

Reflections on the COVID-19 Pandemic

~ With a Focus on Japan ~

by

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Abstract

Introduction and background: I am a local government civil servant who had been assigned to the Health Section, which is now part of the Public Health Department, for 11 years, from April 2001 to March 2012. We felt very uncomfortable as to why there were so many applications for the COVID-19 Vaccine Immunisation Health Relief Scheme in such a short period of time compared to other routine vaccinations up to the COVID-19 outbreak. Around that time, close family members, parents of friends and several colleagues at work developed lung cancer, aplastic anaemia, hair loss and extreme fatigue after vaccination, and three of them died. A causal link between those symptoms and the COVID-19 mRNA vaccine has not been proven and none of the Symptoms of four had applied to the Immunisation Health Relief Scheme. However, several members of each family suspect that the vaccine may be related to each patient's symptoms.

The COVID-19 infections in Japan have moved from "new influenza and other infectious diseases (equivalent to category 2 infectious diseases)" to "category 5 infectious diseases," and annual events and activities that had previously been impossible during the pandemic have resumed; life is returning to the way it was before the COVID-19 pandemic, and awareness of the COVID-19 pandemics is fading and waning. We also realize that we had only a vague understanding of what the COVID-19 pandemic was.

In the COVID-19 pandemic, many things happened simultaneously all over the world. There were also developments unique to Japan that were not seen in other countries. With the memories of many people still fresh in our minds, we thought it was very important to consider what the COVID-19 pandemic was and what problems and issues arose from a comprehensive and exhaustive perspective in order to prevent similar issues in the future.

Method : This is a literature review.

Through my graduate coursework, we gained the experience of doing our own research, and from this experience, we learnt that there is little or no coverage of public health in the major media, such as television and newspapers. The method used in the present review was to select and collect information that was considered important from various information media, including social media such as X and YOUTUBE, in addition to the national and international books and magazines on the COVID-19 pandemic. Information that could be confirmed by official data and articles was organized and summarised.

Academic articles were searched on PUBMED, except for preprints. Data were retrieved from the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Internal Affairs and Communications (MIC) homepages. Information from the news was mainly retrieved from the NHK. Website information was retrieved from those provided by public organizations such as medical associations and other insurance medical-related groups, academic societies, and governments, as well as from official websites provided voluntarily by medical professionals.

Main body of the paper : In addition to the basic information in the time series, which focuses on Japan, this report is based on primary information up to October 2023 and summarized in 25 thematic sections. The entire report is divided into four periods. Information was compiled mainly from Japan, but information from overseas and around the world was also added for comparison with the overall flow, and the descriptions are from Japan.

The four phases are outlined as follows:

Phase I: 2019/10 - 2020/10 (major strains: conventional strains)- From the emergence of new coronavirus infections to the spread of infection-.

Phase II: 2021/11 - 2022/1 (major strains: alpha and delta strains)- Infection spreads, vaccination begins.

Phase III: 2022/2 - 2023/4 (Major strain: Omicron strain BA)- Infection spreads, additional vaccination begins.

Phase IV: 2023/5- (Major strains: Omicron strains XBB-EG)- Shift from "new influenza and other infectious diseases" to "Class 5 infectious diseases (equivalent to influenza)".

Discussion: Based on the content of this article, the following five points of interpretation are discussed.

The first point is the increase in the number of deaths in Japan during the COVID-19 epidemic and the factors behind this increase.

The second point is the urgent approval of the COVID-19 mRNA vaccine.

The third point relates to the dishonest behaviour of the Japanese national authorities.

The fourth point concerns biased media reporting.

The fifth point relates to the actions of the WHO.

In conclusion, the so-called conspiracy theory that 'international organisations like the WHO, big pharmaceutical companies and other interested parties are using man-made viruses to cause pandemics, paralysing the economy, fomenting unrest, getting people vaccinated and making profits' is circulating in the public mind, but at this stage this story We cannot immediately and completely affirm this, but at the same time we do not believe that this possibility can be completely ruled out. Further investigation and verification is needed, including the possibility that this story is true.

We believe that the compilation of information on the overall global pandemic of the COVID-19, with a focus on the situation in Japan, has provided an opportunity to identify new issues to be addressed. One drawback is that we were not able to include information on

grants and other financial outlays in various countries related to COVID-19. I believe that this information should be included in future reviews.

Conclusion: One of the most important concerns about the COVID-19 pandemic is that experts as well as the general public have taken political and media reports at face value and often followed them without doing their own research. We live in an era in which it is important for everyone, not just experts, to research primary sources and make their own decisions. It is also extremely important to know opposing views that differ from our own and to deepen the debate.

The impact of the COVID-19 pandemic is ongoing, and we must continue to pay attention to data, information, and scientific articles from various countries and continue to verify the COVID-19 pandemic with a broad, long-term perspective.

List of abbreviations

The WHO	The World Health Organization
WEF	World Economic Forum
WIV	Wuhan Institute of Virology's
FY	Fiscal Year
DVT	Deep vein thrombosis
The BNT162b2	Pfizer-BioNTech
IHR	International Health Regulations

1. Phase I:2019/10 – 2020/10 (major strains: conventional strains)- From the emergence of new coronavirus infections to the spread of infection-

Information on how social life was restricted to prevent the spread of the COVID-19 and what social phenomena occurred from the early stages of the outbreak is summarized.

1.1. How it occurred, how it spread, and what impact it had?

The timeline is as follows:

Table 1 : 2019/10 - 2020/10 timeline

2019	10	18	Simulated exercise of a new coronavirus pandemic at WEF (1)
	12	8	A patient with pneumonia of unknown cause is confirmed in Wuhan (2)
		12	First patient admitted to Wuhan Central Hospital (2)
		26	A 41-year-old man who works at Wuhan Seafood Market was admitted to the hospital (2)
		30	Local doctor Li Wenliang sends out "SARS" on SNS (3)
		31	Wuhan Health Authorities Report Pneumonia Outbreak to the WHO (4)
2020	1	1	Male (41 years old) transferred from ICU to another hospital in Wuhan (2)
		7	Nature accepts a viral article derived from a man (41 years old) (2)
		8	The WHO denies the possibility of "SARS," "MERS," or "bird flu." Possibility of new coronavirus (5)
		11	First infected person in Wuhan City dies, 7 seriously ill, 41 infected (6)
		14	The WHO confirms new coronavirus outbreak (7)
		15	#First confirmed infection in Japan: Chinese male traveling to Wuhan (8)
		23	Wuhan City transportation service suspended, train station and airport sealed off (9)
		25	Wuhan City 1,975 reported cases (2)
		30	The WHO Director General " Declares a State of Emergency" (10)
		31	#Designated as a "Designated Infectious Disease" under the Infectious Disease Control Law and a "Quarantinable Infectious Disease" under the Quarantine Law (11)
	2	3	#Cruise ship with confirmed infected passengers arrives at Port of Yokohama (12)
		11	WHO New coronavirus named COVID-19 (13)
		13	#First domestic death of a woman in her 80s (14)
		27	#Elementary and junior high schools nationwide announced temporary closure of all schools. From March 2 until spring break (15)

	28	#State of emergency declared in Hokkaido (16)
3	10	#Designated a "State of Historical Emergency (17)"
		Behavioral restrictions begin throughout Italy (18)
	11	The WHO New coronavirus can be described as a pandemic (19)
		# Senbatsu High School Baseball Tournament cancelled for the first time (20)
	17	France: Curfew Restrictions Begin Across the Country (21)
	22	New York State, U.S.A., begins to restrict outings (22)
	24	#Tokyo Olympics and Paralympics postponed one year (23)
4	7	#7 Prefectures "Declaration of State of Emergency" (24)
	10	#Governor of Tokyo announces business categories and facilities to request closure (25)
	16	#"Declaration of Emergency" extended to all prefectures (26)
	26	#Cancellation of National High School Athletic Meet (August) (27)
5	20	#Summer National High School Baseball Tournament cancelled for the first time since the war (28)
7	22	"Go To Travel" campaign launched (29)
8	11	More than 20 million people infected worldwide (30)

*Themes covered in a separate section are listed in bold. #: Happening in Japan

1.2. Maximum increase in the number of infected persons per day (31)

1st wave: + approx. 550 (April 2020)

2nd wave: + approx. 1,500 (July 2020)

1.3. The COVID-19 Pandemic Preparedness

With the declaration of a pandemic by the WHO on January 30, 2020, various measures were taken in Japan, including "declaration of a state of emergency" and action restrictions.

1.3.1. It is designated as a "specified infectious disease" under the Infectious Disease Control Law and as an "Quarantinable infectious disease" under the Quarantine Law.

On January 31, the COVID-19 was designated as a "specified infectious disease" under the Infectious Disease Control Law and "Quarantinable infectious disease" under the Quarantine Law, allowing prefectural governors to recommend hospitalization at medical facilities with infectious disease countermeasures, order closure for a certain period, and impose penalties for failure to comply with inspection and medical measures at airports and ports. The decree went into effect on February 1 (11).

1.3.2. Declaration of State of Emergency (1st)

On March 26, 2020, following a rapid increase in the number of infected people in Tokyo, the government established "government task force" because of the high possibility of the spread of the COVID-19 in Japan (32).

On April 7, in response to the rapid spread of the COVID-19 in urban areas, the government issued a declaration of a state of emergency based on the "Law Concerning Special Measures" against the COVID-19. This declaration was issued in seven prefectures from April 25 to May 6: Tokyo, Kanagawa, Saitama, Chiba, Osaka, Hyogo, and Fukuoka (24).

On April 16, the scope of the "Declaration of Emergency" was expanded to include all

prefectures in Japan, as the infection spread beyond the seven prefectures.

The government designated the above period, which falls on large holiday in May, as "Stay at Home to Protect Lives Week" and urged people to refrain from going out unnecessarily (26).

After the "Declaration of Emergency Situations" was extended, the government lifted the emergency declarations in stages from May 14(33), and the last remaining emergency declarations for Tokyo, Kanagawa, Chiba, Saitama, and Hokkaido were lifted by the national task force meeting on May 25 (34).

1.3.3. Restriction of actions in the world

In Japan, the government called for voluntary curbs on going out. Below are some examples from around the world.

In France, gatherings of family and friends were banned in principle, and people were prohibited from going out, except to buy necessities, for health reasons or for work that did not permit telecommuting. The government imposed a strict curfew on all citizens and imposed penalties on violators (21).

In the U.S. state of New York, all employees and workers, except police officers and medical personnel, were prohibited from going to work, and residents were asked to stay home and not go out (22).

1.3.4. Restrictions on activities/closures or restrictions on operations in Japan

In April, the Tokyo Metropolitan Government requested that six industries and facilities be closed: game arcades and other amusement facilities, universities and tutoring schools, exercise and play facilities, theaters and other conference and exhibition facilities, and commercial facilities. It also requested that restaurants, including taverns, be open from 5:00

a.m. to 8:00 p.m. and that alcoholic beverages be served until 7:00 p.m. (25).

They also requested that "in areas where an alert has been declared, office work should be done at home in principle, and even if it is absolutely necessary to go to work, the number of workers should be reduced by 70% or more. It also called for voluntary restraint in the use of restaurants that serve customers at night in downtown areas nationwide (24).

In May, the panel of experts proposed a new lifestyle. The new lifestyle was defined as "focusing on the basics of infection control, such as avoiding three densities and physical distance." The new lifestyle was defined as "a new way of life" (35).

Along with restrictions and voluntary restraints on events, many professional games, including professional baseball games, were also played without spectators (36).

1.3.5. Ensuring the wearing of masks

Basic examples of " a new way of life " presented at the expert meeting included maintaining physical distance, washing hands, and wearing masks. Thorough mask-wearing continued until March 2023, when the wearing of masks became an individual decision. In fact, even after March, restaurant clerks and others often work while wearing masks.

Although there was no detailed or thorough instruction on how to wear masks, in January 2021, an incident occurred in which a student taking a university entrance exam continued to wear a mask with his nose exposed, invalidating his score. When the supervisor cautioned him to cover his nose with a mask, the man objected, saying that the examination guidelines did not state how to wear a mask. The man continued to tell the supervisor that there was no evidence of this anywhere. During the reading exam, the supervisor identified this as misconduct and showed him a piece of paper notifying him that he could not continue with the exam (37).

After the reading exam, the man was asked to move, but he refused to leave the room,

saying he would "never move." The police then caught the man, 49, in the act of locking himself in the restroom at the university where the exam was given, where his scores were invalidated, for approximately four hours and did not leave the building (38).

1.3.6. Securing the Medical System and Medical Tightness

Every time a new coronavirus outbreak occurred; the medical care crunch was alarming.

Why did so many people die at home without receiving inpatient treatment even though Japan has the largest number of inpatient beds (hospital beds) in the world?

There were "infectious disease beds" and "general hospital beds" available for hospitalization of patients infected with new coronas, mainly in urban areas. In the first wave, there were about 16,000 beds, or 1.8% of the total. In the second wave, there were about 22,000 beds, or 2.49% of the total. In the fifth wave, in which many people died at home, there were only about 38,000 beds, or 4.23% of the total. In the seventh wave, which accounted for 5.14% of the total, there were only about 46,000 beds, and the total number of beds did not increase significantly.

In fact, nearly 30% of the large hospitals did not accept any patients, and even among the approximately 500 large hospitals that did accept patients, the number of patients was less than 10, and only about 10% of these hospitals accepted more than 20 patients.

In addition, while private hospitals, which account for 70% of all medical facilities in Japan, accepted only 15% of all patients, 57% of public hospitals did accept patients, but 70% of these public hospitals accepted only a small number of patients (less than 10).

It is believed that even when secured beds were available, there were often cases where patients were refused due to staff shortages (39).

Table 2: *Number of beds reserved for hospitalization of the COVID-19 patients during the period of infection spread*

Number of beds reserved for inpatients during periods of infection spread.					
	Period around the peak of the wave of infection	Number of infected persons per day (persons)	Number of persons treated (persons)	Number of beds reserved for inpatients (% of total beds in parentheses)	Number of admissions at each time point (persons)
1st wave	2020/05/01	282	8,711(04/28)	16,081(1.80%)	5,514(04/28)
2nd wave	2020/08/05	1,344	11,730	22,190(2.49%)	5,116
3rd Wave	2021/01/06	6,066	42,894	27,650(3.10%)	13,093
4th Wave	2021/05/12	7,059	70,867	32,985(3.70%)	16,620
5th Wave	2021/08/18	24,091	165,477	37,723(4.23%)	21,434
6th Wave	2022/02/02	98,590	664,075	43,503(4.88%)	22,653
7th Wave	2022/08/03	249,805	1,830,868	45,762(5.14%)	30,562

*Based on multiple Ministry of Health, Labor and Welfare data. Statistics on the number of secured beds for inpatients are from May 1, 2020. The number of persons in care is the total of those hospitalized, those staying overnight or receiving care at home, those admitted to temporary medical or inpatient waiting facilities, and the number of persons whose place of care is being adjusted. The total number of beds is 889,824, consisting of infectious disease beds (1,904) and general hospital beds (887,920) (from the Ministry of Health, Labor and Welfare's 2020 Survey of Medical Facilities).

Note. Source:(Tokyo Shimbun TOKYO Web.) 2022 Aug 18 [cited 2023 Nov 25]; Available from:

<https://www.tokyo-np.co.jp/article/196641> (40)

Another problem is that medical institutions are not legally obligated to accept patients infected with the novel coronavirus. The Medical Service Law, which regulates the medical care system, allows each medical institution to decide what kind of patients it will accept in which department, and the prefectural government, which has the authority to supervise hospitals, cannot give instructions or orders to hospitals.

There is also currently no mechanism in place to compensate hospitals for losses resulting from closure or loss of revenue due to patient acceptance (41).

A good example of how the tight medical situation was prevented is the "Matsumoto Model," an initiative of the Matsumoto Medical Region centered on Matsumoto City, Nagano Prefecture. Public and private medical institutions shared the responsibility of accepting patients according to the severity of their illness, and the community worked together to prevent the collapse of medical care (42).

1.4. Controversy about the origin of the COVID-19

How was the origin of the new coronavirus investigated and what are the theories?

1.4.1. The WHO's field survey

Regarding the origin of the new coronavirus, the WHO sent two staff members to the area to investigate in July 2020, about six months after the declaration of the state of emergency and sent an investigation team (10 experts) to China in January 2021, about a year later. Initially, the investigation team announced that "it could take several years to get the results" after completing its inspection of the sites involved (43), but in February, the team stated that it was "extremely unlikely" that the virus had leaked from the Wuhan Virus Research Institute (44). However, the same month, another researcher on the WHO Wuhan investigation team said, "China did not provide us with detailed data, and if the data is being withheld, we do not know (45)."

A report published in March failed to identify the origin or location of the outbreak, and concluded that an outbreak from the virus laboratory was highly unlikely (46).

1.4.2. Theory of spontaneous outbreak of new coronaviruses

The article "A New Coronavirus Associated with Human Respiratory Disease in China," accepted for publication in Nature on January 7, 2020, reported a case of an infected 41-year-old male patient admitted to Wuhan Central Hospital on December 26, 2019. An attempt was made to identify the virus.

The first patient was admitted on December 12, and at the time the article was written, 1,975 cases of the new virus had already been reported. However, there is no description of

the details of the cases, such as where the disease originated. The article concludes that because the man worked in a seafood market in Wuhan, and because this novel coronavirus is most closely related to the bat coronavirus, “the outbreak was associated with the Wuhan seafood market. However, the natural or intermediate host of this novel coronavirus has not been identified, and the isolation of the virus from a single patient is not sufficient to conclude that this virus caused the respiratory symptoms.”

At the end of the article, the proofreader added that the WHO has named this virus the COVID-19 (2).

1.4.3. The theory that the new coronavirus was artificially created

October 27, 2022, The U.S. Senate Committee on Health, Education, Labor and Pensions (Senate Committee on Health, Education, Labor and Pensions) reported the following in its interim report.

“Experts have proposed two dominant theories on the origins of the virus: <1> the virus is the result of a natural zoonotic spillover or <2> the virus infected humans as a consequence of a research-related incident.”

“Such gaps include the failure to identify the original host reservoir, the failure to identify a candidate intermediate host species, and the lack of serological or epidemiological evidence showing transmission from animals to humans, among others outlined in this report.”

“A research-related incident is consistent with the early epidemiology showing rapid spread of the virus exclusively in Wuhan with the earliest calls for assistance being located in the same district as the Wuhan Institute of Virology’s (WIV) original campus in central Wuhan. The WIV is an epicenter of advanced coronavirus research, where researchers have collected samples of and experimented on high-risk coronaviruses.”

“This investigation’s interim report concludes that SARS-CoV-2 and the resulting COVID-19 global pandemic was, more likely than not, the result of a research-related incident associated with coronavirus research in Wuhan, China (47).”

In Japan, an article entitled "Unnatural evolutionary processes of SARS-CoV-2 variants and the possibility of deliberate natural selection" was presented at the 70th Annual Meeting of the Japanese Society for Virology held in Sendai, Japan, from September 26 to 28, 2023 (48).

“The following results presented in this study may support the hypothesis that the Omicron variants were artificially synthesized rather than naturally occurring: 1) the presence of Omicron variant-associated isolates with one mutation site being the Wuhan-type; 2) the almost complete absence of synonymous mutations in the S protein in these isolates; 3) the Omicron variant, which should have been first reported to the WHO from South Africa on November 24, 2021, was already endemic in Puerto Rico in 2020, and there were isolates that were recombinants between Omicron strains BA1 and BA2. In addition, the Omicron mutant-related isolates (BA.1-0.1, BA.1.1-0.1, and BA.2-0.1 isolates) with a Wuhan-type mutation at one of the mutation sites were established. Unnatural evolutionary processes of SARS-CoV-2 variants and possibility of deliberate natural selection.”

“No one has offered an explanation why a naturally occurring virus would utilize a suboptimal furin cleavage site. There has been no mention of the technical possibility of inserting this furin cleavage site or a CGG codon artificially (49).”

1.5. Pre-simulation exercise a month and a half before the appearance of a new coronavirus

On October 18, 2019, the Bill & Melinda Gates Foundation, the Johns Hopkins Center

for Health Security (Johns Hopkins University), and the World Economic Forum hosted “Event 201,” a simulation event to prepare for a “novel coronavirus pandemic.”

According to the news from the Center for Health Security at Johns Hopkins University, released three days before the event (50), the event included the following:

“October 15, 2019 – Former and current global business, government, and public health leaders will play a team of high-level decision makers convened to recommend actions to diminish the large-scale economic and societal consequences of a fictional outbreak of a severe pandemic scenario in the upcoming Event 201. The exercise, and virtual exercise, hosted by the Johns Hopkins Center for Health Security in partnership with the World Economic Forum and the Bill and Melinda Gates Foundation, takes place Friday, October 18, 2019, in New York City.”

“In the 3.5-hour exercise, the players will be presented with a pandemic scenario that highlights unresolved real-world policy and economic issues that could be solved with sufficient political will, financial investment, and attention now and in the future. It will illustrate the pandemic preparedness efforts, response decisions, and cooperation required from global businesses, governments, and public health leaders.”

“The players play their real or former professional roles and come from a number of countries and industries essential to response and to keeping society and economies moving.”

Speakers include the Bill & Melinda Gates Foundation, the Johns Hopkins Center for Health Security, and the WHO (video participation), as well as the CDC in the US and China, former World Bank Group, and major media companies. In addition, the exercise was funded by the Open Philanthropy Project.



Figure 1: *Participants in Event 201 Pandemic Exercise*

Note. Source(Event 201 Pandemic Exercise: Segment 1, Intro and Medical Countermeasures (MCM) Discussion [Internet]) [cited 2023 Nov 25]. Available from : <https://www.youtube.com/watch?v=Vml-DnxRiPM> (51)

President of Global Development at the Bill & Melinda Gates Foundation, the Executive Director of the China Centers for Disease Control and Prevention, and the Deputy Director of Public Health Services and Implementation Science at the U.S. Centers for Disease Control and Prevention were among the 15 players.



Figure 2 : *Event 201 also featured a news program that specifically simulated a pandemic, and a mock meeting was played with realistic images that the audience would normally mistake for the real thing.*

Note. Source (*Event 201 Pandemic Exercise: Segment 2, Trade and Travel Discussion [Internet]*) [cited 2023 Nov 25]. Available from: <https://www.youtube.com/watch?v=QkGNvWfICNM> (52)

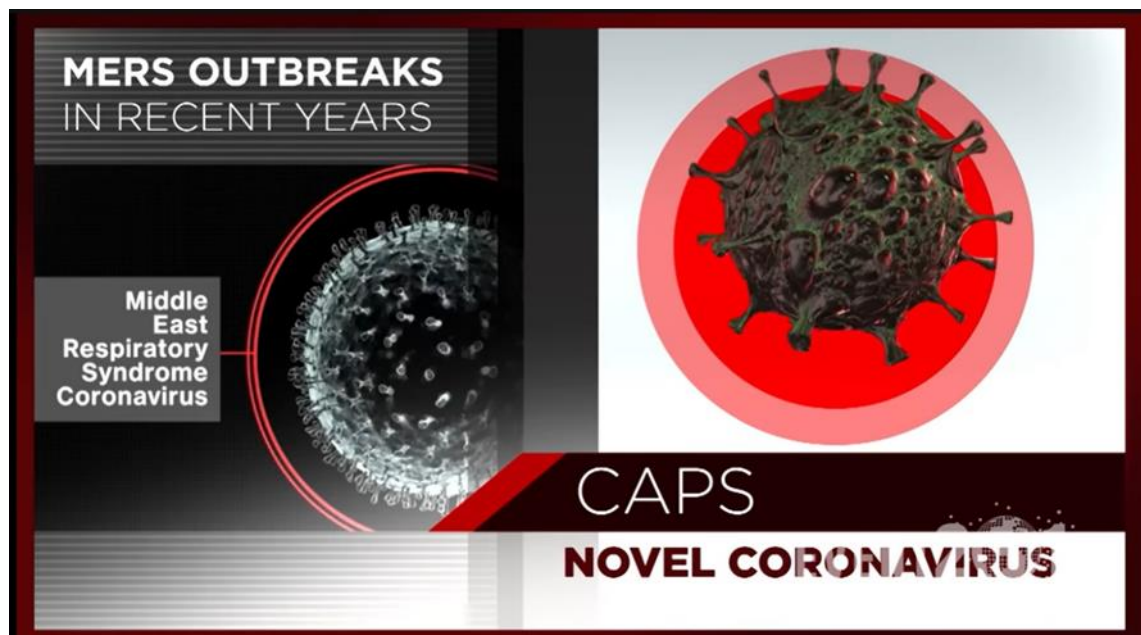


Figure 3 : *Mock newscast airs about corona pandemic*

Note. Source (*Event 201 Pandemic Exercise: Segment 1, Intro and Medical Countermeasures (MCM) Discussion [Internet]*) [cited 2023 Nov 25]. Available from: <https://www.youtube.com/watch?v=Vm1-DnxRiPM> (53)

Most of what was played out during the event discussed what happened, such as the shortage of personal protective equipment, the move by the government to make vaccines mandatory, and the economic insecurity caused by lockdowns and restrictions on social activities, resulting in the breakdown of social ties. In addition, there were exercises on the need for censorship to deal with “false information” such as rumors that the virus was actually man-made and released from a biological weapons laboratory, or questions surrounding the safety of vaccines that were prematurely approved without following the normal procedures.

The purpose of Event 201 is to educate senior leaders at the highest levels of U.S. and international government, as well as global industry leaders (54–58).

2. Phase II :2021/11–2022/1 (major strains: Alpha and Delta strains)

Spread of infection (³th–⁵th wave) and start of the COVID-19 mRNA vaccination-

In the previous issue, we summarized the situation and social phenomena in the early stages of the outbreak. In this issue, we summarize information on the changes in the social environment surrounding society in response to the further spread of COVID-19 infection, focusing mainly about the start of COVID-19 mRNA vaccination.

2.1. Movements before and after the start of COVID-19 mRNA vaccination and changes in the infection situation ?

With the major strains of the COVID-19 changing and spreading around the world, an emergency COVID-19 mRNA vaccine was approved and vaccination began.

The timeline is as follows,

Table 3 : 2021/11–2022/1 timeline

(59)2020	11	18	*Pfizer announces vaccine efficacy rate of 95% (59)
		20	*Pfizer applies to FDA for emergency use authorization for vaccines (60)
		30	*Moderna's application to FDA for an emergency use permit for a vaccine (61)
	12	2	UK approves Pfizer vaccine (62)
		8	Pfizer vaccination begins in the U.K. (63)
		10	*FDA expert committee majority in favor of Pfizer's vaccine (64)
		11	*FDA approves emergency use of Pfizer vaccine (64)
		14	*Pfizer vaccination begins in the U.S. (65)
		15	"Go To Travel" temporarily suspended due to spread of infection (66)
		18	*FDA approves Moderna vaccine (67)

	21	EU approves vaccines from Pfizer, others (68)
	26	#Temporary suspension of new entry of foreigners from all over the world (69)
	31	* Pfizer's article on vaccine effectiveness published in medical journal (70)
2021	1 7	² nd"Declaration of Emergency" 1 Tokyo and 3 prefectures until 2/7 (71)
	9	Require all entrants to submit a pre-departure inspection certificate (72)
	19	#Kono, Minister of Administrative Reform, in charge of vaccination maintenance (73)
	27	More than 100 million people infected worldwide (30)
	2 7	More than 100 million people vaccinated worldwide (74)
	14	# Pfizer Vaccine Approval (75)
	17	#Started prior vaccination of health care workers (76)
	27	European countries move to tighten or extend regulations due to the spread of mutant viruses (77)
	4 25	#Tokyo, Osaka, Hyogo, Kyoto ³ rd"Declaration of State of Emergency" until 5/20 (78)
	5 21	#Moderna and AstraZeneca Vaccine Approval (79)
	7 12	#Tokyo ⁴ th"Declaration of Emergency" until 8/31 (80)
	8 2	#Declaration of state of emergency expanded to 6 prefectures Priority measures in 5 prefectures (81)
	9	#Vaccinated over 100 million people(82)
	24	*FDA officially approves Pfizer's vaccine (83)
	27	#Declaration of state of emergency expanded to 21 prefectures until 9/12 (84)
	10 31	COVID-19 Vaccinations Reach 7 Billion Worldwide (85)
	11	#New mutant virus "Omicron strains" epidemic (86)
	12 4	#MHLW"Rarely serious adverse reactions such as myocarditis after vaccination" alert (87)
	26	#Association of patients with "the COVID-19 mRNA vaccine after effects" established (88)

*Themes covered in a separate section are listed in bold.

#: Happening in Japan *: Happening in the U.S.

2.2. Maximum increase in the number of infected persons per day (31)

3rd wave: + approx. 2,500 (November 2020) Conventional strains

4th wave: + approx. 7,000 (May 2021) Alpha strains

5th wave: + approx. 25,000 (August 2021) Delta strains

2.3. Further the COVID-19 Pandemic Preparedness

In addition to the continuing measures, there was the issuance of a new emergency declaration and the establishment of a new minister in charge of vaccine promotion.

2.3.1. Declaration of Emergency (2nd to 4th time)

In response to the spread of infection, the national government declared a state of emergency for the second to fourth time in January, April, and July. Each prefecture also declared its own state of emergency and imposed restrictions on human activities (71,78,89).

2.3.2. Establishment of a new minister in charge of vaccination promotion

The first Minister of State for Vaccination Promotion (commonly known as the Minister of State for Administrative Reform) was Taro Kono, who was in charge of administrative reform from January 19 to October 3, 2021. At the same time, Kono also served as Minister of Cabinet Office Special Assignment for Regulatory Reform. (Although the official gazette does not list his position, this was an appointment made at the direction of the Prime Minister (73,90).)

The second Minister of State for Vaccination Promotion (commonly known as the Minister of State for Vaccination Promotion) was appointed as Akiko Horiuchi, who is listed in the October 4, 2021, Official Gazette as “in charge of coordinating the affairs under the jurisdiction of administrative departments to promote the smooth implementation of vaccination against COVID-19 mRNA vaccine”. She also served as Minister of State in charge of the Olympic Games and Tokyo Paralympic Games and Minister of State for Vaccination Promotion (91,92).)

2.4. From the COVID-19 mRNA vaccine development to the approval and start of vaccination

In addition to the progress of the COVID-19 mRNA vaccine development, approval, and vaccination methods, we will have a review of academic papers that were the first to evaluate the vaccine.

2.4.1. The COVID-19 mRNA vaccine is developed, approved, and vaccination begin

On February 14, 2021, the production and marketing of the first COVID-19 mRNA vaccine was approved under the Pharmaceuticals and Medical Devices Law. On the 16th of the same month, the government ordinance was revised, and the next day, vaccination of healthcare workers began as a temporary vaccination based on the Immunisation Law. Subsequently, the age range for vaccination was expanded to include the elderly, adults, and children.

While the vaccination of children aged 12 and older was made an obligation of effort along with vaccination recommendations at the start of the temporary vaccination, vaccination of children aged 5 to 11 was not made an obligation of effort because the efficacy of the vaccine against the Omicron strain was not clear, although vaccination recommendations were made at the beginning.

Subsequently, the obligation to make an effort was imposed from September 6, 2022, on the grounds that the efficacy and safety of the vaccine had been confirmed (93).

Vaccine development was implemented under the “Accelerated Parallel Plan” policy. the “Accelerated Parallel Plan” is a policy that, under the condition of a pandemic, the normal schedule for each process is drastically shortened, basic research and non-clinical and clinical trials are conducted in parallel, the review organization for regulatory approval is shortened, and R&D and production systems are developed in parallel, to achieve regulatory approval

and commercial production as quickly as possible. This is a policy (94).

2.4.2. Location and method of the COVID-19 mRNA vaccine (95)

There were three types of the COVID-19 mRNA vaccinations conducted in Japan.

These were those administered by local governments (mass and individual vaccinations), those administered by the Self-Defense Forces (large-scale vaccinations), and those administered by companies and universities (workplace vaccinations).

All of them use “vaccination tickets” (two doses) issued by the municipality in which the resident is registered.

At the beginning of the COVID-19 mRNA vaccination, it was difficult to make an appointment because phone calls and other means were not connected.

The process from reservation to COVID-19 mRNA vaccination is as follows,

- (1) Receive “Vaccination Coupon” and “COVID-19 mRNA Vaccination Notice”.
- (2) Search for medical institutions and vaccination sites where the vaccination is available on the Ministry of Health, Labour and Welfare website “Corona Vaccine Navi”, etc.
- (3) Make an appointment by phone or on the Internet.
- (4) Receive the first vaccination.
- (5) Make an appointment for the second vaccination.
- (6) Receive the second round of vaccinations.

2.4.3. First article on the evaluation of the COVID-19 mRNA vaccine

In December 2020, about 10 months after the WHO declared an emergency situation, Pfizer's COVID-19 mRNA vaccine was the first in the world to be approved in the UK, and vaccination began six days later (62).

In the U.S., Pfizer submitted an emergency use application to the FDA in December 2020, and an emergency use permit was approved about three weeks later. Vaccination began two days after approval (64).

Pfizer's COVID-19 mRNA vaccine was published on December 31, 2020 in the article "Safety and Efficacy of the BNT162b2 COVID-19 mRNA Vaccine" in "The new England journal of medicine (70)."

The article presented the following data:

Vaccination group:

Total: 18,198 persons

Infected: 8 persons; one became seriously ill.

Placebo group (no vaccination):

Total: 18,325 persons

Infected: 162 persons, 9 of whom became seriously ill.

Based on the above data, the incidence of COVID-19 was reduced by 0.05-fold by the vaccine, with an efficacy rate of 95%.

The effect on prevention of severe disease is not discussed within the article, but it is calculated based on the data as follows:

Severe disease in vaccination group:

$1/8 \times 100 = 12.5\%$ (of the total number of patients in the vaccination group)

Severe disease in placebo group (no vaccination):

$9/162 \times 100 = 5.6\%$

Although the sample size is too small to judge, the rate of serious illness in the vaccination group is higher than that in the placebo group, and it cannot be said that vaccination prevents serious illness at least.

“Important questions of course remain. Only about 20,000 people have received this

vaccine. Will unexpected safety issues arise when the number grows to millions and possibly billions of people? Will side effects emerge with longer follow-up?” (96)

In response to this article, an investigation by the British medical journal "bmj" pointed out several points, including data inaccuracies, confounding factors, and the possibility of selection bias.

According to FDA's report on Pfizer's vaccine, “there were 3410 total cases of suspected, but unconfirmed covid-19 in the overall study population, 1594 occurred in the vaccine group vs. 1816 in the placebo group.”

“A rough estimate of vaccine efficacy against developing covid-19 symptoms, with or without a positive PCR test result, would be a relative risk reduction of 19% (see footnote)—far below the 50% effectiveness threshold for authorization set by regulators.”

“371 individuals excluded from the efficacy analysis for “important protocol deviations on or prior to 7 days after Dose 2.” What is concerning is the imbalance between randomized groups in the number of these excluded individuals: 311 from the vaccine group vs 60 in the placebo group.”

“I expressed concern about the potential confounding role of pain and fever medications to treat symptoms. I posited that such drugs could mask symptoms, leading to under detection of covid-19 cases, possibly in greater numbers of people who received the vaccine in an effort to prevent or treat adverse events. However, it seems their potential to confound results was fairly limited: although the results indicate that these medicines were taken around 3–4 times more often in vaccine versus placebo recipients.”

“The primary endpoint in the trials is relatively subjective making unblinding an important concern. Yet, neither FDA nor the companies seem to have formally probed the reliability of the blinding procedure, and its effects on the reported outcomes.”

“Addressing the many open questions about these trials requires access to the raw trial data. But no company seems to have shared data with any third party at this point. Pfizer says it is making data available “upon request, and subject to review.” This stops far short of making data publicly available, but at least leaves the door open. How open is unclear, since the study protocol says Pfizer will only start making data available 24 months after study completion.

Moderna’s data sharing statement states data “may be available upon request once the trial is complete.” This translates to sometime in mid-to-late 2022, as follow-up is planned for 2 years (97).”

The medical journal further reported that the regional director of Ventavia Research Group, the contract research firm that supported Pfizer's important Covid-19 vaccine clinical trial, found improper practices at the contract research firm that raised questions about data integrity and regulatory oversight. The article raised questions about the integrity of Pfizer's data and regulatory oversight.

“But, for researchers who were testing Pfizer’s vaccine at several sites in Texas during that autumn, speed may have come at the cost of data integrity and patient safety. A regional director who was employed at the research organisation Ventavia Research Group has told The BMJ that the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer’s pivotal phase III trial. Staff who conducted quality control checks were overwhelmed by the volume of problems they were finding. After repeatedly notifying Ventavia of these problems, the regional director, Brook Jackson (video 1), emailed a complaint to the US Food and Drug Administration (FDA). Ventavia fired her later the same day. Jackson has provided The BMJ with dozens of internal company documents, photos, audio recordings, and emails.”

“An FDA review memorandum released in August this year states that across the full

trial swabs were not taken from 477 people with suspected cases of symptomatic covid-19” (98)

2.4.4. Market expansion related to vaccine development

The biopharmaceutical market is expanding due to the growing demand for the COVID-19 mRNA vaccine. In the pharmaceutical sector, "growth in biopharmaceuticals will be even more pronounced, with their share reaching more than 50% by 2019. Sales have doubled from 12 trillion yen in 2010 to 24 trillion yen in 2018 and are projected to reach 38 trillion yen by 2024." With a projected CAGR of 9.6% for biopharmaceuticals from 2019 to 2026 (5.5% for conventional drugs), biopharmaceuticals are expected to be a growth area in both name and substance.” (99)

2.4.5. Start of the third additional dose of COVID-19 mRNA vaccine

The third additional COVID-19 mRNA vaccine immunisation was discussed on September 17 at the 24th meeting of the Subcommittee on Immunisation and Vaccine of the Health Sciences Council, and on the same day, the Ministry of Health, Labor, and Welfare decided to conduct the third immunisation (100).

Inoculations began on December 1 for healthcare workers, with an interval of at least 8 months from the date of the second inoculation in principle (101).

By mid-February 2022, 1 million vaccinations were administered per day as a result of the promotion of the distribution of vaccination coupons, the establishment of more vaccination sites, the promotion of active use of vaccination at workplaces, and the promotion of vaccination of those engaged in businesses necessary to maintain social functions in the community.

In February 2022, the target was set at 1 million inoculations per day, but only 700,000

inoculations were given per day (102).

2.5. Concerns about the COVID-19 mRNA vaccine

Some experts and citizens have expressed concern about the COVID-19 mRNA vaccine, which is being promoted worldwide as safe and effective.

2.5.1. Scientists around the world express concern about the COVID-19 mRNA vaccine

Dr. Geert Vanden Bosch (Belgian) (biography below), a senior researcher at a company involved in vaccine development, sent an open letter to the WHO on March 6, 2021, and also published a letter on LinkedIn (an industry-oriented social networking site) urging pharmaceutical companies and others to immediately stop vaccination.

(Biography)

Head of Adjuvant Development Program, GSK Biopharmaceuticals

Director, Adjuvant Development Program, Novartis Pharmaceuticals

Director, International Influenza Vaccine Project, Solvay Biologicals, Inc.

Senior Program Officer, Bill & Melinda Gates Foundation

Senior Program Officer, GAVI Ebola Vaccine Alliance

Dr. Vanden Bosch argues that the current COVID-19 mRNA vaccine should be discontinued immediately for mass vaccination due to side effects and other concerns (103).

Other scientists, including Dr. Michael Yardon, former vice president of Pfizer (104), and Dr. Luc Montagnier, Nobel Prize winner in Physiology or Medicine (discoverer of the AIDS virus(105)), have claimed that the source of the COVID-19 virus is in the laboratory, and are scientists who has raised questions about the safety of the COVID-19 mRNA vaccine.

(Dr. Montagnier passed away in February 2022 at the age of 89.)

2.5.2. Association of patients with "the COVID-19 mRNA vaccine aftereffects" (88)

On December 24, 2021, the Association of Patients with "Sequelae of COVID-19 mRNA Vaccine" was established.

It had 756 members (2023.9.4).

The organization's website had the following message:

“On December 24, 2021, we established an association for the improvement of treatment and social treatment of health problems caused by vaccines.”

“As a personal experience, after the vaccination, I felt some side effects and I went to the hospital to seek for medical attention, but they did not treat me because they did not know the cause, and even the hospital did not believe me when I told them that my body had been acting strangely since the vaccination. In the midst of my loneliness, I sent out a social networking message and met friends suffering from the same situation. I was by no means the only one suffering from post-vaccine body abnormalities, and I still remember the day I finally found hope in the midst of my anxiety.

Vaccines are easily recommended by the government and local governments, but even if abnormalities occur, the drugs cannot be removed from our body, and no matter how painful it is, there is no remedy. Even if you call the call center enclosed in the vaccination ticket for help, they will not even refer you to a hospital. Also, the "relief system" that is available is by no means a system that will refer you to a treatment. We have learned through our own experience that drug abuse was such a thing.”

3. Phase III:2022/2 - 2023/4 (major strains: Omicron strain BA) - Spread of infection (6th-8th wave) and More COVID-19 mRNA vaccines

In the previous issue, we summarized the changes in the environment surrounding

society with respect to the further spread of COVID-19 infection, focusing primarily on the launch of the COVID-19 mRNA vaccine.

In this issue, we summarized the social phenomena, scientific papers, and official data on the impact of the additional the COVID-19 mRNA vaccine.

3.1. How has additional vaccination progressed and how has the infection situation changed? What further social changes have occurred?

While the end of the new corona infection was in sight around the world, Japan recorded the largest spread of infection and the second largest number of deaths in the world. How did Japan lead the world in promoting additional vaccinations up to the sixth dose? Also, was there any expansion in information about the COVID-19 mRNA vaccine and its impact?

The timeline is as follows:

Table 4: 2022/02 - 2023/4 timeline

2022	2	26	#Started vaccinating children ages 5-11 (106)
		28	#Establishment of "Japan Association of Volunteer Doctors" (107)
	3	7	Global death toll exceeds 6 million, The WHO states that "declining, but infection control measures must be thorough" (108)
		23	#Decided to expand the age of 3rd vaccination to 12 years old and older (108)
		25	#Nagoya City established the nation's first consultation service for long-term adverse reactions to vaccines (109)
	5	25	#4 vaccination begins for people 60 and older, etc (110)
	6	19	Officially announced that "vaccination is recommended" even for children under 5 years old U.S. CDC (111)
	7	7	New infections increased about 30% "BA.4" and "BA.5" became mainstream. The WHO (112)
		22	#4 vaccination Expand eligibility to health care workers, etc (113)
		25	#MHLW to provide first lump-sum death benefit for post-vaccination deaths (113)
			#The Japanese Society of Pathology, the Japanese Society of Forensic Medicine, and the Japanese Society of Forensic Pathology jointly issued a statement recommending pathological and forensic autopsies in cases of post-vaccination deaths (114)

	28	The WHO: “Japan has the world’s largest number of new infections” about 970,000 per week (115)
8	6	#1,438,000 more people are receiving treatment at home than ever before (116)
	19	Japan 2 nd in the world in number of deaths per week, most new infections, the WHO (117)
9	14	# Omicron strain compatible vaccine to be free public vaccination to begin next week (118)
	15	The WHO: new coronas "end in sight" (119)
	20	#Launched the Bipartisan Diet Members Caucus for Vaccination of Children and Vaccine Sequelae (120)
10	19	#Vaccines after 3rd dose to shorten interval from 5 months to 3 months (121)
	20	#" Association of Survivors of Post-Vaccine Injuries " established (122)
	21	#Tokyo Metropolitan Government started "BA.5" compliant vaccination 5 th dose at large scale vaccination sites (123)
	28	#New mutant virus "XBB" of Omicron strain confirmed for the first time in Tokyo (124)
11	1	# Tokyo Simultaneous vaccination against coronas and influenza started (125)
	24	#Shionogi filed for approval of a vaccine, the first in domestic development (126)
2023	1	6 #New guidelines for funerals of the infected so that they can say their final goodbyes (127)
	11	# Expert meeting "Record number of deaths continues and there is concern that the number will continue to increase (128)"
	13	# mRNA vaccine Daiichi Sankyo filed for approval, the first domestic pharmaceutical company to do so (129)
	26	#Firmly decided to shift new Corona to "Class 5" on May 8 (130)
3	1	New corona outbreak source "likely leaked from Chinese lab" FBI Director (131)
	12	End of update of Johns Hopkins University (USA) Corona Special Site, which has summarized the global infection situation (132)
	13	#Wearing a mask is a personal decision (133)
	26	#Large-scale vaccination of Self-Defense Forces with the COVID-19 vaccine completed Closing ceremonies in Tokyo and Osaka (134)
	29	The WHO changed its policy of not recommending a second or subsequent dose of additional vaccinations, citing limited benefit (135)
4	4	# "Joint Statement for Freedom and Fairness in the Dissemination of Information" Civil lawsuits, criminal charges (136)
	28	#One-year-old boy dies after the COVID-19vaccination (137)

*Themes covered in a separate section are listed in bold.

#: Happening in Japan

3.2. Maximum increase in the number of infected persons per day (31)

6th wave: + approx. 105,000 (February 2022)

7th wave: + approx. 250,000 (August 2022)

8th wave: + approx. 250,000 (January 2023)

3.2.1. Omicron strain epidemic

In November 2021, the Omicron strain is found in South Africa (124). In the same month, cases of infection are reported in the U.K. and Germany (138), and in December, infection is reported in the U.S. (139). In Japan, a man in his 30s who entered the country from Namibia at the end of November is infected, and in December, a community-acquired infection is confirmed with an unknown route of infection. (140)

In the sixth wave of outbreaks beginning around January 2022, Omicron strain BA.2 spreads, and in the seventh wave from July to September 2022, it was replaced by the highly infectious Omicron strain BA.5.(141)

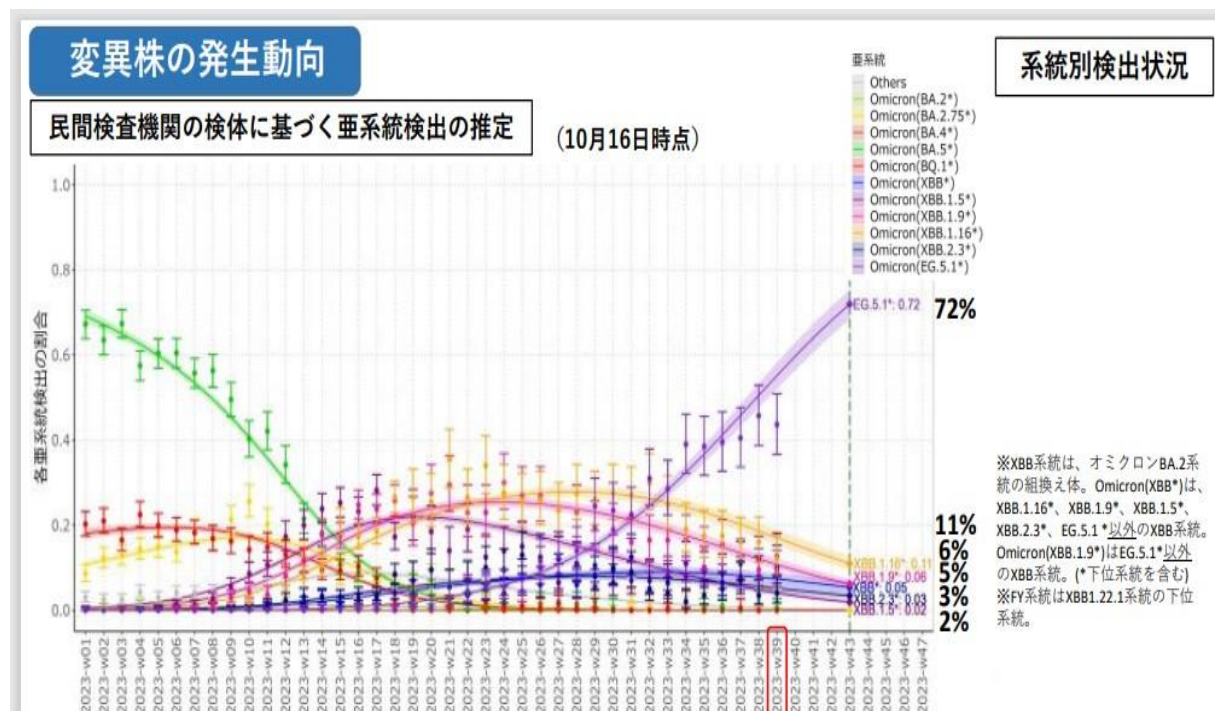


Figure 4: Mutant Outbreak Trends : Estimated sub-strain detection based on private laboratory

specimens (as of October 16, 2023)

Note. Source (Ministry of Health, Labour and Welfare. The ⁵²nd Subcommittee on Immunisation and Vaccine of the Health and Welfare Science Council (rotating meeting) [Internet]) [cited 2023 Nov 26]. Available from: https://www.kantei.go.jp/jp/singi/novel_coronavirus/taisaku_honbu.html (142)

3.2.2. Excess mortality

The National Institute of Infectious Diseases estimated that the number of excess deaths in August 2022 will range from 12,000 to 17,000 and that the maximum excess deaths for the entire year of FY2022 will be 113,000 (143,144).

The number of excess deaths is an indicator of the extent to which the total number of deaths has increased due to some cause and is calculated as “excess deaths = actual death – point estimate of predicted deaths or upper bound of predicted interval of predicted deaths.” Excess deaths are defined as the number of deaths in excess of the number of deaths observed. The number of excess deaths is the number of observed deaths that exceed the 95% one-sided prediction interval (upper limit); since the prediction interval for the number of deaths in FY2023 is based on a five-year period that includes last year's excess deaths, the base value including FY2022 is significantly higher than in previous years, and no excess deaths are observed.

On the other hand, the actual number of deaths continues to be significantly higher than last year.

Comparison of the actual number of deaths is as follows:

August 2021: 116,888 people (+5,747 compared to previous year)

August 2022: 134,527 people (+17,639 compared to the previous year)

August 2023: 130,848 people (+13,960 compared to 2021)(145)

3.3. Expansion of the COVID-19 mRNA vaccine immunisation

The COVID-19 mRNA vaccine coverage was expanded to include children and infants, with an additional fourth through sixth dose.

3.3.1. Start of the COVID-19 mRNA vaccine for children and infants

From the end of February 2022, the first and second inoculations (first dose) for children aged 5 to 11 years started. In late March of the same year, the third dose of vaccination for those aged 12 to 17 began (106,146).

In view of the lack of sufficient data on the efficacy of the vaccine against the Omicron strain in children, the MHLW decided not to make it a “obligation of effort” that parents must make efforts to have their children receive the vaccination for the time being (147).

3.3.2. Start of 4th-6th additional doses of COVID-19 mRNA vaccine

Israel was the first country in the world to administer the fourth dose of vaccination in December 2021. However, the vaccination rate is still low, with only about 50% of the population having completed the third dose and 10% having received the fourth dose (2022/12/08) (148).

In late May 2022, Japan began administering the fourth dose of vaccinations to those aged 60 and older and those aged 18 and older who are at high risk of severe disease, with the aim of preventing severe disease.

In late July, the fifth dose of the Omicron strain-compatible vaccine was administered to workers at medical institutions and elderly care facilities where many people at high risk of serious illness gather, and to those aged 18 and under 60. In late September, the sixth dose of the Omicron strain-compatible vaccine was administered to those aged 12 and over who had

already received the first and second doses (initial vaccination) (73).

In late October, the vaccination interval from the previous vaccination was shortened from more than five months to more than three months (121).

In March 2023, the WHO issued new guidelines for COVID-19 mRNA vaccination, recommending up to one additional dose for healthy adults under 60 years of age and children with underlying disease, and “not recommended” for the second and subsequent doses as they do no harm but provide little public health benefit.

Routine vaccination is recommended only for the elderly, people with underlying medical conditions such as diabetes, immunocompromised people, pregnant women, and health care workers, who should be given top priority (135).

The COVID-19 mRNA vaccine coverage in Japan as of November 21, 2023 is as follows:

Number of COVID-19 mRNA vaccine recipients in Japan (149).

¹st dose 104,723,678 people, Inoculation rate 80.9%

²nd dose 103,443,404 people, Inoculation rate 79.9%

³rd dose 86,637,673 people, Inoculation rate 67.4%

⁴th dose 59,207,246 people, Inoculation rate 47.6%

⁵th dose 36,462,328 people, Inoculation rate 29.3%

⁶th dose 23,670,922 people, Inoculation rate 19.0%

⁷th dose 12,649,271 people, Inoculation rate 10.0%

(Total population is based on the November estimate of 124.31 million by the Statistics Bureau of the Ministry of Internal Affairs and Communications (150).)

In Japan, the following four subcommittees have been established to discuss COVID-19 mRNA vaccine and the COVID-19 (151,152).

➤ Subcommittee on Countermeasures for Infectious Diseases Caused by the COVID-

- Health Science Council (Adverse Reaction Review Subcommittee, Immunisation and Vaccine Subcommittee)
- Health Science Council (Subcommittee on Immunisation and Vaccine)
- Health Science Council (Subcommittee on Infectious Diseases and Immunisation, Board of Disease and Disability Certification)

3.4. Concerns over side effects of the COVID-19 mRNA vaccination

Expert and public concerns about the safety and effectiveness of the COVID-19 mRNA vaccine grew.

3.4.1. “Japan Association of Volunteer Doctors” is established

In November 2021, the Hokkaido Volunteer Doctor’s Association was established by 12 doctors in Hokkaido(153), On February 28, 2022, the Japan Association of Volunteer Doctors was established as a national organization (107). The current membership: physicians, dentists, and veterinarians: 697; healthcare professionals: 838; total 1535 (2023/9/15)

In response to the increasing the number of deaths suspected to be due to adverse reactions to vaccination, the association has appealed for the immediate suspension of vaccination with the COVID-19 mRNA vaccine (154).

The association’s official website includes comparative data between the influenza vaccine and the COVID-19 mRNA vaccine.

According to the data, the probability of death from the COVID-19 mRNA vaccination is about 50 times higher than that of the influenza vaccine (155).

Table 5: *Comparison of Influenza Vaccine and COVID-19 mRNA vaccine by Dr. Seiji Kojima,*

Comparison of Influenza Vaccine and COVID-19 mRNA Vaccine by Prof. Seiji Kojima, Nagoya University

	Influenza vaccine	COVID-19 mRNA vaccine
Period of inoculation	2015-2020 (5 years)	2021-2022 (16 months)
Number of inoculations	262,480,000	282,740,000
Adverse reaction report	1,967 times	34,120 times
Report of a death	35 times	1,761 times

Note. Source (Volunteer Medical Association [Internet]) [cited 2023 Dec 2]. Available from: <https://vmed.jp/2646/> [cited 2023 Dec 2]. Available from: <https://vmed.jp/2646/> (156)

3.4.2. Nagoya City establishes “Consultation Service for Long-Term Adverse Reactions to Vaccines”

On March 25, the “Nagoya the COVID-19 mRNA vaccine Long-Term Adverse Reaction Consultation Service” was established for the first time in Japan as a consultation service for long-term adverse reactions in Nagoya City.

“Nurses receive calls from citizens who suspect long-term adverse reactions that persist for more than two weeks after receiving the COVID-19 mRNA vaccine, and according to the nature of the consultation, they are guided to cooperating medical institutions and introduced to relief programs. With the cooperation of the Nagoya City Medical Association, 91 medical institutions in 16 wards in the city provide support.”(109)“The city had been preparing to open its own contact center because of the inadequate response of the national and prefectural governments to the aftereffects of the COVID-19 mRNA vaccine.” (109)

On April 11, the mayor of Nagoya City announced at a press conference “In the 11 days since its opening, we have received 479 consultations, and we have increased the number of nurses and other staff to receive calls from the initial two to five.” (157)

3.4.3. Recommendations for Pathological and Forensic Autopsies from Academic Societies

On July 25, the Japanese Society of Pathology, the Japanese Society of Forensic Medicine, and the Japanese Society of Forensic Pathology issued a joint statement.

The statement is as follows:

Yoshinao Oda, President of the Japanese Society of Pathology, Shinichi Kubo, President of the Japanese Society of Forensic Medicine, and Toshikazu Kondo, President of the Japanese Society of Forensic Pathology, stated, “Currently, few pathological or forensic autopsies have been performed, and no one has ever been judged to have a causal relationship with vaccination due to a lack of information. The Japanese Society of Pathology, the Japanese Society of Forensic Medicine, and the Japanese Society of Forensic Pathology actively recommend pathological and forensic autopsies of post-COVID-19 mRNA vaccine deaths in order to provide more detailed medical information through autopsies to the Safety Countermeasures Investigation Committee of the Ministry of Health, Labour and Welfare and others.” (114)

Professor Toshikazu Kondo of Wakayama Prefectural University of Medicine, President of the Japanese Society of Forensic Pathology, commented “Ten percent is a small percentage. Unexpected deaths do occur, and we should conduct a detailed investigation and gather knowledge.”

Shinichi Kubo, a professor of forensic medicine at Fukuoka University, asserted “Vaccines are intended for a large number of people, and the government should be responsible for investigating the cause of death.”

Tomohiro Morio, a professor at Tokyo Medical and Dental University who chairs the MHLW’s “Subcommittee to Study Adverse Reactions”, said “It is difficult to distinguish whether a person died of heart failure or stroke after receiving the vaccine or without it, there

are cases reported in which the cause of death is not known because the patient had no pre-existing medical conditions, so it is effective to conduct an autopsy to determine the cause of death.”

Yoshinao Oda, professor of pathology at Kyushu University, said “By clarifying what is happening inside the body through autopsy, we may be able to find ways to prevent or treat adverse reactions. If we can do so, the vaccine will become safer to use.” (158)

3.4.4. Inauguration of the “Bipartisan Diet Members Caucus for the Vaccination of Children with the COVID-19 mRNA Vaccine and the Sequelae of the COVID-19 mRNA Vaccine”

On September 20, 2022, the Bipartisan Diet Members Caucus for the Vaccination of Children with the COVID-19 mRNA Vaccine and the Sequelae of the COVID-19 mRNA Vaccine was established and a general meeting was held. There were a total of 25 members: 18 members of the House of Representatives and 7 members of the House of Councillors. The breakdown by faction was as follows: 16 members of the Constitutional Democratic Party, 2 members of the Restoration Association, 1 member of the Reiwa Shinsei-gumi, 1 member of the Sanseito Party, 1 member of the Liberal Democratic Party, 1 member of the Kokumin Democrats, and 2 members of the Non-affiliated Party.

A letter of recommendation addressed to Chief Cabinet Secretary Matsuno and Minister of Health, Labor, and Welfare Kato was handed over to the Cabinet, out of concern that the COVID-19 mRNA vaccine would be administered without clarification of its adverse reactions.

The recommendations are as follows:

Remove the “mandatory effort” and “vaccination recommendation” of the COVID-19 mRNA vaccine for children aged 5 to 11 years old.

The COVID-19 mRNA vaccine should not be administered to children between the ages of 6 months and 4 years.

Establish a follow-up system that can track adverse reactions, etc., by comparing COVID-19 mRNA vaccine vaccination records with post-vaccination medical data (120).

3.4.5. Inauguration of the “Association of Bereaved Families of Post-COVID-19 mRNA Vaccine Injuries”

On October 20, 2022, 12 bereaved families of those who died after vaccination formed the “Association of Bereaved Families of Post-COVID-19 mRNA Vaccine Injuries” and held a press conference in Tokyo.

On March 9, 2023, they held a press conference at the Ministry of Health, Labor, and Welfare, urging the government to proceed promptly with the certification of the health damage relief system based on the Immunisation Law (122).

3.4.6. Reporting post-vaccination cases and adverse reactions at conferences

A total of 276 abstracts related to case reports or adverse reactions (including adverse reactions affecting tests/diagnosis, etc.) that occurred or were observed after the COVID-19 mRNA vaccine were reported at 84 conferences by September 2022 (this includes cases where multiple cases are presented at the same conference or where the same study group or presenter presents at several different conferences). (159)

3.4.7. Joint Statement for Freedom and Fairness in the Dissemination of Information Civil and Criminal Complaint

In April 2023, 14 university professors, doctors, and lawyers issued “Joint statement

calling for freedom and fairness in the dissemination of information”. On the same day, three of them, as plaintiffs, filed a civil lawsuit against the doctors who defamed them, seeking damages for defamation and insult. The three plaintiffs also filed a criminal complaint with the Tokyo District Public Prosecutor’s Office, alleging that they are guilty of defamation under Article 230, Paragraph 1, and insult under Article 231 of the Penal Code.

The statement said that It filed an order to disclose information to the sender against the three plaintiffs and one family member of a victim of a post-vaccination death, and that disclosure orders were issued against all but one, who is awaiting a deadline (136).

3.5. Articles discussing the risks and questions about the COVID-19 mRNA vaccine

While studies have been published on the effectiveness of vaccines, others have questioned their risks and safety. The studies and their extracts are listed below:

- “Deep vein thrombosis (DVT) occurring shortly after the second dose of mRNA SARS-CoV-2 vaccine”

This a case report published in Italy in March 2021 in *Internal and Emergency Medicine*. Below are some extracts of the study:

“On January ²⁶th, 24 h after the second vaccine dose, she received acetaminophen for persistent fever with chills, fatigue, malaise, and muscle pain. On January ²⁷th, 48 h after the second vaccine dose, persistent fever was still present, and acute right calf pain appeared in the absence of trauma. On January ²⁸th, she was admitted for evaluation at the emergency room because of persistent pain and inability to walk.”

“To our knowledge, this is the first reported case of DVT presenting

as an adverse event post-SARS-CoV-2 vaccination. Arguably, the intense immunological response evoked by the second dose of vaccine could be a trigger for the thrombotic event described, a mechanism recognized in many clinical conditions.” (160)

➤ “Association of Myocarditis with BNT162b2 Messenger RNA COVID-19 Vaccine in a Case Series of Children”

This is a case report from the Department of Cardiology, Children’s Hospital Boston, USA. It was published in the December 2021 issue of *JAMA Cardiology* (a monthly peer-reviewed medical journal dealing with cardiology). Below are some extracts of the study:

“The BNT162b2 (Pfizer-BioNTech) messenger RNA COVID-19 vaccine was authorized on May 10, 2021, for emergency use in children aged 12 years and older. Initial reports showed that the vaccine was well tolerated without serious adverse events; however, cases of myocarditis have been reported since approval.”

“Fifteen patients (14 male patients [93%]; median age, 15 years [range, 12-18 years]) were hospitalized for management of myocarditis after receiving the BNT162b2 (Pfizer) vaccine. Symptoms started 1 to 6 days after receipt of the vaccine and included chest pain in 15 patients (100%), fever in 10 patients (67%), myalgia in 8 patients (53%), and headache in 6 patients (40%).”

“In this small case series study, myocarditis was diagnosed in children after COVID-19 vaccination, most commonly in boys after the second dose. In this case series, in short-term follow-up, patients were

mildly affected. The long-term risks associated with postvaccination myocarditis remain unknown. Larger studies with longer follow-up are needed to inform recommendations for COVID-19 vaccination in this population.”(161)

- “Class switch toward noninflammatory, spike-specific IgG4 antibodies after repeated SARS-CoV-2 mRNA vaccination”

This study is from Germany and was published in August 2022 in *Science Immunology*. Below is an extract of the study.

“RNA vaccines are efficient preventive measures to combat the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic. High levels of neutralizing SARS-CoV-2 antibodies are an important component of vaccine-induced immunity. Shortly after the initial two mRNA vaccine doses, the immunoglobulin G (IgG) response mainly consists of the proinflammatory subclasses IgG1 and IgG3. Here, we report that several months after the second vaccination, SARS-CoV-2–specific antibodies were increasingly composed of noninflammatory IgG4, which were further boosted by a third mRNA vaccination and/or SARS-CoV-2 variant breakthrough infections. IgG4 antibodies among all spike-specific IgG antibodies rose, on average, from 0.04% shortly after the second vaccination to 19.27% late after the third vaccination. This induction of IgG4 antibodies was not observed after homologous or heterologous SARS-CoV-2 vaccination with adenoviral vectors. Single-cell sequencing and flow cytometry revealed substantial frequencies of IgG4-switched B cells within the spike binding memory B cell population

[median of 14.4%; interquartile range (IQR) of 6.7 to 18.1%] compared with the overall memory B cell repertoire (median of 1.3%; IQR of 0.9 to 2.2%) after three immunisations.

This class switch was associated with a reduced capacity of the spike-specific antibodies to mediate antibody-dependent cellular phagocytosis and complement deposition. Because Fc-mediated effector functions are critical for antiviral immunity, these findings may have consequences for the choice and timing of vaccination regimens using mRNA vaccines, including future booster immunisations against SARS-CoV-2” (162).

- “Circulating Spike Protein Detected in Post–COVID-19 mRNA Vaccine Myocarditis”

This report from the USA was published in March 2023 in *Circulation*.

“A notable finding was that markedly elevated levels of full-length spike protein (33.9 ± 22.4 pg/mL), unbound by antibodies, were detected in the plasma of individuals with postvaccine myocarditis, whereas no free spike was detected in asymptomatic vaccinated control subjects (unpaired t test; $P < 0.0001$).” (163)

- “IgG4 Antibodies Induced by Repeated Vaccination May Generate Immune Tolerance to the SARS-CoV-2 Spike Protein”

This is a report from the USA published in May 2023 in *Vaccines*.

“The elevation of serum IgG4 due to repeated vaccination with

mRNA vaccine promotes immune evasion of SARS-CoV-2 and causes the efficiency of vaccination to decline. Therefore, we may need to reflect on the current situation of too easy reliance on mRNA vaccines. In particular, omicron mutant strains have an enhanced immune evasion ability, and should be treated with caution.

One possible mechanism is that frequent vaccination raises serum IgG4, which binds to IgG3, thereby inhibiting IgG3-mediated antibody-dependent cellular cytotoxicity (ADCC), resulting in a state of immune tolerance and promoting immune evasion of SARS-CoV-2.

Almost the same mechanism may promote cancer and “IgG4-related diseases” by frequent vaccination.”(164,165)

➤ “Effectiveness of the Coronavirus Disease 2019 Bivalent Vaccine”

This study from the USA was published in June in *Open Forum Infect Dis.*

“The bivalent COVID-19 vaccine given to working-aged adults afforded modest protection overall against COVID-19 while the BA.4/5 lineages were the dominant circulating strains, afforded less protection when the BQ lineages were dominant, and effectiveness was not demonstrated when the XBB lineages were dominant.”

“The risk of COVID-19 also increased with time since the most recent prior COVID-19 episode and with the number of vaccine doses previously received.” (166)

➤ “Batch-dependent safety of the BNT162b2 COVID-19 mRNA vaccine”

This study from Belgium was published in August 2023 in the *European Journal of Clinical Investigation*.

“We therefore examined rates of SAEs between different BNT162b2 vaccine batches administered in Denmark (population 5.8 million) from 27 December 2020 to 11 January 2022. Data on all SAE cases with corresponding vaccine batch labels reported to the Danish Medical Agency (DKMA) and classified by the DKMA according to SAE seriousness, and numbers of BNT162b2 doses in individual vaccine batches registered by the Danish Serum Institute, respectively, are publicly available and were retrieved upon request.”

” Unexpectedly, rates of SAEs per 1000 doses varied considerably between vaccine batches with 2.32 (0.09– 3.59) (median [interquartile range]) SAEs per 1000 doses, and significant heterogeneity ($p < .0001$) was observed in the relationship between numbers of SAEs per 1000 doses and numbers of doses in the individual batches. Three predominant trendlines were discerned, with noticeable lower SAE rates in larger vaccine batches and additional batch-dependent heterogeneity in the distribution of SAE seriousness between the batches representing the three trendlines.” (167)

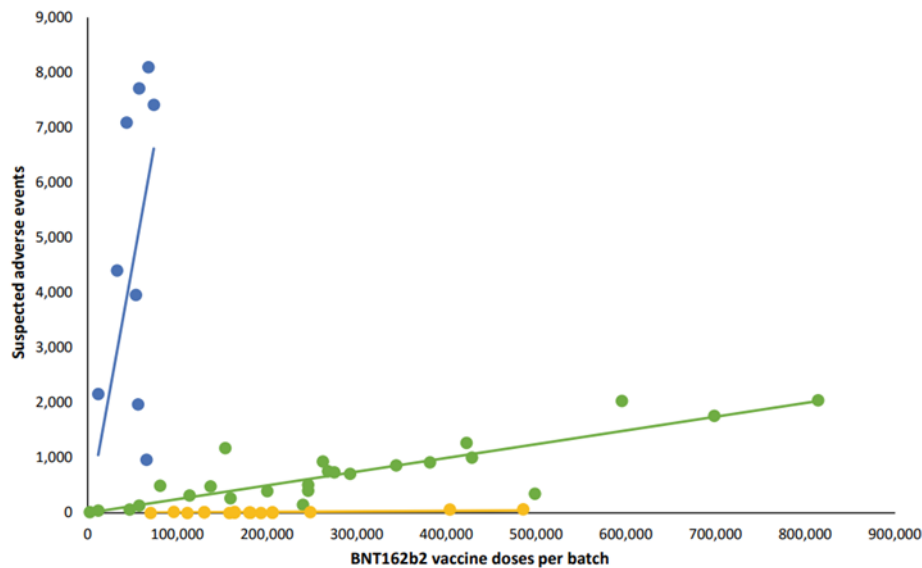


FIGURE 1 Numbers of suspected adverse events (SAEs) after BNT162b2 mRNA vaccination in Denmark (27 December 2020–11 January 2022) according to the number of doses per vaccine batch. Each dot represents a single vaccine batch. Trendlines are linear regression lines. Blue: $R^2 = 0.78$, $\beta = 0.0898$ (95% confidence interval [CI] 0.0514–0.1281), green: $R^2 = 0.89$, $\beta = 0.0025$ (95% CI 0.0021–0.0029), yellow: $R^2 = 0.68$, $\beta = 0.000087$ (95% CI 0.000056–0.000118). Vaccine batches representing the blue, green and yellow trendlines comprised 4.22%, 63.69% and 32.09% of all vaccine doses, respectively, with 70.78%, 27.49% and 47.15% (blue trendline), 28.84%, 71.50% and 51.99% (green trendline), and 0.38%, 1.01%, and 0.86% (yellow trendline) of all SAEs, serious SAEs, and SAE-related deaths, respectively.

Figure 5: *Three different sizes of side effects are found in different batches of the COVID-19 mRNA vaccine*

Note. Source (Schmeling M, Manniche V, Hansen PR. Batch-dependent safety of the BNT162B2 COVID-19 mRNA vaccine. *Eur J Clin Invest.* 2023 Aug;53(8):e13998.) (167)

➤ “Sex-specific differences in myocardial injury incidence after COVID-19 mRNA-1273booster vaccination COVID-19 mRNA-1273”

This study from Switzerland was published in October 2023 in the *European Journal of Heart Failure*.

“In conclusion, using active surveillance, mRNA-1273vaccine-associated mild transient myocardial injury was found to be much more common than previously thought. It occurred in one out of 35 persons, was mild and transient, and more frequent in women versus men. Neither anti-IL-1RA, nor pre-existing vaccine/infection-induced immunity or systemic inflammation seemed to be

dominant mechanisms of myocardial injury. No participant developed MACE within 30 days.” (168)

3.6. Doubts from experts regarding official data released by the Ministry of Health, Labor and Welfare

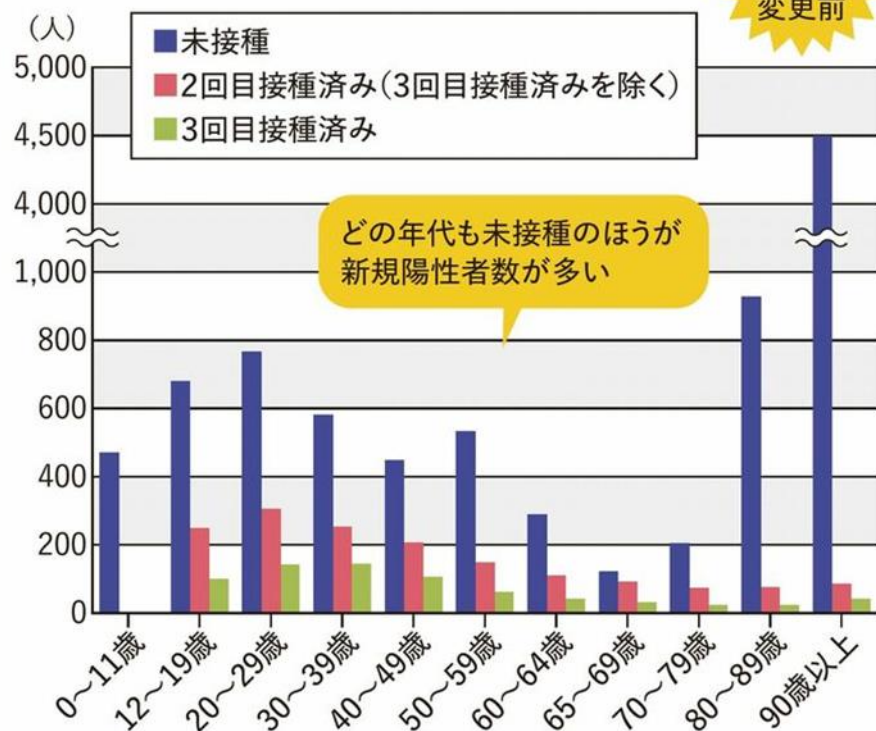
There are suspicions that there may have been intentional manipulation of the data and materials officially released by the Ministry of Health, Labor and Welfare (MHLW).

3.6.1. Downwardly revised efficacy per generation for additional vaccinations (169)

At a regular press conference on June 14, 2022, the Minister of Health, Labor and Welfare, Shigeyuki Goto, apologized for failing to provide sufficient explanation for his data interpretation.

The MHLW had published weekly data on “the number of new positive cases by vaccination history”, which compared the number of new positive cases per 100,000 population between “unvaccinated” persons who had no vaccination history with COVID-19 mRNA vaccine and “twice vaccinated” persons who had two doses , etc. The “unvaccinated” included “persons with unknown number of vaccinations”, which should not have been included. Therefore, in the figures for April 4-10, 2020, which were erroneously tabulated, the number of COVID-19 mRNA vaccine-positive persons in all age groups decreased as the number of times they had been vaccinated increased for the “unvaccinated”, “second dose (excluding third dose)”, and “third dose” persons, depending on their vaccination history.

ワクチン接種歴別の新規陽性者数 (2022年4月4～10日・人口10万人当たり)



※第81回(2022年4月20日開催)新型コロナウイルス感染症対策アドバイザーリーボード事務局提出資料より編集部作成

Figure 6: (Before data correction) The number of new PCR-positive cases is higher among the unimmunized in all age group

Note. Source (PRESIDENT Online [Internet]) 2022 Nov 25 [cited 2023 Nov 30]; Available from: [https://president.jp/articles/-/63781\(170\)](https://president.jp/articles/-/63781(170))

Subsequently, a question from a Diet member pointed out that the correct data did not include “persons with unknown vaccination” in the “unvaccinated” category. Looking at the corrected figures for the same April 11-17 period, the number of new positive cases is higher among those who were vaccinated for the second or third time than among those who were unvaccinated, depending on the age group. Note that the Ministry of Health, Labor and Welfare (MHLW) has ceased to release this aggregate data since it was requested to correct the data.

ワクチン接種歴別の新規陽性者数 (2022年8月22～28日・人口10万人当たり)

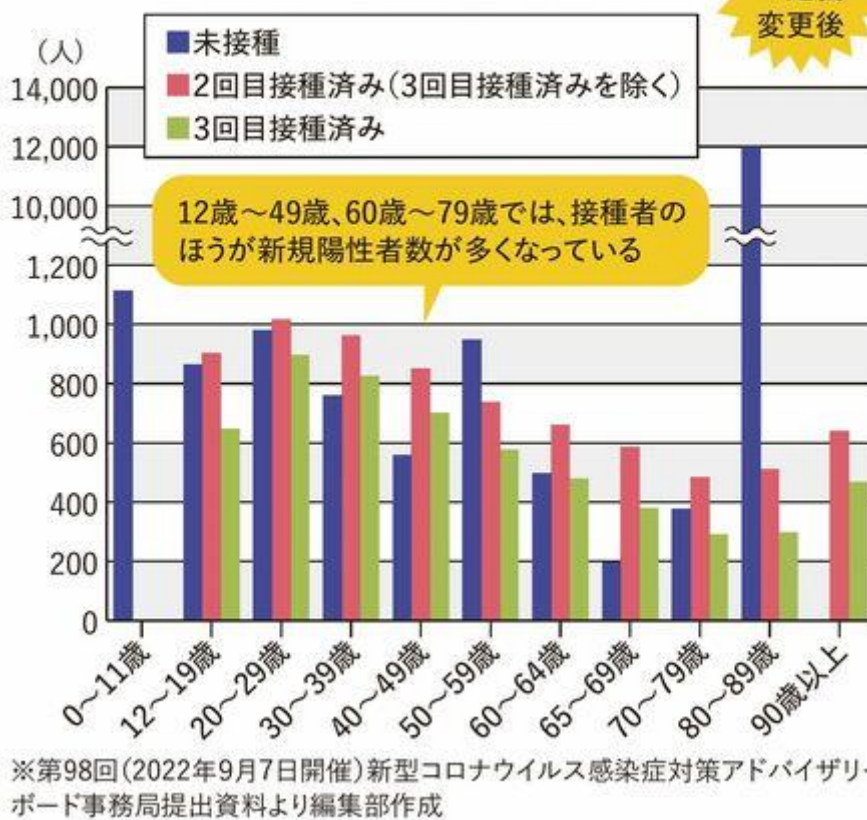


Figure 7: (After data correction) The number of new PCR-positive cases is higher among those who have been immunized than those who have not in all age groups except those in their 50s and 80s (except up to age 11, when no additional immunisation is given)

Note. Source (PRESIDENT Online [Internet]) 2022 Nov 25 [cited 2023 Nov 30]; Available from: PRESIDENT Online (171)

3.6.2. Graph giving a false impression about the risk of myocarditis and pericarditis due to the COVID-19 mRNA vaccine inoculation (169)

On October 15, 2021, the Ministry of Health, Labor, and Welfare (MHLW) issued a pamphlet entitled “Myocarditis and Pericarditis After Vaccination with the COVID-19 mRNA Vaccine”. Here is a chart titled “Comparison of Reported Frequency of Suspected Myocarditis and Pericarditis (Males).” Comparing the number of cases of myocarditis and

pericarditis per million people “who received the vaccine” and “who contracted COVID-19 mRNA vaccine infection,” the number of cases that received the vaccine was an order of magnitude lower. This should give the impression that vaccination also reduces the risk of myocarditis and pericarditis, but in fact, the data in this figure is seriously erroneous.

The data showed that among 4,798 domestic male patients aged 15-39 years who were “hospitalized” after being diagnosed with the COVID-19, four had myocarditis or other complications, and the figure was obtained by calculating “4 persons ÷ 4798 persons × 1 million persons = approximately 834 persons”. In other words, it was not the number of cases of the COVID-19 infection, as the title suggests. This means that data different from the definition was used, which is considered an extremely serious problem.

Furthermore, the data used were up to May 31, 2021, and did not include data for the summer of 2021, when the COVID-19 was prevalent, which we considered inappropriate. Therefore, we examined the data up to around September 28, 2021, and found that there were approximately 300,000 cases of the COVID-19 infection among males in their teens to twenties, of which three patients developed myocarditis or other symptoms. Therefore, it would be correct to assume that the number of men in their teens to 20s infected with the COVID-19 who developed myocarditis, etc., as “3 ÷ 300,000 × 1 million = 10”.

厚生労働省パンフレットに掲載された問題のあるデータ

心筋炎・心膜炎が疑われた報告頻度の比較(男性)



出典:第70回厚生科学審議会予防接種・ワクチン分科会副反応検討部会、2021年度第19回薬事・食品衛生審議会薬事分科会医薬品等安全対策部会安全対策調査会(21年10月15日開催)資料

Figure 8: Problematic data from MHLW pamphlet *Comparison of frequency of reports of suspected myocarditis and pericarditis (males)*. Graph showing the number of cases of myocarditis and pericarditis per million people (vertical axis). Graph on the left is the case where the vaccine was received. Blue is Pfizer and red is Moderna. The second to the left is in the teens, and the third to the fourth are in the twenties. Graph on the right side is the case of the COVID-19. Blue is domestic (15-39 years old) and red is international (12-17 years old).

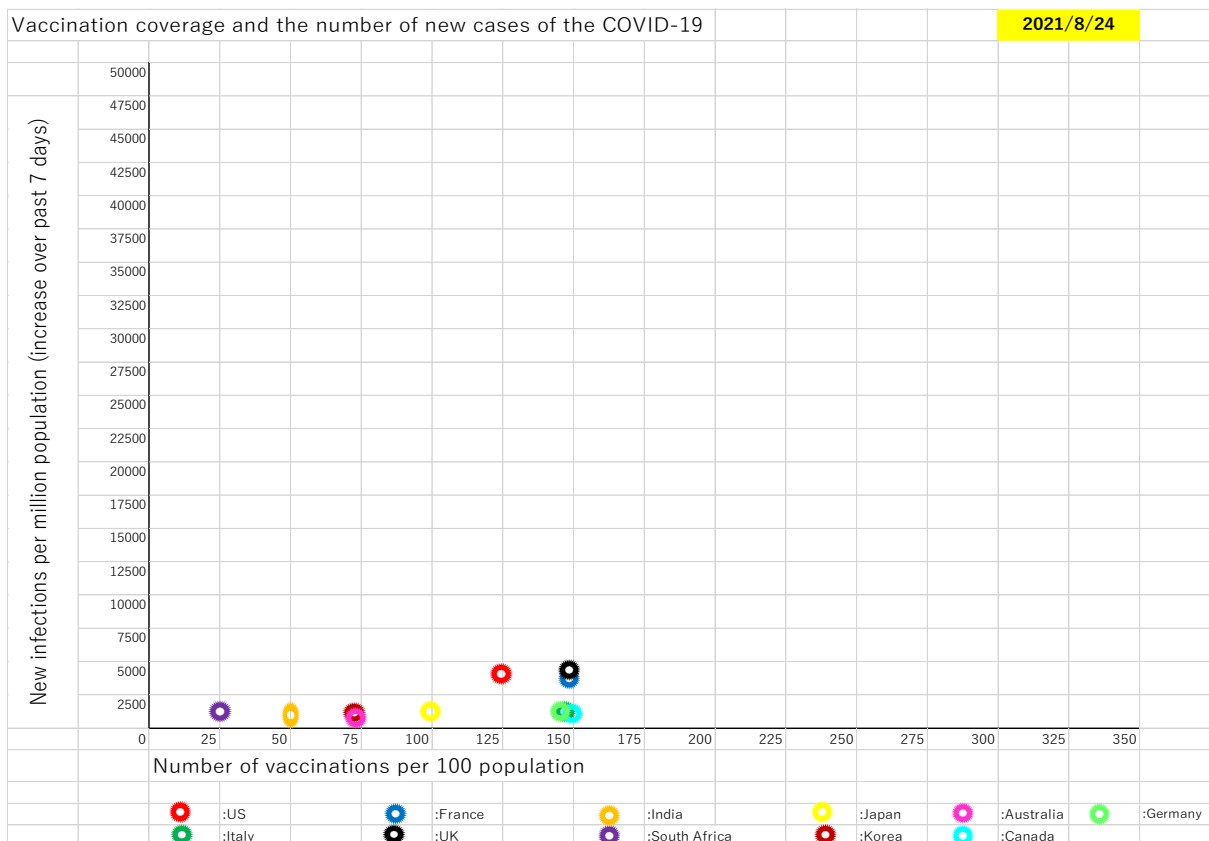
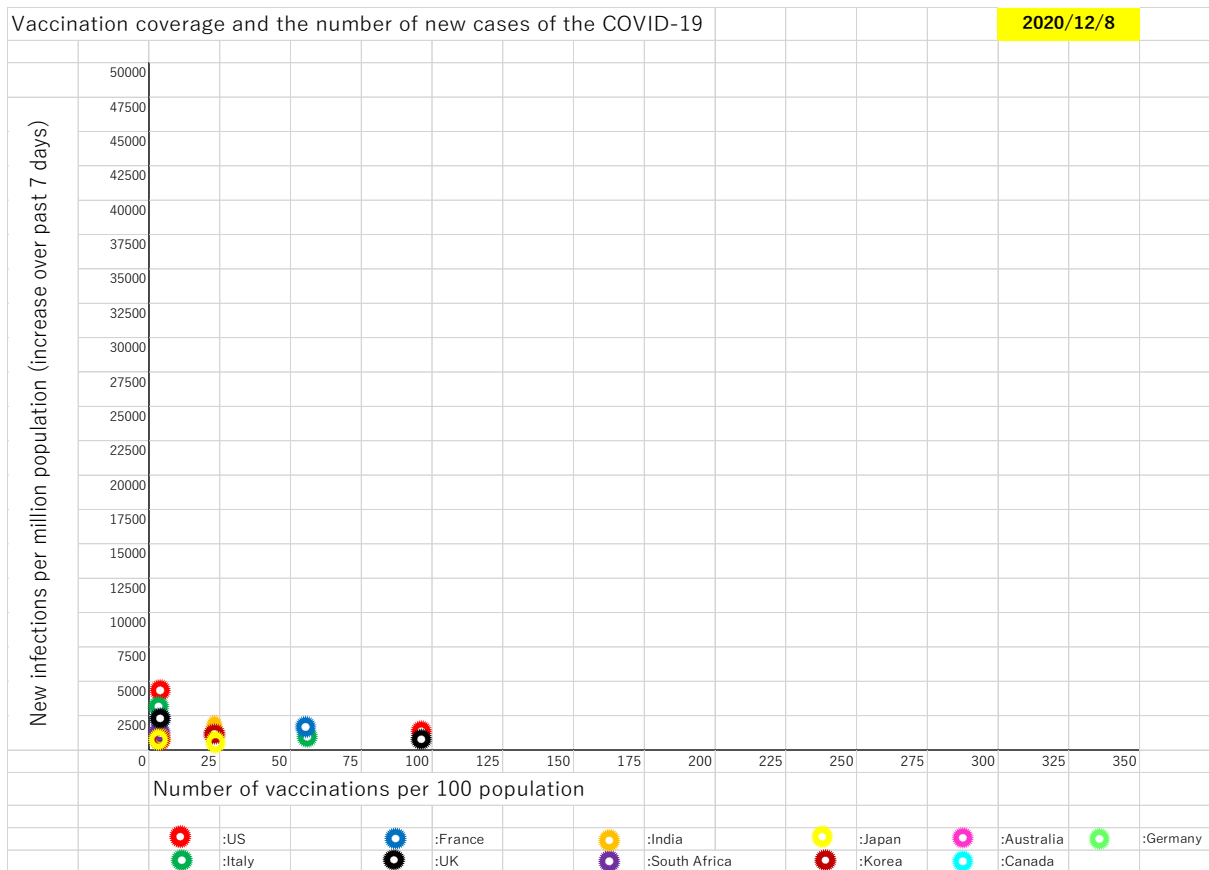
Note. Source (PRESIDENT Online [Internet]) 2022 Nov 25 [cited 2023 Nov 30]; Available from: PRESIDENT Online (171)

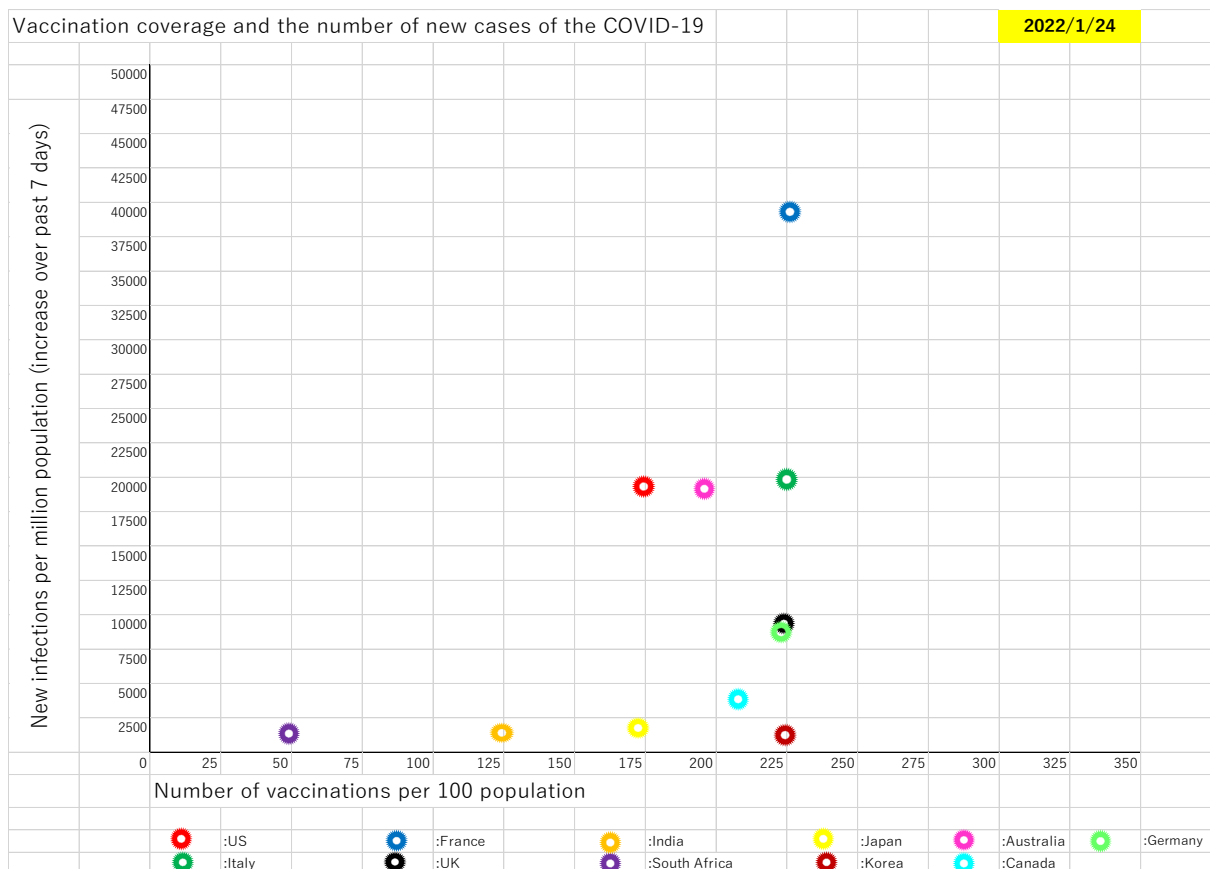
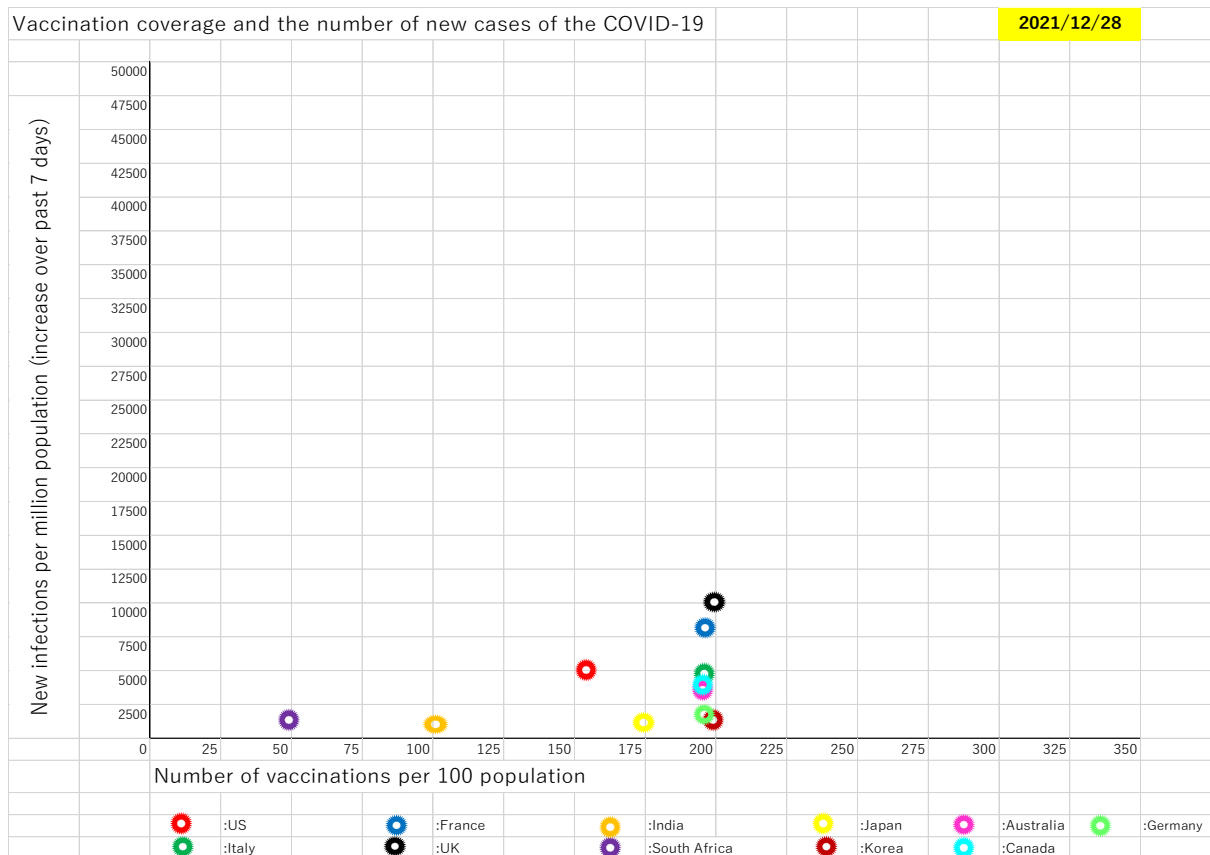
3.7. Number of COVID-19 mRNA vaccines administered worldwide and number of new infections and deaths (172)

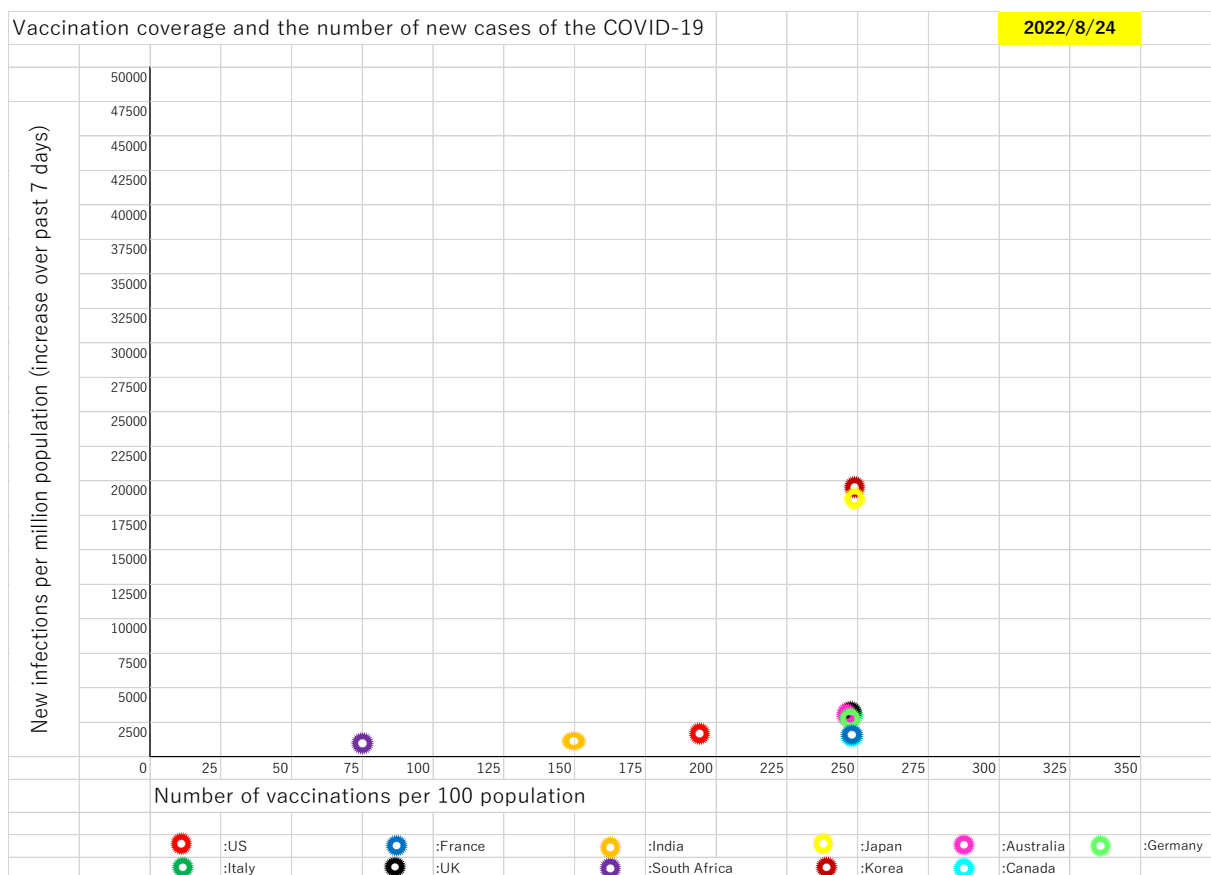
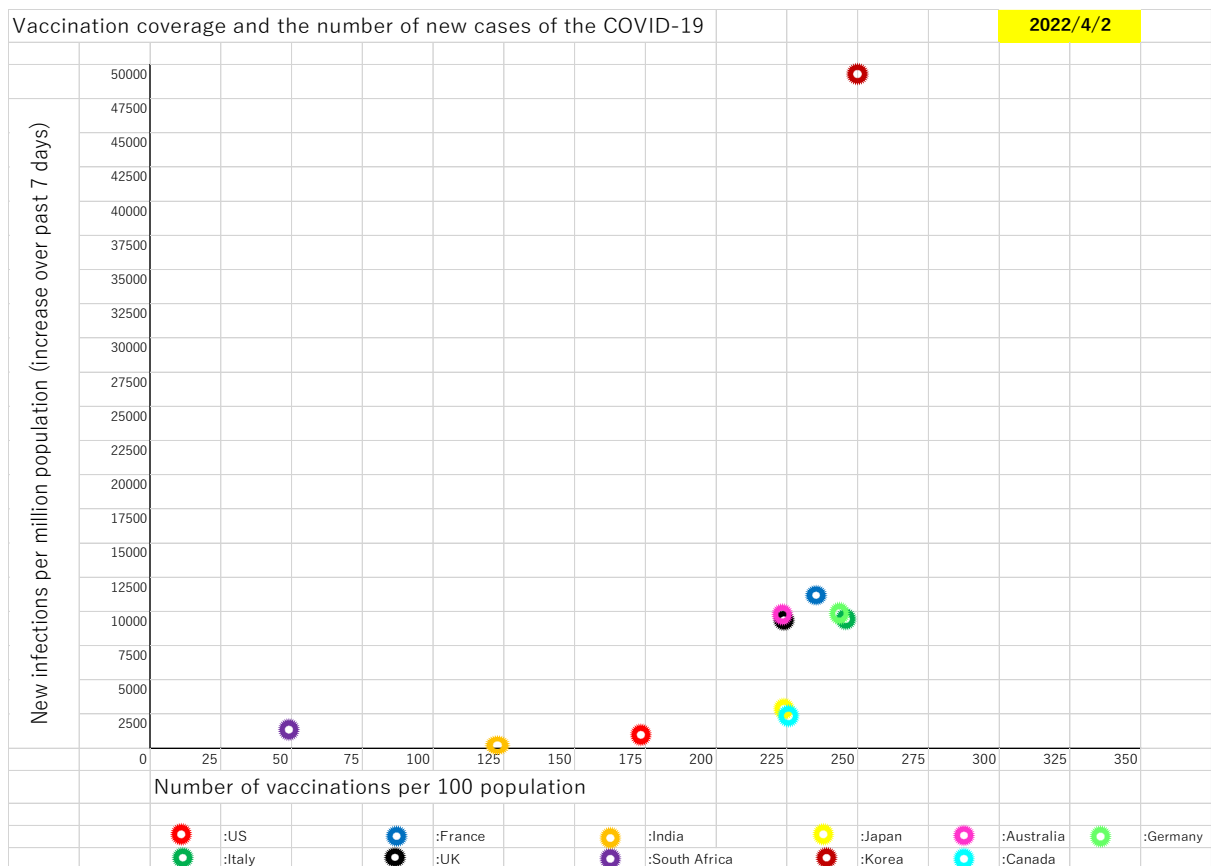
Compared to the following countries: the USA, the UK, Germany, Italy, France, Canada, Australia, South Korea, India, and South Africa, how has the relationship between the number of new coronavirus vaccinations and the number of newly infected persons and deaths in Japan changed?

3.7.1. Association between the number of COVID-19 mRNA vaccines administered worldwide and new cases of infection

The following reference graph shows the relationship between the number of times a person is vaccinated with COVID-19 mRNA vaccine and the number of new infections. The number of new infections is lowest when each person is vaccinated with one dose of COVID-19 mRNA vaccine, and the number of new infections increases as the number of doses of COVID-19 mRNA vaccine is increased. When the number of times the COVID-19 mRNA vaccine is administered does not increase, the number of newly infected cases tends to decrease gradually. Compared with other countries, the number of vaccinations and the number of newly infected persons are both significantly higher in Japan.







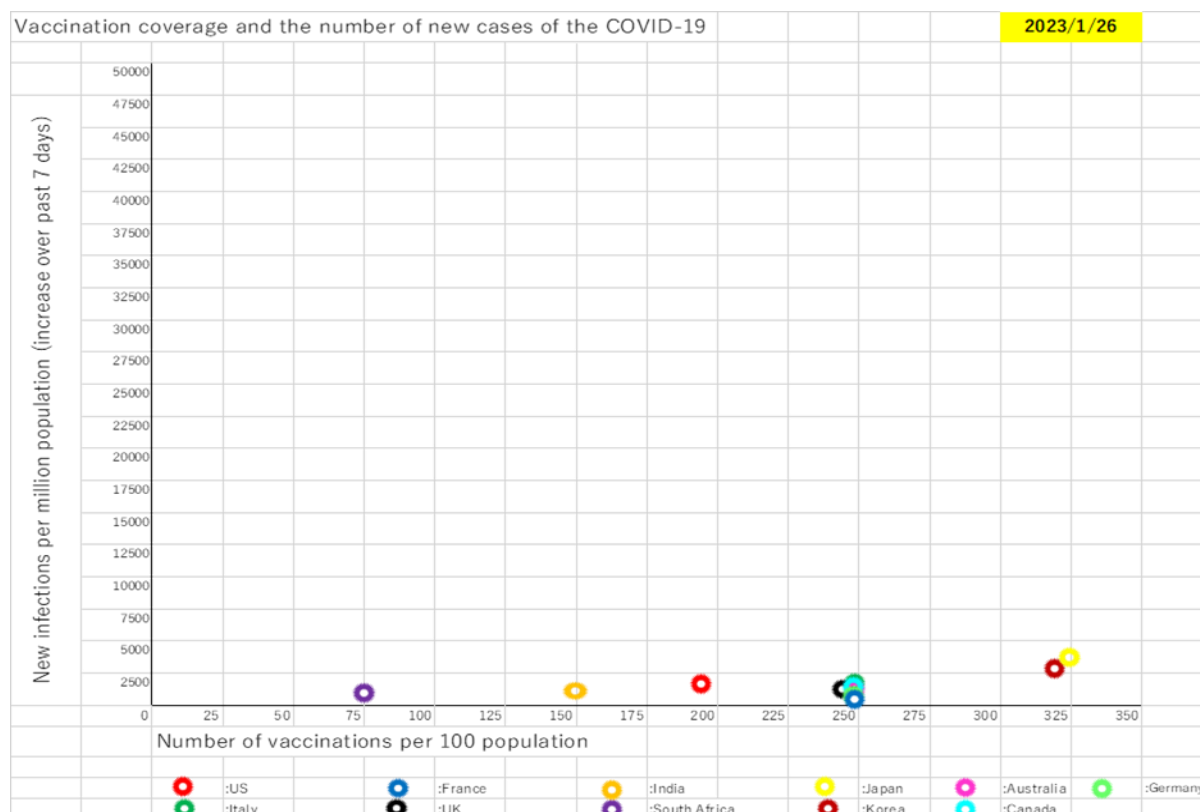


Figure 9: Number of new infections per million population (vertical axis) and number of COVID-19 mRNA vaccines per 100 population (horizontal axis) This transition can be viewed in a video on the website of the Department of Genomic Medicine, Institute for Frontier Medical Sciences, Sapporo Medical University.

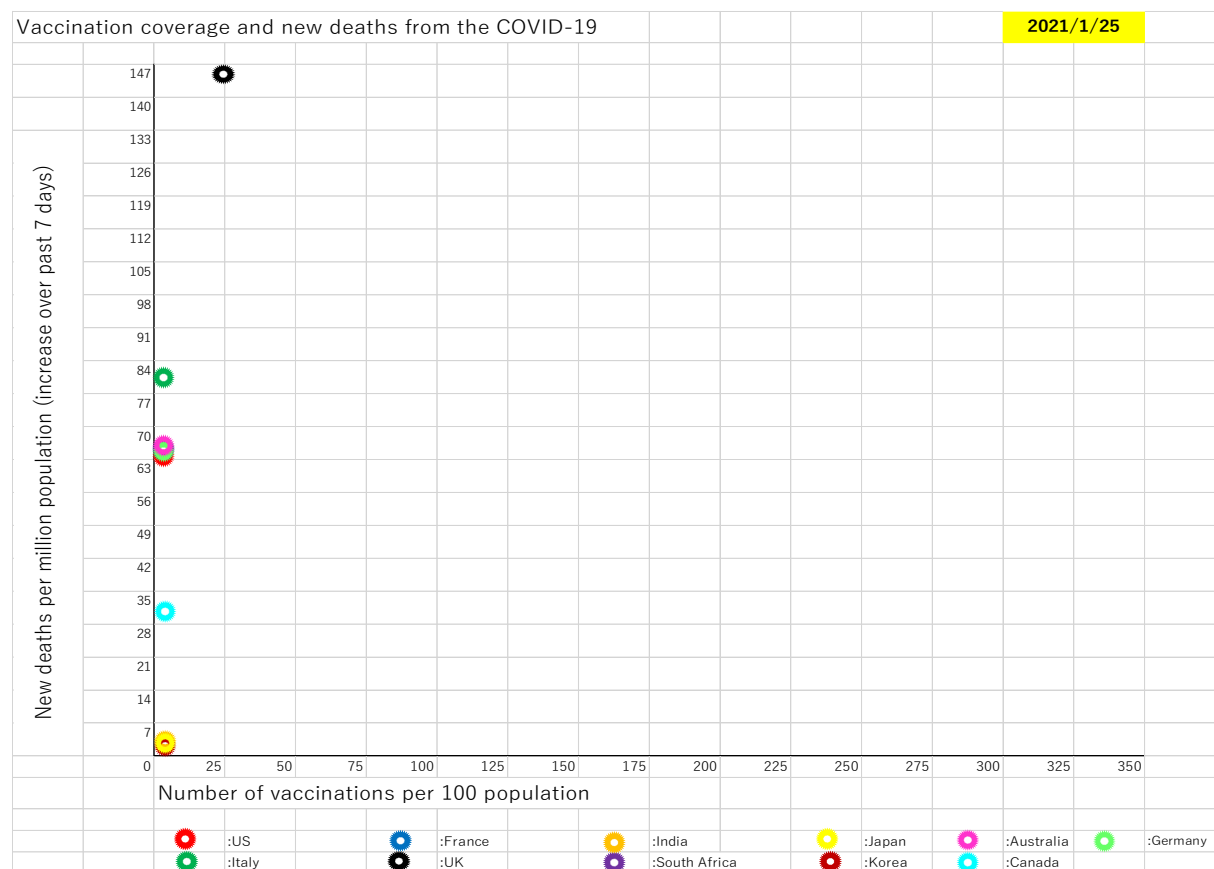
Note. Source: ([Vaccines and Infected Persons] 2023/1/26 Vaccination coverage and number of new cases of novel coronavirus infection per population [Worldwide and by country] [Internet]) [cited 2023 Nov 30]. (Department of Genomic Medicine, Frontier Medical Research Institute, Sapporo Medical University School of Medicine). Available from: [https://www.youtube.com/watch?v=Px_57asv0xY\(173\)](https://www.youtube.com/watch?v=Px_57asv0xY(173))

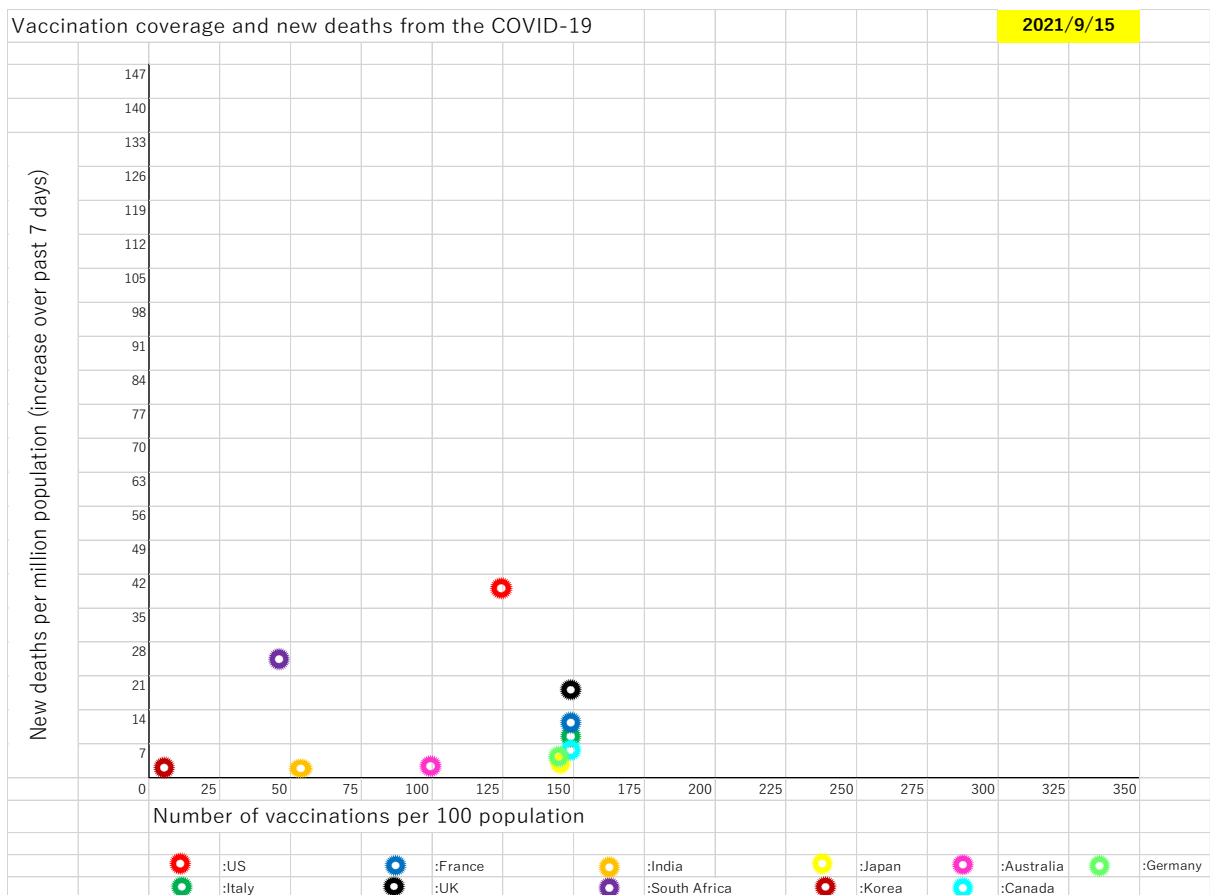
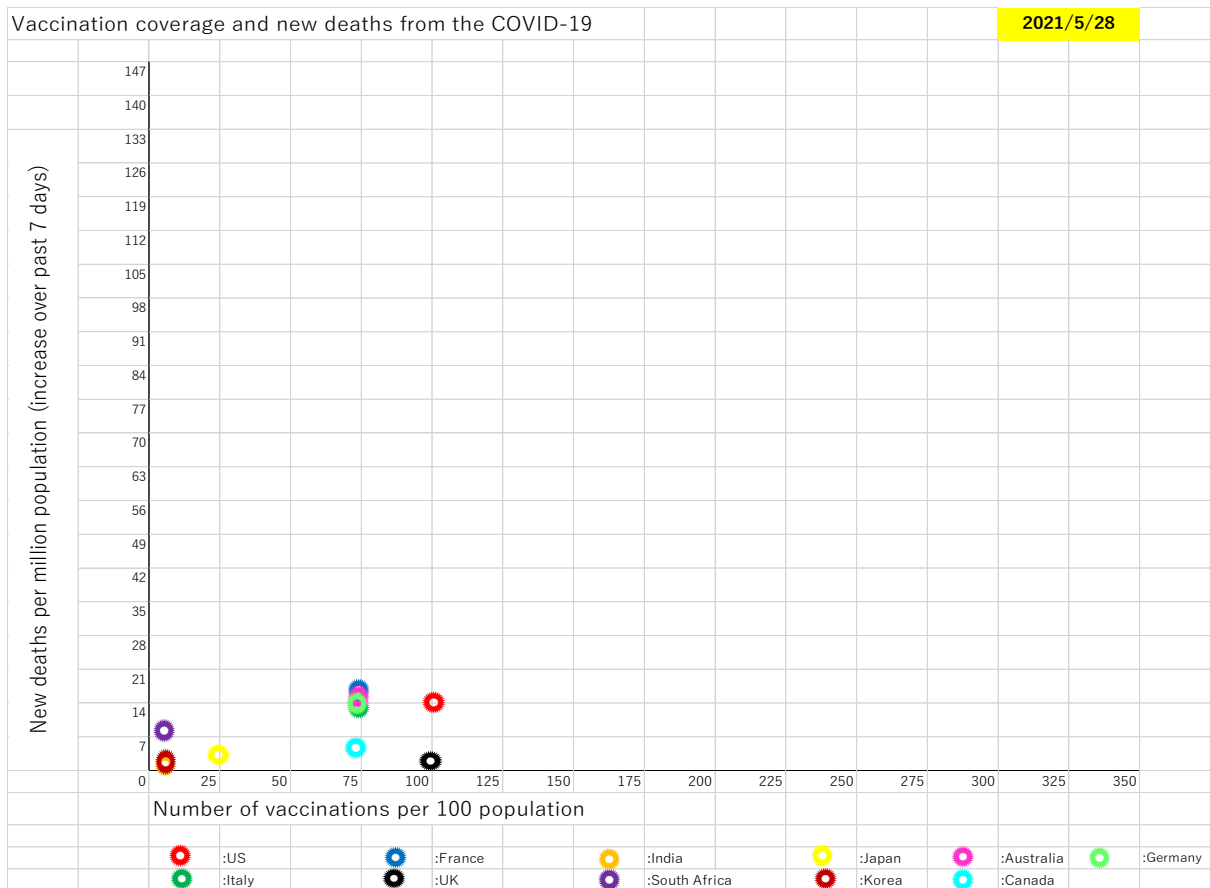
3.7.2. Association between number of COVID-19 mRNA vaccine doses and number of new deaths

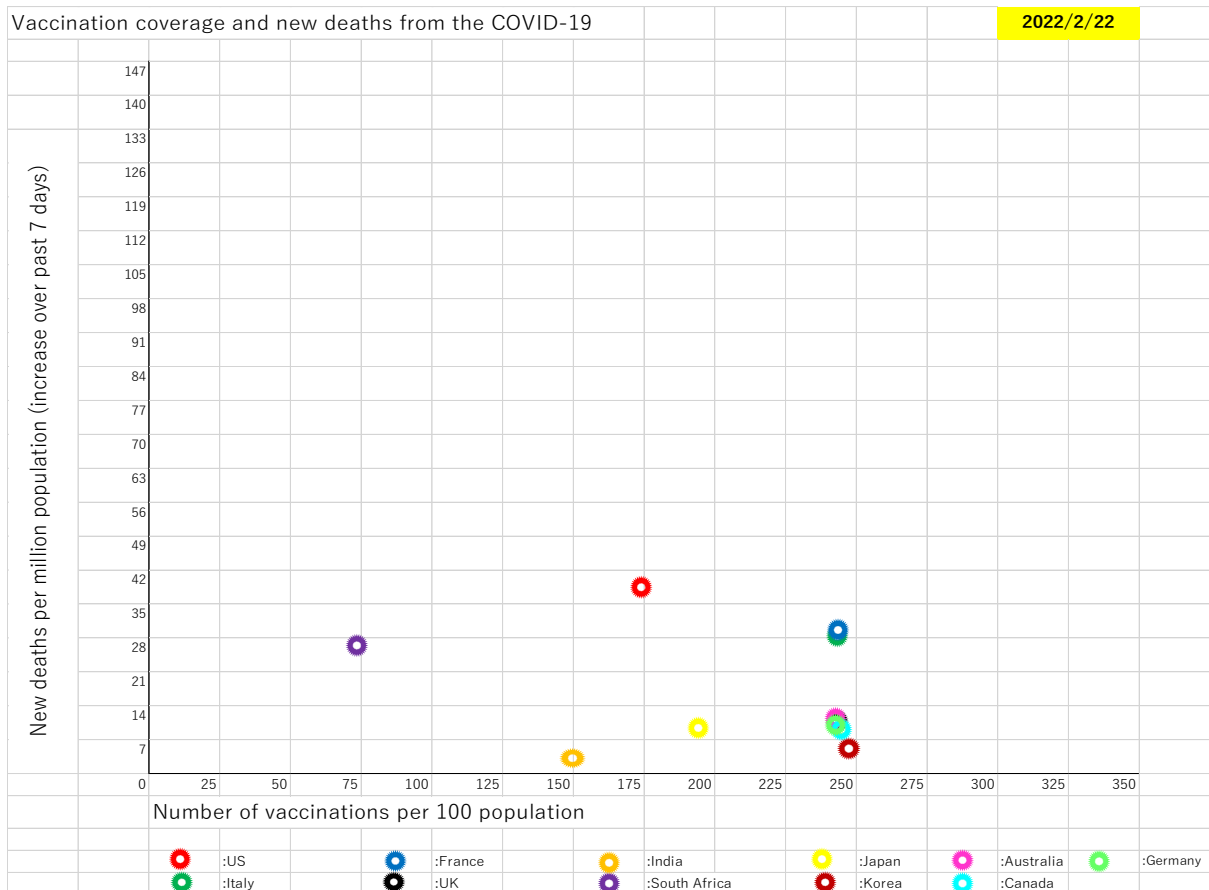
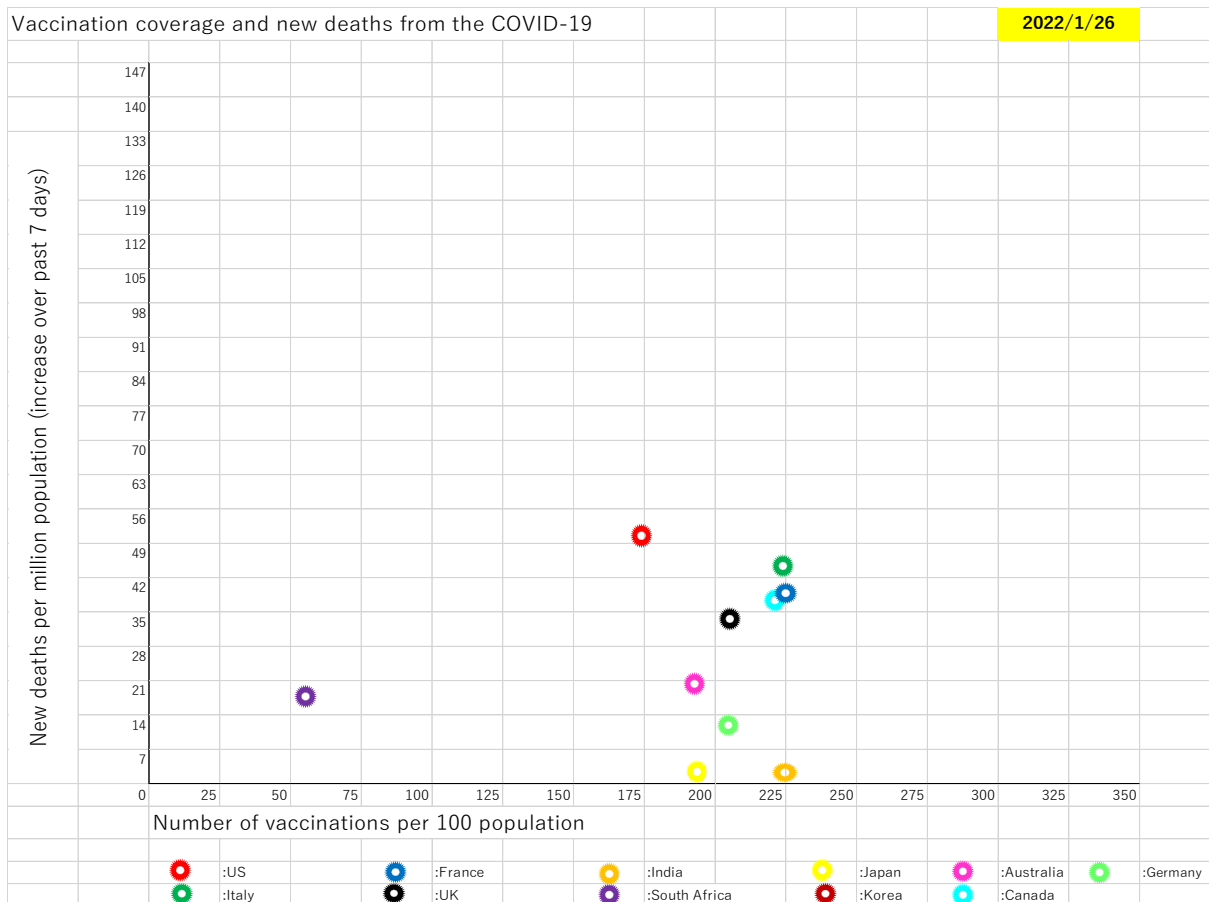
The following reference graph shows the relationship between the number of times the COVID-19 mRNA vaccine was administered and the number of new deaths.

Similar to the relationship between the number of new infections and the number of new deaths, the number of deaths is lowest when the number of COVID-19 mRNA vaccine doses is 0.5 to 1.5, and the number of new deaths increases as the number of doses increases.

Similar to the relationship between the number of new infections and the number of new COVID-19 mRNA vaccinations, the number of new deaths gradually decreases when the number of COVID-19 mRNA vaccinations stops increasing. Compared to other countries, the number of COVID-19 mRNA vaccination and new deaths are significantly higher in Japan.







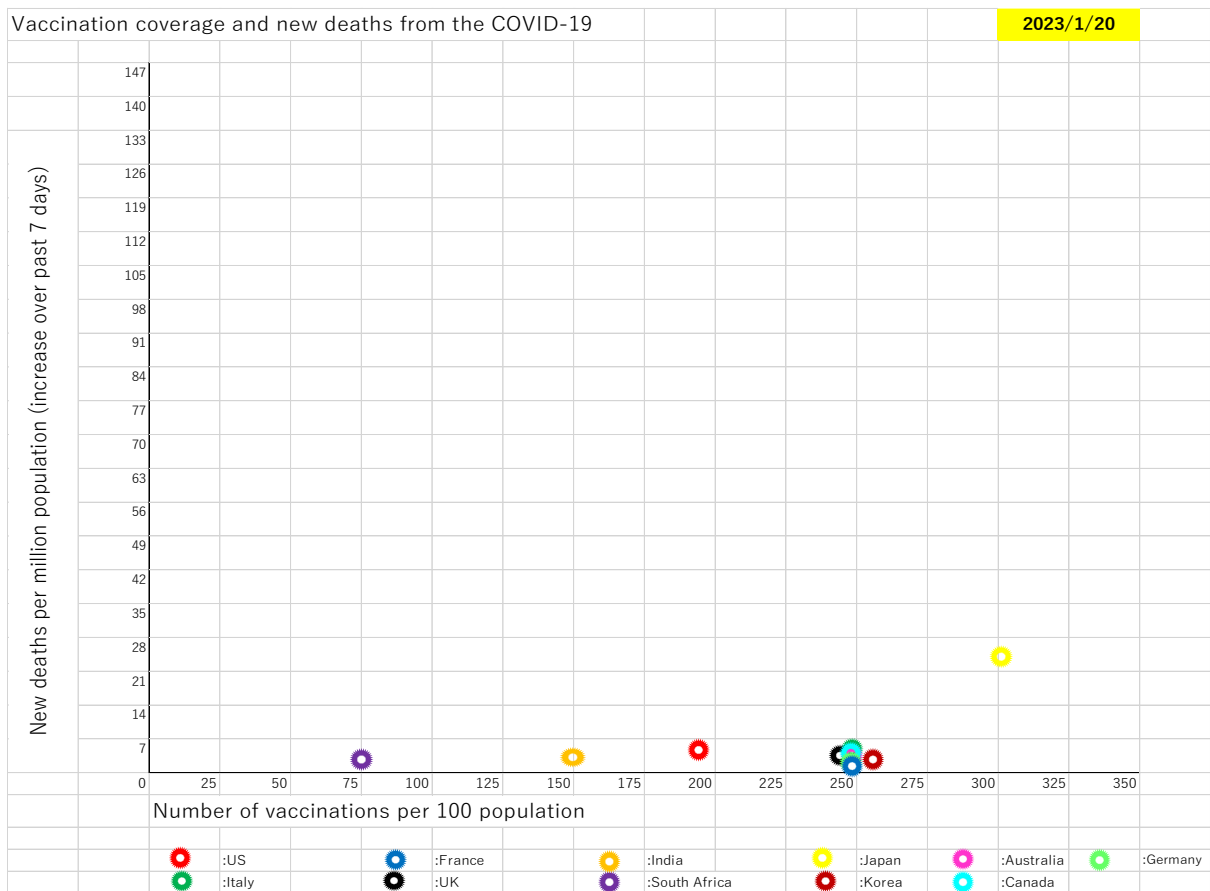
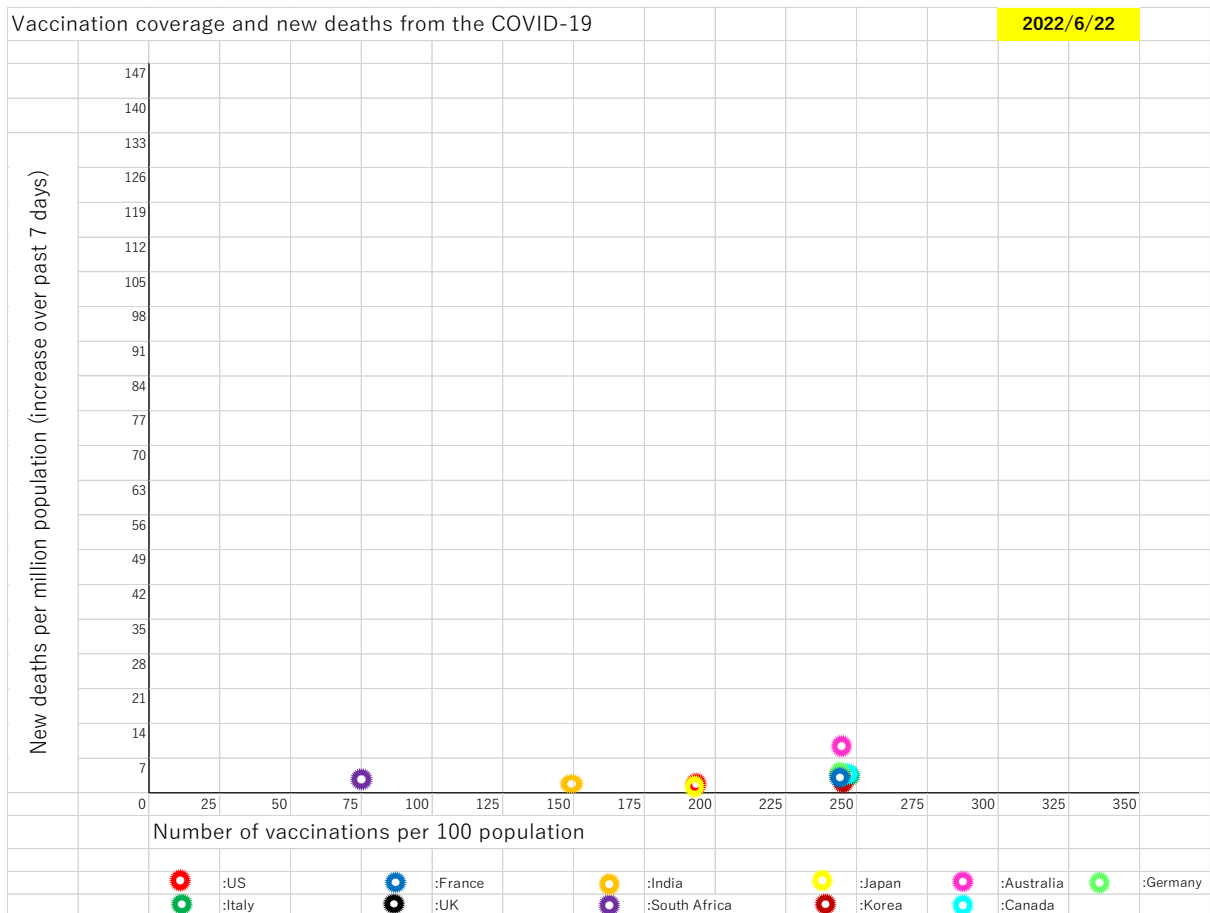


Figure 10: *New deaths per million population (vertical axis) and COVID-19 mRNA vaccination per 100 population (horizontal axis)* This transition can be viewed in a video on the website of the Department of Genomic Medicine, Institute for Frontier Medical Sciences, Sapporo Medical University.

Note. Source: ([Vaccines and Infected Persons] 2023/1/26 Vaccination coverage and number of new cases of novel coronavirus infection per population [Worldwide and by country] [Internet]) [cited 2023 Nov 30]. (Department of Genomic Medicine, Frontier Medical Research Institute, Sapporo Medical University School of Medicine). Available from: [https://www.youtube.com/watch?v=6bef52SQRgk\(174\)](https://www.youtube.com/watch?v=6bef52SQRgk(174))

4. Phase IV:2023/5 - (major strains: Omicron strain XBB-EG) - Lifting of infection control measures and spread of infection and future trends

In this issue, we summarize the impact of further additional COVID-19 mRNA vaccine and the release of infection control measures and future trends.

4.1. Shift of measures from “new influenza and other infectious diseases” to “category 5 infectious diseases” (equivalent to influenza)

As the COVID-19 was coming to an end worldwide, Japan moved the COVID-19 to “Category 5” and eased its infection control measures. The novel coronavirus mutated further and continued to spread in Japan. Additional vaccinations were further promoted, and the national countermeasure agency and other organizations were newly established for the future. How will the world react?

The timeline is as follows:

Table 6: *2023/5 - 2023/10 timeline*

2023	5	5	The WHO Announces the End of the New Type Corona “Emergency Declaration” (175)
		8	#New coronavirus moved to “class 5” (176)
		9	# The number of infected patients is changed from the daily "total count" to the "fixed-point count" based on reports from 5,000 medical facilities across the country (177)

	12	"The corona infection situation has calmed down." Declaration of a national state of emergency is lifted in the U.S. (178)
7	7	#Pfizer Moderna "XBB.1.5" compliant vaccine application (179)
	26	#“Active call for vaccination of all people is unnecessary,” says the Japan Medical Association (180)
	28	#14-year-old woman dies after receiving vaccine. Second case of causal relationship cannot be denied (181)
8	25	#Omi to step down as chairman of the government's Council for the Promotion of Countermeasures against H1N1 Influenza, etc (182)
9	1	#2021 Japanese mortality rate increased for the first time in 10 years (183)
		#Cabinet Infectious Disease Crisis Management Agency established (184)
		#Ministry of Health, Labor and Welfare approves vaccine for Omicron strain "XBB.1.5" (185)
	7	#The Vaccine Problem Study Group is established as a general incorporated foundation (186)
	8	#Subsidies to hospitals for "vacant bed compensation" overpaid by 50 billion yen (187)
	12	#Metropolitan Medical Association “We are in the 9th wave” calls for infection control measures (188)
	13	#Minister in Charge of Vaccination Promotion ends his mission (189)
		#Corona and Influenza Outbreaks Simultaneously in Tokyo (190)
	19	#Government to destroy 86.3 million doses of vaccine (191)
	20	#Vaccine corresponding to Omicron strain derivative "XBB" All generations of vaccination started (192)
		#Omicron stock "EG.5.1" has become mainstream (p32 Figure4)
10	3	Nobel Prize in Physiology or Medicine to Carrico and others for contributions to coronavirus vaccine development (193)
	6	#Vaccine“recommended for all children” Japan Pediatric Society (194)
	19	#Purchased 10 million additional doses of vaccine (195)
	23	# “Infectious diseases and disasters: The national government should give instructions even if there are no regulations” Draft of the Local System Research Committee (196)

*Themes covered in a separate section are listed in bold.

#: Happening in Japan

4.2. Maximum increase in the number of infected persons per day (31)

9th wave: + approx. 15,000 | Tokyo Metropolis only (September 2023) (188)

*Due to the change from actual counts to fixed-point observations, the number of new cases per day nationwide has not been published since May 9, 2023.

4.2.1. Shifted from "New Influenza and Other Infectious Diseases" to "Class 5 Infectious Diseases"

The "Law Concerning Prevention of Infectious Diseases and Medical Care for Patients Suffering from Infectious Diseases" classifies infectious diseases into categories 1 to 5, etc., based on comprehensive consideration of their infectivity and severity in case of infection. The status of new-type coronavirus infectious diseases was shifted from "new-type influenza and other infectious diseases (so-called category 2 equivalent)" to "category 5 infectious diseases," effective May 8, 2023.

The decision to shift to "category 5 infectious diseases" was made in January 2023 based on the opinions of experts that it would take about three months to fully transition the medical system and for local governments and others to prepare for the shift.

As of May 2023, new coronavirus infection is no longer classified as a "Class 2 equivalent," which means that the government is no longer able to request restrictions on behavior, and individuals must use their own judgment in taking infection control measures. In addition, individuals must now pay for their own medical expenses, which used to be free of charge. In addition, the reporting of the number of infected persons has been changed from "total count," in which medical institutions report the number of infected persons every day, to "fixed-point count," in which designated medical institutions report the number of infected persons for one week at a time (176,197).

4.2.2. Started vaccination with 6-7 doses of COVID-19 mRNA vaccine

The sixth additional vaccination on May 8, 2023 was a bivalent vaccine corresponding to the Omicron strain from Pfizer or Moderna. The target population included those who received the first vaccination (the first and second vaccinations were sent at the same time as the first vaccination), elderly persons aged 65 years and older, persons aged 5 to 65 years with underlying medical conditions, and health care workers and workers in facilities for the elderly. The seventh additional vaccination began on September 20, 2023, with Pfizer and Moderna vaccines corresponding to the Omicron strain derivative "XBB" strain. All persons aged 6 months and older were eligible for the vaccine, which continues to be available at no out-of-pocket cost (198).

The National Institute of Infectious Diseases (NIID) estimated that as of September 20, the main epidemic strain is a mutant virus called "EG.5," which is a further mutation from the XBB strain, with "EG.5.1" accounting for 63% of the cases. (Figure4, p32)

In addition, starting with the seventh booster, the "vaccination recommendation," which local governments recommend residents be vaccinated, and the "obligation to make efforts," which states that residents must make efforts to receive the vaccination, are applied only to the elderly and people at high risk of serious illness with underlying diseases, while the vaccination recommendation and obligation to make efforts are not applied to other healthy people under age 65.

Table 7: *History of the COVID-19 mRNA vaccine immunisation policy, etc.*

History of studies on new corona vaccination to date

		21/02	~	21/09	~	21/12	~	22/03	~	22/05	~	22/07	~	~22/09	~	22/12	~	23/05	~			23/Autumn		23/03					
Valuation of fashionable stocks	infectious capacity	<u>Alpha Stock</u> compared with conventional stocks Estimated 1.32 times.		<u>delta stock</u> 1.5 times higher potential than alpha shares		<u>omicron stock</u> Higher potential compared to Delta shares																							
	seriousness	<u>Alpha Stock</u> Estimated 1.4 times higher risk of hospitalization and death than conventional strains		<u>delta stock</u> Possibly higher risk of hospitalization compared to alpha shares		<u>omicron stock</u> Possibly lower risk of hospitalization and serious illness compared to Delta strain																							
Vaccination Policy		2/17 Start of first vaccination		9/17 Commencement of Investigation		12/01 Start of 3rd inoculation Ends on 23/03/31		3/24 Commencement of Investigation		5/25 Start of 4th inoculation on note (supplementary information) symbol Ending on 23/03/31				9/20 Fall Start Inoculation Start		12/13 Commencement of Investigation		5/8 Start of spring inoculation				Start of fall inoculation							
		9.5 months		6.5 months		4.5 months		7.5 months																					
		<u>target group</u> Initially: 16 years old and up Current: From 6 months of age		<u>target group</u> Initially: 18 years old and up Current: 5 years old and up		<u>target group</u> Initially: from 60 years old + Underlying Disease Current: 60 years old and up +Healthcare professionals, etc.		<u>target group</u> Initially: 12 years old and up Current: 5-11 years old without underlying disease		<u>target group</u> 65 years old and up 5 years old - Underlying disease Health care workers, etc.		<u>target group</u> 5 years old and up																	
Efficacy findings	pharmaceutical affairs	At the start of the first vaccination Prevention of disease onset: ○ (confirmed in clinical trials) Prevention of severe disease: - *The effect of prevention of severe disease could not be verified due to Insufficient number of serious cases				At the start of the 3rd inoculation Prevention of disease onset: - Prevention of severe disease: - *Confirmed increase in neutralizing antibody titer				At the start of the 4th inoculation Discussed through papers and other information gathered, not through clinical trials by companies.				At the start of inoculation in the fall of 2022 Prevention of disease onset: - Prevention of severe disease: - *Omicron-enabled bivalent vaccine *There are data of increased neutralizing antibody titer. (BA.1: (BA clinical BA4-5: non-clinical)															
	Real World Data	Infection prevention: ○*1 Prevention of disease onset: ○*2 Prevention of serious illness: ○*2 1BMJ 2021;373:n1088 2Nat Med 28,1063-1071(2022)				Infection prevention: ○*3 Prevention of disease onset: ○*4 Prevention of serious illness: ○*5 3 Nat Med 28,1063-1071(2022) 4 N Engl J Med 2022;386:1532-1546 5 N Engl Med 2021;385:1393-1400				Infection prevention: ○*6 Prevention of disease onset: ○*7 Prevention of serious illness: ○*6 6 NEJM 2022;386:1712-1720 7 NEJM 2022;386:1603-1614				○The Council will organize its views based on scientific findings and other information*8. Prevention of severe disease lasts at least 6 months and prevention of death lasts at least 10 months. Immunological findings also suggest that the efficacy may continue for an even longer period of time. ○Based on the findings of the XX Omicron strain-compatible vaccine, a policy for 2023 was decided. 8 Policy on vaccination with the new corona vaccine in FY2023 and beyond (February 8, 2023, Basic Immunization Policy Subcommittee, Subcommittee on Immunization and Vaccines, Health Sciences Council)															

Note. Source:(The 49th Subcommittee on Immunisation and Vaccine of the Health and Welfare Science Council Document [Internet])(199)

4.3. Movement of organizations regarding the COVID-19 mRNA vaccine (Japan)

There have been various developments regarding the COVID-19 mRNA vaccine by experts, citizens, and others.

4.3.1. Japan Pediatric Society "Recommendations for All Children"

On June 9, 2023, the Japan Pediatric Society presented its position on the following COVID-19 mRNA vaccine for children.

“The JAPP's recommendation remains unchanged: The JAPP recommends COVID-19 mRNA vaccine immunisation (initial series and additional doses at appropriate times) for all children between the ages of 6 months and 17 years. Multiple reports have confirmed that vaccination of children is effective in preventing the onset of disease and severe disease (hospitalization). Adverse events are monitored domestically as suspected adverse reaction reports, and serious events are carefully reviewed, but to date no serious adverse reactions have been identified that would affect the vaccination recommendation.”

Furthermore, on October 6, the Japan Pediatric Society also stated that vaccination is effective in preventing infection and serious illness, and that it continues to “recommend vaccination for all children.” (200)

4.3.2. Japan Medical Association "Aggressive call for vaccination of all people is unnecessary."

The Japan Medical Association stated on July 26, 2023 that “The percentage of people

who become seriously ill is not that high except for those over 65 years old or those with underlying medical conditions. Rather than forcing people to be vaccinated in order to reduce overall infection, the time has come for individuals to make their own choices,” and recognized that “there is no need to actively call for vaccination for all.”

At the same time, they also commented on the health damage relief system based on the Immunisation Law, saying, that "It is very important to deal with people who have become ill after vaccination. There are indications that the examination may be delayed, and the medical association will do its utmost to help.” (180)

4.3.3. "Post-COVID-19 mRNA Vaccine Sequelae" Press Conference by the Association of Patients for Recognition and Relief and Data on the Effects of the COVID-19 mRNA Vaccine

On July 24, the Association of Patients with "Sequelae of COVID-19 mRNA vaccine" held a press conference at the Ministry of Health, Labor, and Welfare (MHLW) to report on the lack of social recognition of "vaccine sequelae" and the lack of treatment and financial relief for the patients.

In addition to patients, supporters included lawyers, journalists, doctors and other medical professionals, university professors, Diet members, local legislators, and mayors.

During the press conference, it was indicated that during the two years since COVID-19 mRNA vaccine inoculation began, the number of cases approved for post-COVID-19 mRNA vaccine health damage relief examinations has reached 3,362, of which 109 were approved for claims for lump-sum death benefits and funeral rites fees (as of July 14, 2023). This number is close to the cumulative total of 3,522 cases approved for health damage relief examinations for all types of immunisations over the past 45 years, and the cumulative total of 151 death lump-sum and funeral allowance claims approved for all types of immunisations

over the past 45 years (201).

As of October 26, the number of cases approved for post-COVID-19 mRNA vaccine health damage relief examination was 4,914, of which 323 cases were approved for lump-sum death benefits and funeral rites payment claims. This number far exceeds the cumulative total of the number of cases approved in the aforementioned Post-Immunisation Health Damage Relief Examinations for all types of post-immunisation health hazards over the past 45 years, as well as the number of death lump-sum payments and funeral service fee claims approved (202).

Other reports of suspected adverse reactions to the COVID-19 mRNA vaccine from medical institutions under the Immunisation Law totaled 36,556 adverse events, of which 8,750 were serious cases and 2,122 deaths were reported (as of July 30, 2023) (203).

4.3.4. Mayor sends out video advising caution about additional vaccinations

On September 20, when the seventh dose of the COVID-19 mRNA vaccine is administered, the mayor of Izumiotsu City, Osaka Prefecture, sent out a video warning about additional vaccinations (204).

On July 22, the city held a symposium titled "Health Promotion for After Coronavirus: The Latest Facts We Have Learned from the COVID-19," at which Izumiotsu Mayor Kenichi Minamide, Nagoya University Graduate School Professor Emeritus Seiji Kojima, Tokyo University of Science Professor Emeritus Yasufumi Murakami, and other speakers spoke.

"The XBB-compatible vaccine has only been tested in mice at the regulatory approval stage. Repeatedly inoculating patients with the COVID-19 mRNA vaccine can lead to a decline in immune function and induction of IgG4 antibodies, rendering the immune system unresponsive and more receptive to the virus." (205).

4.4. Disclosure of contracts between the South African government and pharmaceutical companies

Although the COVID-19 mRNA vaccine contracts between countries and pharmaceutical companies are supposed to be kept private, the contracts were disclosed for the first time in South Africa. In Japan, the Board of Audit also pointed out deficiencies in the contract between the Japanese government and a pharmaceutical company for the COVID-19 mRNA vaccine.

4.4.1. Disclosure of contracts with South Africa

Contracts between countries around the world and pharmaceutical companies for COVID-19 mRNA vaccines are considered private, but the need for public disclosure has been appealed (206).

In August 2023, a South African court ordered the National Department of Health (NDOH) to release the COVID-19 mRNA vaccine contract and other relevant documents; in early September, South Africa terminated its contract with Pfizer and made some of the contract details public.

“It sends a strong signal to powerful pharmaceutical companies and others that in South Africa, transparency cannot be bartered and is not up for sale – there really is no room for this much of secrecy in the health or any other sector” says Fatima Hassan, Director of HJI.

Excerpts from the contract are as follows:

"5.5 The long-term efficacy and effectiveness of the Vaccine are unknown at this time, and adverse reactions to the Vaccine may occur. In addition, the vaccine does not have a serial number (which you, as the purchaser, approve)."

“9.6 (As a condition precedent to supply) the Purchaser (the Government) assumes and fully performs its obligation to indemnify (Pfizer and all Indemnified Persons against claims

and all losses arising out of or related to the Vaccine or its use) and has the legal or regulatory authority (as may be necessary to do so) and appropriate appropriations of funds.” (207,208)

* Parentheses are supplementary notes added by the author.

4.4.2. Findings on Contracts by Japan's National Audit Office

Japan's Audit Office is a constitutional body, independent of the Diet and the courts, and independent of the Cabinet, that inspects the accounts of the government and other institutions established by law and supervises them to ensure that accounting and accounting practices are carried out correctly. (209)

The Audit Office pointed out that the basis for the contract for the purchase of 880 million doses of COVID-19 mRNA vaccine was inadequate.

It said, "The materials lacked descriptions of the contract's history and basis for calculation, making it impossible to verify the validity of the contract.” It was also found that the Ministry of Health, Labor, and Welfare did not record the quantity of vaccines in stock.

It cost 2,471.8 billion yen to secure the vaccines.

Contracts were concluded for 399 million doses from Pfizer of the U.S., 213 million doses from Moderna of the U.S., 120 million doses from AstraZeneca of the U.K., and 150 million doses from Novavax of the U.S. On the other hand, as of March 27, 2023, a total of about 380 million doses had been administered, and a number of doses have actually been disposed of in the field."

The total purchase of 880 million doses of vaccine is approximately 2.5 trillion yen. It is thought that the contract with Pfizer was for 400 million doses at \$20 (3,000 yen) per dose, and other contracts for a total of 480 million doses with Moderna and others (210).

4.5. Massive disposal of COVID-19 mRNA vaccine

September 19, “The Ministry of Health, Labor and Welfare (MHLW) announced that a total of 86.3 million doses of vaccines corresponding to conventional and mutant strains of Omicron, manufactured by Pfizer Inc. and Moderna Inc. in the U.S. and stored by the government, will be disposed of in order to start vaccination of all generations on September 20, and to discontinue use of vaccines corresponding to conventional strains. The vaccines to be disposed of are those produced by Moderna.

Most of the vaccines to be disposed of are those made by Moderna, with the Omicron strain accounting for approximately 51.5 million doses (74%) of the approximately 70 million doses supplied to the domestic market. Pfizer's vaccine for the conventional strain is about 8.3 million doses (3%) of the approximately 274.8 million doses supplied, and for the Omicron strain, about 26.5 million doses (21%) of the approximately 125.1 million doses supplied. The government does not disclose the unit price per vaccine purchased.” (191)

4.6. New Japanese structure for the future

The "Cabinet Agency for Crisis Management and Control of Infectious Diseases" was newly established and the duties of "Minister of State for Vaccination Promotion" were terminated.

4.6.1. Establishment of "Cabinet Office for Infectious Disease Crisis Management"

On September 1, the "Cabinet Office Infectious Disease Crisis Management Control Agency" was established in the Cabinet Secretariat to assume the command post function of Japan's infectious disease crisis management.

The Minister in charge is the Minister of State for Economic Revitalization. The

command is taken by Chief Cabinet Secretary Toshikazu Kurio, Cabinet for Infectious Disease Crisis Management. There are 38 full-time staff members, and in the event of an emergency, the agency will be staffed by 101 people, with a maximum staff of up to 300 people envisioned.

The "Council for the Promotion of Countermeasures against New Strains of Influenza, etc.," which had been in charge until then, will be reduced from over 30 members to 15, and the Subcommittee on Countermeasures against New Coronary Infections, etc., will be abolished on the grounds that it has played a certain role (211,212).

4.6.2. "Minister in Charge of Vaccination Promotion" mission ends

On April 7, 2022, Chief Cabinet Secretary Hirokazu Matsuno, who was the Minister of State for Vaccination Promotion (commonly known as the Minister of Vaccination Promotion), ended his term as Minister of Vaccination Promotion on September 13, 2022.

4.7. World trends for the future

With the Nobel Prize awarded for the COVID-19 mRNA vaccine technology, the WHO is preparing to create a new regime.

4.7.1. Nobel Prize Awarded to Two Vaccine Development Researchers

On October 3, 2023, two researchers who developed the vaccine were awarded the Nobel Prize for the world's first technology that sends "messenger RNA," the genetic information of a virus, into the body to produce antibodies (193).

4.7.2. Establishment of the "Pandemic Convention" and revision of the "IHR (International Health Regulations)" by the WHO

In May 2024, the 77th World Health Assembly of the WHO is scheduled to pass a resolution to revise the International Health Regulations (IHR) and a new international treaty, the Pandemic Convention (213,214).

The following is a partial draft of the proposal. The contents overlap in many parts, and the structure is such that they complement each other.

Excerpts from the proposed IHR partial revision (215,216)

- The WHO has changed from an advisory body to a legally binding body (Articles 1 and 42).
- The Director-General of the WHO will make decisions on PHEIC (Articles 2 and 12).
- The scope of PHEIC is extended to include potential situations (Articles 2 and 12).
- "Respect for people's dignity, human rights and fundamental freedoms" is deleted from the article (Article 3).
- The WHO has the authority to require countries to provide medical examinations, certificates of prophylaxis, vaccine certificates, contact tracing, quarantine, and treatment (Article 18).
- Implement a global health certificate system in digital or paper format, including test certificates, vaccine certificates, recovery certificates, passenger location certificates, etc. (Articles 18, 23-28, 31, 35, 36, 44, Annex 6, 8)
- The WHO (Emergency Committee) has the authority to overrule decisions made by sovereign states regarding health policy, and the WHO (Emergency Committee) makes the final decision (Article 43)

- Expand censorship of what the WHO considers to be misinformation or disinformation. (Annex 1)

Excerpts from the contents of the draft Pandemic Convention (217)

- Strengthens the WHO's central role as the lead and coordinating body (CA+Article 3)
- Provide incentives to pharmaceutical companies for the development, production, capacity expansion, distribution and stocking of their pharmaceutical products to the greatest extent possible (CA+ Articles 3, 9 and 12).
- Compensation to vaccine victims to be limited to a certain period of time only (CA+ Article 10).
- The Director-General of the WHO may, on his/her own authority and without the consent of the relevant government, declare a Public Health Emergency of International Concern (PHEIC) (CA+Article 15).
- All of these policies and measures apply to domestic animals, wildlife, the plant kingdom, and environmental events, including weather, through "one health approach". (CA+ Article 4,5).
- Safety regulations are loosened for "gain-of-function experiments" and safety measures are left to the conscience of each research entity (CA+Article 9).
- The Convention is valid during and between pandemics (*between pandemics, i.e., normal times). (CA+ Article 2)

Uwe Kranz, former Attorney General of the German state of Thuringia and long-time advisor to the European Criminal Police Organization (EUROPOL), and his colleagues, claim that the sovereignty and freedom rights of the people will be in extreme danger if the

WHO International Health Regulations and the WHO Pandemic Convention (CA+) are adopted in May 2024, as these two On July 23, 2023, criminal charges were filed against leading politicians of the Federal Republic of Germany, alleging that the actions of the Federal Government and most of the members of the Parliament in connection with the planned changes to the WHO legal documents ignore an important element of the basic order of liberal democracy and violate its principles (218).

4.8. Various Views on the COVID-19 Pandemic

Various views of experts and others reflecting on the COVID-19 pandemic are presented below:

4.8.1. The WHO's Opinion

On January 20, 2021, an independent committee examining the response of the WHO and other countries to the COVID-19 noted that "the international community and other countries made a number of serious mistakes in the early stages," and although it did not name what country, it recognized that there were problems with the response of China, other countries, and the WHO. He also pointed out that the WHO needs to be reformed in order to respond to the pandemic.

The independent committee was established by the WHO in September 2020 to review the response of the WHO and other countries and to draw lessons for future infectious disease countermeasures.

In its interim report released earlier, the Independent Commission pointed out that there were delays in China's response in the early stages of the outbreak and questioned the WHO's decision not to declare a "public health emergency of international concern" until January 30

of last year, noting that most countries did not take necessary measures after the declaration was made.

Former New Zealand Prime Minister Clark, who co-chairs the committee, and others told the WHO Executive Board on January 19 that "the report identifies a number of serious failures made by the international community and countries in the early stages of the response to COVID-19," and highlighted, although without naming names, problems with the WHO and other countries, including China, in their response.

Former Liberian President Sirleaf, who also serves as Co-Chair, said that "Member countries expect leadership from the WHO, but they do not give the WHO the authority and resources it needs to do its job," and recognized that the WHO reforms, such as addressing funding shortfalls, are essential to strengthening the response to the pandemic (219).

4.8.2. An article published in the *Journal of Evaluation in Clinical Practice* on "What Did COVID-19 Really Teach Us About Science, Evidence, and Society?"

"Some of these failures reflected efforts by influential scientists and their political allies to demonize dissenting scientific views and evidence. From the earliest days of the pandemic, despite weak, absent or contradictory evidence, leading national decision makers, facing the urgent need for, assured the public that they were adopting COVID-19 policies by following the science."

"Rather than politics following the science, science was enlisted to follow the politics."

"study and communication of these disorders during COVID was too often demonized by high-level decision-makers and their scientific advisors, which in turn clouded our ability to openly debate the balance of impacts of the massive public health interventions imposed across large segments of the society."

“Now add the uncertain but plausible possibility that COVID-19 was itself the product of biomedical science and an apparently outrageous consequence becomes inescapable: science itself may have become a threat to overall population health.”

“Indeed, given the uneasy possibilities and accumulating tensions we have mentioned, it is hardly irrational that an increasing proportion of the dissatisfied public is wondering whether truth and the path to a healthier world must lie somewhere else than within prestigious journals and celebrities at the science–policy– communication interface (June 6, 2023).” (220)

**4.8.3. The Graduate School of Business Administration, Kobe University stated that
“COVID-19 measures Health supremacy that creates a society that does not
tolerate dissent”**

“Is the current Japanese society, which does not allow for questioning, deliberation, and personal reflection, the right form of society? The democratic ideology was born out of a history of human beings becoming self-righteous and running amok, especially when they have power, such as authority or capital. At its foundation, the most important thing is to respect the basic human rights of each individual, to reveal information publicly, not to control it, and to have a public dialogue and sublimate it. There are no absolutes in science. There are no absolutes in government either. History has proven that. In the field of public health, it is easy to fall into the trap of health supremacy, and we tend to think that the goal is to be healthy, and that it is our supreme mission to get closer to that goal halfway by force. Or else, we have a history of drug abuse where health is threatened because economic activity has taken precedence (Jan. 12, 2023).” (221)

5. Discussion

This section discusses the interpretation of five points.

The first point is the increase in the number of deaths in Japan during the COVID-19 epidemic and the factors behind this increase. First, the maximum number of new daily COVID-19 infections increased from 550 in early 2020 to 7,000 in May 2021 and 250,000 in August 2022, a 35.7-fold increase compared to 2021 (Section 1.2. Maximum increase in the number of infections per day, section 2.2. same title, section 3.2. same title). The prevalent strain in 2022 was the Omicron strain, which was more infectious than the Delta strain in 2021, but with reduced severity and risk of severe disease. (Section 4.2.2. Start of six to seven doses of new coronavirus vaccine). However, the annual increase in deaths compared to 2020 has tripled in real terms, from approximately 69,000 deaths in 2021 ($\approx 5,747 \times 12$ months) to 212,000 deaths in 2022 ($\approx 17,639 \times 12$ months) (Section 3.2.2. Excess death rate).

There are several possible reasons for this increase in deaths. One reason could be that deaths occurred because fewer beds were reserved for admission and patients could not be admitted, or because patients with other illnesses could not be seen in hospital due to medical pressures. However, as noted in the summary (1.3.6. Securing the healthcare system and medical tightness), the number of inpatient beds initially accounted for 1.8% of the total number of beds in Japan, and as of August 2022, only 5.14% had been secured; it is unlikely that many seriously ill patients were not admitted because of COVID-19, and the actual number of admissions for the COVID-19 was always around 15,000 fewer than the number of beds reserved for inpatients with the COVID-19 infection. Others have suggested that lack of exercise, mainly among the elderly, may have been a factor in the deaths, due to isolation measures such as staying at home. However, no data could be found that revealed the extent to which persistent physical inactivity led to deaths. A further view is that deaths may have increased due to an increase in the COVID-19 infections themselves. However, this cannot be

determined in this study, as further investigation into the accuracy of PCR testing and reported causes of death would be required to determine this.

Finally, there is a view that one phenomenon that has changed significantly in the intervening years - the COVID-19 mRNA vaccination, which started in Japan in February 2021 - is a factor in the increase in deaths (This is summarized in sections: section 3.1. How has additional vaccination progressed and how has the infection situation changed? and section 3.2. How have further social changes occurred?). Although the information that could be made public is only a small part of the information available, there are several studies that prove the efficacy and side effects of the COVID-19 mRNA vaccine, over 276 conference presentations (section 3.4.6. Reporting post-vaccination cases and adverse reactions at conferences; as of September 2022), a high number of applications and deaths of vaccination victims (as of 19 January 2024, the number of applications and deaths of vaccination victims increased to 5,891 and 423, respectively; as of 19 January 2024) (222). It is not possible to conclude that the COVID-19 mRNA vaccination is unrelated to the increase in the number of deaths, due to the following reasons. Further verification is needed. The existence of other factors also needs to continue to be verified.

The second point concerns the urgent approval of the COVID-19 mRNA vaccine. The COVID-19 mRNA vaccine was urgently approved first in the UK and then in the US, based on a single Pfizer paper first published in December 2020 (Section 2.4.3. First paper on the evaluation of the mRNA vaccine COVID-19). It was later pointed out that not only was the paper subject to a number of biases, but also that it was a flawed paper that did not reflect the data correctly.

In the UK and US, almost only a few days elapsed between the publication of the study and the approval and start of vaccination in each country, so fast that it can only be assumed that the details of the implementation were shared in advance, the contents and timing of the

approval were decided beforehand, or the approval was implemented without sufficient consideration (Section 2.1. Movements before and after the start of corona vaccination and changes in the infection situation?).

In terms of implementation, the long-term side effects of the COVID-19 mRNA vaccine are still under review and, as already mentioned, may be related to the actual increase in deaths. The emergency approval itself needs to be further examined to ensure that the correct processes are followed to properly validate the effectiveness and risks.

The third point concerns the dishonest behaviour of the Japanese national authorities. The Ministry of Health, Labour and Welfare (MHLW) has made mistakes that could be seen as impressionistic (section 3.6. Doubts from experts regarding official data released by the Ministry of Health, Labor and Welfare), and deficiencies have been noted in relation to contracts for large sums of money and other matters (section 4.4.2. Findings of the Japanese National Audit Office regarding contracts). This is extremely unusual. This is highly unusual because the Japanese public service is, in the first place, an organisation under very strict control and supervision, where mistakes are frowned upon and where not making mistakes is the highest priority. An urgent investigation into the causes is needed.

The fourth point concerns Bias in media coverage. Since the beginning of 2020, many experts, including medical institutions, scientists and pharmaceutical company officials from all over the world, have warned about the risks of the COVID-19 mRNA vaccine, including its side effects (Section 2.5.1. Scientists worldwide have expressed concern about the COVID-19 mRNA vaccine; and section 2.5.2. Patient association with 'COVID-19 mRNA vaccine sequelae'). In contrast, national authorities continue to promote the safety and efficacy of the COVID-19 mRNA vaccines. Only the safety and efficacy of the COVID-19 mRNA vaccine are reported in the mainstream media, with no negative information about the COVID-19 mRNA vaccine (academic papers, activities to address the damage caused by the

adverse effects of the COVID-19 mRNA vaccine, the number of certifications under the Immunisation Health Relief Scheme, etc.) or news about excess deaths.

The information on the side effects of the COVID-19 mRNA vaccine discussed in this study was considered false information from the beginning of the COVID-19 pandemic (Already at the time of training at the WEF before the COVID-19 pandemic!), but now that we cannot be sure that the COVID-19 mRNA vaccine is not at least related to the increased number of deaths, was it right that it was not released to the public as false information from the beginning? What is hoax information, who decides what is hoax information and how, and what criteria are clearly stated? Is there any illegality in the act itself? How does not publishing certain information as hoax information affect the attempt to be scientific? Further discussion is needed.

The fifth point concerns the actions of the WHO. The WHO, which appears at the beginning and end of this manuscript, has participated in WEF training on the COVID-19 since before the outbreak of the COVID-19 pandemic (Section 1.5. Pre-simulation exercise one and a half months before the emergence of the novel coronavirus), and now, assuming that a future pandemic is bound to happen, the WHO emphasises the need to concentrate and strengthen its public health powers (Section 4.7.2. WHO's enactment of the 'Pandemic Convention' and revision of the 'WHI (International Health Regulations)'). The WHO issued a new warning at the WEF on 17 January 2024, 'Davos AM24 - Preparing for Disease X', that Disease X could be 20 times more lethal than the COVID-19 pandemic (223).

How can we warn that the next unknown pandemic could be 20 times more lethal than COVID-19 when the origin and outbreak history of COVID-19 is still unknown and has not been thoroughly verified? The big question is why the assumption is that the next pandemic will happen and why there is no discussion about how to prevent it in advance. As for the WHO, we believe that its impartiality and transparency, including the source of funding for

its activities and the backgrounds of its current directors, need to be further investigated.

Finally, there is a so-called conspiracy theory in the public mind that 'international organizations like the WHO, big pharmaceutical companies, and other interested parties are using man-made viruses to cause pandemics, paralyze economies, incite unrest, get people vaccinated, and make profits.'

At this stage, we cannot immediately and completely affirm this story, but at the same time, we do not believe that this possibility can be completely ruled out. Further investigation and verification are needed, including the possibility that this story is true.

In the COVID-19 pandemic, Japan is unique in the world, especially with regard to additional COVID-19 mRNA vaccination. This compilation of information on the overall global COVID-19 pandemic, with a focus on the situation in Japan, has provided an opportunity to discover new challenges.

One drawback is that we were not able to include in the text information on grants and other financial expenditures in each country related to COVID-19. This information should be included in a future review. Other topics that could not be included in this article include the impact of social isolation policies and whether or not there is scientific evidence for them, including a comparison of the introduction of vaccine passports in different countries, as well as the introduction of a new COVID-19 mRNA vaccine called the Replicon vaccine, which is approved only in Japan.

6. Conclusions

One of the most important concerns about the COVID-19 pandemic is that experts as well as the general public have taken political and media reports at face value and often followed them without doing their own research despite the fact that the information in the mainstream media, which people generally have access to, is biased in a certain direction.

We live in an era where it is important for everyone, not just experts, to research primary sources and make their own decisions. It is also extremely important to know opposing views that differ from one's own and to deepen the debate. Taking the time to look back at the past is an essential task in order to objectively grasp the whole picture. History repeats itself. Recognising facts from diverse perspectives leads to more diverse debate and dialogue, which is essential for a bright and healthy future.

The impact of the COVID-19 pandemic is ongoing, and we must continue to pay attention to data, information, and scientific articles from various countries and continue to verify the COVID-19 pandemic with a broad, long-term perspective.

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