Subcommittee's Proposal for Governance on Infectious Disease Emergency Management

October 6, 2020

Liberal Democratic Party Policy Research Council
Headquarters for Pneumonia Associated with Novel Coronavirus

Note: This translation should be regarded as provisional. In case of discrepancy or inconsistency between the Japanese text and the English translation, the original Japanese text shall prevail.

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8) Revise the National Institute of Infectious Disease's role in vaccine-related operations

5. Future processes: follow-up by the subcommittee
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1. Scope of the report: Drastic revisions to governance with prolonged epidemic in view

As of August 31, 2020, the outbreak of the COVID-19 epidemic is expanding in Japan and worldwide, with no end in sight. Looking back, outbreaks of infectious diseases have left numerous scars on humankind worldwide throughout human history. Outbreaks that have killed large populations on the scale of entire nations are not rare. Even with today's advanced medicine, humankind continues to face infectious disease epidemics that can have enormous impacts in terms of deaths and social and economic activities.

Table 1. Major infectious disease health risks in the 21st century

2003	Severe acute respiratory syndrome (SARS)
2005	H5N1 avian influenza
2009	H1N1 influenza pandemic
2012-2014	Middle East respiratory syndrome (MERS)
2014-2016	Ebola virus disease (Western Africa)
2014	Dengue fever Japan domestic outbreak
2015-2016	Zika virus
2018-2020	Ebola virus disease (Democratic Republic of the Congo)
2020 -	COVID-19 pandemic

Rapid growth in international travel, high population densities associated with urbanization, increased contact with wild animals due to the development of previously untouched areas, and aging populations have collectively increased the risk of global epidemics of infectious diseases. Adding to the risks of such outbreaks of emerging and re-emerging infectious diseases is the global problem of anti-microbial resistance (AMR) to known pathogens. A 2019 United Nations report warns that if significant measures are not taken, by 2050 AMR will cause the deaths of 10 million people every year around the world, which could cause economic losses that would exceed that of the global financial crisis of 2008 – 2009.[1]

The international community, including Japan, has made numerous attempts to combat serious health emergencies related to infectious diseases. However, despite strengthened surveillance systems, the revision of domestic and international regulations, establishment of international cooperative systems, and construction of financial mechanisms and

[1] United Nations. No time to wait: Securing the future from drug-resistant infections. Report to the Secretary General of the United Nations. April 2019

adoption of global action plans, these attempts failed to halt the global spread of COVID-19 damage. Efforts to develop therapeutics and vaccines for COVID-19 have also been unfruitful thus far.

Thus, we must be prepared for the fact that negative health impact and epidemic-related restrictions on social and economic activity could continue for years. In light of the current circumstances, we are pressed to implement a combination of short- and long-term responses to the pandemic. First, responses must consider immediate responses to current outbreaks, preparation for the seasonal influenza predicted to arrive this winter, and preparation for mutations that could cause higher virulence and infectivity of the disease. Thus, measures conceived in terms of periods from several weeks to months are necessary. Second, drastic and immediate revisions to governance are also necessary to prepare for the future trajectory of the COVID-19 pandemic, which would involve work spanning periods from several months to several years. Investigations into rebuilding the system of the government's infectious disease measures should start now, rather than waiting for the end of the COVID-19 epidemic. Furthermore, if possible, highly urgent items should be discussed as early as possible at the next extraordinary Diet session. Other items should be discussed as early as possible at the next ordinary Diet session to revise relevant laws. First, this will be valuable for risk management of the COVID-19 epidemic, which is projected to continue for an undetermined amount of time[2]. Second, it will enable meaningful preparation for the spread of new strains of COVID-19 with higher infectivity and virulence that may pose a greater threat due to developing infectivity in asymptomatic patients, and the spread of pathogenic AMR.

The crisis management targets that Japan needs to prepare for are not limited to infectious diseases. Rather, they are varied and numerous, also including natural disasters, major accidents, terrorist attacks and wars, the breakdown of financial systems, and large-scale influxes of refugees. In response to these crises, the nation, led by the Cabinet Secretariat, is building a national security system to respond in the case of actual national risks. Nevertheless, given the high incidence and scale of damage, the risks of infection among the entirety of the national security/risk management system that should be addressed at a national level will impact the entire nation, rather than being localized to

[2] During a press conference on August 21, World Health Organization (WHO) Director General Tedros Adhanom stated that "we hope to finish this [COVID-19] pandemic in less than two years."

one area. It is necessary to note that risks of infection have a specific nature in that they require highly specialized decision-making, as well as international cooperation.

The UK government has assessed the risks of the following hazards occurring over the next 5 years, and the potential extent of damage as shown in Table 2. Although the said government has assessed the risk of earthquakes and other natural disasters differently from the level of those risks for Japan, the UK government's assessment can provide insight for Japan in that they have also assessed the risk of new strains of influenza and emerging infectious diseases relatively highly and are preparing accordingly. The UK government has also merged Public Health England, an executive agency of the Department of Health and Social Care, and the NHS Test and Trace operation to be replaced by the National Institute for Health Protection, a new agency created on August 18, in the midst of the COVID-19 epidemic, to respond to the threat of infectious diseases. The new agency combines the public health foundation of the former with the medical care foundation of the latter to reinforce the national system in order to combat the health emergencies associated with the ongoing epidemic.

Table 2 Assessment of the health risks of infectious diseases by the United Kingdom National Risk Register of Civil Emergencies (2017)[3]

Scale of damage during risk event						
	5				**novel influenza**	
	4			Large-scale power outage Flooding	Snowstorm	
	3		Airplane accidents Industrial accidents		**Emerging infectious diseases** Heat wave Atmospheric pollution	
	2		Wildfires	Zoonotic diseases Droughts	Volcanic eruptions Public disorder Storms and gales	
	1		Earthquakes			
		1	2	3	4	5
		Risks that could occur within 5 years				

[3] UK Cabinet Office. National Risk Register of Civil Emergencies. 2017 edition

COVID-19 is a serious public health issue that has had a serious impact on Japan's national economy and society, and it is clear that it may lead to a national crisis. Therefore, the experience of responding to the present crisis should be taken as a lesson to reaffirm that the risk of infectious disease is a national-level threat to national security. Moreover, this acknowledgment should prompt a radical shift in infectious disease risk management governance to cover preparedness in times of non-crisis, and response in times of actual crisis. In attempting to make this shift, it is essential to remember that emerging or re-emerging infectious diseases such as novel influenza with similar features to COVID-19, such as transmissibility in asymptomatic patients, but with even higher transmissibility and pathogenicity, could strike again at any time.

At the same time, as a nation we acknowledge and learn from the consequences of infectious disease countermeasures having dropped in priority over the years. Various fields, such as basic and clinical medical research and the pharmaceutical and vaccine industries, as well as sections of government that deal with policy-making, have all allocated fewer resources, such as funds for research, human resources, and company investments, compared to those received by other areas such as cancer, for example. In fact, interest in the field of epidemiology itself has been constantly declining.

This subcommittee aims to propose mid- and long-term policies related to infectious disease countermeasures in the government and elevate its level of priority in budget allocation, etc. Confirming that these can be stably maintained will make it possible for the public and private sectors to make long-term investments in various areas. Moreover, the state needs to make a great shift in how it prioritizes infectious diseases to ensure that such investments are economically sustainable. Finally, the greatest lesson learned from the current epidemic should be that aiming for national consensus towards this goal is the key to combating any other infectious disease that we might encounter in the future.

As the "Basic policy for countermeasures against COVID-19" stipulates, gradually increasing levels of socioeconomic activity while maintaining a balance with infectious disease countermeasures will create the foundations for stimulating economic activity. Based on this stance, we must also consider and practice novel public health approaches in a public-private partnership, as an alternative to the conventional public health actions, which include simply performing repeated PCR tests.

Based on these views, this subcommittee requests that the government consider immediately revising related laws to devise the following concrete measures as early as

possible. Urgent items should be discussed at the Next Extraordinary Diet Session or at the latest in an early Ordinary Diet Session next year.

Short-term countermeasures are to be investigated by the Liberal Democratic Party COVID-19 Control Headquarters separately from the present recommendation.

2. Emergency response to COVID-19 to date (February – July 2020): Summary and challenges

Summary: Minimizing health impact and maintaining socioeconomic activity

The end goals of infectious disease emergency management are minimizing health damage and maintaining socioeconomic activity. Deaths caused by the infectious disease and excess mortality, i.e., the number of deaths in excess of the average annual number of deaths recorded in a nation, are the appropriate and ultimate indicators of health damage. Maintenance of socioeconomic activity is ultimately assessed by changes to gross domestic product (GDP). The degree and duration of social restrictions, such as lockdowns, may also be used as surrogate indicators of socioeconomic activity. Based on these indicators, Japan has been doing extremely well compared to major Western developed nations in the first eight months of the global pandemic (January through August 2020).

Our achievements include keeping per capita COVID-19 mortality and excess mortality rates low without adopting strict measures, such as a lockdown or curfew orders that would have had a great socioeconomic impact. For this reason, the quarterly GDP growth rates of OECD nation’s shows that the economic downturn in Japan was less than the mean downturn observed in G7 nations.

Figure 1
COVID-19-related deaths in G7 nations
(August 17, 2020)

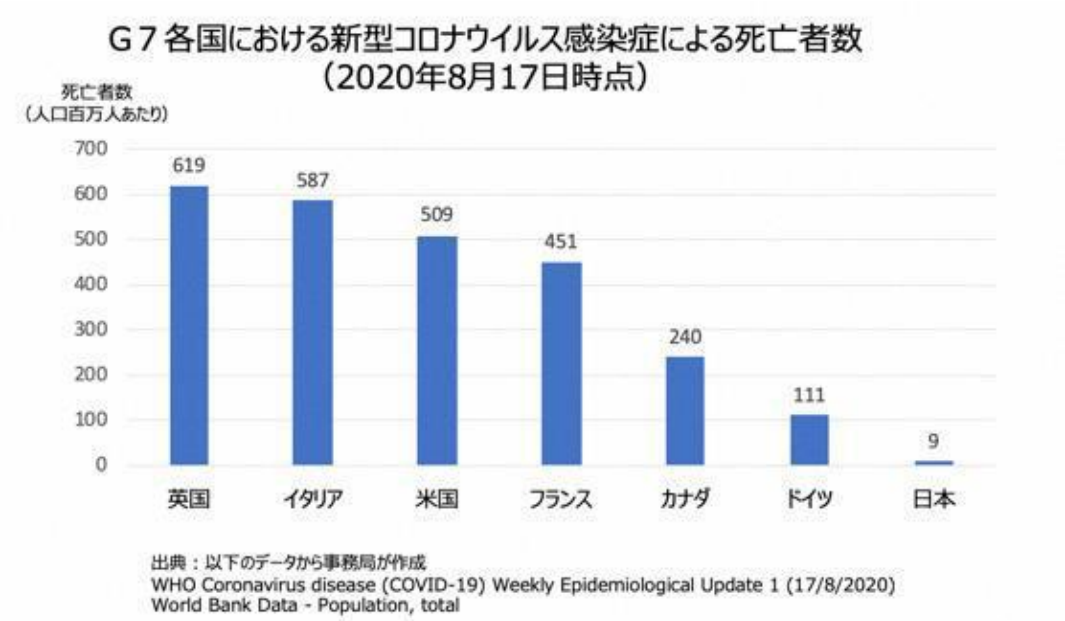
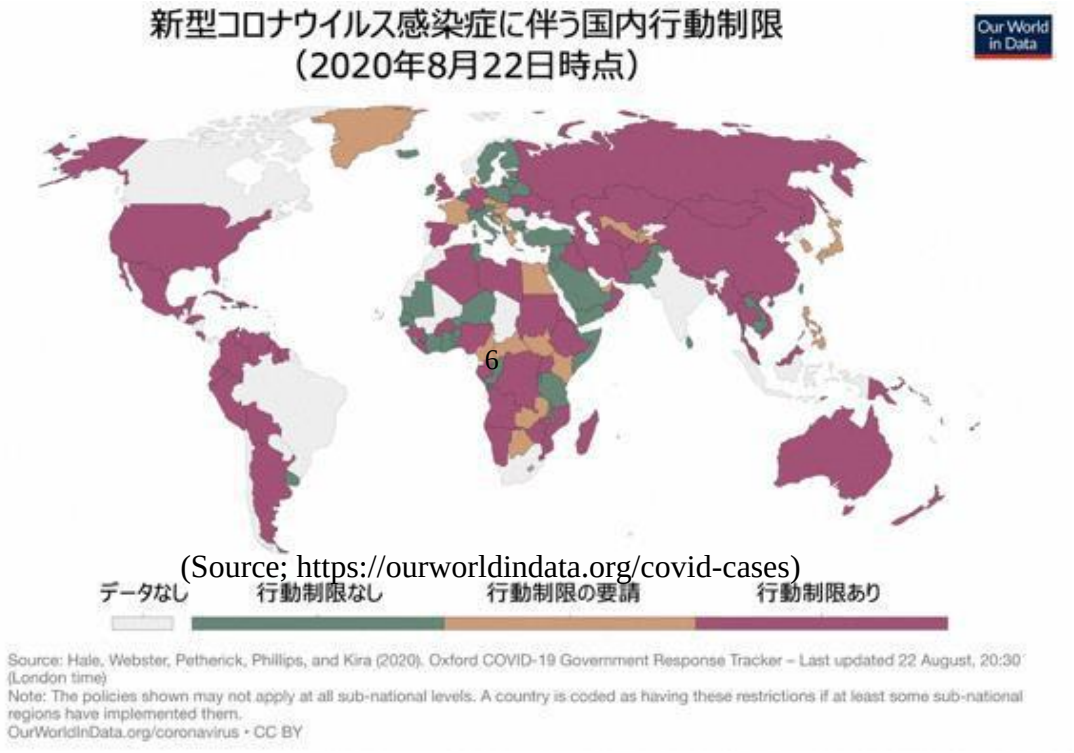


Figure 2
Domestic travel restrictions in the COVID-19 epidemic
(August 22, 2020)



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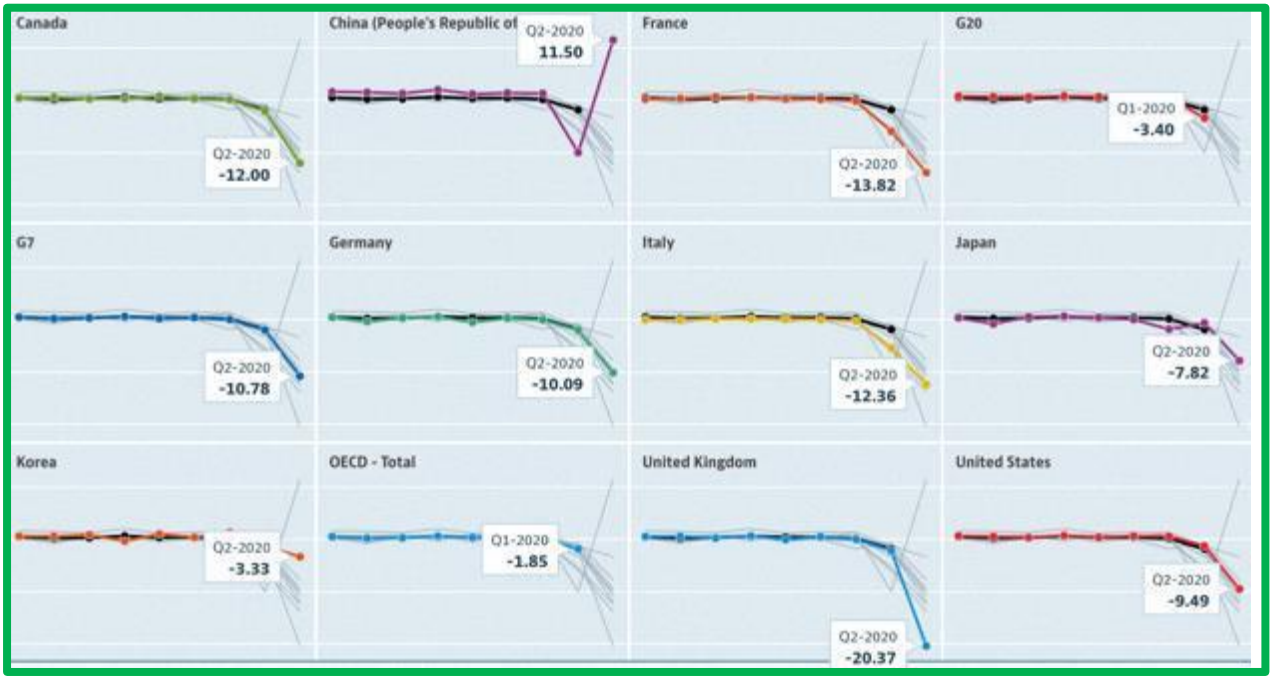
(Source; https://ourworldindata.org/covid-cases)

Table 3 Quarterly GDP Growth Rates of Various OECD Nations

Location	Q2-2018	Q3-2018	Q4-2018	Q1-2019	Q2-2019	Q3-2019	Q4-2019	Q1-2020	Q2-2020
United Kingdom	0.53	0.59	0.21	0.66	-0.06	0.51	-0.00	-2.19	-20.37
France	0.20	0.36	0.65	0.55	0.25	0.16	-0.19	-5.94	-13.82
Italy	-0.00	-0.08	0.16	0.20	0.11	0.01	-0.23	-5.38	-12.36
Canada	0.39	0.61	0.24	0.29	0.80	0.28	0.14	-2.11	-12.00p
G7	0.50	0.21	0.36	0.64	0.24	0.42	0.04	-2.00	-10.78
Germany	0.47	-0.33	0.34	0.61	-0.50	0.31	-0.02	-2.02	-10.09
United States	0.67	0.53	0.33	0.73	0.37	0.64	0.59	-1.26	-9.49
Japan	0.36	-0.81	0.57	0.70	0.41	0.04	-1.80	-0.62	-7.82
Korea	0.62	0.58	0.87	-0.34p	1.01p	0.38p	1.31p	-1.28p	-3.33p
China (People's Republic of)	1.60	1.50	1.30	2.00	1.20	1.40	1.30	-10.00	11.50
G20	0.78	0.70	0.62	0.83	0.67	0.68	0.56	-3.40	..
OECD - Total	0.50	0.23	0.27	0.64	0.36	0.43	0.17	-1.85	..

Figure 3 Quarterly GDP Growth Rates of Various OECD Nations



Considering that COVID-19 mortality is particularly high in older adults, and the mode of transmission (primarily droplet infection), it is quite remarkable that our nation, with its rapidly aging population and extremely dense urban populations, has such a low mortality rate. There are many unknowns to this phenomenon, but may be explained by some of the various hypothesized factors as follows:

a) Government healthcare and public health policies and good access to healthcare services given the universal health insurance system
b) Efforts of healthcare workers and cooperation of citizens
c) Sociocultural factors (absence of hand-shaking culture)
d) Biological and genetic factors
e) Preventive effects of the BCG vaccine for COVID-19
f) Cross-immunity with similar viral strains of past epidemics

Further academic investigations must be awaited to find how much of each of these factors have contributed to the positive outcomes observed thus far. The government/party in power is aware that the minimal health damage compared to other nations cannot be attributed solely to national virtues, such as effective policies or citizens' willingness to cooperate. In particular, this should not be allowed from the perspective of risk management, since relying heavily on voluntary cooperation can give rise to a moral hazard, wherein "free-riders" who do not cooperate will be rewarded. Moreover, we must engage in future measures for the later stages of this pandemic with the understanding that the measures that were successful in the early stages may not continue to be effective.

The following aspects of Japanese measures were superior to those of Western countries:

I. Faithful adherence to the basic public health measures of epidemic control: identification of infected individuals, isolation and treatment, tracking of contacts, and stringent surveys effectively contained clusters.
II. While not sufficient, local government units (prefecture level) monitored the capacity of the main hospitals in their regions to deliver healthcare services and strived to secure hospital beds and perform rigorous triage, which contributed to avoiding hospitals from becoming overwhelmed.

However, some have also criticized the measures, saying that rates of infections and mortality in Japan compared with other Asian countries do not necessarily indicate the superiority of the Japanese response. Therefore, it is important to carefully compare and analyze these factors.

Whether the superior aspects of Japanese public health and healthcare policies will continue to play effective roles in the coming period of anticipated spread of the epidemic is unpredictable, and relies on appropriate investigations and implementation of suitable measures at each stage of the pandemic.

Challenges: Organizational, information technology, and systematic issues

There are also challenges that have surfaced through these measures which can be classified broadly into organizational issues, information technology issues, and systematic issues.

1) Organizational issues

i. Lack of a clear chain of command

Ambiguity in the locus of authority and responsibility came to light. Responses to a national-level crisis must be executed in unity under the government, with the supportive role of local governments. However, since the enactment of the Communicable Diseases Prevention Act in 1897, infectious disease laws have remained unchanged for 120 years on the premise that local governments are responsible for containing infectious diseases in their regions. The law does not explicitly stipulate that the central government orders or provides specific guidance to local governments. As a result, many discrepancies were observed between central and local government responses, and in the responses within local governments. Despite the Prime Minister's order regarding PCR testing, the order of the central government did not reach the peripheries of local governments. This resulted in a level of chaos that caused the Prime Minister to express regret to the public, acknowledging "bottlenecks" in the chain of command.

ii. Shortage of infectious disease emergency management experts

The risks brought about by infectious diseases and their high incidence, the extent of damage, and the resulting impacts are not localized to one area but rather spread nationwide. Expert knowledge is required among government staff and officials to make the best judgments and ensure smooth and effective cooperation and coordination with various government departments and agencies and international counterparts. Government staff must have knowledge of medicine and public health (in particular, in emerging and re-emerging infectious diseases), experience in domestic and international operations in infectious disease risk management, and coordination skills to work with a wide range of staff.

In terms of specialized knowledge in the fields of public health and infectious diseases, expertise in genomic medicine and information technology will be required. The cooperation of these experts is essential in areas not limited to

emerging and re-emerging infectious diseases. The cooperation of the Self-Defense Forces is likewise essential.

2) IT issues

iii. Insufficient application of information technology

In response to a large-scale epidemic, incidence reports, a case registry, genomic analysis of specimens, and contact-confirming applications using smartphones allow for rapid collection and analysis of large volumes of data. These tools and studies are also conditions and prerequisites for drafting effective measures and policies. However, systems that allow effective processing and application of large-scale data in the areas of public health, clinical care, government, research, and publicity for citizens were insufficient for the present epidemic. Specifically, the following problems were observed.

- In the initial stages of the current epidemic, an inefficient system using hand-written report forms sent by fax was still used to report infected cases. An advanced information technology system for collecting and managing data on COVID-19 infected individuals was eventually developed in May. This system, called the Health Center Real-time information sharing System on COVID-19 (HER-SYS), had only 14 items that legally required reporting, while the remaining 95 items relied on voluntary reporting. Furthermore, there are no legal procedures in place to overcome confidentiality issues, which delayed transition to the use of this system. As a result, vastly insufficient data has been collected from local governments thus far.
- Although contact-confirming applications (COCOA：COVID-19 Contact-Confirming Application) have been introduced, there were only around 15 million users as of late August. Thus, such applications have not reached the point of efficiency to function as a nationwide infectious disease countermeasure.4
- The case registry led by the National Center for Global Health and Medicine (NCGM) has registered approximately 6,000 total cases nationwide as of August. However, the use of the registry is not maximized, and to date it has not

been able to effectively disseminate academic findings for infectious disease countermeasures[4].

- Genomic analyses of patients and the virus provide essential information for the development of new treatments and detecting viral mutations. Despite this, in the initial stages of the epidemic there were no tools or programs to allow systemic collection and analysis of specimens, and no system for gathering data related to COVID-19 linked to patient medical data in a rapid, joint, multi-center analysis in the event of an epidemic.
- Data on the cruise ship Diamond Princess was the most important body of information that drew global attention, particularly during the earliest stages of the pandemic. However, as data has not been collected or disclosed by the government, it remains uninvestigated by foreign experts.

iv. Low priority placed on risk communication

As mentioned above, the impacts of COVID-19 thus far in Japan have been minimal overall compared to Western developed countries, both in terms of health damage, social restrictions, and economic recession. Nonetheless, the response by the Japanese government has not been positively evaluated within Japan or internationally.

It is essential to find ways to improve the situation by analyzing the factors leading to this unfavorable evaluation despite daily press conferences having been held by the government officials responsible to explain the situation to citizens.

[4] According to a WHO report, at least 15 countries are using contact-confirming applications, some of which function as digital contact tracing and quarantine tools (DCTQ), with features such as self-isolation monitors (WHO/WPRO: Selecting digital contact tracing and quarantine tools for COVID-19, 19 June 2020).

Figure 4
NHK Public Poll: Cabinet Approval Ratings and Monthly Deaths

出典：
NHK世論調査 内閣支持率 | NHK選挙WEB
厚生労働省 | オープンデータ | 死者数（8月19日公開資料）
(Source: NHK Public Poll Cabinet Approval Ratings / NHK Senkyo Web
& Ministry of Health, Labour and Welfare Open data /Deaths (Published August 19)

3) Systemic issues

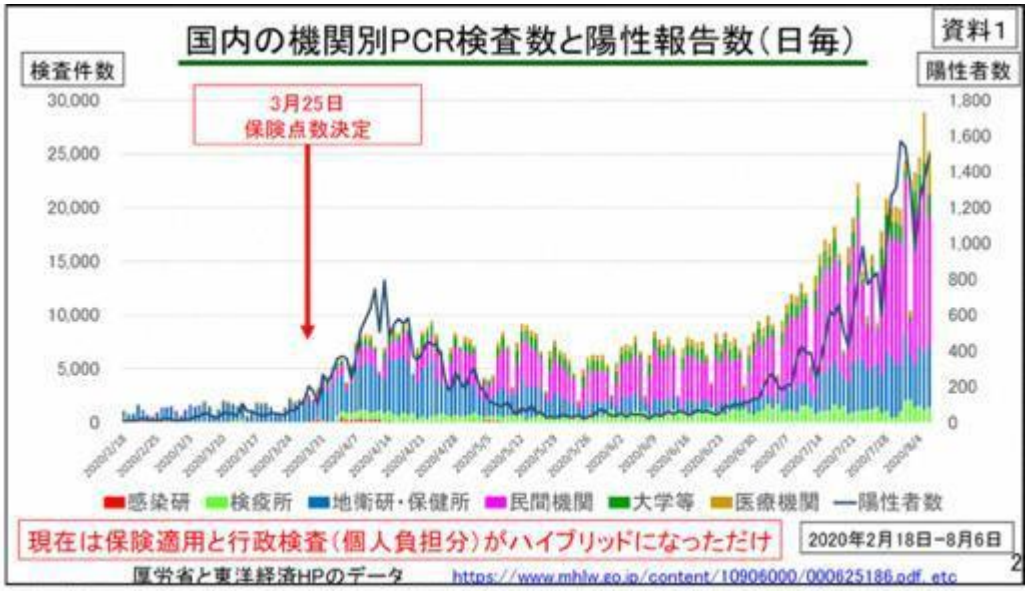
v. Lack of flexibility in system application in times of crisis

Existing laws and systems were not open to flexible interpretations or pragmatic applications, and did not foresee unprecedented events exemplified by the current pandemic. Therefore, it was not possible to implement pragmatic and suitable measures quickly in such a crisis involving numerous, consecutive unpredictable events without a system or procedures to waive existing regulations. For example, it has been obvious since the early stages of the epidemic that the existing system did not allow the Public Health Centers to fulfill their roles as defined by the Infectious Diseases Prevention Act, which include but are not limited to accepting incidence reports, testing suspected infected individuals, health observation of those testing positive and those returning to the country, questioning regarding the infected individual's activities and destinations, follow-up surveys of high-risk contacts, and coordinating infected individuals' hospitalization and patient transport. Despite this, responses were implemented without first making legal revisions that would facilitate smooth and effective public health and other comprehensive support and services. Furthermore, community healthcare and public health roles and responsibilities were not merged in an orderly manner. This led to the inability to select the optimal course

of action flexibly, according to the characteristics of the disease, dysfunctional public health center operations, and the abovementioned “bottlenecks” manifested in the form of broken chains of information-sharing and delays in PCR testing.

Another problem was the lack of cooperation between the public, private, and academic sectors due to overemphasis of the role of public health. This prevented national emergency pandemic efforts from receiving prompt assistance from the non-public sector (e.g., testing companies, universities, and academic associations), which has a greater wealth of resources and knowledge in the field of infectious disease prevention. This was another facet of the limitations of legal and systemic regulations that have not been updated throughout the 120 years since the Meiji era.

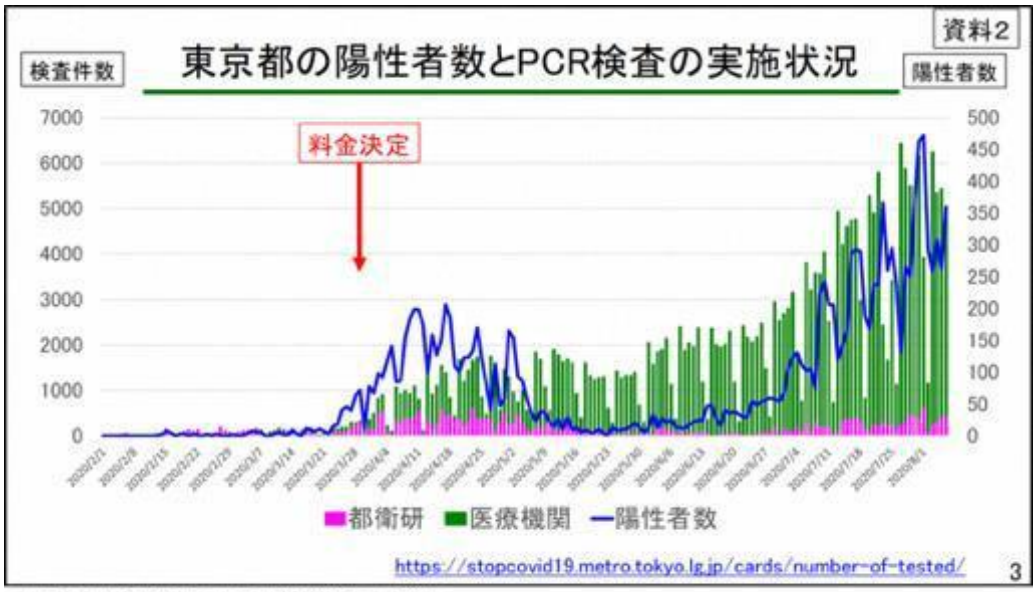
Figure 5
PCR tests and positive case reports in Japan by institution type (daily)



出典：資料3_岩本愛吉 東京大学名誉教授：参考資料
「新型コロナウイルス関連肺炎対策本部 感染症対策ガバナンス小委員会」

(Source; Document 3 from Aikichi Iwamoto, Professor Emeritus of the University of Tokyo’s presentation for the Liberal Democratic Party Infectious Disease Measures Governance Subcommittee, Novel Coronavirus Response Headquarters.)

Figure 6
Positive cases and PCR tests in Tokyo



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(Source; Document 3 from Aikichi Iwamoto, Professor Emeritus of the University of Tokyo's presentation for the Liberal Democratic Party Infectious Disease Measures Governance Subcommittee, Novel Coronavirus Response Headquarters.).

vi. Lack of drastic, situation-specific measures to cut the chain of transmission

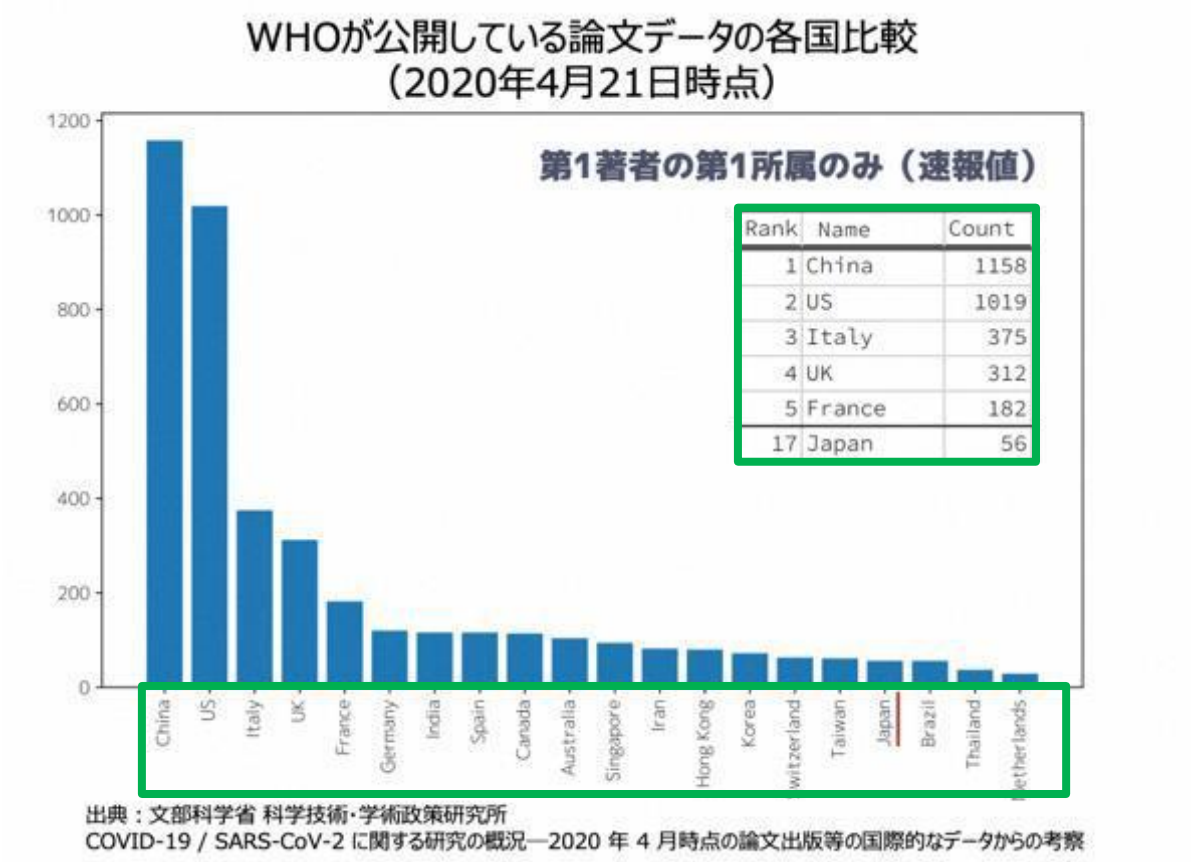
It was not possible to make localized closures targeting epicenters. For example, the second surge of infected individuals between June and July was attributed to the close physical contact between workers and clients in the entertainment zones of major cities (e.g., Kabuki-cho in Shinjuku), after which infections then spread to the general population. As this was predicted from the earliest stages of the epidemic, localized closures would have been the suitable measure from a public health perspective. However, the central government failed to take leadership, which was also due to the legal restrictions. Local governments were slow to exercise authority appropriately according to the law, and this collectively opened the opportunity for infections to spread.

vii. Delays in research and development

Progress in research and development (R&D) is lagging. Compared to Western countries, there is extremely little academic output, which has hindered good decision-making in policies and development of novel therapies founded on scientific evidence. This delay is attributed to two main shortcomings: lack of flow of necessary data from

the field to the National Institute of Infectious Diseases (NIID) and the Ministry of Health, Labor and Welfare (MHLW), and lack of thorough supervision and execution of information disclosure at a national level. This also stems from the fact that infectious disease countermeasures, including data collection, have been entrusted to local governments. This needs to be addressed by unifying all emergency and other relevant data management under the central government through a legal system that permits a) analysis of the most recent data and advanced knowledge, and b) local governments and basic domestic and foreign legal systems to access this data under certain regulations and thus ensure c) accessibility of data for further analysis. Japan is also lagging in the development of vaccines and treatments, which are the focus of short-term interests; drastic revisions to government policies and measures to promote industry are urgently needed. We should be aware of the implications of the high likelihood that vaccination of the Japanese population, expected to be introduced in the first half of 2021, will rely on imports for all or at least the majority of the necessary doses.

Figure 7
Comparison of number of articles by nation: Published by WHO
(as of April 21, 2020)



(Source: National Institute of Science and Technology Policy Discussion of data from the Summary of Studies on CVOD-19/SARS-CoV-2: International State from published articles, etc., as of April 2020)

3. Principles on which to base revised governance of infectious disease emergency management

In revising governance of infectious disease measures, we propose a basic policy comprising the four following components.

1) **Prioritizing infectious disease emergencies as a national security issue**
2) **Restructuring of laws and organizations**
3) **Promoting research and development and evidence-based policy-making**
4) **Efficient communication between citizens and the government**

1) Prioritizing infectious disease emergencies as a national security issue

Depending on the pathogenicity and transmissibility of the pathogens responsible, emerging and re-emerging infectious diseases and associated health risks can lead to the death of many citizens and deterioration of the social structure of the nation. Therefore, infectious disease emergencies need to be considered as an important national security issue.

2) Restructuring of laws and organizations

It is common knowledge that current regulations and structures are not sufficient for responding to major infectious diseases like the current epidemic. Various laws require revision, with some needing urgent attention. Moreover, in order to appropriately enforce the revised laws, reinforcement and restructuring of existing organizations are also needed, which also require budget restructuring.

3) Promoting research and development (R&D) and evidence-based policy-making

Promoting rapid R&D and policy-making based on scientific data and evidence are essential in fighting an unknown infectious disease. Reconstructing a system of R&D to address health risks of infectious diseases must start during times of non-emergency, through cooperation with the private and public sectors. This further requires facilities for studying human and veterinary epidemiology, such as universities, and a system that allows researchers affiliated with Bio Safety Level (BSL) 4 facilities and research institutions to provide their scientific guidance and input appropriately to parties with the authority to make policy-related decisions.

4) Efficient communication between citizens and the government

Inevitably, restrictions and sacrifice are demanded of individual citizens in managing infectious disease emergencies. Furthermore, depending on future amendments to the law, emergency laws may become even stricter than current laws. Given that infectious

disease-related health risks are national security issues, optimized communication between citizens and the government is essential so that citizens can cooperate with measures that are based on scientific evidence and conform to the laws and regulations of Japan in order to overcome these challenges.

4. Recommendations

Given the above basic principles of revisions to infectious disease measures governance, items (1) to (8) below are to be proposed at the next Ordinary Diet Session with the aims of making the necessary amendments to the law.

1) Prioritize infectious disease emergencies as national security threats

Discussions on important topics related to Japanese national security are held by the National Security Council pursuant to the Act of Establishment of the National Security Council. The Ministries which formed the Ministries of Internal Affairs before WWII, including the Ministry of Health, Labour and Welfare, are currently responsible for domestic crisis management. Except for the Ministry of Health, Labour and Welfare, they comprise the members of the Nine Ministers' Meeting of the National Security Council. Given that the risk of infectious disease is a national security issue, the Ten Ministers' Assembly, including the Minister of Health, Labor and Welfare, who has primary responsibility in infectious disease risk management, should investigate how to secure a system to review national security.

With regard to major measures and policies related to infectious disease, the "National Security Strategy" should be reformed to incorporate polices related to infectious diseases.

2) Organize and reinforce the chain of command

i. Coordination function of the Cabinet Secretariat and its reinforced chain of command

In current infectious disease countermeasures, we have seen delays between the guidelines and policies drawn by the Novel Coronavirus Response Headquarters and their execution by relevant ministries and agencies. Management of health risks related to infectious diseases is a part of national risk management, and accordingly demands reinforcement of the Cabinet Secretariat risk management system. Specifically, the following measures are considered:

a. Organizational structure specializing in infectious disease risk management

The Deputy Chief Cabinet Secretary for Crisis Management in the Cabinet Secretariat (a position above the administrative Vice-Minister of ministries and

agencies, equal to parliamentary secretary positions) is appointed with authority over management of risks other than those related to national defense. These include threats such as natural disasters, aircraft and railway accidents, terrorist attacks, evacuation of nationals, inflow of refugees, and epidemics. Compared to the various other types of threats, infectious diseases require a high degree of specialized knowledge in healthcare and public health, and occur more frequently than other threats and disasters. Moreover, this threat is unique in that it could rapidly spread to concurrently damage entire nations and the whole world. Based on these characteristics, a new post of Cabinet Secretary for Infectious Disease Crisis Management should be created to head the office supporting the Special Measures Minister, and will have the same authority as the Deputy Chief Cabinet Secretary for Crisis Management.

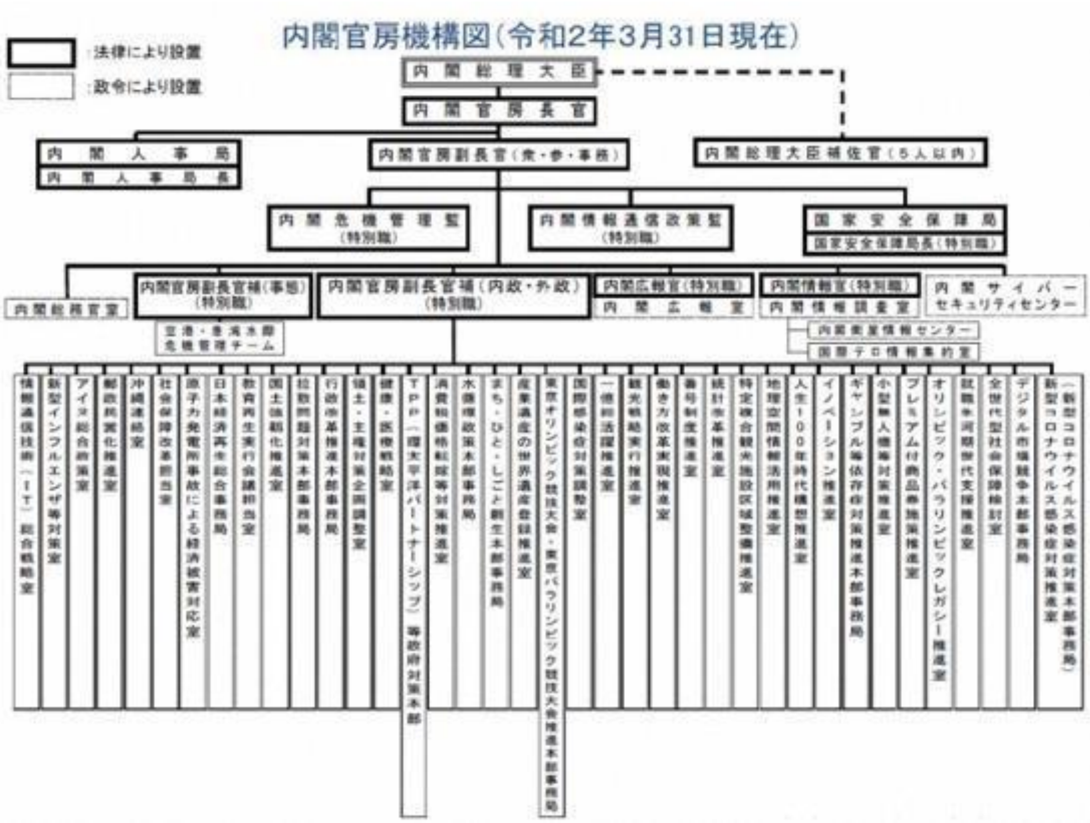
Under their direction, existing related departments and groups (the Office for Pandemic Influenza and New Infectious Diseases Preparedness and Response, Cabinet Secretariat , International Infectious Disease Control Coordination Office and Office for Novel Corona Virus Control, Cabinet Secretariat: currently around 70 – 80 staff) have been united and additional staff added to form an infectious disease risk management organization. Their tasks and responsibilities will include preparing for naturally occurring diseases, risk of man-made epidemics (bioterrorism and biological weapon attacks), and an anti-microbial resistance (AMR). Furthermore, this merged department should work in close communication and cooperation with the National Security Agency to implement economic measures and effective measures[5].

[5] Infectious disease countermeasures are considered together to be a national security policy. In that sense, it is possible that a new organization will be created under the National Security Agency.

Figure 8

Organizations of the Cabinet Secretariat

(As of March 31, 2020)



b. Reorganization of the roles of the central and local governments

To exercise its general executive authority, the Cabinet Secretariat has authority over various ministries and agencies of the government. Moreover, in an emergency, the central government must also have strong power, enabling it to deal directly with local governments that have jurisdiction over Public Health Centers and Public Health Institutes distributed nationwide. In order to do so, the necessary law amendments need to be discussed with an understanding of local governments. Specifically, in addition to expanding the power of the Minister of Health, Labor and Welfare to instruct local governments (i.e., mayors of various prefectures) where Public Health Centers are located, the scope of measures that the Minister of Health, Labor and Welfare are allowed to execute in the place of prefectural mayors should also be expanded.

Furthermore, in addition to re-organizing the chain of command between the central and local governments, the authority of the governors, including designated

cities and designated mid-level cities, needs to be organized systematically in order to respond to infectious disease crises.

c. Establishing a uniform legal system related to infectious disease risk management

The legal system related to infectious disease risk management is currently divided into new strains of influenza special measures law, infectious disease laws, quarantine laws, local public health laws, and individual laws.

This situation is an obstacle to the unified and seamless execution of infectious disease risk management by the government, due to incongruences between individual and specific measures under various law or inconsistencies in terminologies used. Therefore, various related laws should be organized and unified to maximize the functions of the government's centralized chain of command and ensure smooth activities to protect lives and the economy, and establish a new infectious disease risk management legal system.

ii. Delegate authority to the government to respond in emergencies

Organize a legal system that gives executive authority to the central government to respond in an infectious disease crisis that meets predetermined conditions[6]. This will allow lockdowns (curfews and business closures) for specific areas or durations and promote the use of contact-confirming applications, including compulsory use[7].

iii. Unify operations between public health and clinical medicine

Aim for unified operations and mutual cooperation between public health and clinical medicine based on the experiences responding to the present COVID-19 epidemic.

a. Testing systems viewpoint

The roles of the government (MHLW and NIID), prefectural governments, etc. (Public Health Centers, Public Health Institutes), and private sector medical institutions and testing facilities are not written out clearly in infectious disease laws. Initially, universities and private sector medical and testing facilities could

[6] In general, the Japanese government should make decisions independently, but may refer to the WHO's Public Health Emergency of International Concern (PHEIC) as well.

[7] For restrictions on private rights, restricted entry to the country, and other emergency measures, the COVID-19 Special Measures Minister appointed by the Cabinet shall give directions founded on clear legal grounds and authority with cooperation of the MHLW, Ministry of General Affairs, Ministry of Economy, Trade and Industry, Ministry of Defense, and Ministry of Foreign Affairs.

not be utilized within the frameworks of "government testing," which includes the "Active Epidemiological Investigation (Contact tracing)," founded on the infectious disease law.

The government has been expanding the number of PCR tests by interpreting the infectious disease law differently or more broadly, or by extending coverage by the national health insurance. However, under the current laws there are limitations in implementing screening in medical institutions, daycare facilities and nursing homes, and companies, or mass testing of essential workers in a provisional manner. Moreover, these legal systems should be reconsidered in preparation for future epidemics involving diseases with much higher infectivity or virulence and strong infectivity in asymptomatic patients.

Thus, a flexible testing system should be built that allows active application of tests by private medical institutions and testing institutions, such as university medical schools, that are conducted to meet clinical medical needs in addition to government testing conducted by Public Health centers and Public Health Institutes in response to public health needs.

First, as a nation, clear goals should be set in terms of domestic and foreign testing facilities and testing capacities. At the same time, a clear system that allows the government (MHLW and NIID) to give orders to prefectural governments, etc. (Public Health Centers, Public Health Institutes) must be established.

Currently, government testing is performed as part of the "Active Epidemiological Investigation" for "Individuals with legitimate reason to be suspected to be infected by this infectious disease" (Item 3, Article 15, Infectious Disease Law). In order to allow medical institutions and physicians to order screening tests and tests for essential workers at their own discretion without involving the Public Health Centers, there should be national legal frameworks for testing in response to infectious disease emergencies. These tests should be paid for with public funds (if covered by health insurance, the out-of-pocket portion should be covered by public funds). All such test results, including negative cases, should be reported to systematize data processing.

The government should also provide directives on the tests voluntary performed by private companies and groups to maintain and stimulate economic activity while considering the division of roles between the public and private sectors. In such cases, consideration should be given to ensure there are no impediments to demand for tests at the time of a large-scale outbreak, which can be implemented by the Health Security Agency (HSA), which will be mentioned later.

b. Perspectives on hospitalization

In the future, legal frameworks should clearly define infected patients according to their severity, in line with criteria used in medical institutions, according to symptoms. Asymptomatic and mildly symptomatic patients should be isolated in hotels and other accommodation facilities, or in their homes. The framework to offer necessary human, material, and medical support should be clarified.

During a large-scale epidemic, the number of beds in designated medical institutions alone will not be able to accommodate all necessary hospitalizations when there is a surge in the number of patients. Legal frameworks to provide public funds to assist patients who are hospitalized in general medical institutions, according to the judgment of a community medicine physician and supportive measures to medical institutions, need to be created.

c. Perspectives on data

In order to fuse public health and clinical medical data and further boost its application, a system should be constructed to enable the sharing of data between the two to manage and digitalize collected data on infectious diseases.

3) Create and reinforce a group of infectious disease emergency management experts

In infectious disease risk management, a clear chain of command, mentioned in (2) above, and the various functions displayed in Table 4 below, are necessary. Accordingly, it is absolutely crucial to realize ① to ⑥ below.

Table 4

Organization	Information	System
➢ Joint operations of healthcare and public health	➢ Linking data from medicine and public health	➢ Unified legal system related to infectious disease emergencies
➢ Central and local government staff with specialized knowledge on how to respond to infectious disease risk	➢ Risk communication experts	➢ Assign the government effective authority for emergency response based on legal frameworks
➢ Chain of command for emergency response operations	➢ Staff in charge of monitoring infectious disease data from around the world during peace time	➢ To facilitate responses to the risk of infectious disease, separate the government's policy planning, drafting, and coordinating function from daily crisis response operations
➢ Secure a flexible organizational structure that allows surge capacity (staff with emergency experts from within and outside the government)	➢ Staff in charge of regularly sharing data on Japan's crisis response status with the international community	➢ R&D Facility 1 (Laboratory for basic research) ➢ R&D Facility 2 (Hospitals for treatment and clinical studies)
➢ Skill maintenance of central and local government staff through regular trainings and exercises	➢ IT network for unified collection and management by the government of domestic and foreign data on the risk of infectious disease	➢ R&D Facility 3 (Data collection and management system for epidemiological research)
➢ Thorough financing function		➢ Emergency Operations Centers (EOC) set up within the Cabinet Secretariat, MHLW, and Health Security Agency respectively

		▪ IT infrastructure that supports EOC data collection, analysis, and communication ▪ Sufficient physical space for the operations of a crisis response team physically united in one place under unified command ➢ A R&D fund that invests in diagnostics, drugs, and vaccines for emerging infectious diseases from non-crisis times

① Guarantee a technical response based on scientific evidence

In response to the risk of infectious disease, technical experts present scientific and technical options based on scientific findings available at the time to the government (Cabinet Secretariat and MHLW), and the Cabinet makes the ultimate decision as the central decision-making body. The body comprised of these technical experts will be called the Infectious Disease Emergencies Expert Council (provisional title) and will be legally positioned as a permanent advisory council to the Cabinet Secretariat. This Council will be composed of government and non-government experts in non-crisis times. In times of large-scale epidemics and other emergencies, experts with knowledge of specific infectious diseases will be added to the Council in order to ensure first-line expertise as a balanced advisory agency for the abovementioned Novel Coronavirus Response Headquarters. The configuration and content of Council discussions should be clearly disclosed to promote transparency of the government's decision-making process and the scientific evidence on which it is based.

② Technical and research organization for the responses to the risk of infectious disease: Establish the Health Security Agency（HSA; provisional title）

Four key duties, including medical responses, public health responses, risk response operations, and R&D, are necessary for drastic reinforcement of Japanese infectious disease risk management. Actions related to the implementation of these duties must be pursued in a consistent and collaborative manner, which would require support by a technical organization, the Health Security Agency（HSA, provisional title).[8] In order to respond adequately to infectious disease-related health risks, an organization that unites the four duties mentioned above is necessary. However, no such organization currently exists in Japan. Therefore, a new system should be built upon several existing parent organizations.

[8] The U.S. CDC and CDC-like organizations, such as the Chinese Center for Disease Control and Prevention, Korea Disease Control and Prevention Centers, and European Centre for Disease Prevention and Control, do not have medical facilities. They also fulfill roles other than infectious disease risk management, such as management of non-infectious disease measures. At the same time, the clinical function is also demanded as an essential element of infectious disease risk management. Therefore, in order to execute all of the functions required for infectious disease risk management, the HSA will be established as a technical organization to lead infectious disease risk responses by further evolving it beyond the functions of other countries' CDC-type organizations.

Furthermore, in establishing a new technical organization, it is important to clearly distinguish between the central, governmental functions (headquarters function) and technical functions (technical function).

The Cabinet Secretariat and the MHLW will create a strategy and execute infectious disease risk management for Japan as a whole, with a wide field of view based on their planning, drafting, and executive functions in policies related to infectious disease risk management. The HSA will study the vast body of scientific research on technical topics in basic medicine, clinical medicine, and public health necessary for daily crisis response operations. After identifying the tactics related to these individual fields, the HSA will simultaneously support operations of frontline organizations nationwide, coordinate the dispatch of expert teams as needed, and take responsibility for rapid data transfer to the central government. Thus, the Cabinet Secretariat and MHLW teams will be composed of different types of personnel. While the Cabinet Secretariat team will be composed primarily of administrative officials with expertise in infectious disease risk management, the MHLW team will be composed of a wide range of experts, from officials with expertise in infectious disease risk management, to clinicians, researchers in virology, bacteriology and epidemiology, IT engineers, and logistics specialists.[9]

In establishing the HSA, it is essential that it has the organizational structure that allows it to fulfill the responsibilities expected in this system. In other words, the government's chain of command in emergency must be defined clearly, sufficient funds must be allocated, and flexible placement of personnel (e.g., offering internationally competitive wages to attract competent foreign workers with expertise in R&D) must be possible. We will investigate setting up a new organization as a Specified National Research and Development Agency that meets these conditions.[10] [11] In order to do this, the NIID and NCGM, existing organizations that are currently partially fulfilling the

[9] The U.S. government has an organization called the United States Public Health Service Commissioned Corps with specialized capacity to work with public health risk management. Under the direction of the Surgeon General, it is on call to respond to any public health crisis 24 hours a day, 365 days a year. Working under the direction of the U.S. Department of Health and Human Services (HHS), the United States Public Health Service Commissioned Corps is stationed in HHS headquarters and in the CDC. CDC personnel comprise a certain percentage of staff. The Public Health Service Commissioned Corps staff can be dispatched to state governments as needed, and supports organizations serving on the frontlines of public health under a direct chain of command from the government.

[10] Based on legal evidence, the government (competent minister) can adequately implement risk measures under the direction of the government in the sense that it can ask the Specified National Research and Development Agency for measures in response to changes in the situation of affairs (Paragraph 1, Article 7, Act on Special Measures related to promoting research and development by the Specified National Research and Development Agency).

[11] Currently, three institutions are designated Specified National Research and Development Agencies: Riken, National Institute of Advanced Industrial Science and Technology, and the National Institute for Materials Science.

abovementioned four responsibilities (medical responses, public health responses, risk response operations, and R&D), will work under joined and integrated operations to form the nucleus of the new organization.

Specific measures will be promoted, even as we are mid-crisis in the COVID-19 epidemic, through drawing up specific measures and creating procedure tables for the establishment of the HSA, the R&D organization for responses to the risk of infectious disease in preparation for the imminent expansion of the COVID-19 epidemic. At the same time, necessary specific measures will be implemented as promptly as possible in order of feasibility in the interim period until the new organization is established. In particular, sections i and ii below outlining the Emergency Operation Center (EOC) and Emerging and Re-emerging Infectious Diseases Research Center (provisional title) require prompt budgetary measures.

i. Set up Emergency Operation Centers (EOCs) in the Cabinet Secretariat, MHLW, and infectious disease risk response technical organizations

In infectious disease risk management, the HSA will be established as a new technical organization that handles the daily management and operations in close cooperation with frontline organizations nationwide (medical institutions, Public Health Centers, Public Health Institutes, etc.) under the direction of an EOC specializing in infectious disease risk management, to be established in the Cabinet Secretariat. This technical organization will play an intermediary role between the government (Cabinet Secretariat and MHLW) and frontline organizations, and will offer specialized technical support in healthcare and public health functions. Emergency Operation Centers (EOCs) are necessary in order to achieve this.

That EOC will function as the hub for information collection, organization, and integration, as well as the chain of government command related to the risk of infectious diseases. At the same time, it will function as the technical response hub so that related agencies and organizations can respond flexibly under a unified top-down direction as decided by the government. Accordingly, unique EOCs must be established within the Cabinet Secretariat, MHLW, and HSA, and work in a coordinated manner in order to ensure functionality.

The following two elements are the minimum conditions that must be met by EOCs:

- Sufficient physical space for daily operations of emergency response staff physically united in one place under a unified command
- IT infrastructures that support the collection, analysis, and transmission of EOC data
-

The EOCs set up in the Cabinet Secretariat and MHLW will differ in scale from the EOC set up in the HSA, reflecting their differences in function. The Cabinet Secretariat EOC will plan and execute infectious disease risk management for the entire Japanese nation through a wide field of view, based on its planning, drafting, and executive function in related policies. Meanwhile, the MHLW EOC will study the vast body of scientific research on technical topics in basic medicine, clinical medicine, and public health necessary for the implementation of daily crisis response operations. After drawing up strategies related to those operations, it will simultaneously support operations in frontline organizations nationwide. That is, the MHLW EOC will require more capacity than the Cabinet Secretariat EOC (Fig. 9, 10, 11, 12).

In order for EOC-relayed responses to be implemented promptly during emergencies, it is important to proactively utilize EOCs in non-crisis times. Furthermore, skills of staff involved in risk response operations in the EOC should be maintained through regular training so that they can perform risk response operations whenever an emergency strikes.

ii. Emerging and Re-emerging Infectious Diseases Research Center (provisional title)

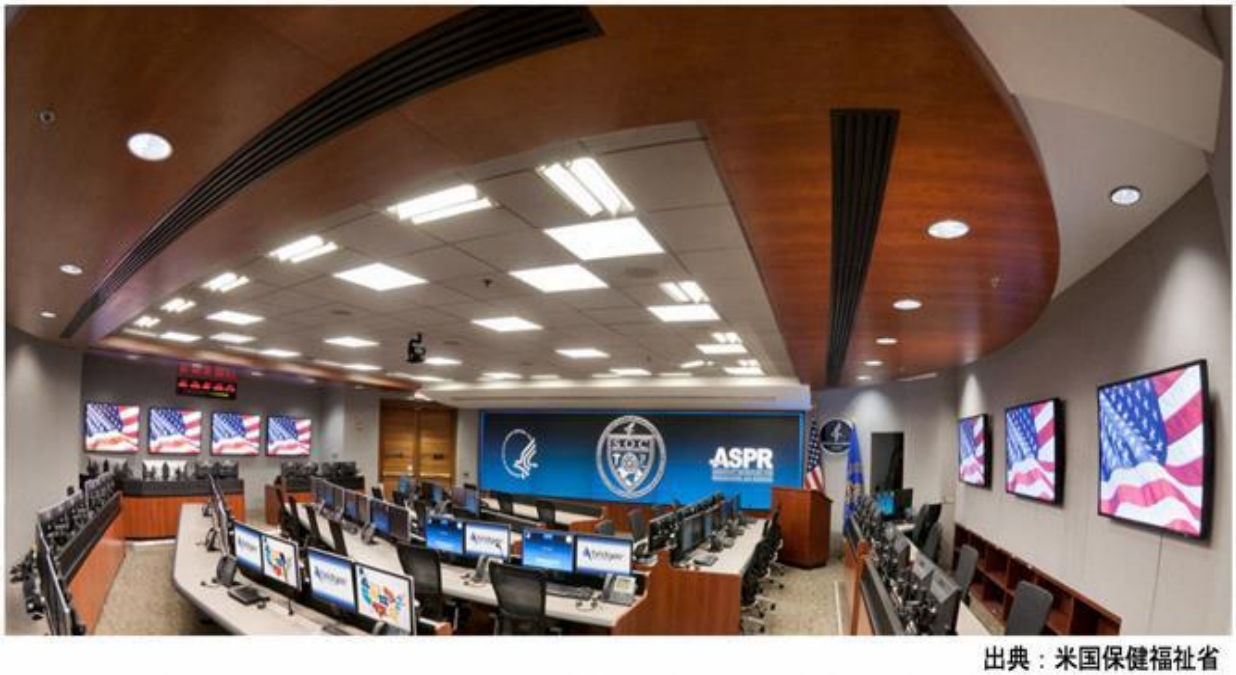
Research in the interim period, until the establishment of the HSA, will emphasize the promotion of clinical research and a system that can be utilized immediately as a research facility for testing and development of drugs and vaccines. During this interim period, the NIID and NCGM will use the research facility in a joint and integrative manner to promote close coordination between clinical, microbiological, and epidemiological researchers. This collective effort will radically strengthen the Japanese R&D force to enable it to offer immediate responses to emergencies, as well as to actively share data with the world, according to a given set of rules. The said research facility will be furnished with experimental and research facilities for BSL level 3 viruses and bacteria.

Figure 9: Image 1 of EOC to be set up in the Cabinet Secretariat and MHLW

出典：WHO

Source: WHO

Figure 10: Image 2 of EOC to be set up in the Cabinet Secretariat and MHLW



出典：米国保健福祉省

Source: USA Department of Health & Human Services

Figure 11: Image 1 of the EOC to be set up in the Health Security Agency (provisional title) (A space where 200 people or more can operate. To also be used in non-crisis times.)

出典：City of Los Angeles
Source: City of Los Angeles

Figure 12: Image 2 of the EOC to be set up in the Health Security Agency (provisional title) (A space where 200 people or more can operate. To also be used during peace time.)

出典：CDC

③ Public Health Centers and Public Health Institutes to be placed under the jurisdiction of the central government in emergencies

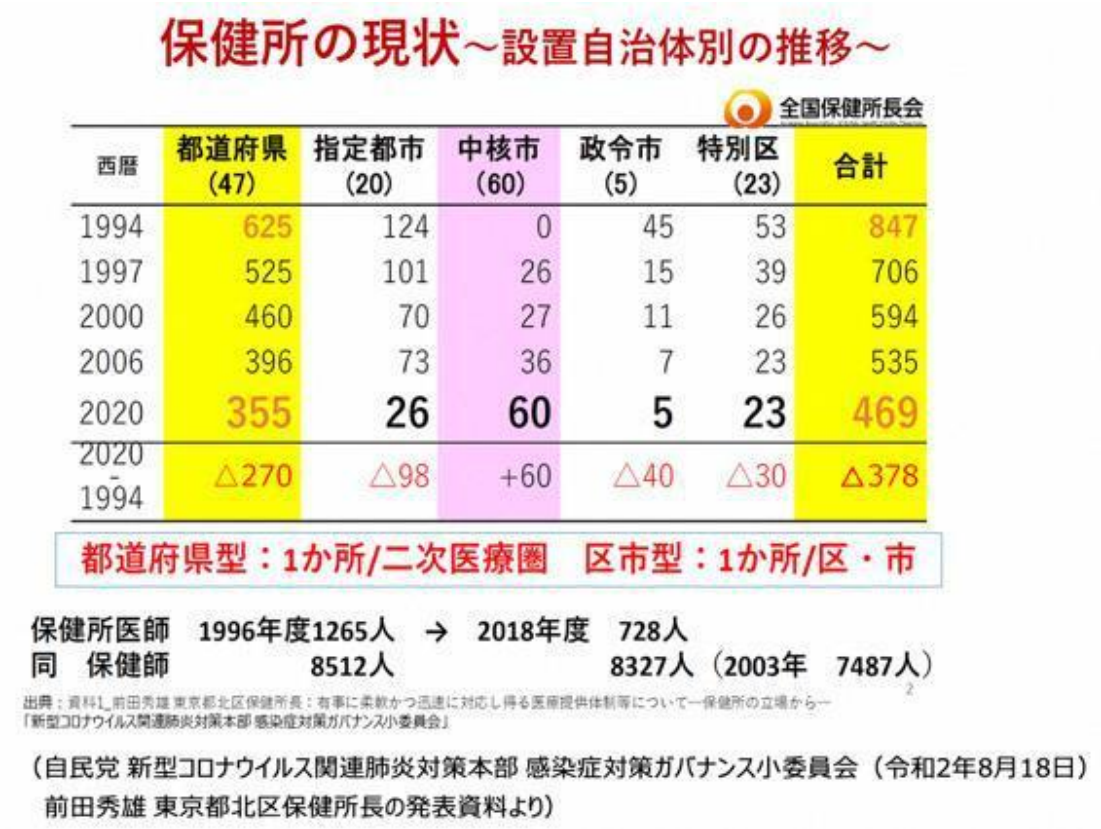
In order for the government to have centralized responsibility in infectious disease risk management and to implement risk responses under said centralized chain of command, frontline organizations across the nation must also be incorporated into that chain of command. Specifically, this would entail empowering the MHLW to give commands to governors and expanding the scope of measures that the MHLW can execute in the place of prefectural mayors. In doing so, the HSA, which will integrate the technical support related to infectious diseases under the direction of the government, will provide technical support for individualized risk responses in the Public Health Centers, Public Health Institutes, and medical institutions across Japan.

④ Maintenance and reinforcement of the functions of Public Health Centers and Public Health Institutes

Until the 1990s, there were approximately 850 Public Health Center locations throughout Japan. However, the merging of local governments has reduced the number to approximately 470 facilities today.

Table 5

Current state of Public Health Centers – Changes over time per local government under which centers are established



(source: Dr, Hideo Maeda, Director of the Kita Ward Public Health Center. Tokyo's presentation for the Liberal Democratic Party Infectious Disease Measures Governance Subcommittee, Novel Coronavirus Response Headquarters. (August 18, 2020).

Furthermore, Public Health Institutes have not clearly defined their legal position or function in the Administrative Vice-Minister of Health and Welfare's Notice: Guidelines for Establishment of Public Health Research Centers" (March 14, 1997 MHLW Health Policy Bureau Report No. 26） nor any document on law enforcement. Therefore, certain prefectural and other local municipalities may be suffering from insufficient staffing or funding.

Public Health Centers and Public Health Institutes are the organizations closest to the frontlines of risk response in an infectious disease emergency. Organizing related laws will ensure the establishment of such facilities under local governments, as well as create a system to place Public Health Centers and Public Health Institutes effectively under the central government's chain of command in the event of a health risk as mentioned above.

Moreover, technical staff members are currently limited to those licensed with national certifications in healthcare (physicians, veterinarians, dentists, pharmacists, public health nurses, etc.). Given that expertise in public health is required in addition to these clinical specializations in responding to health risks, positions for candidates with Masters Degrees or Doctoral degrees in Public Health will be newly created.

⑤ Building surge capacity (preparation in non-crisis times to make immediate response possible)

In responding to crises, it is important to consider the gap between personnel needed in non-crisis times versus the number of staff needed during emergency times. Indeed, it is difficult to remain fully staffed for an emergency at all times. This is why staff members who can be on-call for emergencies should be identified before an emergency happens, and be working in other jobs and fulfilling other responsibilities in non-crisis times while maintaining their ability to create ad hoc organizations to respond to emergencies.

Moreover, the medical system should have the capacity to respond to infectious disease-related health risks at all times. Thus, emerging and re-emerging infectious diseases need to be promptly added to the list of "Five Projects, Five Diseases" under the medical plan defined by the prefectures.

⑥ Staff training

Although training programs such as the Field Epidemiology Training Program (FETP) offered by the NIID and the Infectious Disease Emergency Specialist Training Program (IDES) offered by the MHLW currently exist, there is insufficient follow-up

after completion of these programs. Therefore, recruitment of emergency staff from graduates of these programs has been low. In that sense, the primary goal of these training programs currently remains unachieved.

The FETP and IDES programs should be expanded dramatically, and graduates should be recruited in emergencies. Moreover, systems that allow recruitment from expert associations, such as the Japanese Society of Public Health, should be established. With cooperation of the NIID and the NCGM, drills and training meeting international standards should be conducted by the National Institute of Public Health of Japan. Moreover, a system should also be built at the government level. Schools of public health throughout Japan should also be considered for participation.

Cooperation with university hospitals (Ministry of Education), and Self-Defense Forces hospitals (Ministry of Defense) should also be attempted.

4) Digitize responses to infectious disease risks and application of large-scale data

Necessary revisions need to be made to laws related to handling of large-scale medical and public health data in responses to the risk of infectious disease.

In responses to the risk of infectious disease, it is important to propose measures based on rapid information transmission, sharing, and analysis. The amount of data that should be handled is extremely large, ranging from incidence reports of infectious diseases to patients' chart data, and genomic data of specimens. Moreover, confidentiality issues require numerous steps and procedures, such as regulations concerning the protection of personal information and obtaining consent to provide information due to ethical considerations.

In order to expedite and facilitate efficient handling of information, collection of information and specimens and the lines of management should be converged and centralized under the MHLW and NIID and legally founded[12], as well as completely digitized and shifted online. Use of online systems and centralized management by the national government for infectious disease-related data collection should be prescribed in related laws. Collected data on numbers of patients and excess deaths should be presented in a format compatible to global standards in research (e.g., CVS files). Prompt publication of the data with consideration for personal information without being impeded by the so-called "2000 problems" with the personal information

[12] Surveys, information, and data from Public Health Centers and Public Health Institutes will converge within the HSA. At the same time, data, and trends in a large-scape epidemic; surveys on the causes; and authority and roles on data collection, management, and disclosure will be strengthened.

protection system should be made compulsory to promote active use of the data. This should be investigated on the premise that it would enable rapid development.

The costs associated with creating the system for this purpose will be covered by public financing by the government. At the same time, it is important to ensure that the beneficiaries of this system are the population and medical staff who provide medical services using the data.

5) Strengthen the relationship and communication between the general population and government

i. Clear accountability of the government and citizens' responsibilities

To protect citizens' lives and the economy in implementing responses to the risk of infectious disease, the government must pose restrictions on citizens' assets, rights, and freedoms that would not be ratified during non-crisis times in adherence with public health guidelines provided by the law. This is why the government has the responsibility to disclose the scientific evidence and decision-making process when exercising that power.

On the other hand, the population is requested to commit to voluntary, community-based preventive measures with the understanding that individual behaviors can affect the spread of the epidemic for the entire nation and determine the fate of citizens' lives and societal and economic stability in direct and indirect ways.

After the roles and responsibilities of the government and the people have be redefined, they will be written into law as principles. Investigation into how to ensure effectiveness (penalties, etc.) will also be pursued.

ii. Appointment of risk communication experts

For infectious disease risk management, the cooperation of the entire population is essential, in addition to the government and local government staff who actually perform the tasks related to risk management. To ensure that citizens cooperate, the government must provide thorough risk communication; that is, wide and routine sharing of data and explanation related to the risk, guaranteeing information transparency and accountability. However, these conditions require human resources with specialized training in risk communication. In some foreign countries, these experts routinely engage in communication at times of crisis. Risk communication and behavioral science specialists will be appointed to the organization specialized in infectious disease risk management set up in the

Cabinet Secretariat and the MHLW to increase transparency and accountability in information transmitted from the government in emergencies.

6) Build legal frameworks and procedures that ensure flexible system operations in crisis

In crises, difficult situations that would be unconceivable in non-crisis times may easily occur. In the face of events beyond expectations, the Incident Commander and their staff must handle and overcome the challenges through the flexible use of existing systems and structures. Legal frameworks that allow such use of the system need to be built. Furthermore, health risk contingency drills must be practiced in non-crisis times to practice the procedures pursuant to flexible use of the system in an emergency.

Furthermore, revisions to government ordinances and law amendments take a certain period of time, and are not suitable in situations where a major epidemic is expected, because such a situation requires a quick and appropriate first response. As a result, a quick and flexible response to emerging and re-emerging infectious disease epidemics can only be made possible by modifying regulations or considering the creation of new types of emerging infectious diseases, and implementing appropriate measures depending on infectivity findings and other characteristics of the disease to prevent its spread gradually as needed.

7) Establish a fund for industry-academia-government partnership in research and development of new drugs for infectious disease crisis

In the event of a health risk, R&D of diagnostics, drugs, and vaccines based on knowledge of the characteristics of the pathogen of emerging and re-emerging infectious diseases must be started promptly. Particularly during an epidemic involving an unknown infectious disease as is unfolding currently, the nation must promptly disclose basic data on the infectious disease, such as the isolated pathogen and genomic data. The value of the disclosed data will be further increased by constructing data publication tools or systems so that pharmaceutical companies, universities, and other research laboratories will be able to use them in testing drugs or the R&D of new treatments. Moreover, under the leadership of the nation, a scheme that allows the prompt collection of “all-Japan” findings (e.g., a consortium that involves pharmaceutical companies, medical workers, and other industries such as IT companies), the three elements of research funds, research organizations and facilities, and researchers should be secured before a health crisis actually occurs through partnership between industry-academia-government. In other words, it is desirable that an infectious disease risk management pharmaceutical R&D fund be established. These

efforts should help build systems that will allow fast-tracked R&D in the area of risk management of emerging and re-emerging diseases and other infectious disease, on which market mechanisms are less likely to apply.

However, the ultimate goal lies in the outcomes of research (i.e., a product that becomes widely used). Therefore, measures that increase access to the deliverables (drugs, vaccines, etc.) must be implemented at the same time. For example, measures could include government procurement agreements of products (procurement and stockpiling of the product even if the epidemic is over, and priority review vouchers to incentivize developers and manufacturers).[13]

8) Revise the National Institute of Infectious Disease's role in vaccine-related operations

Vaccine manufacturers are responsible for conducting in-house testing before supplying the vaccines that they manufactured or imported to the market, conforming to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. The NIID performs the national test on all lots (i.e., double-checking). This national test system ensures standard quality, safety, and efficacy of products, and hence it has been considered a rational and necessary function of the NIID. However, encouraging our nation's vaccine makers to develop a quick supply is also an important challenge. In these contexts, irrationally excessive quality standards and regulations could turn to be obstacles, which drives foreign vaccine manufacturers to join the international market, R&D, and overseas sales of Japanese vaccine manufacturers' products, or international cooperation such as in Gavi, the Vaccine Alliance. Moreover, such stringency also shortens the expiry date of products, as well as requires more time for delivery, which could collectively hamper our national security, public health, and international competition.

The national vaccine testing system conducted by the NIID, a completely separate organization from the Pharmaceuticals and Medical Devices Agency（PMDA）, which conducts drug approval and screening, inevitably requires manufacturers to deal with dual approval, dual discussion, and consequently, creates a dual burden in that they must have their products approved by the two institutions. As a side note, in the

[13] The Biomedical Advanced Research and Development Authority (BARDA) can be named as an example of such a fund, with a venture capital feature that invests to help the growth of biotechnology companies owning seeds of crisis-response drugs. The Japanese counterpart, called the Global Health Innovative Technology (GHIT) Fund, which works with the development of drugs for tropical diseases for which market principles do not apply, has been making great achievements through the joint investment mechanism of the Japanese government, industry, and international public utility foundations.

U.S., Canada, and many countries in the EU, such testing is generally conducted by the same agency that is responsible for drug approval and screening.

Thus, the NIID and NCGM will evolve into the HAS. Together they will be reborn as an infectious disease control organization, unique in the world in that it possesses a clinical function. In order to specialize into an organization with the most advanced expertise, the national testing of vaccines, which does not necessarily require cutting-edge findings, will be transferred from the NIID to the PMDA, which has been in charge of approval and safety assessment of pharmaceutical drugs. Based on the assumption that there are no changes to the safety standards, testing will be implemented promptly and accurately based on quality standards and regulations conforming to global standards. At the same time, we seek to accelerate and increase efficiency of safety and quality control by classifying tests into two categories according to the risk level of the product: "a) Document review only, or b) Document review and random sample or whole-lot testing" to lower the burden and increase competitiveness of the vaccine industry.

Furthermore, the data and outcomes of research that the NIID has been collecting on infectious disease should be published quickly so that it is widely available for analysis from varied angles and for effective development of vaccines by manufacturers.

5. Future processes: follow-up by the subcommittee

In order to accomplish the infectious disease risk management governance reform described in the above sections, it is essential to pursue necessary procedures with regards to budget and positions at the same time as the general reforms to the entire set of related legal systems.

Specifically, the following will be executed steadily by the government, and this subcommittee will follow-up regularly on this process.

1) Law amendments

Reforms to the entirety of the relevant legal system (novel influenza special measures act, infectious disease act, quarantine act, community health laws, Cabinet laws, Act for Establishment of the Ministry of Health, Labor and Welfare, etc.) with congruency requires considerable discussions and work. Therefore, we will promptly begin preparation with the aim of amendments for urgent items in the next Extraordinary Diet Session, or, at the latest, in an early Ordinary Diet Session next year. At the same time, considering the short-term responses to COVID-19, particularly

considering appropriate measures during the seasonal influenza season this winter and necessary procedures for vaccinations tentatively scheduled for the first half of next year, there are challenges that rapidly require considering law amendments.

Therefore, laws will be amended in two stages. First, the various specific issues that must be discussed in the Extraordinary Diet Session this fall are as follows:

i. To secure vaccines to vaccinate all citizens in the first half of next year, the government will compensate vaccine manufacturers for the losses they incur
ii. Further increase effectiveness of powers that are stipulated by the current laws
iii. Determine the legal position of resting at home
iv. Re-organize the power and coordination of and between mayors of cities and special wards where Public Health Centers are located

In order to do this, collective reforms will be implemented again next year to emphasize congruency between all related laws and incorporate necessary elements to realize the recommendations within this document.

2) Budget/Positions

The budget has already been appropriated for the second supplementary contingency reserve this year. If there is a tentative third supplementary budget, costs will be covered by a supplementary budget as needed. Increased positions needed in accordance with the law reform will be covered as needed by the general budget.