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COVID-19 Vaccine Injury Compensation Claims in Israel: Characteristics, Approval Rates, and Factors Associated with Compensation

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Abstract

Background

Vaccine-injury compensation programs (VICPs) are an essential component of national immunization programs, yet little data has been published regarding the characteristics of submitted claims or factors associated with compensation decisions. We analyzed all COVID-19 vaccine injury compensation claims (VICC) submitted and assessed in Israel.

Methods

We conducted a cross-sectional study of all COVID-19 VICC submitted between February 2021 and March 2026. Data from all adjudicated claims were retrospectively analyzed under MoH Helsinki Committee approval (#008-2026). Standardized demographic, clinical, and causality assessment data were collected by all adjudicating specialists. Factors associated with claim approval were evaluated using univariate and multivariable analyses.

Results

Overall, 313 claims submitted by 268 individuals were adjudicated by five specialists; 69 (22%) claims involving 67 (25%) individuals were approved for compensation. Approval was independently associated with the absence of a relevant prior comorbidity (aOR 0.3, $p = 0.022$), claims following the first two vaccine doses (aOR 0.3 for ≥ 3 vs. 1–2 doses, $p = 0.013$), and a shorter interval from vaccination to symptom onset (aOR 0.97/day, $p = 0.001$). Approval rates did not differ according to adjudicating specialist, legal representation, sex, ethnicity, psychiatric comorbidity, vaccine type, or injury severity. The most frequently compensated conditions included myocarditis/pericarditis (n = 52 claims, 42% approved), facial palsy (n = 18, 44%), and inflammatory skin diseases (n = 14, 57%), whereas no cardiovascular, thrombotic, or neoplastic conditions were approved. Compensation decisions were strongly associated with established causality assessment criteria, including temporal association, absence of alternative explanations, and supportive epidemiological evidence.

Conclusions

Approximately 40 COVID-19 VICC were submitted per million vaccinated individuals in Israel, of which one-quarter were approved. Compensation decisions were consistently associated with established causality assessment principles rather than demographic or procedural factors. These findings provide the first comprehensive description of the Israeli COVID-19 VICP and contribute to greater transparency regarding vaccine injury compensation.

Introduction

Mass vaccination against coronavirus disease 2019 (COVID-19) represented one of the largest public health interventions in modern history. By 2023, more than 13 billion vaccine doses had been administered worldwide, resulting in substantial reductions in severe disease, hospitalization, and mortality. Although COVID-19 vaccines demonstrated a very favorable safety profile in both clinical trials and post-marketing surveillance, concerns regarding rare adverse events following immunization (AEFI) emerged. These included well-established associations such as myocarditis following mRNA vaccines and vaccine-induced immune thrombotic thrombocytopenia following adenoviral-vector vaccines, as well as numerous other reported conditions for which evidence of causality remained uncertain.

To maintain public trust in vaccination programs, some countries have legislated vaccine injury compensation programs (VICPs), which provide financial support to individuals who experience serious vaccine-related injuries [1–3]. These programs are generally based on a “no-fault” principle, whereby compensation can be awarded without requiring proof of negligence by manufacturers, healthcare providers, or public health authorities. Beyond supporting affected individuals, VICPs are considered an important component of vaccine policy and societal solidarity, helping balance the societal benefits of vaccination with the acceptance of rare but potentially serious adverse outcomes. In addition, VICP’s offer protection from individual lawsuits to vaccine manufacturers, thereby lowering vaccine costs and ensuring adequate supply [3].

The unprecedented scale of COVID-19 vaccination led many countries to adapt existing compensation systems or establish dedicated mechanisms for COVID-19 vaccine injury claims. However, substantial heterogeneity exists between national programs regarding eligibility criteria, evidentiary standards, adjudication processes, and compensation rates. Published data from countries including Taiwan [4], Canada [5], France [6], Australia [7], Japan [7], Singapore [7], Thailand [8], and the United States [9] have demonstrated marked differences in approval rates and case characteristics. Nevertheless, most reports focus primarily on aggregate approval statistics, while detailed analyses of the clinical, demographic, and causality-assessment factors associated with claim adjudication remain scarce.

Israel launched one of the world's earliest and most intensive COVID-19 vaccination campaigns, relying almost exclusively on the BNT162b2 mRNA vaccine (Comirnaty). In February 2021, COVID-19 vaccines were added to the Israeli Vaccine Injury Compensation Law, originally enacted in 1989. Under the Israeli system, claims submitted to the ministry of Health are initially evaluated by medical specialists who perform individualized causality assessments. Most claims are resolved through this administrative process rather than formal legal proceedings. Consequently, despite the high public interest surrounding vaccine safety, little information has been publicly available regarding the nature of submitted claims, their outcomes, or the factors influencing adjudication decisions.

The present study aimed to provide a comprehensive analysis of all COVID-19 vaccine injury claims assessed in Israel between 2021 and 2026. Specifically, we sought to characterize the demographic and clinical features of claimants, describe the spectrum of claimed injuries, determine approval rates, and

identify factors associated with compensation decisions. In addition, we evaluated the role of established causality-assessment criteria in the adjudication process. By increasing transparency regarding vaccine injury compensation, these findings may contribute to a better understanding of post-vaccination safety concerns and support public confidence in vaccination programs.

Methods

This was a cross-sectional study of factors associated with claim approval in a national COVID-19 vaccine injury compensation program.

Description of the settings and the legal situation:

A vaccine injury compensation program law was legislated by the Israeli parliament in 1989. The law provides financial compensation to individuals who sustain permanent disability attributable to vaccination. According to the law, a legal committee that includes a judge and two physicians with relevant expertise can approve a claim if there is a causal relationship between vaccination and the claimed injury. The compensation is then given according to the degree of disability, with a maximum of ~ 1,048,000 NIS (~ 310,000 EUR, last updated at July 2024). The committee's decision can be appealed in a district court. Originally, the law focused on childhood vaccines (DTP, polio, MMR, Hib, HBV), but in February 2021, shortly after the onset of the Israeli COVID-19 vaccination campaign, COVID-19 vaccines were added to the law.

Since the legislation of the vaccine injury compensation law, a pragmatic mechanism was implemented for a claim adjudication. Each claim is received by the Israeli national insurance company, and a single physician with relevant expertise evaluates and adjudicates it according to a causality assessment. There are no guidelines for this process, or a pre-specified list of recognized injuries, and adjudication is performed using each specialist discretion, based on current literature and expertise. If the injury is adjudicated as vaccine-related, the claimant gets directly compensated, without the need for the legal committee to assemble and discuss the claim. The compensation fee is determined according to the degree of disability. If the claimed injury is deemed non-related to the vaccine, it is rejected, while preserving the claimant's right to seek formal review by the legal committee. With this mechanism the majority of claims are not evaluated in court, and data on them is not available to the general public.

Included cases and data extraction: All claims concerning COVID-19 vaccine-injuries from February 2021 to March 2026 were included. A claim was defined as a request for compensation related to a specific medical condition. Individuals could submit more than one claim if multiple distinct injuries were alleged. Data from each claim assessment were extracted by the assessing specialist using a common standartized questionnaire. Extracted data included baseline demographic and clinical details, parameters related to the administered vaccines and the claimed medical condition that ensued. In addition, the specialists recorded their causality assessment using defined criteria including: temporal association, biological plausibility, alternative causes for the injury, adverse events after additional doses, improvement with time, prior reports on the specific condition in the medical literature and

findings from epidemiological studies assessing causality. The Naranjo score, used originally to assess the degree of causality for adverse events of medications [10] was calculated for each claim for the purpose of the study, although not used in the adjudication process.

Ethics: Identified data was available only to the assessing specialist during the original causality assessment. Study data was de-identified prior to analysis. The study was approved by the central Helsinki committee of the Israeli Ministry of Health (#008-2026), and informed consent was waivered. Clinical trial number: not applicable.

Statistical analysis: Categorical variables were summarized as frequencies and percentages, and compared between approved and rejected claims using chi-square and Fisher's exact tests, and continuous variables were summarized as mean (SD) or median (IQR), and compared using independent samples t-test or Mann-Whitney test. The association between ordinal variables and claim approval was studied using the Cochran-Armitage trend test. Logistic regression was used to study the independent association between claim approval and potential predictors. As multiple claims could be filed by a single individual, data was collected per claim. For the analysis of individual-unique factors (e.g. age and sex), claims were treated as approved if ≥1 claim was approved. For claim-unique factors (e.g. injury severity or diagnosis) only individuals with a single claim were analyzed. NCSS 2026 v26.0.3 software was used for analyses.

Results

Overall, 313 claims submitted by 268 individuals were included. Five specialists adjudicated these cases. Four were infectious diseases experts and one was a rheumatologist who adjudicated a single claim. More than half of claims were evaluated in 2025, and 77% were filed using a private attorney. Most (87%) individuals had a single claim, 10%, 3% and 0.4% had 2–4 claims, respectively. The sex distribution was equal, the mean age was 46±17 years, 90% were Jews, and 9% were Arabs. Most individuals (70%) had prior comorbidities, and in 43% that comorbidity was assessed as related to the claim (being a risk factor for the medical condition of the claim or might clinically present as the condition of the claim). Nevertheless, most (88%) individuals had no prior disability. In 20% there were either a psychiatric comorbidity or the use of psychiatric medications. The injury was claimed to result after the first vaccine dose in 24% of individuals, and in 47%, 25%, 3%, and 1% after the 2nd, 3rd, 4th and 5th doses, respectively. Nearly all claims involved the BNT162b2 (Comirnaty, Pfizer) vaccine, with only 5 and 1 claims related to Spikevax (Moderna) and Vaxzevria (AstraZeneca), respectively. Overall, the claimed injuries were mostly clinically significant, with 63% of them resulting in emergency department visit, 50% in hospitalization, 33% of them in a disability impeding work or daily activities, and in 8 cases of death.

Claim approval rate

At least one claim was approved for 67 individuals (25%). A univariate analysis for association of factors and approval rate is displayed in Table 1. Approval was associated with an earlier year of claim

assessment, younger individuals, lack of a prior comorbidity related to the claim, lack of prior disability, claims related to the first 2 vaccine doses, and a shorter time from the last vaccine dose to symptom onset: 5 (interquartile range [IQR] 3–14) days vs. 21 (IQR 5–90) days. There was no association between approval rate and legal assistance, number of claims per individual, sex, ethnicity, psychiatric comorbidities, vaccine type, timing of the first dose related to the onset of the vaccination campaign, and the severity of the injury. In addition, there was no statstical difference in the approval rates between the different adjundicating specialists. In a multivariate analysis for demographic and clinical parameters, approval rate was found to be associated with lack of prior relevant comorbidities, claims after the first 2 doses and a shorter time to symptom onset (see Table 2).

Table 1
Comparison between approved and rejected COVID-19 vaccine injury claims – demographic and clinical data

Category	Parameter		Approved claims	Rejected claims	*p* value
N			69 claims, 67 individuals (66 with 1 claim, 1 with > 1 claim)	244 claims, 201 individuals (173 individuals with 1 claim, 28 with > 1 claim)	
Claim application and allocation to specialist	Specialist assessing claim[a]	1	50/171 (29.2%)	121/171 (70.8%)	0.1
		2	4/25 (16%)	21/25 (84%)	
		3	8/50 (16%)	42/50 (84%)	
		4	5/21 (23.8%)	16/21 (76.2%)	
		5	1/1 (100%)	0/1 (0%)	
	Claim represented by an attorney[a]	Yes	49/202 (24.3%)	153/202 (75.7%)	0.45
		no	18/62 (29%)	44/62 (71%)	
	Year of claim assessment[a]	2022	9/15 (60%)	6/15 (40%)	**< 0.01**
		2023	15/48 (31.2%)	33/48 (68.8%)	
		2024	9/46 (19.6%)	37/46 (80.4%)	
		2025	32/140 (22.9%)	108/140 (77.1%)	
		2026	3/18 (16.7%)	15/18 (83.3%)	
	Number of claims per individual patient[a]	1	60/233 (25.8%)	173/233 (74.2%)	0.67
		2	6/26 (23.1%)	20/26 (76.9%)	
		3	2/8 (25%)	6/8 (75%)	

Category	Parameter		Approved claims	Rejected claims	*p* value
		4	0/1 (0%)	1/1 (100%)	
Demographics	Age, mean±SD, years[a]		42.2±16.5	47.2±17.5	**0.04**
	Sex[a]	Male	37/142 (26.1%)	105/142 (73.9%)	0.79
		Female	31/126 (24.6%)	95/126 (75.4%)	
	Ethnicity[a]	Jewish	58/241 (24.1%)	183/241 (75.9%)	0.26
		Arab	9/24 (37.5%)	15/24 (62.5%)	
		Other	0/2 (0%)	2/2 (100%)	
	Any comorbidity[a]	yes	45/188 (23.9%)	143/188 (76.1%)	0.61
		No	21/78 (26.9%)	57/78 (73.1%)	
	Comorbidity related to the claim[b,c]	Yes	16/88 (18.2%)	72/88 (81.8%)	**0.02**
		No	43/135 (31.9%)	92/135 (68.1%)	
	Psychiatric comorbidity[a,d]	Yes	12/53 (22.6%)	41/53 (77.4%)	0.63
		No	55/213 (25.8%)	158/213 (74.2%)	
	Disability status prior to vaccination[a]	no disability	64/230 (27.8%)	166/230 (72.2%)	**< 0.01**
		mild disability not interfering with daily activities	1/16 (6.3%)	15/16 (93.7%)	
		moderate disability interfering with daily activities	0/11 (0%)	11/11 (100%)	

Category	Parameter		Approved claims	Rejected claims	*p* value
		severe disability	0/3 (0%)	3/3 (100%)	
Vaccination	type of vaccine[a]	Pfizer (mRNA)	66/262 (25.2%)	196/262 (74.8%)	0.7
		Moderna (mRNA)	2/5 (40%)	3/5 (60%)	
		AstraZaneca (viral vector)	0/1 (0%)	1/1 (100%)	
	Number of doses prior to the development of the AE	1–2	52/154 (37.7%)	112/164 (68.3%)	**0.001**
		3–5	8/69 (11.6%)	61/69 (88.4%)	
	Timing of dose 1 vaccination after campaign onset[a,e], median (IQR), weeks		6 (4–10)	6 (2–10)	0.94
AE	time from vaccination to symptom onset, median (IQR), days[b]		5 (3–14)	21 (5–90)	**< 0.00001**
	ED visit[b]	Yes	45/166 (27.1%)	121/166 (72.9%)	0.46
		No	15/67 (22.4%)	52/67 (77.6%)	
	Hospitalization[b]	Yes	39/140 (27.9%)	101/140 (71.1%)	0.37
		No	21/93 (22.6%)	72/93 (77.4%)	
	Disability resulting from the AE[b]	None	12/62 (19.4%)	50/62 (80.6%)	0.72
		Mild, not interfering with work and daily activity	26/91 (28.6%)	65/91 (71.4%)	
		Moderate, interfering with work but	11/33 (33.3%)	22/33 (76.7%)	

Category	Parameter		Approved claims	Rejected claims	*p* value
		not daily activity			
		Severe, interfering with daily activity	6/37 (16.2%)	31/37 (83.8%)	
		Death	3/8 (37.5%)	5/8 (62.5%)	

Abbreviations: SD, standard deviation; AE, adverse event ; IQR, interquartile range; ED, emergency department.

[a] Counted per each individual (regardless of the number of claims).

[b] Counted per each claim, only for individuals with one claim.

[c] Any comorbidity that can manifest as the injury or that the injury might reflect an exacerbation of.

[d] Diagnosis of a psychiatric illness or receipt of psychiatric medications.

[e] COVID-19 vaccination campaign onset in Israel was on December 20, 2020

Table 2
multivariate analysis of demographic and clinical parameters related to claim approval

Term		Adjusted OR	p value
Year of claim assessment (compared to 2022)	2023	1.03 (0.22–4.87)	0.970
	2024-6	0.3 (0.1–1.4)	0.125
Comorbidity related to the claim		**0.3 (0.1–0.9)**	**0.022**
Age (per year)		0.98 (0.96-1.00)	0.098
Disability status prior to vaccination		0.2 (0.02–1.4)	0.100
Number of doses prior to the development of the AE (≥3 doses vs. 1–2)		**0.3 (0.1–0.8)**	**0.013**
Time from vaccination to symptom onset (per day)		**0.97 (0.95–0.99)**	**0.001**

Abbreviations: OR, odds ratio; AE, adverse event

Diagnoses

The diagnoses of the claimed injuries were grouped into logical categories (see Fig. 1). Approval rates of > 30% were noted for inflammatory and autoimmune skin and neurologic diseases and for myocarditis and pericarditis. Approval rates lower than 30% were noted for other inflammatory and autoimmune diseases, allergic disorders, chronic pain disorders (including fibromyalgia, small-fiber neuropathy and irritable bowel syndrome), and various orthopedic and neurologic disorders. No claim related to cardiovascular, cerebrovascular, thrombotic or neoplastic disorders was approved. The most common diagnoses and their approval rates (n=total claims, % approved) were perimyocarditis (52, 42%), facial palsy (18, 44%), fibromyalgia (18, 6%), CVA (15, 0%), myocardial infarction (8, 0%), and hearing loss (8, 25%).

Eight claims dealing with mortality after COVID-19 vaccination were evaluated. Three fatalities for which a causal relationship to vaccination was considered sufficiently likely to warrant compensation included cases of toxic epidermal necrolysis, status epilepticus and fatal myocarditis. Five fatalities that were assessed as not related to vaccination included sudden deaths, hemorrhagic strokes and a case of disseminated intravascular coagulation.

Causality assessment process

The associations between different parameters of the causality assessment and the approval rates are shown in Table 3. Approval was associated with a temporal association, biological plausibility, prior reports of the AE, lack of alternative causes and population-based studies that supported causality. Naranjo scores were highly correlated with the approval rates, with 1.9%, 21.4% and 63.3% approval rates for doubtful (≤ 0), possible (1–4), probable (5–8) scores, respectively. No claim was assessed as definitely caused by the vaccination (≥ 9). In a multivariate analysis, odds for approval were 16 and 11-fold higher for a temporal association and population-based studies supporting causality, respectively, and 10 and 20-fold lower for presence of an alternative cause or population-based studies showing lack of causality (see Table 4). There was no correlation with prior reports of the AE.

Table 3
comparison between approved and rejected COVID-19 vaccine injury claims – causality assessment parameters. All data is counted per each claim, only for individuals with one claim.

Category	Parameter		Approved claims	Rejected claims	*p* value
Causality assessment	Temporal association[a]	Yes	59/140 (42.1%)	81/140 (57.9%)	**< 0.0001**
		No	0/64 (0%)	64/64 (100%)	
		Problem onset before vaccination	1/28 (3.6%)	27/28 (96.4%)	
	Biological plausibility	Yes	57/125 (45.6%)	68/125 (54.5%)	**< 0.0001**
		No	3/107 (2.8%)	104/107 (97.2%)	
	Prior reports of the AE after COVID-19 vaccines	Yes	59/177 (33.3%)	118/177 (66.7%)	**< 0.0001**
		No	1/55 (1.8%)	54/55 (98.2%)	
	Improvement with time	Yes	35/120 (29.2%)	85/120 (70.8%)	0.27
		No	25/110 (22.7%)	85/110 (77.3%)	
	Relapse or exacerbation after another dose	Yes	48/160 (30%)	112/160 (70%)	0.07
		No	9/47 (19.2%)	38/47 (80.8%)	

Abbreviations: AE, adverse event

[a] Presentation of injury within a period assessed by specialist to be associated with the vaccination.

[b] Including well-accepted epidemiological methodologies, such as comparative cohort studies, self-controlled case series, etc.

[c] Based on the Naranjo score system for causality assessment: previous conclusive reports on the specific AE (+ 1 for yes, 0 for no); temporal association (+ 2 for yes, -1 for no); improvement with time (+ 1 for yes, 0 for no); AE reappearing after another vaccine dose (+ 2 for yes, -1 for no, 0 for no additional dose); alternative causes (-1 for yes, + 2 for no), AE confirmation with objective tests (+ 1 for yes, 0 for no).

Category	Parameter		Approved claims	Rejected claims	*p* value
		No additional dose	3/26 (11.5%)	23/26 (88.5%)	
	Alternative causes	Yes	16/150 (10.7%)	134/150 (89.3%)	**< 0.0001**
		No	43/82 (55.4%)	39/82 (47.6%)	
	AE documented by objective tests	Yes	49/181 (27.1%)	132/181 (72.9%)	0.31
		No	10/50 (20%)	40/50 (80%)	
	Population-based studies results[b]	Consistent with causation	31/42 (73.8%)	11/42 (26.2%)	**< 0.0001**
		Inconsistent	20/43 (46.5%)	23/43 (53.5%)	
		Consistent against causation	1/109 (0.9%)	108/109 (99.1%)	
		No data	8/37 (21.6%)	29/37 (78.4%)	
	Naranjo score[c] category	Doubtful (≤ 0)	1/52 (1.9%)	51/52 (98.1%)	**< 0.0001**
		Possible (1–4)	27/126 (21.4%)	99/126 (78.6%)	
		Probable (5–8)	31/49 (63.3%)	18/49 (36.7%)	
		Definite (≥9)	0	0	

Abbreviations: AE, adverse event

[a] Presentation of injury within a period assessed by specialist to be associated with the vaccination.

[b] Including well-accepted epidemiological methodologies, such as comparative cohort studies, self-controlled case series, etc.

[c] Based on the Naranjo score system for causality assessment: previous conclusive reports on the specific AE (+ 1 for yes, 0 for no); temporal association (+ 2 for yes, -1 for no); improvement with time (+ 1 for yes, 0 for no); AE reappearing after another vaccine dose (+ 2 for yes, -1 for no, 0 for no additional dose); alternative causes (-1 for yes, + 2 for no), AE confirmation with objective tests (+ 1 for yes, 0 for no).

Table 4
multivariate analysis of parameters related to causality assessment of claim approval

Term		Adjusted OR	p value
Temporal association		**16.0 (1.7-147.3)**	**0.014**
Biological plausibility		6.39 (0.9–43.8)	0.059
Prior reports of the AE after COVID-19 vaccines		1.7 (0.1–19.1)	0.657
Relapse or exacerbation after another dose	No additional dose given vs. no	0.5 (0.1–3.1)	0.451
	Yes vs. no	0.2 (0.02–1.9)	0.159
Alternative causes		**0.1 (0.03–0.3)**	**< 0.001**
Population-based studies results (vs. no data)	**Consistent with causation**	**11 (2.3–53.8)**	**0.003**
	Inconsistent	3.4 (0.7–15.3)	0.118
	Consistent against causation	**0.05 (0.004–0.59)**	**0.017**

Discussion

VICP's are considered an essential part of vaccination policies in many countries, recognized by the World Health Organization [11]. These programs are based on the recognition, that although vaccinations have major public and individual health benefits, and although vaccines are authorized after extensive safety evaluations, they can carry small individual risks for harm. Providing compensation to individuals who experience vaccine-related injury reflects a principle of social solidarity: individuals accept a small risk associated with vaccination while contributing to a broader public health benefit. No-fault compensation also provides an alternative to potentially lengthy and costly litigation. The first country to establish a VICP was Germany in 1961, in response to a supreme court verdict concerning vaccine-related injury [1]. The US have established a VICP in 1986, also following increased litigation during the 1970's and 1980's, that has endangered future vaccine development and manufacturing [12] .

We analyzed 313 COVID-19 vaccine injury compensation claims assessed in Israel between 2021 and 2026. By the end of 2025, approximately 6.75 million Israelis had received at least one dose of a COVID-19 vaccine, corresponding to approximately 40 compensation claims per million vaccinated individuals. Overall, 25% of claims were adjudicated as vaccine-related and approved for compensation. Israel's

COVID-19 VICP demonstrated an overall approval rate of 25%, placing it in line with international benchmarks reported for COVID-19 vaccines, varying from 1.8% for the American Countermeasures Injury Compensation Program (CICP) [9], 3% for the United Kingdom Vaccine Damage Payment Scheme (VDPS) [13], 13% for the Taiwanese Vaccine Injury Compensation Program [4, 13], 20% for the Canadian Vaccine Injury Support Program (VISP) [5, 13], 18% for the Australian COVID Vaccine Claim Scheme [7], 27% for the French national compensation program (ONIAM) [6, 13], 38% for the Vaccine Injury Financial Assistance Programme for COVID-19 Vaccination (VIFAP) in Singapore [7], 84% for Thailand [7, 8], and 74% for the Japanese Health Damage Relief System [7, 13]. The Direct comparison of approval rates between national vaccine injury compensation programs should be interpreted cautiously because programs differ substantially in their legal framework, evidentiary standards, eligibility criteria, and compensation thresholds. Beyond approval rates, compensation programs differ substantially in their institutional design and standards for establishing causality. Some programs use predefined lists or tables of recognized vaccine-related injuries and specified time intervals, whereas others rely primarily on individualized causality assessment. Programs also differ in whether adjudication is performed by dedicated compensation agencies, expert committees, or individual medical assessors, and in the evidentiary threshold required for compensation. These structural differences are particularly relevant when interpreting international variation in approval rates. The Israeli system is characterized by individualized medical assessment without a predefined injury table, followed, if necessary, by the possibility of formal review by a legal committee.

A few parameters were associated with higher odds of claim approval: a shorter time from vaccination to symptom onset, which seems obvious since the suggestion of temporal association is a key criterion for causality assessment. Injuries that occurred after the first two vaccine doses were 3 times more likely to be approved. Indeed, the most established causally linked AE to COVID-19 mRNA vaccines, perimyocarditis, was identified mainly after the first one or two doses [14–18], with conflicting evidence for causality after subsequent boosters [19–22]. One AE that was actually reported more frequently after booster doses was chronic spontaneous urticaria [23, 24]. Patients with a prior relevant comorbidity had lower approval rates, probably because they had an alternative explanation for their AE. A similar finding was reported from the Taiwan VICP data [4]. A younger age was also associated with approval, although with marginal statistical significance in multivariate analysis. This finding might stem from a lower age of perimyocarditis cases (mean 35 vs. 48 years for the rest of individuals), and was also reported elsewhere [4]. In our study, the approval rates declined between 2022–2026, but this was not found significant after correcting for other parameters, which might be explained if stronger claims were submitted earlier.

More importantly, various factors that might lead to biases in the adjudication process did not seem to influence it, including presence or absence of legal representation, the number of claims per individual, sex, ethnicity, prior psychiatric comorbidity, and the severity of the injury. This, and the lack of significant differences between different specialists, supports the consistency of the adjudication process across specialists in our study.

The most frequently compensated conditions included injuries that were correlated to mRNA COVID-19 vaccines in multiple epidemiologic studies, although sometimes with conflicting findings, including perimyocarditis [14–18, 20], facial palsy [25–30], and chronic spontaneous urticaria [23, 24, 31]. No claims concerning thrombotic, cardiovascular and cerebrovascular events were approved, as mRNA vaccines, which were used almost exclusively in Israel, were not found to be associated with any of these in multiple studies [28,30,32–35]. This is in contrast with adenoviral-vector vaccines, which were associated with thrombotic thrombocytopenic events [36].

Analysis of the causality assessment procedure showed that decisions were based on well-established factors, including temporal associations, biological plausibility, absence of alternative causes for the injury and reliance on population-based epidemiologic studies. In contrast, the mere existence of published case reports or case series with similar events was not independently associated with claim approval. This likely reflects the large number of adverse events reported in temporal association with COVID-19 vaccination during an unprecedented global vaccination campaign involving billions of doses. Although such reports may generate important safety signals, they generally provide limited evidence of causality in the absence of supporting epidemiological data. The Naranjo score was originally developed for adverse drug reactions and has not been specifically validated for vaccine injury compensation assessments. Nevertheless, when adopting the Naranjo score to estimate causality, no claim was found to be definitely caused by vaccination, with approved claims assessed as possible or probable vaccine-related. Although no formal guidelines for approval are specified by the Israeli VICP law, assessments were performed with a fairly low threshold for approval, lower than usually used in epidemiologic studies, and considerations influencing adjudication tended to emphasize the individual injury and suffering over very stringent scientific findings.

The strengths of this study include a detailed analysis of multiple parameters in each claim, rather than only aggregate approval rates that are reported from most other VICPs, and the inclusion of all claim assessments during the study period. Nevertheless, it has some important limitations. Data were collected retrospectively, and therefore might incorporate some recall biases, and collection was performed by the assessing specialist, which might affect its objectivity, although this is expected to bias the analysis of causality assessment, and not more robust demographic and clinical parameters. The two analyses were therefore performed separately. As Comirnaty (Pfizer) was used almost exclusively in Israel, the generalizability of the findings for other vaccines is limited.Claim approval in other countries might be different due to varied legal standards, compensation thresholds, and adjudication procedures. In addition, the study evaluated adjudication outcomes rather than the broader performance of the compensation program. We did not have information on time from claim submission to resolution, administrative costs, compensation amounts, subsequent appeals or litigation, claimant satisfaction, or public perceptions of the program. We therefore cannot directly determine whether the program improved vaccine confidence, reduced litigation, or achieved its broader societal objectives.

A previous qualitative analysis of the Israeli VICP was published during the COVID-19 pandemic in 2021, but before the VICP began analyses of COVID-19 vaccine injury claims [37]. This analysis, based on the

history of childhood vaccination injury claims, had described the process as difficult, adversarial, with little or no claims compensated in the end. The authors have therefore concluded that the implementation of the VICP law in Israel has failed to achieve its social goals. That study was limited to analysis of the process in court. Nevertheless, almost all cases that are compensated are settled after the claim adjudication between the claimant and the national insurance company. These processes, which represent most claims, are far less transparent to the public. The claims that end-up in court are limited to claims rejected by the professional adjudicator, and therefore their analysis is heavily biased for selection. Our study is the first to describe the real situation including all adjudicated cases. Our findings provide a different perspective on the functioning of the program. One-quarter of claimants received compensation, and approval was not associated with several demographic or procedural characteristics, including sex, ethnicity, legal representation, or the adjudicating specialist. Although these findings cannot establish that the adjudication process was free of bias, they provide some evidence of consistency across the measured characteristics. The lack of an association between legal representation and claim approval may also suggest that legal representation was not necessary to obtain a favorable decision through the administrative adjudication pathway. However, our data did not include claimant experiences, procedural burden, time to resolution, or satisfaction with the process, and therefore cannot determine whether claimants perceived the process as accessible or non-adversarial.

Public transparency of these data might have some unbeneficial consequences. First, reporting of compensation for various adverse outcomes might serve vaccine-hesitant individuals as proof for the risk of vaccination, although many of the compensated conditions were not clearly proven to be associated with vaccination. Second, reporting might lead to more future claims and greater public spending on compensation, but this consequence could be argued to be fair, as increased awareness will enable individuals to practice their legal rights. Nevertheless, greater transparency regarding the VICP process and its outcomes may have important benefits. Public acknowledgment that rare vaccine-related injuries can occur, together with a transparent mechanism for evaluating and compensating such injuries, may demonstrate institutional accountability and the principle of reciprocity between the state and individuals participating in vaccination programs. Such transparency should be accompanied by careful risk communication emphasizing the distinction between an adverse event occurring after vaccination and an event shown to be causally related to vaccination. Although our study did not assess vaccine confidence or public trust directly, transparent reporting of both accepted and rejected claims, together with the criteria underlying these decisions, may contribute to informed public discussion and institutional trust [11] .The experience of the COVID-19 pandemic also provides lessons for future mass vaccination campaigns. When novel vaccines are deployed rapidly and to very large populations, rare adverse events may emerge only after widespread use, while public concern about vaccine safety may develop rapidly. A compensation mechanism should therefore be incorporated into pandemic vaccination preparedness rather than developed only after safety concerns emerge. Such a mechanism should include a clearly defined and accessible claims process, timely expert adjudication, transparent causality criteria that can be updated as epidemiological evidence accumulates, and periodic public reporting of claims and outcomes. The Israeli experience suggests that individualized expert

assessment can accommodate evolving scientific evidence even in the absence of a predefined list of compensable injuries. At the same time, greater standardization and transparency of adjudication criteria could improve consistency, accountability, and public understanding during future vaccination campaigns.

Conclusions

This study provides the first comprehensive description of the Israeli COVID-19 vaccine injury compensation program, including administrative adjudications that have previously been largely unavailable for public analysis. Approximately one-quarter of claimants received compensation, and adjudication decisions were strongly associated with established causality-assessment criteria, while approval was not associated with several demographic and procedural characteristics. These findings provide new information on the functioning of a national no-fault compensation mechanism during a mass vaccination campaign. The Israeli experience highlights the potential importance of accessible compensation mechanisms, transparent reporting, consistent causality assessment, and adaptability to evolving scientific evidence. Incorporating these principles into preparedness planning may strengthen the accountability and transparency of vaccination programs during future public health emergencies.

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Author contributions

TBN conceived the study, collected data, designed the analytical framework, and drafted the initial manuscript. SS, GR, and AEM collected data and critically revised the manuscript. All authors have reviewed and approved the final manuscript.

Competing interests

Tal Brosh-Nissimov reports a relationship with Merck & Co Inc that includes: consulting or advisory. Tal Brosh-Nissimov reports a relationship with GSK that includes: consulting or advisory. Tal Brosh-Nissimov reports a relationship with Pfizer Inc that includes: consulting or advisory. Tal Brosh-Nissimov reports a relationship with Gilead Sciences Inc that includes: speaking and lecture fees. Tal Brosh-Nissimov reports a relationship with Medison Israel that includes: speaking and lecture fees. Galia Rahav reports a relationship with Merck & Co Inc that includes: consulting or advisory. Galia Rahav reports a relationship with GSK that includes: consulting or advisory. Galia Rahav reports a relationship with Pfizer Inc that includes: consulting or advisory. Galia Rahav reports a relationship with Gilead Sciences Inc that includes: speaking and lecture fees. Galia Rahav reports a relationship with Medison Israel that includes:

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Data statement

Original data contains sensitive and confidential information and cannot be shared. Additional aggregative data can be requested from the corresponding author.

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Figures

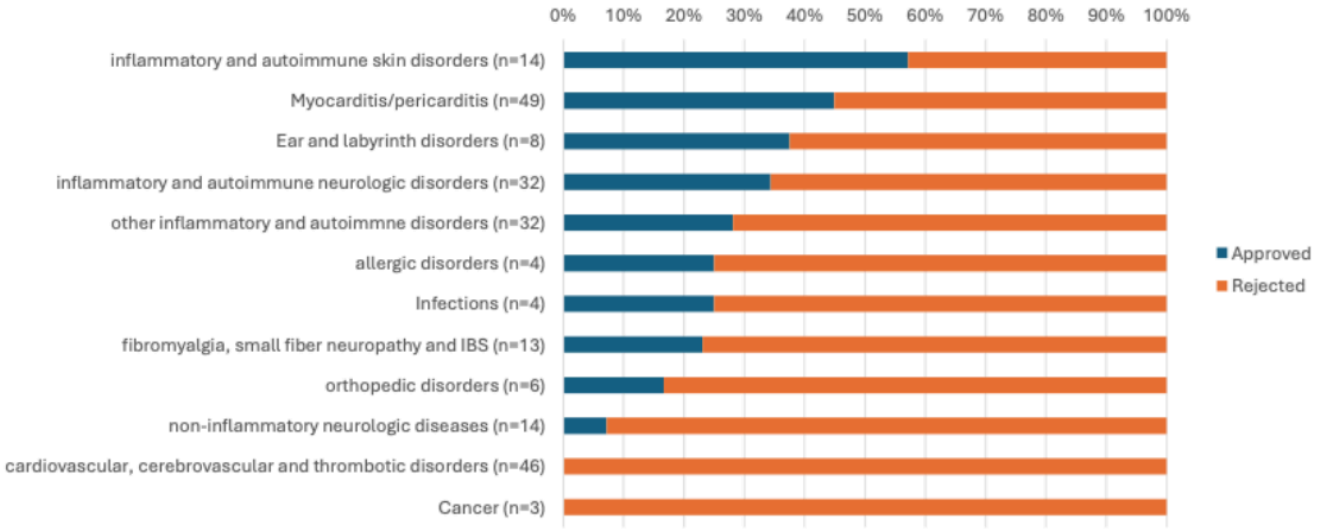


Figure 1

Grouped categories of adverse events, by decreasing rate of approval[a]

Abbreviations: IBS, irritable bowel syndrome

[a] Data in the figure includes only individuals with one claim.