The University of Yamanashi battles COVID-19 (Part 5)

Universities need to lead the way in bolstering Japan's substandard PCR-testing framework

By Shinji Shimada, President of the University of Yamanashi, and Hiroyuki Kōjin, Specially Appointed Professor in the Medical Department of Quality and Patient Safety, University of Yamanashi Hospital

(April 22, 2020 (Wed.))

Contents

1. A monopoly on PCR tests

The last two entries in this PCR series have used telling data from Japan and around the world to show that Japan's PCR-testing framework resembles one from the developing world, thereby damaging the country's reputation internationally,[1)] and that the system may be undercounting confirmed cases by anywhere from 5,000 to 43,000 patients as of April 11.[2)] The final entry in our PCR series again probes statistical data to bring the factors behind Japan's dismal situation into clearer view, providing a contextual basis for developing optimal solutions to this national crisis.

Figure 1 traces Japan's PCR test counts over time, utilizing data from the official Ministry of Health, Labour and Welfare (MHLW) website on COVID-19 PCR tests performed (current as of April 9).[3)] As the visualization indicates, regional institutes of public health and health centers accounted for virtually all the tests administered through around March 24; the green line for the total tally fits with the orange bars almost exactly. After that point, however, the line for the total national tally diverges from the orange bars and swings upward.

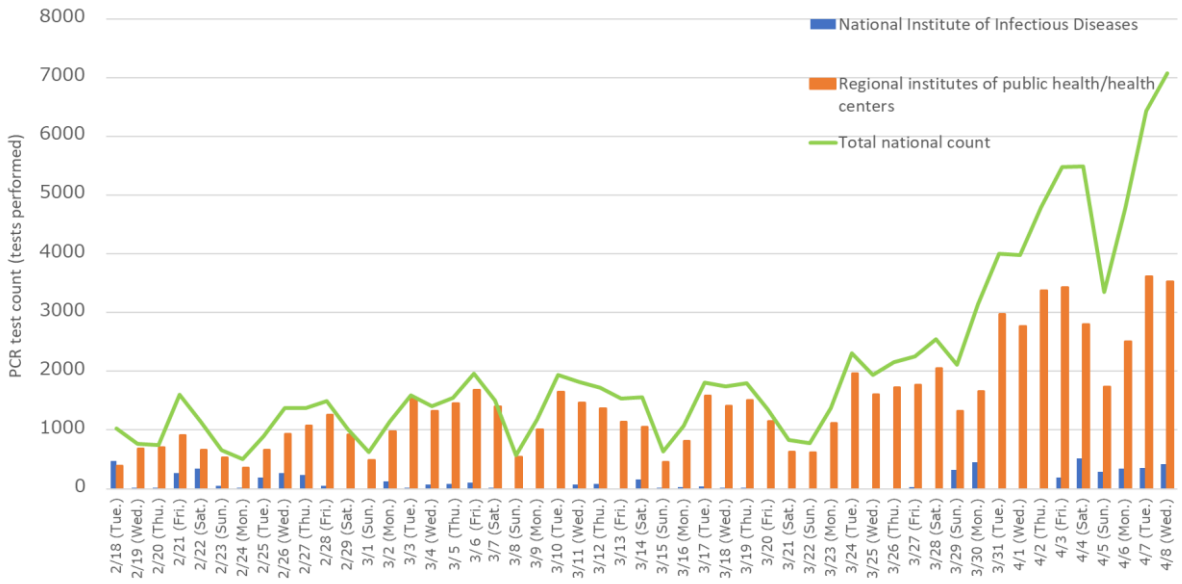

Figure 1. PCR test counts in Japan over time (February 18-April 8)

Created based on data from the MHLW

Drawing on the same MHLW data, Figure 2 illustrates the number of PCR tests performed by type of testing facility. As the graph shows, the biggest factor behind the surge in the total national PCR test count from March 25 onward has been the emerging presence of private testing companies (the light-green portions of the individual bars). On April 15 (not visible in the graph), private testing companies represented a full quarter of the tests performed—approximately 2,000 of the 8,000 tests conducted in Japan—highlighting their role as the primary driver of the rising national test total.

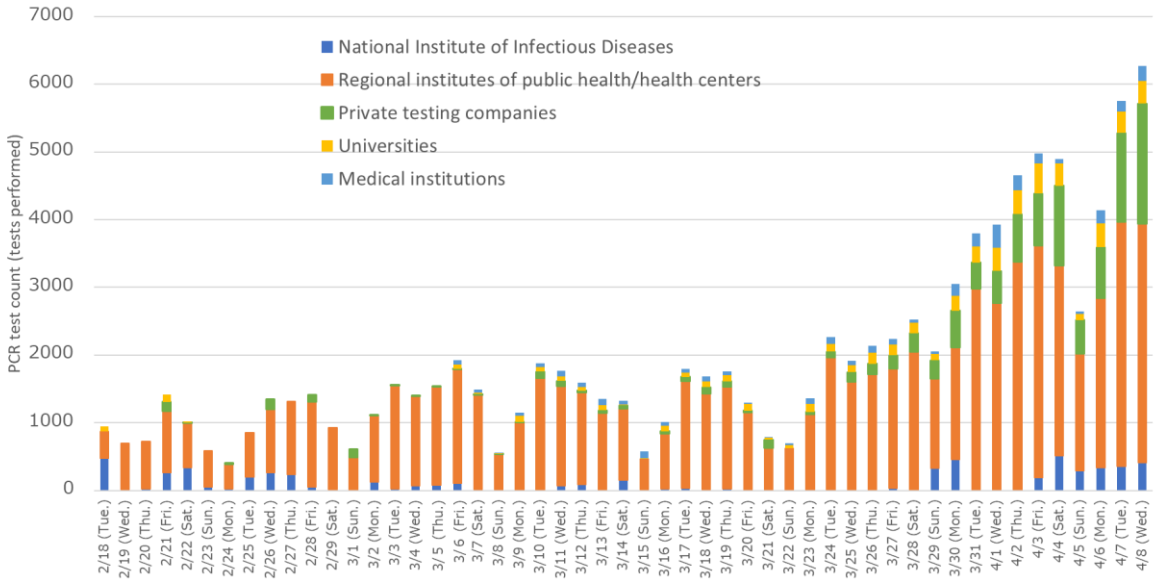

Figure 2. PCR test counts by type of testing facility (February 18-April 8)

Created based on data from the MHLW

We have argued that the scope of Japan's PCR-testing framework is akin to the systems in developing nations, and Figure 2 elucidates the main reason for that inadequate structure: that Japan's regional institutes of public health and health centers wielded what amounted to monopoly on PCR tests through late March. In its "On defining a concrete basic policy for countermeasures to the COVID-19 outbreak" (February 24), the Novel Coronavirus Expert Meeting noted that it would be "necessary to focus the country's limited PCR-testing resources on cases exhibiting severe symptoms or the potential for severe symptoms so that the medical system can be prepared for a sudden spread of the infection."[4] Ignoring the push for broader PCR testing evident in countries across the globe, the Japanese government essentially left its regional institutes of public health and health center in sole control of PCR-testing resources—an approach that stifled the country's testing capacity to paltry levels, far below international standards, and thereby set Japan up for the humiliating fate of being a highly developed country with a PCR test count befitting a developing nation.

We have no intention of finding fault with the regional institutes of public health and health centers, which continue to scrape and battle against waves of adversity. The people at these organizations deserve our deepest gratitude and respect for standing day in and day out on the front lines of the national crisis we now find ourselves in. At the same time, however, the need for a policy shift is clear; regional institutes of public health and health centers simply lack the capabilities to achieve what we believe to be crucial improvements to Japan's PCR-testing framework on their own power. The following section details the need for a rapid paradigm shift away from the existing approach and toward a broader, more effective PCR-testing framework.

2. Why PCR test numbers drop on Sundays

Figure 3 combines two sets of data, Japan's day-to-day COVID-19 PCR test counts (as of April 9) from the MHLW website[3] and the same figures for Taiwan from the University of Oxford's "Our World in Data" repository,[4] to visualize the numbers of new PCR tests performed by day of the week in the two countries. The four red boxes correspond to the four weekends during the period in question (March 8–April 8). Looking at the trajectory of the blue line in those windows, one can obviously see sharp drops in each one. The line for the Taiwanese count shows some evidence of similar dips in some cases, but the shifts are not nearly as drastic; calling the weekend decreases in Taiwan "significant" would be a stretch. Considering the precipitous declines that Japan's testing framework sees on Fridays, Saturdays, and Sundays, one could easily assert that the weekend numbers represent a contributing factor in Japan's developing country–level PCR test counts.

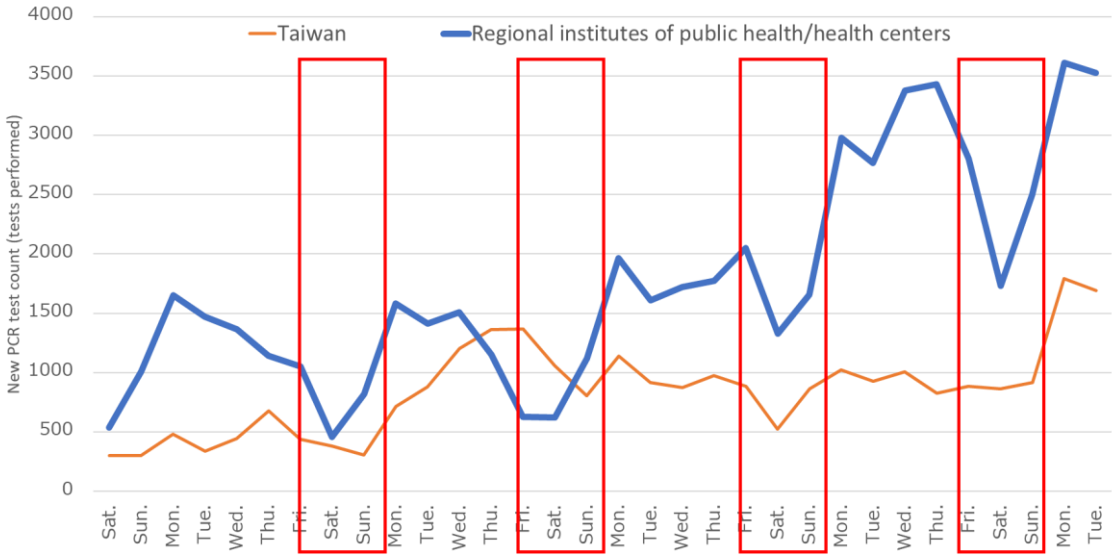

Figure 3. New PCR test counts by day, Japan/Taiwan (March 8-April 8)

Sources: Japan: MHLW; Taiwan: Our World in Data [University of Oxford]

To show how Japan's testing framework operates on a geographical basis, we compiled data on PCR test counts by prefecture,[6)] daily testing capacity by prefecture,[7)] and confirmed cases by prefecture[8)] from the MHLW website into Table 1. The third column of figures contains the "operating index" for each prefecture, which we calculated by dividing the prefecture's total tests performed by its corresponding daily testing capacity. Essentially, the quotient represents the number of days that the testing framework would have run at full capacity to handle all the cases; a higher value indicates a framework running at a higher utilization rate. The indices for the various prefectures covered a broad span, ranging from 2.2 to 45.9—but that maximum value of 45.9 (Ibaraki) is still nothing close to "full capacity." The total cumulative period in question had a duration of 84 days, meaning that Ibaraki's system would have been at capacity for just over half the time. While there is certainly no need for systems to be running non-stop, the fact that the positive rates for PCR testing by prefecture swing from 0.0 all the way up to 32.7 suggests that the distribution of the testing was uneven from prefecture to prefecture and that the government should have started redistributing its "limited PCR-testing resources"[4)] more quickly.

Table 1. Prefectures ranked according to "operating rates" for PCR testing at regional institutes of public health/health centers, with positive test rates (top 10/bottom 10)

Rank	Prefecture	A. No. of tests performed (1/15-4/7)	B. Daily testing capacity (as of 4/6)	Operating index (A/B)	Positive test rate (%) (aggregate through 4/10)	Rank	Prefecture	A. No. of tests performed (1/15-4/7)	B. Daily testing capacity (as of 4/6)	Operating index (A/B)	Positive test rate (%) (aggregate through 4/10)
1	Ibaraki	2,204	48	45.9	3.7	38	Yamagata	617	80	7.7	3.5
2	Yamanashi	1,163	30	38.8	2.7	39	Fukuoka	2,436	324	7.5	5.5
3	Mie	847	24	35.3	1.7	40	Toyama	298	40	7.5	3.6
4	Tokyo	6,332	220	28.8	30.3	41	Kochi	758	108	7.0	6.7
5	Osaka	7,244	260	27.9	32.7	42	Ehime	504	80	6.3	5.1
6	Gunma	804	30	26.8	2.3	43	Shimane	244	40	6.1	1.0
7	Kanagawa	6,021	230	26.2	16.3	44	Fukui	356	66	5.4	14.9
8	Nara	760	30	25.3	7.1	45	Tokushima	246	96	2.6	1.3
9	Okinawa	838	38	22.1	7.2	46	Tottori	294	120	2.5	0.3
10	Nagano	964	44	21.9	3.1	47	Iwate	86	40	2.2	0.0
							Total	72,950	4899	14.9	9.5

Regional institutes of public health and health centers are all administrative agencies.[9, 10] Without a doubt, regional institutes of public health stand as some of the most trusted authorities on the surveillance and testing of viral infections.[11, 12] Still, the data speaks to an important reality: the dropping PCR test counts on weekends and erratic prefecture-to-prefecture variation in operating indices are products of the inevitable fact that the organizations operate under official administrative regulations. Despite facing an unprecedented national crisis, the government chose to rely exclusively on administrative agencies to get the job done. The binding limitations that come with being an official, governmental body essentially handcuffed the testing framework from the start. To make the necessary expansions in PCR testing, Japan will need to break away from the existing paradigm as soon as possible. At the heart of that paradigm is the vertical, compartmentalized structure of the government's administrative system. Regional institutes of public health and health centers are run by prefectural or municipal governments, but the central-government body with supervisory authority over matters pertaining to medical administration is the Ministry of Health, Labour and Welfare. The compartmentalization goes further when universities enter the picture. University hospitals across Japan, of which the University of Yamanashi Hospital is one, are considered “sub-organizations” of universities, which means that they fall under the jurisdiction of another, separate ministry: the Ministry of Education, Culture, Sports, Science and Technology. Why have regional institutes of public health and health centers been almost exclusively responsible for the bulk of Japan's PCR-testing framework? To find the answer, just follow the red tape. The main reason is that the central-government authority presiding over Japan's COVID-19 response just happens to be the same authority under which the regional institutes of public health and health centers operate: the Ministry of Health, Labour and Welfare. University hospitals, despite all the crucial resources, equipment, and abilities they offer, sit on the outside looking in by virtue of their “separate” status under the Ministry of Education, Culture, Sports, Science and Technology. The presence of that deep-rooted administrative structure pervading the Japanese government, marked by severe compartmentalization and territoriality, casts a long shadow over the country's failures in addressing COVID-19.

3. Universities, answer the call: Save Japan's public-health organizations

Ever since we started writing these entries in early March, we have consistently called Japan's PCR framework a "national embarrassment" and underlined the pressing need for a change in course.[1, 2, 15, 16] The majority of the official discourse on the testing program to this point, from the releases by the Novel Coronavirus Expert Meeting[4] to statements from the presidents of the Japanese Association for Infectious Diseases and Japanese Society for Infection Prevention and Control,[18-20] has advocated a highly restrictive, exclusive approach that limits PCR tests to patients with severe symptoms only. Voices calling Japan's approach to PCR testing into question have risen to the fore in the press and other settings since the start of April,[13, 14] however, prompting Prime Minister Shinzō Abe to address the issue during a floor session in the Lower House of the Diet on April 2.[17] It would certainly appear that the tides are turning in the government's basic approach to PCR testing. Concrete initiatives are already beginning to emerge as individual communities look to steer their systems in different directions, such as Shinjuku Ward formulating the "Shinjuku model" [21] and the city of Yokosuka setting up outpatient PCR services.[22]

To process more PCR-test samples, Japan will obviously need a stronger PCR-testing system—and the segments in the best position to contribute toward that goal are private testing companies and universities (see Figure 2). Testing in the private sector has taken off since late March, accounting for an increasingly large percentage of Japan's PCR test count, but universities have yet to make their presence felt; the growth in numbers pales in comparison. At meetings of the Japan Association of National Universities on January 29 and March 4, I (Shimada) met with a relatively tepid response when I tried to convince the other attendees about the potential threat of an outbreak.[15, 23] If national universities fail to take on those roles, though, who will answer the call? What organization would even be able to?[23] The situation might seem past redemption now that COVID-19 has begun to show the brunt of its force in major cities across Japan, but it remains far too early to thrown in the towel. Now is the time for national universities outside Japan's metropolitan areas to recognize the urgency of the crisis, answer the call, and help provide the nation with what it needs most: a more effective testing structure.

Japan is home to 16 university hospitals designated as medical institutions for class-I infectious diseases and, figuring in branch hospitals and other similar establishments, 28 university hospitals designated for dealing with class-II infectious diseases.[24] First and foremost, these hospitals need to take it upon themselves to lead the way in fortifying Japan's PCR-testing framework.

The University of Yamanashi Hospital is not one of those designated medical institutions for infectious disease. However, I (Shimada) gave the hospital a directive in late January to set up a PCR-testing system. Our Clinical Laboratory Department, determined to prevent in-hospital infections at any cost, did everything in its power to make the tests as sensitive as possible and

issue results immediately. By continuing embody an academic, science-first focus and take advantage of PCR testing, the professionals in the field were in exactly the right environment and right frame of mind to diagnose a case of meningitis/encephalitis associated with COVID-19 (a male in his twenties)[15, 25] and COVID-19 in an infant.[15] The decision to perform those PCR tests at the University of Yamanashi Hospital also helped Kanagawa Prefectural Hospital diagnose a case of COVID-19 associated meningitis.[26] What Japan needs at this juncture is more than just high *numbers* of PCR tests—high-*quality* testing is crucial, too, which makes it all the more imperative that university hospitals answer the call. With their commitment to academic, science-first ideals, university hospitals have to pull their collective knowledge and capabilities together in giving Japan the robust, quality PCR-testing system it so desperately needs.

All together, this series has used data to show how Japan's feeble PCR-testing framework, not unlike the systems in developing nations, has let as many as 40,000 potential COVID-19 carriers go under the radar and put Japan in an unenviable, embarrassing spotlight on the global stage. The country is losing its international credibility as a result. No one knows how long the battle with COVID-19 might go on. This is an unprecedented crisis—which is exactly why the entire community of medical professionals needs to stay the course, never giving in to authority or following orders in blind obedience, and focus constantly on doing the right thing.

4. Acknowledgements

As president of the University of Yamanashi, I would like to extend my heartfelt gratitude to everyone at the University of Yamanashi Hospital, especially the personnel providing care and nursing support for COVID-19 patients despite all the confusion surrounding the crisis and to Tom Kain, who translated this series into English. My thanks also go to Yamanashi Prefecture Governor Kōtarō Nagasaki, who continues to provide the hospital with valuable support, along with other prefectural officials, everyone at the Ministry of Health, Labour and Welfare and other relevant ministries, and all those now contributing to the fight against the COVID-19 pandemic.

References

1) Shinji Shimada and Hiroyuki Kōjin. "The University of Yamanashi battles COVID-19: Japan's PCR test count parallels levels in developing countries" (last accessed on April 18, 2020).
2) Shinji Shimada and Hiroyuki Kōjin. "The University of Yamanashi battles COVID-19: Counting the undercounted: Just how many COVID-19 cases have gone overlooked?" (last accessed on April 18, 2020).
3) MHLW. Information on COVID-19 PCR testing in Japan (published April 11, 2020) (last accessed on April 11, 2020).
4) Novel Coronavirus Expert Meeting. "On defining a concrete basic policy for countermeasures to the COVID-19 outbreak," February 24, 2020 (last accessed on April 18, 2020).

5) University of Oxford. Our World in Data (last accessed on April 13, 2020).
6) MHLW. Total COVID-19 PCR test counts (by prefecture; calculated based on responses from regional institutes of public health and health centers) (last accessed on April 11, 2020).
7) MHLW. Daily COVID-19 PCR testing capacity (by prefecture; calculated based on responses from regional institutes of public health and health centers) (last accessed on April 11, 2020).
8) MHLW. Numbers of COVID-19 cases and PCR tests performed (by prefecture) (last accessed on April 11, 2020).
9) Ministry of Health and Welfare Notification no. 26 (March 14, 1997). On functional enhancements to regional institutes of public health (last accessed on April 19, 2020).
10) Community Health Act (Act No. 101 of 1947), Article 5, Paragraph 1 (last accessed on April 19, 2020).
11) Tomoko Ogawa. "The roles of virology laboratories at regional institutes of public health: Case studies of measles/rubella and the detection of Japanese encephalitis." Clinical Virology 45: S40, 2017.
12) Takako Misaki. "Viral infections: Recent trends and themes: Utilizing regional institutes of public health." Japanese Journal of Pediatric Medicine 49: 1576–1580, 2017.
13) "Japan's sanctuary: Novel Coronavirus Expert Meeting's recommendations have the world scratching its head." Sentaku 2020 (4): 110–113.
14) "Japan lags behind in coronavirus testing: Fewer than 2,000 tests a day, just 1/17 of Germany's pace." *The Nikkei* (daily edition), April 2, 2020, front page.
15) Shinji Shimada. "The University of Yamanashi battles COVID-29: How quick-acting risk response in late January paved the way for a diagnosis of meningitis associated with SARS-CoV-2" (last accessed on April 19, 2020).
16) Shinji Shimada and Hiroyuki Kōjin. "The University of Yamanashi battles COVID-19: Two new challenges: An eight-month-old infant with COVID-19 and a 47-person staff reduction" (last accessed on April 19, 2020).
17) "Government to conduct national survey of PCR-test criteria: Concerns about variation and undertesting grow." *Tokyo Shimbun*, April 3, 2020, TOKYO Web (last accessed April 13, 2020).
18) Japanese Association for Infectious Diseases President Kazuhiro Tateda and Japanese Society for Infection Prevention and Control President Masaki Yoshida. "COVID-19: Shifting from border control to a drawn-out battle against the spread of the infection (as of February 21, 2020) (last accessed on April 19, 2020).
19) Japanese Association for Infectious Diseases President Kazuhiro Tateda and Japanese Society for Infection Prevention and Control President Masaki Yoshida. "Clinical responses to COVID-19: How to avoid confusion on the front lines and save the lives of severe cases (April 2, 2020) (last accessed on April 19, 2020).
20) "JAID, JSIPC say hold off on PCR testing for individuals with mild symptoms, recommending self-quarantine instead," m3. com, April 3, 2020 (last accessed on April 19, 2020).

21) "How the 'Shinjuku model' could keep the medical system from collapsing under COVID-19: Shinjuku-ku establishes COVID-19 testing spots and symptom-specific admission protocols" (last accessed on April 19, 2020).
22) Yokosuka City Government. "Yokosuka to launch outpatient PCR service (group-testing facility) for COVID-19 testing" (April 17, 2020) (last accessed on April 19, 2020).
23) "COVID-19—Reports from the field: To treat the infection or pursue advanced care?" *Yomiuri Shimbun*, April 18, 2020, morning edition.
24) MHLW. Designations of medical institutions for infectious diseases (As of April 1, 2019) (last accessed on April 19, 2020).
25) Moriguchi T. et al. A first case of meningitis/encephalitis associated with SARS-Coronavirus-2. Int J Infect Dis. 94: 2020, 55-58 (last accessed on April 19, 2020).
26) "COVID-19 case at Kanagawa Prefectural Hospital underscores need to consider meningitis in cases of impaired consciousness." JIJI Press, April 8, 2020 (last accessed on April 19, 2020).