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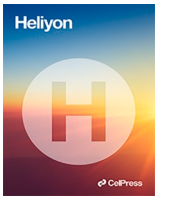

Research article

# A solution towards a viable compensation mechanism for injury from COVID-19 vaccines in Malaysia: A qualitative study

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ABSTRACT

*Background:* It has been established that the existing compensation mechanism is not the favoured platform for vaccine recipients with Adverse Effects Following Immunisation (AEFI). With the mass production of vaccines during the COVID-19 pandemic, intensified by the mandatory National COVID-19 Immunisation Programme in Malaysia, an alternative resolution mechanism for compensation is long overdue. This qualitative study aims to propose a viable alternative dispute resolution (ADR) mechanism for those who suffer AEFI from COVID-19 vaccination, particularly the economically disadvantaged, older people, and disabled individuals in Malaysia.
*Methods:* The researchers conducted an in-depth focus group discussion in September 2022 involving seven participants representing key stakeholders in vaccine compensations from governmental agencies, non-governmental organisations (NGOs), and private institutions who were experts in litigation and legislation, consumer protection, and medical practices in Malaysia. The study utilised ATLAS.ti 22 to conduct a thematic analysis.
*Findings:* The analysis yielded three themes: existing mechanisms and their challenges, the role of ADR, and the solution for a vaccine injury compensation mechanism. The participants shared their knowledge and experience regarding the existing vaccine compensation mechanisms in Malaysia, i.e. the common law of Tort and Consumer Protection Act 1999, and explained how each mechanism relates to specific challenges or arguments that provide the basis on which they are unable to accord fair compensation to the vaccine recipients. The participants debated the merits and disadvantages of the types of ADR for AEFI and unanimously proposed a specific healthcare centre for compensation (SHCC) as the most viable compensation mechanism for AEFI.
*Conclusion:* SHCC offers a new ADR to serve as a compensation mechanism for claimants affected by the COVID-19 vaccines while also contributing to achieving Sustainable Development Goal 16: peace, justice, and strong institutions.

## 1. Introduction

A vaccine is a biological substance that is administered to individuals to elicit immunity against a specific disease [1]. It has been shown to protect against a list of deadly illnesses by combining with the body's natural defences to generate protection and decrease

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the chance of infection. Malaysia recognised the significance of vaccinations in safeguarding long-term public health and established the National Immunisation Programme in 1950, which is a free programme provided for all Malaysian children in government facilities [2]. The success of the vaccination programme was demonstrated by the decline in the incidence of poliomyelitis since the introduction of the oral polio vaccine in 1972, with no instances documented since 1986 [3].

However, like most medical products, vaccines have the risk of side effects [4]. Even if a vaccine is well produced, there may be design, manufacturing, or distribution flaws [5,6]. As an example, there were 98 verified cases of intussusception following rotavirus vaccine immunisation reported to the Vaccine Adverse Event Reporting System of the United States, with 60 developing intussusceptions within one week after vaccination [7].

In the context of the COVID-19 vaccines in Malaysia, Pfizer BioNTech vaccine recipients had a small increased risk of venous thromboembolism, cardiac arrhythmias, and convulsions/seizures; however, no correlation was found between the CoronaVac vaccines and any adverse events, with the exception of arrhythmias [8]. Conversely, the AstraZeneca vaccine was linked to an increased incidence of thrombocytopenia and venous thromboembolism [8]. Thrombosis with thrombocytopenia syndrome (TTS) is a well-known, but extremely rare, serious side effect of the adenoviral vector of COVID-19 vaccines such as AstraZeneca [9]. During the Malaysian COVID-19 vaccination programme, the National Pharmaceutical Regulatory Agency (NPRA) received 44 reports of possible myocarditis/pericarditis following the administration of Comirnaty and 2 reports of possible myocarditis/pericarditis following the administration of AstraZeneca [10].

Due to these side effects of vaccinations, advocates of a variety of medical ideologies have rejected the idea of vaccination [11]. These ideologies contradict the microbiological paradigm that explains how vaccines, and by extension the immune system, work. Homoeopathy, Christian Science, chiropractic, hydrotherapy and crystal healing are just some of the alternative medical theories [11]. The anti-vaccination movement also cites the adverse effects of vaccines as one of the propaganda for non-vaccination [12]. In Malaysia, there are three salient determinants of COVID-19 vaccine hesitancy, namely a) those that are susceptible to the influence of leaders and anti- or pro-vaccination lobbies, b) the belief in conspiracy theories, and c) the absence of trust in the vaccine's safety [13].

Considering this evidence, it seems that resistance to vaccination has always existed. Although only a small portion of the public has strong anti-vaccination beliefs, hesitation regarding COVID-19 immunisation was – and is - visible in several nations [14]. However, the continued presence of alternative medicines among *anti*-vaccinationists should not undermine the significant improvements in vaccine technology over the last 200 years and their impact on anti-vaccine activism [11]. Ideally, with a proper compensation mechanism in place, the government can assure the people that they will receive a safe vaccination and that their rights will be protected.

It is important to highlight that the issue of accountability has not received significant attention, although the association between manufacturers and liability has been well-known for decades [15]. The issue of liability has been a topic of debate since the Thalidomide tragedy in the early 1960s [16]. Manufacturers were subject to product liability laws, which were tightened to improve the level of safety, efficacy, and product quality through toxicological studies and clinical trials in humans [17]. In Malaysia, the only mechanism that aggrieved parties can use to obtain compensation is a civil action, which is usually governed by tort law and the Consumer Protection Act 1999 (CPA 1999) [18], and is similar to the Consumer Protection Act 1987 (CPA 1987) [19]. For those who experienced Adverse Events Following Immunisation (AEFI) after receiving the COVID-19 vaccine, an administrative programme called the Special Financial Assistance Adverse Effects of the COVID-19 Vaccines (SFA) was established [20].

These mechanisms have, nonetheless, flaws that call for further revision [21]. For example, the tort system remains the primary method of resolving monetary damages, including medical disputes, because it has the feature of providing medically wounded individuals with a monetary incentive to pursue a claim against the person who is alleged to be at fault [22]. The tort system, however, has inherent flaws due to its adversarial nature. Compensation is frequently unpredictable, and success may or may not be attributable to the claims' merits [23]. Due to existing inadequacies in tort law and consumer protection legislation, such as the CPA 1987, compensation claims for adverse effects of medical products are particularly challenging [24]. To be reimbursed under the tort system, the victim must attribute the act of carelessness or assign blame to a specific individual [25,26].

The shortcomings of the system for compensating individuals injured by vaccinations, as highlighted by prior studies [23–26], were the impetus for this study to enhance the existing vaccine compensation mechanisms. Using a qualitative focus group discussion (FGD), the present study investigates viable solutions related to vaccine injury compensation in Malaysia from a variety of stakeholder perspectives. The goal is to propose the best solution for vaccine compensation dispute resolution in Malaysia, especially in strengthening the existing processes in terms of accountability and compensation.

## 2. Methods

This study applied a qualitative focus group research design. FGD is a very effective method for this study's data collection because it enables the evaluation of a wide range of ideas, the exploration of novel concepts, and the promotion of externalisation of the decision-making process [27]. FGD can also be an important tool for engaging stakeholders, seeking their views on implementation-related issues and gaining a better understanding of the environment and contextual elements that may influence implementation [28]. In addition, focus group interviewing emphasises group interaction that can be effective in gathering comprehensive information about settings (e.g. normative care practises or workflows), experiences with health services and models of care, and perspectives on interventions and implementation strategies [28]. Hence, the method is most appropriate for identifying stakeholder-relevant outcomes [29,30]. This study aims to identify a viable solution for vaccine injury compensations through analysis of the available Alternative Dispute Resolutions (ADR) in the Malaysian setting.

The collection of data via FGD in this study added to the recognition of the mechanisms for vaccine injury and their improvement for better implementation in Malaysia. The processes undertaken for the qualitative focus group research design in this study are shown in Fig. 1 below.

The topic guide for the FGD in this research was first developed by referring to the existing literature on compensation mechanisms for vaccine damage [31,32]. The topic guide encompasses the research objective, research question and assessment instruments as well as the protocols of the FGD session. The research objective is to propose a COVID-19 vaccine compensation dispute resolution mechanism for those who suffer AEFI from COVID-19 vaccination in Malaysia. The research question is how the formation of the proposed COVID-19 vaccine compensation dispute resolution mechanism can help provide justice and due protection to victims. Then, this research project obtained ethics approval from the Research Ethics Committee of Universiti Malaysia Terengganu (UMT/J-KEPM/2022/103) in June 2022.

Following the approval, the selection of participants was made based on stratified purposive sampling to incorporate input from various perspectives of the participants [33]. We identified the stakeholders' organisations and the authoritative persons in that organisation. Their backgrounds were screened to ensure that they met the criteria, and so that various, but not redundant, perspectives can be gathered [34]. The careful selection of participants for the FGD immensely contributed to the establishment of an alternative compensation mechanism for vaccine injury. The participants, who were identified by the researchers, were drawn from three areas of expertise: legal professionals, medical professionals, and consumer protection experts. The selected participants acted in the capacity of individual experts representing their areas of expertise.

As displayed in Table 1, participants with different professional backgrounds, areas of expertise, and more than 20 years of work experience in Malaysia were chosen to emphasise diverse experiences. Five of the participants had legal backgrounds and held senior positions in their respective agencies or ministries. Two out of seven participants were medical practitioners. They were stakeholders with knowledge of vaccine compensation from governmental agencies, non-governmental organisations (NGOs), and private institutions. Participants from the governmental agencies were those who had a pay grade of 52 or above, which is comparable to having a bachelor's degree in law or other related field and at least 20 years of experience in a relevant field. Participants from private institutions were actively involved in the management of vaccine issues throughout the COVID-19 vaccination programme in Malaysia. The participants were approached by extending formal invitations through personalised letters via email. These letters provided a comprehensive overview of the research and expressed the researcher's interest in seeking their valuable opinions and expertise for the FGD.

For validation purposes, the topic guide for the FGD was tested during a pilot session. The pilot session was held to gather opinions from experts in qualitative focus group research design [35]. Two experts in qualitative research and two experts in law participated in the pilot test. These experts were recruited from Malaysian universities after reviews made on their research projects, publications, and expertise. The experts for this pilot session were not the same participants selected for the FGD. Evaluation by the experts on the questions was obtained and views related to the arrangement, the flow of the session, the roles of researchers, and the session guide were used to refine the protocols for the FGD. The topic guide for the FGD was modified and finalised based on the responses of the experts. Upon finalising the topic guide, a focus group session was set at a time and place that was convenient for the participants. All the participants were sent an email inviting them to the session.

The FGD session was held on September 21, 2022, in Putrajaya, Malaysia. The seven participants attended the session, all of whom contributed to the discussion. The seating layout of the session was arranged in a way that allowed for close and intimate discussion as shown in Fig. 2 below.

The FGD session was facilitated by one researcher who served as the moderator of the session and two researchers who served as an observer and a note taker, respectively. The topic guide was distributed to each participant before the session. During the FGD, the moderator began with a briefing on protocols for the focus group session, including seeking permission from the participants by requesting them to sign a consent form. They were informed that no personal details which could identify them would be made public throughout the data collection, analysis, or publication of the study to protect their anonymity and confidentiality. Then, to ensure that the discussions were framed within the context of the research objectives, participants were briefed on i) the background of the existing


**Fig. 1.** Methodology for focus group discussion (Source: Authors).

**Table 1**
Participants for focus group discussion.

| No. | Areas of Expertise | Position | Institution |
|---|---|---|---|
| 1. | Consumer Protection | Legal Advisor | Government/Enforcement Agency on Consumerism |
| 2. | Litigation and Legislation | Head of Legal Department | Private/Pharmaceutical Firm |
| 3. | | Lawyer | Private/Law Firm |
| 4. | Litigation and Legislation/Consumer Protection | Judiciary | Government/Agency on Consumer Protection |
| 5. | | | |
| 6. | Medical Practices | Medical Practitioner | Non-Government Organisation/Agency on Consumer Protection |
| 7. | | | Government/Health Facility |

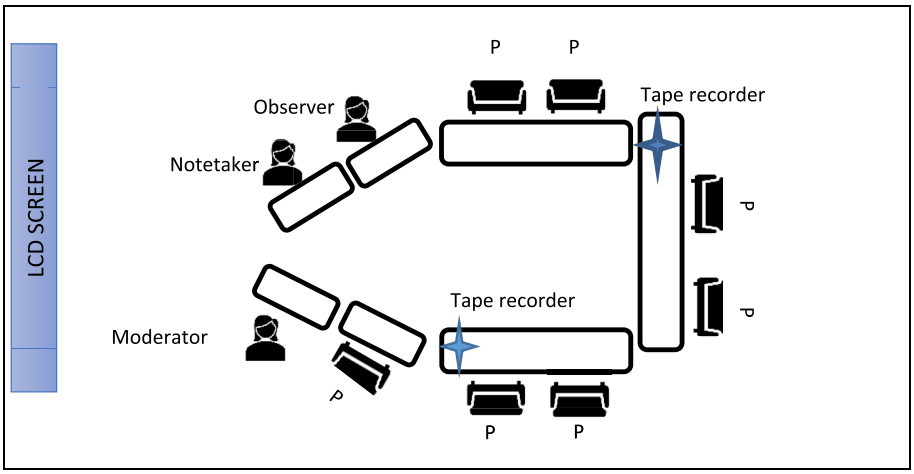


**Fig. 2.** Seating arrangement during focus group discussion (Source : Authors).

compensation mechanisms that consist of the tort law, CPA 1999, breach of contract and SFA, and ii) the aims of the FGD, which are to discuss the roles of potential ADR and ultimately suggest a viable solution for vaccine injury compensation. The participants were all provided with an opportunity to respond to each question and were encouraged to respond to other participants' points of view. The FGD ended when the moderator identified that there were no new topics to be discussed in the session.

The FGD session was recorded, and the audio recordings were transcribed verbatim into transcripts. All participant information was anonymised during the transcription of the data to maintain confidentiality. The transcripts were double-checked with the participants, with no participants requesting any changes. As the FGD was conducted in both Malay and English languages, the responses in Malay in the transcript were translated into the English language by a professional proofreader. The English transcripts were verified by the researchers prior to the analysis. The transcripts were then coded using a computer-based tool, the ATLAS.ti 22 software. Coding is described as the process of connecting raw data with theoretical terms which involves grouping, summarising and/or categorising the raw data based on the codes [36]. Both deductive and inductive coding approaches were used as the hybrid approach, which has


| Deductive Code | Inductive Code |
|---|---|
| Mechanism | • Law of Tort<br>• CPA 1999<br>• Government Assistance |
| Alternative Dispute Resolution | • Mediation<br>• Tribunal<br>• Special Court |
| Solution | • Committee<br>• Centre Guideline<br>• Fair Amount Compensation<br>• Create Public Awareness |

**Fig. 3.** Coding and analysis for focus group discussion (Source : Authors).

been suggested to provide a more rigorous thematic analysis [37]. The coding procedures, as illustrated in Fig. 3, were performed in two stages.

In the first stage, the deductive approach was employed by generating the codes based on the pre-determined research objectives. The codes are "mechanism", "alternative dispute resolution", and "solution". This approach is relevant to maintain alignment with the aim of the study and the research questions. In the second stage, the inductive approach was used by developing in vivo codes from participants' own words. The codes were the sub-codes to the codes in the first stage that were identified from the researchers' observations during the FGD. This approach is important to highlight the data that is representative of the findings. The coding process through ATLAS.ti 22 resulted in the development of several themes that relate to the research and the relationship across the data.

While the computer-based tool may aid with the coding and categorising of large amounts of narrative text [38], the tool does not negate the need for subject matter expertise [39]. Hence, the themes derived from the coding process were reviewed and refined by the researchers. This process was performed through discussions among the researchers by utilising researchers' knowledge in legal studies, referring to the raw data, and reaching a consensus on identifiable similarities and differences across the themes. For example, the codes Civil Law Act 1956 (CLA 1956) [40] and CPA 1999 were identified under the theme 'civil suit' and the SFA was identified under the theme 'government assistance'.

## 3. Findings

This section discusses the findings of the study based on the identified research objectives. Prior to discussing the findings, it is important to also understand the background of the participants. Table 2 displays the profiles of the participants involved.

Based on the analysis of the data, 3 themes were identified; existing mechanisms and their challenges, the role of alternative dispute resolution, and the solution for vaccine injury compensation mechanism. Hence, the findings of the study are tabulated into three themes as detailed in the following subsections.

### *3.1. Theme one: existing mechanisms and their challenges*

The participants acknowledged the existing compensation mechanisms in Malaysia and explained their connections to specific challenges that form the basis for the difficulties encountered by the vaccine recipients.

#### *3.1.1. Civil suit*

In Malaysia, the CLA 1956 is based on common law-making legal principles derived from judicial rulings, a key source of tort law. Malaysian courts have adopted and adhered to existing English common law tort rules when addressing local matters. Based on the participants' feedback, any negligence can be brought to court under tort law.

The first discussion was based on the CLA 1956, which applies the Common Law of the United Kingdom (UK) to personal injury claims. One participant, who is a lawyer, referred to CLA 1956 in explaining that claims are allowed for negligence-based lawsuits against medical malpractice as stated in section 7 of the CLA 1956. This piece of legislation allows AEFI claimants to seek compensation.

Participant (P) 3 stated that:

> "Civil Law Act is the applicable law in all personal injury cases. In Malaysia, there are numerous tort cases. So, in this case, the Civil Law Act applies. Claims under the Civil Law Acts can be due to injury such as accident, claim for broken hand, and broken leg. On the other hand, in Malaysia, vaccine-related injuries are considered new types of cases of personal injury." (P3)

Five out of the seven participants who had legal backgrounds were aware of the existing compensation mechanisms that were highlighted by the researcher during the preliminary briefing of the FGD. Three participants from governmental agencies were familiar with the CPA 1999. The participants acknowledged that there are only two ways to acquire compensation via mechanisms relating to injuries, which are negligence under the CLA 1956, and product liability under the CPA 1999.

Nevertheless, the participants also acknowledged several challenges faced by claimants via these mechanisms. The first challenge is the burden of proof imposed by the legislation. For a claimant to prove negligence, the burden of proof lies with the plaintiff to prove the pre-requisite elements i.e., duty of care, breach of duty, causation and damages or injury sustained. The most significant challenge

**Table 2**
Participants' profile.

| | Frequency | Percentage (%) |
|---|---|---|
| **Experience** | | |
| 20 years and above | 7 | 100 % |
| **Gender** | | |
| Men | 1 | 14 % |
| Women | 6 | 86 % |
| **Employment Sector** | | |
| Government | 3 | 44 % |
| Statutory Body | 2 | 28 % |
| Private | 2 | 28 % |

is demonstrating the causal link between the COVID-19 vaccine and the injury suffered by the claimant [41].

P1 contended:

> "The chain of causality in legal disputes cannot be broken, thus the major issue is linking the element of causation if you wish to succeed in a claim." (P1)

P1 also acknowledged it was challenging to prove that the COVID-19 vaccine caused the injury; given the complexity of the human body, the cause can only be determined by an expert or medical specialist:

> "Take note of the chain of causation. If the claimant has strong evidence linking the injury to the vaccine, then you have a strong case. Look at the analysis, is it due to the vaccine or any other intervening factors in terms of technology? So, take another look at the chain of causation again." (P1)

P1 added the importance of high technology to trace the causation:

> "It is critical to understand to what extent our technology can pinpoint the vaccine, because lawyers may argue that other variables could have caused the harm." (P1)

The shortcomings of these legislations are notorious as they demand the claimant to prove that the side effect is caused by a defect in the product. The defects in question are manufacturing defects, design defects, or defects of the act of distribution. The biggest challenge for the claimant is to prove the causal relationship between the defect and the product in question, where usually the claimant does not have the financial resources for litigation and obtaining sophisticated data and expert analysis [42,43]. A review of Loveday v Renton [1990] 1 Med LR 177 indicates that the burden of proof of the judicial system makes it difficult for the plaintiff to prevail because it can only be determined by an expert [44]. From the case, it was held that there were alternative explanations that seemed more plausible than vaccine injury. In all the cases in question, which had allegedly led to lifelong disabilities in otherwise healthy children, symptoms appeared within the first 48 hours [45]. Several of them had clear alternative diagnoses, including Reyes syndrome and viral encephalitis, while others were infantile spasms: a seizure disorder whose association with vaccination DPT had been rejected in several previous studies and was largely disregarded until 1988 [45]. Therefore, according to Mr. Justice Stuart Smith, there was no evidence that the vaccine had any long-term neurological effects [45].

As a result, all compensation claims involving medical products in the Commonwealth countries have been rejected by the court, especially due to the failure to prove this causal relationship (Richardson v. LRC Products Ltd [2000] PIQR P164 [46], Peterson v. Merke Sharpe & Dohme (Aust) Pty Ltd [2010] 184 FCR 1 [47], and Carey-Hazell v. Getz Bros & Co (Aust) Pty Ltd [2004] FCA 853 [48]). The landscape in Malaysia is similar as claimants will most likely face the same challenges, given that the CPA 1999 (Malaysia) adopted the CPA 1987 (United Kingdom) [43]. Therefore, the problem remains the same, and vaccine recipients are yet to be protected from AEFIs in terms of financial liability and compensation through the mechanism of the CPA 1999 or tort under common law.

The second issue raised in the discussion concerned legal fees. The participants commented that court cases would involve payments to attorneys and expert witnesses, and are known to involve high litigation costs. The cost would also increase due to a prolonged litigation process, which raises the fee for the attorneys' services.

P3 mentioned the following:

> "Claimant needs to hire a lawyer after they file the claim. The price is pretty high." (P3)

The prolonged duration of cases to be heard and deliberated in each court increases the legal fees. P1 stated that if cases are brought to the Sessions Court, there is a high chance that the case will be brought to the Court of Appeal of Malaysia, and the claimant will suffer financially.

P3 added:

> "If the legal action is filed at the Sessions Court, the appeal will take several years and those claimants, I think, will suffer financially." (P3)

P3 also stated that bringing a civil suit is impractical as there are implications:

> "In my opinion, it is costly, and time-consuming due to the tedious appeal process and so on. Therefore, it's quite impractical." (P3)

P2 shared the experience relating to court cases:

> "Everything is moving so slowly. For example, in one case, the case was filed in court when the victim was a week old, and now the victim is four years old, and the case is still being tried in court. Obviously, no one needs to go through this as not everyone can afford it. Only the financially secure individuals can afford the expensive legal bills." (P2)

The third is the issue of time-barring in bringing a civil suit. The participants were referring to the time set for a civil claim to be filed in court, which is known as the statute of limitations. The claimant will generally be barred from making any claims after the statute of limitations has been set in. In cases relating to vaccine injury, the injury suffered by the vaccine recipients may only appear after the time limitation has set in, hence making them unable to make any claim.

### *3.1.2. Government assistance*

The participants identified government assistance as another mechanism, specifically referring to the Special Financial Assistance

for Adverse Effects of the COVID-19 Vaccine initiated by the Ministry of Health, Malaysia on March 22, 2021 [20,49]. Any AEFI claims that experience adverse effects following the COVID-19 vaccination brought to the attention of the ministry would be investigated, considered, and approved by the Committee for SFA.

P3 stated:

> "The Ministry of Health can provide financial assistance up to RM50,000 for typical [AEFI] cases and up to RM500,000 for permanent [disability] cases or death." (P3)

According to P3, the programme serves as 'financial assistance' only:

> "The term is 'financial assistance' and not 'compensation'. The phrase 'compensation' would trigger a wave of lawsuits. Consequently, the phrase 'financial assistance' is utilised." (P3)

The participants noted that the SFA is only available for victims with serious AEFI following their COVID-19 vaccination. However, this programme is only limited to the COVID-19 vaccination, and there is currently no standardised table outlining serious cases of AEFI that would qualify for compensation. In addition, the burden of proof is on the claimants to prove that the vaccine caused the injury suffered.

There were several issues identified by the participants regarding SFA. Firstly, SFA is offered to those with limited eligibility. Secondly, the amount of compensation to be awarded is an important element that contributes to the issues associated with the current mechanisms. According to the government's administrative programme, the maximum compensation amount for death or permanent disability is up to RM500,000. The government uses the term "financial assistance" in this programme because the allocated amount is solely for providing financial help and is not considered compensation from the government.

> "The one who suffers the most is the claimant who might be bedridden. It's not just the claimant who suffers, the family also suffer. If the claimant is only 28 or 29, for example, and if the claimant can live up to 70 years old, how can the claimant and the family survive?" (P3)

According to this participant, the restricted amount is only up to RM500,000, which is insufficient if someone requires care for many years. Because of the specified range, the researchers discovered additional limited criteria in this programme. The only way to increase the compensation amount is by initiating a lawsuit under the CLA 1956, which will inevitably encounter numerous undisputed challenges that must be overcome for a successful claim. In addition to the abovementioned challenges, the participants identified several other challenges that must be overcome for a claim to be successful.

P4 highlighted the challenge of obtaining cooperation from government medical practitioners to act as a witness in a civil suit for fear of consequent disciplinary action.

> "The doctors could be afraid of the disciplinary action that would be taken against them since the doctors are working with the Ministry of Health." (P4)

Another challenge is people's lack of awareness relating to their rights. Two participants claimed that people often lack awareness regarding the legal implications of particular situations. They may not know their legal rights in a given circumstance because they might not recognise that they have legal rights and, as a result, may not seek legal counsel. The level of awareness of legal knowledge is crucial since it helps in the development of a legal culture. Every member of society would therefore need to learn the fundamentals of the law.

P1 stated:

> "The level of awareness is very, very low." (P1)

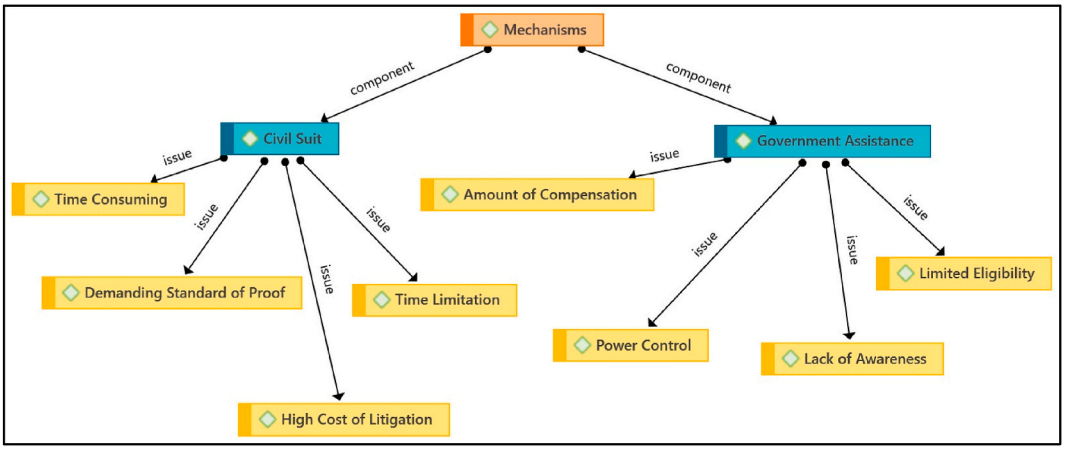


**Fig. 4.** Existing mechanisms and their challenges (Source : Authors).

Third is their reliance on fate. 'Fate' is defined as "something that happens outside of a person's control, regarded as pre-determined by a supernatural power" [50,51].

P1 emphasised that some people were fortunate to have survived the pandemic and believed that they should accept their fate and tend to refrain from seeking justice when something bad occurs.

> "The factor is the level of society that accepts their fate and is grateful for still being alive." (P1)

In summary, regarding the existing mechanisms and their challenges, the participants acknowledged that there are two main mechanisms, as illustrated in Fig. 4, namely: i) pursuing a civil suit, and ii) utilising the government's assistance programme.

### 3.2. Second theme: the role of alternative dispute resolution

The participants were solicited for their expert opinion on the role of ADR in resolving the COVID-19 vaccine compensation dispute as opposed to pursuing a civil suit and utilising the SFA. The main theme is explained within three aspects, which are mediation, tribunal, and special court. Fig. 5 shows that the participants began with a list of potential ADRs, including mediation, tribunals, and special courts, and elaborated by outlining the process and drawbacks of the compensation systems in Malaysia.

#### 3.2.1. Mediation

Although some participants agreed that mediation may help to address the COVID-19 vaccination compensation mechanism, others objected and pointed out the mediation's drawbacks. According to P1, any civil case in Malaysia must first go through mediation to see whether the issue can be resolved there. However, the chance that a case will be resolved through mediation is minimal because the plaintiff has already filed a lawsuit against the opposing party and is not seeking a settlement through mediation.

> "Every legal dispute must first go through mediation, so why is this mediation taking place in a civil court? Due to the fact that there is a potential that the parties can settle their disagreement through mediation, albeit this chance is not very large." (P1)

In addition, P3 expressed that the process of mediation might require a significant amount of time to reach a resolution.

> "The mediation is conducted once all of the necessary documents have been produced; it can be done, but it will take time, absolutely." (P3)

P1 noted that if the other party does not agree with the agreement reached during mediation, the decision may still be challenged.

> "Mediation can be difficult. If AstraZeneca is the target of the award, this involves a huge corporation. Of course, the company will appeal the ruling, isn't it obvious? Yes, they present a challenge." (P1)

In summary, although Malaysian civil courts have already adopted mediation, it still needs the consent of both parties, and the participants suggested that the majority of people were not receptive to it.

#### 3.2.2. Tribunal

Malaysia has a Tribunal for Consumer Claims under the CPA 1999. P1 and P3 appeared to agree that the tribunal should be amended to address the COVID-19 vaccine compensation mechanisms. They suggested extending the jurisdiction of the tribunal to hear vaccine injury cases:

> "Tribunal will facilitate and guide the claimant. I think that is more practical nowadays. In contrast to the other mechanism, for the tribunal, there is a need to pass additional or another piece of legislation." (P1)

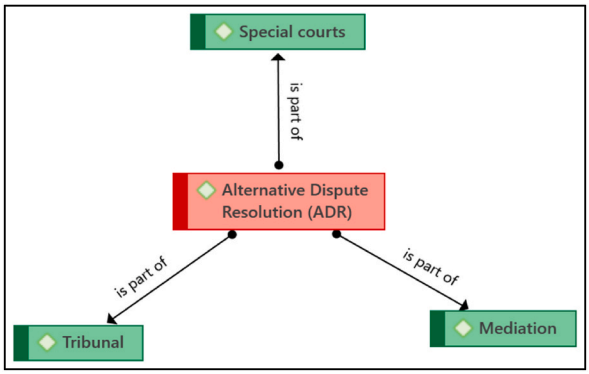


**Fig. 5.** ADR for vaccine injury compensation dispute (Source : Authors).

> "Tribunal could be a solution as a compensation mechanism. It is the most feasible solution given that it has the necessary infrastructure. However, several amendments to the Consumer Protection Act 1999 have to be made especially in regards to the jurisdiction." (P3)

P1 referred to the jurisdiction of the Tribunal for Consumer Claims under the CPA 1999, where the tribunal has no jurisdiction to hear a case involving personal injury and/or death. P2 and P4 did not deny that medical devices, including vaccines, are 'products' as defined under the CPA 1999. This argument relates to the participants' idea to expand the jurisdiction of the tribunal mentioned thereof. However, this idea was not well-accepted by P1, from the judiciary of the relevant ministry.

P1 explicitly stated that the tribunal has no jurisdiction to award cases involving personal injury or death:

> "I am aware that you had high aspirations for the creation of a tribunal, but you will be disappointed. You are going to be disappointed not because we don't want to work, but rather because of the limitation of powers under the law and also the principle of dispute resolution which involves personal injury that should not be taken lightly by the judiciary. The rights of those who suffer harm or loss of life are severely compromised in cases involving personal injury, such as AEFI COVID-19, and the burden of proof is exceedingly onerous for the parties involved, but no tribunal has ever heard a dispute involving personal injury." (P1)

P2, who referred to section 98 (1) CPA 1999, added:

> "Even though section 112 outlined the types of awards that could be made in a tribunal, including compensation, indemnity, and cost-reduction measures, there is no jurisdiction to hear such personal injury claims. How can we lower the expense of AEFI on our health? A tribunal lacks authority. If a tribunal hears such cases, it must call expert witnesses, and there will undoubtedly be attorneys to support the conclusions or analysis of the experts. Serious injury cases must have a lawyer representing them to refute the claim. The claimant would want the rights to be heard at the highest level (court) and not at the level of a tribunal, which would negate the purpose of establishing a tribunal where the parties shall not be represented by counsel." (P2)

P1 also commented on the maximum award of RM50,000 that could be awarded by the Tribunal for Consumer Claim. The amount of the award compared to the injury sustained is nominal and, even if awarded, would be challenged by the pharmaceutical company (vaccine producers) in the High Court.

> "In comparison to the vaccine recipients, the pharmaceutical business is massive. The recipients are simply a drop in the bucket. However, this does not absolve the recipients of the responsibility to protect themselves." (P1)

Due to the gap in the existing jurisdictions, victims of the vaccine will never be able to file a claim under the Tribunal for Consumer Claims. In addition, other participants highlighted the issue of accountability, as the chain of events leading to a vaccine injury involves multiple parties starting with the manufacturer, distributor, and vaccine administrator.

P2 contended:

> "Since the claimants cannot identify the source of the problem, how are they going to identify the person who will be held accountable? The burden of proof is upon the claimants to prove their claim." (P2)

#### *3.2.3. Special court*

In Malaysia, the government has established several specialised courts over the past four decades. Examples include the Construction Court and the Intellectual Property (IP) Court, which was established in response to criticisms from the international community that Malaysia has not sufficiently improved IP rights enforcement [52]. P1, P2 and P3 proposed to establish a new special court for vaccine injury compensation.

> "We need to rename this tribunal as a special court. It must be a special court, one that falls under the Malaysian legal system's special courts." (P1)

P2 added:

> "My suggestion is that we can actually set up a special court, this court need not be called a court; it might be termed a centre for reparation. It could be a centre of medical reparation that is seated by judges with a panel of other medical experts who deliberate and advise on this matter." (P2)

The establishment of a special court, however, would encounter additional obstacles. P3 remarked that special courts also faced the challenge of high litigation costs, as lawyers' fees must be paid.

> "It's a bit costly but not as expensive as mediation. You have to hire a lawyer and it is costly." (P3)

According to the discussions of the aforementioned ADRs, mediation is a process which involves the consent of both parties to resolve the matter via a certified mediator. The main criteria of mediation are non-litigious, voluntary, and optional legal representatives. The disadvantage of mediation is that if the parties reach a settlement, it cannot be enforced in court, and if it later gives rise to any disputes to the agreement, there is no written evidence to support it [53]. In regards to the tribunal, the participants established that although the compensation mechanism is quick, easy, and inexpensive [54], the tribunal has no jurisdiction to hear such cases.

The suggestion to expand the jurisdiction or increase the award is not a viable solution as expressed by P2, and personal injury or death due to AEFI of COVID-19 vaccination is not a matter to be taken lightly and heard in a tribunal. A special court, on the other hand, could be a solution to this matter. However, establishing a special court would require support from all the relevant parties. It will require the enactment or amendment of the relevant legislation in regard to the establishment of this platform. An adversarial atmosphere may thus be formed as a result of the petitioners' burden of proof to establish that a covered vaccine caused the harm [21].

### 3.3. Theme three: the solution for vaccine injury compensation mechanism

The analysis of the FGD concluded by soliciting suggestions from the participants regarding potential solutions for the compensation mechanisms concerning vaccine injuries in Malaysia. Through the FGD, a model was developed by the participants after carefully deliberating on all available compensation mechanisms in Malaysia and also taking into consideration existing mechanisms in other countries. Numerous factors were considered, particularly the seriousness of the situation regarding compensations for vaccine injuries that have an impact on the livelihood of the vaccine recipients. Since the participants were diverse in terms of their expertise, input on key aspects was considered such as benefits, financial obligations, and governance.

The participants suggested the establishment of a specific healthcare centre for compensation (SHCC) that would allow those who have suffered injuries because of any medical case to accord compensation. For the SHCC to be viable, several strategies are proposed by the participants. Fig. 6 below outlines the four suggested strategies for the proposed centre.

#### 3.3.1. Committee

A legal and medical expert sitting committee is necessary for the centre to be neutral and free of any bias since they can complement one another. For example, legal proceedings often require the assistance of medical professionals. They can help with criminal cases as well as regulatory issues, medical product liability, and allegations of clinical negligence. If there is any disagreement between a medical or legal expert, a neutral person must decide the matter fairly. P2 suggested three sitting individuals, including a legal expert, a medical expert, and a neutral third party.

> "To establish SHCC, the committee shall consist of three pertinent members. One would represent the judiciary, followed by one from the medical council and one more from a third neutral party. As a result, when a claim is being deliberated, the committee would be able to appreciate a person's view based on their expertise; legal and medical aspects respectively." (P2)

P1 agreed with P2 and added:

> "I mean, if we want to establish this dispute resolution body, you have to decide who is the member of the committee to deliberate on a person's claim. Obviously, there must be a legal representative and medical experts to determine the cause of injury. Then next is to assess if all the regulations and all the procedures are in place." (P1)

As a result, knowledge from different fields must be represented in the meetings to allow for integration among the committee members in decision-making. Based on the participants' views, legal experts will place greater emphasis on the balance of probabilities and medical experts will rely more on scientific evidence when determining the standard of proof.

#### 3.3.2. Centre guidelines

Any organisation, whether public or private, is free to create and implement rules to make the actions more approachable for the

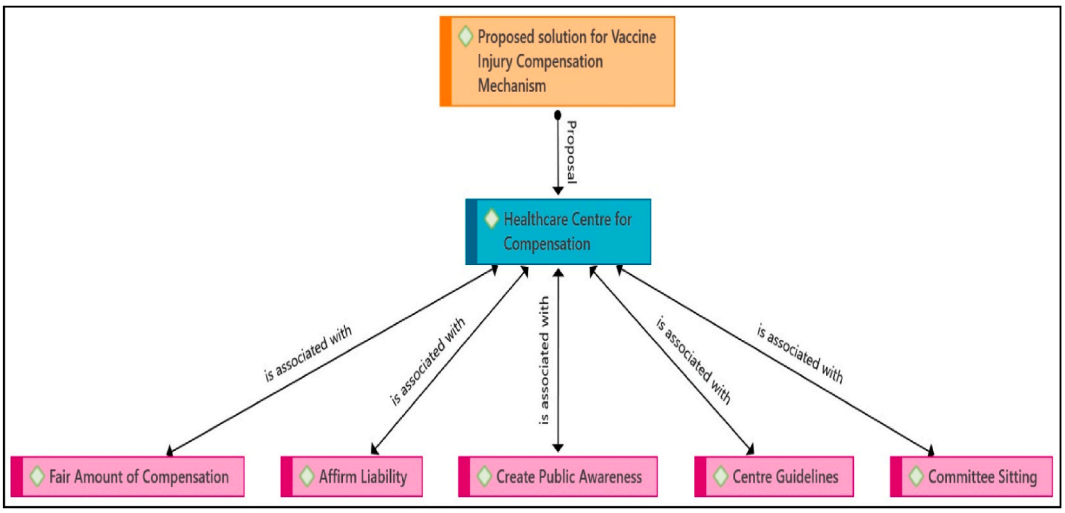


**Fig. 6.** Proposed solution for the vaccine injury compensation mechanism (Source : Authors).

participants and probably of greater quality. The participants emphasised the significance of the centre systematising the pertinent causal factors for compensation. This may entail classifying the seriousness of injuries that call for compensation or figuring out which eligible AEFIs are eligible for compensation.

P1 made the following suggestion:

> "The capacity to first determine the type of injuries, then to determine the cause of the injuries, to provide documentation of support such a claim, to determine the date of the injuries, and finally whether any laboratory reports exist, is required." (P1)

Considering this aspect, formulating appropriate guidelines for the centre could aid in reaching its objective effectively and efficiently.

#### *3.3.3. Fair amount of compensation*

P2 emphasised the importance of the centre in offering a fair and reasonable amount of compensation, encompassing not only wages but also other associated benefits.

> "We seek a fair recognition of liability and reasonable reparation each should not be even RM50,000, but fair reparation implies it doesn't matter who you are on what economic level." (P2)

> "For claimants aged 20 and above, if they suffer injury due to vaccine COVID-19, it is covered by their own life and personal insurance. Therefore, it's crucial that reparation not only be paid for but also provided when necessary." (P2)

#### *3.3.4. Create public awareness*

The final strategy for the proposed centre for vaccine injury compensation is to create public awareness. Participants suggested that the centre offers continuous education through knowledge sharing and publicity.

P4 and P1 stated:

> "Setting up this health tech hub where we can provide affordable, inclusive and sustainable medical healthcare innovation. This is where we raise awareness and build a base for our healthcare professionals." (P4)

> "Thus, how far do you want your claim to be taken seriously? That's why I want to share the information as accurately as possible." (P1)

Finally, some recommendations were proposed by the participants to enhance the efficiency of the COVID-19 vaccine injury compensation mechanisms in Malaysia. All of them unanimously agreed that Malaysia should have a dedicated centre for resolving disputes related to vaccine injury compensation that not only hears COVID-19 vaccine cases but can also be expanded for cases involving other medical products. The centre must be fair and just for the compensation to be self-sustaining over time, which is essential for its effectiveness.

## 4. Discussion

Highlights on the challenges of the existing compensation mechanisms for vaccine injury indicate that the law and available remedies are prone to complications in implementation, to the extent that the rules governing the judicial or administrative investigation procedures may lead to delays in compensation. The creation of a comprehensive no-fault vaccine injury compensation system is feasible and would contribute to the promotion of justice. Additionally, manufacturers should be given a minimal level of economic security because they are crucial to the development and accessibility of vaccines. Through the utilisation of compensation claims applications in Malaysia, this study provides evidence demonstrating that the country has existing compensation mechanisms for people who are affected by vaccines. These mechanisms include civil suits and limited government assistance, particularly in cases of COVID-19 vaccine injuries.

In Malaysia, there has only ever been one civil lawsuit for a vaccine injury. The case is Muhammad Muhaimin Bin Yauza & Ors v JK Maizatulniza Binti Mat Jais & Ors [2016] MLJU 333 [55], which is a claim in tort for medical negligence in administering vaccine case in Malaysia. In other countries, such as the United Kingdom (UK) and the United States (US), the Vaccine Injury Compensation Programmes (VICP) was subsequently amended to deal with vaccine-related cases as a result of an agreement between the government and the country's pharmaceutical companies on upfront compensation for risks [56]. The VICP is a no-fault compensation scheme that has been introduced in several countries to compensate vaccine recipients for adverse reactions to correctly administered vaccines. The decision of the Supreme Court of Germany in the case of a smallpox vaccine recipient who suffered injuries in 1961 marked the beginning of the VICP. Germany was thus the first nation to introduce VICP [56]. Calls for a no-fault compensation programme emerged in most US states in the 1970s after reports of adverse effects following vaccination with diphtheria, tetanus, and pertussis [15].

The VICP is designed in 25 countries (16 in the European region, 6 in Asia, 2 in America, and 1 in Oceania) to compensate those who have suffered severe vaccine injuries. The term "no-fault" means that those affected, or their legal representatives do not have to prove negligence or fault on the part of the vaccine manufacturer, the vaccine provider, or the health system in order to receive compensation. Most of the existing VICPs are implemented at the central or federal level and are state-funded. The VICPs provide compensations covering medical expenses, disability pensions and death benefits (depending on the country) to individuals who experience injuries caused by vaccines licenced in the country [57,58]. The claims and decision-making processes are strictly administrative and

non-civil and standards of proof linking vaccination and injury are required [57,59]. There are various approaches worldwide with regard to vaccine compensation mechanisms, such as the comprehensive disability welfare scheme that also covers vaccine injury in Australia [60].

In the UK, standardised compensation is awarded, where a lump sum payment of £120,000 (€140,000) is offered. However, economic losses, pain, suffering and emotional distress could only be compensated in a few compensation schemes [61]. With the shortcomings of the existing compensation mechanisms in Malaysia such as the strict burden of proof under the CLA 1956 and CPA 1999 [57,59–65], the time-consuming and high cost of litigation [66], time limitation [67], and complicated procedure [68], establishing a SHCC seems to be a possible solution for the people who are injured by vaccination, including the COVID-19 vaccination.

In general, this study would benefit policymakers as the establishment of the SHCC is consistent with the Malaysian Ministry of Health's Strategic Plan 2021–2025 [69], which is to strengthen safety and quality in the health care system and support one of the guiding and enabling principles the Vision of Shared Prosperity 2030, which is Integrity and Good Governance that will have an impact on the people, especially low-income citizens, older people, and the disabled. This study is also in line with the 16th Sustainable Development Goal (SDG), which is "to promote just, peaceful and inclusive societies" [70]. Hence, the proposal for a compensation dispute resolution mechanism in this study, which will be developed in the form of a framework of acts, policies or guidelines, can benefit government agencies and companies involved in the supply of the COVID-19 vaccine. Based on the participants' views, a proper compensation mechanism can also help instil confidence among the public that their rights will be protected in cases of AEFI from vaccination.

## 5. Conclusion

This study aims to propose a viable ADR mechanism for those suffering from AEFI due to COVID-19 vaccination. The strength of this study lies in its extensive information on vaccine injury compensation in Malaysia in terms of the mechanisms available for filing claims and recommendations for new alternative dispute resolution mechanisms to be implemented in Malaysia. Hence, this study provides valuable information regarding Malaysia's situation and viable improvements on the existing compensation mechanism for vaccine injury.

Based on the research findings, it is evident that the current mechanisms have deficiencies and limitations that hinder vaccine recipients from seeking fair compensation for AEFI or vaccine-related injuries. The most effective solution to address this problem, based on the perspectives shared by the participants, is the establishment of a SHCC. Although initially, existing ADRs have been identified as potential mechanisms, the SHCC could be a new type of ADR that is tailored for healthcare issues, especially for AEFI. Regarding the viability of this proposed solution, as suggested by the participants, governmental support, political will, and cooperation from relevant stakeholders are needed to ensure the success of this new mechanism. Based on the criteria put forward by the participants, it is believed that the SHCC would be a more practical option for evaluating and determining the compensation being sought.

However, it is important to note that the limitation of this study is that it mainly focuses on the legal perspective of vaccine compensation; hence, there is limited stakeholder input based on the objective of this study. This study only incorporates the perspectives of experts in the following areas: legal professionals, medical professionals, and consumer protection activists. It does not encompass viewpoints of vulnerable or 'high-risk' groups who have suffered harm or injury from vaccination. It should also be emphasised that this study primarily examines Malaysian law and excludes viewpoints from other nations. However, because Malaysia uses the common law legal system, references to decided cases in the UK are also included. In addition, this research only employs qualitative research methodology, which includes FGD. As far as the issues of injuries are concerned, this research focuses on injuries caused by the COVID-19 vaccine.

Based on the findings of the research, it is proposed that the establishment of a SHCC is necessary to facilitate the fair assessment and provision of suitable remedies or compensation for the victims. However, the implementation of this scheme is not specifically covered in the current study, nor is it clarified. Therefore, it is recommended that future research focuses on crucial aspects related to the establishment of the centre. This would include exploring elements such as the governance structure of the centre, the administrative authority responsible (i.e. ministry), relevant guidelines, expert committees, and appropriate compensation measures.

## Ethics declaration

Approval of the ethical committee was obtained from the Universiti Malaysia Terengganu Research Ethics Committee of the Office of Research Management (Approval No: UMT/JKEPM/2022/103, Date: June 16, 2022). All participants were given information about the purpose of the study, anonymity, and confidential rights. They were also informed that they had the right to withdraw at any time without consequences or any penalty. All participants provided consent for the research, and their anonymity was preserved.

## ICMJE criteria

All authors attest they meet the ICMJE criteria for authorship.

## Data availability statement

The data is not deposited into a publicly available repository. The data that has been used is confidential.

## CRediT authorship contribution statement

**Fahirah Syaliza Mokhtar:** Writing – review & editing, Writing – original draft, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Akmalia Mohamad Ariff:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Nazura Abdul Manap:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Data curation, Conceptualization. **Nurul Masirah Mustaffa:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Conceptualization.

## Declaration of competing interest

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