When Protection Turns Perilous:
Call for a Vaccine Injury Compensation Framework in Singapore

Introduction

In the bustling maternity wards in Singapore, newborns receive their first vaccines as a safeguard against a range of infectious diseases. Among them is the Bacillus Calmette-Guérin (BCG) vaccine, a long-standing preventative measure against tuberculosis (TB).[1] Since the mid-1950s, this vaccine has been administered at birth to all Singaporean infants as part of the National Childhood Immunisation Schedule (NCIS).[2] For most, the BCG vaccine is a routine shot with few complications. However, in rare cases, it can lead to catastrophic outcomes.

This is the story of Tom, an otherwise healthy infant who developed disseminated BCG infection affecting multiple organs – also known as BCGosis – after receiving the vaccine. What began as a small swelling at the injection site soon escalated into a life-threatening systemic infection, leading to months of hospitalisation and intensive care. Tom's condition required aggressive treatments, including multiple courses of antibiotics and surgical interventions to manage the infection that had spread to his long bones. Despite the best efforts of medical professionals, his recovery was prolonged and incomplete.

Even after being discharged from the hospital, Tom's journey was far from over. The infection left lasting damage, necessitating lifelong medical follow-up to monitor for complications such as chronic inflammation and potential reactivation of the infection. He faced the prospect of recurrent hospital visits for evaluations, ongoing medications to manage symptoms, and possible revision surgeries to address skeletal deformities caused by the infection, including damaged bone growth or joint issues.

For Tom's family, the emotional and financial burden was immense. They grappled with the stress of navigating his complex medical needs while managing the mounting costs of specialised care. Tom's story calls attention to the rare but devastating consequences of vaccine-related adverse events and it stresses the urgent need for a robust, transparent compensation framework to support affected individuals and families.

Background

Adverse Events Associated with Vaccination

The BCG vaccine, a live attenuated strain of *Mycobacterium bovis*, remains a cornerstone of TB prevention in Singapore. TB is an endemic disease in Singapore, with latent TB infection being relatively common, particularly among older age groups, as prevalence rates can reach up to 30%.[3] It

[1] Qu, M., X. Zhou, and H. Li. "BCG Vaccination Strategies Against Tuberculosis: Updates and Perspectives." *Human Vaccines & Immunotherapeutics* 17, no. 12 (December 2, 2021): 5284–5295.
[2] *Ministry of Health Singapore*. "Nationally Recommended Vaccines." Accessed December 22, 2024. https://www.moh.gov.sg/seeking-healthcare/overview-of-diseases/communicable-diseases/nationally-recommended-vaccines.
[3] *Ministry of Health Singapore*. "Update on Tuberculosis Situation in Singapore, 2024." Accessed December 22, 2024. https://www.moh.gov.sg/newsroom/update-on-tuberculosis-situation-in-singapore-2024.

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is strongly recommended under the NCIS and has been routinely administered at birth since the mid-1950s. While it is generally well-tolerated by the majority of infants, local complications such as abscesses or lymphadenitis (lymph node swellings) occasionally occur. In extremely rare instances, the vaccine can lead to systemic complications, including disseminated BCG infection, or BCGosis, with an incidence estimated at 1 to 3.4 per million doses.[4] This life-threatening condition is associated with high mortality, and survivors suffer lasting complications.

While the aforementioned case of baby Tom is fictional, the scenario is rooted in reality. A 15-year retrospective review conducted by KK Women's and Children's Hospital, a major tertiary maternal and child hospital in Singapore, documented 10 cases of similar severe outcomes from BCG vaccination, including life-threatening BCGosis in infants.[5] BCGosis can lead to lifelong medical burdens, including recurrent infections, chronic health issues, and, in many cases, permanent disabilities. In some patients, multi-organ failure and fatality ensue. Survivors require ongoing medical care, such as regular hospital visits, long-term medication, and even multiple surgeries.

It should be noted that the BCG vaccine is only one of the 14 vaccines currently listed in the NCIS,[6] among which vaccinations for measles and diphtheria are mandatory by law for children under the provisions of the Infectious Diseases Act (IDA).[7] Apart from the risk of BCGosis with the BCG vaccine, other clinically serious outcomes such as anaphylaxis, encephalitis, myocarditis and sensorineural hearing loss have also been reported for the other NCIS vaccines[8]. In fact, the average treatment of some serious outcomes such as Guillain-Barre syndrome (GBS) and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) cost patients approximately US$530,000[9] and US$160,000,[10] adjusted for costs in 2024. While these vaccinations are highly recommended or mandated as a matter of public health due to their net benefit, the burden of loss is unfortunately borne only by the individual.

The financial strain on families from such severe vaccine injuries is enormous, and is further exacerbated by the absence of a comprehensive vaccine injury compensation framework locally. In addition to the physical toll, the emotional and psychological impact on families is often overwhelming, as they navigate the complexities of managing a child's chronic condition while facing increased financial and caregiving demands. This highlights the very real risks that, although rare, demand our attention and call for local policy reform in vaccine injury compensation.

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[4] Lee, P. P. "Disseminated Bacillus Calmette-Guérin and Susceptibility to Mycobacterial Infections: Implications on Bacillus Calmette-Guérin Vaccinations." *Annals of the Academy of Medicine*, *Singapore* 44, no. 8 (2015): 297–301.

[5] Ong, R. Y. L., Y. A. Chong, K. Y. Lee, S. H. Chan, and B. T. Khor. "Disseminated Bacillus-Calmette-Guérin Infections and Primary Immunodeficiency Disorders in Singapore: A Single Center 15-Year Retrospective Review." *International Journal of Infectious Diseases* 97 (2020): 117–125.

[6] *Ministry of Health Singapore*. "Nationally Recommended Vaccines." Accessed December 22, 2024. https://www.moh.gov.sg/seeking-healthcare/overview-of-diseases/communicable-diseases/nationally-recommended-vaccines.

[7] Singapore Statutes Online. *Infectious Diseases Act 1976*. Accessed December 31, 2024. https://sso.agc.gov.sg/Act/IDA1976.

[8] Asatryan, A., Pool, V., Chen, R. T., Kohl, K. S., Davis, R. L., and Iskander, J. K. "Live attenuated measles and mumps viral strain-containing vaccines and hearing loss: Vaccine Adverse Event Reporting System (VAERS), United States, 1990–2003." *Vaccine* 26, no. 9 (2008): 1166-1172.

[9] Frenzen, P. D. "Economic cost of Guillain-Barré syndrome in the United States." *Neurology* 71, no. 1 (2008): 21-27.

[10] Guptill, J. T., Runken, M. C., Eaddy, M., Lunacsek, O., and Fuldeore, R. M. "Treatment patterns and costs of chronic inflammatory demyelinating polyneuropathy: a claims database analysis." *American Health & Drug Benefits*12, no. 3 (2019): 127.

Moreover, childhood immunisation remains the most cost-effective strategy in reducing childhood disease burden,[11] but for some parents, the potential for deleterious adverse effects can create substantial fear and anxiety. Having a robust vaccine injury response and compensation framework can help allay some of these concerns.

Vaccine Injuries Financial Assistance Programme in Singapore

Although there is no existing vaccine injury compensation scheme for vaccines under the national immunisation schedule, the Vaccine Injury Financial Assistance Programme (VIFAP) in Singapore was launched in March 2021 as part of the national COVID-19 vaccination campaign.[12] Established by the Ministry of Health (MOH), VIFAP offers one-time goodwill payments to Singaporeans, permanent residents, and long-term pass holders in the event of severe adverse effects resulting in hospitalisation, permanent disability, or death due to the COVID-19 vaccines. Designed as a no-fault compensation system, the programme aims to avoid prolonged litigation in the courts, bolster public trust in vaccines, and offer financial support to those affected by vaccine injuries.[13]

According to the Health Sciences Authority (HSA), some individuals (less than 50%) may experience mild symptoms, such as pain and soreness at the injection site, headache and mild fever, that resolve on their own in a few days. However, in rare instances (approximately 0.005%), some may experience more serious side effects, such as perimyocarditis (inflammation of the heart muscles) and severe allergic reactions.[14] The intent of a programme like VIFAP is thus to reassure the public and encourage vaccine uptake by ensuring that financial help is available in rare cases of serious complications (in addition to medical subsidies already available at public restructured hospitals). Other avenues, such as Medisave, MediShield Life, and MediFund,[15] also exist to assist with the cost of medical treatment.

To qualify for the VIFAP, individuals must be a Singapore Citizen, Permanent Resident, or long-term pass holder who has received the COVID-19 vaccination under the national vaccination programme (meaning one of the nationally sanctioned vaccines, e.g., the Pfizer and Moderna vaccine), and experienced a serious side effect that required inpatient hospitalisation, caused permanent severe disability, or was fatal. The serious side effect must be assessed by a doctor to be related to the individual's COVID-19 vaccination. An (undisclosed) independent clinical panel appointed by the MOH will then review and assess the application to determine eligibility for assistance. COVID-19

[11] Nandi, A. and Shet, A. "Why vaccines matter: understanding the broader health, economic, and child development benefits of routine vaccination." *Human vaccines & immunotherapeutics* 16, no. 8 (2020): 1900-1904.

[12] *Ministry of Health Singapore*. "COVID-19 Vaccine Injury Financial Assistance Programme." Accessed December 22, 2024. https://www.moh.gov.sg/seeking-healthcare/overview-of-diseases/communicable-diseases/covid19/covid19-vaccine-injury-financial-assistance-programme.

[13] Ibid.

[14] *Health Sciences Authority Singapore*. "COVID-19 Vaccines Safety Updates." Accessed December 22, 2024. https://www.hsa.gov.sg/COVID19-vaccines-safety-updates.

[15] Medisave is a national medical savings scheme which helps individuals put aside part of their income into their account to meet their future hospitalisation, day surgery and certain outpatient expenses. MediShield is a catastrophic medical insurance scheme which helps Medisave account holders meet the cost of treatment for serious or prolonged illnesses. Medifund is an endowment fund that serves as a safety net to help needy Singapore citizens who are not able to pay for their heavily subsidised medical care at restructured hospitals.

vaccinations received under the private vaccination programme (e.g., Sinopharm) are not eligible for the VIFAP.[16]

The financial assistance provided is predetermined and varies based on the severity of the serious side effect, as outlined in Table 1. Payment will be issued at the highest eligible amount, with individuals qualifying for only a single payout (e.g., S$225,000 for death or permanent severe disability, irrespective of hospital stay or treatment costs).

Table 1: Tiered assessment and financial assistance under the VIFAP for events considered related and eligible for claim[17]

Tier	Type of serious side effects	One-time payment amount
1	Results in death or permanent severe disability	S$225,000
2	Requires admission to High Dependency or Intensive Care, with subsequent recovery	S$10,000
3	Requires inpatient hospitalisation, with subsequent recovery (excluding visits to the emergency department without subsequent inpatient admission)	S$2,000

Problem

The COVID-19 pandemic has heightened both public awareness and concern surrounding vaccines, especially with the rapid global roll-out of COVID-19 vaccines.[18] As vaccination campaigns expanded, so too did the discussion about potential adverse events.[19] While the incidence of vaccine-related injuries remains statistically low, increased awareness and anecdotal reports have contributed to an enhanced perception of risk. This perception, influenced by availability bias, can sometimes manifest as an irrational fear of vaccines, prompting some individuals to avoid vaccination altogether.[20]

While the majority of concerns in recent years have centred around the novel COVID-19 vaccines, there is a concerning spillover effect that threatens to extend to other vaccines, including childhood immunisations.[21] Although it is challenging to generalise beyond the COVID-19 context, a study found that one-third of Singaporean parents were hesitant to vaccinate their children against COVID-19,[22] which is worrying, especially for future public health efforts. As public apprehension grows, vaccine hesitancy may not be limited to COVID-19 alone, but could affect broader immunisation

[16] *Ministry of Health Singapore*. "COVID-19 Vaccine Injury Financial Assistance Programme." Accessed December 22, 2024. https://www.moh.gov.sg/seeking-healthcare/overview-of-diseases/communicable-diseases/covid19/covid19-vaccine-injury-financial-assistance-programme.
[17] Ibid
[18] Lazarus, J. V., T. M. White, K. Wyka, S. C. Ratzan, K. Rabin, H. J. Larson, F. Martinon-Torres, E. Kuchar, S. S. Abdool Karim, T. Giles-Vernick, S. Müller, C. Batista, N. Myburgh, B. Kampmann, and A. El-Mohandes. "Influence of COVID-19 on Trust in Routine Immunization, Health Information Sources and Pandemic Preparedness in 23 Countries in 2023." *Nature Medicine* 30, no. 6 (2024): 1559–1563.
[19] Ng, Q. X., S. R. Lim, C. E. Yau, and T. M. Liew. "Examining the Prevailing Negative Sentiments Related to COVID-19 Vaccination: Unsupervised Deep Learning of Twitter Posts over a 16-Month Period." *Vaccines* 10, no. 9 (2022): 1457.
[20] Casigliani, V., D. Menicagli, M. Fornili, V. Lippi, A. Chinelli, L. Stacchini, G. Arzilli, et al. "Vaccine Hesitancy and Cognitive Biases: Evidence for Tailored Communication with Parents." *Vaccine X* 11 (July 2, 2022): 100191..
[21] Soveri, A., L. C. Karlsson, J. Antfolk, O. Mäki, L. Karlsson, H. Karlsson, S. Nolvi, M. Karukivi, M. Lindfelt, and S. Lewandowsky. "Spillover Effects of the COVID-19 Pandemic on Attitudes to Influenza and Childhood Vaccines." *BMC Public Health* 23, no. 1 (2023): 764.
[22] Low, J. M., Soo, C. W. T., Phuong, T. A., Zhong Y., and Lee, Y. L. "Predicting vaccine hesitancy among parents towards COVID-19 vaccination for their children in Singapore." *Frontiers in Pediatrics* 10 (2022): 994675.

efforts for diseases such as measles, rubella, and diphtheria-diseases which, if left unchecked, can result in a resurgence of preventable outbreaks and public health epidemics.

In this regard, a robust and transparent vaccine injury compensation framework becomes critical. Such a framework not only acts as a safety net for those who suffer from rare or unintended adverse reactions, but it also serves as a mechanism to reassure the public of the government's commitment to ensuring the safety of its vaccination programmes. The establishment of such a programme beyond COVID-19 vaccines would offer a safeguard for those complying with the nation's vaccination policies, which protect against 14 infectious diseases: TB, hepatitis B, diphtheria, tetanus, pertussis, poliovirus, *Haemophilus influenzae* type b, measles, mumps, rubella, varicella (chickenpox), pneumococcal disease, human papillomavirus, and influenza.[23]

Without a national vaccine injury compensation framework, it is also difficult for individuals to seek legal recourse given that the risk of adverse events is intrinsic to vaccinations, and often independent of individual physiology, clinical practice, regulatory safeguards and manufacturing standards.[24] Furthermore, these rare but serious vaccine-related adverse events generally cannot be attributed to a negligent party (e.g., the manufacturer or healthcare provider who administered the vaccine).

However, the structure and effectiveness of vaccine injury compensation programmes vary widely across different countries. These programmes differ in their scope, eligibility criteria, benefits, funding mechanism, and the process by which claims are assessed. These variations likely directly influence the programme's impact on compliance rates, public trust, and the overall budgetary implications for governments. Some countries with relatively well-established systems offer comprehensive support, while others have more limited or restrictive frameworks.

This case study aims to examine and compare these international models and draw lessons from them, with the goal of proposing a suitable comprehensive vaccine injury compensation programme for Singapore. The proposed framework should balance public safety and trust, budgetary feasibility, and effective delivery of support for affected individuals. A well-structured compensation system will not only help mitigate vaccine-related risks but also strengthen the nation's public health immunisation efforts, contributing to a safer and healthier population.

Comparative Analysis

While vaccine injury programmes are available across various countries, this comparative analysis focuses on middle-to-high income countries in Asia with established vaccine injury compensation frameworks. The selection of countries is driven by the variety of mechanisms in place across Asia, rather than solely based on a country's income status. The choice of Japan, Thailand, and Taiwan for this comparative analysis is because of their diverse approaches to vaccine injury assessment and compensation, which offer insights for tailoring a framework suitable for Singapore's unique context. Each country represents a distinct model in terms of policy design, funding mechanisms, and administration, providing a broad spectrum of practices to analyse and adapt. The analysis delves into the funding mechanisms, including the scope of coverage, and the processes through which claims are adjudicated and compensation is allocated, aiming to identify key lessons that can guide

[23] *Ministry of Health Singapore*. "Nationally Recommended Vaccines." Accessed December 22, 2024. https://www.moh.gov.sg/seeking-healthcare/overview-of-diseases/communicable-diseases/nationally-recommended-vaccines.

[24] Attwell, K., Drislane, S., & Leask, J. (2019). Mandatory vaccination and no fault vaccine injury compensation schemes: An identification of country-level policies. *Vaccine*, *37*(21), 2843–2848.

the development of a contextually appropriate vaccine injury compensation programme for Singapore.

Japan's Approach – Inclusivity, Flexible Causality Standards, and Range of Benefits

Authorised by the Immunisation Act of 1976, Japan's Health Damage Relief System was established the following year and is managed under the Ministry of Health, Labor, and Welfare.[25] The programme provides compensation for a wide range of vaccine-related injuries and is designed to offer financial relief to individuals affected by both the direct medical costs and the long-term consequences of vaccine-related injuries. This includes compensation for medical expenses, medical allowances, nursing pensions for children with disabilities, disability pensions, lump-sum payments for survivors, and funeral expenses.

The programme encompasses vaccines targeting two distinct categories. Category A vaccines are designed to prevent mass outbreaks of highly contagious diseases and are typically administered to children, such as the BCG vaccine for TB and vaccines for measles and rubella. Category B vaccines address diseases that are important for public health but may not specifically target children, such as influenza and human papillomavirus (HPV) vaccines. In response to the COVID-19 pandemic, Japan amended its Immunisation Act in 2020 to introduce special provisions for COVID-19 vaccines, ensuring their inclusion in the programme and providing a framework for compensation in case of adverse effects.

The Disease and Disability Review Board, consisting of fewer than 30 members from medical, scientific, and legal fields, evaluates vaccine injury claims. The review process follows a flexible standard of proof, categorising cases as (i) definitely related, (ii) probably related, (iii) unable to decide due to lack of information, or (iv) not related. This classification system aligns closely with the causality assessment framework recommended by the World Health Organisation (WHO) for adverse events following immunisation.[26] The WHO guidelines categorise causality into several levels to determine the likelihood of a causal relationship between the vaccine and the adverse event. These levels include:

1. Definitely Related: Strong evidence exists to confirm a causal link between the vaccine and the adverse event, supported by clinical, epidemiological, and laboratory data.
2. Probably Related: The evidence suggests a high likelihood of a causal relationship, but some uncertainty remains due to limited data or confounding factors.
3. Unable to Decide Due to Lack of Information: The available information is insufficient or inconclusive to make a determination about causality.
4. Not Related: Strong evidence indicates no causal relationship between the vaccine and the adverse event, often due to alternative explanations or the absence of temporal association.

Compensation is granted for the first three categories, even when a strict causal relationship cannot be definitively established.[27] These relaxed criteria for determining causality is particularly significant, as it allows claimants to receive compensation in cases where symptoms cannot be conclusively linked to a vaccine, yet where a plausible connection exists. The ease with which

[25] Enami, Takeshi, and Hiroko Otsubo. "The Current State of Immunization Administration in Japan." *Japan Medical Association Journal* 53, no. 2 (2010): 111–117.
[26] *World Health Organization*. "Adverse Events Following Immunization (AEFI)." Accessed December 22, 2024. https://www.who.int/groups/global-advisory-committee-on-vaccine-safety/topics/aefi/aefi.
[27] Enami, Takeshi, and Hiroko Otsubo. "The Current State of Immunization Administration in Japan." *Japan Medical Association Journal* 53, no. 2 (2010): 111–117.

claimants can receive compensation in cases of doubt is a key feature of the programme, making it one of the more generous systems in the region.[28]

In addition to direct compensation, a range of benefits to support individuals and families affected by vaccine-related injuries are also made available. These benefits include medical expenses and allowances (to cover the costs of medical treatment, hospital stays, medications, and other healthcare needs associated with the vaccine injury), nursing pension (for the ongoing care of children who develop disabilities as a result of vaccination), disability pensions (for long-term financial support to individuals who suffer permanent disabilities due to vaccine-related adverse events), lump-sum payment for survivors, and funeral expenses (to cover the costs associated with burial or cremation in the event of a vaccine-related fatality).[29]

Between February 1977 and December 2019, 3,419 individuals received compensation under the programme. In fiscal year 2019, 134 health damage relief claims were processed, of which 88 were approved, with an annual budget of approximately US$10.8 million allocated for these claims.[30] If claimants find the decision of the Disease and Disability Review Board unsatisfactory, they reserve the right to request reconsideration from the prefectural governor. Additionally, claimants may pursue legal action if they feel that the compensation awarded is inadequate.

Notably, Japan's compensation framework is primarily funded through contributions from pharmaceutical companies and partially supported by the national treasury. Pharmaceutical companies in Japan are legally required to contribute to the compensation system as part of their licensing and market authorisation process. These contributions are stipulated under the Pharmaceutical and Medical Device Act, which governs the sale and distribution of drugs and medical devices in Japan[31]. This legal obligation ensures consistent funding while holding manufacturers accountable for the safety of their products. The hybrid funding mechanism ensures that pharmaceutical companies bear a significant portion of the financial responsibility, while the government provides additional backing to sustain the programme. This approach reflects a shared accountability model, where industry contributions are complemented by public funds, ensuring financial stability and continuity of the compensation scheme.

Taiwan's Approach – Wide Vaccine Coverage and Financial Sustainability

Taiwan's Vaccine Injury Compensation Programme (VICP) was established in June 1988 under the Ministry of Health and Welfare in response to a local case where a child developed polio after receiving the oral poliomyelitis vaccine. The programme offers compensation for individuals who experience adverse reactions following vaccination, including death, disabilities, severe illnesses, and other significant injuries. It covers a broad spectrum of vaccines, including those for routine and compulsory use, self-paid vaccines, specially imported vaccines, off-label vaccines, and vaccines used for post-exposure prophylaxis.[32] In 2020, Taiwan amended the Infectious Disease Prevention Act to

[28] Kang, C. R., Y. J. Choe, and S. J. Yoon. "COVID-19 Vaccine Injury Compensation Program: Lessons Learned from a Review of 10 Implementing Countries." *Journal of Korean Medical Science* 39, no. 13 (April 8, 2024): e121.
[29] Ibid
[30] *Ministry of Health, Labour and Welfare*. "Flattening 31 Years: Summary of Forecast." Accessed December 22, 2024. https://www.mhlw.go.jp/wp/yosan/yosan/19syokanyosan/dl/gaiyo-
[31] Fujiwara, Y., Y. Onda, and S. Hayashi. "No-Fault Compensation Schemes for COVID-19 Medical Products." *The Lancet* 397, no. 10286 (2021): 1707–1708.
[32] Taiwan Centers for Disease Control. *Vaccine Injury Compensation Program Overview*. Accessed December 22, 2024. https://www.cdc.gov.tw/Uploads/archives/81f39836-ca2f-433c-8a72-b7d6d3e2cd81.pdf.

include special provisions for COVID-19 vaccines, aligning with global efforts to provide compensation for emerging vaccination-related injuries during public health crises.[33]

The VICP Working Group, a key deliberative body, is responsible for reviewing vaccine injury claims. Comprising 19 to 25 experts in fields such as medicine, pharmacy, public health, law, and social justice, the group ensures that claims are assessed from multiple perspectives. Notably, more than one-third of the members are experts in law and social justice. The standard of proof in Taiwan's VICP is based on three levels: associated, indeterminate, and not associated. Compensation is provided for cases determined to be associated or indeterminate, with amounts varying depending on the severity and likelihood of causality. Compared to Japan, the compensation rates (both in terms of percentage of approved applications and amount covered) in Taiwan are generally considered moderate.[34]

If claimants are dissatisfied with the decision or the compensation awarded, they have the right to appeal to the Petitions and Appeals Committee. If dissatisfaction persists following the committee's decision, claimants can file a lawsuit against the Ministry of Health and Welfare, ensuring that individuals have recourse to additional legal channels if necessary.

The Compensation Relief Fund, which finances the VICP, is primarily funded by a premium of NT$1.5 (roughly US$0.05) per vaccine dose purchased through the National Vaccine Fund.[35] The National Vaccine Fund is a pool funded by contributions from multiple stakeholders. Taiwan has a National Health Insurance (NHI) system that provides universal healthcare coverage, which includes most vaccines administered under the national immunisation programme.[36] For vaccines covered by the NHI, the small premium is indirectly funded by the NHI system itself. This means the cost of the premium is absorbed as part of the broader healthcare financing structure funded by payroll contributions, government subsidies, and premiums paid by insured individuals. In other words, the NHI essentially pays the vaccine premium on behalf of its enrollees.

For vaccines not covered by the NHI or vaccines purchased privately, the small premium may be included in the vaccine's price. In this case, individuals receiving the vaccine (or their employers in the case of vaccination for occupational reasons) bear the cost directly. For vaccines provided free of charge under national immunisation campaigns (e.g., childhood immunisations), the government typically covers the entire cost, including the small premium, as part of its public health expenditure. The small premium is seamlessly integrated into the overall cost of vaccine provision, so end-users are rarely aware of it. The fund generated by these premiums is ring-fenced for vaccine injury compensation, ensuring financial sustainability without imposing excessive impact on the national healthcare budget or the population.

[33] Ibid

[34] Kang, C. R., Y. J. Choe, and S. J. Yoon. "COVID-19 Vaccine Injury Compensation Program: Lessons Learned from a Review of 10 Implementing Countries." *Journal of Korean Medical Science* 39, no. 13 (April 8, 2024): e121.

[35] Bach-Golecka, Dobrochna, ed. Compensation Schemes for Damages Caused by Healthcare and Alternatives to Court Proceedings: *Comparative Law Perspectives*. Vol. 53. Ius Comparatum - Global Studies in Comparative Law. Cham: Springer Nature, 2021.

[36] Chen, C. S., and T. C. Liu. "The Taiwan National Health Insurance Program and Full Infant Immunization Coverage." *American Journal of Public Health* 95, no. 2 (2005): 305–311.

Thailand's Approach – Expedited No-Fault Compensation System

Thailand established a no-fault compensation system for medical accidents in 2004 under the National Health Security Office (NHSO).[37] The programme mandates preliminary compensation to alleviate suffering and manage injuries resulting from medical treatment. The system addresses a broad range of medical injuries resulting from healthcare services, including those that occur without negligence. This ensures that patients receive support regardless of the cause of the injury. This scheme was expanded in 2021 in response to the COVID-19 pandemic to cover adverse effects from COVID-19 vaccinations, aiming to bolster public confidence in the vaccination. Unlike other countries with specific vaccine injury compensation programmes, Thailand's system is broader and addresses a variety of injuries, including deaths, irreversible disabilities, less serious disabilities, injuries, and chronic diseases.[38] The compensation programme is primarily funded by the national treasury.[39]

The adjudication of claims under the no-fault compensation system for medical injuries, including those related to vaccinations, is managed by the NHSO. Affected individuals or their representatives can file a claim with the NHSO.[40] The claim should include relevant medical records and documentation detailing the injury and its association with the medical treatment or vaccination received. The claim is reviewed by a relatively small expert subcommittee, typically comprising of five members including a doctor specialising in infectious diseases or other related fields, and with the Director of the NHSO acting as chairman of the sub-committee.[41] This subcommittee assesses the claim to determine the likelihood that the injury resulted from the medical intervention or vaccination. The subcommittee evaluates the medical evidence to establish a probable link between the medical service or vaccine and the reported injury. The standard of proof is purportedly less stringent than in traditional legal settings, focusing on the plausibility of causation rather than definitive evidence.

Based on the assessment, the subcommittee decides on the eligibility of the claim. If deemed eligible, the severity of the injury is classified to determine the appropriate compensation amount. The compensation amounts are predefined, correlating with the injury's severity. For instance, injuries resulting in chronic illness may lead to compensation of less than 100,000 baht (about S$4,000), while loss of organs or moderate disabilities may result in compensation ranging from 100,000 to 240,000 baht (S$4,000 to S$10,000). In cases of death or permanent disability, the compensation can be between 240,000 to 400,000 baht (S$10,000 to S$16,000).[42]

A unique feature of Thailand's system is the provision of preliminary compensation. This compensation is designed to provide immediate financial relief to victims for the treatment of injuries and alleviate suffering.[43] The preliminary compensation does not imply a full settlement but aims to ensure that individuals receive timely support during their recovery process. While it is

[37] National Health Security Office. *No-Fault Compensation for Medical Injuries (Article 41): Understanding Thailand's Approach*. Bangkok: NHSO, 2021. Accessed December 20, 2024. https://stream.nhso.go.th/assets/portals/1/files/64-6_NoFaultCompensation%28Article41%29_Book%28Eng%29.pdf.
[38] Ibid
[39] Ibid
[40] Ibid
[41] "Thailand Covid Vaccine NFCS." *Faculty of Law*, University of Oxford. Accessed December 24, 2024. https://www.law.ox.ac.uk/nofault-compensation-schemes-for-covid-19-vaccines/thailand-covid-vaccine-nfcs.
[42] National Health Security Office. *No-Fault Compensation for Medical Injuries (Article 41): Understanding Thailand's Approach*. Bangkok: NHSO, 2021. Accessed December 20, 2024. https://stream.nhso.go.th/assets/portals/1/files/64-6_NoFaultCompensation%28Article41%29_Book%28Eng%29.pdf.
[43] Ibid

unclear whether the no-fault compensation system fully replaces litigation in court, claimants have the option to appeal decisions made by the expert subcommittee. The appeal is then reviewed by a higher authority within the NHSO to ensure fairness and thorough consideration.[44]

Comparison with Singapore's Approach

Singapore's VIFAP, introduced in 2021, provides targeted financial support for individuals experiencing serious side effects following COVID-19 vaccination. The programme is a no-fault scheme, with no overarching legislation or regulation governing compensation.[45] It offers one-time goodwill payments to Singaporeans, permanent residents, and long-term pass holders for severe adverse effects, such as hospitalisation, permanent disability, or death, determined to be directly related to COVID-19 vaccines. In contrast to broader and more comprehensive systems in Japan, Taiwan, and Thailand, Singapore's VIFAP is narrowly focused on COVID-19 vaccines, with no equivalent framework addressing vaccines under the national immunisation schedule.

With regard to the review processes, Singapore's VIFAP relies on an independent clinical panel appointed by the Ministry of Health (MOH) to evaluate causality and determine eligibility for compensation. However, the details of how causality is assessed remain opaque.[46] There is also a severity criterion, and the adverse event must have required hospitalisation to be eligible for claim. Thailand's NHSO also uses a smaller expert subcommittee, primarily composed of medical professionals, to assess claims. Meanwhile, Japan and Taiwan engage larger, multidisciplinary review boards for their vaccine injury compensation programmes, which include both medical and legal experts. Japan's review panel, consisting of fewer than 30 members, applies a flexible standard of proof, allowing compensation even when causality is not definitively established. Similarly, Taiwan's VICP involves a working group of 19 to 25 experts from diverse fields, including law and social justice, ensuring a thorough and balanced evaluation process.

Another key distinction among these systems lies in their funding approaches. Singapore's VIFAP, like Thailand's compensation programme, is financed through the national budget, drawing directly from public funds. In contrast, Japan and Taiwan employ more sustainable funding mechanisms. Japan's system is partially supported by contributions from pharmaceutical companies, while Taiwan collects a small surcharge on each vaccine dose to maintain its compensation fund. These approaches ensure financial sustainability while reducing reliance on national budgets, offering a model that Singapore could potentially adapt for broader vaccine coverage.

How Should Singapore Extend Vaccine Injury Compensation?

In light of the identified gaps in existing frameworks and comparative insights from regional counterparts, several potential directions may be explored to extend Singapore's vaccine injury compensation beyond COVID-19. These options vary in terms of funding mechanisms, scope of coverage, and governance models. Each approach entails trade-offs between cost, transparency, administrative complexity, and public accountability.

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[44] Ibid

[45] Ministry of Health Singapore. "COVID-19 Vaccine Injury Financial Assistance Programme." Accessed December 22, 2024. https://www.moh.gov.sg/seeking-healthcare/overview-of-diseases/communicable-diseases/covid19/covid19-vaccine-injury-financial-assistance-programme.

[46] Kang, C. R., Y. J. Choe, and S. J. Yoon. "COVID-19 Vaccine Injury Compensation Program: Lessons Learned from a Review of 10 Implementing Countries." *Journal of Korean Medical Science* 39, no. 13 (April 8, 2024): e121.

Similar to Japan and Taiwan, compensation is provided for adverse events assessed as definitively related, probably related, inconclusive/indeterminate, or not related to the vaccine, even in the absence of definitive proof of causation. Thereafter, claims are allocated based on clearly defined tiers of severity. This tiered approach would align the level of financial assistance with the magnitude of the adverse event, to ensure equitable support. This three-tiered structure (Figure 1) would also allow for manageable claim volumes and financial sustainability, while delivering timely, proportionate aid to individuals and families who most need it.

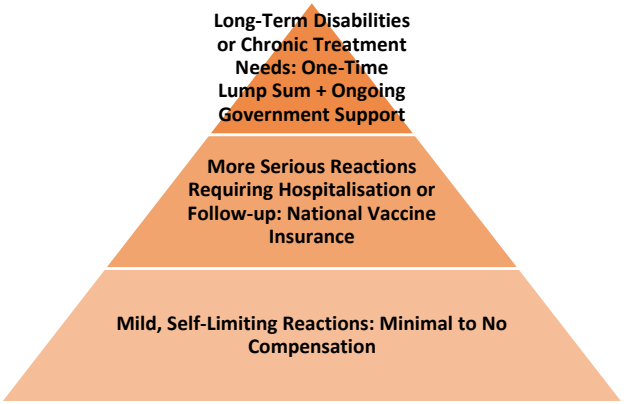

Figure 1: A tiered, needs-based approach to vaccine injuries and compensation

Mild, Self-Limiting Reactions: Minimal to No Compensation

Most vaccine reactions, e.g., redness and pain at the injection site, mild fevers, transient headaches, are self-limiting and typically resolve without further medical intervention. These constitute the vast majority of adverse events and, given their relatively minor impact, do not warrant structured compensation under a national scheme. Continuing the current approach of "no compensation for mild events" under the VIFAP makes sense according to the principles of (1) Proportionality (the administrative burden and cost of compensation for minor, transient symptoms would outweigh the benefits to individuals) and (2) Justice (by maintaining a threshold of seriousness, administrators and physicians can focus resources on more serious injuries, ensuring that affected individuals receive adequate and timely support). For these reasons, public education instead of financial support, should be emphasised, with official communication lines providing health literacy and guidelines to manage mild side effects at home.

More Serious Reactions Requiring Hospitalisation or Follow-up: National Vaccine Insurance

Individuals who require hospitalisation or repeated outpatient care (beyond routine check-ups) for a vaccine-related complication may fall into a second tier. These are patients who develop events such as severe infections at the injection site, significant allergic reactions, or temporary neurological symptoms requiring inpatient observation. For such cases, Singapore could establish a dedicated national vaccine insurance scheme, financed through a combination of shared contributions and no-fault coverage. By charging a modest premium on each vaccine dose-similar to the Taiwanese model-this could be ring-fenced to fund insurance payouts.

Pharmaceutical companies could also be encouraged to co-contribute, in line with the Japanese approach of shared responsibility. A compelling argument can be made for involving pharmaceutical companies in supporting Singapore's vaccine injury compensation framework, akin to Japan's model. Japan's shared-responsibility funding arrangement, in which pharmaceutical companies are legally obliged to contribute to a central fund, exemplifies an approach that balances industry

accountability with public sector commitment. Given Singapore's status as a biomedical hub and its strong ties to multinational pharmaceutical firms,[47] there is scope to explore such partnerships. Companies already view Singapore as a strategic regional base for research and development, and product launches, and many engage in local corporate social responsibility (CSR) initiatives. By framing contributions to a vaccine compensation fund as part of broader CSR obligations, Singapore could underline the principle of shared accountability-demonstrating to the public that stakeholders involved in developing and distributing vaccines also invest in safeguarding those rare cases of adverse events.

The insurance would offer no-fault compensation. If medical experts deem it "likely" or "possibly" related to vaccination, the individual would be eligible for a standard payout, alleviating the need for protracted causality disputes. Broader support and benefits should also be provided for those whose injuries fall into this moderate category, meaning they might receive support for hospital bills not fully covered by MediShield Life or Medisave; partial lost wages for parents needing time off work; or additional follow-up costs (e.g., physiotherapy, home nursing). This approach ensures that those with more substantial medical needs are not caught in a financial limbo. Furthermore, preliminary or "bridging" compensation-akin to Thailand's expedited payout-could be considered to help families meet short-term costs promptly. Final compensation calculations would then be determined once the extent of recovery or the residual disability is clearer.

Long-Term Disabilities or Chronic Treatment Needs: One-Time Lump Sum and Ongoing Government Support

In rare but devastating instances, vaccine reactions can result in permanent disability or chronic conditions requiring lifelong medical attention. These cases demand a more robust safety net and beget equity considerations. A two-pronged strategy would be ideal.

First, a lump-sum payment could help offset immediate costs such as extended hospitalisation, surgeries, assistive devices, or home modifications to improve accessibility. Second, for individuals whose long-term independence or earning capacity is permanently affected, ongoing support could be integrated with existing government disability schemes. This may include continued rehabilitation, subsidised specialist care, allied health services, and caregiver support.

By coordinating short-term compensation with longer-term social protection measures, families may be spared the need to navigate multiple agencies in a fragmented system. However, any such approach would require careful calibration to Singapore's policy, fiscal and administrative context, including decisions on how such compensation would be funded (e.g., through a national vaccine insurance scheme or blended financing model, as discussed earlier).

Considerations for Operationalising a Tiered Framework

Operationalising such a tiered framework helps ensure that scarce public resources are allocated both efficiently and fairly. Not every adverse event merits cash compensation, but when significant harm does occur, fast and equitable remedies help maintain public trust in vaccination programmes. Still, moving from a narrowly focused COVID-19 scheme to a full-spectrum vaccine injury model calls for careful planning:

[47] Raj Thampuran and Kong Hwai Loong, "The biomedical sciences: research for better health" in *The Singapore Research Story*, ed. Hang Chang Chieh, Low Tech Seng and Raj Thampuran (Singapore: World Scientific, 2016), 101-33.

1. *Governance and Oversight:* Building on the current VIFAP infrastructure, the composition of the claims evaluation panel could be broadened to include a multidisciplinary team-comprising clinicians, legal experts, and scientists-who would assess applications based on evolving local pharmacovigilance data and adverse event reports from the HSA. Standards for causality assessment could follow international guidance, such as the WHO framework, which classifies adverse events as definitively related, probably related, indeterminate, or not related.
2. *Financial Sustainability:* A hybrid or insurance-based funding model can mitigate the risk of heavy reliance on annual budget allocations. Shared contributions from the state, manufacturers, and a small per-dose levy ensure long-term viability with minimal burden on end-users.
3. *Clear Public Communication:* Authorities must explain why mild cases are excluded, highlight the thresholds that trigger compensation, and outline the system's core mission: to protect individuals from undue financial strain when rare but serious vaccine-related injuries arise.

Conclusion

At the time of writing, Singapore does not offer a dedicated vaccine injury scheme for immunisations outside of COVID-19, leaving the extent of governmental support for families like Tom's uncertain. While most vaccine-related adverse events are mild and short-lived, it is crucial to ensure robust protection for the minority who experience serious or long-term harm. By pairing short-term insurance-style payouts with ongoing assistance for those requiring more extensive support, Singapore can better address these rare but significant cases while preserving public trust and the broad public health benefits of immunisation. Importantly, expanding beyond COVID-19 coverage sends a clear signal that the government is fully invested in public well-being and stands behind its recommended immunisations. In today's climate of heightened vaccine awareness and hesitancy, a transparent, no-fault compensation framework helps build confidence and faith in national vaccination programmes. It also aligns with the broader social contract: those who accept the societal good of vaccination should not be left unprotected if rare adverse events occur.

Discussion questions

1. Why does the absence of a broad vaccine injury compensation framework pose risks to public trust in Singapore's immunisation programmes?
2. How do the funding and causality standards in Japan, Taiwan, and Thailand inform potential reforms for Singapore's existing VIFAP?
3. What factors should policymakers prioritise-financial sustainability, comprehensive coverage, or administrative simplicity? Can these goals be balanced?
4. What are the ethical justifications for establishing a comprehensive, no-fault compensation scheme, and how might these influence policy design?
5. How can the government ensure long-term sustainability of a national vaccine compensation fund without burdening patients, undermining the pharmaceutical industry, or straining public budgets?

Appendix

Comparison of National Vaccine Injury Compensation Frameworks for Singapore, Japan, Taiwan and Thailand

Country	Framework Overview	Administration	Eligibility	Benefits
Singapore	Operates a Vaccine Injury Financial Assistance Programme (VIFAP) specifically for national **COVID-19 vaccines only**	Managed by the Ministry of Health (MOH), adjudication handled by an independent clinical panel appointed by MOH	Covers serious side effects resulting from the COVID-19 vaccines administered in Singapore (that required hospitalisation); causality determined by an independent clinical panel	- Provides lump-sum payments based on the severity of the injury or outcome - The framework does not cover non-COVID vaccines; other vaccine-related injuries rely on general healthcare and insurance coverage
Japan	Governed by the Vaccination Act, with the Health Damage Relief System established in 1977	Managed by the Ministry of Health, Labor, and Welfare, deliberations handled by the Disease and Disability Review Board	Covers injuries, disabilities, and deaths resulting from routine vaccinations for Category A and B diseases and temporary vaccinations; claims for Category B diseases have specific filing deadlines for compensation claims	- Compensation includes medical expenses, nursing pensions for disabled children, disability pensions, lump-sum death payments, funeral expenses, and survivor pensions - Compensation is granted *even when causality is not fully established* - Pension payments are considered for ongoing disabilities
Taiwan	Established in 1988, governed by the Infectious Disease Prevention Act and specific regulations for the Vaccine Injury Compensation Fund.	Managed by the Ministry of Health and Welfare, with the Taiwan Center for Communicable Diseases (CDC) handling administrative duties; the Vaccine Injury Compensation Programme (VICP) Working Group conducts deliberation	Covers injuries, disabilities, severe illnesses, and other adverse reactions from routine, compulsory, self-paid, specially imported, off-label, and post-exposure vaccines; claims must be filed within five years of injury or within two years of recognising the injury's cause	- Compensation is tiered based on the severity of injury and the causal relationship - Payments are made in lump sums, with specific compensation ranges for death, disabilities, severe illnesses, and other adverse reactions - The Compensation Relief Fund is financed by a premium on vaccines, allowing flexibility and sustainability in funding; compensation amounts vary widely based on the level of severity and established causality
Thailand	Operates a no-fault compensation system for medical accidents established in 2004 under the National Health Security	Managed by the NHSO; claims reviewed by a small expert subcommittee (including physicians) for	Covers a broad range of medical injuries—including those from vaccinations—without requiring proof of negligence; claimants must show a plausible	- Preliminary compensation offered for immediate financial relief; final compensation determined after further review - Tiered payouts range

	Office (NHSO); expanded in 2021 to cover COVID-19 vaccine-related injuries	causality determinations	link between their injury and the vaccine or medical procedure	from approximately 100,000 to 400,000 baht (S$4,000–S$16,000), depending on severity or permanence of the injury - Funded primarily by the national treasury; claimants can appeal decisions or seek further legal recourse if dissatisfied