

Comparative analysis of fourteen COVID-19 vaccine injury compensation systems and claim approval rates

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ABSTRACT

Purpose: No-fault vaccine injury compensation schemes provide financial redress for adverse effects from vaccines without establishing fault. Due to the rapid vaccine development and distribution, these programs are crucial for vaccinees during the COVID-19 pandemic. Investigating the performance differences of these schemes worldwide and finding a more balanced approach is essential to responses to future pandemics.

Materials and methods: This study examines the structure and effectiveness of 14 no-fault vaccine injury compensation schemes, analyzing data on approval rates for COVID-19 vaccine injury claims. Data sources include government reports and academic studies to compare diverse operational models and funding sources.

Results: This study included 167,532 COVID-19 vaccine injury compensation applications, with up to 137,076 claims reviewed and up to 38,658 approved, incorporating both exact and approximate official numbers. Approval rates for the reviewed claims vary widely across jurisdictions, with Japan (74.29 %) having the highest rates, and the United States (3 %) and the United Kingdom (2.64 %) the lowest. The median approval rate across all 14 jurisdictions is 26.76 %, between South Korea's 26.09 % and France's 27.42 %. These variations reflect diverse standards and policies. No clear correlation exists between funding sources and approval rates. For example, government-funded schemes in France and Japan show higher approval rates, while similar models in the United States and the United Kingdom have low rates. In New Zealand and other countries with broader medical compensation schemes, approval rates are higher than the international median.

Conclusion: Governments may adopt more flexible standards to redress vaccine injuries by referring to international practices and the latest medical evidence. High-approval-rate countries offer insights into inclusive criteria, while low-approval-rate countries may need to reassess stringent criteria. Middle-ground countries could incorporate new medical findings to refine standards, ensuring equitable outcomes for those affected by vaccine injuries.

1. Introduction

No-fault compensation schemes (NFCS) for vaccine injuries ensure that individuals who suffer adverse effects from vaccines receive compensation without proving fault or negligence, based on the rationales that negligence is often absent in such cases [1], and that communities benefiting from vaccination programs accept the responsibility to compensate those harmed by them [2]. These schemes are crucial during the novel coronavirus disease 2019 (COVID-19) pandemic due to rapid vaccine development and distribution, which has heightened

public safety concerns. These schemes provide a streamlined process for compensation, covering medical expenses, lost income, and non-economic damages like pain and suffering. This approach also fosters public trust in vaccination programs by addressing adverse outcomes transparently and fairly [3].

Globally, no-fault compensation schemes exhibit considerable variation with their funding sources. Some countries operate their schemes with general taxes or special levies. Some countries utilize an insurance-based model, with funding derived from vaccine manufacturers' insurance contributions. In contrast, other countries employ a social security

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model to cover all accidents including vaccine injury [1,2]. During the ongoing pandemic, these compensation schemes have been adapted to address the unique challenges of novel vaccines, playing a crucial role in sustaining public trust and ensuring vaccine uptake. [4]

While COVID-19 vaccines have delivered significant global public health benefits, ensuring timely and equitable compensation for the few adverse reactions remains crucial from a justice standpoint. Currently, data on the implementation outcomes of compensation programs for COVID-19 vaccine-related injuries, such as the number of claims filed and approval rates, remains limited. Expanding from the analysis of 10 jurisdictions by Kang et al. [4], the present study covers a broader sample, explores the factors behind differences in compensation outcomes, and addresses policy considerations to enhance access to compensation and better prepare vaccine injury programs for future pandemics.

1.1. COVID-19 Vaccine Injury Compensation Systems in the World

Before January 2020, there were 29 national NFCSSs, a number that increased to 38 following the outbreak of the COVID-19 pandemic. [5] COVID-19 vaccine injury compensation systems vary significantly worldwide. In the United States, the National Vaccine Injury Compensation Program (VICP) has long provided a no-fault compensation mechanism funded by an excise tax on vaccines. [6] European countries have implemented diverse approaches, with some offering robust no-fault compensation programs while others relying on traditional liability-based systems. [7]. In France and Italy, product liability litigations against alleged vaccine injuries are not precluded, but liability rules are de facto not applied in Italy.[8] Under the UK's Vaccine Damage Payment Scheme (VDPS), there is an upper limit for compensation. The maximum payment is a one-off, tax-free amount of £120,000 for individuals who are severely disabled as a result of vaccination. [7] In Asia, countries like Japan and South Korea have well-established VICPs, offering comprehensive coverage for vaccine-related injuries. [3] However, a lack of standardization across these systems results in varying levels of protection and efficiency in compensating vaccine injuries globally.

2. Materials and methods

Data on applications, reviews, and approvals from no-fault vaccine injury compensation schemes were collected from official government or review agency websites where available. To maintain the data integrity used in this study, data from media reports were not used to replace, complement or improve the precision of the curated official data.

In assessing the effectiveness of compensation programs, two key

metrics are used: the Review Approval Rate (RAR) and the Review Rate (RR). The RAR measures the proportion of approved claims among those reviewed, calculated by dividing the number of approved claims by the number of reviewed claims. This metric provides insight into the program's selectivity. The RR, on the other hand, reflects the proportion of reviewed claims out of all submitted applications, calculated by dividing the number of reviewed claims by the total number of applications received. RR indicates the review progress of all compensation applications at a given date.

3. Results

3.1. Number of applications received and claims approved for COVID-19 vaccine injury

Shown in Table 1 is the number of claims, applications, review approval rates and review rates for 14 jurisdictions based on the best available official data: Australia, Canada, Denmark, Finland, France, Hong Kong, Japan, New Zealand, Norway, South Korea, Taiwan, United Kingdom, United States, and WHO-COVAX.

3.2. Australia

Australia initially lacked a no-fault vaccine injury compensation program. In 2021, the government introduced the COVID-19 Vaccine Claims Scheme to compensate individuals for injuries caused by COVID-19 vaccines. The scheme covers losses or expenses of \$1000 or more arising from the administration of a COVID-19 vaccine or an adverse event recognized as vaccine-related [23]. Funded by the national treasury, the program had processed fewer than 200 compensation payments out of 3803 claims as of 30 August 2023, with less than 40 % of claims finalized. [19]. The RAR was about 13.15 %.

3.3. Canada: pan-Canada and Québec

Canada initially did not have a nationwide no-fault vaccine injury compensation program until 2021, when the federal government established the Vaccine Injury Support Program (VISP) to compensate for serious and permanent injuries and deaths resulting from COVID-19 vaccination. Funded by the national treasury, the VISP covers all nine provinces and three territories except Québec. As of November 30, 2024, the pan-Canada program had a 19.92 % RAR [17].

In contrast, Québec has operated its own Vaccine Injury Compensation Program since 1985, making it the only province with a pre-existing system for vaccine-related injury compensation. Between 2021 and May 31, 2023, there were 201 compensation claims, of which 22 were reviewed and 3 approved [24], resulting in an RAR of 13.64 %.

Table 1

Application and compensation data for COVID-19 vaccine injury claims of 14 jurisdictions, listed in descending order by Review Approval Rate. *: An approximate number or constraint given by the official data source.

Jurisdiction	Approved Claims	Reviewed Claims	Total Applications	Review Approval Rate	Review Rate	Data Reference Date	Ref.
Japan	8755	11,785	12,733	74.29 %	92.55 %	2025.1.20	[9]
WHO-COVAX	16	23	172	69.57 %	13.37 %	2024.5.31	[10]
Hong Kong	534	998	1415	53.51 %	70.53 %	2025.1.26	[11]
New Zealand	1696	4183	4229	40.55 %	98.91 %	2024.7.1	[12]
Finland	800	2606	2717	30.70 %	95.91 %	2024.12.31	[13]
Norway	351	1171	1673	29.97 %	69.99 %	2024.1.1	[14]
France	116	423	1376	27.42 %	30.74 %	2023.12.31	[15]
South Korea	24,557	94,129	97,699	26.09 %	96.35 %	2023.12.5	[16]
pan-Canada	209	1049	3060	19.92 %	34.28 %	2024.11.30	[17]
Taiwan	820	6103	8165	13.44 %	74.75 %	2024.4.25	[18]
Australia	< 200 *	< 40 % *	3803	~13.15 %	< 40 % *	2023.8.30	[19]
Denmark	331	2902	3069	11.41 %	94.56 %	2025.1.29	[20]
United States	92	~ 25 % *	13,333	3 % *	~ 25 % *	2024.12.18	[21]
United Kingdom	181	6850	14,088	2.64 %	48.62 %	2024.7.1	[22]
Total			167,532				

However, COVID-19 vaccination data for Québec is grouped with other vaccines and is therefore not included in the overall figures in this study.

3.4. Denmark

Denmark's NFCS, established in 1978 and expanded to include COVID-19 vaccines in 2020, is managed by the Danish Patient Compensation Association and funded by the government. It covers both temporary and permanent injuries from vaccines in the national program, providing compensation for both economic and non-economic losses, including lost earnings, pain and suffering, and lasting harm. Filing claims is free, although successful claims incur a deductible. The scheme also provides funeral expenses or survivor benefits, with adjustments based on age and disability levels. As of January 29, 2025, Denmark had received 3069 COVID-19 vaccine injury compensation claims, with 331 approved, 2571 denied, resulting in an RAR of 11.41 %. [20].

3.5. Finland

Voluntary pharmaceutical injuries insurance has been in place in Finland since 1984. Since 2012, the insurance has been operated by the Finnish Mutual Insurance Company for Pharmaceutical Injury Indemnities. It is funded through members' insurance contributions and covers nearly all medicines sold in Finland. COVID-19 vaccines procured through the EU mechanism are included, with government-backed insurance guarantees to address potential claims. As of December 2024, Finland had received 2717 COVID-19 vaccine injury claims, of which 2606 were reviewed, with 800 approved and 1806 denied, resulting in an RAR of 30.70 %. [13]

3.6. France

France established a no-fault compensation scheme for compulsory childhood vaccinations in 1964 with the passage of Law n°64-643. In 2002, this scheme was expanded into a broader no-fault medical accident program, now managed by the Office National d'Indemnisation des Accidents Médicaux (ONIAM). The funding for ONIAM comes from various sources, including compulsory health insurance schemes and subsidies from the national treasury, as outlined in Article L1142-23 of the Public Health Code. As of the end of 2023, ONIAM reported receiving 1376 COVID-19 vaccine compensation claims. Of these, 423 cases had been reviewed, with 116 claims approved, resulting in an approval rate of 27.42 %. [15]

3.7. Hong Kong

Hong Kong's no-fault compensation scheme for COVID-19 vaccines, launched on February 26, 2021, is funded by the government and administered by AXA Hong Kong, a private insurer appointed to manage claims. The scheme covers injuries from vaccines approved under the COVID-19 Vaccination Programme, providing compensation for temporary or permanent harm, including death. Claims require medical certification, and eligibility extends to recipients, their guardians, or their estates. As of January 26, 2025, Hong Kong had received 1415 applications, with 998 cases having undergone causality assessment. Of these, 534 cases were determined "consistent with" or "undetermined" regarding their causal relationship with vaccination, while 464 cases were deemed "unrelated" or "unclassifiable," resulting in an RAR of 53.51 %. [25]

3.8. Japan

Japan's no-fault compensation scheme for vaccine-related injuries, established in 1976, operates under the Immunization Act and is overseen and funded by the Ministry of Health, Labour and Welfare (MHLW)

alongside local governments. The scheme covers all vaccine-related injuries, disabilities, or deaths without a severity threshold and includes COVID-19 vaccines, added as "temporary vaccinations" after a 2020 amendment. Compensation includes medical expenses, disability pensions, and lump-sum death benefits, funded jointly by municipal, prefectural, and national governments. In the case of COVID-19 vaccines, they are publicly funded, and the central government covers the compensation costs. [8] As of January 20, 2025, Japan had received 12,733 COVID-19 vaccine-related claims, reviewed 11,785, and approved 8755, achieving a 74.29 % RAR [9].

3.9. New Zealand

New Zealand's NFCS, in place since 1974, is part of its social security system and managed by the Accident Compensation Commission (ACC) with governmental funding. The scheme covers injuries caused by all vaccines, including COVID-19 vaccines since February 2021, and does not require a minimum severity threshold for claims. Claims must be submitted by a doctor, and there are no upfront fees. Compensation is available to vaccine recipients, their representatives, or beneficiaries and includes support for both financial losses and rehabilitation to help individuals return to normal activities. As of July 1, 2024, New Zealand received 4229 COVID-19 vaccine injury compensation claims with 1696 approved and 4183 reviewed and had an RAR of 40.55 %. [12]

3.10. Norway

Norway's NFCS, under the 2001 Patient Injury Act, includes COVID-19 vaccines as of December 2020. Funded by the central government and administered by Norsk Pasientskadeerstatning (NPE), it covers injuries from EU-approved vaccines, providing compensation for economic losses, non-economic damages, and legal fees in specific cases. Claims are free to file, and payments are secondary to other benefits like social security. As of January 1, 2024, Norway received 1673 COVID-19 vaccine injury compensation applications, with 351 cases granted compensation, resulting in an RAR of 29.97 %. [14]

3.11. South Korea

The Vaccine Injury Compensation Program (VICP) was introduced in Korea in 1995 under the Infectious Disease Control and Prevention Act. Korea's VICP provides medical expenses, fixed nursing fees, lump-sum payments for disabled persons, lump-sum death payments, and funeral expenses as compensation for vaccine injuries in cases where illness, disability, or death occurs due to the national vaccination program. [4,26]. As of December 5, 2023, South Korea had 97,699 applications, of which 94,129 were reviewed and 24,557 approved for compensation [16], resulting in an RAR of 26.09 %.

3.12. Taiwan

Taiwan's NFCS, established in 1988 and expanded to include COVID-19 vaccines in 2021, is administered by the Taiwan CDC and funded through a special levy on vaccine sales. It provides compensation for temporary and permanent injuries from government-approved vaccines, excluding mild or expected adverse reactions. Filing claims is free, and successful applicants receive lump-sum payouts determined by injury severity and causality. As of April 25, 2024, Taiwan had received a total of 8165 applications for COVID-19 vaccine-related compensation claims, reviewed 6103 cases, of which 820 cases were granted compensation—198 deemed "associated" and 622 "intermediate"—while 4775 cases were denied as "unassociated" [18], resulting in an RAR of 13.44 %.

3.13. United Kingdom

The UK's no-fault compensation scheme, established under the Vaccine Damage Payments Act 1979 and extended to COVID-19 vaccines in 2020, provides a tax-free lump sum of £120,000 for severe disabilities (60 % or greater) caused by vaccination. Administered by the NHS Business Services Authority and funded by the government, it covers vaccine recipients, their representatives, or estates at no cost to file claims. As of July 1, 2024, 14,088 COVID-19 vaccine-related claims were submitted, with 6850 processed, resulting in 181 approvals, 607 invalid cases, 6062 denials including 360 cases for failing to meet the 60 % disability threshold [22]. The RAR was about 2.64 %.

3.14. United States

The US has created the National Vaccine Injury Compensation Program (VICP) by passing the National Childhood Vaccine Injury Act of 1986. But the compensation for COVID-19 vaccines belongs to the Countermeasures Injury Compensation Program (CICP) established by the Public Readiness and Emergency Preparedness Act of 2005 [27]. The U.S. Government Accountability Office (GAO) reported a significant influx of 13,333 COVID-19-related claims as of December 18, 2024, but despite the surge, only about one-fourth have been reviewed, with just 92 cases (3 %) deemed eligible for compensation, underscoring the stringent criteria or challenges faced by claimants in meeting eligibility requirements. [21]

3.15. World Health Organization's COVAX

The World Health Organization's COVID-19 Vaccines Global Access (COVAX) initiative, involving 146 economies, was created to ensure equitable COVID-19 vaccine access, especially for lower-income countries. Its NFCS supports individuals facing rare vaccine-related adverse effects, addressing gaps in national compensation programs. As of May 31, 2024, a total of 172 claims or inquiries related to vaccine injuries were received by COVAX, with 23 cases meeting the eligibility criteria for COVAX-distributed vaccines and 16 of them were granted compensation, resulting in an RAR of 69.57 %. [10]

4. Discussion

4.1. Approval rates differ significantly across jurisdictions

Shown in Fig. 1 is the total number of applications across different jurisdictions. The data highlights significant variation in compensation

claims application, with South Korea reporting the highest at 97,699 and WHO-COVAX the lowest at 172. These extremes underscore the wide disparities in claim submissions across different regions.

Fig. 2 illustrates significant variation in approval rates for COVID-19 vaccine injury claims across jurisdictions. Japan (74.29 %) leads with the highest RARs, suggesting a more lenient approach. Hong Kong (53.51 %) and New Zealand (40.55 %) have moderate approval rates, indicating balanced evaluations. Finland (30.70 %), France (27.42 %), Norway (29.97 %) and South Korea (26.09 %) might reflect what can be considered a cautious yet fair approach. At the lower end, Taiwan (13.44 %), Australia (~ 13 %) and Denmark (11.41 %) apply stricter scrutiny, while the United States and the United Kingdom have the lowest RARs, about 3 % and 2.64 %, respectively, reflecting stringent criteria. These discrepancies highlight diverse standards and policies for vaccine injury claims.

4.2. The structures of national NFCS operate in a variety of ways

Each country or region's NFCS is shaped by its social security system and historical context. In a few countries or regions, NFCSs were specifically established for COVID-19 vaccines. However, most countries had pre-existing NFCSs prior to the COVID-19 pandemic, and in some cases, these systems have been integrated into their broader social security frameworks. For example: (1) New Zealand's NFCS is operated by the Accident Compensation Corporation (ACC), which provides comprehensive coverage for various accidents and vaccine-related injuries. (2) France's ONIAM compensates for both medical accidents and vaccine-related injuries. (3) Finland and Norway's NFCSs cover injuries related to both pharmaceuticals and vaccines. (4) In Japan, South Korea, and Taiwan, NFCSs were established through special legislation to compensate for vaccine injuries, while adverse drug reactions are handled under separate laws. (5) Canada, Australia, the United States (CICP), and Hong Kong limit their NFCS coverage exclusively to COVID-19 vaccine injuries, excluding injuries associated with other vaccines. Each country's NFCS reflects its unique historical and institutional differences. In countries with broader medical compensation schemes, such as New Zealand, Nordic countries, and France, approval rates exceed the international median.

4.3. No apparent correlation between the funding source of compensation and the approval rates among countries

For COVID-19 vaccine injury compensation, countries worldwide have the following models for funding sources: (1) Public funding/ national treasury: This approach is currently used by most jurisdictions,

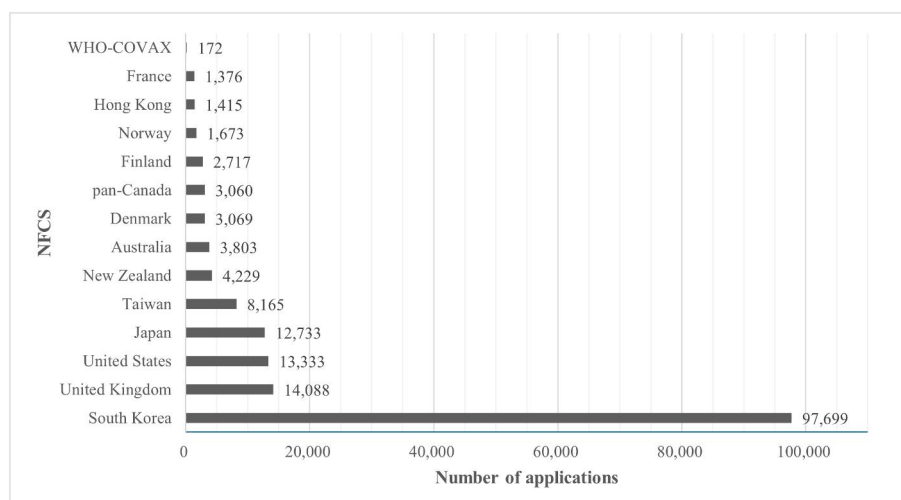


Fig. 1. Total number of COVID-19 vaccine related injury compensation applications across 14 different jurisdictions.

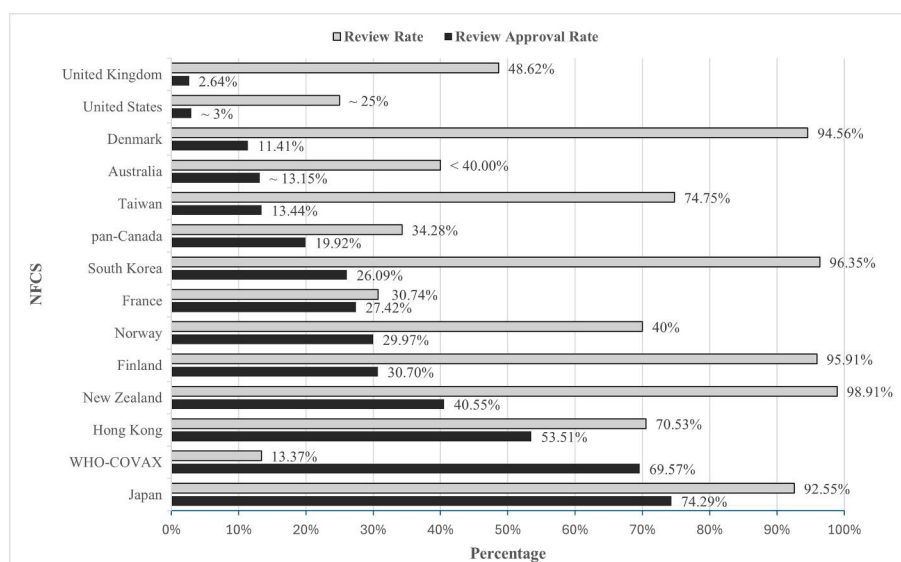


Fig. 2. Review rates and review approval rates of COVID-19 vaccine-related claims across 14 different NFCs.

such as the comprehensive no-fault vaccine injury compensation schemes in Germany, France, the United Kingdom, Denmark, Québec, and Japan prior to the COVID-19 pandemic [1]. Some countries have established specialized compensation schemes for COVID-19 vaccine injuries funded by the government, such as the United States' CICI [28], Canada [29], and Hong Kong [11]. (2) Manufacturer funding/contribution from pharmaceutical companies: This model is used in the Nordic countries, including Sweden, and Finland [2,30]. (3) Special levy on vaccine sales: This funding model is adopted by Taiwan [1]. (4) Social Security: New Zealand's Accident Compensation Corporation operates under this model [12].

The data collected on the approval rates of various countries exhibits no obvious correlation between the funding source and the approval rates of vaccine compensation applications. For example, Japan and Hong Kong use government funds as a source of compensation, and their passing rates are higher than 50 %. However, despite government funding, the United States and the United Kingdom have some of the lowest approval rates internationally. In Finland, compensation costs are covered by the insurance contributions of vaccine manufacturers, with approval rates of 30.70%. In Taiwan, compensation costs are funded by a special levy from vaccine manufacturers, with approval rates of 13.44%.

4.4. Causal assessment criteria may be an influencing factor for the international variety of approval rates

Under a no-fault vaccine injury compensation scheme, there is no need to establish fault on the part of government officials, manufacturers, or medical personnel. Instead, compensation approval rates are primarily influenced by the medical and legal standards used to assess the causal relationship of vaccine injuries. For example, Japan's compensation policy expressively states that "Strict medical causal relationship is not required, and it is also applicable when it cannot be denied that symptoms after vaccination are caused by the vaccination." [31]. With such open and flexible criteria, Japan has a relatively high approval rate. On the other hand, Taiwan's causal assessment standards heavily rely on "medical evidence from a population-based study or pathogenesis study that is published in a domestic or foreign journal" and laboratory test [32], making its approval rate relatively low. In the US, the Public Readiness and Emergency Preparedness Act requires that eligible vaccine injuries under the CICI are limited to those having "the direct causation" and "compelling, reliable, valid, medical and scientific

evidence" [33]. With such strict causal criteria, it is unsurprising that the US's approval rate is among the lowest in the world.

Traditionally, many countries have adopted the balance of probabilities (preponderance of the evidence) standard [1] or preponderant probability (slightly greater than 50 % chance) [2] to decide whether an injury was caused by vaccination. In the COVID-19 vaccine context, most countries do not publish official causal assessment criteria or guidelines like those in Japan, Taiwan, and the US, making international comparisons incomplete. However, our current study highlights that causal assessment criteria might be the most significant factor behind international differences in approval rates.

4.5. Variations in recognized adverse reaction conditions for covid-19 vaccines across NFCs

Currently, only a few countries have publicly disclosed the specific post-COVID-19 vaccination conditions eligible for compensation. The United States recognizes a relatively small number of conditions, with only five officially acknowledged: myocarditis, myopericarditis, Guillain-Barré syndrome, anaphylaxis, and syncope [34]. For Hong Kong, six major conditions: anaphylaxis, hospitalization, Bell's palsy, myocarditis, pericarditis, and erythema multiforme [11]. For Denmark, more post-COVID-19 vaccination conditions including milder ones are recognized, which are categorized according to vaccine manufacturers: (1) Pfizer/BioNTech: facial paralysis, allergic reaction, inflammation of the pericardium, inflammation of the heart muscle, inflammation of the muscles (myositis), inflammation of the spinal cord (myelitis), inflammation of the thyroid gland (thyroiditis), nerve inflammation (Guillain-Barré syndrome), broken finger as a result of fainting due to malaise and fever, hives, skin rash; (2) Moderna: facial paralysis, inflammation of the pericardium, inflammation of the spinal cord (myelitis), vasculitis, skin disorder, tooth damage resulting from fainting due to malaise and fever, hives. (3) AstraZeneca: blood clot in combination with low platelet count and bleeding (VITT syndrome), blood clot in the brain, prolonged fever and fatigue, nerve inflammation (Guillain-Barré syndrome), hives, skin rash; (4) Johnson & Johnson: blood clot in combination with low platelet count and bleeding (VITT syndrome), inflammation of the brain and spinal cord (acute disseminated encephalomyelitis, ADEM) [20].

Taiwan recognizes a relatively larger number of adverse reactions for COVID-19 vaccines. Examples include (1) AstraZeneca: VITT, thrombocytopenia, immune thrombocytopenic purpura, various types of thrombosis (e.g., pulmonary embolism, retinal artery occlusion, central

retinal vein occlusion, superior mesenteric vein thrombosis, etc.), spontaneous diffuse subarachnoid and intraventricular hemorrhage, autoimmune inflammatory encephalitis, rhabdomyolysis, myasthenia gravis, retinal vein branch occlusion in the eye, myocarditis, optic neuritis, posterior uveitis, Guillain-Barré syndrome, eosinophilic pneumonia, and herpes zoster; (2) Moderna: myocarditis, Stevens-Johnson syndrome, AQP-4 antibody-positive neuromyelitis optica, and Miller-Fisher syndrome; (3) Pfizer/BioNTech: myocarditis, pericarditis, aphasia, and anti-NMDA receptor encephalitis [35].

Japan recognizes a wide range of adverse reaction conditions related to COVID-19 vaccines, including thrombocytopenic purpura, myocarditis, myopericarditis, anaphylaxis, urticaria, autoimmune encephalitis, Guillain-Barré syndrome, sudden hearing loss, acute myocardial infarction, various thromboses, limb paralysis, facial myoclonus (facial nerve paralysis), aphasia, myelitis, migraines, cerebral infarction, hemorrhagic stroke, Stevens-Johnson syndrome, acute disseminated encephalomyelitis (ADEM), neuromyelitis optica, chronic inflammatory demyelinating polyneuropathy (CIDP), lymphadenitis, hyperthyroidism, alopecia areata, ruptured aortic arch aneurysm, trigeminal neuralgia, nephrotic syndrome, herpes zoster, Ramsay Hunt syndrome, and rhabdomyolysis [31].

Notably, while countries with higher RAR approval rates, such as Japan, recognize a greater number of adverse reaction conditions for COVID-19 vaccines, Taiwan, despite also recognizing many adverse conditions, has a relatively low overall RAR approval rate. In contrast, Hong Kong, which recognizes fewer adverse conditions, has a notably high overall RAR approval rate. More importantly, the adverse reaction conditions acknowledged by the above countries could serve as valuable references for other nations when reviewing compensation claims, potentially increasing the range of recognized adverse reactions to COVID-19 vaccines.

4.6. Governments may consider re-examining claim cases based on the latest evidence

The significant differences in approval rates for COVID-19 vaccine injury compensation claims across countries underscore the need for governments to revisit their evaluation processes based on the latest evidence. While adopting a more lenient approach may risk prioritizing generosity over scientific rigor—potentially setting a harmful precedent that could fuel vaccine hesitancy [36]—countries like Japan, which have higher approval rates, may offer valuable insights into adopting more inclusive criteria or implementing thorough review processes. Hong Kong, for instance, has explicitly taken a more flexible approach to establishing causation in its vaccine compensation program [11].

On the other end, the United States, with a strikingly low RAR about 3 %, may need to reassess its stringent criteria to ensure fair treatment of applicants. Countries with middle-to-low approval rates, such as Finland, Norway, France, and South Korea, might benefit from a more balanced approach by incorporating new medical findings and evolving vaccine data to refine their compensation standards. Jurisdictions with lower RARs like Denmark (11.41 %), Australia (~13.15 %) and Taiwan (13.44 %) might need to adopt a more lenient approach to re-evaluate previously denied claims.

Salmon et al. recently emphasized in the *New England Journal of Medicine* that rare but serious adverse events following immunization (AEFI) may not remain rare when viewed in the context of millions or billions of vaccinations [37]. Establishing a causal link between AEFI and vaccination is particularly challenging due to the limited evidence currently available in the scientific literature. A more extended period may be necessary for conclusive findings to emerge, as this will require a larger body of studies to be conducted. Notably, in the early stages, only a few cases of acute disseminated encephalomyelitis (ADEM) were reported following COVID-19 vaccination, primarily as anecdotal reports in the medical literature [38,39]. However, a later study involving a much larger cohort of 9.9 million individuals revealed a 3.78-fold

increase in the incidence of ADEM following immunization with messenger RNA (mRNA) vaccines [40]. Therefore, re-examining claims in light of the latest evidence is essential for ensuring more equitable outcomes, fostering public trust, and providing appropriate compensation to those adversely affected by vaccines. Such reassessment is critical not only for maintaining public confidence in vaccination programs but also for addressing any unintended consequences comprehensively.

4.7. Limitations

Some countries or regions that previously lacked a no-fault vaccine injury compensation system have established compensation schemes specifically for COVID-19 vaccines in recent years. Examples include Australia [19], Singapore, Canada [17], Hong Kong [25]. As of the end of 2024, this study found that certain countries, such as Singapore [41], have yet to publish application and review statistics. The Australian government, for instance, only submitted a brief report to Parliament in August 2023 [19]. Germany, which established its no-fault vaccine injury compensation system as early as 1961, has similarly not published official statistics on COVID-19 vaccine injury compensation applications or approval rates, with only media-reported figures available [42]. Additionally, while Malaysia and Thailand also provide compensation for COVID-19 vaccine injuries [43], this study was unable to identify any official data released by their governments, relying instead on media reports. Consequently, media-reported data from Germany [42], Malaysia [44], Poland [45], Slovenia [46], and Thailand [47] were excluded from the statistical analysis in this study, resulting in a reduced sample size for international comparisons. Nonetheless, this study has expanded the number of countries and organizations with available statistics to 14, making it the most comprehensive investigation to date.

Second, the timeframes of these international data vary due to differences in national data publication schedules and update frequencies. Some countries and regions, such as Denmark, Japan, Taiwan, Canada, and the United States, continue to publish updated data. However, other countries, such as Australia, have only provided data up to August 2023 [19] and Australia ceased to accept new compensation applications as of September 30, 2024 [23]. These variations limit the consistency of the timeframes across the dataset. Nevertheless, since this study focuses on public policy regarding vaccines and examines differences in national systems, rather than conducting an epidemiological cross-sectional study, clinical trial, or meta-analysis, these temporal differences in the data do not affect the validity of the research.

Thirdly, few countries have established and published causality assessment criteria, making it challenging to analyze the factors influencing the international differences in approval rates with greater accuracy. Despite these limitations, this study offers valuable insights into international public health policy. The incomplete national data and absence of official causality assessment standards underscore the need for increased transparency and openness to maintain trust in no-fault vaccine injury compensation schemes.

5. Conclusion

This comparative analysis of COVID-19 vaccine injury compensation systems highlights significant disparities in approval rates across various jurisdictions, reflecting differing policies and criteria. High-approval jurisdictions like Japan and Hong Kong employ more inclusive criteria, while countries with low approval rates, such as the United States and the United Kingdom, may need to reassess their stringent standards to ensure fair treatment of claimants. The lack of a clear correlation between funding sources and approval rates suggests that the causal assessment criteria and local policy behind these programs, rather than their financial structures, are the primary drivers of outcomes. Before the COVID-19 pandemic, Urho pointed out that the New Zealand and Finnish schemes performed particularly well [30]. In this study, the approval rates of countries with broader medical

compensation schemes, such as New Zealand, Nordic countries, and France, exceed the international median.

The need for ongoing re-evaluation of claims based on the latest scientific findings is crucial, especially with emerging data on rare adverse events. Such reassessment is vital not only for ensuring equitable compensation but also for maintaining public trust in vaccination programs during and beyond the COVID-19 pandemic.

Governments may consider adopting more flexible standards and recognizing more adverse reactions caused by COVID-19 vaccines, informed by international practices and the latest medical evidence, to balance the protection of vaccinated individuals' rights with the urgent need for vaccine rollout during the pandemic. Institutional transparency and clear legal standards are essential to maintaining a trustworthy no-fault vaccine injury compensation scheme.

CRediT authorship contribution statement

Chao-Fang Chu: Writing – review & editing, Writing – original draft, Methodology, Investigation, Data curation. **Tzu-Hao Chang:** Validation, Supervision. **Jen-Ji Ho:** Writing – review & editing, Validation, Supervision, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Jen-Ji Ho and Chao-Fang Chu report that financial support was provided by National Science and Technology Council. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Data availability

This manuscript only contains publicly available data

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