The 7th Nikkei FT Communicable Diseases Conference

# Yokohama Communicable Diseases Statement 2020

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## 0. Introduction

As globalization deepens the interconnectedness of nations, Japan engages in growing interaction with Europe and the US but also with Asian nations in economic, social, and cultural spheres. With the relationships between African countries also actively strengthening, the risks brought about by emerging and re-emerging communicable diseases such as Ebola virus disease, tuberculosis, malaria, and antimicrobial resistant (AMR) bacteria, are ever increasing at global level. Moreover, the COVID-19 pandemic which began in 2020 has highly alerted the global society that the communicable diseases threatens not only the people's health, but also social and economic activities. Thus, it is of extreme importance to take this as an opportunity to further discuss communicable disease countermeasures and share the outcomes of the discussion between all the related parties including the public citizens.

This conference was first held in 2014 as the Nikkei Asian Conference on Communicable Diseases, bringing together the representatives of the private sector, academia, and government officials responsible for health from both within and outside Japan, with an objective to propose P3 (Public-Private Partnership) projects to tackle various challenges against communicable diseases. Taking advice from participants of the 6th Nikkei Asia Africa Conference on Communicable Diseases that this conference would contribute not only to Asian and African but also to global communicable disease control, this year the conference title has been changed to the Nikkei FT Communicable Diseases Conference. Even though overseas traveling was restricted due to the influence of the COVID-19 pandemic, key figures from around the globe gathered in person and virtually in Yokohama, Kanagawa for the 7th Nikkei FT Communicable Diseases Conference on Nov 6 and 7, 2020.

The conference started by reviewing the national and global efforts against COVID-19, and then moved on to discussions focusing on future countermeasures. Important topics included a rapid and pertinent first response (including border control), a transverse and accurate information gathering system, containment measures, scientific research projects to support communicable disease control, a system in which the government can make policy decisions and act upon optimum plans proposed by experts based on the latest scientific knowledge, a system where regional hospitals can cooperate and provide medical care, securing a supply chain of medicine and medical supplies required for communicable disease control, proper distribution of information (risk

communication) that will lead to public understanding and modification of behavior, the usage of ICT (Information and Communication Technology), the balance between personal privacy and public benefit, and public participation in policy decision making during the midst of an epidemic. As the examples of the latest developments to overcome the COVID-19 pandemic, Japanese innovations in diagnostic drugs, treatment drugs, and vaccines and cutting-edge technology seeds born in and outside Japan were also introduced. It was confirmed that the preparedness towards an unseen future pandemic is essential, under the common consensus that many of the issues and countermeasures being applied not only to COVID-19 but to other emerging and re-emerging communicable diseases as well.

In order to plan and execute various P3 projects, since 2014, volunteers among participants of the Nikkei FT Communicable Diseases Conference have been organizing the "Asia Africa Medical Innovation Consortium (AMIC)" which consists of consortiums working in multiple themes. The newest progress status and development of such P3 initiatives was also reported at the conference. For example, AMIC's Asian Clinical Trials Platform consortium has been working on a P3 clinical trials platform to be installed in Thailand and Indonesia and reported that they are successfully moving forward with support from the Japanese government. Through open discussions between a wide range of personnel, the conference participants confirmed the necessity and efficacy of P3 initiatives.

Furthermore, such future actions as deregulation for emergency use of Japanese treatment drugs overseas in case of an outbreak such as Ebola or COVID-19, Malaria P3 projects in Asia and Africa, proposals to support the development of new antimicrobial resistance (AMR) drugs, plans to improve public health such as universal health coverage (UHC), the active use and promotion of the latest technological innovations for communicable disease control, proposal for new P3 initiatives such as the foundation of a pandemic lab (so called "Emergency response central testing lab") as a preparation towards future communicable disease pandemics, were suggested.

Through an active plenary panel and diverse sessions, conference participants unanimously adopted the Yokohama Communicable Diseases Statement 2020. The statement will be widely addressed not only in Japan, where the achievements will be reported at related government meetings, but also widely to the global society in Asia, Africa and around the world. Using this deeper level of international understanding as leverage, Japan will be able to fulfill its responsibilities to make a stronger commitment to combatting communicable diseases worldwide.

Please refer to the following links for the statements from the previous conferences;

https://project.nikkeibp.co.jp/event/6thnac2019/statement2019_en.pdf
https://project.nikkeibp.co.jp/event/5thnac2018/statement2018_en.pdf
https://project.nikkeibp.co.jp/event/4thnac2017/okinawastatement2017_en.pdf
https://project.nikkeibp.co.jp/event/3rdnac2016/3rdnac_tokyo2016_statement_en.pdf
https://project.nikkeibp.co.jp/event/2ndnac2015e/OkinawaCommunicableDiseasesStatement2015.pdf
https://project.nikkeibp.co.jp/event/1stnac2014/OkinawaCommunicableDiseasesStatement2014.pdf

## 1. Countermeasures Against COVID-19 in Japan (Interim Report as of Nov. 2020)

As of the end of October 2020, the number of people who tested positive for COVID-19 in Japan was about 100,000 and the number of deaths was 1,755 (*1). The number of confirmed cases per million people was 794, the number of deaths per million was 13.9, and the observed case-fatality rate was 1.75%. (Population of Japan: about 126 million). Looking at the figures, the numbers pale in comparison to Taiwan, which experienced Severe Acute Respiratory Syndrome (SARS), and to South Korea which experienced Middle East Respiratory Syndrome (MERS). However, the figures are better compared to the United States and European countries. Considering Japan's high proportion of the elderly population, COVID-19 infections and deaths have been kept low as of October 2020. Japan's infection control measures are internationally recognized as relatively successful.

However, we cannot say that Japan was sufficiently prepared, as the country had never in the past confronted a critical situation due to emerging communicable diseases such as SARS. Also, during the 2009 outbreak of the H1N1 influenza, the mortality rate in Japan remained low. Although communicable disease control began with such disadvantage, it is thought infection was suppressed to a certain degree due to the combination of the following factors:

(1) publicized the so-called "3C's" slogan (Avoid Closed spaces, Crowded places, Close-contact settings) to citizens at a relatively early stage

(2) healthcare providers pushed to secure access to medical care

(3) workers at public health centers and local governments made efforts to identify and respond to clusters at an early stage

(4) citizens had strong hygiene awareness and took action

However, we cannot deny the possibility of a "Factor X" particular to Japanese and other Asians such as cross-immunity and genetic factors. Also, the domestic epidemic strains may possibly be less pathogenic compared to those in other countries. Thus, it is necessary to continue looking into why Japan has been able to control the infection to a certain extent. After this year's conference, Japan was hit by the 3rd wave of COVID-19, thus we must introduce new countermeasures and stronger communicable disease control. The following is a summary of Japan's communicable disease control measures; an outline according to theme, issues that have risen, and actions to take in order to solve the issues.

*1 https://www.mhlw.go.jp/stf/newpage_14546.html (Japanese)

## 1-1 Domestic Preparedness

### [Outline and Issues]

As mentioned above, it can be said that Japan was not sufficiently prepared. Since 2000, the world has faced numerous crisis of new communicable diseases such as SARS in 2003, MERS in 2012, and Ebola hemorrhagic fever in 2014. However, in Japan, very few people were infected and the country did not experience the crisis. Moreover, during the 2009 outbreak of H1N1, Japan's mortality rate per 100,000 population was the lowest in the world.

Following the outbreak of the H1N1 pandemic in 2009, the Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response ("Tokusoho") was enacted in April 2012 in order to strengthen measures against communicable diseases. At the same time, preparations for highly pathogenic bird flu and pandemic influenza were being discussed in Japan. However, these discussions did not include other possible communicable diseases which are highly infectious but not highly pathogenic like COVID-19.

Initially, the government dealt with COVID-19 under the Infectious Disease Law and the Quarantine Act. However, as the infection spread, the government revised this in March 2020 in order to be ready just in case. COVID-19 was added to the revision, giving legal authority to prefectural governors to issue a state of emergency, and request or

instruct people to refrain from going out or going to school. However, these restrictions had no legal force or penalties for violation as they do in Europe and in North America.

In addition, the lack of preparation became apparent in many respects in adopting measures for communicable disease control. There was an overwhelming shortage of manpower in medical institutions during the acute phase at the start of the COVID-19 outbreak. Likewise, there was a lack of manpower to handle numerous tasks in public health centers, public health institutes, and local governments. The system was found to be fragile. There was not adequate coordination between local governments and public health institutes, and between the national government and local governments. The roles and discretion of the national government and local governments were not clearly defined. As there are frequent changes in the government's elite personnel, only a limited few had experience in crisis management of communicable diseases. It was also revealed that the academia system was not adequately organized to promptly carry out research that would contribute to communicable disease control in such emergencies. The government was also not prepared to make policy decisions based on expert evaluations or communicate them to the public in a clarifying manner.

**[Actions to Take]**

We must learn from the fact that Japan was not able to utilize the knowledge gained from the 2009 H1N1 influenza outbreak, and prepare for various emergency scenarios.

① Establish national governance for crisis management and conduct proper risk management.

② Simulate emergency situations, develop human resources, and identify relevant communities and companies. For example, develop human resources and networks that can solve research questions contributing to communicable disease control at times of an emergency.

③ Establish a system in the government that can act as a control tower, responding to emergencies as one team. The team would include related government ministries, companies and academia.

## 1-2 Border Control

### [Outline and Issues]

Japan dealt with border control in the early stages of the spread in response to the cluster on the British-registered cruise ship Diamond Princess. The cruise embarked on January 20 from Yokohama Port, making stops in Okinawa and Hong Kong. Infected people were found on board the ship which returned to Yokohama on February 3. A total of roughly 3,700 passengers and crew members were forced to wait on board. When they finally disembarked on March 1, 706 people had been infected and 4 had lost their lives. At that time, Japan had set up a control tower function in the prime minister's office making it possible for cross-ministerial cooperation among the Ministry of Health, Labour and Welfare, the Ministry of Land, Infrastructure, Transport and Tourism, the Ministry of Foreign Affairs and the Ministry of Defense. This led to the success of suppressing newly infected cases after the start of quarantine on board. However, there was a delay in informing the public about the specific measures being taken on board and what the results were. For this reason, it led to misunderstandings inside and outside of Japan.

It was a complicated situation in which the ship was registered in the UK, operated by the US and docked in Japan. Nevertheless, from a humanitarian perspective, Japan took steps to cover all necessary costs. However, it was pointed out that if the situation involved the interests of multiple countries and presumed difficult for one country to make decisions, it would have been possible to promptly inquire the WHO or the United Nations for international consultation and coordination. If the measures taken by the Japanese government become the accepted rule if in the future, it raises concerns because countries may refuse to let ships dock when there is an outbreak on board. We must simulate such situations and discuss border control issues as a broader international matter.

As measures for border control, the Japanese government has taken steps since January to prevent COVID-19 from entering the country and to stop the spread of the virus. They include measures such as immigration restrictions, travel advisories, testing of returnees, and stepping up quarantine. On January 30, the WHO declared that the outbreak constitutes a Public Health Emergency of International Concern (PHEIC) and the US issued a "Do not travel" advisory and an evacuation advisory. On February 2, persons with a recent travel history to China were banned from entering Japan and on March 5, landing restrictions were put in place for flights coming in from China and Korea.

Judging from the genome sequence analysis of viruses collected from across Japan, it is thought that the transmission of the virus that stemmed from Wuhan, China and came into Japan up until the end of January has been completely contained. However, regarding entry from Europe, where infection had been surging since March 2020, the Japanese government did not put landing restrictions in place despite the government expert panel's urgent request to take action. Border closure was delayed and denial of landing from European countries was not put into place until April 3. Behind the delay in responding to Europe, discussions were being held to examine the consistency of domestic and regional infection control and border control. In addition, information from related ministries and agencies were being collected. Making decisions based on such information took time, and as a result, the delay allowed the EU virus strain to make its way into Japan and spread. Furthermore, the system used by local medical institutions and public health centers to systematically collect data on infection was inadequate. As the government could not immediately grasp the country's infection status, critical information was not reflected in policy decisions.

[Actions to Take]

① When taking measures to both activate the flow of people and goods (the economy) and to suppress the influx of communicable diseases, the timing of execution should be determined with sound judgement. The judgement should be based on analyzing the information collected comprehensively and routinely from relevant ministries and agencies.

② It is necessary to build a system to accurately and quickly grasp the domestic influx of communicable diseases. This is not limited to the issue of quarantine. Rather, a system which systematically aggregates and analyzes the information accumulated in domestic medical institutions and public health centers is crucial.

③ For cases such as outbreaks on cruise ships, it is necessary to have international and transparent discussions that include organizations such as the WHO, and swiftly develop a structured set of rules on how to share the responsibility for cases involving multiple countries; ship registration, operation, and port of call.

④ As closing and reopening of borders have a significant impact on the lives of citizens and on economic activities, it is necessary to carefully explain and gain understanding from the people through thoughtful risk communication.

### 1-3 Surveillance and Collaboration System (Public Health Centers and Prefectures)

**[Outline and Issues]**

The goal of COVID-19 surveillance is to accurately understand the spread of the infection and to enable public health authorities to effectively manage COVID-19 risks. In the interim guidance on surveillance released on May 10, the WHO stated that the objectives of COVID-19 surveillance include:

- enable rapid detection, isolation, testing, and management of suspected cases
- identify and follow up contacts
- guide the implementation of control measures
- detect and contain outbreaks among vulnerable populations
- evaluate the impact of the pandemic on health-care systems and society
- monitor longer term epidemiologic trends and evolution of the COVID-19 virus
- understand the co-circulation of the COVID-19 virus, influenza and other respiratory viruses

Surveillance in Japan has been conducted using a system where information from public health centers is collected by the Local Infectious Disease Surveillance Center in each prefecture. This information is gathered by the Infectious Disease Surveillance Center at the National Institute of Infectious Diseases and reported to the Ministry of Health, Labour and Welfare. The public health centers standing at the forefront of COVID-19 surveillance has stretched beyond its capacity in providing consultation services. Citizens complained about their phone calls not getting through.

Data gathering on the outbreak of COVID-19 took place as follows: If an individual is confirmed positive, the doctor fills out a COVID-19 form by hand. It is faxed to the public health center where a staff enters the information into the National Epidemiological Surveillance of Infectious Diseases (NESID) system. Abiding by this conventional procedure made it difficult to collect information with speed and accuracy.

As a result, the Health Center Real-time information-sharing System (HER-SYS) was created separately from the conventional surveillance framework. Currently, 99% of local governments can aggregate information of infected cases by typing into this system. However, many medical institutions are not entering data into HER-SYS. Doctors are still sending the information by fax, and the staff at public health centers must type them into the system. This is time-consuming and there is a time lag in the calculation of data. HER-

SYS is designed to collect prognostic information such as hospitalization, discharge and death, but lacks the ability to systematically process the information.

The source of information on the number of infected cases viewed daily by the public is the press release sent out to the media by local governments nationwide. These are the numbers that the public tend to believe and rely on. COVID-19 clusters are occurring all over the country and detailed information is accumulated in local medical institutions and public health centers. However, there is no system to systematically aggregate that information.

Public health surveillance requires much effort by medical institutions and public health centers, but currently, the burden exceeds their capacity and HER-SYS is not being fully utilized. As a result, various countries are voicing complaints that Japan, which drew worldwide attention for the success of keeping the number of infected cases and deaths under control, is not providing enough information. In order to realize effective public health surveillance, it is a top priority to reduce the burden by allocating more human resources and increasing the budget.

**[Actions to Take]**

① Promptly build a system that can quickly share COVID-19 status information between local governments and the central government.

② Provide human and financial support to local medical institutions and public health centers that are critical for surveillance.

③ Introduce bold innovations such as apps in order to carry out surveillance effectively.

### 1-4 Purpose and Strategy for Testing

**[Outline and Issues]**

There are 3 types of diagnostic tests for the novel coronavirus. The PCR test, antigen test, and antibody test. In order to utilize these modules aiming to prevent the spread of infection and severe illness in patients, we need to understand the efficacy, limitations, and purpose of each test.

The PCR test, which detects the genomic sequence of the virus, was the only diagnostic test available in Japan at the start of the pandemic and therefore attracted much attention. It was publicized that the number of tests being conducted in Japan was very low, leading to public anxiety and the low number of COVID-19 tests became a social issue.

After studying the correlation between the number of tests per population and number of positive cases in various countries, it was confirmed that countries with high positive cases were doing more testing. It was also apparent that an increase in the number of testing does not necessarily lead to better control of the spread of infection. Yet, testing is an important tool in communicable disease control, and it was agreed that Japan should increase testing capacity and strategically utilize diagnostic tests along with other measures.

There are 3 purposes for conducting a PCR test.

1. To gather information of COVID cases and quarantine patients in hospitals in order to prevent the spread. (Administrative testing)
2. To provide appropriate medical care and prevent hospital acquired infections. (Medical testing)
3. To clear individuals for social and economic activities. (Private testing)

After COVID-19 was designated as an infectious disease, the Ministry of Health, Labour and Welfare established a standard for conducting PCR tests. Cases with “a fever higher than 37.5 ℃ or respiratory symptoms” were tested. By limiting the conditions to conduct tests, the number of positive cases was controlled, which is one aspect of why Japan was able to avoid a collapse in the medical system.

On July 16, the Novel Coronavirus Infectious Disease Control Subcommittee put together the “basic rules and strategies for testing”. It classified testing subjects into the following 3 categories and stated the basic approach for testing.

(1) Symptomatic: Must secure immediate testing to these clinically suspicious patients

(2a) Asymptomatic with high risk of infection/high pre-test probability: Should test close contacts and groups which could form a cluster

(2b) Asymptomatic with low risk of infection/low pre-test probability: Need to discuss whether testing will contribute to stopping the spreading of infection

There is no doubt that testing is an essential tool to control the spread of infection, but we must not overestimate its capacity and carry on with a clear purpose and reason and conduct tests in a structured system.

[Actions to Take]

① As testing capacity increases, we must build and implement a strategy on who must be tested and for what purpose.

② Nucleic acid amplification tests (such as PCR tests), antigen tests and antibody tests should be utilized in accordance with their characteristics.

③ Medical institutions and private testing centers must secure quality control of their tests.

④ The purpose of PCR tests (and other tests) needs to be explained to the public to gain understanding.

⑤ Consider the establishment of a private testing organization (tentatively called the Pandemic Lab) which will conduct general testing in normal times but can respond to emergency situations such as a communicable disease pandemic and conduct required testing.

## 1-5 ICT and Infection Control Measures Utilizing Big Data

[Outline and Issues]

How to utilize ICT and big data in measures against the novel coronavirus have attracted attention. In addition to the aforementioned HER-SYS, Japan has taken the following initiatives:

(1) Contact-Confirming Application (COCOA)

In March 2020, Singapore's domestic distribution of a smartphone app to trace infection routes became a hot topic and many countries followed with similar efforts. In Japan, the government's Anti-Covid-19 Tech Team that launched in April 2020, developed a contact tracing app in collaboration with the Ministry of Health, Labour and Welfare.

Several private companies were developing or pursuing the idea and the government was considering moving forward to ensuring compatibility between the apps. However, on May 4, 2020 Apple and Google, developers of smartphone OS (operating system) announced they will limit the development of apps using their technologies to public health authorities. As a result, the Ministry of Health, Labour and Welfare decided to collectively develop the app within the framework of HER-SYS.

COCOA uses short-range wireless communication technology (Bluetooth) on smartphones to detect "contact" when users are within 1 meter of each other for 15 minutes

or more. The “contact” record is encrypted and recorded only in the user’s smartphone for 14 days. Personal information is not obtained. When a person who tested positive enters the “processing number” issued by HER-SYS into the app, the notification server will notify the app of the person who may have had close contact with the infected person.

The Ministry of Health, Labour and Welfare released a trial version on June 19, 2020. However, even after the one-month trial ended, developers were still busy debugging the system. As of November 2, 2020, the app has reached approximately 19.21 million downloads. The adoption rate in Japan is only 15.1%. One reason being that not many people have a full understanding of COCOA. Behind this is the public’s general distrust in politics and the government.

Some of the world’s contact tracing apps, such as ones in China, South Korea and Taiwan, acquire location information from smartphone GPS data and capture personal movement history. This GPS type is desirable when considering solely infection control. However, in Japan a consensus on privacy matters could not be reached which led the government to respect the Act on the Protection of Personal Information and settle with an app that does not acquire personal information. At the conference, it was discussed that although we should implement an app with functions to conduct public health measures, we should always consider both public welfare and personal rights based on the Japanese constitution and infectious disease control law.

(2) Utilization of Mathematical Models and Big Data

As a measure against the novel coronavirus, the government adopted a mathematical model of infectious diseases for the first time. In this model, the effective reproduction number (the average number of people one person can infect if they have the virus) goes down if measures are taken, and goes up if nothing is done.

On April 7, 2020, Japan declared a state of emergency. Prime Minister (at the time) Shinzo Abe stated that “if we could reduce human-to-human contact by 80%, new cases will peak in 2 weeks and start to decrease after that.” The basis for this statement was a simulation conducted by the Cluster Response Team of the Ministry of Health, Labour and Welfare. In order to evaluate the 80% reduction, they looked at the population decline rate at points where people gather, such as major stations and downtown areas. Big data called “human flow data” provided by cell phone companies, railway companies and search engine companies were used.

(3) Large-scale Survey by the Ministry of Health, Labour and Welfare using the LINE app

LINE signed an agreement with the Ministry of Health, Labour and Welfare and conducted the "National Survey for New Corona Countermeasures" via the LINE app 4 times between late March and early May, 2020. The 5th survey was conducted in August. Out of more than 84 million LINE users, the 2nd largest number of responses was 24.67 million (29.7% response rate). The 5th survey had the lowest number but still received 15.39 million responses (18.2% response rate). We can see the percentage of people with fever by region as well as the preventative actions people have taken.

In the 5th survey, it became evident that those in the service industry such as food stores and restaurants, entertainment venues, and taxi drivers found it be particularly difficult to avoid the "3Cs". However, even in such professions, the number of symptomatic cases were small for those who took protective measures. It can be said that infection can be prevented even in the so-called "3Cs profession" if infection control measures are taken.

The main issues in utilizing IT for novel coronavirus countermeasures are as follows:

① Lack of end-user perspective such as the poor usability of HER-SYS
② Real-time data necessary for policy decision-making cannot be collected
③ Difficulty to collect big data necessary for making detailed analysis using mathematical models
④ Difficulty to share and use data because data-entry forms and formats are not unified.
⑤ Too much time and effort spent by the Ministry of Health, Labour, and Welfare to build systems such as HER-SYS, COCOA and G-MIS (Gathering Medical Information System on COVID-19)
⑥ Society's slow adoption of infection control tools that utilize IT, such as COCOA

[Actions to Take]

The following actions are needed to solve the issues above:

① System development with more focus on user interface (UI) and user experience (UX)
② Build a system that anonymizes individuals and allows the data to be used only for countermeasures in the event of an emergency such as an outbreak of communicable diseases. A national consensus on the system is also needed.
③ Standardization of rules specified in the so-called "Problem Posed by 2,000 Personal Information Protection Systems"(P2K problem) that hinder wide-range cooperation and utilization of personal information

④ Further promotion of open data (secondary data made available in machine-readable format that can be accessed by anyone)

⑤ Collect IT-related information and develop IT human resources in order to build necessary systems and develop software utilizing cloud services and open source in the event of an emergency

⑥ Promote cooperation with private companies and citizen engineers and develop a career path that can go back and forth easily between private companies and the government like a “revolving door”

⑦ Ensure effective political leadership in emergency situations as well as public trust in politics and the government

## 1-6 Treatment & Measures Against Asymptomatic Individuals (Hospitalization and Quarantine)

**[Outline and Issues]**

In February 2020, COVID-19 became a designated infectious disease (Category Ⅱ Infectious Disease) in Japan which requests hospitalization in a medical institution or recuperation at home or at a lodging facility. However, during the so-called first wave in April 2020, it took several days until the patient was admitted after first showing symptoms since the number of PCR tests being conducted was extremely limited and the general guide for medical consultation and testing was very strict. Furthermore, because only a few medical institutions were able to admit COVID patients and because the clinical state of the disease had not been clear and treatment methods were not yet developed, quite a few cases developed into a serious case.

Afterwards, asymptomatic people and those with only mild symptoms became allowed to recuperate at home or at a lodging facility, and hospital capacity increased with deregulation and compensation from the Ministry of Health, Labour and Welfare. This led to an improvement in the system to hospitalize and quarantine. Testing systems also improved, testing technology became more diversified, and treatment drugs showing some evidence were being developed.

In May 2020, the government fast-tracked the approval of the antivirus drug Veklury (remdecivir) for severe cases, and Avigan (favipiravir) was approved for moderate cases. For both moderate and severe cases, the development of convalescent plasma therapy and antibody drugs is also under way. As for anti-inflammatory drugs, dexamethasone has

been approved for use. Anticoagulation therapy is also used depending on the patient's condition. Hence, during the second wave, the days it took until hospital admission was shortened and the deathrate after hospitalization decreased in every age group.

Many academic and corporate institutions continue to work on the development of treatment drugs, diagnostic technology and research of the disease. Recently, the National Center for Global Health and Medicine (NCGM) identified five markers such as CL17 that can predict the onset of critical symptoms.

However, there is still a demand for a treatment drug that can deliver high efficacy such as reducing the death rate of moderate and severe patients. It is important to continue research and development to identify symptomatic and mild cases which have a high risk of secondary infection or possess high probability of becoming critically ill. Implementing a structured quarantine system to admit patients in medical institutions, lodging facilities, or their own homes depending on the risks is also important.

**[Actions to Take]**

Research and development in the following areas are required for treating patients and handling asymptomatic cases.

① R&D for antivirus and immunomodulatory drugs that demonstrate high efficacy in moderate and severe patients.

② Development in testing technology that can identify mild and asymptomatic patients who may develop into a severe case. As for testing using the predictive markers identified by NCGM, further research in a larger scale is needed to prove its efficacy. Development of testing equipment and diagnostic drugs should also continue.

③ Current PCR tests are very sensitive and can even pick out individuals who have low probability to cause secondary infection. There is a need to promote the development of testing technology that can select those who are asymptomatic or only have mild symptoms but still have a high risk of transmitting the virus.

### 1-7 Vaccine Development and Distribution

**[Outline and Issues]**

Vaccine development for COVID-19 is ongoing worldwide at a faster pace than ever before. For the ones that are ahead of the process, phase III clinical trials have begun, and some are applying for approval at the same time.

According to the WHO (*2), as of November 2020, 48 vaccines are in the clinical trial phase and 164 are in the preclinical phase. As we look at the 11 which are undergoing phase III clinical trials, we see that many of them are mRNA vaccines or viral vector vaccines which have rarely reached commercial application or have never been delivered widely. If safety can be confirmed in the phase III clinical trials, it can be assumed that some of these vaccines will be commercialized in Japan as well.

As for vaccines under development in Japan, the following are leading ahead; (1) AnGes - plasmid DNA vaccine (2) KM Biologics - inactivated vaccine (3) Shionogi - protein subunit vaccine (4) Daiichi-Sankyo - mRNA vaccine (5) ID pharma - non-replicating viral vector vaccine (6) Research Institute for Microbial Diseases. Compared to other countries, Japan has been late to begin vaccine development. Currently most have just begun clinical trials or are in the preclinical phase. It is estimated that many will enter phase III clinical trials by 2021. Most of the vaccines being developed in Japan are based on accumulated knowledge and experience. These will take more time until commercial application, but this trait may set them apart from the vaccines developed at an early stage of the pandemic.

Never in Japan or anywhere else in the world, have so many vaccines been developed and put to worldwide application in such a short period of time. What we can learn from phase III clinical trials is limited, and therefore must bring to attention of the possibility that some individuals may not effectively be protected by the vaccine, and that we may see adverse reactions whether or not it is related to the administration of the vaccine.

**[Actions to Take]**

The following actions are needed in order to push vaccine development in Japan and to widely administrate the vaccines after they are approved.

① Set up cold chain logistics to widely transport and store the vaccines in an appropriate condition.

② Build a structured information gathering system to swiftly collect real world data (RWD) and respond to adverse incidents after commercial application.

③ As part of crisis and security management, provide both pull incentives and push incentives so academia and corporations can put more effort in vaccine development at all times.

④ Support companies so they can develop and distribute vaccines not only in Japan but in other countries as well.

*2 https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

## 1-8 Containment System (Contact Tracing and Counter-Cluster Measures in Japan)

**[Outline and Issues]**

Japan's containment strategy was to strictly avoid the "3 Cs", closed spaces, crowded places, and close-contact settings.

From detailed surveying by public healthcare centers and medical institutions, from an early stage Japan was able to grasp the characteristics of how the novel coronavirus spreads. The influenza virus is highly contagious and one patient can spread the disease to multiple people. On the other hand, with the novel coronavirus (SARS-CoV-2), regardless of the severity of symptoms only 1 out of 5 patients spread the disease, meaning that 80% do not infect anyone else. Within that 1 in 5 (20%) who are contagious, there can be a super spreader which leads to a cluster of patients and widespread of infection. This means that this communicable disease spreads by forming clusters, leading to the strategy of preventing the spread by controlling the clusters at the early stage of an outbreak.

In many other countries, prospective contact tracing was adopted to identify everyone who had close contact with the patient and monitor them for symptoms. In addition to that, Japan implemented retrospective tracing taking into account the novel coronavirus' characteristic mode of transmission and investigated the patient's past activities to identify a common place of infection to comprehensively search close contact individuals.

Japan's counter-cluster measures;

(1) Find a common source/place of infection, conduct retrospective tracing to those who were present, hospitalize or quarantine individuals who were found to be positive.
(2) Warn the public at an early stage about the 3 Cs and the characteristics of what can cause a cluster of infections.

Another point to take note is that there can be a diverse type of clusters. In the early stages of the outbreak, travelers who had been overseas were the main catalyst of a cluster, but as the pandemic developed over time, 5 other situations where identified as having a high risk of infection. “Gatherings that accompany eating and drinking alcohol”, “Eating and drinking in a large group for a long period of time”, “Having conversations without wearing a mask”, “Living together in close quarters” and “Bringing the guard down when location changes”. A cluster may occur in various types of situations.

The level and method of containment should be reviewed according to the increase or decrease in the number of COVID cases. Thorough and careful risk communication to the public is also important since Japanese law does not allow compulsory measures and relies on each citizen to make responsible decisions.

**[Actions to Take]**

① Counter-cluster measures are the basis for containment since the virus has a characteristic to spread via clusters.
② Diverse counter-cluster measures to meet various situations are required as the number of cases increase.
③ Government must present scientific evidence and place an effort on risk communication to the public to encourage citizens to change their behavior voluntarily.

## 1-9 Scientific Research Projects to Support Communicable Disease Control (Research Questions)

**[Outline and Issues]**

At the beginning of an outbreak, knowledge and data regarding communicable disease control is very limited. In order to administrate communicable disease control during an ongoing pandemic, various research questions must be answered before implementation.

In the case of COVID-19, research questions popped up one after another. What kind of people are likely to cause secondary infection? What kind of people are probable to develop into severe cases? Are there any indications of infection before the onset of symptoms? Of course, large scale clinical trials were called for to confirm the safety and efficacy of treatment drugs and vaccines.

However, as the virus began to spread rapidly doctors were swamped with daily medical practices and it became difficult to work on research plans or clinical trials. No one had the time to design a proper research project and conduct widescale research on a national level. Large scale clinical trials were conducted in Europe, USA, and Brazil where the pandemic hit hard, but in Japan clinical trials and research were only conducted in a small scale.

Ideally, there should be researchers who specialize in communicable disease epidemiology and statistics, those who can work in coordination with clinical doctors to design clinical trials and research projects to answer research questions. However, there are very few experts in the field of communicable disease epidemiology and statistics who can design such research projects.

**[Actions to Take]**

There is a need to work on the following during normal times in order to be able to swiftly design a research project at the time of an outbreak to find answers to research questions needed for communicable disease control.

① Develop human resources in the much needed field of communicable diseases and statistics. (especially in Japan)

② Identify experts in communicable disease epidemiology and statistics in order to make it possible to coordinate a research project in times of emergency. The answers to research questions will serve as a base for communicable disease control.

## 1-10 Individual Freedom and Public Welfare in Communicable Disease Control

**[Outline and Issues]**

With the declaration of a state of emergency, there was a restraint on "individual freedom" such as the freedom to travel and convene as desired. These are rights protected by the Constitution of Japan. Under the novel coronavirus special measures law, the request is voluntary and does not impose any penalties. The contact tracing app is sensitive to personal information, therefore does not acquire any data on personal travel records or phone numbers. Communicable disease control must analyze the information of infected individuals and those who are possibly infected. It is important to find a balance between achieving the "public benefit" of communicable disease control and protecting "personal freedom and rights". Currently, there is a lot of talk to revise the novel coronavirus special measures law, but there has been no fundamental or essential discussion regarding it. It is

important to discuss these issues on a P4 platform (Public Private People Partnership) and achieve a national consensus.

Furthermore, in order to prevent the spread of communicable diseases, it also necessary to discuss the responsibility of each citizen on a P4 platform (Public Private People Partnership). According to the basic principles of the infectious diseases control law(Article 2), "measures to be taken by the national government and local public entities for the purpose of preventing the outbreak and spread of infections is [omit] to fully recognize the circumstances surrounding the patients of infections so as to be able to deal with new and other infections promptly and appropriately, and the comprehensive and systematic adoption of these measures while respecting the rights of the patients." At the time of enactment in 1998, it was stated as "considering the rights of patients" but was revised in 2007 to "respecting the rights of the patients" in response to human right issues that occurred in past cases of communicable disease control. （*3）Keeping in mind this kind of history regarding communicable disease control, when discussing the responsibilities of the general public, attention is needed so that it does not go against the basic principles of human rights.

*3　https://www.niid.go.jp/niid/ja/law.html?start=6　(Japanese)

Discrimination has been one of the issues during this novel coronavirus pandemic. There have been many cases where the media reported information that revealed the identity of the patient which then led to online slandering and discrimination on social media. Particularly, the fact that there was so much online discrimination towards medical and healthcare workers who were at the frontline fighting against COVID could have led to a collapse in the medical system. In September 2020, a working group focusing on prejudice, discrimination and privacy was set up by the Novel Coronavirus Infectious Disease Control Subcommittee. They plan to release an interim report in November.

Another issue has been the burden on women. With schools closed and telework being expanded, it was mostly the women who were forced to take on more housework and childrearing. Domestic violence in a stay-at-home environment has also been pointed out as an issue.

Women are also having more difficulty in securing jobs. According to a report by the research group studying the influence of COVID on women within the Japanese

Cabinet Office, there was a huge decrease in employment in April 2020. Specifically, a 370,000 decrease in men and a 700,000 decrease in women which shows a large difference. Looking at the number of suicides, 651 women took their own lives during July and August of 2020 which marks the highest in the past five years. If you compare the numbers of each month, female suicides began to increase in June and reached the highest of 187 deaths in August. The number of male suicides in the same month was 64. This phenomenon of more female suicides than males is unprecedented.

**[Actions to Take]**

① Discuss the fundamental and essential issue of how to balance "individual freedom" and "public benefit" in times of crisis without trivializing the issue to the appropriateness of the novel coronavirus special measures law. Discussions should take place to achieve a national consensus.

② Put together a preparation group to consider the launch of a volunteer group from participants of the Nikkei FT Communicable Diseases Conference to further discuss this topic on a deeper level among various members.

## 1-11 Decision Making in Emergency Situations

**[Outline and Issues]**

When a large-scale cluster developed on the cruise ship Diamond Princess in February 2020, the Novel Coronavirus Response Headquarters of the Ministry of Health, Labour and Welfare gathered medical experts from across the country to form a COVID-19 communicable disease control advisory board. Later on February 14th, the advisory board held the Novel Coronavirus Expert Meeting to offer advice from a medical standpoint.

Ideally, the government should make policy decisions after experts assess the risks of proposals suggested by an advisory board. However, since the government was too occupied responding to the Diamond Princess cluster situation, it failed to explain the perspective of COVID-19 to the public. As COVID cases gradually increased in Japan, experts plunged forward taking part in communicable disease control which was beyond their official duties.

The Novel Coronavirus Expert Meeting was not formed under any specific law and therefore its placement and authority was never clarified. This subsequently led to an impression that the experts in the meeting were in-charge of all the decision making. Some

of the experts who participated in the meeting commented "We discussed issues day and night to the best of our abilities, but I'm afraid we may have seemed like a solitary and unstable organization to the public".

Later on July 6th, the Advisory Council on Countermeasures against Novel Influenza and Other Diseases set up an all Japanese Novel Coronavirus Infectious Disease Control Subcommittee which included economic experts as well. This is the course of events which led to the call for a structured decision-making policy.

**[Actions to Take]**

① Government should make policy decisions, and politicians should be prepared to explain the content and reason to the public in a comprehensive manner. We must identify experts in academia and private sectors to form a community so that government can summon an all-Japanese team for communicable disease control in a state of emergency.

③ After the acute stage of a pandemic, move on to P4 (Private Public People Partnership) initiatives. For example, invite experts on risk communication or include a citizens' point of view into policy making on communicable disease control.

## 1-12 Public Behavior Modification and Risk Communication

**[Outline and Issues]**

In March 2020, Japan's Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response was revised to include COVID-19. Hence it became legal to issue a state of emergency and allow prefectural governors to request citizens to stay home and schools to close. However, these requests cannot be enforced, and non-compliance carries no penalties as in Europe and the United States. Thus, in order to suppress the spread of COVID-19 infections, it has become important for citizens to voluntarily change their behaviors and refrain from going out, on top of wearing masks, washing their hands, gargling and sanitizing their hands.

Experts in Japan investigated what impacted the citizens to comply with stay-at-home requests up until June 2020(*4). The investigation revealed that school closures, the declaration of a state of emergency, and governor requests to refrain from going out had a certain impact on the people's behavior. What had an even greater impact was the information on the number of infected people updated daily by the government and prefectures. It was clear that a major factor that contained the infection was the citizens'

own thoughts to immediately refrain from going out. Moreover, the Cluster Response Team of the Ministry of Health, Labour and Welfare and their expert panel identified situations that have a high risk of clusters to occur. Citizens were told to avoid the "3Cs" (Closed spaces, Crowded places, Close-contact settings). These actions coupled with the citizens' high level of hygiene awareness led to voluntary decisions not to go out.

On the other hand, there were some cases where the citizens went too far. When some information released by the local government had contained personal information that could identify the individuals who were infected, those people became a target of slander and defamation. There was discrimination and bashing against people in the "Nightlife districts" (Establishments providing food and drinks with entertainment) identified as high-risk areas for clusters and even against healthcare workers. With limited scientific knowledge, people were exposed to a flood of information through media reports and social media that were rapidly spreading not only accurate information, but also fake news, misinformation, hoaxes, and rumors. It was an "infodemic". In addition to the importance of mass media reporting and delivering accurate information based on the latest scientific knowledge, we reaffirmed the significance to enlighten the public that scientific knowledge is subject to constant change with scientific progress.

Including a "fun" element is also important in communicable disease control. Taiwan confronted the coronavirus panic and conspiracy theories based on the idea of "humor over rumor." Expert staff of the government used hashtags in social media and even posted pictures of a dog, adding humor to scientific facts.

Risk communication should not be based only from a management perspective. Perspectives of the actual parties involved must be included. Risk communication without the perspective of the actual parties will only promote risks. Now that we are past the acute phase of the pandemic, risk communication regarding COVID-19 should be conducted through a Public-Private-People Partnership (P4). We must listen to the voices of citizens including minority parties. In order to make communicable disease control a natural and integral part of our lives, it is important to involve society as a whole.

[Actions to Take]

One of the major factors that affected the infection status in Japan was that citizens decided to modify their behaviors, such as voluntarily staying at home. Even though the whole world is still anxious about how this pandemic will unfold, in order to effectively

practice communicable disease control it is necessary to have the citizens understand the current infection status and various countermeasures.

① Deepen risk communication including a citizens' perspective in order to promote behavioral changes.

② After the acute phase of the pandemic, we must create a system to reflect the ideas of citizens, including minorities, for policy decisions.

③ Mass media must report and deliver accurate information based on the latest scientific knowledge.

④ Come up with a way of communication including a fun element that will allow the public to engage in scientifically-backed measures.

*4 https://www.carf.e.u-tokyo.ac.jp/research/5602/

### 1-13 Further Innovation and Infrastructure Improvement

**[Outline and Issues]**

The COVID-19 pandemic has brought attention to the structural vulnerabilities of Japanese society. Information gathering of infected individuals was not fast enough, and the use of ICT tools in communicable disease control was insufficient. Crowded trains are the norm since many citizens work in the city. In order to solve these issues, we must utilize ICT, promote digital transformation (DX) and various other innovations to realize a de-centralized networking society instead of a centralized one.

Other than promoting DX in government administration and using ICT in communicable disease control, it is also important to shift to contactless ways, such as incorporating more robotics, unmanned distribution, and developing cashless technology. With more companies and individuals shifting to remote work, the average working style has changed. People now have more freedom and flexibility to balance work and their private lives. We can also expect the development of new services to support and improve this new lifestyle.

The shortage of masks and medical equipment revealed the issues in the supply chain of medical supplies and the medical device industry. With the global spread of infection, many countries are taking a shift towards protective trade. Japan had promoted international division of labour for medical ingredients calling for reciprocal development with Asian countries continuing economic growth. This leads to concerns if a pandemic

reoccurs. Japan must prepare for a crisis in the international supply chain of medical ingredients, respirators, masks, etc. Upon the outbreak of COVID-19, Japan was able to administer the antivirus drug Avigan (Favipiravir) and swiftly conduct observational studies. This drug had been stored as a treatment drug for novel influenza. However, the country still relies most of the manufacturing of pharmaceutical ingredients and intermediates to other countries, and therefore it is important to create a system to precure these within Japan in case of a crisis.

One thing to be noted is the flexible management of Japan's Pharmaceutical and Medical Devices Act. On April 3, the Pharmaceutical Evaluation Division and the Medical Device Evaluation Division of the Pharmaceutical Safety and Environmental Health Bureau under the Ministry of Health, Labour and Welfare released a policy stating that "pharmaceutical regulations will be clarified in order to secure and manufacture respirators and other supplies for novel coronavirus disease control". This means a speedier approval and screening process for medical drugs, devices, in vitro diagnostics (IVDs) and regenerative medical products.

Innovations and improvement in infrastructure adapting to the new normal is necessary. In order to progress smoothly, we can predict that reevaluation of various regulations will be unavoidable.

However, it became evident that fear of every move being monitored by the government was hindering the contact-confirming app from becoming widespread. It is necessary to have a wide discussion and reach a consensus on how much restriction on personal rights should be allowed to achieve public benefit. In order for continuous innovation, a structural platform for P4 (Public Private People Partnership) communication should also be considered.

[List of Innovations introduced at the Conference]

- Public-private coordinated PCR testing system in Kobe city (Sysmex)
- Real time PCR test with faster results (KYORIN Pharmaceutical Co., Ltd.)
- Nucleic acid amplification test by LAMP method with higher amplification efficiency and shorter diagnostic time (EIKEN CHEMICAL Co., Ltd.)
- Antigen and antibody test kit that one can take at home while communicating with medical institutions via phone or email (LOKI CONSULTING)

- App providing one stop service of information sharing between parents and schools for the child's body temperature and physical condition, including medical interviews via chatbot and medical counseling by doctors (LEBER)
- App to share COVID-19 case data between various medical institutions, a system to monitor condition of COVID-19 patients, and an app that links together physical condition data and PCR test results for individuals participating in events (Allm Inc.)
- Unique system using blockchain technology for personal medical information, and an information managing and sharing service linking data on daily social economic activities (DataGateway)
- Innovation in Africa such as online medical advice service before testing or diagnosis, and a database showing real time information of available ICU beds and inventory of masks etc. (AAIC)
- AI diagnostic support service for chest x-rays and CT scans (Delft Imaging Systems)
- Sustainable tuberculosis treatment service during the novel coronavirus pandemic such as AI diagnostic support service for chest x-rays and CT scans (Stop TB Partnership)
- System using AI technology with shorter time required for searching candidate compounds etc. (Dassault Systems)
- System to quickly acquire antibodies from human peripheral blood in case of communicable disease pandemic (EVEC, Inc.)
- A closed testing device that can conduct sampling and measuring of specimens and even diagnosis (NIPRO)

Etc.

**[Actions to Take]**

① Swiftly assess innovations ongoing in private corporations, and utilize them in a system for communicable disease control.

② Be prepared at all times so that influence on the supply chain is minimal during a pandemic.

③ Develop new business models such as P3 to facilitate and accelerate innovation.

④ Discuss the launch of a P4 (Public Private People Partnership) platform to realize sustainable innovation.

## 1-14 International Cooperation System

### [Outline and Issues]

The pandemic has shown that communicable diseases in the age of globalization cause suffering not only to the country of origin. It has proven to be a major disaster that directly leads to a global threat in a very short period. This is also clear from the fact that border control measures cannot be established by one country alone. Multilateral cooperation that transcends domestic interests is essential to confront global communicable diseases.

It is difficult for one country alone to develop therapeutic drugs and vaccines necessary for countermeasures in a short period of time, hence it is essential to cooperate with multiple countries. In April, the Japanese government announced its policy to internationally expand clinical research on Fujifilm Toyama Chemical's anti-flu drug, Avigan (Favipiravir) regarded as a promising therapeutic drug, providing emergency grand aid of $1 million.

Regarding vaccine development capabilities, the Japanese government is actively partnering with pharmaceutical companies such as Pfizer in the US and AstraZeneca in the UK. International cooperation is also important in terms of securing medical equipment. Many countries are moving to restrict exports of medical supplies, revealing a global supply chain crisis for medical supplies such as ventilators and masks. On April 15, the Japanese government requested an increase in the production of medical equipment and devices such as ventilators and masks and also consulted with ASEAN member states to call for the provision of these medical supplies to Japan.

It goes without saying that Public-Private Partnership (P3) will be critical in promoting and accelerating innovation originating in Japan for future emerging and re-emerging communicable diseases that of course include COVID-19.

Many P3 efforts are already underway in the research and development of therapeutic drugs, vaccines and diagnostic technologies. ICT and big data owned by private companies were used for contact tracing apps and for analyzing contact frequency. In the future, P3 will become even more important. Not only academia experts but also experts from private companies need to be involved in the government communicable disease control measures. P3 will also be crucial in order to further promote international cooperation in sharing Japanese knowledge on communicable disease control measures as well as treatment and diagnostic technologies to developing countries.

The WHO is accelerating efforts to strengthen 4 areas: diagnosis, treatment, vaccines, and health systems. In April 2020, the "ACT Accelerator" (Access to COVID-19 Tools Accelerator) was established as a framework for international collaboration to fairly distribute the results of the WHO efforts to each country. As powerful nations compete to procure vaccines, GAVI (the Vaccine Alliance), CEPI (Coalition for Epidemic Preparedness Innovations) and the WHO co-launched "COVAX Facility", a P3 initiative to jointly purchase and distribute vaccines to people all over the world. The Japanese government was quick to announce its participation and leadership among developed countries. Now, over 180 countries and regions have joined to unite against "vaccine nationalism". When the vaccines currently in development are approved for practical use, they are expected to be supplied in accordance with international cooperation. P3 initiatives involving numerous countries and companies have never been carried out on such a large scale. It can be said that P3 itself has shown new possibilities through COVID-19.

On the other hand, Japan's ability to spread information across the world is weak, missing the opportunity to make valuable international contributions. For example, Japan has been recognized to have one of the highest levels of COVID-19 treatment in the world. Japan possesses various medical information accumulated through trial and error which is useful for healthcare professionals around the world struggling to treat patients. Even though this useful information is an opportunity to make an international contribution, Japan lacks the effort to compile the information, translate it into English and spread it across the globe. Consequently, the information is not shared with healthcare providers worldwide.

Another example is the nucleic acid amplification test using the LAMP method in which Japan was the first in the world to put to practical use. Although it is an excellent platform in terms of precision and cost, it is not well known because of the lack of Japan's ability to spread information globally. Japan already has outstanding experience and technology. It can be said that actively sharing such information with the world is an important part of international cooperation that Japan should focus on.

**[Actions to Take]**

① Japan needs to make a strong commitment to various initiatives around the world such as the ACT Accelerator.

② Japan needs to actively spread the country's innovations to the world.

## 2. Progress and Future Issues of P3 Projects Launched by the Conference

Through open discussions among a wide range of participants and P3 (Public Private Partnership) collaboration, the Nikkei FT Communicable Diseases Conference has propelled various efforts against communicable diseases. Aiming to plan and implement P3 projects throughout the year, volunteers from the Nikkei FT Communicable Diseases Conference organize the "Asia Africa Medical Innovation Consortium (AMIC)". During this past year, AMIC's Asian Clinical Trials Platform consortium and Malaria consortium have shown progress. A new AMR consortium has also kicked off and is currently working to create a concrete proposal to the government.

Although it can be assumed that government, private corporations and academia resources will continue to be occupied to deal with COVID-19, it was stressed in the conference that each AMIC consortium needs to continue their activities to solve the problems they each face. We are considering the formation of new consortiums like Dengue Fever where Japanese P3 could contribute. Furthermore, conference members confirmed the need to further develop P3 projects and discuss what kind of platform could create a structure for rapid response in times of an unknown communicable disease pandemic in the future.

### 2-1 Asian Clinical Trials Platform P3 Project Report

Clinical trials for diseases uncommon in Japan cannot be conducted in Japan. In order for Japan to develop new drugs and diagnostic drugs for these diseases, it is necessary to setup clinical trials abroad where the patients exist. There is a need for a network for epidemiological studies on communicable diseases, a network of medical facilities, human resource development, and strong relationships between local authorities and the government. The Asian Clinical Trials Platform P3 project was launched at the 2017 Communicable Disease Conference, and an official proposal was submitted to the government in 2019.

In July 2020, it was officially adopted by AMED (the Japan Agency for Medical Research and Development) as a subsidized project "Pilot project and clinical research/trial platform which will promote international research collaboration between Japan and Asian countries in the field of communicable diseases" under the "Research project in clinical research/trials and building a clinical research/trial network in Asia". It is a JPY3 billion

public project with various sub-projects underway related to the novel coronavirus, tuberculosis (Indonesia) and malaria (Thailand).

P3 projects are already producing results. The 5-aminolevulinic acid (ALA) supplement by Neopharma Japan which was initially made to prevent the reinfection of malaria after elimination of the parasite and drug treatment has shown research results that it could be effective against the novel coronavirus.

### 2-2 Malaria P3 Project Report

200 million people were reported to be infected with malaria in 2016. Since its launch in 2016, the malaria consortium has been organizing P3 projects in Asian and African regions in the 3 fields of testing & diagnosis, drug development and vector control for prevention. A government proposal was submitted in 2018 and deep discussions have continued, but after the outbreak of the novel coronavirus actions against malaria have dwindled globally and the death toll is estimated to rise. It was once again confirmed that it is important to reinforce and continue our efforts.

Since last year's conference in September, measures against asymptomatic malaria was again a focal issue in Asia, and projects continued under the Asian Clinical Trials platform with NCGM taking the lead. Among the high-sensitivity tests in development (EIKEN CHEMICAL: An ultra-high sensitivity testing method using LAMP technology for Malaria gene detection, SYSMEX CORPORATION: the XN-31 automated hematology analyzer utilizes the principle of fluorescence flow cytometry to rapidly detect parasites), the automated hematology analyzer was approved in June 2020 in Japan and is under evaluation at Mahidol University. Mahidol University and NCGM also agreed to launch a co-project to evaluate the performance of the malaria LAMP method in epidemic areas in Thailand. They aim to create a surveillance system for early detection of an outbreak that can supplement current testing methods. As for new treatment methods (Neopharma Japan: 5-ALA supplement to prevent reinfection after elimination of parasite and drug treatment), evaluation of efficacy is ongoing with the Laos Pasteur Institute as part of an international collaboration for structured clinical research and clinical trials.

In Africa, research led by Osaka City University's SATREPS project is looking into the possibility of eradication of Malaria in tropical Africa mainly with diagnosis and treatment in severe cases of pediatric malaria (XN-31 and 5-ALA supplement mentioned

above) and vector control (Sumitomo Chemical: Olyset Plus which is a long lasting insecticidal bed net that can give protection from insecticide resistant mosquitos, and SumiShield, which is an indoor residual spray). In coordination with JBCA (the Japan Business Council for Africa) which was launched by the government after TICAD 7, in January 2020 we accompanied the Cabinet Secretariat's observation trip to Ghana and spoke with members of the local Ministry of Health. This marked the beginning of a public-private coordinated effort towards communication with local governments and health ministries. From now on we will work to harmonize regulations towards implementing new technology and products in each country, support the government in meeting WHO Prequalification (PQ), and accelerate our activities, mainly the development of new diagnostic and treatment technology in coordination with the Asian Clinical Trials Platform initiative.

### 2-3 Antimicrobial Resistance (AMR) P3 Project Report

If no measures were taken against AMR, it is estimated that the annual number of deaths will rise to approximately 10 million in 2050. In Japan, deaths related to two types of antimicrobial resistant bacteria are estimated to be 8,000 per year. As the novel coronavirus pandemic is drawing global attention, AMR can be called a "silent pandemic". However, research and development for treating AMR is drastically decreasing due to its difficulty, high costs and low profit. Even if commercialized, the use of antimicrobial drugs is usually held back in order to prevent the emergence of drug-resistant strains, and therefore it is difficult to secure retail and expect enough profit that matches investment. This is making large pharmaceutical companies to withdraw from the antimicrobial drug market or sell out its enterprise. Some members at the conference expressed concerns not only about AMR related deaths but also about necessary surgeries not taking place from fear of surgical infections.

Many countries are adopting "push incentives" which support the funding of research and development, however, except for a few experimental cases, there are no fully established "pull incentives" that offer support after drug approval. Aiming to secure profit after approval and to build a pull incentive system to sustainably support R&D of AMR drugs, AMIC decided to launch an "AMR consortium" at the 6th Nikkei Asia Africa Conference on Communicable Diseases.

The AMR consortium has since been discussing a feasible system in Japan, preparing a proposal to the government by defining and classifying antimicrobial resistant

bacteria and pull incentives, figuring out the budget scale and funding schemes, and planning on how to alert the public about AMR and prompt a better understanding. Namely, “MER (Market Entry Reward)” which ensures a predictable return on investment on top of the sales income based on the amount used, “SM (Subscription Model)” where a fixed price is paid periodically no matter how much is used, and a “profit guarantee system” which ensures the same annual profit as other drugs for antimicrobials. The total budget for this is estimated to be around 20 to 80 billion JPY per item. (2 to 8 billion JPY annually if compensation period is 10 years)

Moving forward, it will be necessary to alert the public and deepen an understanding towards the risk of AMR and proper use of antimicrobials, strengthen international cooperation, and accelerate discussions on funding and pharmaceutical prices. It will also be important to include a wide range of stakeholders in the discussions for a “One Health” approach. As for ways to approach the public, we must utilize new types of communication tools to achieve effective risk communication. Industry, academia, government and private sectors will continue to work together towards the realization of a pull incentive system.

### 2-4 Candidates for the Next Communicable Diseases P3 Project

P3 projects led by AMIC consortiums have produced some results, showing that Japanese technology seeds can contribute to global communicable disease control. The conference also discussed about the seeds of future P3 projects.

Dengue fever is a communicable disease transmitted by mosquitos. Over 4 billion people in 128 countries are at risk of infection, and there has been a case in Tokyo in 2014. With global warming on the rise, it could become a more familiar disease in Japan. The live attenuated dengue vaccine being developed by KM Biologics (Kumamoto city) shows an immune response to all types of the dengue virus which lasts for five years in clinical trials conducted with monkeys. Since there were no serious adverse events in the phase 1 clinical trials, it will move on to phase 2 aiming to confirm safety on adults in an endemic region. The Global Health Innovative Technology Fund (GHIT Fund) pointed out that the whole world is focusing on the novel coronavirus, but there is still a need to heighten awareness of NTDs (Neglected Tropical Diseases). On the brighter side, the novel coronavirus pandemic has led to innovations in R&D, access and delivery.

As for countermeasures against COVID-19 in Japan, we must expedite the construction of a specific action plan on how to be prepared for the next pandemic, and how to solve the issues we are currently facing. There has been no fundamental discussion in Japan on how to balance the right to personal freedom and communicable disease control which is for the public benefit. P3 projects launched by this conference could be a good place to start the discussion. Since testing capacity has been an issue with the novel coronavirus, there was talk about establishing an emergency response central testing lab (tentatively called the Pandemic Lab). There was also a suggestion to launch a new working group to discuss the functions of a control tower organization "Community Against Pandemic (tentative name)" where industry, government, academia and the public would work together to make strategical decisions based on information gathering, data science, and real-world data.

## 3. Conclusion

Japan was able to suppress the 2009 H1N1 influenza pandemic but could not prevent the COVID-19 pandemic. Although Japan's case fatality rate is lower than other parts of the world, as of yet no country has obtained effective measures to stop the COVID-19 pandemic. Despite being in the midst of the pandemic, the conference was held to reflect on such experience. We thoroughly inspected the country's response to the COVID-19 pandemic up until mid-November 2020, extracted problems, discussed the solutions and made some proposals and agreements. It is our hope that the fruits of this conference will contribute to suppress the second wave of the novel coronavirus pandemic as well as other emerging and re-emerging communicable diseases.

The Asian Clinical Trials Platform initiative, which was agreed at our 6th conference, has begun to steadily move forward toward building bases in Thailand and Indonesia with the support of the Japanese government. The AMR consortium, established after the 6th conference, is finalizing detailed proposals for P3 initiatives. The endeavors to tackle communicable diseases (tuberculosis, malaria, Ebola, etc.) through P3 projects launched by the conference have already produced some good results, confirming that P3 initiatives are effective for communicable disease measures. P3 proposals for dengue fever were also made during this conference. Additionally, a P3 project to launch a "Pandemic Lab (tentative name for an emergency response central testing lab)" was also discussed in preparation for the next pandemic.

However, there are still challenges for P3 to overcome in communicable disease control. It is imperative to raise political attention to communicable diseases in response to the growing public interest in the novel coronavirus pandemic. Furthermore, efforts are necessary to maintain continued public awareness of communicable diseases after COVID-19 is contained. By further strengthening cooperation among stakeholders in Japan and other countries, it is our hope to see concrete progress being made at the 8th conference regarding the "Actions To Take" proposed in this statement. The contents discussed in the conference breakout sessions are included at the end of this statement for reference.

[7th NIKKEI FT Communicable Diseases Conference]

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**<Reference>**

**Contents of the 7th Nikkei FT Communicable Diseases Conference**

**Lunch Sessions / Special Sessions / Breakout Sessions**

Lunch Session 1 (BD Japan)

"The role of testing in communicable diseases -Learning from COVID-19"

In the early stages of the novel coronavirus outbreak, tests and diagnosis for the cluster that broke out on the cruise ship "Diamond Princess" were conducted in collaboration with Toho University using Becton Dickenson Japan PCR testing devices. During April and May when public health centers were conducting the tests, it took several days for the results to come out. This resulted in the high consumption of personal protective equipment such as masks in medical institutions such as the Toyonaka Municipal Hospital. The situation improved after it became possible to carry out rapid testing at the hospital. Issues in the testing system became apparent in this pandemic, and industry, government and academia need to work together to build a system for crisis management. It is also important to measure cost effectiveness from the perspective of medical economics and consider how to cut down the use and preserve the limited medical resources, including human resources. Revising the testing system should lead to conserving medical resources.

Rapid testing is also important in communicable diseases caused by antimicrobial resistance (AMR), a problem that is becoming more serious in Japan. Rapid testing will allow proper and targeted use of antimicrobials and lead to suppressing the occurrence AMR. Toyonaka Municipal Hospital has adopted a device to check for methicillin-resistant Staphylococcus aureus (MRSA) infection. Conducting this test in advance has helped prevent infection, but such method has not expanded nationwide. It was pointed out from multiple stakeholders including doctors working at the forefront that we should establish a system for communicable disease testing that offers medical fee reimbursement and insurance coverage for equipment use.

Lunch Session 2 (The Japan Pharmaceutical Manufacturers Association)

"Strengthening Future Measures against Communicable Diseases through PPP

-Towards Prompt Supply of Essential Therapeutic Drugs and Vaccines"

In Japan, in order to shorten the development period of therapeutic drugs for COVID-19, progress is being made on drug repositioning, which is an approach to utilize already approved compounds. For vaccine development, industry and academia are working

together to focus on new methods such as messenger RNA. The country is moving forward by improving the production system and securing vaccines from overseas manufacturers. Japan was one of the first countries to commit to "COVAX," a framework in which each country jointly invests and purchases vaccines for the novel coronavirus, and currently, more than 180 countries are participating.

On the other hand, the AMR Action Plan compiled in 2016 has not shown much progress. Promoting AMR research and development was one of the pillars indicated in the plan, since antimicrobial resistance (AMR) has continued to become more serious in Japan. In July, more than 20 pharmaceutical companies around the world, including 5 from Japan, pledged about US$1 billion and provided funding to venture companies that develop antimicrobial drugs. The "AMR Action Fund" was also established with the goal of launching 2 to 4 items in the next 10 years. It is also necessary to have pull incentives to prepare the market environment after launching and allow companies to continue development.

Even after the complete suppression of the novel coronavirus, other communicable diseases and threats such as AMR will occur. In order to effectively promote measures including research and development against communicable diseases, it was suggested we should have a "control tower" that can draw up national strategy plans. Communicable disease control is a part of national security in the US. As activities by private companies decline when it comes to communicable diseases, it is important to establish a system to ensure researchers stay in academia.

### Special Session (Bill & Melinda Gates Foundation)

### "Embodiment of "Sanpo-yoshi"- Global Health and the Japanese Private Sector"

The Japanese government has contributed US$130 million to the "Gavi Vaccine Alliance," an international organization that promotes access to vaccines for developing countries. In order to promote R&D and production of the novel coronavirus (COVID-19) vaccine, they have also contributed US$98 million to the Coalition for Epidemic Preparedness Innovations (CEPI), an international public-private partnership. In addition, Japan was the first developed country to pledge funding to ACT Accelerator, a countermeasure framework for COVID-19 supported by Gavi.

These frameworks such as Gavi and CEPI have been supported by the Bill and Melinda Gates Foundation. According to a research method commissioned by the Gates Foundation, if the first 2 billion doses of vaccine concentrate in the wealthy countries, the global death toll could be double that of a fair worldwide distribution.

Shionogi & Co., Ltd. reported that there could be more than 10 million AMR related deaths by 2050, exceeding the number of deaths from cancer. The company identifies communicable diseases as the most important treatment field.

However, there are 2 issues. One is that only 0.4% of researchers in Japan specialize in communicable diseases. Also, unlike the field of cancer and rare disease research where profit can be generated, the issue is how to continue the business of communicable diseases which is likely to fall into the red. It is necessary for public and private sectors to create a system to support companies with pull incentives. Furthermore, in order to continue innovative R&D, it is essential to further refine efforts such as developing patent-based businesses in advanced countries while giving up patent incomes in emerging countries.

Takeda Pharmaceutical Company announced that it has established a joint system with other pharmaceutical companies to develop Takeda's fractionated plasma products and hyperimmune globulin medicine for treating patients at risk of severe COVID-19. Clinical trials have already begun and they plan to make treatment available as a non-profit drug in 2021. The company is also conducting Phase 3 clinical trials for a dengue vaccine which they expect to apply for regulatory approval in early 2021.

Since June 2019, NEC has been working together with the Gavi Vaccine Alliance and Simprints, a British scanner technology startup. They aim to make vaccine accessible by developing fingerprint authentication for infants. With the support of the Gates Foundation, a demonstration experiment began in Tanzania in August 2020 and in Bangladesh in November.

Japanese companies have inherited the "Sanpo-yoshi" management philosophy of the Omi merchants in the Edo period, in which there is a 3-way benefit for sellers, buyers and the community. In order to realize Sanpo-yoshi, a medium to long-term strategy that includes financing and human resource development is indispensable. Strategic partnerships between different sectors are also important for expanding and commercializing sustainable models in developing countries.

In order to support the efforts of Japanese companies on global health, The Gates Foundation funded Mitsubishi UFJ Research & Consulting which established "WELCO Lab" in October 2020. 13 companies are currently taking part in this new business initiative.

**Special Session I (Research Foundation for Microbial Diseases of Osaka University - BIKEN Foundation)**

**"Challenges in Preventing and Controlling Emerging Infectious Diseases**
**- A look at BIKEN's Vaccine Development Platform"**

The Research Foundation for Microbial Diseases of Osaka University (BIKEN Foundation) which started in 1934 is an institution where industry, government and academia are working together to develop a vaccine against the novel coronavirus (COVID-19).

The foundation is currently conducting research on various types of vaccines such as inactivated vaccines, live-attenuated vaccines, protein-based vaccines (including VLP vaccines), and recombinant vaccines (including viral vector vaccines). Utilizing its long history of experiences in R&D and manufacturing, the foundation plans to select an optimal candidate for development and aim for practical application.

**Special Session II (KM Biologics)**

**"Expectations for development of COVID-19 vaccines in Japan:**
**Development of an inactivated vaccine by KM Biologics"**

KM Biologics succeeded the main businesses of Kaketsuken and joined the Meiji Group in 2018. The company develops and provides a wide range of biopharmaceuticals including human vaccines, animal vaccines, plasma derivatives and neonatal screening. With regards to the novel coronavirus (COVID-19) the company is working on the following:

(1) Creation and development of an inactivated vaccine
(2) Creation and development of a live attenuated vaccine
(3) Formulation of AstraZeneca's viral vector vaccine
(4) Manufacturing and supplying adjuvant for GlaxoSmithKline

For the manufacturing of COVID-19 vaccines, the company will utilize the novel influenza vaccine manufacturing facility built under a government project.

**Breakout Sessions A-1 & A-2 (SHIONOGI／ DAIICHI SANKYO CO., LTD.)**

**"Challenges and Efforts to Address the Threat of Infectious Diseases**
**- Learning from the Cases of AMR and COVID-19"**

The global outbreak of the emerging communicable disease COVID-19 has strongly reminded us of the threat of communicable diseases. Many of the arising issues such as AMR are common with other emerging and re-emerging communicable diseases.

From the standpoint of national crisis management, preparation is paramount. We must continuously work on a system that will wisely utilize clinical data into R&D, develop human resources and expand a scientific foundation regarding communicable disease control. In order to create a market environment where corporations can secure business continuity, there was talk about the need for new systems such as push and pull incentives that can secure sustainability not just for the development but also for manufacturing and distribution of vaccines and treatment drugs. Participation in global scale frameworks was also encouraged.

In order to realize these activities, stronger coordination between industry, government and academia will be key. Foundation of an organization that can serve as a control tower for tackling various issues is called for. We must also make sure that the system incorporates the voices of the public.

**Breakout Session A-3 (SYSMEX CORPORATION)**

**"Be confident fighting malaria -Innovative diagnostics towards achieving SDGs"**

Malaria is one of the three main communicable diseases in the world. Early diagnosis and efficient testing are key to providing proper treatment. The automated hematology analyzer utilizing fluorescence flow cytometry can not only rapidly detect malarial parasites, but it is highly sensitive and does not require expertise compared to traditional testing devices which use antigen and antibody response.

The issues regarding malaria-countermeasures are different in each region. In Asia, AMR and the occurrence of new types of malaria along with medication adherence are the main issues. In Africa, there is also a serious social issue of malaria-related anaemia leading to poor labor productivity. Innovations in malaria testing could help to resolve such social issues. As the novel coronavirus (COVID-19) pandemic is calling for solutions which can adapt to our society, corporate innovations can not only contribute to communicable disease control but also to the achievement of SDG goals.

**Breakout Session B-1 (H.U. Group Holdings, Inc.)**

**"Optimal COVID-19 test selection based on characteristic of testing method"**

When testing for the novel coronavirus (COVID-19), a PCR test and antigen test detects the current state of infection, while an antibody test detects if one was infected in the past. The Japan Medical Association task force submitted a progress report in May which outlined three issues on why PCR tests were not being conducted enough.

1. The issue of human resources, equipment and testing facilities
2. A supply side issue of corporations
3. Issues in the administration system of testing facilities

Furthermore, a US report has shown that the sensitivity of PCR tests varies by more than 7000 depending on the reagent, which tells us there are still issues in standardization and accuracy control. On the other hand, a test with high sensitivity has a demerit of possibly detecting fragments of the virus from patients who are not contagious. According to data released by the Ministry of Health, Labour and Welfare, it's been taking about 5 days from the onset of symptoms until a patient is diagnosed with COVID-19. If patients are contagious for 7 to 10 days after the onset of symptoms, this period must be shortened in order to suppress the spread of infection. Rapid antigen tests and high-sensitive antigen tests that match PCR tests are available now, and we must utilize them as needed. Nasopharyngeal swabs have the risk of causing coughs or sneezes, but nasal swabs and testing with saliva is also available now. This could be a positive for hospitals and clinics now that we are entering flu season as well. Organizing a structure for standardization and accuracy control is also essential. The development of Japanese drugs is also crucial to secure a stable supply within the country.

**Breakout Session B-2 (Saraya Co., Ltd.)**

**"Infection prevention and control in the era with COVID-19: New Normal of healthcare-associated infections and public health"**

A "zero tolerance" stance in healthcare-associated infection is necessary for IPC (infection prevention and control) of COVID-19. On the other hand, it is difficult to cease social and economic activities outside the hospital, so we must find a balance between countermeasures against this public health crisis and take actions in two stages.

On the Diamond Princess cruise ship, those who tested positive and those who were suspected to be infected were quarantined in their rooms, but asymptomatic individuals were sharing facilities with other passengers. The surrounding environment of COVID-19 patients is highly contaminated with SARS-CoV-2, and contact through various environmental surfaces is thought to be one of the causes of the spread of infection. It has been reported that SARS-CoV-2 retains infectivity on environmental surfaces for about 3 days, which means hand hygiene and sanitizing the whole area where a patient has been is especially important.

Our society still lacks effective vaccines and medical drugs, hence NPI (non-pharmaceutical interventions) is necessary. We must take measures from a public hygiene

standpoint such as the use of ABHR (alcohol-based hand rubs). Experts in this field should cooperate to advertise measures based on scientific evidence and explain the usage of hygiene products in detail to build trust with the public users.

Saraya has been working with the Osaka Research Institute for Microbial Diseases (Masato Igawa Laboratory) since May 2020, conducting efficacy evaluation tests using the new coronavirus pathogen (SARS-CoV-2) in their products and sterilized components.

The development of new drugs and vaccines during this state of emergency is also imperative. We must establish "adaptive design clinical trials" which allows modifications to the trial and/or statistical procedures in treatment groups predicted to show higher efficacy.

**Breakout Session C-1 (FUMAKILLA LIMITED)**

**"Inactivation of novel corona virus by low-alcohol products**

**- Possibility of contributing to countermeasures in daily life**

In order to prevent the spread of COVID-19, it is important to prevent contact infection as well as droplet infection. Since February 2020, not only facemasks but antiseptic supplies including quasi-pharmaceutical products and everyday commodities were sold out in many stores. However, scientific verification of the efficacy of these goods to eliminate the novel coronavirus (SARS-CoV-2) was not conducted.

FUMAKILLA has been selling low alcohol antiseptic wipes since 1986 and their wide variety includes kitchen wipes, garment wipes, hand wipes and so on. By combining fermentation alcohol, grapefruit seed extract which has a natural antibacterial characteristic and pH adjusters, their products are said to eliminate bacteria and viruses quickly. A virus inactivation test conducted at Hiroshima University showed that these antibacterial components had an effect to inactivate the novel coronavirus.

Enveloped viruses such as the influenza and coronavirus are packaged in a lipid membrane which dissolves with alcohol. This is why alcohol antiseptics are generally effective. Furthermore, since grapefruit seed extract is slower to evaporate and remains on the surface, it can be said that the effect to eliminate and destroy the virus is sustained longer.

Kitasato University conducted a virus inactivation experiment in test tubes with various products on the market containing ethanol and surfactants that may have a disinfection effect on the novel coronavirus. The results showed that ethanol with a density of over 50% can disinfect a solution containing 30,000 novel coronaviruses in one minute of contact time.

These commodities and quasi-pharmaceutical products with viral inactivation properties can be utilized to clean not only solid surfaces such as hands and fingers but also clothes and other daily items made with fabric. Such information and products should be made known globally.

**Breakout Session C-2 (FUJIFILM Toyama Chemical Co., Ltd.)**
**"Treatment Drug for COVID-19 – Effectiveness and Validation"**

COVID-19 has become a global pandemic. Beginning treatment at an early stage of exposure to SARS-CoV-2 or at a pre-symptomatic stage, is said to reduce the number of severe cases and deaths.

An animal model (hamsters) with COVID-19 pneumonia has shown that administration of Avigan (favipiravir) has an antiviral effect. Administering the drug post-exposure at a pre-symptomatic stage results in higher efficacy. At the Diamond Princess cruise ship, Avigan was administered to asymptomatic individuals and mild case patients, and results showed it has an effect to break the fever earlier. There were no severe cases or deaths in the cruise ship case.

Clinical trials on non-severe pneumonia patients has shown efficacy to reduce the period of disease, and Avigan is currently waiting for approval. We must enhance contact tracing, consider randomized controlled trials on the efficacy of post exposure prophylaxis (PEP), begin PEP or drug treatment in case of outbreaks in long-term care facilities and nursing homes to contain the infection, and gather high quality data within Asia utilizing the Asian Clinical Trials Platform.