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A QUALITATIVE SOCIO-LEGAL RESEARCH IN DEVELOPING SUSTAINABLE VACCINE INJURY COMPENSATION MECHANISM IN MALAYSIA: ISSUES AND CHALLENGES

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Abstract: Vaccination has been demonstrated to combat severe illnesses to decrease infectious disease effectively. Nevertheless, the possibility of adverse events following immunisation (AEFI), commonly known as vaccine injury cannot be disregarded. Hence, it is reasonable for impacted parties to seek compensation for any injury sustained due to vaccination. However, many are still concerned about the dissatisfaction with the current compensation mechanism for vaccine-induced injuries. Thus, this study aims to examine the current issues and hurdles encountered by vaccine injury compensation mechanisms in Malaysia through legal proceedings, using a qualitative approach, interviews, and document reviews for data collection. The findings found four mechanisms for injured parties to obtain compensation. They are the Civil Law Act 1956, the Consumer Protection Act 1999, the Contracts Act 1950 and the administrative programme. Ten issues have been discovered relating to existing vaccine injury mechanisms. They are the lack of consumer awareness, gaps in consumer protection literacy, strict burden of proof, time-consuming litigation, high cost of litigation, time limitation, defendants' defensiveness, the lacunae in the law and complicated procedure. This study holds great importance regarding enhancing vaccine injury compensation mechanisms. The research proposes remarkable measures to overcome the difficulties associated with vaccine injury compensation mechanisms, with the ultimate goal of attaining social equality that leads to the success of the National Immunisation Programme (NIP) as well as contributing towards the achievement of Sustainable Development Goals (SDG) 16: Promote just, peaceful and inclusive societies.

Keywords: Vaccine injury, compensation, vaccine, VICP, Malaysia.

Introduction

The scientific validity of vaccines has been established in their ability to safeguard against more than 20 dangerous diseases by interacting with the innate immune system, providing protection and reducing the risk of disease acquisition (WHO, 2021a). Malaysia launched the National Immunisation Programme with the diphtheria vaccine in 1950, acknowledging the significance of vaccines in promoting long-lasting public health.

Research findings have revealed instances of vaccine failures across the globe, which have led to catastrophic outcomes for the public. One such example is the withdrawal of the RotaShield vaccine by the World Health Organisation (WHO) in 1999 following the identification of a correlation between rotavirus and intestinal obstruction (CDC, 2001; Murphy *et al*., 2001). In 2007, the Haemophilus influenzae type B (Hib) vaccine underwent recall due to potential contamination with the bacterium Bacillus cereus (Huang *et al*., 2010). The month of August in the year 2021 bore witness to the tragic demise of two Japanese men who had received the second dose of the Moderna COVID-19 vaccine, originating from the same batch. Following this, there were reports of vaccine contamination, leading to the suspension of production of 1.63 million doses of the Moderna COVID-19 vaccine in Japan. Approximately 500,000 individuals had already received the vaccine before discovering the issue (Yu *et al*., 2021; Chooi *et al*., 2022).

Regarding liability in vaccine manufacturing, it is typically the responsibility of the recommending government to provide primary education on vaccine risk (Goldberg, 2022). Access to courts and remedies is crucial for ensuring justice, and plaintiffs can choose from multiple options based on their situation and resources. The ability to access courts and remedies is an essential aspect of access to justice. Typically, medical disputes in Malaysia are resolved through tort law, which operates on a fault-based system, or contract law (Kassim, 2008; Naimat *et al*., 2022), or by demonstrating that the product is defective under the Consumer Protection Act 1999 through product liability (Mokhtar & Ismail, 2013; Roslan *et al*., 2023).

Tort law is the primary governing body for civil claims, which is the only means for those who have sustained injuries to seek compensation. Although there has only been one vaccine injury case in Malaysia, the possibility of severe vaccine injuries taking place in the country cannot be ignored. In Malaysia, the National Pharmaceutical Regulatory Agency of Malaysia (NPRA) received a total of 16,933 AEFI reports from the National Adverse Drug Reaction Monitoring Centre between 2010 and 2021 (NPRA, 2021a). In 2021, there was a surge in AEFI reports with a total of 28,976 cases, of which 1,652 were classified as a serious consequence of COVID-19 vaccines (NPRA, 2021b). Generally, medical malpractice injuries are categorised under tort law, provided that it can be substantiated that the doctor acted negligently or made an error.

Regarding expenses, past encounters with compensation for vaccine-associated injuries indicate that concerns about sustainability are unwarranted, as the costs are typically manageable and predictable. In the meantime, it is crucial for all nations without expected compensation for COVID-19 vaccine-related adverse events to prioritise greater transparency in communication regarding compensation protocols for vaccine-related side effects (Frati, 2022). Thus, concern arises about the likelihood of vaccine litigations leading to unfairness in Malaysia, considering that adversarial legal proceedings can undermine public confidence in the legal system (Kamin-Friedman & Davidovitch, 2021). As a result, this research aims to investigate the mechanism for vaccine injury compensation under Malaysian law and assess the difficulties that affected claimants who have sustained injuries after vaccination to encourage relevant stakeholders to take necessary measures to redress this issue by providing this empirical study.

Conceptual Framework

The function of "compensatory damage" within tort law is a subject that has been explored by Goodin (1989). In various social events, including workplace accidents, victims have sought aid. The concept of compensatory indemnification has been upheld solely in instances of grave fault, thereby necessitating some subjectivity, as posited by Demogue (1918). According to empirical research conducted by McMichael and Viscusi *et al*. (2022), compensatory damage awards are linked to the severity of the injury, which is associated with economic loss. Consequently, the Theory of Compensation presents a comprehensive framework for vaccine injury compensation mechanisms.

In pursuing justice for the victims, the principles of justice, according to Rawls (1999), are derived from a fair agreement or arrangement that considers the similar circumstances of all parties involved, without anyone being able to design principles that exclusively benefit their situation. As such, medicine is considered a public trust and must always uphold its commitment to justice, as Galiatsatos *et al.* (2020) emphasised. Evaluating the extent of procedural justice is a dependable method for gauging claimants' perceptions of their interactions and communications with legal experts throughout the compensation process. Based on procedural justice, a procedure is deemed just if individuals feel at liberty to express their thoughts and emotions and have some degree of control over it. Procedural

justice is often discussed about distributive justice and concerns whether the resolution is fair (Stivers *et al*., 2023).

According to theory, improving the fairness of compensation could increase the claimants' satisfaction. In Malaysia, the resolution of medical disputes is performed through the utilisation of the tort system, which is commonly acknowledged as the fault-based system. The ability of the litigants to present a convincing argument is a determining factor in the outcome of a case adjudicated through the tort system. The legal doctrine of torts concentrates on the responsibility, culpability, or wrongdoing of the defendant rather than the claimant's causation of harm (Bell, 2021). Laws are imperative for consumer protection, as emphasised in Malaysia's consumer protection laws that prioritise paternalism to ensure maximum consumer protection (Zakuan & Ismail, 2021). The authority is responsible for ensuring that consumers can fully exercise their rights. When a consumer purchases and uses a product that subsequently proves to be detrimental to their health, such an individual is deemed to have been denied their right to healthcare. Consequently, the authority must take steps to address such a predicament. Product liability seems to offer a viable solution in situations where a defective product adversely affects the consumer, as observed by Zakuan and Ismail (2021).

Despite resorting to litigation, Malaysia has initiated a no-fault system for compensating vaccine injuries caused by COVID-19 vaccines. Despite its benefits, a no-fault system should not be seen as a complete solution to the drawbacks of litigation, as it brings challenges compared to other methods. Figure 1 scrutinises the principles and assumptions that underpin the framework for compensating vaccine injuries, which have triggered significant controversy related to a prominent issue for this study.

The field of law possesses the potential to contribute towards the attainment of the Sustainable Development Goals (SDG) cohesive vision for worldwide health and progress. Sustainability is an idealised representation of the relationship between nature and society

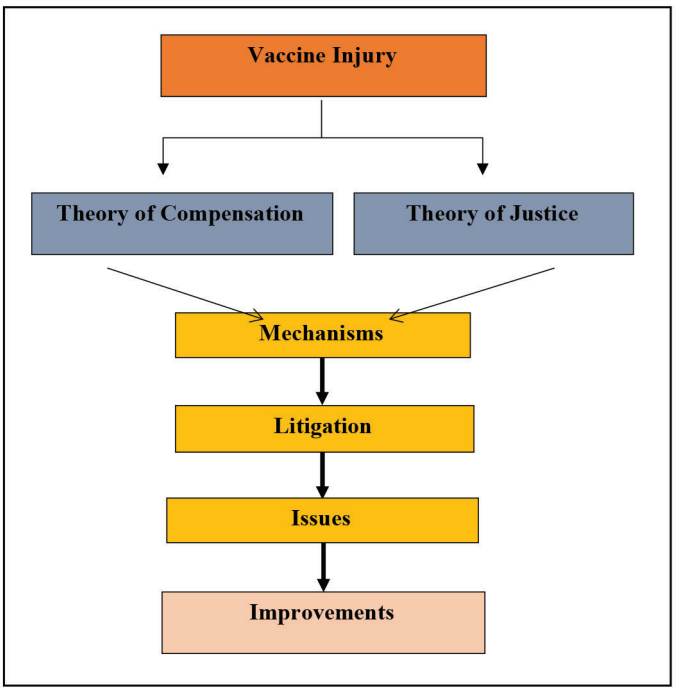

Figure 1: Conceptual framework for developing vaccine injury compensation mechanisms
Source: Author

within specific reference frameworks pertaining to environmental, social, and economic goals. Scholars, researchers, and experts often contend that a system is sustainable owing to its specific aims. Sustainability is often associated with environmental, social, and economic objectives that guide human actions towards a sustainable future (Salas-Zapata & Ortiz-Muñoz, 2019). Thus, each individual is entitled to access affordable and high-quality healthcare services. By ensuring impartiality and accountability in all healthcare systems, the judicial system and the rule of law can effectively achieve truly inclusive healthcare coverage, fulfilling the promise of the SDG to leave no one behind (Gostin *et al*., 2019).

Methodology

This study employs a qualitative methodology to analyse the complexities surrounding the obstacles faced by individuals impacted by vaccination. Qualitative legal research aims to understand and explain the reasons, beliefs and motives underlying people's experiences, while quantitative legal research aims to quantify the research topic, measure and count problems, and then generalize the findings to a larger population (Bhat, 2020). To attain this goal, it is essential to conduct semi-structured interviews, where informants are allowed to express their viewpoints and seek clarifications, thereby creating an environment conducive to revealing more valuable information, including their attitude on sensitive matters which is conducted in this study, as the investigation involves examining existing mechanisms (Kamin-Friedman & Davidovitch, 2021). This fosters an environment conducive to divulging more valuable information, including their stance on delicate matters.

The content analysis process was employed by conducting a comprehensive literature review to locate and identify pertinent information on the legal and conceptual structures governing Malaysia's vaccine injury compensation mechanism. The accomplishment of the study's objectives is facilitated through the process of document review. Considering Malaysia's status as a member of the Commonwealth, the researcher has integrated laws and vaccine injury case law from within Malaysia and other Commonwealth countries like the United Kingdom. This includes the Civil Law Act of 1956, the Consumer Protection Act of 1999, the Consumer Protection Act of 1987 of the United Kingdom, and the Contract Act of 1950. Additionally, this study also evaluates the guidelines for vaccine programmes. Various materials, such as textbooks, journal articles, government reports, newspaper articles, and online databases, were consulted to obtain secondary sources for the literature review.

In preparation for the data collection phase, the interview protocol questions underwent critical examination by a panel of experts to ensure the validity of the interview protocol. Furthermore, the interview questions were designed to generate in-depth responses to the research questions. The present research study was granted the essential approval from the Research Ethics Committee of Universiti Malaysia Terengganu (UMT/JKEPM/2022/103) in June 2022. Moreover, the informed consent form has been signed by all the research informants, thereby providing their explicit authorisation for their involvement in the study. The interview protocol has undergone a validation process. Specifically, a qualitative methodology expert and two legal experts were utilised to validate the interview protocol. The instruments were initially piloted and revised following the conceptual framework and study objectives to explore stakeholder (i.e., legal expert) perspectives on enhancing vaccine injury compensation mechanisms.

A group of ten (10) informants were selected through purposive sampling based on their occupational roles and experience in dealing with consumer issues and product liability. For this study, it was considered sufficient to include 10 informants in the interview process, as this number aligns with the sample size used in previous legal studies conducted by Hennink and Kaiser in 2022. Beyond eight

interviewees, no novel information or data was obtained, thus signifying the attainment of data saturation. Data saturation refers to a stage in the research process wherein no fresh information is extracted from the data, and the data analysis process yields identical results repeatedly (Islam & Aldaihani, 2022).

The research methodology was formulated with due attention to incorporating the opinions and ideas of significant stakeholders, namely legal experts, along with addressing the crucial aspects of the subject in question. In the fourth phase of the data analysis, the primary data obtained from the ten (10) informants who participated in the semi-structured interviews were combined with the content analysis derived from the literature review. In the research, the methodology employed was a case study approach in analysing the qualitative data collected. The analysis entailed the establishment of codes, categories, and pertinent themes that were representative of the informants' perspectives on matters relating to the compensation mechanisms for vaccine injuries. The software application known as ATLAS.ti 22 serves the purpose of analysing data derived from interview transcripts. The ATLAS.ti 22 software application facilitates the process of data analysis by providing a range of features, such as the co-occurrence code, search tool, and network view. These features also promote a better understanding of managing emerging categories of qualitative data and ease the task of code validation, as Ronzani *et al.* (2020) suggested.

Results

The study's findings have revealed that detention centres in Malaysia are confronted with crucial challenges that require prompt attention in managing vaccine injury compensation mechanisms. Moreover, the outcomes underscore the informants' perspective on pertinent compensation for individuals impacted by the vaccine and the difficulties and obstacles they encounter.

The Vaccine Injury Compensation Mechanisms in Malaysia

The results of data analysis indicate that Malaysia lacks specific compensation programmes for vaccine injuries, aside from those provided by the English common law through the civil court. The existing laws in Malaysia, namely the Civil Law Act 1956,

Table 1: Sample selections

Agency	Expertise	Informant
Ministry of Health	Medical product liability	1
Ministry of Domestic Trade and Consumer Affairs (KPDNHEP)	Product liability	2
Tribunal for Consumer Claims Malaysia (TTPM)	Consumer claims	1
Malaysian Mediation Centre (MMC)	Alternative dispute resolution	1
Pharmaceutical Company	Medical product liability	2
Lawyer	Civil claims	1
Judge	Civil claims	1
Academician/Former High Court Judge	Alternative dispute resolution	1
	Total	**10**

Consumer Protection Act 1999, and Contracts Act 1950 may be utilised to seek compensation. Notably, implementing the COVID-19 vaccine has given rise to the Special Financial Assistance Adverse Effects of the COVID-19 Vaccine Programme, which provides aid to recipients affected by the vaccine. The informants cited the mechanisms for claiming compensation under Malaysian law, as illustrated in Figure 2.

Informants, who responded, identified these mechanisms and the data in Figure 3 refers to the number of themes which informants applied. The Civil Law Act of 1956 has been the most frequently cited theme for vaccine damage compensation mechanisms, followed by the Consumer Protection Act of 1999, the administration, and the Contracts Act of 1950. The explanation of the use of these mechanisms is discussed.

i. *Civil Law Act 1956*

All informants cited tort law as one of the available mechanisms for individuals whom vaccines have impacted to pursue compensation. Occasionally, informants employed an alternate phrase rather than the term "tort" in their reply, such as "litigate" or "civil litigation," which explicitly refers to the Civil Law Act 1956. Due to the Civil Law Act of 1956, which originates from common law, legal principles disclosed in judicial decisions have become the foremost foundation of tort law in Malaysia. Malaysian courts have embraced and adhered to established English common law tort regulations when deciding local issues. According to the feedback obtained from the informants, any form of carelessness can be subject to litigation under tort law. The phrase "litigating" referenced by the informants

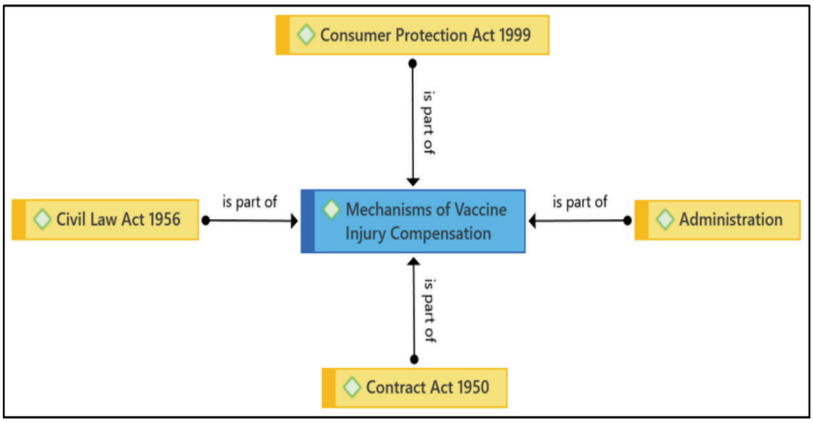

Figure 2: Existing mechanisms for vaccine injury compensation in Malaysia

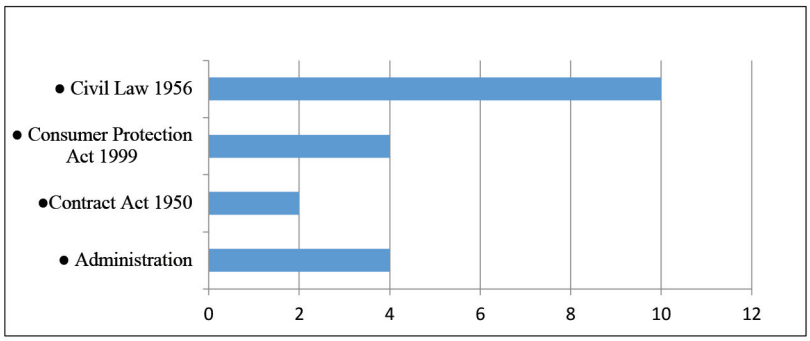

Figure 3: Number of informants who discussed mechanisms involved in vaccine injury compensation

implies that the case will be brought under the framework of the Civil Law Act 1956. The informants provided insight into the concept, which is reflected in their responses.

> "As far as I am aware, we solely use the tort law. There is currently no tribunal or other unique framework. One could file a claim for medical malpractice under tort law. (However) That (the tort law) is what is now accessible as far as I'm aware."
>
> (Informant 8)

> "You have to go to the court and claim. On top of this, you can seek exemplary damages, punitive damages, and all the compensation under the Evidence Act (and other relevant laws)."
>
> (Informant 3)

> Informant 4 asserted that the matter in question pertains to tort liability,
>
> "It is a tort in nature or from a subject matter perspective. It falls under tortious liability."
>
> (Informant 4)

> The case of Donoghue v Stevenson [1932] AC 562 was brought to attention by Informant 7 as the primary precedent for the tort of negligence or one of the most notable decisions in common law.
>
> "Informant 7: …but my opinion is the same. Consumers are protected by other laws, such as the law of tort.
>
> Question: Under the law of tort?
>
> Informant 7: Yes, as decided in the case of Donoghue v. Stevenson (civil claim could be taken to) against the manufacturer…."
>
> (Informant 7)

Lord Atkin, in the landmark case of *Donoghue v Stevenson* (1932) AC 562, introduced and firmly established the concept of the "neighbour principle". This principle, as expounded by Lord Atkin, imposes a legal duty on each and every individual to act in a manner that is reasonable and not likely to cause harm to others in their immediate vicinity. Thus, the "neighbour principle" is deemed a fundamental and indispensable aspect of the law, applicable to all individuals without exception. As the House of Lords stated on 26 May 1932, Lord Atkin's pronouncement on the "neighbour principle" has since become a cornerstone of modern legal jurisprudence.

> "...a manufacturer of products, which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him with no reasonable possibility of intermediate examination and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in an injury to the consumer's life or property, owes a duty to the consumer to take that reasonable care"

Based on the preceding information, it can be deduced that the informants agreed that the Civil Law Act of 1956 was the most commonly utilised legislative provision by those interviewed due to its superior appropriateness as a legal avenue for pursuing compensation for vaccine-induced injuries. It is a consequence of the fact that individuals are empowered to initiate legal proceedings for personal injuries to obtain financial compensation.

ii. *Consumer Protection Act 1999*

Four out of ten informants expressed that the Consumer Protection Act of 1999 provides an additional means of seeking compensation for injury caused by vaccination. As per the second informant's opinion, the Consumer Protection Act of 1999 can be used to establish the definition of goods.

> "Compensation? Under KPDNHEP, we have the Consumer Protection Act 1999. In this Act, the scope covered under the tribunal or consumer claims can be referred to in the definition of

> 'goods'. Goods are primarily purchased or consumed for personal, domestic, or household purposes. By this definition, the Act covers whatever we consume or use for personal use including the COVID-19 vaccine."
>
> (Informant 2)

According to the Consumer Protection Act 1999, the scope of the term is comprehensive, encompassing all consumer products, including fixtures like furniture and air conditioning systems, alongside services such as water and electricity. Although vessels and vehicles are specified within the definition, notable capital goods like ships and aircraft are not included, given their typical procurement for commercial applications. According to Informant 4, adopting vaccine injury compensation measures in European countries substantiates its suitability in Malaysia.

> "If you were to suggest this to be under the Consumer Protection Act 1999 as it would be comparable to foreign jurisdictions, that would be a plus point. Even in the European Union, it is also under the Consumer Protection Act, without having any elements of sales or purchases."
>
> (Informant 4)

Therefore, despite the absence of litigious cases filed against the Malaysian Consumer Protection Act 1999, it is crucial to note that defective vaccine products fall under the product liability jurisdiction, as it has undergone legal scrutiny in the United Kingdom.

iii. *Contracts Act 1950*

Merely a meagre 20% of the informants acknowledged the established liability encapsulated under the Contracts Act 1950. Informant 8 explained that the contractual liability is contingent upon the agreement's provisions mutually assented to by the parties or those intrinsically embedded within. This is primarily because the contractual liability is grounded upon the contract. For instance, if items malfunction within the initial six months from the date of delivery, there is a presumption that the supplier has indeed breached the contract at the time of provision. Informant 8 accentuated the following:

> "Question: You mentioned the 'clause of the contract' earlier. If we were to make a claim under a contract, how would that be?
> Informant 8: To claim under a contract means that one would normally refer to the contract agreement. Thus, we would look at the contract and the terms in the contract."
>
> (Informant 8)

As indicated by the second informant, the analysis of related precedent cases will rely on the discernment of the presiding judge.

> "Yes, that means one can take action under the Contract Act. But then again, they would say that they are not offering anything to ensure that there are no side effects. The manufacturer or the medical professionals would not say there are no side effects. That would be up to the court to test the case. But there is no case so far, and I don't think there are any vaccine-related cases."
>
> (Informant 2)

The fact that the Consumer Protection Act 1999 was passed after a breach of contract involving product liability makes it more pertinent for this subject. Therefore, the element of breach of contract is required for someone to bring a claim under the Contract Act of 1950. However, this alternative is not considered the primary one for consumers who suffer vaccine-related injuries.

iv. *Administration*

The Malaysian government has established an administrative pathway rather than a legal one for providing financial aid to those impacted by COVID-19 vaccines, distinguishing it from other forms of assistance. Fulfilment of the Ministry of Health's guidelines is a prerequisite for eligibility in this programme, as reported

by the informants. One informant, Informant 3, stressed the importance of meeting these guidelines to qualify for the aid.

> "As far as I know, the Ministry of Health does have a compensation scheme for AEFI. The government already provided relief for the adverse effect of inoculation."
>
> (Informant 3)

Informant 5 added:

> "These guidelines are issued by the Ministry of Health. Their financial department issued these guidelines."
>
> (Informant 5)

The guidelines for the Special Financial Assistance pertaining to the Adverse Effects of the COVID-19 Vaccine are exclusively designated for individuals who have been affected by the COVID-19 virus. This initiative, established by the Ministry of Health in Malaysia, indicates that the eligibility criteria for this programme are restricted.

Issues with Existing Vaccine Injury Compensation Mechanisms

The second inquiry in this examination posits the question, "What are the issues with the current vaccine injury compensation mechanisms in Malaysia?" The findings of this study reveal that two distinct groups are responsible for the problem. Firstly, consumer attitudes - defined as an individual's perceptions, feelings, and behavioural intentions towards a given subject - and secondly, the process challenges.

The existing vaccine injury compensation mechanisms are flawed due to key factors. These factors are categorised into two groups: Lack of consumer awareness and gaps in consumer protection literacy fall under consumer attitudes, while the strict burden of proof, time-consuming procedures, high litigation costs, time limitations, defendants' defensiveness, lacunae in the law, complicated procedures, and limited requirements are classified under the challenges of the claim process. Figure 4 illustrates these factors.

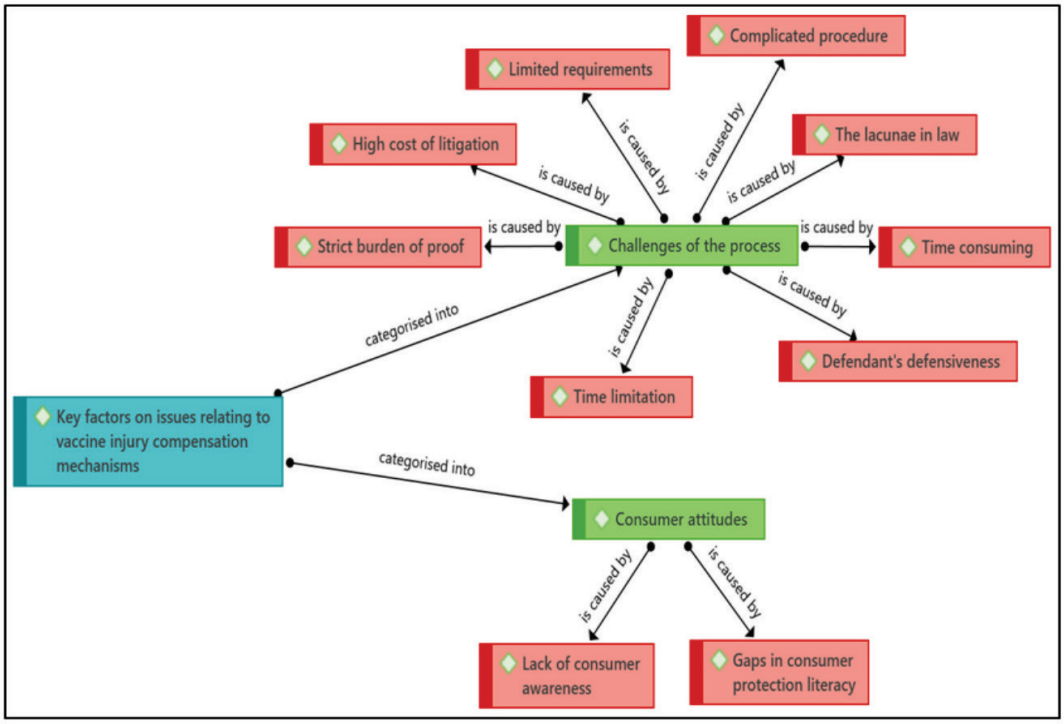

Figure 4: Key factors of issues related to vaccine injury compensation mechanisms

Consumer Attitudes

According to the informants, there is a perception that the general public has inadequate knowledge regarding consumer rights, which is one of the main reasons for the deficiencies in the present vaccine injury compensation mechanisms. In Figure 5, it is evident that the informants stressed the significance of consumer awareness and education concerning obtaining compensation for vaccine-related injuries. While two informants shared their views on the level of consumer education, four mentioned the absence of consumer awareness. Moreover, consumer attitudes towards consumer rights play a pivotal role in determining the effectiveness of dispute resolution of vaccine injury compensation mechanisms.

i. ***Lack of Consumer Awareness***

The issue of compensation mechanisms for vaccine injuries significantly impacts consumer attitudes, with informants identifying a lack of consumer awareness as the primary factor. Informant 1 emphasised the significance of any institution in promoting public understanding of the involved procedures, as this awareness is absent in society, particularly in Malaysia. Informant 8 discussed the importance of consumers taking action to comprehend the details of the products, reading and understanding the laws regarding product responsibility. It is crucial for consumers to take action to comprehend the details of the products and understand the laws regarding product responsibility, as emphasised by Informant 8.

> "Regarding that, it depends on the governance. In Malaysia, it depends on the industry and their take on consumer awareness and protection.
>
> (Informant 1)

> "Thus, it is a matter of awareness. We must ask the supplier to identify themselves. Consider what a typical user would experience. What would you say when you contact the manufacturer? Do you wish to comment on something that you are not unable to identify, such as the existence or absence of any of the aforementioned submissions? For instance, one could wish to see how the Panadol (paracetamol product) is doing. In summary, the issue is on the level of awareness of the people in using products that have a provision for liability."
>
> (Informant 8)

The viewpoint expressed by the survey informant was that individuals should be acknowledged for their actions. This issue was clarified by the presence of legal resources and the corresponding number of consumer complaints related to vaccine injury in Malaysia. According to the informants, the extent of comprehension of consumers is a critical factor that impacts their understanding.

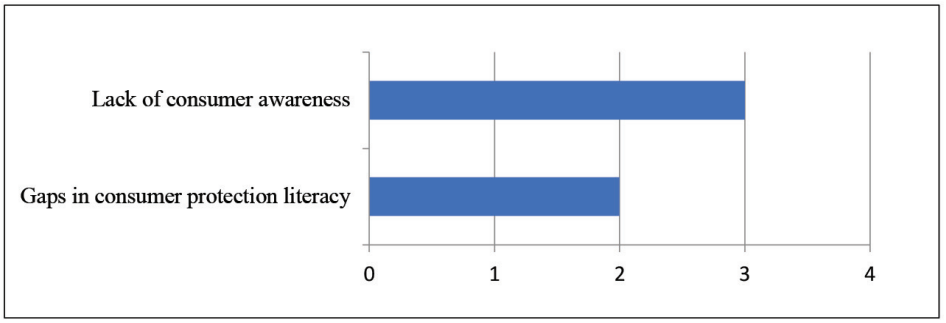

Figure 5: Number of informants who discussed the lack of consumer awareness and the gaps in consumer protection literacy

ii. ***Gaps in Consumer Protection Literacy***

The informants for this theme have identified the second factor in consumer attitudes as consumer education. The significance of educating the public about serious or non-serious AEFI that requires further action has been emphasised by Informant 3. Additionally, it has been suggested that promoting this information on social media would be an effective means of reaching the public.

> "Yes, approaches should be made to the community such as through social media. For example, TikTok videos by the Ministry of Health on the SOP to be followed, or simple diagrams on the criteria, to claim compensation. One would think he/she deserves to be compensated because he feels pain in his hand when the pain is just a common effect of vaccination that happens to everyone. Thus, for compensation purposes, one would need to differentiate between what would be considered 'normal' or 'peculiar' circumstances…"
>
> (Informant 3)

Informant 8 provided an in-depth analysis of the discrepancy between awareness and education, outlining that education is primarily concerned with acquiring knowledge or attaining a certain level of education. It is plausible for an individual to possess a high degree of education and still be unaware of certain matters or, conversely, lack the necessary level of education to comprehend the complexities of the law fully.

> "Question: Is it awareness or knowledge?
>
> Informant 8: Knowledge is one and background is another. Knowledge is the level of our cognition, right? One might be studying up to Form 5 but his/her awareness would be linked to his/her environment too. Just like when comparing Kuala Lumpur, Kedah and Kelantan, you would see the differences in the way people there make their assessments."
>
> (Informant 8)

All three informants emphasised the importance of education in addressing this issue, as the scope of educational backgrounds is vast, and it is a worthwhile investment to transform an individual's cognitive processes. Although some individuals may have a sufficient understanding of the legal system, they may lack the necessary knowledge to advocate for their rights owing to the details of the court proceedings.

Challenges of the Process

Eight challenges have been identified in the process of seeking compensation. Legal or administrative procedures may pose any of these obstacles to victims. The informants recounted their experiences in their respective industries, describing their problems. Figure 6 shows the number of informants that highlighted these issues.

i. ***Strict Burden of Proof***

60% of the informants indicated that the responsibility of demonstrating evidence lies with the affected individuals seeking recompense. The legal process entails that the plaintiff must establish the negligence or duty of care and connect it causally to the faulty product under the Consumer Protection Act of 1999. As Informants 6 and 7 noted, this aspect is considered the most challenging in compensating for vaccine injuries. Informant 7 further emphasised that the expert witness plays a vital role in determining the likelihood of a favourable outcome.

> "To me, in the end, it would need to be the burden of proof. The research on COVID-19 is not conclusive yet, and we know that research would take about 12 to 18 years to be conclusive. Let's say, the minimum would be five years. But we just got this COVID-19 two years ago. So, time is not enough to have conclusive research findings.

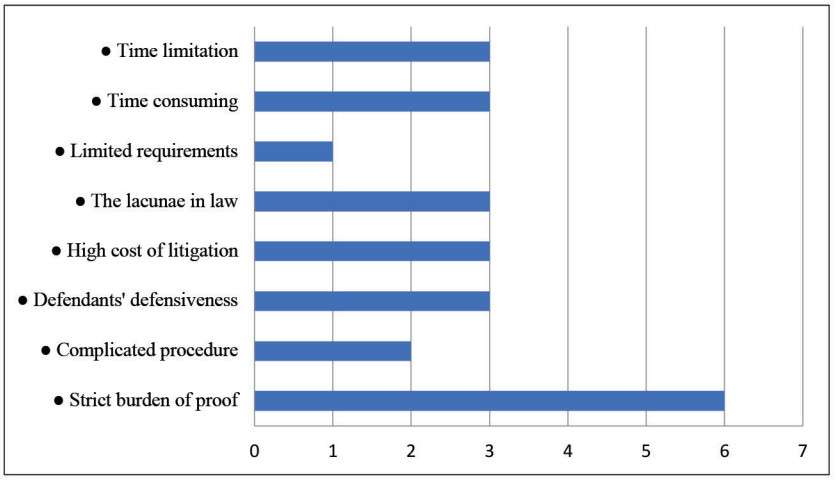

Figure 6: Number of informants who discussed the challenges of the process

Therefore, the compensation for COVID-19 cases cannot be applied using a tribunal. The cases can be easily challenged, such as the causation might not be by the vaccine. This is because we are still in the middle of nowhere with research on COVID-19. We cannot even prove whether Pfizer is better than AZ (AstraZeneca), or SINOVAC is useless. Nobody can prove that now because there is not enough evidence to say so. Due to that, it would be dangerous to set a court or (tribunal) for COVID-19."

(Informant 7)

"Question: The craft of this matter is on how to address this issue. An issue cannot be addressed when the delivery condition is not conclusive. Thus, we need to research based on the available data by referring to conclusive results on the side effects of COVID-19 vaccination. As far as I know, no conclusive evidence exists that people have died due to COVID-19 vaccination. I think that would be the main challenge in this issue of compensation.

Informant 6: We need proof, right? It would always be difficult for the plaintiff. On this issue, the Ministry would need to address them because we do have a lot of complaints now."

(Informant 6)

Another informant commented:

"If it is a defective product, you can initiate the action by going to court. The basic principle is that the court will conduct an investigation, call all witnesses and ask for evidence. So, you would have to prove that the product is defective. The burden of proof is on you."

(Informant 3)

Therefore, the claimant is obliged to provide irrefutable evidence to receive compensation for any injury caused by vaccinations through either a legal or administrative process.

ii. *Time-consuming*

Three informants expressed that the prolonged and challenging duration of the judicial proceedings presented a significant hindrance. The justification for the prolonged duration of the legal process was put forward by the Informant 7. This is because injuries caused by vaccines may involve physical issues that are difficult to detect, thereby hindering the court's ability to expedite these cases while maintaining impartiality for all parties.

> "Medical issues are not insignificant issues and people will not take them lightly because they involve human anatomy. When it involves your anatomy, it relates to your constitutional right, which is the right over your body. People would go to great lengths to safeguard this right. It can be seen in simple scenarios involving facial products that affect the look and far more significant in circumstances involving mislabelling and wrongful prescriptions that can cause injury or even death. As a result, no one is going to rush justice. Medical issues will also jeopardise the medical profession. We must defend not only the customer but also the industry if we are to achieve justice. You must consider justice in a broader meaning, in a broader context."
>
> (Informant 7)

According to one of the informants, the proximity of the manufacturer plays a significant role in making the task more challenging.

> "It would be challenging to sue foreign manufacturers since the procedure would be lengthy. Local manufacturers can be the defendant and this can be done through mediation."
>
> (Informant 9)

Despite this lengthy problem, interviewers also reported several other problems with the procedure, which are covered in more depth below.

iii. ***High Cost of Litigation***

The high litigation costs are solely due to the obstacles that arise during the legal process. The informants have indicated that the plaintiff must establish a causal link during the legal proceedings, which entails enlisting the services of an expert witness at a substantial cost. Consequently, legal cases entailing payments to attorneys and expert witnesses are notorious for their excessive litigation costs. The prolonged nature of the legal process further compounds these costs. Informants 7 and 8 have emphasised the aforementioned points.

> "In my perspective, strict liability requires that we, as plaintiffs, understand what we are doing. Without having the knowledge or expertise, one can be manipulated by the manufacturer because they have experts on hand. As a result, we would need to hire our experts to oppose them. But we might not have enough resources. We are not aware of anyone who is an expert on COVID-19. We don't even have figures and data to back up our concerns about the COVID-19 vaccine. Thus, hiring a COVID-19 expert would be costly."
>
> (Informant 7)

> "Question: In the case of product liability, the Act might be invoked due to the injury caused by the product. However, the Act places the burden of evidence on the user, therefore, proving a product flaw would be challenging. Sir, do you agree with me?
>
> Informant 8: Yes, that would be extremely difficult, and no one could do it alone. It is necessary to hire experts. However, employing specialists costs money, which is a barrier for many people. Money is required to pay the doctors for their services."
>
> (Informant 8)

Thus, it is undeniable that the judiciary system incurs significant expenses, making it difficult for individuals affected by legal issues, particularly those with limited financial resources, to initiate legal proceedings.

iv. ***Time Limitation***

As noted by Informant 8, reference was made to the Consumer Protection Act of 1999.

> "The phrase 'where damage is caused by a defect product, the manufacturer shall be liable' is found on page 628 in reference to product liability. Let's

> examine the phrase 'damage caused by a defective product'. Several challenges must be faced by the person who experienced the adverse effect. First, the adverse effect must happen within a reasonable period. What does 'a reasonable period' mean? Legal experts would conclude that a fair time frame is two weeks or two months. However, some people, including those from rural regions, might not discover the harm brought by the vaccine for up to a year. What then constitutes a 'reasonable period'?"
>
> (Informant 8)

To clarify, the Consumer Protection Act 1999 section 99 states that in section 99 (2) the jurisdiction of the Tribunal shall be limited to a claim based on a cause of action that accrues within three years of the claim. Only one informant made mention of this observation, which suggests that the issue may not be a matter of significant concern that has been brought to attention. The temporal constraint for tort law is set at six years. The limitation factor is also a challenge faced while examining the guidelines of the Special Financial Assistance Adverse Effects of COVID-19 Vaccine Programme that the Malaysian government is implementing.

v. *Defendants' Defensiveness*

In a civil tort or product liability case, a defendant may assert numerous defences to circumvent accountability. In the interviews, four informants focused on the defendant's defence strategies that hindered the plaintiff's case due to their expert counsel. The following excerpt is a statement provided by Informant 7.

> "If we are to say it is product liability, they would already have a defence. They would have a defence even from the beginning. They already know what they would be accused of. As for the victim, there is no expert for them to rely upon. My opinion on strict liability is that the plaintiff needs to know what they are doing. Without knowledge or expertise, the manufacturer can manipulate one because they have the experts with them. Thus, we too would need to hire our experts to challenge them."
>
> (Informant 7)

Informant 7 added that the defendant may also argue that a third party's carelessness contributed to or even caused the damage.

> "You can't just take the product in isolation because it involves a lot of chain of events in this matter. First, the product manufacturer. That chain of events cannot be broken. In the course of justice, there would be a lacuna if we break the chain of events."
>
> (Informant 7)

From now on, the liability following both the Consumer Protection Act 1999 and the claims of negligence may be restricted as long as the defendant can successfully prove that the negligence of the claimant was the primary cause of the damage or facilitated its occurrence.

vi. *The Lacunae in Law*

A lacuna in a set of thorough regulatory laws is commonly known as a gap in the law. As stated by Informant 2, there is still a lack of clarity regarding the jurisdiction of vaccine items in Malaysia, specifically if it falls under the Ministry of Domestic Trade and Consumer Affairs or the Ministry of Health. If the government fails to provide a clear resolution to this issue, it can potentially worsen the situation for customers, who will be confused and uncertain about which ministry to approach.

> "Maybe because we are not clear on whose jurisdiction the vaccine is. The user is unclear on where he wants to go or whom he needs to approach regarding vaccine issues. There is not even a specific platform for vaccine issues. If he goes to KPDNHEP, I believe, KPDNHEP will say they are not in charge because it involves a medical product. He would then go

to social media. He wouldn't go to Tribunal for Consumer Claim, right?"

(Informant 2)

Informant 4 raised a question on the meaning of the consumer aspect in the Consumer Protection Act 1999.

"Informant 4: The challenging part would be determining the aspect of consumerism because of the sales and purchases aspects.

Question: Then we have to look into the terms in the Consumer Protection Act, right?

Informant 4: What makes a consumer a consumer? What makes a person fall under this jurisdiction?"

(Informant 4)

Informant 7 drew attention to the discrepancy surrounding the responsibility for vaccine injury. It was noted that doctors are required to prescribe the vaccines, while consumers cannot independently bring a lawsuit against the manufacturer. Informant 7 expressed concern over the difficulty of challenging the Consumer Protection Act 1999 and highlighted the greater relevance of the Civil Law Act 1956 due to the practical requirements for individuals administering the vaccine.

"Question: If we look at it, even under the CPA (Consumer Protection Act), the tribunal has no jurisdiction to hear cases involving injury and death.

Informant 7: Yes, because we have to balance between protecting the consumer and being fair to the industry. You can't just take the product in isolation because it involves a lot of chain of events in this matter. First, the product manufacturer. That chain of events cannot be broken. In the course of justice, there would be a lacuna if we break the chain of events."

(Informant 7)

Thus, the present study has unveiled a deficiency within the realm of consumerism regarding medicinal products prescribed by physicians, thereby posing a potential challenge in terms of liability.

vii. ***Complicated Procedure***

The issue was raised in two distinct scenarios by the informants. Informant 3 emphasised that strict adherence to the Standard Operating Procedure (SOP), which is obligatory for all establishments, may sometimes hinder the timely resolution of an issue and result in loss of interest from clients.

"Regarding the efficiency of the government, I would be able to give my perspective because I also work in GLC. It's not a matter of being inefficient but it is a matter of adhering to a lot of SOPs, as at the end of the day we are answerable to our auditor, and we also need to consider Section 78 ACC Act. Some things might be admirable overseas, but in Malaysia, we still have to adhere to many SOPs. We can improve but we can't do it overnight."

(Informant 3)

While Informant 6 posited complex procedures due to the involvement of a non-local manufacturer, it is imperative to note that in the present situation, if an individual obtains vaccines from a government hospital, the government will bear the responsibility.

"Generally, the defendant is the government of Malaysia that has to conceive the liability. However, I am not sure about COVID cases. There might be a possibility to sue the manufacturer if the situation were serious. Say Pfizer operates in the US. That would probably require challenging procedures."

(Informant 6)

Thus, the standard operating procedures (SOPs) delineated in guidelines, such as those outlined in the Special Financial Assistance Adverse Effects of COVID-19 Vaccine

Programme in Malaysia, pose a significant challenge to vaccine mechanisms since they govern the behaviour of the consumer in terms of adherence to or disregard of the SOP. The legal procedure is facing a similar predicament. The subsequent challenge is elaborated upon in the following discussion.

viii. *Limited Requirement*

During a particular interview, it was emphasised that the limited requirement led to administrative challenges. The third informant explained this by stating that:

> "Regarding compensation, it would be limited to certain events and certain situations. Compensation would be sufficient for those events and situations. Yet, if it involves permanent injury, one will have to go to the court."
>
> (Informant 3)

The subsequent challenge is elaborated upon in the following discussion.

Discussion

The present investigation has determined that individuals who have suffered injuries as a result of receiving the vaccine are entitled to seek compensation under several legal acts, namely the Civil Law Act of 1956, the Consumer Protection Act of 1999, the Contracts Act of 1950, and under administrative fund programme, the Special Financial Assistance Adverse Effects of COVID-19 Vaccine, which is exclusively designated for injuries stemming from the COVID-19 vaccine. To illustrate, in Malaysia, the case of *Muhammad Muhaimin bin Yauza and Ors v JK Maizatulniza binti Mat Jais and Ors* [2016] MLJU 333 pertains to a claim filed under the Civil Law Act of 1956, whereas no litigation has been initiated with respect to the Consumer Protection Act of 1999 and the Contracts Act of 1950. The responsibility of the physician towards the patient is subject to the jurisdiction of the judiciary, with the presiding judge overseeing the case (Luther, 2021).

There is informant indicated that the vaccine product falls within the scope of the term 'goods' as defined by the Consumer Protection Act of 1999, in line with Section 3 of the aforementioned legislation, 'goods' means goods which are primarily purchased, used or consumed for personal, domestic or household purposes, and includes: (a) Goods attached to, or incorporated in, any real or personal property; (b) animals, including fish; (c) vessels and vehicles; (d) utilities; and (e) trees, plants and crops whether on, under or attached to land or not, but does not include choices in action, including negotiable instruments, shares, debentures and money. The aforementioned assertion is strengthened by the legal precedent established in the case of *A v The National Blood Authority* [2001] 3 All ER 289, where the court deemed the transfusion of hepatitis C-infected blood as a product following the Consumer Protection Act 1987 of the United Kingdom. Similar to its counterpart in the United Kingdom, the case of *O'Byrne (represented by his mother and litigation friend) v Aventis Pasteur SA* [2010] UKSC 23 exemplifies a legal proceeding under the Consumer Protection Act 1987, under Part I of the statute, which is also applicable in Part X of Consumer Protection Act 1999. On August 1, 2001, the claimant initiated a legal action seeking compensation for damages against Aventis Pasteur MSD Ltd. The claimant contended that the company bore responsibility under section 2 of the Consumer Protection Act of 1987 due to the flaw present in the product manufactured by Aventis Pasteur MSD Ltd, which had caused injury to the claimant.

The implementation of the Special Financial Assistance for Adverse Effects of COVID-19 Vaccines in Malaysia seems to follow the globally implemented Vaccine Injury Compensation Programme (VICP), which is an alternative approach to compensate individuals affected by vaccine-related impacts (Mungwira *et al*., 2020). According to Schellekens (2018), VICP is a no-fault liability form of compensation that does not require the identification of a party at fault or the proof of negligence and

subsequent causation. This often results in the defendant aggressively defending it, as it bears the name of the company. The VICP was established as an alternative to the usual civil law system for handling vaccine injury claims. It intended to create a no-fault litigation process in which the plaintiff must prove that the vaccination caused the injury rather than that the injury was caused by medical negligence (Henry *et al*., 2015; Nguyen, 2022). However, it should be pointed out that a deficiency exists in the provision of financial assistance in the Malaysian programme, as it does not adequately compensate the affected parties. Nevertheless, this investigation demonstrates that the current mechanisms remain insufficient due to issues that may account for the lack of vaccine injury lawsuits in Malaysia despite the thousands of reported cases of such injuries annually.

The issues identified with regard to the second objective show that the current vaccine injury compensation mechanism needs to be improved. For example, the strict burden of proof, the cost of litigation and the defendants' defensiveness keep cases from reaching court. According to the experience of the expert interviewed, it is extremely difficult for the plaintiff to prove a defective product under the provisions of the Consumer Protection Act 1999, as this is only possible with the help of an expert witness and high-tech innovations. Moreover, the defendant would strengthen its defences against the plaintiff. For example, the manufacturer could counter that the causal link between the product and the disease could not be scientifically proven when the product was made available to the public, or it could blame third parties involved in the vaccination. For example, in the case of *Loveday v Renton* [1990] 1 Med LR 177, it was believed that there were more plausible explanations for all of the cases under consideration other than vaccination injury as none of the nine vaccine-related neurological illness cases that had allegedly resulted in lifelong disability in otherwise healthy children had symptoms that appeared within the first 48 hours. Several had strong alternative diagnoses, including Reyes' syndrome and viral encephalitis. Others involved infantile spasms, a seizure disorder whose link to DPT vaccination had been rejected in several earlier investigations and were widely disregarded by 1988. In the case, *O'Byrne (represented by his mother and litigation friend) v Aventis Pasteur SA,* Aventis Pasteur MSD Ltd contended in its defence that it merely acted as a distributor and not as the manufacturer. In response to a subsequent inquiry, Aventis Pasteur MSD Ltd identified Aventis Pasteur SA as the producer.

Litigation related to medical malpractice has persisted for as long as two decades before being resolved (Azmi *et al*., 2021). An exemplary instance of this phenomenon can be observed in the legal dispute between *W and Others versus Sanofi Pasteur MSD SNC* [2017] ECR I, which took almost 11 years to conclude. However, in Malaysia, it is an undisputed fact that in deciding cases of negligence, proving each element required by law is challenging. It required many resources and involved a lengthy time to succeed in a case like *Fio Na v Hospital Assunta & Anor* [2007] 1 CLJ 229, which took 24 years to resolve. The prolonged litigation process leads to a significant increase in litigation costs as plaintiffs are obligated to retain the services of expert witnesses and compensate attorneys. Given that vaccines may not take up to six years to develop (WHO, 2021), the six-year statute of limitations under tort law seems long enough for the informants not to view this as a serious issue. However, due to timing constraints, the Malaysian government's Special Financial Assistance Adverse Effects of COVID-19 Vaccine project guidelines analysis is challenging. According to the scheme, serious AEFI must have happened within three months of the vaccination, and applications are only considered if they are presented within one year of the date on which the AEFI occurred (NADMA, 2021). Evidence and records of necessary documents must be submitted, which is also a concern for VICP (Fei & Peng, 2017; Goldberg, 2022). Court fees, settlements, and other costs necessary to resolve the issue may

be included in additional compensation (Azmi *et al*., 2021). Besides, lack of consumer awareness and knowledge may also play a role in a consumer's decision not to take action (Karim & Talaat, 2011; Durovic, 2020).

A comprehensive consumer education strategy is crucial to promote greater consumer participation. In particular, raising awareness can empower individuals, especially those with limited education, to improve their lives. To address vaccine injury compensation in Malaysia, it is necessary to establish a new mechanism that considers economic losses. The administrator must provide clear eligibility provisions for compensation, encompassing economic and non-economic losses. This is because the primary objective of claimants is to receive compensation for their injuries or damages rather than to assign blame. Hence, it is evident that there is a scope for enhancement in the current mechanism or exploration of alternate approaches to address this conflict concerning eligibility criteria, time limits, and compensation amounts to ensure justice and fairness. In order to realise the health-related Sustainable Development Goals (SDGs) as set forth by the United Nations and to maximise the benefits of vaccination, it is crucial to develop and implement policies that can reinforce the enforcement of the Vaccines Administration Law, which holds great importance in the chronicles of vaccines. The comprehensive legal framework encompasses almost every aspect of vaccination, including upstream progression and generation, regulation, programme implementation, safety and efficacy monitoring, vaccine financing, and vaccine injury compensation (Chen *et al*., 2022).

Conclusion

This research has analysed Malaysia's current vaccine injury compensation system by utilising a conceptual framework that incorporates the principles of justice and compensation. This study suggests that Malaysia should have a legal framework addressing the issue of vaccine injury to provide a compensation option for those affected by the vaccine product. From a pragmatic viewpoint, the primary discoveries of the investigation may furnish advantageous insights to ameliorate vaccine injury mechanisms and elevate Malaysia's standing with regard to vaccine injury system policy. This is pertinent as the legal structure always adapts to remain pertinent in changing times and circumstances. The objective is to establish a viable programme that does not burden the government financially during national crises. As indicated by Emanuel *et al*., 2021, compelling corporations to disseminate vaccine-associated information without appropriate compensation may imperil their long-term viability. Consequently, governments should reinforce or enact a legal framework, such as a constitutional or statutory right to health, to guarantee rights based on the principles of impartiality and non-discrimination, encompassing affordability, financial security and accountability.

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