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Abstract:

In Japan, the policy for polymerase chain reaction (hereafter PCR) testing changed significantly after 7 May 2020; from 4 February to 6 May, PCR testing was limited to certain patients with severe symptoms. After 7 May, the PCR test was made available to a broader range of patients due to health insurance coverage. The study aims to test whether there is a significant relationship between the conditions under which PCR tests are performed, the number of tests after 7 May, and the positive results. Using a multiple regression model, we obtained the unexpected result even if we assume that PCR testing had been carried out during 4 February to 6 May at the same level as after 7 May. The number of positive cases would have been even lower than the actual number, which we have attained. This suggests that even if PCR testing had been plentiful throughout the entire period, the number of positives that would have been captured would not necessarily have been more significant than the actual number. This estimation might suggest that the infectivity of COVID-19 varied over time. It may suggest that, over time, the infectiousness and spreading power of COVID may be transformed. Therefore, further research investigating the epidemic impact of COVID is required, which is critical for humankind.

Phases of the Pandemic

Keywords:

polymerase cain reaction (PCR) test; positive cases; outbreak; COVID-19 pandemic; Japan

I. Introduction

1.1 Background of the Study

The World Health Organization (hereafter WHO) recognised a new disease in Wuhan, China, on 31 December 2019 (WHO, 2020). The WHO confirmed a cluster of pneumonia-causing diseases in Wuhan City on 5 January 2020. It was posted about this in Outbreak News (WHO, 2020). Only 18 days later, on 23 January, Chinese authorities announced and immediately enforced a lockdown across Wuhan. Regular flights were suddenly cancelled, and Japanese travellers lost the means to return to Japan. The Japanese government prepared a charter flight as an emergency measure; on 29 January, Japanese residents in Wuhan City boarded and returned on the first flight. The number of people affected by COVID-19 originating from Wuhan, China, spread across national borders. Japanese citizens were optimistic about escaping its impact. However, the tide changed after the cruise ship Diamond Princess, which carried crew and passengers suspected of having COVID-19, arrived at Yokohama Port. When the quarantine first started, passengers from all over the world attracted international media attention; soon, the infection changed from being someone else's to Japan's problem (Table 1).

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The authors are specialists in the social sciences and the field of social statistics. This research aims to contribute to the commentary on the current disruptive environment in the public health domain by providing society with information about who has been and who will be dealing with the impact of this epidemic, detailing a new landscape based on models created using estimated data.

The data used for the study is provided by the Japanese Ministry of Health, Labour, and Welfare as open data (Ministry of Health, Labor and Welfare, 2020a), which is published online. According to the data obtained from the ministry, the changes in the number of PCR tests conducted in Japan over the two different periods between the outbreak – until 6 May 2020 – and the off-peak – after 7 May to 16 July 2020, is noticeable.

This is mainly because Japanese national health insurance started to apply to the PCR tests conducted from 7 May onwards; since then, the number of tests has increased drastically throughout Japan. Therefore, this paper targets the first outbreak period from 4 February to 6 May, defined as the 'first half of the epidemic' and the 7 May to 16 July as the 'second half of the epidemic'.

Our research is based on the notion that the number of the PCR tests conducted should be the basis for estimating the number of cases in the first half of the pandemic. We have quantified and modelled the estimations of the number of PCR tests and positive case numbers. From this approach, a theoretical number of PCR tests administered is estimated using a regression equation based on statistics concerning the second half of the pandemic. In addition, we attempt to provide a basis for determining whether the condition after July is more severe by comparing the estimated theoretical number of positive rates in the first half and the number of positive cases from the second half.

Table 1. Domestic and Overseas Events Related to COVID-19

16-Jan 29-Jan 29-Jan 1-Feb	The first infection was reported in Kanagawa Japan	Dec 2019 Dec 2019 5-Jan	Wuhan City Health and Welfare Committee confirmed 59 unexplained viral pneumonia infections on December 12-29 (Jetro article) WHO recognizes new disease in Wuhan, China
29-Jan 29-Jan	The first infection was reported in Kanagawa Japan		
29-Jan 29-Jan	The first infection was reported in Kanagawa Japan	5-Jan	
29-Jan 29-Jan	The first infection was reported in Kanagawa Japan	12-Jan	WHO confirms cluster of pneumonia-causing diseases in Wuhan WHO names the new virus 2019-nCoV
29-Jan		23-Jan	Wuhan, China Lockdown Announcement
29-Jan		26-Jan	Taiwan bans group travel from China
	The first charter flight from Wuhan returns to Japan	28-Jan	WHO Tedros Secretary Xi Jinping Jintao held talks in Beijing
	Hotel Mikazuki in Katsuura City, Chiba Prefecture accepts 191 returnees	31-Jan	Italian government declares a state of emergency
1-reb 18-Feb	Diamond Princess enters Yokohama Port and quarantine begins Professor Iwata of Kobe University points out inadequate measures against onboard	4-Feb 12-Feb	WHO Secretary-General Tedros announces that it is not a pandemic NY Dow Jones Industrial Average hits a record high of 29,551.42 this year
20-Feb	Diamond Princess infected, 3 first dead	12-1 00	TVI Dow soiles industrial Average into a record ingli of 25,551.42 this year
20-Feb	500 negative passengers disembark on the Diamond Princess PCR-negative people return home by public transport and are controversial	21-Feb	Blockade of Codogno district in Lombardy, Italy
26-Feb	Government announces telework recommendation in new corona countermeasures	29-Feb	WHO announces that it is not yet a pandemic
	Governor of Hokkaido Suzuki and Mayor of Sapporo Akimoto make an urgent joint		
l-Mar	All passengers and crew of the Diamond Princess disembark		
2-Mar	None of the SDF personnel who entered the support were infected and were praised. Government requests closure of elementary, junior high and high schools nationwide		
5-Mar	The government postponed the time being the visit to Japan of Xi Jinping Jintao of		
5-Mar	Announcement of immigration restrictions from China and South Korea		
	Infected people via Europe are found in Japan	11-M ar	WHO Secretary-General Tedros suggests a possible pandemic
17-Mar 19-Mar	Government expert meeting calls for stronger border measures Shigeru Omi of expert meeting points out the possibility of explosive infection	17-M ar	French government announces strict outing regulations EU ECDC European Centre for Disease Prevention and Control advocates "Stay
1)-IVI ai	The word cough etiquette is popular	22-M ar	Enter Lockdown, NY, USA
24-M ar	Tokyo Olympics will be postponed	23-M ar	Enter lockdown across the UK
25-Mar	Diamond Princess finishes quarantine and leaves Yokohama Port	23-M ar	The NY Dow Jones Industrial Average recorded a minimum of 18,591.93. \$ 11,000
	Talent Ken Shimura dies		down in 5 weeks
	Masks and alcohol disappear from the market, high prices trade online		
l-Apr	The government announces that two cloth masks (abenomask) will be distributed to		
3-Apr	Strengthening border measures such as inspection	1-Apr	CDC Centres for Disease Control and Prevention announces "Social distancing" vide
7-Apr	Decided to cancel Sumo Summer Basho in May Government declares a state of emergency in 7 prefectures	5-Apr	British Prime Minister Corona suffers and is hospitalized
p.	The horizontal words lockdown, overshoot, cluster, and stay home by the governor	8-Apr	Wuhan, China Unlocked
	Home delivery "Uber Sweets" spreads rapidly due to stay home	•	
	The number of newly infected people peaks		
	Government expands state of emergency to all prefectures The government announces a special fixed amount of 100,000 yen per person	11-Apr 12-Apr	EU countries blame Sweden for not locking down
	Tokyo will name it Stay Home Week until May 6th	12-Api	British Prime Minister Johnson discharged
	Bread making, decluttering, and handmade masks are popular at home during the May		
4-May	Government Declares State of Emergency to Extend Until May 31	1-May	The concept of "New Normal" begins to flow in the EU
- > -	The words "three dense" and "social distance" are popular	4-May	Italian government announces gradual relaxation of lockdown
	Governor Yoshimura of Osaka Prefecture announces "Osaka model" to judge PCR test insurance coverage started		
7-May	Ministry of Health, Labour and Welfare approves remdesivir as a treatment		
8-May	Other than cancellation of leave request (specific caution prefectures)	10-M ay	British government announces mitigation of lockdown
l4-May	Decided to cancel the state of emergency in 39 prefectures	11-M ay	French government announces relaxation of outing restrictions
21-May	Kansai 2 prefectures 1 prefecture cancellation decision		
25-May l-Jun	Announcement of "gradual mitigation" government policy after full cancellation Many elementary, junior high and high schools have been closed		
· Jun	Many universities continue to be closed and distance classes are held	3-Jun	Italy lifts entry restrictions from EU
l 6-Jun	Government announces details of "Go To Campaign"	8-Jun	Partial relaxation of lockdown in New York, USA
18-Jun	Cancellation of self-restraint of movement across prefectures	17-Jun	Taiwan relaxes entry restrictions
19-Jun 6-Jul	Professional baseball unattended game started The government announces the concept of "new lifestyle" in government public		
10-Jul	Relaxed restrictions on holding events. Maximum of 5000 people such as		
	Rapid increase in positives, Tokyo raises to the most serious level of 4 levels	14-Jul	China lifts ban on group travel across provinces
l6-Jul l9-Jul	Government announces "Go To Travel" excluding Tokyo		
22-Jul	The original sumo wrestling Nagoya place is held at Ryogoku Kokugikan without The 1st stage of Go To Travel was started (other than Tokyo)		
3-Aug	Tokyo local Gov. announced shortening business hours for restaurant in Tokyo	11-Aug	Russia begins vaccination with vaccine Sputonic V
31-Aug	Tokyo local Gov. declaired to resume business hours for restaurant in Tokyo	27-Aug	Hawaii Oahu Lockdown Reopens
	The 1st stage of Go To travel was finished	0.0	
15-Sep 19-Sep	Government announces "Go To Eat" campaign from October Movie theatre all seats sales lifted	9-Sep	Hawaii Oahu Lockdown Release Postponed
	Increased professional baseball and soccer from 5,000 to 50% of capacity	21-Sep	Russia starts selling Corona Building based on Avigan
	FUJIFILM Toyama Chemical announces application for approval of Avigan	23-Sep	Hawaii Oahu Unlock Down
	The government announces a policy to allow re-entry and re-entry of residents		
1-Oct	2nd stage of Go To Travel started	2-Oct	U.S. President Donald Trump suffers from corona and is hospitalized
Mid. Oct.	Go To Travel and Go To Eat Increase people going out	5-Oct 8-Oct	US President Donald Trump discharged Over 5 million infected people in Brazil
561.		9-Oct	The NY Dow Jones Industrial Average returns to 28,586.90.
		12-Oct	Twitter restricts President Trump's "immunized" remarks
14.51	7. 1. 1.1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.	14-Oct	State of emergency again declared due to spread of French infection
	Tokyo announced that it will reach 374 infected people by the 13th Tokyo Medical Association calls for cancellation of Go To campaign	31-Oct 10-Nov	Announced lockdown in UK, Belgium, Greece and Austria
20-Nov 2-Dec	Tokyo officially decides to refrain from Go To Travel in Tokyo	2-Dec	Pfizer Inc. of the United States announces that the vaccine is effective UK approves Pfizer vaccine
3-Dec	The government decides to bear the Go To travel cancellation fee	12-Dec	UK and US FDA urgently grants Pfizer vaccine
28-Dec	The government declares state of emergency until 11-Jan	30-Dec	AstraZeneca vaccine authorized by UK
2021		2021	
l 1-Jan	The government declares extension of emergency until 7-Feb		
7-Feb	The government declares extension of emergency until 7-Mar	3-Feb	Moderna Covid-19 vaccine authorized by USFDA
	Japan approved the Pfizer vaccine and began administering The government declares cancellation of emergency except Tokyo, Kanagawa,	5-Feb	Sinovac Biotech Covid-19 vaccine authorized by China government
29-Feb	Saitama, Chiba	27-Feb	Johnson & Johnson's Covid-19 vaccine authorized by USFDA
7-Mar	The government declares extension of emergency until 21-Mar	1-Mar	Sweden has avoided Covid-19 lockdown so far
	IOC approved that no admittance from oversea audience by JOC decision		
25-M ar	Tokyo Olympic torch relay has been begun from Fukushima pref.	25-M ar	Israel government announced half of population injected 2nd vaccine
5-Apr	Government has decided to activate the anti-spreading measures to Osaka, Hyogo, Miyagi from 5 Apr to 11 May.	29-M ar	Death risk rising among young adults found in Brazil by AstraZeneka vaccine.
	Government has decided to activate the anti-spreading measures to Tokyo, Kyoto,		B 11 10 10 10 10 10 10 10 10 10 10 10 10
12-Apr	Okinawa from 12 Apr to 11 May.	14-Apr	Denmark halt to use AstraZeneca vaccine due to blocked blood vessel
	The government declares state of emergency in Tokyo, Osaka, Hyogo, Kyoto from	27-Apr	France Macron sets to emerge from lockdown from 3 May
23-Apr			
23-Apr	25 April until 11 May	-	
23-Apr 7-May		12-M ay	US starts to ease restrictions in each states

II. Review of Literatures

2.1 Operation of PCR Tests and Observation

The principle of a PCR test is to amplify millions of copies of a single molecule of DNA in a short amount of time (Kucirka et al., 2020). Three consecutive steps are required to achieve amplification. Step 1, denaturation, which heating a double-stranded DNA template to separate DNA strands. Step 2, annealing which binding a short DNA molecule called a primer to the adjacent region of the target DNA. Step 3, elongation which the polymerase synthesises the complementary strand of the template starting from each primer. This three-step 'cycle' is repeated 25–35 times to exponentially synthesise an exact copy of the target DNA (Thermo Fisher SCIENTIFIC, 2020; Mullis, 1987).

However, only about 70% of people show a positive result to the PCR test, which is negative. There are as many as 30% of cases. Sensitivity, specificity, and positive predictive value are indicators of test accuracy. Sensitivity is the percentage of people who have a disease that tests positive, while specificity is the percentage of people who do not have a negative or positive result. The median rate is the percentage of people who test positive and suffer from the disease (The University of Tokyo Health Promotion Headquarters Health Center, 2020).

2.2 Statistical Discussions Based on Public Data

Mathematical analysis was conducted in immunology include the SEIR model (Hokkaido University School of Medical Statistics, 2020). This is a model that takes these four letters of four categories of data: non-immune [Susceptible], infected and incubating [Exposed], affected [Infectious], and recovered [Recovery]. Furthermore, three additional data categories are required to measure the transition rate: basic reproduction arithmetic [RO], average incubation period, and average infectious period. SEIR is an elaborate model that outsiders cannot retest because it only uses data available to experts. These constraints mean that researchers cannot easily use the SEIR model.

Figure 1 shows the number of COVID-19 PCR tests and the number of positive individuals in Japan collected from Ministry of Health, Labour, and Welfare open data (Ministry of Health, Labor and Welfare, 2020a) and plotted chronologically.

In Figure 1, The grey line is the number of PCR tests on the left axis, and the black line is a daily record of the number of positive individuals on the right axis. In the first half of the year, the conditions for undergoing the test were rigorous. It was required that the patient exhibit a fever of 37.5 degrees centigrade or higher for four days or more, together with cold symptoms, fatigue and dyspnea (Ministry of Health, Labor and Welfare, 2020b). Before 6 May, the conditions of PCR tests were restricted to specific groups of patients; thus, the statistical number of PCR tests conducted during this time is relatively low, 9,252 as of 13 April 2020 (Ministry of Health, Labor and Welfare, 2020a). This is lower than the number of tests conducted by other developed countries; according to an OECD report on diagnostic testing data (OECD, 2020), Japan is the second-lowest member state regarding the number of tests conducted (Figure 2).

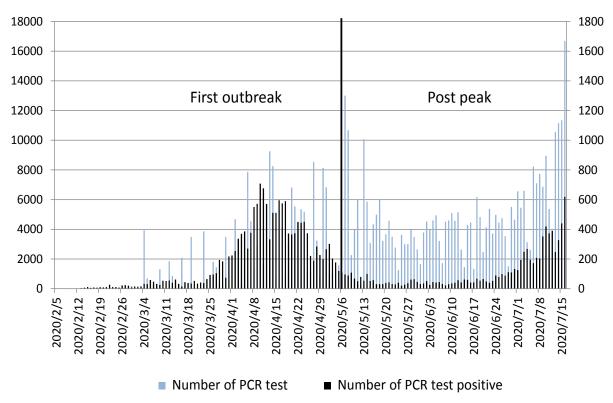


Figure 1. Changes in the Number of COVID-19 PCR Tests and the Number of Positive Individuals in Japan (Adopted from (Ministry of Health, Labor and Welfare, 2020a) and Assorted by the Authors)

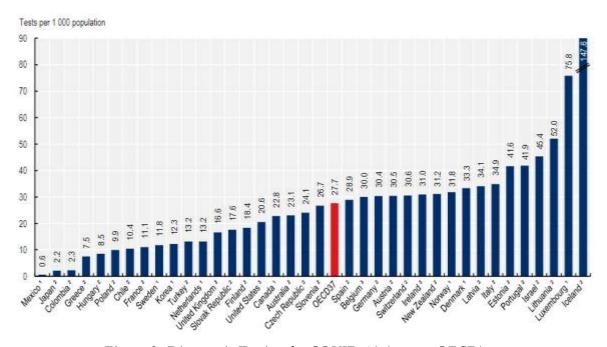


Figure 2. Diagnostic Testing for COVID-19 (source: OECD)

For instance, since the national insurance has got to be applied to the PCR tests on the 7 May, the number of conducting PCR tests on the day jumped to 13,005: then after this date, the average number of tests conducted until 16 July remained around 5,000 per day. The total number of PCR tests conducted between 16 January and 6 May, defined as the outbreak period, was 158,267 in total, with 15,660 positives and a positive ratio of 9.89%. Then, look into the same statistics in the second half of the off-peak period: Between 7 May to 16 July, the total number of PCR tests conducted was 352,135 with the number of positives 7,845. The positive ratio was 2.23% when the numbers of PCR tests in the first and second periods are subjected to a t-test, sig. <0.1%; this implies that there is a significant difference between the two periods.

There is a significant difference in the number of positives, sig. <5%. The black bar graph in Figure 1 represents a positive person, and the grey bar graph represents the total number of PCR tests conducted on a single day. The period when the number of infected people exceeded 500 every day was when the spread of infection was most feared 10 April - 18 April; exceeding 300 people were detected to positives after the second week of July was viewed as mostly infected by virus. However, the PCR tests conducted in the first and second halves of the pandemic are not the same. In engineering, it is a standard practice to compare things by making the environment the same or simulating the same conditions. Therefore, we will try to simulate the number of PCR tests conducted in the first and second halves of the pandemic under the same conditions.

III. Results and Discussion

3.1 Results

a. Data and Analytical Approach

The data provided by the Ministry of Health, Labour and Welfare open data (Ministry of Health, Labor and Welfare, 2020a) includes the number of PCR tests performed per single day, the number of Positive PCR tests per single day, the cumulative number of inpatients, the cumulative number of discharge/medical treatment cancellations. And the cumulative number of deaths. The following five factors were obtained as a result of this work: the number of PCR tests performed per single day; the number of positive PCR tests per single day; the number of inpatients per single day; the number of discharge/medical treatment cancellations per single day; and the number of deaths per single day. The raw data used for this study is displayed in Appendix.

Using these five data groups, we created a multiple regression model for the second half. The attained model was going to be used to estimate the number of PCR test could have been conducted and the hypothetical number of positive cases. IBM SPSS Version 26 was used for the analysis. The dependent variable was the actual number of PCR tests conducted in the second half of the period. Out of four independent variables in estimating the actual text numbers are significant. The four variables were sequentially inputted using the stepwise method with SPSS. Except for two variables, the number of discharges/cancellations and the number of deaths resulting from no significance in estimating the dependent variable, two variables; the number of positive cases, and the number of inpatients has been presented as significant variables for the estimation. The model's validity is 0.648 for R and 0.420 for R2, implying that the attained model can explain 64.8% of the whole dataset. The Durbin Watson value is 1.799, which also implies the model is reliable and compatible with the dataset. The beta is large enough in other indices, and the significance probability is 5% or less, so the developed model is reliable and trustworthy.

The regression equation in this model is summarised as in Equation 1:

Number of PCR tests per single day = 3080.798 + 15.537 * Number of positive PCR tests per single day - 1.362 * Number of inpatients per single day ------ (Equation 1)

b. Estimate of the Number of PCR Tests that might have been Carried Out

As Equation 1, the estimated number of standardised PCR tests per single day is obtained from the data showing the number of positive PCR tests per single day and the number of inpatients per single day in the previous period. The cumulative number of PCR tests measured in the previous term was 156,387, while the estimated value was 510,695. In other words, it can be inferred that if the inspection process were to be the same in the first half as in the second half, the number of inspections would have been 3.26 times greater. Figure 3 demonstrates two values: the estimated drawing of the black line and the actual values that draw the ash line.

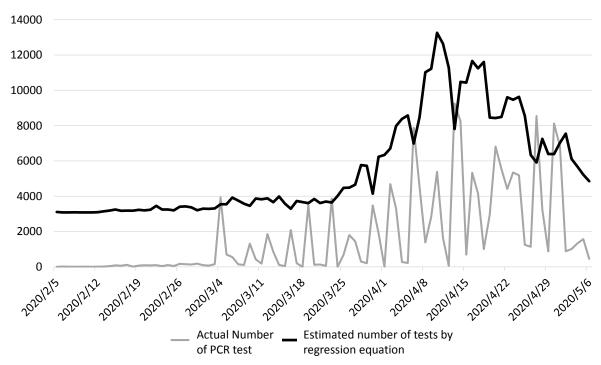


Figure 3. A Comparison of the Actual Number of PCR Tests and the Estimated Number of Tests

c. Estimation of the Positive Cases from the Estimated Number of PCR Tests

According to The University of Tokyo Health Promotion Headquarters Health Center (2020), if the number of PCR tests increases, the specificity is 99%, so 1% of people will get a positive result even though they are not affected [false positive]'. The late-measurement positive rate was 352,135 PCR tests, with 7,845 positives. That is,

$$7,845 / 352,135 = 2.23\%$$
.

Assuming the nature of COVID-19 and constant human antibody response, the number of positives is calculated by multiplying the estimated number of standardised PCR tests in the first half of the epidemic by the 2.23% late-measurement positive rate:

$$510,695 * 2.23\% = 11,235$$
 people.

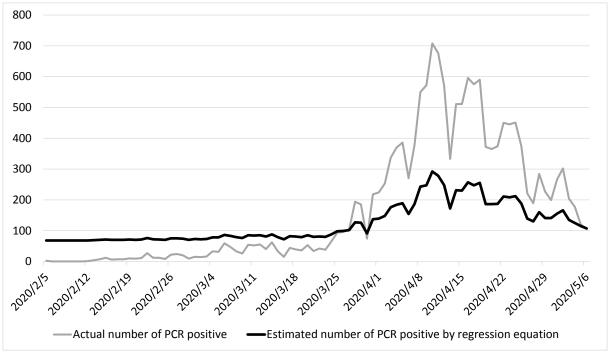


Figure 4. A Comparison of the Actual Number of Positive Cases and the Estimated Number of Positive Cases

Based on the estimated number of PCR tests that could have been carried out, the estimated number of positive cases before 6 May is shown in Figure 4. It shows that the estimated number of positive cases that draw the black line is lower than the actual number of positive cases that draw an ash line.

3.2 Discussion

The estimated number of positive cases is calculated as 11,235, 4,156 less than the number of actual positives in the first half of the epidemic 15,391. This suggests that the properties of COVID-19 have changed, as the second half is more attenuated than the first half, or that the human antibody response has changed enormously or both. Alternatively, it may mean that an unknown factor has been added.

This study dealt with the number of PCR tests and the number of PCR positive cases, but the number of PCR positive cases and deaths have not yet been studied. Regarding the cause of death, the Ministry of Health, Labor and Welfare issued a notice on June 8, 2020, stating that PCR-positive cases should be reported as due to COVID-19 without specifying the cause of death. (Ministry of Health, Labor and Welfare, 2020c). However, in the case of influenza, statistics are kept by clearly separating direct and indirect deaths. After the notification, statistics that distinguish between direct and indirect deaths are not available in the case of COVID-19 in Japan. This is expected to be an obstacle to future statistical analysis.

IV. Conclusion

Although this study has provided a practical and feasible analytical model for further research, it remains at a pilot test level. For example, Relationship among deaths numbers and PCR test numbers and PCR positive numbers and other elements, is not yet to analyzed. We have acknowledged the potential of a future collaborative approach that includes specialists in infectious diseases and immunology, in addition to statisticians and engineers that can develop

robust predictive models to support public health decision making. The negative impact of COVID-19 and other virus-oriented diseases is not limited to the medical and health domains (van Eeden et al., 2020). It should be at the top of public health agendas, with particular attention paid to vulnerable citizens, including disabled people, infants and other younger children (Dijk, 2020). COVID-19 has caused extensive societal, economic, and psychological impacts on humans within a disrupted environment. Additionally, how best to support stressed and overworked medical staff (Missel, 2020) is a priority. Therefore, further actionable interventions that can establish a safe and secure lifestyle in the 'new normal' era are essential.

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Appendix. Data Used for the Analysis

	Appendix. Data Used for the Analysis												
Date	PCR Test number (day) PCR positive num (day)	mber Positive rate	e PeriodTAG	Hospitalization (cummurative)	Hospitalization (day)	Discharge (cummurative)	Discharge (day)	Death (cummurative)	Death (day)	PCR test number by regression equation	PCR positive number by regression equation		
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