implemented in accordance with the characteristics of the disease, including the protection of the elderly and people suffering from underlying diseases who are at high risk of severe illness.

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