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Consideration of the Relief System for Injury to Health with Vaccination -A Focused Analysis of Applications Related to COVID-19 Vaccinations-

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Consideration of the Relief System for Injury to Health with Vaccination -A Focused Analysis of Applications Related to COVID-19 Vaccinations-[†]

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This paper aims to examine the Relief System for Injury to Health with Vaccination from various perspectives. While the system covers a range of vaccines under routine immunization programs, this study focuses primarily on data related to the relief system for COVID-19 vaccinations. The specific considerations are as follows. By comparing the use of the relief system for COVID-19 vaccinations with that for other routine vaccinations, what insights can be gained? Is there a disparity in the recognition or rejection of applications among municipalities? What explains the differences in the number of applications across prefectures? How does Japan's relief system compare to those of other countries in terms of its characteristics? These are the primary questions this paper seeks to address. Additionally, the paper will discuss issues arising when applications for relief are rejected.

JEL : I10, I38

Keywords: COVID-19, Long vax, Relief system for injury to health with vaccination

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[†] In preparing this manuscript, data was provided through information disclosure requests from the Nagoya City and 23 prefectures. Additionally, some data and information about systems were provided by two individuals and one organization (the sources of the data and the names of the providers are listed in the data sources). I would like to take this opportunity to express my gratitude for their cooperation despite their busy schedules.

Please note that any errors that may exist in this manuscript are entirely the responsibility of the author.

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1. Introduction

This manuscript aims to examine various systems, including the Relief System for Injury to Health with Vaccination, from multiple perspectives. In Yasuoka (2023), the focus was on analyzing issues such as worsening health conditions following COVID-19 vaccinations, challenges in daily life, and difficulties in accessing social security systems. These considerations were explored primarily through interviews presented in the form of academic papers. In fact, various vaccinations existed prior to the COVID-19 vaccine, and the issue of health damage related to vaccinations has already been explored in previous research. Noguchi (2022) has examined this issue from multiple perspectives. Amid such existing research, the author has conducted analyses such as those presented in the previously mentioned works by Yasuoka (2023) and Yasuoka (2024). These two studies not only address issues such as challenges in daily life and the inability to access social security systems related to health damage caused by COVID-19 vaccinations, but they also feature data analysis as a distinctive aspect of their research. Through the data, these studies were able to revisit and examine issues related to the Relief System for Injury to Health with Vaccination.

For example, they revealed disparities among municipalities in the number of days from application to approval or rejection of claims under the program. Additionally, they clarified which types of claims for illnesses require longer or shorter periods for approval. Such datadriven analyses have not been thoroughly explored in prior research, making these findings highly significant.

The purpose of this manuscript is to analyze health damage associated with COVID-19 vaccinations, with a particular focus on examining various aspects of the Relief System for Injury to Health with Vaccination. The structure of this manuscript is as follows: In Section 2, a comparison is made between the number of applications for the Relief System for Injury to Health with Vaccination related to COVID-19 vaccinations and those for other routine vaccinations, using data from Hyogo Prefecture. By comparing factors such as approval rates and the time taken from application to approval or rejection, this section examines whether there are distinctive features in the utilization of the system for COVID-19 vaccinations compared to other routine vaccinations. Section 3 focuses on an analysis of rejection rates. While Yasuoka (2024) conducted an analysis using data from eight municipalities in the Hanshin region, this manuscript expands the scope of analysis to include comparisons among a wider range of municipalities, prefectures, and national level. Furthermore, it examines the temporal characteristics of rejection rates in the Ministry of Health, Labour and Welfare's review process. Section 4 examines the application status of the Relief System for Injury to Health with Vaccination across prefectures, focusing on whether application rates in each prefecture correlate with factors such as aging rates and vaccination rates. The motivation for

this analysis stems from the observation that elderly individuals may face difficulties in obtaining information about the program through sources like the internet, which could result in fewer applications and affect application rates. Section 5 provides an overview of compensation mechanisms for health damage in other countries and compares these systems to Japan's Vaccine Injury Compensation Program. This comparison highlights the distinctive features of Japan's system.

Section 6 addresses issues related to cases where applications are rejected, exploring the challenges faced by applicants in such situations as a critical problem of the current system. Finally, Section 7 concludes the manuscript, summarizing the findings and their implications.

2. Comparison of the number of applications for the Relief System for Injury to Health with Vaccination between COVID-19 vaccination and other vaccinations

By comparing the number of applications to the Relief System for Injury to Health with Vaccination associated with COVID-19 vaccinations and those from other routine vaccinations, this section aims to identify whether there are any distinctive characteristics in the application trends related to COVID-19 vaccinations. The data was obtained through a disclosure request (information disclosure request) to Hyogo Prefecture in November 2023. As for other routine vaccinations, these include vaccinations primarily targeting the elderly, vaccinations for infants and young children, and HPV vaccinations.¹ Considering that the data for all past routine vaccinations would be extremely voluminous and retrieving historical data would be time-consuming, I decided to use data from 2018 (Heisei 30) onwards. The summarized results obtained from the data are presented in the following table.

¹ Details of routine vaccinations are outlined in the Ministry of Health, Labour and Welfare's 'Frequently Asked Questions.' Vaccinations for Type A diseases (such as measles) are mandatory for all eligible individuals and are fully subsidized by public funds. Vaccinations for Type B diseases (such as seasonal influenza) may receive partial public funding in certain cases. In addition to these routine vaccinations, there are also voluntary vaccinations. For example, seasonal influenza vaccinations are considered routine for the elderly but are categorized as voluntary for younger individuals. In the case of voluntary vaccinations, adverse reactions do not qualify for the Vaccination Injury Compensation Program; instead, individuals must utilize the health damage relief system managed by PMDA (Pharmaceuticals and Medical Devices Agency). For more details, refer to the Pharmaceuticals and Medical Devices Agency (PMDA) documents: 'Eligibility for Benefits under the Relief System for Adverse Drug Reactions' and 'Handling of the Relief System for COVID-19 Vaccination.'

		Other Routine	
	COVID-19 Vaccination	Vaccinations	
		(2018~)	
Number of Applications	546	30	
Average Number of Days Until	212 0 days	257.9 dama	
Approval or Rejection	515.9 days	257.0 days	
Median Number of Days Until	211 days	251 5 days	
Approval or Rejection	SILuays	251.5 days	
Standard Deviation of Days Until	142 days	102.0 days	
Approval or Rejection	145 days	102.9 days	
Denial Rate	14.7%	10%	
	Number of Approvals : 307	Number of Approvals :	
	Number of Denials :	18	
	47+6(Non-approval)	Number of Denials : 2	

Table 1: Comparison of COVID-19 Vaccination and Other Routine Vaccinations under theRelief System for Injury to Health with Vaccination Based on Hyogo Prefecture Data (Source:Obtained through a Disclosure Request)

(Note: The number of days until approval or rejection refers to the period from the date the application is forwarded from the prefecture to the national government to the date of national approval or rejection. In reality, the notification of application results takes longer than the number of days shown in the table, as the period also includes the time it takes for the application to be forwarded from the municipality (the application window) to the prefecture and then to the national government.)

As of December 1, 2023 (Reiwa 5), the estimated population of Hyogo Prefecture is 5,366,910. Based on this figure, the number of applicants for the Relief System for Injury to Health with Vaccination due to COVID-19 vaccination is approximately 1 in 10,000 people. In contrast, the ratio for other routine vaccinations is smaller.² When examining this data, it is important to note that the target populations for the two types of vaccinations differ. COVID-19 vaccinations have been administered across nearly all age groups, whereas other routine vaccinations are often limited by age or gender. This raises the question of whether a

² For information on the population of Hyogo Prefecture, refer to the Hyogo Prefecture 'Estimated Population Annual Report: Population Trends.'

direct comparison is appropriate, as the number of eligible recipients differs between the two. Nonetheless, the significantly higher number of applications for the compensation program related to COVID-19 vaccinations is striking and cannot be overlooked.

Additionally, the 'Average Number of Days Until Approval or Rejection' and the 'Median Number of Days Until Approval or Rejection' are both longer for COVID-19 vaccinations compared to other routine vaccinations. Furthermore, the 'Standard Deviation of Days Until Approval or Rejection' is also larger for COVID-19 vaccinations. While it is known that the time required for approval or rejection varies by applicants—some being processed quickly while others take longer—the data indicates that this time discrepancy is more pronounced for COVID-19 vaccinations.

The Ministry of Health, Labour and Welfare's Disease and Disability Certification Committee should aim to expedite the approval or rejection process to at least match the efficiency of other routine vaccinations. The longer processing times for COVID-19 vaccination cases, as suggested by this data, appear to result from delays in deliberations within the committee.

Although the exact reasons cannot be definitively stated, it is possible that the high volume of applications is causing a backlog in reviews. Another plausible explanation is that COVID-19 vaccinations, being relatively new, may lack sufficient information about associated adverse reactions, leading to prolonged deliberations. These factors could collectively explain the observed delays.

3. Considerations on the Denial Rate

The following section examines the extent to which applications for the Relief System for Injury to Health with Vaccination have been approved and, conversely, the extent to which they have been denied. Here, the denial rate (the proportion of applications resulting in a denial among those for which a decision has been made) will be compared at both national and local government levels. The comparison is presented on the table below.

	Denial Rate	Data
National Government Level ³	19.8%	2024/6
Hanshin Local Government Level ⁴	8.3%	2023/11
Hyogo Prefecture ⁵	14.7%	2023/11
Aichi Prefecture ⁶	16.6%	2024/4
Nagoya City ⁷	9.8%	2024/6

Table 2 : Denial Rates in the Relief System for Injury to Health with Vaccination (For sources, please refer to the respective footnotes.)

As shown in Table 2, it is evident that denial rates vary between the national and local governments. However, it is important to note that the timing at which the denial rates were calculated differs for each data set due to variations in data collection.

Furthermore, there is a notable trend in the denial rates, as illustrated in the figure below.

³ Ministry of Health, Labour and Welfare, "Deliberation Results of the Disease and Disability Certification Review Committee, Infectious Diseases and Vaccination Subcommittee, COVID-19 Vaccination Health Damage Review Division 3."

⁴ Yasuoka (2024)

⁵ Data obtained through disclosure requests.

⁶ Aichi Prefecture, "Aichi COVID-19 Information Website."

⁷ Data obtained through disclosure requests. It is worth noting that Nagoya City provides its own financial support for applications. For detail information, We can check the following information: Nagoya City, "About the Health Damage Relief System for COVID-19 Vaccination." The author took a keen interest in Nagoya City's initiative to establish such a system and posed various questions, to which the city provided thoughtful and detailed responses. The author would like to take this opportunity to express my gratitude.



Figure 1 : Denial Rate in the Relief System for Injury to Health with Vaccination (Data: The Ministry of Health, Labour and Welfare "Disease and Disability Certification Council (Subcommittee on Infectious Diseases and Vaccination Review, Subcommittee on Health Damage Review for COVID-19 Vaccination under the Subcommittee on Infectious Diseases and Vaccination Review." The denial rates are shown for each meeting held from the "143rd Meeting (Subcommittee on Infectious Diseases and Vaccination Review) (August 19, 2021)" to the "18th Meeting (Second Subcommittee on Health Damage Review for COVID-19 Vaccination under the Subcommittee on Infectious Diseases and Vaccination Review) (June 20, 2024)."⁸)

These review committees cover not only medical expenses and allowances but also the approval or denial of lump-sum death benefits and disability pensions. Therefore, it is reasonable to expect fluctuations in the denial rates at each meeting. However, compared to the low denial rates observed in 2021, the rates in 2024 have risen significantly. The reason for this increase remains unclear.

4. Considerations Regarding the Application Status of the Relief System for Injury to Health with Vaccination in Prefectures

This section aims to examine whether the application status of the Relief System for Injury to Health with Vaccination varies across prefectures and, if so, what factors may be associated

⁸ This data was kindly provided by Motohiro Ohtsuka. The author would like to take this opportunity to express their gratitude.

with these differences. Detailed application counts for each prefecture will not be included here.

The method used for regression analysis is the ordinary least squares (OLS) method. The dependent variable is the application rate, defined as the ratio of the number of applications to the population size. The application rate was chosen to remove the influence of population size, as regions with larger populations would naturally have higher application numbers. The explanatory variables included in the analysis are: ①Aging rate, ②Vaccination rate, ③ Subsidy dummy, and ④Regional dummy.

- (1) Aging rate⁹ The aging rate was included as an explanatory variable based on the assumption that prefectures with a higher aging rate may have a higher proportion of vaccinated individuals relative to the population, potentially leading to a greater number of adverse reactions and, consequently, more applications. On the other hand, it was also considered that older individuals, unlike younger generations, might face challenges in accessing information via the internet or may not even be aware of the Relief System for Injury to Health with Vaccination. This lack of awareness could hinder access to the system, potentially leading to a decrease in the application rate despite the high aging rate.
- ② Vaccination rate¹⁰ The vaccination rate, specifically the proportion of individuals who received the third dose relative to the total population, was included as an explanatory variable. It was assumed that prefectures with higher vaccination rates would experience more adverse reactions, leading to a greater number of applications. However, using the third-dose vaccination rate as the standard warrants further consideration as a general analytical approach. It remains debatable whether the analysis should focus on the first or second dose, or whether vaccination rates for each dose should be included as separate explanatory variables. This is an issue that requires further discussion.
- ③ Subsidy dummy The application for the Relief System for Injury to Health with Vaccination is processed through municipal offices, and support for the application process is provided in cities like Nagoya.¹¹ However, instead of providing support for

⁹ Ministry of Internal Affairs and Communications Statistics Bureau "Population Estimates (As of October 1, 2023) - Nationwide: Population by Age (Single Year), Gender; Prefectures: Population by Age (Five-Year Age Groups), Gender"

¹⁰ Ministry of Health, Labour and Welfare "Total Number of Vaccine Doses Administered to Date (By Prefecture)"

¹¹ Nagoya City has a system called the "Nagoya City Health Damage Relief Application Support

applications at the prefectural level, there exist independent systems established by prefectures, separate from the national relief system. Here, dummy examples of support have been included for Yamanashi Prefecture and Aichi Prefecture.¹²

④ Regional dummy Items not captured by factors ①-③ were included as regional dummy variables: "Hokkaido Dummy," "Tohoku Dummy," "Kanto Dummy," "Chubu Dummy," "Chugoku Dummy," "Shikoku Dummy," "Kyushu Dummy," and "Okinawa Dummy." If all these dummy variables are set to zero, it indicates the Kansai region. By including these dummy variables, it is possible to consider the application rate for each region as influenced by the characteristics specific to that area.

Regarding the number of applications, data was obtained from newspaper reports for some prefectures, while for others where such reports were unavailable, information was collected through information disclosure requests or direct inquiries.¹³ The number of cases submitted by each prefecture to the national government under the Relief System for Injury to Health

¹² In Yamanashi Prefecture, there is a system called the "COVID-19 Vaccine Side Effect Leave Compensation Grant," which provides a fixed amount of financial assistance if an individual is unable to work due to side effects from the COVID-19 vaccine. (Reference: Yamanashi Prefecture, "Various Support Systems and Consultation Services Related to COVID-19.") In Aichi Prefecture, there is a system called the "COVID-19 Vaccine Side Effect Compensation Benefit," which provides partial assistance for medical expenses. (Reference: Aichi Prefecture, "Aichi COVID-19 Information Website.") These systems were added as dummy variables with the assumption that they might contribute to increasing the application rate for relief programs. However, it may be more accurate to consider cases like Nagoya City, where direct assistance is provided for the documents required for applications. Nonetheless, for the purpose of examining whether independent support systems by prefectures impact application rates, dummy variables were used to represent such prefectural-level support mechanisms.

¹³ The number of applications was determined through newspaper reports, information disclosure requests, and direct inquiries to government offices. However, to calculate the application rate, population data was necessary. This data was obtained from Statistics Bureau of Ministry of Internal Affairs and Communications, "Population Estimates (As of October 1, 2023) -Nationwide: Population by Age (Single Year), Gender; Prefectures: Population by Age (Five-Year Age Groups), Gender". Note that for Shimane Prefecture, the figure used is not the number of applications but the number of approved cases.

Fund," which provides assistance for document fees and medical expenses related to the application process. (Reference: Nagoya City "About the Health Damage Relief System for COVID-19 Vaccination.")

with Vaccination is assumed to be tracked by the Ministry of Health, Labour and Welfare (Division of Infectious Disease Control, Health and Welfare Bureau for Health and Safety). However, upon inquiry, it was confirmed that they do not have such data. As a result, the author collected data on the number of applications from all prefectures. Details regarding the data collection process for application numbers are provided in the appendix.

Regression Statistics	
Multiple Correlation Coefficient	0.683556
R Square	0.467248
Adjusted R Square	0.299812
Standard Error	1.44E-05
Number of Observations	47

Analysis of Variance Table

	Dograaa of			Observed	
	Eroodom	Variation	Variance	Variance	Significance F
	Freedom			Ratio	
Regression	11	6.41E-09	5.82E-10	2.790604	0.010264
Residual	35	7.3E-09	2.09E-10		
Total	46	1.37E-08			

	Coefficient	Std. Error	t value	P value	95% Lower Limit	95% Upper Limit
Intercept	0.000129	7.44E-05	1.740395	0.090576	-2.2E-05	0.00028
Aging Rate (%)	-0.00019	0.000157	-1.21308	0.233222	-0.00051	0.000128
Vaccination Rate (third dose, %)	3.76E-05	0.000164	0.229627	0.819719	-0.00029	0.00037
Subsidy Dummy	-1.3E-05	1.22E-05	-1.09027	0.283043	-3.8E-05	1.14E-05
Hokkaido Dummy	-5.3E-07	1.67E-05	-0.0317	0.974888	-3.4E-05	3.34E-05
Tohoku Dummy	-1.9E-05	1.51E-05	-1.28593	0.206909	-5E-05	1.12E-05
Kanto Dummy	-3.6E-05	1.25E-05	-2.91124	0.006225	-6.2E-05	-1.1E-05
Chubu Dummy	-1.2E-05	1.07E-05	-1.08433	0.285633	-3.3E-05	1.01E-05
Chugoku Dummy	-7.1E-06	9.29E-06	-0.76769	0.447822	-2.6E-05	1.17E-05
Shikoku Dummy	-2.2E-06	1.05E-05	-0.21011	0.834803	-2.4E-05	1.91E-05
Kyushu Dummy	5.08E-06	8.39E-06	0.60527	0.548904	-1.2E-05	2.21E-05
Okinawa Dummy	-3.6E-06	2.26E-05	-0.1591	0.874501	-4.9E-05	4.23E-05

Table 3 : Regression Analysis Results

Table 3 presents the results of a regression analysis using the least squares method, with the application rate for each prefecture as the dependent variable and explanatory variables

including the aging rate, vaccination rate, subsidy dummy variables, and regional dummy variables. From the results of this regression analysis, the following points can be observed:

- (1) Prefectures with higher aging rates tend to have lower application rates. However, the result is not statistically significant.
- ② Subsidy policies do not increase application rates. However, the result is not statistically significant.
- ③ The presence of regional dummy variables lowers application rates, except for the Kyushu dummy. For the Kanto region, the effect is statistically significant at the 1% significance level.

Since ① and ② lack statistical significance, it is considered that delving deeper into their interpretation does not hold much essential meaning; therefore, they are omitted. Regarding ③, it can be said that the regional characteristics of the Kansai region contribute to higher application rates compared to the Kanto region. However, the reason for this remains unclear.

However, a possible explanation could be that factors such as the awareness of the relief system and the ease of application might influence the application rate. Applying for the relief system poses a significant challenge for individuals, as they need to prepare various documents. Additionally, whether medical institutions correctly complete required forms, such as medical certificates, and whether they are cooperative in preparing such documents, can significantly impact individuals' decisions to apply. If the forms are not completed correctly, corrections would be necessary, causing further delays in the application process and potentially lowering the application rate as a result.

That said, it cannot be conclusively stated from this analysis that the Kanto region is experiencing circumstances that make it harder to apply. A more detailed analysis would be required to draw such a conclusion.

The author would also like to examine the effects of subsidies. Earlier, data on Nagoya City's Relief System for Injury to Health with Vaccination was presented, but considering the population size of Nagoya City itself, it is not particularly notable for having a high application rate.¹⁴ Therefore, it can be said that subsidies for document-related costs, among others, are

¹⁴ The specific number of applications in Nagoya City (obtained through a disclosure request in June 2024) will not be disclosed here. However, as of December 1, 2024, the population of Nagoya City is 2,332,369, and the application rate per population is below the level of 1 per 10,000 people, which is not particularly high. The level of 1 per 10,000 people is considered the average level in

unlikely to significantly increase the application rate. This suggests that, rather than financial subsidies, raising awareness of the system and improving the ease of applications such as creating conditions that allow for swift applications without documentation errors might have a greater effect on increasing application rates.

5. The Relief System for Vaccine-Related Health Damage in Foreign Countries

This section explains the relief system for vaccines abroad. The mechanism for providing relief for health damage caused by adverse reactions to vaccines in foreign countries is discussed by Kang, Choe, and Yoon (2024). This paper compares the relief systems for health damage caused by vaccinations across various countries, including Japan. It also examines and compares factors such as the scope and rate of compensation among these countries. Key findings from the paper include the existence of a system in Australia, not present in Japan, that provides compensation for lost income, as well as the observation that Japan has a relatively high compensation rate. This paper was authored by Korean researchers. Therefore, this section will focus on the circumstances in the Republic of Korea and Australia. Upon investigating the situation in Korea, it was found that as of the end of September 2024, the number of COVID-19 vaccine compensation applications stood at 99,821, with an approval rate of 28.6%.¹⁵These figures are limited to health damages caused by the COVID-19 vaccine. On the other hand, from 1995 to 2020, the number of vaccine compensation claims was 1,260, with an approval rate of 57%.¹⁶Notably, Australia has a system that provides compensation for lost income.¹⁷ As evidence of lost income, individuals are required to provide proof of their income at the time they experienced health damage. Considering the existence of this system, it appears that Australia offers more comprehensive compensation compared to Japan. However, as of September 30, 2024, new applications are no longer being accepted.¹⁸ However, in Japan, for regular COVID-19 vaccinations administered on or after April 1, 2024, the claim period for medical expenses and medical allowances is set at five years, indicating

Japan. (Reference: Nagoya City "Population and Number of Households as of the First Day of Each Month (Citywide and by Ward)")

¹⁵ Uihaksinmun (The Medical News) "The Yoon Administration Failed to Fulfill Its Pledge for a National Responsibility System for Vaccine Damage." The author would like to thank Jumpei Sakai for providing information regarding Korea.

¹⁶ Yonhap News Agency "[Fact Check] Vaccine Side Effects: National Compensation Procedures and Precedents"

¹⁷ Australian Government "Lost earnings." The author would like to thank COVERSE (https://coverse.org.au) for providing information about Australia.

¹⁸ Australian Government "COVID-19 vaccine claims scheme."

that a deadline has been established.¹⁹

6. Problems with the Relief System for Injury to Health with Vaccination

Regarding the Vaccination Health Damage Relief System, there are cases where claims are approved and others where they are denied. In the author's case, the application was for subsidy for medical care expenses and medical allowances. While one symptom was approved, other symptoms were denied. However, when a single symptom is approved, the medical expenses related to its treatment become free of charge (strictly speaking, the costs are paid upfront and later reimbursed in cash). Additionally, a monthly medical allowance can be received, and the amount of this allowance varies depending on the number of medical visits each month.²⁰

To have denied symptoms reviewed or changed, what can be done? For instance, methods such as filing an appeal for review, a lawsuit for cancellation, or a state compensation lawsuit (national compensation lawsuit) are available. According to materials from the Ministry of Health, Labour and Welfare: "If there is an objection to a decision of non-payment, an appeal for review can be submitted to the governor of the prefecture. If a decision to cancel the disposition is made, the Minister of Health, Labour and Welfare is required to grant approval in accordance with the law.²¹ Furthermore, Article 3, Paragraph 2 of the Administrative Case Litigation Act states: "In this Act, a 'lawsuit seeking the revocation of a disposition' refers to litigation seeking the revocation of an administrative agency's disposition or other acts involving the exercise of public authority (excluding rulings, decisions, and other acts specified in the following paragraph, hereinafter simply referred to as 'disposition')." This allows for the filing of a revocation lawsuit.²² A state compensation lawsuit is based on Article 1 of the State Redress Act, which states: "When a public official exercising public authority on behalf of the state or a public entity causes damage to another person unlawfully, either intentionally or negligently, while performing their duties, the state or public entity shall be liable for compensation." A lawsuit is filed based on this provision.²³

¹⁹ Ministry of Health, Labour and Welfare: "Regarding the Handling of Relief Measures for Health Damage Caused by COVID-19 Vaccination from FY 2024 Onward." Ministry of Health, Labour and Welfare "About the Relief System for Injury to Health with Vaccination."

²⁰ Ministry of Health, Labour and Welfare "About the Relief System for Injury to Health with Vaccination."

²¹ Ministry of Health, Labour and Welfare: "About the Relief System for Injury to Health."

²² e-gov Legal Text Search "Administrative Case Litigation Act."

²³ e-gov Legal Text Search "State Redress Act."

The author once consulted through Legal Terrace to determine whether filing such a lawsuit would be possible.²⁴ However, in the author's case, some symptoms were recognized, resulting in the provision of medical allowances. Even if additional symptoms were recognized, the reimbursement would amount to only a few tens of thousands of yen for medical expenses. Considering the costs of attorney fees, litigation expenses, and the time required, the consultation concluded that the cost-effectiveness would clearly be poor.

Furthermore, to obtain evidence, it would be necessary to request the disclosure of personal information to acquire meeting records from the municipal investigation committee, which serves as the application office for the Relief System for Injury to Health with Vaccination, as well as records from the Ministry of Health, Labour and Welfare's Disease and Disability Certification Review Committee. However, the materials obtained, although they pertained to the author's personal information, were heavily redacted, making it impossible to grasp the situation.

Given these circumstances, it can be concluded that overturning a previously denied case would require a significant amount of effort.

7. Conclusions: Issues to Be Considered and the Potential for Data Analysis

This paper has examined the Relief System for Injury to Health with Vaccination from various perspectives. This section would like to discuss issues that should be considered in the future and the potential for data analysis.

First, an issue that warrants further consideration is the relationship between vaccination and workers' compensation (Industrial Accident Compensation Insurance). According to materials from the Ministry of Health, Labour and Welfare, vaccinations are generally considered to be voluntary and are not typically recognized as part of work duties. However, in the case of healthcare workers or staff at facilities for the elderly, it is stated that if health damage results from vaccination, they are eligible for workers' compensation benefits. For other employees, eligibility is determined based on factors such as whether there was a work order from the employer.²⁵Although vaccination is said to be voluntary, there have been harassment issues where unvaccinated employees were made to work in locations separate from their colleagues. This raises doubts about whether individuals could truly exercise their free will in such circumstances.²⁶ This issue is not related to the Relief System for Injury to

²⁴ Details about Legal Terrace can be found on the Japan Legal Support Center's official page, "About Legal Terrace."

²⁵ The Ministry of Health, Labour and Welfare: "Q&A on COVID-19 (For Workers)"

²⁶ NHK Shiga WEB NEWS "One Firefighter Disciplined for New Vaccine Harassment Case in

Health with Vaccination but rather to workers' compensation. However, it remains a matter that warrants consideration.

Next, the author would like to explain the potential for data analysis. The data in Figure 1 mentioned earlier includes information on attending and absent committee members for each review meeting. Using the denial rate for each review meeting as the dependent variable and employing dummy variables for explanatory variables—assigning 1 for attending members and 0 for absent members (including those who were not scheduled to attend)—it is possible to examine the correlation between attending members and the denial rate.

In this paper, although the analysis is quite simple, the author attempted an analysis using the least squares method. A portion of the results is shown in Table 4. The explanatory variables are the number of attending members, whether the review meeting occurred in 2024, and individual committee members. "Attend" represents the number of attending members, and "2024dummy" is a dummy variable that takes a value of 1 if the meeting occurred in 2024 and 0 otherwise. Variables A through D represent committee members who showed significant effects.

However, A and B are significant only at the 10% level, making it difficult to strongly assert their significance. On the other hand, C and D are significant at the 5% level. It is also evident that some members increased the denial rate, while others decreased it. The 2024 dummy is significant at the 1% level, indicating that the denial rate significantly increased in 2024 compared to previous years.

These findings, showing varying results in the correlation between committee members and the denial rate, are intriguing. Nonetheless, more detailed analysis will be necessary to draw definitive conclusions.

	Coefficient	Std. Error	T value	$\Pr(> t)$
Attend	2.00931	8.86847	0.227	0.8217
2024 dummy	20.29652	4.01363	5.057	6.11e-06 ***
А	-35.79291	19.28345	-1.856	0.0693
В	-91.94464	49.01568	-1.876	0.0665
С	32.10472	14.98964	2.142	0.0371 *
D	-42.88092	20.14758	-2.128	0.0383 *

Table 4 : Correlation Between Attending Committee Members and the Denial Rate

The next potential data analysis involves examining whether there are lot differences in the

Koka"

number of adverse reaction reports. In fact, studies indicating lot differences do exist.²⁷ Similar analyses could also be conducted using Japanese data. However, caution is required in such cases. One must consider the possibility of uneven distribution of vaccine lots. It cannot be assumed that all lots were distributed equally across all age groups or among individuals with or without underlying health conditions. For example, a specific lot might have been predominantly supplied to older adults. In such cases, age-related biases could be introduced, making it difficult to determine whether the observed differences are due to lot variation or other factors. This is an important consideration.

Finally, regarding the Relief System for Injury to Health with Vaccination, it would also be important to examine approval rates by disease type at the time of application. Although the author applied for recognition of multiple symptoms, only one of the symptoms was approved, while the others were denied. The reason for the denial was that, considering the time from vaccination to the onset of symptoms, no causal relationship could be established. There are various reasons for denial, which include the following:²⁸

- ① The symptoms fall within the range of typical adverse reactions.
- ② Based on current medical knowledge, other potential causes unrelated to the vaccination are plausible, making it unlikely that the vaccination was the cause. It is considered improbable that the disease was triggered by the vaccination.
- ③ The time elapsed between the vaccination and the onset of the disease does not align with what would be expected.
- ④ The symptoms are attributable to pre-existing conditions or symptoms present prior to vaccination, and it is not considered that the vaccination exacerbated them.
- (5) Denial for reasons not falling under points (1) through (4).

For the symptoms denied in the author's case, the reason stated corresponded to point (3): the time elapsed between the vaccination and the onset of the symptoms was deemed inconsistent. Symptoms can manifest relatively quickly in some cases or appear later in others, and individual differences must also be considered. It raises questions as to whether the review process adequately accounts for such variations.

Additionally, are there certain diseases that are more likely to be approved or denied during the application process? Analyzing such tendencies would also be an intriguing area of study.

²⁷ Schmeling M., Manniche V. and Hansen P.R. (2023)

²⁸ Referring to materials obtained through a personal information disclosure request regarding "Reasons for Certification and Denial" from the Ministry of Health, Labour and Welfare.

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Hokkaido	Hokkaido Web Page	2024/6
	https://www.pref.hokkaido.lg.jp/fs/1/0/2/6/0/6/7/3/_/HP%E5	
	%85%AC%E8%A1%A8R6.6.5.pdf	
	(Currently unavailable)	
Aomori	Confirmed at the government office.	2024/6
Iwate	Confirmed at the government office.	2024/6
Miyagi	Confirmed at the government office.	2024/7
Akita	Confirmed at the government office.	2024/6
Yamagata	Confirmed at the government office.	2024/6
Fukushima	Confirmed at the government office.	2024/7
Ibaraki	Confirmed at the government office.	2024/6
Tochigi	Shimotsuke Shimbun Digital	
	"Only One Case Recognized for Relief After Vaccination-Related	
	Death: 18 Applications from Tochigi Prefecture, National	2024/6
	Review Delayed "https://www.shimotsuke.co.jp/articles/-	2024/0
	/756378	
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Gunma	Jomo Shimbun "72 Cases of Health Damage After COVID-19	
	Vaccination Recognized for Relief: Applications in Gunma	
	Prefecture as of the End of January"	2024/6
	https://www.jomo-news.co.jp/articles/-/422958	
	(2025年1月4日参照)	
Saitama	Saitama Prefecture "December 2023 Regular Session - General	
	Questions: Full Text of Questions and Answers (Isao Kimura) "	2023/12
	https://www.pref.saitama.lg.jp/e1601/gikai-	2023/12
	gaiyou/r0512/4/b0400.html (2025/1/4 checked)	
Chiba	Confirmed at the government office.	2024/6
Tokyo	Tokyo Metropolitan Health and Medical Information Center	
	"Relief System for Injury to Health with Vaccination"	2024/6
	https://www.hokeniryo.metro.tokyo.lg.jp/kansen/info/	2024/0
	corona/coronavaccine/kyusai (2025/1/4 checked)	
Kanagawa	Tokyo Shimbun "COVID-19 Vaccine Side Effects: Kanagawa	
	Prefecture Recognizes 17 Deaths Among 315 Cases of Health	2024/3
	Damage" https://www.tokyo-np.co.ip/article/315100	

Appendix The source of application numbers for each prefecture (The column on the right indicates the date of acquisition.)

	(2025/1/4 checked)	
Niigata	Confirmed at the government office.	2024/6
Toyama	Confirmed at the government office.	2024/6
Ishikawa	Confirmed at the government office.	2024/6
Fukui	Yahoo Web Page	
	https://news.yahoo.co.jp/articles/bca2c8362ea54a0d39fd1c	2024/6
	<u>35f1bfd4b80e2d677c</u>	2024/0
	(Currently unavailable)	
Yamanashi	Confirmed at the government office.	2024/6
Nagano	Confirmed at the government office.	2024/5
Gifu	NHK Gifu NEWS WEB "Suspected Side Effects of COVID-19	
	Vaccines Announced: 39 Deaths Reported"	2024/2
	https://www3.nhk.or.jp/lnews/gifu/20240313/3080013153.html	2024/3
	(2025/1/4 checked)	
Shizuoka	Shizuoka "Status of Health Damage Recognitions in the	
	Prefecture and Nationwide (Fiscal Year 2023)"	
	https://www.pref.shizuoka.jp/kenkofukushi/covid19/kojin/	2024/6
	1053087/covid19-vaccine/1057221/1057196.html	
	(2025/1/4 checked)	
Aichi	Aichi "Aichi COVID-19 Information Website."	
	https://www.pref.aichi.jp/site/covid19-	2024/6
	aichi/hukuhannoutoumimaikin.html (2025/1/4 checked)	
Mie	Confirmed at the government office.	2024/6
Shiga	Shiga "Regarding Side Effects After COVID-19	
	Vaccination" <u>https://www.pref.shiga.lg.jp/ippan/kenkouiryouhuk</u>	2024/6
	ushi/yakuzi/318358.html (2025/1/4 checked)	
Kyoto	Confirmed at the government office.	2024/6
Osaka	Osaka "Relief System for Injury to Health with Vaccination"	
	https://www.pref.osaka.lg.jp/o100050/kansenshoshien/covid-	2024/6
	19vaccine/kennkouhigaikyuusai.html (2025/1/4 checked)	
Hyogo	Confirmed at the government office.	2023/11
Nara	Nara "Relief System for Injury to Health with COVID-19	
	Vaccination" https://www.pref.nara.jp/59045.htm	2024/6
	(2025/1/4 checked)	
Wakayama	Yahoo Web Page	2024/6

	https://news.yahoo.co.jp/articles/13f20415b57642cbd862087eb	
	<u>3243d7fd037a165</u> (Currently unavailable)	
Tottori	Confirmed at the government office.	2024/6
Shimane	Confirmed at the government office.	2024/6
Okayama	Confirmed at the government office.	2024/6
Hiroshima	Hiroshima "Response to Side Effects After COVID-19	
	Vaccination"	2024/6
	https://www.pref.hiroshima.lg.jp/site/hcdc/coronafukuhannou.	2024/0
	<u>html</u> (2025/1/5 checked)	
Yamaguchi	NHK Web Page	
	https://www3.nhk.or.jp/lnews/yamaguchi/20231127/	2023/11
	4060018782.html (Currently unavailable)	
Tokushima	Tokushima "Application Status for the Relief System for Injury to	
	Health with COVID-19 Vaccination"	2024/6
	https://www.pref.tokushima.lg.jp/opinion/7220120/	2024/0
	(2025/1/5 checked)	
Kagawa	Asahi Shimbun DIGITAL "Two People Granted Lump-Sum	
	Payments After Death Following COVID-19 Vaccination: Third	
	Case in Kagawa Prefecture"	2023/9
	https://www.asahi.com/articles/ASR9C748NR9CPTLC008.html	
	(2025/1/5 checked)	
Ehime	Confirmed at the government office.	2024/6
Kochi	Kochi "Effectiveness and Side Effects of COVID-19 Vaccination"	
	https://www.pref.kochi.lg.jp/doc/2021080200225/	2024/6
	(2025/1/5 checked)	
Fukuoka	Confirmed at the government office.	2024/7
Saga	NHK Web Page	
	https://www3.nhk.or.jp/lnews/saga/20231221/5080016187.htm	2023/11
	1 (Currently unavailable)	
Nagasaki	Nagasaki Shimbun "Nagasaki Prefecture COVID-19 Vaccine	
	Health Damage: 120 Applications Submitted to the Government,	
	8 Deaths Recognized" https://www.nagasaki-np.co.jp/kijis/	2024/6
	?kijiid=9c79c771fc1e4adf9ca2a8d22965a805#google_vignette	
	(2025/1/5 checked)	
Kumamoto	Yahoo Web Page	2024/6
	https://news.yahoo.co.jp/articles/b00f2c146bb3e7090ae7d	2024/0

	90706f1615acd4e6d05	
	(Currently unavailable)	
Oita	Oita Good Shimbun Web Page	
	https://www.oita-	2022/11
	press.co.jp/1010000000/2023/11/06/JDC2023110602588	2023/11
	(Currently unavailable)	
Miyazaki	Confirmed at the government office.	2024/6
Kagoshima	Minami-Nippon Shimbun (373news.com) "COVID-19 Vaccine	
	Health Damage: 95 Cases Recognized, Including 3 Deaths; 162	
	Applications Submitted, 50 Cases Under Review in Kagoshima	2024/3
	Prefecture" https://373news.com/_news/storyid/191320/	
	(2025/1/5 checked)	
Okinawa	Confirmed at the government office.	2024/7