

# Vaccine injury redress programmes

An evidence review

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## Abbreviations

Abbreviation	Explanation	Jurisdiction
ACC	Accident Compensation Corporation	New Zealand
Chinese ¥	Chinese yuan	China
DDCC	Disease and Disability Certification Council	Japan
DHHS	Department of Health and Human Services	USA
DOJ	Department of Justice	USA
FASS	Farmaceutiska Specialiteter i Sverige (Pharmaceutical Specialities in Sweden)	Norway and Sweden
GB£	Great Britain pound sterling	UK
GAO	Government Accountability Office	USA
GBS	Guillain–Barré syndrome	
HRB	Health Research Board	Ireland
HRSA	Health Resources and Services Administration	USA
HSB	Health Service Bureau	Japan
MHLW	Ministry of Health, Labour and Welfare	Japan
MMR	measles, mumps, and rubella vaccine	
MPV-A	multi-peptide vaccine	
NHS	National Health Service	UK
NHSLA	National Health Service Litigation Authority	UK
NPE	Norwegian Patient Injury Compensation	Norway
NT\$	New Taiwan dollar	Taiwan
PAFSC	Pharmaceutical Affairs and Food Sanitation Council	Japan
PFSB	Pharmaceutical and Food Safety Bureau	Japan
PHC	public health clinic	USA
PICOC	population, intervention, comparison, outcome, and context	
PMDA	Pharmaceuticals and Medical Devices Agency	Japan
SEK	Swedish krona	Sweden
LFF	Swedish Pharmaceutical Insurance Association	Sweden
UK	United Kingdom	UK
US\$	United States dollar	USA
USA	United States of America	USA
USCFC	United States Court of Federal Claims	USA
VDPS	Vaccine Damages Payment Scheme	UK
VICP	vaccine injury compensation programme	Japan, Korea, Taiwan, and USA
VICPWG	Vaccine Injury Compensation Programme Working Group	Taiwan
WHO	World Health Organization	International

## Executive summary

### Purpose

Consideration of introducing a no-fault vaccine injury compensation programme (VICP) in Ireland has been under examination since 2001, when the Oireachtas Joint Committee on Health and Children recommended that a vaccine damage compensation scheme be set up at the earliest possible date. In 2007, the Vaccine Damage Steering Group was established by the Department of Health and Children to review the issue further. This review culminated in the publication of a report by the Steering Group in 2009, which again recommended the establishment of a VICP. More recently, the current Programme for a Partnership Government in Ireland includes a commitment to establish a scheme, on a no-fault basis, that will respond to the needs of people with disability arising from vaccination.

The Department of Health (DOH) has now commissioned the Health Research Board (HRB) to undertake a more detailed analysis of the international literature in order to assess the evidence concerning the parameters and critical success factors associated with no-fault VICPs in other jurisdictions. It is envisaged that the DOH will use the completed review to inform current deliberations on designing and implementing a no-fault VICP in Ireland in line with proposals set out in the current Programme for a Partnership Government.

### Review questions

Building on an evidence brief completed in 2017, the DOH asked the following questions:

1. What design features and/or contextual conditions are thought to impact on the **operating costs** associated with no-fault vaccine damage schemes?
2. What design features and/or contextual conditions are thought to impact on **timely access** to no-fault vaccine damage schemes?
3. What design features and/or contextual conditions are thought to impact on the **number of applicants** seeking redress via no-fault vaccine damage schemes?
4. What design features and/or contextual conditions are thought to impact on **the volume and costs of awards** made under no-fault vaccine damage schemes?
5. Do no-fault vaccine damage schemes enjoy **public acceptance**?
6. What **cost-control mechanisms** covering no-fault vaccine damage schemes are reported in the literature?

### Methods

The HRB chose the integrative review approach as the overarching framework for this review. An integrative review is a specific review method that summarises past empirical or theoretical literature in order to provide a more comprehensive understanding of a particular phenomenon.

We undertook a comprehensive search up to end of June 2018 and we had no start date limit. We searched for relevant literature combining a number of approaches, including systematic searching, snowballing, and supplementary searches. Such a multifaceted search approach is in line with the overarching framework of an integrative review, where the main objective in this case was to identify the maximum number of relevant papers that may contribute to answering our review questions. Papers containing data that would help to answer at least one of our questions were prioritised for inclusion. Papers could investigate standalone VICPs or broader medication or treatment injury compensation schemes that also covered vaccine injury. We included papers which contained empirical or theoretical data. We actively sought non-English language papers and translated them using Google translate. In total, we included 33 papers that provided relevant data to answer our questions.

We developed and piloted a bespoke data extraction sheet. We also developed a coding schema based on the key features of VICPs reported in the literature. Both instruments allowed us to extract relevant data from the papers we reviewed. We chose the constant comparative method to analyse the data, as none of the papers that we included in our review asked either the same or similar



questions as our review questions. The constant comparative method is compatible with the analysis of varied data from diverse methodologies.

We have compiled this review using the best available data to answer our questions. The lack of formal evaluations and rigorously designed studies comprising empirical data limits the nature of the conclusions that we can draw from our review. Instead, we have relied on drawing data from an eclectic mix of resources, including discussion papers from health policy and legal literature, case law, surveys, interviews with stakeholders, and papers citing analyses of administrative data relating to the compensation schemes.

The major weakness in the data sources we relied on is that the majority are not orthodox research papers and do not document their research methods, so they are not suitable for quality appraisal. However, this can also be considered a strength, as we chose to select material for inclusion on the basis of its relevance. Some commentators suggest, when considering the relevance of a potential data resource, the question to ask is whether the document contributes in some way to knowledge synthesis or answering our questions. All 33 documents contributed to answering at least one of our questions. Another limitation of our included documents was that some of them were more than 15 years old, however each country had at least one document published in the last 3 years.

## Key findings

We provide a brief overview of some of the key features of the compensation schemes we reviewed and how these features relate to our key parameters of interest. We do not replicate the summary findings for each of our included countries, as summaries for each country are presented at the end of the country sub-section in the report and are clearly labelled in the table of contents. The summary findings related to VICPs in Denmark, Finland, Norway, and Sweden are grouped under the title 'Nordic countries'. Also, findings related to the schemes in China, Japan, Korea, and Taiwan are grouped under the title 'Asian countries'. Findings related to the schemes in New Zealand, the United States of America (USA), and United Kingdom (UK), are presented individually as they are very different to other schemes.

## New Zealand

In New Zealand in 2005, medical mishap and medical error were replaced with a new concept of treatment injury. In effect, this reform to the New Zealand injury compensation programme meant that the need to prove negligence by a health professional was removed and the programme became a full no-fault administrative intervention redesigned to improve the chances of compensation for claimants. In addition, vaccine injuries were included as medical injury. There is broad agreement that the compensation scheme in New Zealand has met the primary objective of improving injured patients' access to compensation. The 2005 reforms to the scheme, which included the removal of the need for claimants to prove negligence, have been key to speeding up access to compensation. Since these reforms, health professionals are more actively involved in assisting claimants to submit claims for compensation which assists the scheme to streamline the handling of claims, and this development has been a major contributory factor in improving timely access to compensation. It is estimated that the administrative costs and overhead costs represent approximately 10% to 17% of total expenditures, compared with 50% to 60% among malpractice systems in other countries. Contextually speaking, the scheme is embedded in a wider suite of social and employment insurance resources, and these external supports for claimants seem to keep both the overhead running costs and the compensation costs to a manageable level. Unlike most of the other schemes we reviewed, there is a high level of public awareness of the scheme in New Zealand, and it appears to enjoy support from the public and has buy-in from physicians and health professionals in general. We identified three cost-control mechanisms in New Zealand: no legal fees, caps on lump-sum monetary awards for permanent disability, and a 12-month filing deadline. In addition the scheme does not provide compensation for pain and suffering, only for permanent disability.

## Nordic countries

In the four Nordic countries – Denmark, Finland, Norway, and Sweden – compensation for vaccine injuries is handled as part of a wider drug injury compensation scheme; the wider drug injury scheme is part of or a sister to a medical treatment scheme. The overhead costs of administering the drug injury compensation schemes in the four Nordic countries are low when compared with the costs that would apply if legal actions were pursued instead. In all four countries' schemes, the objective of improving timely access to compensation seems to have progressed quite well. The removal of negligence or fault from the schemes has greatly contributed to keeping costs low (by removing legal costs) and improving access to compensation. All four schemes employ a more relaxed standard of proof based on the principle of preponderance of probability (or the principle that the medicine more likely than not caused the injury) is more favourable for claimants than the rigorous causation requirements that would pertain in the courts. However, there are variations in how some of the Nordic countries apply the standard of proof; for example, Finland approves 30-40% of claims for compensation, compared with 36% in Norway and circa 30% in Denmark and 35% in Sweden, which suggests a more liberal application in the case of Finland. The four schemes are embedded in societies that provide substantial social security, employment insurance, and healthcare measures to assist injured persons. The drug injury compensation schemes are a 'top-up' to other sources of Government-based compensation in order to provide comprehensive cover to claimants for injuries related to drugs, including vaccines. This wider contextual assistance helps to keep the costs of compensation from the scheme at modest levels. There are three cost-control mechanisms common to all Nordic countries' drug injury schemes: no legal fees, maximum values on the total award expenditure available for injured persons in a single year, and time limitations on claims. We have very limited data on Norway, but the data from Denmark, Finland, and Sweden indicate that the schemes act as a top up to payments through social and health care services. Of note, these schemes do compensate for pain and suffering.

## Asian countries

Four countries in Asia – China, Japan, Korea, and Taiwan – operate a standalone VICP. In China, a highly structured three-stage claims handling and adjudication process, which involves cumbersome and repetitive procedures, delays timely access to compensation for claimants. The scheme employs a strict standard of proof which normally requires the claimant to demonstrate that a vaccine has caused the injury claimed for by drawing on evidence from rigorous epidemiological studies. The decision to require such a high standard of proof appears to keep the approval rate for compensating claimants quite low. Claimants to the scheme are unhappy with the scope and amount of compensation that is paid out, and have often engaged in public protest in an attempt to overturn decisions that ruled against their claims. The programmes in both China and Japan distinguish between Class I and Class II vaccines; Class I are routine and encouraged by the Government, and Class II vaccines are advised and non-routine. In Japan, injuries incurred by claimants in receipt of Class I vaccines receive higher amounts of compensation for their contribution to protecting society (known as 'herd immunity') than their Class II vaccine counterparts. Otherwise, data on the VICP in Japan are scant. Both Korea and Taiwan operate a more relaxed standard of proof, which is in line with WHO recommendations. In Korea, claims are approved for compensation if the injuries claimed for are a) definitely related, b) probably related, or c) possibly related to a vaccine, and almost 68% of vaccine compensation claims are successful. In Taiwan, the level of causal relationship is categorised into three classes: an injury is related, an injury is possibly related, or an injury is unrelated. The first two classes of injury are compensated and, over a 15-year period, 40% of claims were successful. The scheme in Taiwan has a good record of resolving claims in a timely fashion, and it appears that the consistent efforts of the expert working group are primarily responsible for speeding up the processing of claims in a timely manner.

## USA

The USA operates a standalone VICP. The scheme incurs a high level of overhead running costs, mainly due to the high level of legal representation that claimants require in order to navigate the scheme. Up until 1995, the scheme relied mainly on the Vaccine Injury Table to decide whether injuries claimed for were caused by certain vaccines; the table contained a number of vaccines and associated injuries that had scientific consensus. In 1995 (and again in 1997), a number of vaccine injuries were removed from the table and a number of vaccines were added without all associated injuries; these revisions narrowed the size and scope of the Vaccine Injury Table and the number of off-Table claims increased. Subsequently, the special masters who handle all claims and adjudications in the scheme required that claimants submit high levels of epidemiological evidence to demonstrate causation for their off-Table claim. This resulted in the federal courts ruling against the special masters and recommending that a lower standard of evidence, perhaps based on medical opinion, could suffice in most off-Table cases. However, the discretionary deliberations on the part of the special masters around what constitutes causation appear to continue in the scheme, which means that most claimants require legal representation to assist them, which in turn keeps the costs of running the scheme higher than was initially intended. Initially, Congress intended that the scheme would resolve all claims in less than the statutory 240 days limit. However, the evidence strongly suggests that the scheme has rarely met this objective and that timely access to compensation is consistently slowed down by the long-drawn-out claims handling and adjudication process on behalf of the special masters and the ever-increasing level of legal representation that claimants seem to rely on to navigate the scheme. The literature suggests that the public's awareness of the VICP is low and that the Department of Health and Human Services do not make the adequate efforts to advertise the programme and inform the public about it. In addition, research suggests that the satisfaction of the VICP users is mixed and tends towards dissatisfaction. There are cost-control mechanisms in the USA's VICP documented in the literature: a maximum limit on pain and suffering awards, a three-year filing deadline, life planners for petitioners, and for the DHHS. In addition, the current Vaccine Injury Table may act as a proxy cost-control measure in the USA, as it restricts the number of applications and increases the claimants' costs through an off-Table adjudication process.

## UK

The Vaccine Damages Payment Scheme (VDPS) was created under the Vaccine Damage Payments Act 1979. The scheme was not designed to be a no-fault scheme, nor did it claim to provide compensation for vaccine injuries so it is quite different to other schemes which seek to protect vaccine production and compensate vaccine users who suffer harm. The scheme sets a high injury threshold, requiring that for compensation to be awarded, a claimant must demonstrate that his or her injury meets the criteria of the person being at least 60% disabled (equivalent to partial limb amputation or severe hearing loss). The VDPS provides a single tax-free payment of up to GB£120,000 made by the Government to a person who has suffered such severe mental and/or physical disablement. Up to the end of 2013, a claim must be submitted to the Secretary of State via the Vaccine Damage Payment Unit, which would then obtain relevant medical evidence from the doctors or hospitals involved in the applicant's treatment. In the event that the claimant is unsuccessful, the applicant could request a review by the Vaccine Damage Payment Unit or could appeal to the First-tier Tribunal and the Upper Tribunal. Legal representation was very rare between 2000 and 2013. Since 1 May 2014, the VDPS has been the joint responsibility of the Department for Work and Pensions and the Department of Health. The Department of Health is responsible for policy, for example, changes to the list of vaccines covered by the Act. The Department for Work and Pensions is responsible for assessing claims for damages. Since the mid-eighties, the award approval rate has declined in the UK, and it is claimed that failure to prove causation is the main reason for this decline. In total, there were 6,196 claims between 1979 and May 2017. Since the schemes inception to May 2017, 79% of claims were rejected based on the claimants' inability to prove causation and the overall approval rate from the same period was just over 6%. There has been a serious decline in the number of approved awards overtime, currently at single digit numbers. These average numbers, presented in the research used in this review, hide the decreasing numbers of applicants each year and also are a proxy indicator of reduced public acceptance. The cost-control mechanisms for paying damages are: a

maximum award of GB£120,000, a filing deadline of 6 years, and damages are only awarded to severely disabled cases.

# 1 Introduction

This report presents the findings of a configurative review carried out by a team at the Health Research Board (HRB) Evidence Centre. The review outlines the design features and social context associated with international vaccine damage redress schemes and the impact of both aspects of the schemes on costs, the timescale of redress, the volume of applications, and the awards by each scheme. The report provides further examination of the level of public acceptance of each scheme and of how costs are controlled for each programme and, in the final part, attempts to examine the impact of schemes on the level of vaccine uptake in each country.

## 1.1 Purpose of the review

The Vaccine Damage Steering Group was established by the Department of Health and Children in early 2007 “to review the general details of vaccine damage compensation schemes operating in other countries and identify the most relevant models from a clinical, administrative and fairness point of view.” p6<sup>1</sup> The Steering Group examined a number of international schemes and drew on site visits to the United Kingdom (UK) in order to formalise its proposals. The group recommended “that an ex-gratia payment [not compensation] scheme be established [in Ireland]. A three-tiered structure depending on the severity of damage was recommended as follows; minor damage: €15,000, moderate damage: €75,000 and severe damage: €200,000.” p13<sup>1</sup>

The urgency of this matter is increasing, as the Health Products Regulatory Authority has received reports for people with clinical information confirming a diagnosis of narcolepsy in individuals who were immunised with the pandemic influenza 2009–2010 vaccine. The majority of these reports relate to people who were children or adolescents at the time of administration of the vaccine. Claims have been initiated against the Minister of Health, the Health Service Executive, and GlaxoSmithKline Biologicals S.A. in which the plaintiffs variously allege personal injury, claiming the development of narcolepsy (including cataplexy in a number of such cases) resulting from the administration of the H1N1 pandemic vaccine.

The absence of a vaccine damage compensation scheme will result in exposure of the State to a large number of claims through the existing legal process. In moving forward, the current Programme for a Partnership Government includes a commitment to “put in place a scheme, on a no-fault basis, that will respond to the needs of people with disability arising from vaccination.” p62.<sup>2</sup> As part of the current commitment, the Department of Health (DOH) asked the HRB Evidence Centre in 2017 to undertake an evidence brief in order to update some of the work undertaken by the Vaccine Damage Steering Group in 2009. Of relevance to the current review, the HRB Evidence Centre summarised the key characteristics of international vaccine injury compensation programmes (VICPs) and included existing reviews and/or evaluations of programmes.<sup>3</sup>

In the current configurative review, the DOH asked the HRB Evidence Centre to further elucidate the design features of international schemes that, with reference to the national context, may impact on the performance of such schemes, as well as how the schemes are accepted by the public, how costs are managed, and whether the existence of a scheme might impact vaccination levels.

## 1.2 Research questions

1. What design features and/or contextual conditions are thought to impact on the operating costs associated with no-fault vaccine damage schemes?
2. What design features and/or contextual conditions are thought to impact on timely access to no-fault vaccine damage schemes?
3. What design features and/or contextual conditions are thought to impact on the number of applicants seeking redress via no-fault vaccine damage schemes?
4. What design features and/or contextual conditions are thought to impact on the volume and costs of awards made under no-fault vaccine damage schemes?
5. Do no-fault vaccine damage schemes enjoy public acceptance?
6. What cost-control mechanisms covering no-fault vaccine damage schemes are reported in the literature?

## 1.3 Background

### 1.3.1 Approaches to vaccine injury

Halabi and Omer (2017)<sup>4</sup> identify three types of approaches to addressing vaccine injury: (i) patients may bear the costs associated with their injuries; (ii) they may seek compensation through litigation in the courts; or (iii) they may seek compensation from public systems which draw from public funds and, in some cases, private sector contributions. The latter option included by Halabi and Omer<sup>4</sup> is becoming increasingly viable in many jurisdictions, and a recent review by Looker and Kelly<sup>5</sup> included VICPs available in 19 jurisdictions; the current review identifies an additional scheme operated in China, although with scant information available, bringing the total number of jurisdictions operating VICPs worldwide to 20 (Table 1 and Table 2).<sup>6</sup> In addition to these 20 jurisdictions, Looker and Kelly also state that “there has also been significant public pressure in other countries, including Australia, Canada and Ireland, to establish similar schemes.” p372. <sup>5</sup> This pressure has come from politicians,<sup>7,8</sup> as well as individuals<sup>9,10</sup> and support groups<sup>11</sup> for those affected by known vaccine injuries, who are seeking State and industry acknowledgement of the fact that vaccines are not 100% safe for every person all the time along with an acceptance of responsibility for those damaged by vaccine side-effects. Indeed, published academic opinion seems to support the introduction of such programmes.<sup>12,13</sup> In addition, recent vaccination regimes have been placed in the spotlight in these countries by those insisting, in the absence of scientific support, that their health issues have ensued from vaccination.<sup>14</sup>

### 1.3.2 Arguments for and against compensation programmes

Wilson and Keelan<sup>12</sup> identify the main arguments in favour of introducing VICPs as being ethical, biological, and protecting the manufacture of vaccines. The ethical argument for compensation schemes centres on the social good achieved by vaccination policy; that is, in promoting vaccination, policy-makers aim to achieve ‘herd immunity’ within the population. Herd immunity involves achieving a certain level of vaccination coverage within a population and is crucial for disrupting the circulation of the virus and thus shielding those who cannot be vaccinated for medical reasons or who have not yet been vaccinated, or those for whom vaccination was ineffective. As people are encouraged by government and policy-makers to be vaccinated at least partly for the benefit of others in the pursuit of herd immunity, the cases where an individual reacts severely to a vaccine should receive reciprocal consideration from those responsible for the vaccination; this often takes the form of a compensation scheme.

As biological agents, vaccines have a recognised, albeit statistically low, chance of causing harm.<sup>15</sup> In testing vaccines, an estimate of the potential harm is reached and the adoption of a vaccine into a vaccination programme is deemed worthwhile when the overall public good outweighs the possible sum of the individual negative consequences of vaccination. Yet, despite the very low statistical chance of such adverse events, it has been noted that not only are a small number of adverse events highly likely on a population level, but the victims must face 100% of the negative consequences,

100% of the time. While some of the associated costs are absorbed by, for example, public health services, additional costs may be otherwise left to the victims.

In the past, the security of the vaccine supply has been threatened by litigation, where vaccine-injured parties sought redress through the courts. In the United States of America (USA), this was one of the primary reasons for introducing a VICP after a number of vaccine producers refused to continue producing vaccines and others increased the prices of their vaccines.<sup>16</sup> This issue has been included as an obstacle limiting the current supply and development of vaccines for rare diseases in resource-poor countries.<sup>4 17</sup> The USA no-fault programme, along with those in other countries, are structured so that those seeking compensation must first go through the VICP. Similarly, entering into a compensation agreement for personal injury in New Zealand precludes litigation except in certain circumstances, e.g. gross negligence. There is evidence that the litigation burden has been lifted from manufacturers in the USA, where security of supply was a major driving force in the creation of the compensation programme. There is a high level of acceptance of compensation awards made,<sup>18</sup> few unsuccessful claimants have resorted to litigation,<sup>19</sup> and there has been a sharp decline in vaccine liability cases in the USA courts since 1992.<sup>19</sup> In 2011, the Supreme Court ruling in *Bruesewitz versus Wyeth LLC* held that the Vaccine Act preempts all design defect claims against vaccine manufacturers, thus, since 2011, the litigation possibility is largely closed.<sup>18</sup> However, it is worth noting that while the creation of the VICP in the USA was intended to ensure a secure supply of vaccines, there was no increase by 2005.<sup>20</sup> By 2018, vaccine manufacture had increased, for example, there were 26 flu vaccine manufacturers in the USA by 2018.<sup>21</sup>

Wilson and Keelan also recognise that there may be opposing arguments to the introduction of VICPs. For example, in the context of considering the introduction of such a programme in Canada, the authors consider two opposing arguments: “the perception that such a program may undermine confidence in vaccines; and concerns about the cost of such a program and its relative priority versus other immunization program needs” p123-124.<sup>12</sup> However, the evidence does not support the link with vaccine confidence, and costs have been found to be both manageable and predictable.<sup>12</sup> Since the VICP was established in the USA, further concerns have been raised around the safety of vaccines developed in an environment which shields manufacturers from liability for their products, in particular the lack of a statutory obligation to extract safety data and the lack of an incentive to improve existing vaccines in light of new scientific developments.<sup>22</sup> Despite these concerns, recent calls to introduce compensation schemes in Croatia, Canada, India, Australia, and even on a global scale have focused on the many benefits of the VICPs rather than the possible negative consequences.<sup>4 13 15 23 24</sup>

### 1.3.3 Key characteristics of existing schemes

In 2011 Looker and Kelly (2011)<sup>5</sup> undertook a review of international no-fault VICPs. The aim of this review was to update the reviews undertaken by Mariner (1987)<sup>25</sup> and Evans (1999)<sup>26</sup> by examining similar programme elements. Looker and Kelly<sup>5</sup> undertook a comprehensive search for relevant literature, and their work was arguably the most comprehensive up-to-date review of international no-fault vaccine compensation programmes undertaken so far.

Keane and Long’s evidence brief of 2017<sup>3</sup> provided to the DOH collated the two key reviews in the area: those of Looker and Kelly (2011)<sup>5</sup> and Keelan and Wilson (2011).<sup>27</sup> Here we summarise, update, and explain aspects of the 20 schemes included by these reviews while a more general overview is provided in Table 1 and Table 2.

### **1.3.3.1 Administering VICPs**

In Germany (and in China), the no-fault VICP is administered by the State (or county). In the province of Quebec in Canada, the programme is administered through the provincial Ministry of Health and Social Services.

In Switzerland, the scheme, which was formerly administered at the cantonal/state level, has been updated to a federally administered scheme in order to ensure consistency across regions. Administrative schemes operating nationally are typically overseen by the department of the national government with responsibility for public health; this is the case in Switzerland, France, Japan, and Korea. In contrast, the UK scheme is overseen by the Department for Work and Pensions, while the legal scheme in the USA is overseen jointly by the Department of Health and Human Services, the Department of Justice, and the courts.

In the Nordic countries reviewed, vaccine injury compensation is part of broad no-fault compensation schemes for both medical treatment and medicines. In Denmark and Norway, the scheme is administered by the Department of Health, whereas in Finland and Sweden the scheme is voluntary for pharmaceutical companies and is not operated by the Government. In Sweden, the international pharmaceutical industry collaborates with both the insurance industry and the Government to administer the scheme; pharmaceutical companies and importers voluntarily pay contributions towards the scheme. In Finland, pharmaceutical manufacturers established the Finnish Cooperative for the Indemnification of Medicine-Related Injuries and negotiated with the insurance sector to establish their own voluntary scheme. In Norway, although the scheme is Government-run, it is also funded by contributions from the pharmaceutical industry.

In New Zealand, there is no separate administrative entity to address vaccine injuries. Instead, vaccine injuries are covered by the broad Accident Compensation Corporation, which is a statutory corporation that provides no-fault compensation for any injuries or death suffered while receiving treatment from health professionals.

### **1.3.3.2 Funding VICPs**

Several countries finance their programmes from national, state, or municipal treasuries or, in the case of Japan and Switzerland, funds are drawn from some or all of these sources.

New Zealand's general no fault scheme is financed from several sources, including levies on employers, employees, and motor vehicle owners; Government funding; and investment returns. Treatment injuries are compensated from the levies on employers and employees.

The Swedish and Finnish voluntary schemes are industry funded, while Norway and Denmark use a manufacturers' levy. The USA introduced a tax on each vaccine to create its compensation fund. Taiwan's funding source includes a vaccine tax and Government funds.

Looker and Kelly observe that

“In most countries, the compensation schemes are a secondary source of funding for medical and disability expenses. In general, patients receive primary support from the national public or private insurers. The compensation schemes can be relatively modest in size and not need to cover the full range of expenses that might be considered in a tort or product liability case.” p374<sup>5</sup>

Thus, much of the costs are absorbed by social security, welfare, and national health schemes, and many schemes acknowledge this by framing compensation payments as a 'top-up' payment or by raising eligibility requirements to exclude all but 'severe' injuries.



### **1.3.3.3 Eligibility criteria for VICPs**

Eligibility can reference the injury sustained or the vaccine received. In New Zealand, temporary minor injuries can be compensated once a causal link is established. There are typically more claims than in the USA, but awards are on average much lower in comparison.<sup>28</sup> All vaccines administered by a healthcare professional are covered under the treatment injury scheme in New Zealand and, similarly, countries operating no-fault medical or pharmaceutical schemes (such as Sweden, Finland, and Denmark) compensate injuries received from all vaccines. Other countries compensate only recommended or compulsory vaccines.

In terms of injury sustained, Denmark and Korea cite a minimum threshold of treatment received for injury (US\$470 and US\$300, respectively) to be eligible for compensation, while Finland requires disability to last a minimum of 14 days. Typically, injury must at least exceed a normal post-vaccine reaction, as is the case in France, Germany, and the USA. However, more stringent eligibility applies in the UK, Switzerland, Italy, Quebec, and Japan, where severe injury is the minimum level of injury eligible; in the UK, severe injury is defined as 60% disability.

### **1.3.3.4 Process underpinning the administration of VICPs**

Most of the information provided by Looker and Kelly<sup>5</sup> on the process underpinning VICPs was also reported by Keelan and Wilson,<sup>27</sup> with some minor additions reported by Looker and Kelly.

According to Looker and Kelly, “All countries, except Finland and Sweden, have passed legislation to enact their compensation schemes and government departments operate the programmes in most countries. Most schemes require claims to be filed with an administrative body that makes initial eligibility and compensation decisions on claims. Many countries use an administrative process for deciding compensation eligibility and payment amounts. These schemes usually have an internal review process, with the option of external review if a claim is deemed complex or contentious. Proponents of these schemes believe this administrative approach is less adversarial, has lower costs, lessens the need to apportion blame and maximizes the opportunity for those with genuine vaccine injuries to receive just compensation.” p374-75<sup>5</sup>

As reported by Looker and Kelly on the filing of claims, “While the procedures for filing a claim in the USA are modelled quite closely on the civil litigation process, the scheme includes a process for pre-determining causation if a vaccine injury is included on its Vaccine Injury Table. This process presumes causation if any injury listed in the table occurs within a specified time frame after vaccination...While an alternate mechanism exists for injuries which fall outside the table specifications, most claims have been for ‘on-table’ injuries.” p375<sup>5</sup>. It has been noted that, in recent years, most cases brought forward have been off-Table, precluding a quick resolution and necessitating a weighing of the evidence within the vaccine court, a process that has become increasingly adversarial and lengthy.<sup>29</sup>

According to Looker and Kelly, regarding the appeal of decisions on claims, “All countries examined have a formalized appeal process for claimants. In some places, including Scandinavia and the USA, appeals can be lodged disputing the size of the compensation payment. Some countries impose time-limits on lodging an appeal.” p375<sup>5</sup>

Most countries prioritise the timely resolution of claims, although the processing time varies depending on the size of the scheme and whether the scheme is part of a broader no-fault VICP. For example, in New Zealand, where the scheme is part of a broader no-fault programme, it can take up to nine months to make a decision, but often it only takes weeks. In France, there is a statutory responsibility to process claims within six months. By contrast, in the USA, a resolution deadline of 240 days was set in the legislation, but a report from the Government Accountability Office in 2014 showed that only 11% of cases were processed within one year and 51% of cases took more than five years.<sup>30</sup>

### **1.3.3.5 Standard of proof in VICPs**

According to Looker and Kelly, “No-fault vaccine injury compensation programmes are based on the premise that the adverse outcome is not attributable to a specific individual or industry but due to an

unavoidable risk associated with vaccines. A problem for all compensation schemes is determining whether there is a causal relationship between a vaccine and a specific injury... Despite its importance, there is no single, clear consensus on the definition of causation.” p375<sup>5</sup>

The most commonly accepted criteria for establishing epidemiological causation in tort law are the Bradford Hill criteria.<sup>31</sup> According to Looker and Kelly, “While they do not provide a definitive checklist for assessing causality, these criteria provide a framework for separating causal and non-causal explanations of observed associations.” p375.<sup>5</sup> The purpose of compensation schemes is to provide an alternative option to civil litigation. This is achieved by lessening the stringency around the standard of proof; crucially however, the compensation on offer is typically available more quickly, but the amount is usually lower than what a vaccine-injured individual may receive through litigation.

In New Zealand, vaccine injuries are considered part of the family of ‘treatment injuries’. According to Looker and Kelly, “This reflects a more genuine no-fault system, ensuring compensation for injured vaccine recipients regardless of whether the injury is judged avoidable or not.” p375<sup>5</sup>

In the USA and other countries (including Taiwan and Sweden) which adopt a vaccine injury table, any post-vaccination condition which matches an entry on the table is accepted for compensation. However, the USA adopts a standard of ‘causation-in-fact’ in off-Table cases. This requires three criteria to be met: a medical theory causally connecting the vaccination with the injury; a sequence of cause and effect showing that the vaccination was the reason for the injury; and a showing of a proximate temporal relationship between vaccination and injury.<sup>5</sup>

In the design stage of their scheme, many international vaccine injury schemes described a compassionate scheme offering victims the benefit of the doubt. However, only some countries have maintained that spirit in the design features of their programmes. Taiwan and Korea both consider ‘possible causation’ sufficient to justify compensation within their schemes. In contrast, many other countries require a slightly more stringent definition of causation. Most schemes adopt a ‘balance of probabilities’ as the standard of proof. This standard is called ‘preponderance of evidence’ or ‘preponderance of probabilities’ in other jurisdictions. According to Looker and Kelly, “While apparently reluctant to define this specifically, commentators interpret this as a ‘slightly more than 50%’ chance of a drug having caused an injury.” p375<sup>5</sup> While others explain that the vaccine is more likely than not to have caused the injury.

It is important to note that focusing on the official ‘standard of proof’ in each country misses the reality of how national schemes operate when they are administrative (like Japan, New Zealand, and Nordic countries) as opposed to adversarial (USA). The claimant in administrative schemes does not need to establish fault or causation as s/he would in an adversarial system. The concept of ‘fault’ is usually replaced by a list of clinical/factual criteria that the scheme’s administrator can easily apply. Establishing causation is usually more difficult and a concept of an administrative rather than legal ‘standard of proof’ is applied from the view point of a medical doctor (as a matter of fact on whether the injury was likely to be caused by the vaccine) rather than a lawyer (based on assessing probabilities that the vaccine caused the injury using epidemiological causation criteria).<sup>32</sup>

### **1.3.3.6 Litigation rights associated with VICPs**

According to Looker and Kelly, on the issue of litigation rights and claims to no-fault VICPs, “Most countries legislate that claimants can seek either damages through the courts or a compensation scheme payout but not both. Denmark and the UK adjust compensation payments if damages have been received through the courts.” p375<sup>5</sup>

Individuals can choose litigation in the USA only after their claim has gone through the VICP whether it has been rejected or the claimant deems the compensation insufficient. However, the type of litigation that a claimant can pursue is very narrow, as the National Childhood Vaccine Injury Act of 1986 both restricts the type of claims that can be asserted and limits the damages that may be awarded.<sup>18</sup> The restrictions on claims was reiterated in 2011 by the Supreme Court ruling in *Bruesewitz versus Wyeth LLC*, where the Vaccine Act was considered to preempt all design defect claims against vaccine manufacturers.<sup>18</sup> In addition, the Act unambiguously creates a presumption of adequacy for all warnings that comply with US Food and Drug Administration standards.<sup>18</sup>

The right to pursue litigation remains in Germany, Switzerland, the UK, Italy, Taiwan, and Denmark. However, a more strict form of causation applies in tort law, so mounting a successful case is more difficult and often more time-consuming and costly, restricting access to litigation to those with adequate resources.

Under European Court of Human Rights,<sup>33</sup> people, resident in member countries of the Council of Europe, cannot be denied the right to bring a claim in court. Hence it is not possible to legislate that claims for vaccine injury can be dealt with through an administrative system only. It is thought to be lawful to require that claims should first be brought to an administrative scheme, and if claimants are not satisfied with the outcome and compensation, then can proceed to court.

### **1.3.3.7 Costs in no-fault VICPs**

#### **1.3.3.7.1 Compensable patient costs**

The main cost saving in administrative schemes is legal costs. A number of jurisdictions structure the claims process so that claimants can avoid the costs and expense of legal representation by codifying the determination of causation, facilitating access via a medical route rather than legal representation, and maintaining expertise to draw upon in complex or novel cases.<sup>27</sup>

New Zealand's no-fault scheme reimburses all demonstrable costs; Looker and Kelly<sup>5</sup> give the example that if a sore arm at the injection site resulted in missed work, this would be compensated in New Zealand.

Three countries – Switzerland, the UK, and Norway – offer a lump-sum payment only; see Tables 1 and 2 for maximum available payments. All three countries have strong social security systems which supplement this lump sum. In the case of the former two countries, payments are made only for severe injury, and in Switzerland part of the decision-making process involves an estimation of subsidiarity, or the amounts of compensation/reimbursement available elsewhere to claimants.<sup>34</sup> Prior to 2016, Switzerland operated a system at the cantonal (state) level; however, disparities in awards made by different states were one of the contributing factors to the move to a federally administered scheme. Currently, China's scheme operates at the county level, and it has been reported that this issue with inconsistency is common in China.<sup>6</sup>

In the USA, once entitlement is accepted, an informal negotiation is often used to resolve the issue of damages and entitlement. Compensation usually includes a lump-sum payment and an ongoing annual payment, which covers unreimbursed medical costs, lost wages, future care, and pain and suffering. A lump-sum payment is paid in cases of death (Tables 1 and 2). In the case of death, the decedent's estate can claim these costs.<sup>19</sup> In addition, the attorney's fees are paid from the compensation fund whether a case is successful or not.<sup>5</sup>

In Taiwan, compensable costs are categorised as compensation for death, impairments, severe illness, and other adverse events, and payment is graded according to whether the determination was that the injury was related or possibly related to the vaccine. Thus, payments can be made at a lower cost with a lower standard of proof in order to resolve causation with the benefit of the doubt in the claimant's favour.<sup>35</sup> Wang provides a compensation table detailing the possible injuries suffered and possible causation levels with the level of award for each eventuality.<sup>35</sup> The maximum payment is for death or extremely severe impairment that has been found to be related to the vaccine. In either of these cases, the award would be 6 million New Taiwan dollars (NT\$6 million; approximately US\$200,000).<sup>35</sup>

A similar table of possible costs is available for Japan,<sup>36</sup> where the maximum payment in the case of death was reported as approximately 7 million yen as of 2013 (approximately US\$200,000). Costs covered are graded by the severity of the injury and not by the causal relationship with the vaccine, and can include healthcare and medical costs, a pension for families raising children with disabilities or for the bereaved, disability pension, a lump-sum benefit for bereaved family, and funeral assistance.<sup>36</sup>

Keelan and Wilson<sup>27</sup> report on the compensable costs in Sweden, Denmark, Italy, Germany, France, and the province of Quebec, which variously include compensation available for medical and funeral

costs, death, disability pensions, lost wages, and non-economic losses (Denmark, Germany,<sup>37</sup> and France only); see Table 3 for exact information.

#### **1.3.3.7.2 Overall scheme costs**

A summary of the available, albeit limited, cost information is available in Table 3. Due to the conflation of vaccine compensation with social security programmes and pharmaceutical, medical, or personal injury schemes in different countries, no detailed information on the overall cost of the VICP is available for many countries. However, reports from New Zealand estimate the costs of the entire no-fault medical scheme up to 2005 (starting in 1974) at US\$29 million per year.<sup>28</sup> It is currently unclear how changes implemented in 2005 have affected the scheme – see Bismark and Paterson<sup>28</sup> provide an overview of the 2005 changes.

In the USA, from 1989–2017 the average yearly cost of payouts was US\$130 million, while in the UK, the average annual cost from 2002–2012 was GB£284,000. It is worth noting that no claims have been paid out for a number of recent years in the UK, and the number of payouts per year has been approaching zero since 2009.<sup>32</sup>

By contrast, average yearly awards in Taiwan are the lowest of the available figures (US\$200,000), reflecting in part the lower award levels associated with their less stringent causation requirements.

**Table 1 VICPs worldwide (no-fault schemes)**

Country	New Zealand	Finland	Norway	Sweden	Iceland	Denmark	Taiwan	Italy
<b>Approach</b>	Pure no-fault scheme for all accidental injury	No-fault scheme for medicines	No-fault scheme for medicines and medical treatment	No-fault scheme for medicines	No-fault scheme for medicines and medical treatment	No-fault scheme for medicines and medical treatment	Limited no-fault scheme	Limited no-fault scheme
<b>Year (revised)</b>	1974 (2005)	1984	1995	1978	2001	1972 (1978)	1988	1992
<b>Legislation</b>	Yes	No	Yes	No	Yes	Yes	Yes	Yes
<b>Administrator</b>	Accident Compensation Corporation (ACC), since 2005	Private drug insurance	Ministry of Health and Care Services	Private drug insurance	Icelandic Health Insurance (IHI)	Danish Patient Compensation Association	Ministry of Health and Welfare	Ministry of Health
<b>Vaccines covered</b>	All vaccines	All vaccines	Government-recommended vaccines	All vaccines	Not available	All vaccines	Compulsory and emergency vaccines	Compulsory and recommended vaccines
<b>Eligible complaint</b>	Any injury beyond normal effects	Loss of functional ability for 14 days	Damages above 10,000 Norwegian kroner (US\$120) or 15% disability	Injuries listed in Pharmaceutical Specialities in Sweden) FASS or medical literature	Not available	Damages above 3,000 Danish kroner (US\$470)	Not available	Permanent injury or death
<b>Standard of proof</b>	Not available	Balance of probability	Balance of probability	Preponderant probability	Not available	Preponderance of evidence	Related or possibly related injury	Preponderant probability
<b>Filing deadline (years after)</b>	First aware of injury (1)	First aware of injury (3)	First aware of injury (3)	First aware of injury (3)	Not available	Onset of symptoms (3), vaccination (10)	Onset (5), facts establishing a relationship (2)	Injury (2), death (none)
<b>Type(s) of costs compensated (lump sum if indicated)</b>	Medical, earnings, support for dependents, plus lump sum for impairment	Pain and suffering, additional expenses and losses arising from injury less statutory benefits	Pain and suffering, additional expenses and losses arising from injury less statutory benefits	Pain and suffering, additional expenses and losses arising from injury less statutory benefits	Not available	Pain and suffering, additional expenses and losses arising from injury less statutory benefits	Medical, funeral, illness, impairments, other events	Medical, disability pension, death benefits

Country	New Zealand	Finland	Norway	Sweden	Iceland	Denmark	Taiwan	Italy
<b>Funding source for scheme</b>	Taxes on employers, wage earners, auto licensing, Government investment income	Drug manufacturers', distributors', and suppliers' tax	National Treasury plus drug companies' premiums	Percentage levy of drug manufacturers' annual sales	Not available	National Treasury	Tax on vaccines plus local Government funds	National Treasury
<b>Process and decision-making</b>	Review by ACC Treatment Injury Advisory Committee	Pharmaceutical insurance claims officer	Norwegian System of Patient Injury Compensation (NPE)	Claims manager with Zurich Insurance and medical expert	Not available	Claim reviewed by case workers at the Patient Compensation Association	VICPWG decides if evidence exists of relationship, or other possible cause	Not available
<b>Litigation rights</b>	No, has right of appeal	No	No, has right of appeal	No, has right of appeal	Not available	Yes, and has right of appeal	Yes, and has right of appeal	Yes, and has right of appeal

Note: VICPWG = Vaccine Injury Compensation Programme Working Group (Taiwan)

Sources <sup>5 13 26-28 35-40</sup>

**Table 2 VICPs worldwide (administrative and legal schemes)**

Country*	China	France	Germany	Japan	Korea (South)	Quebec (Canada)	Switzerland	UK	USA
<b>Approach</b>	Administrative	Administrative	Administrative	Administrative	Administrative	Administrative	Administrative	Administrative	Legal
<b>Year (revised)</b>	Not available	1963 or 1964	1961 (2001)	1970	1994	1988	1970 (2016)	1979	1988
<b>Legislation</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b>Administrator</b>	32 provincial governments and their districts	Ministry of Solidarity and Health	States (pension system) under federal regulation	Ministry of Health, Labour and Welfare	Korea Advisory Committee on Vaccine Injury Compensation	Minister of Health and Social Services	Federal Department of Home Affairs	Department for Work and Pensions	Department of Justice, Department of Health and Human Services, Office of Special Masters, and the United States Court of Federal Claims
<b>Vaccines covered</b>	Government-recommended vaccines	Required or compulsory vaccines	Government-recommended vaccines (child and adult)	Government-recommended vaccines	Government-recommended vaccines	Government-recommended vaccines and those listed in legislation	Recommended vaccines	Government-recommended vaccines and those listed in legislation	Government-recommended vaccines and those listed in legislation
<b>Eligible complaint</b>	Severe disability or death directly attributable to vaccine	Any injury directly attributable to vaccine	Injury that exceeds a normal post-vaccine reaction.	Disability or death	Patient must have spent at least 300,000 South Korean won (US\$300) on treatment	Serious injury or death	Severe injury	Injury resulting in 60% (or greater) permanent disability	Any injury likely caused by the vaccine

Country	China	France	Germany	Japan**	Korea (South)	Quebec (Canada)	Switzerland*	UK	USA
<b>Standard of proof</b>	Clinical manifestations, medical examination results, vaccine quality inspection results, and other evidence***	Clear and convincing evidence	Must show vaccine is capable of causing the damage	Not available	Definite, probable, and possible causality is accepted	Balance of probabilities	According to World Health Organization (WHO) guidance	Balance of probabilities	Vaccine injury table or by proving causation in fact (three-prong standard to prove causation)
<b>Filing deadline (years after)</b>	Not available	Injury stabilisation (4)	None	Death (5), adverse event (5), no limit for disability	Adverse event (5)	Adverse event (3)	Vaccination date (5) or before 21st birthday	Vaccination date (6) or before 21st birthday	Onset of non-fatal injury (3), fatal injury (2)
<b>Type(s) of costs compensated (lump sum if indicated)</b>	Depends on the province	Medical, funeral, disability pension, death benefits, non-economic loss, losses to relatives	Medical, funeral, disability pension, non-economic losses Supplemental payments if disability lasts for more than six months	Medical, funeral, disability, bereavement, pension, set by law	Not available	Medical (unreimbursed), rehabilitation, death benefits	Lump-sum compensation according to set rules; maximum of 70,000 Swiss francs	Lump-sum payment; maximum of GB£120,000	Medical (unreimbursed), lost wages, non-economic losses, future care costs, death, attorney's fees
<b>Funder</b>	Not clear, but most likely provincial government	National Treasury	General revenues of the <i>Länder</i> (states)	Treasury (50%), prefecture (25%), municipal (25%)	Government	Provincial Ministry of Health and Social Services	Funded by the federal Government and cantons	National fund	Tax on every vaccine dose distributed



Country	China	France	Germany	Japan**	Korea (South)	Quebec (Canada)	Switzerland*	UK	USA
<b>Process and decision-making</b>	Three-step administrative process at provincial and district levels	Choice of ministerial commission or administrative tribunal	Internal <i>Länder</i> office of social recompensation. Also uses medical expertise	Not available	Review by Korea Advisory Committee on Vaccine Injury Compensation	Claim reviewed by three members of the medicine evaluation committee, and final decision by the Minister of Health and Social Services	Assessment of damages (evaluates compensation from other sources) and causality by expert opinion	Evaluation by medical officer, recommendation made to Department for Work and Pensions	80% of settlements are negotiated prior to a decision about causation Vaccine court
<b>Litigation rights</b>	Not available	No, has right of appeal	Limited but has right of appeal	Yes, plus right of appeal	Not available	Yes, plus right of appeal	Limited but has right of appeal	Yes, plus right of appeal. Claim through court takes account of lump sum paid	Yes, if settlement rejected, plus right of appeal

Note: Austria (since 1973), Slovenia (2004), and Hungary (2005) offer administrative schemes which compensate for medical, disability pension, and funeral costs, but no further information could be found on these schemes. China offers lump-sum compensation for severe injury following vaccination through an administrative scheme operated at a county level; however, it has been described as adversarial and inefficient, with large discrepancies in payouts between counties; see Fei and Peng 2017<sup>6</sup>. \*Switzerland moved from a State-administered federal scheme similar to Germany's to a UK-type scheme in 2016. \*\*Since 1980 in Japan, non-mandatory vaccines are covered under a relief scheme for adverse reactions following the proper use of pharmaceuticals. This covers the same costs as the mandatory scheme. A levy on vaccines contributes 25% of the relief, the manufacturer covers 25%, and the Treasury covers 50%. \*\*\*The Chinese Government recommended that clinical manifestations, medical examination results, vaccine quality inspection results, and other evidence be used as standard of proof but medical experts use epidemiological causation criteria.

Sources: <sup>5</sup> 13 19 26 27 32 36 41-43

**Table 3 VICPs worldwide – claims and awards information**

Country	France	Germany	Japan	Korea (South)	Quebec (Canada)	Taiwan	UK	USA
<b>No. claims/year</b>	39 (2006–2016)	Not available	70 (up to 2007)	86 (2011–2016)	Average 4.5 per year	Average 89 per year up to 2013	In total, there were 6,196 claims between 1979 and May 2017, but numbers have declined over the years	Average 643 per year (1989–2017)
<b>No. compensated/year</b>	Not available	Average 100 per year (1961–2001)	80%	65%	Not available	39%	6% of adjudicated claims	34% (1989–2017)
<b>Amount paid out/year</b>	Not available	Not available	Not available	Not available	Not available	NT\$6 million per year (US\$200,000)	GB£284,000 (2002–2012)	US\$130 million (1989–2017)

Sources: <sup>5</sup> 19 25-27 32 36 37 41-45

## 2 Methods

### 2.1 Introduction

We chose the integrative review approach as the overarching framework for this review. According to Whittemore and Knafl, “An integrative review is a specific review method that summarizes past empirical or theoretical literature to provide a more comprehensive understanding of a particular phenomenon or healthcare problem.” p546.<sup>46</sup> The integrative review differs from more orthodox reviews, such as meta-analysis or meta-ethnography, because it provides a framework to assemble data from a variety of sources, such as administrative data and documents, legal papers and cases, and different types of research studies, while the more orthodox reviews depend on both the primary research design and the study hypothesis of the included studies being similar, if not identical. The integrative review approach is seen as particularly useful when investigating complex phenomena. According to Hopia *et al.*, “the integrative review is the broadest type of review and has the potential to capture the complexity of varied perspectives and emergent phenomena.” p663<sup>47</sup>

We chose the integrative review approach because of its capacity to allow us to assemble data from both empirical and theoretical literature in order to answer our questions. We learned from our scoping work during the initial stages of this project and from an evidence brief<sup>3</sup> that the literature on no-fault VICPs contains an eclectic mix of potential data sources, including a limited number of orthodox quantitative and qualitative research papers, as well as unorthodox papers. What we mean by ‘unorthodox papers’ is papers that do not elaborate on their methods, but draw on case reports, legal rulings, and administrative data to outline arguments for and against such schemes. In addition, we learned from our previous work that it was highly unlikely that we would identify a sufficient number of papers that had previously asked the same or similar questions to the questions we were asking in our review. Therefore, it was likely that we would be drawing on data sources that contained fragments of data in order to help us build answers to our questions, and this likelihood was further justification for choosing the integrative review approach.

### 2.2 Literature search and selection process

#### 2.2.1 Outline to the search process

It must be noted at the outset that although we sought to follow a systematic approach to locating relevant papers, we also needed to adapt our approach to suit the focus of our enquiry. This means that it was not feasible to pursue a more linear, orthodox approach modelled on the population, intervention, comparison, outcome, and context (PICOC) guidelines, as from the outset, we were not dealing with substantive concepts that were secure and we were not confining our search to only certain study designs. We had already identified, from previous work on an evidence brief on the subject of VICPs, that the literature did not appear to contain evaluations or many empirical studies on such schemes.<sup>3</sup> Subsequent contact with other researchers confirmed our experience.<sup>48 49</sup> Therefore, we needed to employ a more iterative approach to searching for relevant papers, which meant that we sometimes relied on snowballing techniques to identify relevant literature, picking up terms in papers as we read them in order to use them in further searches, as well as mining papers for citations and searching for papers that cited included studies. The inclusion of snowballing searches is a common approach in reviews undertaken to inform broad, policy-relevant topics.<sup>48</sup> In this respect, the process we undertook in order to identify relevant studies for inclusion in this review is not entirely replicable. However, we have undertaken a comprehensive search for relevant literature up to the end of June 2018, combining the best principles of systematic searching, snowballing, and supplementary searches. There was no start date. Such an approach is entirely in line with the overarching framework of an integrative review, where the main objective in this case was to identify the maximum number of relevant papers that may contribute our review. Our approach is supported by Brunton *et al.*<sup>50</sup> and Whittemore and Knafl. Whittemore and Knafl say “In general, a comprehensive search for an integrative review identifies the maximum number of eligible primary sources, using at least two to three strategies... and, the literature search process of an integrative review should be clearly documented in the method section including the search terms,

the databases used, additional search strategies, and the inclusion and exclusion criteria for determining relevant primary sources.” p548-49.<sup>46</sup>

### 2.2.2 Search terms used

The primary systematic search strategy was essentially based around three key concepts: no-fault, redress, and vaccination. Test searches that included additional concepts relating to our review questions (such as operating costs, public access, or public acceptance) were also carried out. The testing of these terms did not retrieve additional relevant articles, and they were not included in the primary search strategy. We also search-tested the inclusion of countries that were known to operate vaccine compensation schemes; however, adding search terms for specific countries did not retrieve additional relevant articles, but it did limit the returns to articles mentioning those countries in indexed fields only.

Searches were developed for each topic by sourcing keywords (free terms) and controlled vocabulary (e.g. MeSH terms) for each concept from relevant papers in the bibliographic database MEDLINE, from the MeSH database, and in the open-source PubMed search tool PubReMiner. Alternative terms for specific vaccines were sourced on the Wikipedia page, List of vaccine topics ([https://en.wikipedia.org/wiki/List\\_of\\_vaccine\\_topics](https://en.wikipedia.org/wiki/List_of_vaccine_topics)).

The primary search strategy was constructed for MEDLINE on the Ovid platform. This was translated and adapted as required for each database. Some terms were translated into non-English languages, where possible. A complete search strategy for Ovid MEDLINE can be found in Appendix 1.

Terminology for the concept of ‘redress’ was found to be challenging, as the equivalent term ‘compensation’ is used widely but with different meanings in biological science research, as well as in engineering, computing, automation, etc. An exclusion line was used in some searches, where possible, to remove some of the irrelevant meanings of compensation. For databases such as Web of Science, it was possible to remove topics such as engineering as precisely as the inbuilt topic filters allow, but filters were used sparingly in order to retain as much sensitivity as possible in the search.

### 2.2.3 Search engines and databases

The bibliographic databases chosen to search were MEDLINE on the Ovid platform, EBSCO’s CINAHL, Elsevier’s Scopus, Web of Science, Wiley’s Cochrane Library, and two law databases: Hein’s HeinOnline and Gale’s LegalTrac. The legal databases were considered important to include alongside the clinical/scientific databases, as much of the literature on clinical injury redress is to be found in law journals. The initial search strategy was developed for MEDLINE and translated for other databases. Database searches were carried out in the week of 9–13 July 2018. A table of databases, platforms used, and dates of searches can be found in Appendix 2.

### 2.2.4 Supplementary searches

In order to maximise the retrieval of relevant articles from countries where research may be published in languages other than English, follow-up searches were carried out in some non-English websites and databases. MEDLINE includes approximately 96% English-language citations and may not cover a wide enough range of sources to capture all relevant articles. While researchers from non-English-speaking countries may choose to publish in English, relevant data may also be published in other languages. A bias towards publishing positive results in English-language journals and negative results in other languages has also been noted for randomised controlled trials. Previous studies have found the use of non-English databases (such as Mandarin- or Cantonese-language databases) to be useful for systematic reviews.

Details of the non-English databases and websites searched are available in Appendix 3. These were basic searches, given the limited abilities of the information specialists in the non-English languages used. Google Translate was used to translate search terms where English-language searches were not useful. No articles from these searches were relevant for final data extraction. Searches were carried out from 16–20 July 2018 and followed up from 10–14 September 2018.

English-language abstracts were assessed where available for non-English articles. For articles with no English-language abstracts, MeSH (or other) keywords were examined. The authors are not fluent in many of the languages which would be relevant to the redress scheme research, a recognised issue

for researchers from English-speaking countries. Translating websites (such as Google Translate, Naver Papago, and Fanyi.Baidu.com) were used to translate non-English articles that appeared relevant.<sup>51</sup> The time frame of this review did not allow for further investigation, but further exploration of the non-English databases and research sites might reveal other relevant material.

Brief searches were carried out using relevant keywords (e.g. 'vaccines', 'vaccination', 'redress scheme', 'no-fault', etc.) on Google.com, Google Scholar, and DuckDuckGo.com (Appendix 4). However, given the time constraints of the review, this type of searching was not prioritised.

We also sent an email request to administrators of VICPs in all 20 countries that were mentioned in the literature as operating such a scheme. We requested information on evaluations, reviews, or reports on such schemes. According to the replies we received back from about half the countries contacted, it was claimed that no such reports existed on the schemes. In some cases, we were referred to the home website for information on the country's scheme. We also contacted colleagues in the EPPI-Centre in London who have undertaken a review of no-fault compensation schemes for birth injuries.<sup>48</sup> We requested that they send us the results from their search strategy that included a mention of vaccines. From the number of records they sent us, we were unable to identify any additional relevant titles that could contribute to our review. We also contacted colleagues in Canada who had undertaken a scoping review on vaccine injury compensation to see if we had missed any relevant publications from our own searches.<sup>49</sup> Our colleagues in Canada confirmed our own findings from our searches – that there was a lack of empirical evidence or evaluations on such schemes – and they were unable to suggest any papers that would add to what we had already collected.

### 2.2.5 Title/abstract screening

Results of the systematic literature search were exported to EndNote X7.1.1. These results were de-duplicated (766) and exported to EPPI-Reviewer 4 for screening (2,819). Title/abstract screening of the articles was carried out in EPPI-Reviewer by three of the authors (MK, TM, CL). Articles were screened independently by the authors, and decisions on inclusion/exclusion were then compared until consensus was reached. At the title/abstract-screening stage, articles were retained if the title or abstract indicated that the article directly discussed vaccine injury schemes (or drug injury schemes which were known to include vaccines). The exclusion criteria for this review included: no discussion of a no-fault vaccine redress scheme, discussion of medical malpractice or medical injury schemes, and papers that contained only minor mention of a no-fault vaccine redress scheme with no substantial discussion of same. The elimination of articles with little or no mention of such schemes reduced the number of potentially useful articles to 115.

### 2.2.6 Full-text screening

Articles retained from the title/abstract-screening stage were included in a two-stage full-text screening process involving four of the authors (MK, TM, JL, CL). The screening process was not blinded, and decisions on inclusion were made by consensus after discussion. For this screening stage, articles were retained where we noted substantial discussion of specific vaccine injury redress schemes or drug injury schemes covering vaccines. A flow chart documenting the search results and screening process can be seen in Figure 1.

A number of articles (16) that were identified by snowballing as likely candidates were included in the second stage of the full-text screening process. A second round of full-text screening was then carried out. From this screening process, a number of highly relevant articles were identified and included for data extraction (33). Appendix 5 includes the references used to extract the data for the findings.

Screening stages	Number
Total papers identified following database searches	3,585
Number of duplicates excluded	-766
Number of unique titles	2,819
Number of unique titles excluded during title and abstract screening	-2,704
Number of unique titles remaining following title and abstract screening	115
Number of additional papers identified through other searching	16
Number of unique titles before full text screening	131
Number of unique titles excluded following stage 1 full text screening	-78
Number of unique titles remaining at this stage	53
Number of unique titles excluded following stage 2 full text screening	-23
Number of unique titles remaining following 2 full text screening	30
Number of unique titles through reference chasing	3
Total number of papers extracted for findings chapter	33

**Figure 1 Outline of search results and screening process**

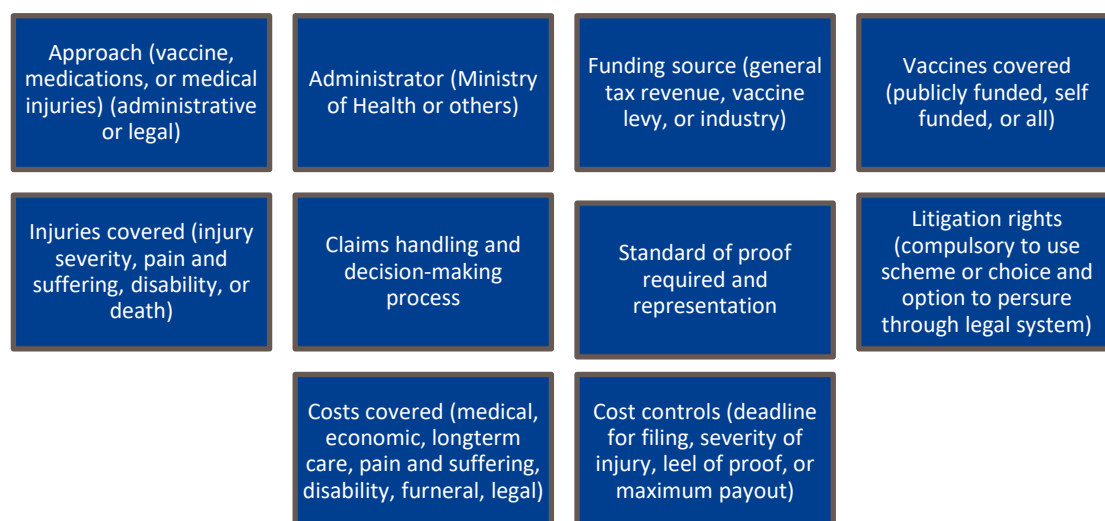
The main reason for including the 33 papers identified was that they included data on either a standalone VICP or on a broader drug and/or treatment injury compensation scheme that included vaccine injuries. In addition, the 33 papers we included contained data that would help to answer at least one of our seven review questions, and they focused on compensation schemes in 11 of the 20 countries we knew to have such schemes. We excluded papers that did not focus on drug injury schemes and did not cover one of the 20 countries known to operate a compensation scheme for vaccine injuries. Most of the papers we excluded from our full-text screening focused on medical malpractice schemes but did not include data on drug injury compensation schemes. We did not exclude any paper for reasons to do with methods, as we were seeking to develop a comprehensive understanding of vaccine compensation schemes, and so both papers that reported and did not report their methods were included as candidates. Our 33 candidate papers included 12 that focused on the standalone vaccine compensation scheme in the USA; eight that focused on the broader treatment injury scheme in New Zealand, which included vaccine injury compensation; and eight that focused on four countries in Asia, three of which have standalone vaccine compensation schemes and one of which is part of the broader drug injury scheme. We also included two papers with a focus on the broader drug injury compensation in the four Nordic countries, and four papers that provided data on the scheme in the UK. A description of the type of data contained in the papers we included can be seen in Figure 2.

Country	Number of papers	Type of data
USA	12	Review of health policy and legal literature; case law; primary data, including survey of applicants and interviews with stakeholders; and secondary data analysis of administrative data
New Zealand	8	Review of health policy and legal literature, case reports, primary data from site visits, and secondary data analysis drawing on administrative data
Asian countries	7	Review of health policy and legal literature; case law; primary data, including survey of applicants and interviews with stakeholders; and secondary data analysis of administrative data
Nordic countries	2	Review of health policy and legal literature; primary data, including survey of applicants and interviews with stakeholders; and secondary analysis of administrative data
UK	5	Review of legal papers and documentation related to scheme. Data from a doctoral thesis and from the former National Health Service Litigation Authority (NHSLA)

**Figure 2 Number of papers included by jurisdiction and type of data**

### 2.3 Data reduction and extraction

We designed a bespoke data extraction sheet to capture a) the authors' explicit claims and the evidence to support such claims and b) when explicit claims were not present, the reviewers' inferences (see Appendix 6). Three reviewers (TM, CC, MK) piloted this data extraction sheet on two studies: Kim, Lee, *et al.*,<sup>41</sup> which examined the surveillance and compensation claims for adverse events following immunisation from 2011 to 2016 in the Republic of Korea, and Wang,<sup>35</sup> which reported on the VICP in Taiwan. We chose these two papers as they contained empirical data and were a close fit to a review of these schemes. We then designed a conceptual schema of key elements in the design of no-fault compensation programmes, drawing on the work of Looker and Kelly<sup>5</sup> and Keelan and Wilson<sup>27</sup> (see Figure 3).



**Figure 3 Conceptual schemata used to code data from included papers**

We then went into the two papers looking for data that claimed an association between any of the 10 programme elements and our questions. For example, do the data show an association between any of the 10 elements and changes in the number of applicants for such schemes? We also sought out data on contextual factors relating to the operation of the schemes that we had not previously

identified in the literature but which could be important for later analysis. For example, swine flu epidemics can lead to an increase in applications but not necessarily in awards. In addition, does the introduction of a national surveillance system to capture the outbreak of adverse events associated with vaccines act as a 'wider contextual factor'? In other words, what impact does such a system have on public confidence in vaccines? On reviewing the two papers, we noted these issues for further discussion and analysis in our work. Based on the piloting of our data extraction sheet, we decided that it was fit for purpose and that we could use it to inform the future stages of our data extraction.

We then developed a bespoke Excel sheet into which we planned to insert relevant data. In Excel, we designed an overall classification system for managing the data based on dividing the data into subgroups that would later facilitate analysis. This initial subgroup classification was based on the geographical location of the vaccine compensation scheme and included the USA, New Zealand, the Nordic countries, the Asian countries, non-Nordic Europe, and multiple countries; the latter included data on more than one jurisdiction. In addition, we included separate columns for each of our questions for each country.

We then commenced the process of reducing and extracting relevant data from the papers included in our review. According to Whitemore and Knafl, "data reduction involves techniques of extracting and coding data from primary sources to simplify, abstract, focus, and organize data into a manageable framework." p550.<sup>46</sup> The pilot work we had undertaken using our bespoke data extraction sheet proved useful in this regard, as we were able to use the sheet to extract relevant data. Four reviewers (MK, CL, JL, TM), working in pairs, extracted the relevant data into the Excel sheet. Data were extracted from papers when the data helped to answer any one of our questions, for example about costs, access to schemes, and number of compensation awards. The conceptual schemata that we designed helped us to locate relevant data in the papers that described the key features of compensation schemes. We followed the same approach taken in piloting the data extraction sheet; we searched for data that contained an author's explicit claims about how features of the scheme affect issues such as costs, access to schemes, and number of compensation awards, and we examined the data in each paper in order to assess where we as reviewers could draw inferences regarding features of the scheme and the core constructs in our questions.

## 2.4 Data analysis

### 2.4.1 Method employed to analyse data

We chose to use the constant comparative method as the guiding framework for our analysis. This approach to analysis has been recommended as suitable to the overarching framework of an integrative review.<sup>46</sup> We chose the constant comparative method as suitable, as none of the papers included in our review asked either the same or similar questions to our review questions. This meant that we needed to choose a framework for analysis that would allow us to develop sub-questions related to our review questions and iteratively move between segments of the data, constantly comparing the data and its fit to our conceptual schemata and our sub-questions. In addition, we also wanted to choose an approach that would facilitate our analysis of data from diverse sources. The constant comparative method is a useful approach to facilitate such needs as, according to Whitemore and Knafl, "the constant comparison method ... converts extracted data into systematic categories, facilitating the distinction of patterns, themes, variations, and relationships...Initially, extracted data are compared item by item so that similar data are categorized and grouped together. Subsequently, these coded categories are compared which further the analysis and synthesis process. In the integrative review method, this approach to data analysis is compatible with the use of varied data from diverse methodologies." p550.<sup>46</sup>

In addition, we needed to choose an approach that would allow some flexibility to generate some theoretical inferences about how features of the schemes or the context within which they operate affect access to compensation within the scheme, the costs of running the scheme and paying out compensation, and the number of claimants to the various schemes. In essence, we needed an approach to analysis that would elevate our use of the data from mere description and summarising to developing theoretical claims. The constant comparative method is useful in pursuing such elaboration as, according to Glaser,<sup>52</sup> the pioneer of the approach, "the constant comparative



method is concerned with generating and plausibly suggesting (not provisionally testing) many properties and hypotheses about a general phenomenon.” p438

## 2.4.2 The steps we took to undertake constant comparative analysis

### 2.4.2.1 Data cleaning

#### 2.4.2.1.1 Cleaning the data for relevance

Our first task was to ensure that all the data that had been extracted from the included papers and deposited in the Excel sheet was ready for analysis. This meant that we needed to undertake some cleaning of the data as an initial step. We first went through the data that had been coded to each question and determined whether the data were speaking to that question. When the data were not relevant to the question they were coded under, we transferred the data to the relevant question or deleted the data if we deemed they were not relevant at all.

#### 2.4.2.1.2 Cleaning the data for accuracy and consistency

We then went through all the data to match the data extracted directly with the paper from which they were derived and add context where necessary. We then matched the data in the extract with the correct page number from their source and inserted appropriate quotation marks to illustrate their verbatim status.

#### 2.4.2.1.3 Cleaning the data to identify missing data

We then examined the data coded under each question to determine their completeness. If the coded data were unclear, ambiguous, or incomplete, we returned to their source papers to collect additional data in order to complete the coded data for each question and add explanations where appropriate.

### 2.4.2.2 Data coding

#### 2.4.2.2.1 First phase of coding and categorising the data

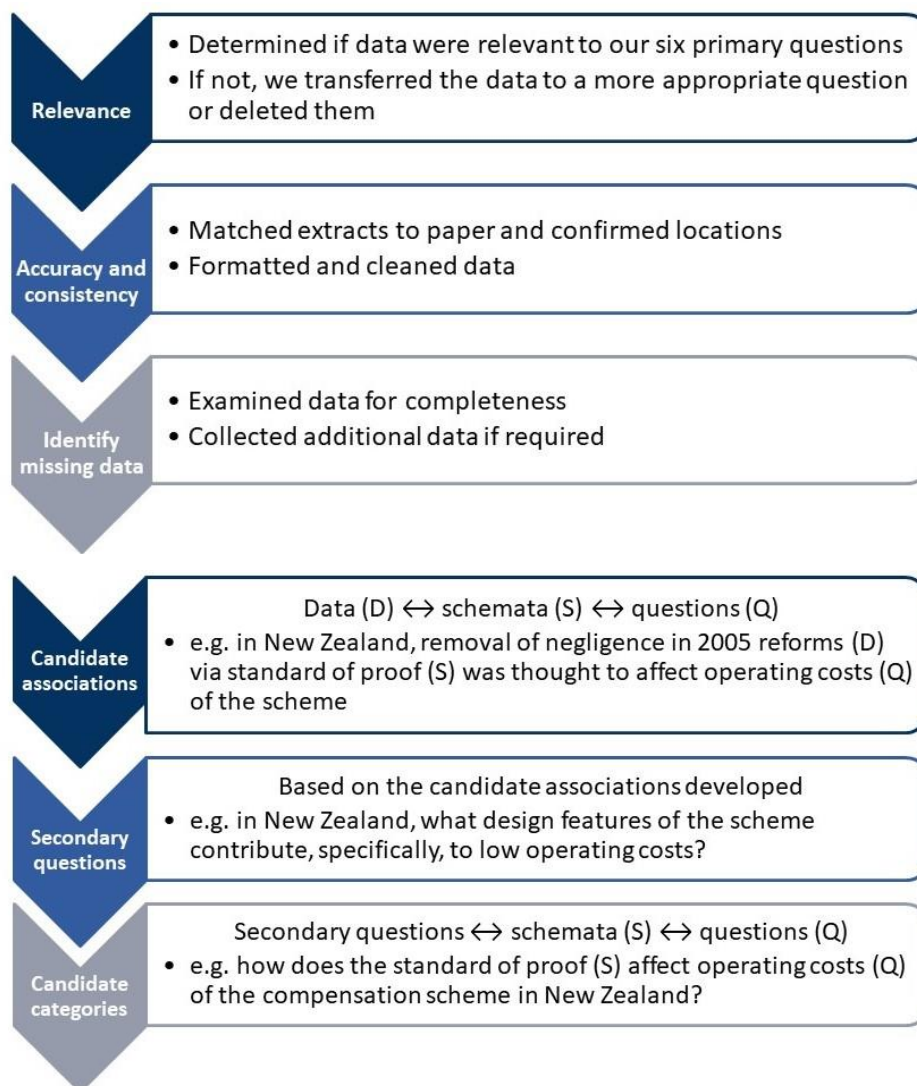
We then constructed our own coding sheet with seven columns, including the author of the paper and the six review questions. We went through the data collected and stored in the Excel file for each question and coded the data against our conceptual schemata. We coded each segment of the data for a candidate association between a dimension of the schemata, the properties in the data segment, and the six questions. Using the data collected from the initial coding sheet referred to above, we then constructed a table of secondary questions that speak to each of the six primary review questions and we categorised each set of secondary questions against the relevant dimension of our conceptual schemata. See Appendix 7 for an example of this work, drawing on data from the USA scheme.

#### 2.4.2.2.2 Second phase of coding and categorising the data

We then returned to the data collected and stored in the Excel file and asked the secondary questions of the data. We collected and stored the relevant data as evidence in our evidence-coding form for further analysis. See Appendix 8 for an example of the type of data extracted from the scheme in the USA.

#### 2.4.2.2.3 Third phase of coding and categorising the data

The third phase of our analysis involved us moving iteratively between a) the evidence that spoke to each of the secondary questions, b) the primary review questions, and c) the dimensions of our conceptual schemata. We then began to construct candidate categories that combined data on our secondary questions with dimensions of our schemata and how these spoke to our primary review questions. When we talk of categories, we mean building categories of data/evidence that speak to each of the six primary review questions and from which we can begin to elicit some plausible theoretical inferences. Figure 4 outlines a visual display of the steps taken to analyse the data.



**Figure 4 An outline of how data were analysed using the constant comparative method**

## 2.5 Data evaluation and relevance

The diversity of the data sources we included in this review did not allow for a uniform appraisal of their quality. Most of the resources were not orthodox research papers; they were more akin to discussion documents that sought to elaborate on the strengths and weaknesses of the various schemes. These resources drew on a hybrid of materials, including legal and policy papers, grey literature relating to the schemes under scrutiny, and secondary descriptive accounts of administrative data regarding features of the schemes. A small number of the resources we drew on reported data using surveys and interviews to collect primary data from stakeholders; however, these papers merely mentioned the method of collecting the data and provided no account of sampling or data analysis, which rendered them unsuitable for conventional quality appraisal. We have documented the sources of data used in each paper that we included in an Excel file, which is available to readers on request.

We decided to adopt a more flexible approach to the selection of data sources in this review, as we could not use the methodological quality of the papers as a criterion for decisions on what to include or exclude. We chose instead to select papers for inclusion on the basis of their relevance; as Pawson<sup>53</sup> suggests, when considering the relevance of a potential data resource, the question to ask is whether the document contributes in some way to knowledge synthesis. We continued to ask this question of each paper throughout our work on this review, which meant that we rejected papers

that initially signalled in the title and abstract that they may be candidates for inclusion, but on closer scrutiny of the full text we judged that they did not contain relevant data that would contribute to the review. See Appendix 9 for examples of excluded papers. All 33 documents used in the review contributed to answering at least one of our questions (Appendix 5). Another limitation of our included documents was that some of them were more than 15 years old. However, each region had at least one document published in the last 3 years.

## 2.6 Strengths and weaknesses of our methods

The key factor that impacted on our approach to this review and on the methods we chose to undertake this work is the nature and extent of the data that are available on VICPs. Aside from a small number of reviews of the schemes in the USA and in Asia, there is no report available that could be considered to be a close fit to an evaluation of the schemes. In addition, there are very few papers available that contain empirical data on the schemes, which limits the amount of observational evidence that one can draw on to support or refute inferences about the schemes. Our experiences in documenting these limitations mirror, to a large extent, the experiences of fellow reviewers in Canada. According to Hapuhennedige, “we assumed that there was a wealth of information on this topic [VICPs], and that there would be sufficient empirical evidence regarding its cost-effectiveness, health impact, potential for improving immunization rates, or at the very least, the impact on vaccine confidence. As it turns out, this topic is more complicated than we had anticipated, with minimal sources of evidence.” p6.<sup>49</sup>

The lack of formal evaluations and rigorously designed studies comprising empirical data limits the nature of the conclusions that we can draw from our review. Instead, we have relied on drawing data from an eclectic mix of resources, including discussion papers from health policy, as well as legal literature, case law, surveys, interviews with stakeholders, and papers citing analysis of administrative data relating to the schemes. The major weakness in the data sources we relied on is that, aside from being low in number, the majority are not orthodox research papers and do not document their methods, so they are not suitable for conventional quality appraisal. However, this can also be considered a strength, as we chose to select material for inclusion on the basis of its relevance.

In the absence of data derived from more rigorously designed studies, there is a case to be made for relying on the ‘best available data’,<sup>54</sup> and this is one of the principles we articulated while undertaking this review. From the outset of our discussions with the Department of Health, we were faced with the choice of either a) agreeing that there was little point in undertaking the work, given the strong likelihood of the lack of rigorously designed studies, or b) deciding to amend our approach to the review in order to provide a basis on which the Department could consider its options for designing a VICP for Ireland. We agreed with the Department to opt for the latter option and, in so doing, we are echoing some of the current thinking around gathering evidence to guide public health decision-making. According to Morestin *et al.*, “many experts have broadened their definition of the concept of evidence [for public policy decision-making] so that decisions can be informed by the best available data and not just by the best possible data... [including] not only the findings from research, but also other knowledge that may serve as a useful basis for decision-making in public health.” p13.<sup>55</sup> We would argue that our review is based on some of the best available data and, in particular, the analysis derived from our review of legal papers has enriched our understanding of how some of these schemes operate in their own specific contextual conditions.

In addition, our work on this review was strengthened by relying on the expertise of an information specialist (CL) who expertly navigated a complex web of data repositories without many *prior* concrete details about the nature of the phenomenon we were investigating. In addition, at least three reviewers undertook the screening of papers, the extraction of relevant data, and the development of a bespoke data extraction instrument, and data-management instruments were piloted prior to using them for formal tasks. Two reviewers undertook a rigorous analysis of the data we had extracted and often returned to the relevant papers to collect additional data or seek clarification. Finally, we have endeavoured to document all our decisions throughout our review and to provide a rationale for taking those decisions, which we submit has added to the transparency and accountability of this work.

## 3 Findings

### 3.1 Introduction

In this section, we present our main findings from our analysis of the data. We present the findings from our review of VICPs in 11 countries as they apply to each of the questions in our review. In some cases, we did not find relevant data to speak to all six questions for some countries, and we note this clearly when it applies. For example, we only found relevant data that answered one question about the scheme in the UK. In our introduction to the schemes in each country, we elaborate on the sources of data that we are drawing from and we provide a brief introductory account of the schemes. These accounts do not follow a structured list of similar information about the schemes, as the papers we reviewed elaborated on the schemes using different degrees of coverage. However, we have sought to provide some important information about all the schemes we have reviewed.

An important point to bear in mind when we elaborate on constructs in our questions such as timely access and public approval is that there is no uniform definition of these constructs among the papers we reviewed. For example, timely access to compensation in the USA means resolving claims within 240 days as set out in the congressional intent behind the scheme, whereas timely access is rarely defined in other jurisdictions and instead is presented as a fluid construct.

Finally, throughout the elaboration of our findings, the reader will encounter a number of statements that are presented in red font and italicised. These statements are the inferences we have drawn which suggest that certain design features of the scheme or contextual conditions surrounding the scheme have an impact on the constructs in each question. These inferences have been developed based on our in-depth analysis of the data; they are grounded in our interpretation of the theoretical and empirical data that we collected and analysed regarding the different schemes and how they operate in their distinct contexts. We present these inferences as a 'close fit' categorisation of how certain design features or contexts can affect topics of interest such as overhead costs, timely access, number of claimants and awards, amount of compensation, and public approval. However, we acknowledge that these inferences are grounded in a hybrid mix of theoretical and empirical data, and subsequent evaluations of these schemes based on data from studies using more robust designs may well reveal the flaws in our interpretations. Finally, it is important to note that we present our inferences primarily to cover Questions 1–4; our statements on Questions 5 and 6 are more descriptive than interpretive.

### 3.2 New Zealand

#### 3.2.1 Introduction

In order to review the situation in New Zealand, we extracted data from the eight papers focusing on New Zealand that we included. Bismark and Paterson<sup>28</sup> and Manning (2014)<sup>56</sup> both reviewed relevant literature about the scheme in New Zealand. Corkill (2013)<sup>57</sup> provided data from a number of case reports and a review of select literature about the New Zealand scheme, while Keelan *et al.* (2011)<sup>27</sup> included relevant literature about New Zealand as part of a wider review of vaccine compensation schemes globally. Kachalia *et al.* (2008)<sup>58</sup> and Mello *et al.* (2011)<sup>59</sup> collected primary data from site visits with stakeholders in New Zealand, and Wilson *et al.* (2013)<sup>60</sup> used secondary data analysis, drawing on administrative data about the scheme in New Zealand. The data derived from the paper by Blake (2010)<sup>61</sup> included a mix of personal anecdotes and some select administrative data relating to the scheme.

In New Zealand, compensation for vaccine-related injuries is paid out under the wider compensation scheme for treatment injuries, known as the Accident Compensation Corporation (ACC).

### 3.2.2 Question 1: What design features and/or contextual conditions are thought to impact on the operating costs associated with no-fault vaccine damage schemes?

It could be inferred that the removal of negligence from the 2005 reforms which reframed the standard of proof has contributed to keeping overhead costs low, in particular dispensing with the the need for legal costs.

For example, a feature of the programme that is thought to keep overhead costs low is the absence of legal costs and low overall administrative running costs. According to Bismark and Paterson, “the New Zealand system does not incur large legal and administrative costs. The system has been very cost-effective, with administrative costs absorbing only 10 per cent of the ACC’s expenditures compared with 50–60 per cent among malpractice systems in other countries.” p281.<sup>28</sup>

More recent data provided by Mello *et al.* suggest that there has been a modest increase in overhead costs, but by comparison with the USA, for example, they are demonstrably low. According to Mello *et al.*, “[New Zealand] has low overhead costs—around 17 per cent of the total cost of the system, compared to an estimated 55 per cent to 60 per cent in the US[A].” p7.<sup>59</sup>

#### Key point

- **The removal of negligence or fault, which reframed the standard of proof, is claimed to have reduced overhead costs within the scheme in New Zealand.**

### 3.2.3 Question 2: What design features and/or contextual conditions are thought to impact on timely access to no-fault vaccine damage schemes?

It would appear that one of the main aims of the 2005 reforms was to facilitate the timely provision of compensation, which had previously been delayed due to the need for claimants to prove negligence. In the case of persons claiming compensation for vaccine injuries, this meant removing the need to prove negligence against the pharmaceutical manufacturers or the medical professionals that administered the vaccines. According to Manning, “In 2005, the criteria for cover were again changed when cover for treatment injury replaced cover for medical misadventure. The key objective was to remove the need for an injured claimant to prove a health practitioner’s or organization’s negligence to establish cover. The aim was to provide greater fairness for claimants, faster claims handling and a higher acceptance rate.” p24.<sup>56</sup>

So, the question arises: Has the aim of improving access to compensation been achieved, and if so, what measures are thought to have contributed to this achievement? Manning provides data that compare the time it took to resolve a claim when negligence was part of the system with the time it takes to resolve claims after negligence was removed. According to Manning,<sup>56</sup> “The median decision time was an average of 5 months for medical misadventure claims. The weighted average decision time for treatment injury claims in 2012–2013 was 22.8 business days. ACC classifies claims into three levels of complexity: straightforward (48% of claims), for which the average determination time in 2012 was 3.4 days; moderate (40% of claims), which take on average 30 days; and complex (12% of claims), which take on average 80 days to determine.” p31

Our reading of the data provided by Manning suggests that timely access to compensation has improved across the different categories of claims, with even the most complex claims taking, on average, half the time they took when negligence was part of the standard of proof. So what measures have contributed to this improvement? From our review of the papers on the scheme in New Zealand, it would appear that the support provided by health professionals to claimants in submitting their claims for compensation has been a major factor in improving timely access to compensation. Our assumption is supported by Kachalia *et al.*<sup>58</sup> and by Bismark and Paterson.<sup>28</sup>

Prior to the 2005 reforms, it would appear that health professionals had concerns about assisting applicants to submit claims for compensation. These concerns mainly centred around the health professionals’ belief that the negligence standard that applied prior to 2005 was punitive and stigmatising towards them, and this meant that they were not favourably disposed towards assisting with the scheme, which in other quarters was seen to delay investigations. According to Kachalia *et al.*, “On July 1, 2005, the medical injury scheme underwent several substantive changes, most

notably to relax the scheme's compensation criteria and jettison the medical error standard... it was felt that the fault standard had detrimental effects on the physician-patient relationship and physicians' willingness to participate in the claims process. Clinicians found the error standard punitive and stigmatizing, and consequently tended to be reluctant to provide information about injuries to the ACC. This reaction slowed claim investigations and reduced the information available for learning about quality improvement." p12.<sup>58</sup>

It would appear that these concerns among health professionals were duly noted when the architects of the 2005 reforms were redesigning the system, as one of the key objectives was to encourage health professionals to assist claimants. According to Bismark and Paterson, "on 1 July 2005, medical mishap and medical error were replaced with a new concept of treatment injury. This change broadened coverage to include all personal injuries suffered while receiving treatment from health professionals... A key objective of the change is to encourage health professionals to assist injured patients to make claims earlier, thereby facilitating timely provision of Accident Compensation Corporation (ACC) assistance." p280.<sup>28</sup>

From our reading of the included papers, it would appear that there was a very clear reason to get health professionals involved: to minimise delays in access to compensation for claimants. According to Manning, "A second and related aim was to improve the timeliness of determining claims arising out of treatment. Delays would be minimized by gaining the cooperation of providers to participate in the claims process, provide medical reports and support claimants, if negligence was deleted from the statutory provisions." p29.<sup>56</sup>

The efforts to encourage the involvement of health professionals would appear to have been successful, as it is now a requirement in New Zealand that health professionals are co-signatories to all claims for compensation within the scheme. According to Kachalia *et al.*, "physicians are integral to the filing of claims [in New Zealand]. Their participation is required as a prerequisite to claiming. Patients must initiate claims through a physician (or other statutorily qualified provider). The claims form is completed jointly, but filed by the physician. The filing physician need not be the physician involved in the injury; in practice, it is typically the patient's general practitioner." p11.<sup>58</sup>

The following data, cited by Mello *et al.*, reveal the extent of involvement by health professionals in assisting applicants to lodge claims. According to Mello *et al.*, "In New Zealand, 46 per cent of treatment injury claims are lodged by patients' primary care providers, who receive reimbursement for the time they spent filing the claim if the claim is accepted. Of the remaining claims, 44 per cent are filed by public or private hospital staff, and 10 per cent by other providers, on behalf of patients." p5<sup>59</sup>

Mello *et al.* outline quite clearly the benefits of physicians helping claimants to file their claims in pursuit of compensation and providing claimants with appropriate support. According to Mello *et al.*, "All of the systems [including New Zealand's] report that jettisoning negligence determinations has been effective in enabling clinicians and patients to maintain their therapeutic relationship and cooperate in the pursuit of compensation... the systems [including New Zealand's] are able to process claims expeditiously. Whereas in the US[A], the average time from injury to disposition of a malpractice claim is five years, in Sweden and Denmark it is eight months. In New Zealand it is 16 days." p5.<sup>59</sup> However, the data that the HRB has for Denmark and Sweden indicate that their average waiting times are seven months and four months, respectively.

From the data we analysed, we further infer that the removal of negligence and the active involvement of health professionals in supporting claimants have contributed greatly to a more streamlined claims handling and adjudication process, which has improved timely access to compensation for applicants. Kachalia *et al.*, who collected primary data from stakeholders of the scheme in New Zealand, highlight some of the advantages to the scheme for claimants that arose when negligence was removed and the need for related adversarialism was replaced with an administrative procedure. According to Kachalia *et al.*, "Interviewees in [New Zealand] cited quicker adjudication as one of the most important perceived advantages of the move away from negligence... Procedural innovations, such as the use of neutral experts and a streamlined, administrative fact-finding process, explain part of the difference." p21.<sup>58</sup>

In addition, it would appear that this more streamlined claims handling and adjudication process, by comparison with what pertained in the somewhat adversarial climate of negligence, operates through a number of key mechanisms that improve consistency in decision-making. For example, Kachalia *et al.* point out the value of the adjudication process relying on precedent and institutional memory in maintaining consistency around decisions taken by the panel of expert reviewers. According to Kachalia *et al.*, “[New Zealand] relies on a set of technical inputs to make their compensation standards a workable basis for decision-making. Chief among those inputs was a panel of neutral expert reviewers, who gained experience over time in applying the criteria. Adjudications also relied on precedent and institutional memory within the compensation agency to ensure consistency in decision-making. The judicious use of precedent proved particularly effective in achieving administrative efficiencies. A claim of first impression may be quite labor- and time-intensive, but subsequent determinations of the same or similar type will benefit from this initial investment, provided that initial decisions are carefully cataloged.” p22.<sup>58</sup>

The judicious use of precedent referred to by Kachalia *et al.* has also been picked up on by Mello *et al.*, who claim that the use of precedent from prior decisions regarding the compensation of treatment injuries can reduce the time and the burden incurred in deliberations. According to Mello *et al.*, “In addition to fostering consistency in decision-making, review of prior decisions has proved effective in reducing the time and labor necessary to decide cases, as reviewers are not reinventing the appropriate methodology with each new case.” p6.<sup>59</sup>

Thus far, we have been discussing compensation for general treatment injuries in New Zealand. In respect of specific compensation for vaccine injuries, Keelan *et al.*, in a review of international vaccine compensation programmes published in 2011, provided some data in respect of compensation for vaccine-related injuries. Keelan *et al.* claim that the objective of providing timely access to compensation in New Zealand is being achieved; however, it must be noted that Keelan *et al.* compare the average time it takes to process claims in the New Zealand administrative no-fault scheme with the average time it takes to pursue a claim through the courts. According to Keelan *et al.*, “the common core objective for most no-fault compensation programmes is to provide just, timely, and proportionate compensation to those whose injuries can be credibly associated with an immunization...in [New Zealand] this core programme objective has been successfully met.” p26.<sup>27</sup>

In summary, it would appear that the claims we have inferred regarding improved access to compensation for claimants in New Zealand are also echoed on the ground by stakeholders of the scheme. According to Mello *et al.*, who collected primary data through interviews with stakeholders, “There is broad agreement [in New Zealand] that the medical injury compensation scheme has met the primary objective of improving injured patients’ access to compensation.” p8.<sup>59</sup>

#### **Key points**

- ***The removal of negligence in the 2005 reforms has reframed the standard of proof and contributed to timely access to compensation for claimants in New Zealand.***
- ***Timely access is also achieved by medical professionals assisting patients to complete their claims forms in New Zealand.***
- ***Streamlining the claims handling and adjudication process (by involving medical professionals and documenting decisions to set precedent) has improved timely access to compensation for claimants in New Zealand.***

### 3.2.4 Question 3: What design features and/or contextual conditions are thought to impact on the number of applicants seeking redress via no-fault vaccine damage schemes?

From the data we analysed, it would appear that reforms to the scheme in 2005 to broaden the scope of injuries eligible to claim for compensation has contributed to an increase in claims for compensation. During the 2005 reforms, it was estimated that the number of claims for compensation for treatment injuries in New Zealand would increase. It was anticipated that by broadening the scope of injuries eligible for compensation claims, the number of claims would increase by at least half. As Bismark and Paterson point out, “The ACC expects that following the 2005 reforms, the number of compensation claims will go up by 50%, and many more claims will be successful...most of the new claims will involve minor, temporary injuries, which were previously ineligible for compensation. The reforms are expected to cost an additional US\$5 million a year.” p281.<sup>28</sup>

From the data available on the number of claimants to the scheme in New Zealand, it would appear that the projected increase in claims did occur. According to Corkill, “There has been a significant increase in the number of claims lodged with ACC – from 1,434 in 2004–2005 to 5,210 in 2009–2010 [or a 263% increase]. ACC considers the growth is attributable to high-volume, low-cost injuries such as allergic reactions” p672<sup>57</sup>, or a 263% increase.

In addition, it was claimed that the reforms in 2005 to make it easier for claimants to navigate the claiming process would also contribute to an increase in the number of claims lodged. However, as Mello *et al.*<sup>59</sup> point out, even though reforms to the scheme have made it easier for claimants to submit their applications, this has not opened the floodgates, and the increase in the number of claims has been modest. According to Mello *et al.*, “although the easier claiming process [in New Zealand] has resulted in higher rates of claims than are seen in the US[A], it has not opened the floodgates to an unmanageable number of claims [in Mello *et al.*’s opinion]. System administrators estimate that about 10 per cent of injured patients file claims, as compared with 2 per cent to 3 per cent in the US[A].” p5.<sup>59</sup>

The available data would suggest that by comparison with other jurisdictions, the volume of compensation claims for vaccine-related injury in New Zealand is high. According to Keelan *et al.*, “New Zealand has a vaccine-injury case-load ten times the United States or the United Kingdom, at 21.5 cases per million. The case-load does not appear to depend on the likelihood of receiving a settlement, as the United Kingdom’s case load is similar to the United States at 2 per million with a claim success rate in the United Kingdom of between 1–2% (over the past few years) versus the United States’ claimant success rate of 72%.” p13.<sup>27</sup>

#### Key point

- **Broadening the scope of eligible injuries for compensation increased the number of claims for compensation in New Zealand.**

### 3.2.5 Question 4: What design features and/or contextual conditions are thought to impact on the volume and costs of awards made under no-fault vaccine damage schemes?

From the data we analysed, it would appear that the proportion of claims successfully compensated have increased since the reforms in 2005. For example, according to Manning, “The acceptance rate for treatment injury claims has been on average approximately 63% in the 8 years since 2005 to the year ended October 2013, whereas for medical misadventure 38% of claims on average were accepted in the period April 1992 to June 2005.” p31.<sup>56</sup>

In addition, we have a snapshot of data for the number of adjudicated claims successfully compensated in the year 2009, which worked out to around 66%. According to Blake, “In 2009 there were 6,400 treatment injury claims of which 3,153 were accepted, 1,607 were declined and 1,650 had still not been finalized by the end of the 2009 year.” p129.<sup>61</sup>

In the papers we reviewed, no inferences were drawn regarding why the apparent increase in successful awards had occurred. However, we infer that this increase in the volume of awards



compensated is mainly due to the broadening of the injury eligibility criteria and the removal of negligence. Since the reforms in 2005, an expanded number of treatment injuries are eligible for compensation, including injuries from vaccines. This means that relatively minor injuries can qualify for compensation, and payments can be quite modest in such cases. As Keelan *et al.* point out, “Since the programme’s eligibility requirements regarding the severity of the injury are broad, the payouts are relatively small when compared with other jurisdictions, and the compensated injuries relatively minor awards generally range from a few hundred dollars to several thousand dollars.” p21.<sup>27</sup>

In addition, Keelan *et al.* provide a snapshot of the number of successful awards for vaccine injury over a four-year period which suggests that over that period, approximately 49% of vaccine-injury claims were successful, which is lower than the success rate in Asia and the USA. According to Keelan *et al.*, “Since the inclusion of vaccine-related injuries under the scheme in 2005 (until 2009), there have been 344 vaccine-related injury claims filed and 170 accepted for compensation.” p21.<sup>27</sup>

Regarding the costs of compensation paid under the scheme, there are data to suggest that the cost of compensation for non-economic losses has remained quite low, but the cost for economic-related losses has been estimated to cover 60% of total expenditure from the scheme. For example, data cited in the paper by Mello *et al.* suggest that compensation paid for non-economic costs is considerably smaller when compared with similar costs paid in the USA. Mello *et al.* claim that such costs are low in New Zealand due to the wider support available to injured parties from other social insurance resources. According to Mello *et al.*, “[In addition to the availability of other social insurance programmes and free healthcare,] payments for noneconomic losses are much smaller than is typically the case in the US[A]. Because of these features, the average total award size in [New Zealand] is much lower than in the US[A]. In 2009, the average compensation per paid claim was approximately... [US]\$324,000 in the US[A]. In New Zealand, [average direct compensation] was much lower, around US\$4,450.” p7.<sup>59</sup>

In addition, Mello *et al.* point out that because claimants can claim from the wider social insurance resources for a variety of losses and expenses, they do not need to submit these claims to the scheme, which means that the average costs of claims can be kept low. According to Mello *et al.*, “The availability of [other social insurance schemes] also keeps average claims costs lower because ‘collateral-source offset’ rules stipulate that the medical injury systems need not pay for lost wages [national employment insurance pays 80% of salary at the time of injury], medical expenses [free at the point of delivery], and other expenses that are covered by the national insurance system.” p7.<sup>59</sup>

However, it has been estimated that around 60% of total expenditure in the scheme is money paid out to compensate the loss of earnings. According to Wilson, “We aggregated ACC data on expenditure into two categories: earnings-related compensation, and all other ACC support combined (e.g., medical treatment, vocational rehabilitation, independence support). We chose these two categories for two reasons. First, earnings-related compensation is by far the largest class of ACC claims, accounting for about 60% of total spending. Second, the factors affecting the two categories are likely to be different; in particular, the amount of earnings-related compensation a person receives (80% of lost earnings) is closely related to his or her preinjury income, whereas the amount of other ACC support received depends on other factors.” p125.<sup>60</sup>

It could be argued that the 80% earnings-related compensation is perhaps one of the key features of this scheme and that it acts as a control mechanism for other costs in the scheme – in particular, keeping awards for non-economic costs low. According to Blake, “You will appreciate that the lump sum payments, where granted, are very substantially less than those awarded in civil litigation, but do not forget the injured patients receive the 80% earnings-related compensation as well, and if they are off work for two or three years that is a very substantial sum.” p129.<sup>61</sup>

Finally, in the paper by Corkill, there are some data available to explain why claims for compensation are rejected. According to Corkill, “ACC has included the most common reasons for declining a claim as being:

- No physical injury could be included: 46%.
- No causal link between treatment and injury: 28%.
- Injury was an ordinary consequence of treatment: 12%.
- Injury was wholly or substantially caused by the underlying health condition: 10%.” p672.<sup>57</sup>

In addition, Keelan *et al.* outline the principal reasons for declining claims for vaccine injury compensation in New Zealand are, in order of frequency:

- “No compensable injury: 113
- Injury was an ordinary consequence of treatment: 41;
- No causal link between the immunization and injury: 14.” p21.<sup>27</sup>

#### **Key points**

- **Broadening the eligibility criteria to cover injuries amenable for compensation can increase the number of successful awards in New Zealand.**
- **Embedding the scheme in a wider suite of social insurance and tax-funded healthcare resources can reduce direct expenditure by the injury compensation scheme in New Zealand.**

### **3.2.6 Question 5: Do no-fault vaccine damage schemes enjoy public acceptance?**

#### **3.2.6.1 Support from physicians**

We asked the following question of the data we analysed: Does the compensation scheme for treatment injuries in New Zealand enjoy the support of members of the medical profession? We did not identify any papers that directly sought to answer this question. However, we did identify a number of instances in the included papers where one could draw an inference about the support for the scheme from the medical profession. For example, Kachalia *et al.* suggested that the New Zealand scheme, despite its difficulties, had buy-in from physicians. According to Kachalia *et al.*, “the operational success of the standards would not have been possible without buy-in from [physicians].” p23.<sup>58</sup>

It would appear that part of the reason for physicians buying into the scheme in New Zealand was the removal of negligence as part of the 2005 reforms. According to Kachalia *et al.*, “New Zealand’s porous boundary under the medical misadventure standard engendered substantial resentment among physicians in that country. The new scheme with the treatment injury standard has in part allayed these concerns because the ACC must now report only in instances in which there is a risk of harm to the public.” p23.<sup>58</sup>

In addition to physicians apparently showing some support for the scheme, the 2005 reforms are also thought to have built better relationships between patients and physicians. As Mello *et al.* point out, “All of the systems report that jettisoning negligence determinations has been effective in enabling clinicians and patients to maintain their therapeutic relationship and cooperate in the pursuit of compensation.” p5.<sup>59</sup>

#### **3.2.6.2 Support from general public**

We also asked this question of the data we analysed: Does the scheme in New Zealand enjoy support from claimants and the wider general public? From data collected about New Zealand, it would appear that public support for the scheme is relatively high. This support appears to be premised on the belief that the scheme is fair and the award payments prompt. According to Kachalia *et al.*, who undertook this fieldwork, “Successive interviewees echoed the view that patients are ultimately the critical constituency. Any compensation system must be trustworthy and deliver what patients want. What patients appear to want most from their compensation scheme in New Zealand, according to

the people who run the scheme, is to know that if they are injured by medical care, a consistent and fair system of adjudication, one that is not biased toward provider interests, will deal with their claim promptly... This assurance takes time to build... the New Zealand scheme, despite the flux in its decision rules over time, appears to have accomplished this assurance.” p23.<sup>58</sup>

### 3.2.6.3 Public awareness

Finally, it is important to note that unlike other jurisdictions, it would appear that public awareness of the scheme in New Zealand is quite high. This high level of public awareness is thought by some authors to influence the high number of claims that are lodged for compensation within the scheme. According to Keelan *et al.*, “New Zealand’s unusually high claim rate (indexed to population) reflects its relatively permissive definition of injury and the highly public role the ACC plays in New Zealand public policy. Research on the ACC suggests that unlike most jurisdictions, most New Zealanders are aware that compensation is available for unexpected injuries related to medical treatment, including immunization. This suggests that the key barriers in other jurisdictions to filing claims and meeting eligibility criteria are absent in the New Zealand model.” p21-22.<sup>27</sup>

#### Key point

- ***The medical injury scheme enjoys the support of medical professionals, claimants, and the public in New Zealand.***

### 3.2.7 Question 6: What cost-control mechanisms covering no-fault vaccine damage schemes are reported in the literature?

#### 3.2.7.1 Legal fees

The main cost –control mechanism is there are no legal fees associated with the scheme in New Zealand.

#### 3.2.7.2 Lump-sum awards

Of the papers we analysed, empirical evidence provided by Manning states that successful claimants in New Zealand can receive compensation from the medical injury scheme for non-economic costs, such as lump-sum entitlements for permanent physical impairment. These awards are capped, which may act as a cost-control mechanism within the scheme. Manning claims that compensation is provided in the form of “a modest lump sum entitlement for permanent physical impairment of up to NZ\$100,000 for 80% or more whole-person impairment.” p23.<sup>56</sup>

There appears to be some dissatisfaction with the caps on non-economic costs, with some people believing the amount awarded to be inadequate. According to Mello *et al.*, “The systems use fixed award amounts, schedules, and caps to make payments for noneconomic loss, provoking controversy about the adequacy of awards. New Zealand provides lump-sum payments for noneconomic loss associated with permanent impairment (the loss, or loss of use, of a bodily part, system, or function). However, the payments historically have generated some controversy because they are relatively modest (currently capped at US\$85,500), have been adjusted only infrequently, and are conditional on permanent impairment, meaning that individuals whose impairment is temporary or whose injuries involve pain but not impairment do not have their noneconomic loss compensated.” p7.<sup>59</sup>

#### 3.2.7.3 Filing deadline

A final cost-control mechanism of the scheme presents itself in the form of a strict deadline regarding the filing of all treatment injury compensation claims. The relative statute of limitation is 12 months.

#### Key points

- ***There are three cost-control mechanisms: no need for legal fees, caps on lump-sum monetary awards for permanent disability, and a 12-month filing deadline in New Zealand.***
- ***In addition, the wider employment insurance part of the scheme reimburses salary payments up to a maximum of 80% of NZ\$120,000 in New Zealand.***

### 3.2.8 Summary

In New Zealand in 2005, medical mishap and medical error were replaced with a new concept of treatment injury. In effect, this reform to the New Zealand injury compensation programme meant that the need to prove negligence was removed and the programme became a full no-fault administrative intervention redesigned to improve the chances of compensation for claimants. From the data we analysed, it would appear that the removal of negligence, which reframed the standard of proof, has contributed to keeping overhead costs down by removing the need to cover the cost of legal fees. For example, it is estimated that in New Zealand, administrative costs and overhead costs are between approximately 10% and 17% of total expenditures, compared with between 50% and 60% among malpractice systems in other countries.

There is almost unanimous consensus in the literature we reviewed that the removal of negligence in the 2005 reforms has improved access to compensation for claimants. The data suggest that prior to the 2005 reforms, it took on average five months to resolve a claim, and in 2012–2013 it took an average of 23 days. One of the key mechanisms which seems to have brought about this improvement in access to compensation is the active involvement of health professionals in assisting claimants. Indeed, physicians' and health professionals' participation is required as a prerequisite to claiming. A 2011 paper we reviewed showed that health professionals are involved in 90% of claims.

In addition, the claims handling and adjudication process has become more streamlined since the 2005 reforms, and this change has also contributed to improved access to compensation for claimants. In effect, the adjudication process is believed to have become much quicker and is facilitated by the expert panel of adjudicators drawing on precedent and institutional memory in maintaining consistency around decisions taken. There is broad agreement that the compensation scheme has met the primary objective of improving injured patients' access to compensation.

The reform in 2005 to broaden the scope of eligibility for the types of injuries that compensation can be claimed for would appear to have led to an increase in the number of claims. The data show that the number of claims did increase from 1,434 in 2004–2005 to 5,210 in 2009–2010. However, it is also suggested that this increase does not represent the floodgates opening, as only 10% of injured patients file claims.

In addition, it would appear that broadening the eligibility criteria for the types of injuries that are covered under the scheme would also have affected the number of successful awards compensated. For example, the data show that 38% of claims were awarded compensation between 1992 and 2005 and 63% were awarded compensation between 2005 and 2013. Contextually speaking, the scheme is embedded in a wider suite of social insurance resources, and this can also affect the way overall expenditure is distributed within the scheme between non-economic and economic compensation.

For example, it is estimated that in 2009, the average non-economic payment was US\$4,450. Non-economic compensation is generally a lump-sum payment for associated permanent impairment (the loss, or loss of use, of a bodily part, system, or function) and is conditional on permanent impairment, meaning that individuals whose impairment is temporary or whose injuries involve pain but not permanent impairment do not have their non-economic loss compensated. In addition, it is estimated that 60% of total expenditure in the scheme is money paid out to compensate the loss of earnings, which is for economic losses. Within the payment for economic losses, the scheme can pay 80% of earnings-related compensation, which we infer is perhaps one of the key features of this scheme in that it acts as a control mechanism for other costs in the scheme.

In general, it would appear that the scheme enjoys broad public support and approval. For example, the literature demonstrates that there is a high level of public awareness of the scheme, that it enjoys the support from the public, and that it has buy-in from physicians and health professionals in general.

There are three cost-control mechanisms: no need for legal fees, caps on lump-sum monetary awards for permanent disability, and a 12-month filing deadline in New Zealand.

## 3.3 Nordic countries

### 3.3.1 Introduction

We identified three publications that provided data on the drug injury compensation scheme in the Nordic countries of Denmark, Finland, Norway, and Sweden. The drug injury compensation scheme includes vaccine injury compensation. The three publications we included are Hodges (2006),<sup>62</sup> Macleod and Hodges C (2017)<sup>63</sup> and Urho (2018),<sup>64</sup> which combined primary data extraction, secondary analysis of administrative data, and a review of a select body of relevant literature. From the three publications we included, we did not extract any vaccine injury-specific data. Instead, we have extracted data on the wider drug injury compensation schemes, which include vaccines and so fit our questions. Where appropriate, we have used these data to make some inferences about the influence of key features and contextual conditions on our areas of interest, i.e. access, number of applicants, and the volume and cost of awards.

### 3.3.2 Denmark

#### 3.3.2.1 Introduction

It would appear that Denmark did have a standalone VICP between 1978 and 2003, which has now become subsumed under the Danish drug injury compensation scheme. According to Hodges, “Denmark had introduced a Vaccine Compensation Act in 1978 [Act No. 82]... This was repealed by Act No. 430 of 10 June 2003, which disapplied the arrangements for vaccine injuries caused from 1 January 2004, from when vaccine injuries were included in the general medicines arrangements.” p146.<sup>62</sup>

One of the key features of drug injury compensation in Denmark today is the removal of negligence and the underpinning premise of the no-fault approach. According to Hodges, “The basis of the scheme [in Denmark] is no-fault compensation. In other words, drug-related injuries caused by pharmaceuticals and vaccines made available in [Denmark] are indemnified regardless of whether the producer, importer, or any doctor has been negligent.” p149.<sup>62</sup>

Another notable feature of the drug injury compensation scheme in Denmark is that it is publicly funded from central taxation and is heavily supported by a network of wider publicly funded social security supports; this latter feature means the injury compensation scheme is confined to covering a limited number of costs through drug-injury-related compensation, such as pain and suffering and a small portion of lost earnings. According to Hodges, “If someone suffers an injury in Denmark, he would continue to be paid some money by the state. The level of payment is generally full salary, until employment is terminated. Publicly funded social security covers any shortfall. These arrangements do not cover pain and suffering, which would be covered under the pharmaceutical scheme, which would also compensate for permanent disability, or loss of working capacity. Medical expenses are free under the public health system (only 2% of hospitals are private) and such expenditure could not be reclaimed from the pharmaceutical scheme.” p161-162.<sup>62</sup>

### **3.3.2.2 Question 1: What design features and/or contextual conditions are thought to impact on the operating costs associated with no-fault vaccine damage schemes?**

We did not extract any specific data on the overhead costs of administering vaccine injury compensation under the drug injury compensation scheme in Denmark. However, the overhead costs of running the drug injury compensation scheme in Denmark are covered by the State from general taxation, and according to Hodges, “The administration costs of the scheme [in Denmark] are clearly low. The annual administration cost in 2004 was DKK1.97 million (€265,000).” p160.<sup>62</sup> We did not identify any additional papers that may have provided a more up-to-date account of the costs of administering the scheme in Denmark, and we did not extract any data from the two papers we reviewed to suggest that certain features of the scheme affected overhead costs.

#### **Key point**

- *In 2004, overhead costs were low in Denmark, but whether or not design features affect these costs is unclear.*

### **3.3.2.3 Question 2: What design features and/or contextual conditions are thought to impact on timely access to no-fault vaccine damage schemes?**

From the two papers we reviewed on the drug injury compensation scheme in Denmark, we did not extract any data that directly assessed if applicants for vaccine injury compensation in particular received timely access to compensation. However, we did extract some data regarding the claims handling and adjudication process for drug injuries in general, from which we can draw some general inferences about the scheme that may also apply to vaccine injury claimants.

For example, the scheme is based on the principle of finding no fault regarding negligence, which means that applicants do not have to incur any legal expenses or engage in adversarial proceedings. According to Hodges, “the average case processing time of a claim under the medicines scheme in Denmark was 204 days in 2004; [the scheme ensures] the complete avoidance of the costs of the legal system. The scheme also avoids confrontation between the parties.” p163-164.<sup>62</sup>

In addition, there is one body, the Danish Patient Insurance [or Compensation] Association, charged with the responsibility of processing all claims, collecting relevant information, and making the key decisions which may contribute to a more streamlined approach that is favourable to claimants who may otherwise be required to collect and submit relevant documentation themselves and endure separate hearings regarding the merits of their claim and deliberations on the appropriate amount of compensation. According to Hodges, “[the Danish Patient Insurance Association] make the decisions on the facts, on causation, and on the appropriate level of award... The Danish Patient Insurance Association has the power to require all municipal authorities, hospitals, pharmacies, physicians, and others to disclose all relevant information that is of importance in relation to handling cases.” p147-148.<sup>62</sup>

The removal of adversarial dispute and the delegation of the claims handling and decision-making to one central body would appear to be key features in satisfying the original intent of the scheme in Denmark. According to Hodges, “The scheme [in Denmark] has satisfied the policy objective of improving the chances of injured persons obtaining compensation than might obtain under the law of torts and the legal process.” p164.<sup>62</sup>

#### **Key points**

- *The principle of finding no fault regarding negligence makes it easier for all parties to cooperate with the scheme in Denmark.*
- *The single-agency claims handling and adjudication process has improved timely access to compensation, and its legal powers of disclosure allow it rapid access to relevant documentation in Denmark.*

### 3.3.2.4 Question 3: What design features and/or contextual conditions are thought to impact on the number of applicants seeking redress via no-fault vaccine damage schemes?

We did not extract any data from the two papers we reviewed on the number of claims for vaccine injury compensation specifically under the scheme in Denmark. There was only one reference to the number of applicants for drug injury compensation, which includes any vaccine injuries, and this suggested that the average number of claims per year in Denmark is 200. p172.<sup>62</sup>

However, we checked the Danish Patient Compensation Association website for claims data for the drug injury compensation scheme for an update on the number of applicants, and the website now reports that “each year [they] receive close to 600 claims concerning medicinal injuries.”<sup>38</sup>

#### **Key point**

- ***There are no specific data on only claims for vaccine injuries, and so we cannot identify design features that affect numbers of claims for vaccine injuries in Denmark.***

### 3.3.2.5 Question 4: What design features and/or contextual conditions are thought to impact on the volume and costs of awards made under no-fault vaccine damage schemes?

Based on the two papers we reviewed regarding the drug injury compensation scheme in Denmark, we did not extract any data on the number of awards for vaccine injuries or the amount of compensation paid out for such injuries. However, in the paper from Hodges,<sup>62</sup> there are data on the number of drug injury claims paid and the amount of compensation awarded for drug injuries in general, from which we can make some inferences. For example, the average percentage of successful claims per year between 2004 and 2006 was 30%, and the number of successful claims paid per year was 50. The average compensation per claim was €30,000 for the same period. The total cost of compensation paid per year was €1.9 million between 2004 and 2006, excluding administration costs. p172.<sup>62</sup>

Hodges goes on to claim that “the Nordic schemes [including Denmark] provide only a low level of compensation payments and make availability subject to certain boundaries.” p174.<sup>62</sup>

So, the question is, are there any features of or contextual conditions associated with the scheme in Denmark that may contribute to keeping compensation payments low? From the data we analysed, we have inferred that the standard of proof required to demonstrate causation may be a feature of the scheme that contributes to keeping compensation awards relatively low. The standard of proof is that it is more likely than not that the injury is associated with the medication, or more than 50% likely that the injury was associated with the drug.

On the one hand, it could be argued that the standard of proof required in Denmark is much lower than what pertains in the legal system. For example, according to Hodges, “The standard of proof in the Danish Law can be translated as ‘overwhelming likelihood.’ ...In percentage terms, the concept means rather more than 50% [if the injury is more serious than what the patient in fairness should accept]. In any event, the standard is less than that required for a legal claim, which requires full proof by a claimant, or 100%.” p151.<sup>62</sup>

However, on the other hand, Hodges<sup>62</sup> draws our attention to the potential boundaries faced by claimants having to demonstrate causation between an injury and a particular pharmaceutical drug; boundaries that, if not overcome, may contribute to keeping the amount of awards compensated at low levels. According to Hodges, “It should, however, be asked whether the various boundaries that are applied may result in difficulties for claimants, such as difficulties over proving causation...The greatest reasons for rejection in Denmark have been that the injuries are insufficiently serious or there was no physical injury. It might be anticipated that a significant proportion of claims made will be rejected, since there is nothing to be lost by submitting a claim and there is faith in the impartiality of the expert assessment.” p167.<sup>62</sup>

In addition, we infer that a key contextual condition that may contribute to keeping levels of compensation payments low in Denmark may be that the drug injury compensation scheme is

embedded within a generous system of social security measures. This means that, as some authors have claimed, the drug injury compensation scheme in Denmark is often referred to as a top-up to the principal payments and supports delivered under the wider social security system. According to Hodges, “The pharmaceutical schemes are made affordable because they effectively operate as a top-up scheme to the other state social security measures, with very limited rights of recourse.” p173.<sup>62</sup> In addition, there are no legal fees.

#### **Key points**

- ***The standard of proof (i.e. ‘balance of probabilities’, ‘51% or more’, ‘more likely than not’) adopted and the requirement that the injury is serious or that there is a physical injury contribute to keeping the proportion of compensation awards relatively low in Denmark***
- ***The wider contextual influence of social security and healthcare measures (which cover the majority of lost earnings and provide free medical care when required) and the removal of the requirement for legal fees also helps to keep the costs of direct compensation relatively low in Denmark.***

### **3.3.2.6 Question 5: Do no-fault vaccine damage schemes enjoy public acceptance?**

In the case of Denmark, we did not identify any mention of public support or approval for vaccine injury compensation in the two papers we reviewed. However, we did extract data from both papers that indirectly speak to issues pertaining to public support and approval for the drug compensation scheme in general.

It is an established norm that if the general public does not have adequate and sufficient information about VICPs, then it is difficult to assess their level of support or approval for such schemes. During his site visit to Denmark, Urho<sup>64</sup> commented on the lack of information going out to the general public about the drug compensation scheme in general. According to Urho, “[in Denmark], the general public’s access to information turned out to be unsatisfactory according to most interviewees. The pharma industry does not disseminate enough information about the compensation scheme or information never reaches all patients. It appears that information is given in leaflets that patients hardly ever read.” p476.<sup>64</sup>

However, in the paper published by Hodges,<sup>62</sup> it is claimed that the levels of payments made under the drug injury compensation scheme and the absence of legal fees are features of the scheme that make it attractive to claimants, thereby inferring that the scheme enjoys some level of public support and approval among claimants in Denmark. According to Hodges, “The equation of levels of payments paid under the schemes with those for damages under the tort system satisfies theoretical principles of fairness, and also makes the schemes attractive to claimants, by offering the advantages of the same levels of compensation without the direct transaction costs of the legal system (i.e., having to pay lawyers’ fees).” p163.<sup>62</sup>

#### **Key point**

- ***Although there is no direct evidence, there is some indirect evidence of public support in Denmark.***

### **3.3.2.7 Question 6: What cost-control mechanisms covering no-fault vaccine damage schemes are reported in the literature?**

The absence of legal costs are regarded as the main cost-control mechanism.

There are a number of boundaries set on the scope of payments in the drug injury compensation scheme in Denmark, which it would appear are generated in order to take into consideration the publicly funded nature of the scheme. For example, there is a cap on the total liability of any individual claim that is paid out under the scheme. According to Hodges, “Denmark specifies a cap on the value of an individual claim... In considering the figures for Denmark, it is necessary to remember that payments are funded solely by the State, so one would not expect the levels to be set at overly generous amounts. Thus, Denmark has a cap on a claim by an individual (€670,000) that is only around 60% of the equivalent in Sweden.” p152. <sup>62</sup> In addition, there are financial caps on the



following awards: €20.15 million for all injuries during a year, €13.43 million for each serial injury, and €3.36 million for all injuries relating to each clinical trial. p153.<sup>62</sup>

An additional threshold that appears to be influenced by the public funding of the scheme is that all claims must exceed a certain amount. According to Hodges, “Only in Denmark must the value of a claim exceed a certain specified value... € 400...This mechanism is intended to discourage trivial, cost-inefficient or even fraudulent claims. This mechanism is particularly understandable where the state is funding the compensation payments, as in Denmark.” p152.<sup>62</sup>

Similar to other jurisdictions, Denmark has also set a deadline against when claims can be filed for compensation under the drug injury compensation scheme. According to Hodges, “Denmark adopted the rules that claims must be filed within three years from the date the patient has or should have had knowledge of the injury, and that claims are barred ten years from the date that the medicine was dispensed to the patient.” p156.<sup>62</sup>

#### **Key points**

- ***There are minimum and maximum values on individual awards and a maximum value on the total award expenditure available for injured persons in a single year in Denmark.***
- ***There are time limitations on claims: claims must be filed within three years and are barred after 10 years from the date that the medicine was dispensed in Denmark.***
- ***Social services cover a significant portion of lost earnings and the health service covers medical costs as required, thus keeping direct costs from the scheme low in Denmark.***
- ***The scheme pays a top-up on lost earnings on an annual basis, so payments are deferred and only paid for as long as the person needs them in Denmark.***
- ***There are no legal expenses, as this is a no-fault scheme in Denmark.***
- ***No cost is paid twice in Denmark.***

### 3.3.2.8 Summary

We acknowledge that our coverage of the drug injury compensation scheme in Denmark is primarily limited to data we extracted and analysed from one paper that was published more than 12 years ago. In addition, the data we extracted from Hodges<sup>62</sup> exclusively relates to the drug injury compensation scheme in general, of which vaccine injury compensation is only one small part. Therefore, the inferences we draw relate primarily to data on how features of the drug injury compensation scheme or its contextual conditions may impact on the parameters of interest: timely access to compensation, the number of applicants, and the volume and cost of compensation awards for vaccine injury victims.

To summarise, we infer that the removal of adversarial dispute and the delegation of the claims handling and decision-making to one central body would appear to improve the chances of injured persons obtaining compensation in a timely fashion. The single-agency claims handling and adjudication process allows timely access to compensation, and the agency's legal powers of disclosure allow it rapid access to relevant documentation. We further infer that the relatively low levels of compensation awards are perhaps influenced by some of the difficulties in proving causation, e.g. showing that the injury is sufficiently serious and that there is greater than a 50% probability that the drug was the cause of the injury.

The one main contextual influence that would appear to act favourably on the scheme is the wider context of social security supports within which the scheme is embedded; the scheme acts as a top-up. Apparently, this context ensures that the scheme is affordable while meeting both the administrative and compensation costs, and although the scheme is exclusively funded from central taxation, these contextual contingencies enable the scheme to remain modest in size and in costs.

The medical injuries scheme pays a top-up on lost earnings on an annual basis, so salary payments are deferred and only paid for as long as the person needs them. One other feature of the scheme is that no cost is paid twice. In 2004, 30% of the medical injury claims were successful; it would be expected that the vaccine injury success rate would be higher, as noted in the VICPs in Asia.

There is some weak indirect evidence of public support for the medical injuries scheme in Denmark. There are a number of cost-control mechanisms in the scheme: no legal fees; minimum and maximum values on individual awards and a maximum value on the total award expenditure available for injured persons in a single year; time limitations on claims; and social services covering a significant portion of lost earnings while the health service covers medical costs as required. The absence of legal costs are regarded as the main cost-control mechanism.

### 3.3.3 Finland

#### 3.3.3.1 Introduction

Compensation for vaccine injuries in Finland is administered through the wider pharmaceutical injuries insurance scheme. Urho<sup>64</sup> outlines some recent changes that the insurance scheme has undergone in Finland. According to Macleod and Hodges<sup>63</sup> and Urho, “At the beginning of the year 2012, the drug injury insurance was transferred to a new insurance company (the Pharmaceutical Injuries Insurance) established by the Finnish Co-operative for Pharmaceutical Injury Indemnities. The policyholder of the drug injury insurance remains the same. The insurer in this new system is the Pharmaceutical Injuries Insurance that grants the drug injury insurance to the Co-operative to protect the users of medicines. Compensation is payable under Pharmaceutical Injuries Insurance in respect of any bodily injury (pharmaceutical injury) resulting from therapeutic use of a pharmaceutical, provided that the product manufacturer, importer, distributor or marketer is a member of the co-operative, and in the normal course of business, supplied the pharmaceuticals for consumption in Finland.” p477-478.<sup>64</sup> In addition, Urho points out that “Today, [the old Finnish Pharmaceutical Insurance Pool] handles only those claims that concern narcolepsy caused by the Pandemrix vaccine in Finland.” p477.<sup>64</sup> Similar to Denmark, the Pharmaceutical Injuries Insurance scheme is a no-fault scheme and there are no requirements for legal representation. However, the scheme is funded by pharmaceutical companies rather than general taxation.

The Pharmaceutical Injuries Insurance scheme is funded from levies paid by all members of the Finnish Co-operative for Pharmaceutical Injury Indemnities. Hodges describes in detail the precise funding mechanism that applies in the scheme: “The medicines scheme in Finland is financed by a percentage levy set annually based on pharmaceutical companies’ turnover of sales in the country. The approach is based on the general theory that the manufacturers who have larger market shares may be more likely to have products that give rise to the greater percentage of injuries.” p159.<sup>62</sup>

In the event that an applicant to the scheme is unhappy with the initial decision not to take on their claim, there are a number of opportunities for them to seek a review of this decision. According to Hodges, “An applicant who is dissatisfied with the decision [on compensation] of the insurance institution can request an opinion to be given by the Pharmaceutical Injuries Board, which is comprised of neutral doctors and lawyers or judges appointed by the Pool. Opinions are issued by the Board free of charge. Any dispute between an insurer and an injured person may also be referred to arbitration if the parties so agree. An injured person may also bring an action against the insurer in the former’s local court.” p148.<sup>62</sup>

#### 3.3.3.2 Question 1: What design features and/or contextual conditions are thought to impact on the operating costs associated with no-fault vaccine damage schemes?

We did not extract any explicit data from the three papers we reviewed that provided an estimate of the overhead costs for operating the VICP in Finland. The only data we included relate to the administration costs of running the drug injury scheme in general. According to Hodges, “The administration costs of the scheme [in Finland] are clearly low. In 2003, the annual administration cost was €50,000 in Finland.” p160.<sup>62</sup> Macleod and Hodges<sup>63</sup> reported administration costs of 17% of the total income in 2012 and 11% in 2015.

#### **Key point**

- ***In 2015, overhead costs were low in Finland at 11% of total income, but whether or not the scheme’s design features affect these costs is unclear***

### 3.3.3.3 Question 2: What design features and/or contextual conditions are thought to impact on timely access to no-fault vaccine damage schemes?

From the three papers we reviewed, we did not extract any data that described whether claimants to the scheme had their claims resolved in a timely fashion. However, we did extract data from the paper by Urho<sup>64</sup> which suggested that the pharmaceutical industry and the Finnish Pharmaceutical Insurance Pool were quite satisfied that claims were being handled quickly and decisions taken within an appropriate time frame. Macloed and Hodges<sup>63</sup> describe the claims handling process which comprises a six-stage process: written notice of injury, information gathering, statement of a medical advisor, decision, payment of compensation, and complaints (if dissatisfied with the decision). The time required to go through this process is not estimated in any of the three publications.

We infer from the claims made on behalf of the pharmaceutical industry and the Finnish Pharmaceutical Insurance Pool that it is the activities undertaken in the claims handling and adjudication process of the scheme that enable claims to be resolved expeditiously. According to Urho, “the insurance system [in Finland] has worked very well. No considerable flaws were discovered. The claims process was proven to be expeditious and flexible; even very hard and complex cases, such as serious permanent disabilities or cases where the patient had deceased were settled... The claims handling system, taken care of by the Insurance Pool, has worked without hitches and both entities – the Pharmaceutical Industry and the Insurance Pool – have been satisfied with it. Ever since the scheme’s inception, it would have been possible for these parties to terminate the agreement every year but neither of them have wanted to do that.” p479.<sup>64</sup>

We further infer that the absence of evidence of claimants pursuing litigation through the courts and instead pursuing claims through the scheme is an indirect signal that claimants, like the stakeholders mentioned above, are satisfied with the existence of the scheme and that their claims are handled in a timely manner. According to Urho, “The scheme has offered an alternative to time-consuming and expensive litigations which have been almost entirely avoided. Another proof of the success of this voluntary compensation scheme is its longevity. It has been operated for more than 30 years. In retrospect the scheme has met all the expectations set to it at the outset.” p479.<sup>64</sup> According to Macloed and Hodges “since the new scheme was introduced in 2012 only a single case has been brought to court.” p262<sup>63</sup>

#### **Key point**

- ***The six-stage process undertaken to handle and adjudicate claims in Finland is described, but not linked to timelines. We infer that these activities may enable claims to be resolved expeditiously, as the Government, the pharmaceutical industry, and the claimants appear satisfied that claims are dealt with in a timely manner.***

### 3.3.3.4 Question 3: What design features and/or contextual conditions are thought to impact on the number of applicants seeking redress via no-fault vaccine damage schemes?

From the three papers we reviewed on the drug injury compensation scheme in Finland, we were unable to make any inferences on what features of the scheme were thought likely to affect the number of applicants. However, from the data we did extract, it would appear that the numbers of claims for drug injuries in general have experienced a modest increase to 2011<sup>62</sup> <sup>63</sup> and a decrease in 2012 to 2014 possibly due to moving the scheme to a new home and tightening the awards criteria.<sup>63</sup>

Regarding claims for vaccine injury compensation, according to Urho, “In Finland, 316 claims had been submitted in total regarding suspected narcolepsy cases before the end of March 2018. Of these, the Insurance Pool accepted 232 claims for compensation and declined 68.” p485.<sup>64</sup> We know that compensation claims for narcolepsy are confined to the H1N1 influenza vaccine that was recommended to the public in 2009 and 2010 to prevent an epidemic of swine flu from occurring. Therefore, it can be accepted that these claims are exclusively for vaccine injury compensation.

#### **Key point**

- *There are no contextual factors within the drug injury scheme described in the examined papers that are thought to affect the number of applicants in Finland, but such numbers have increased over time.*

### 3.3.3.5 Question 4: What design features and/or contextual factors are thought to impact on the volume and costs of awards made under no-fault vaccine damage schemes?

From the limited amount of data available on the number of awards given out for vaccine injury compensation, it would appear that the rate of successful claims is relatively high, with approximately 77% of cases deliberated on being compensated for their injuries related to the H1N1 vaccine. According to Urho, “In Finland, 316 claims had been submitted in total regarding suspected narcolepsy cases before the end of March 2018. Of these, the Insurance Pool accepted 232 claims for compensation and declined 68.” p485.<sup>64</sup>

In addition, a notable feature of the drug compensation scheme in Finland in general is the relatively high number of compensation awards given out for drug injuries in contrast to some of its Nordic neighbours. From an analysis of 130 handled compensation cases in Finland, Urho states that “The share of compensated cases (circa 50%) [up to 2011] is higher than in Sweden and Norway, where the compensation percentages are only about 30% of the total number of claims.” p479.<sup>64</sup>

Furthermore, it would appear that Finland’s higher rate in awarding compensation claims is not a contemporary phenomenon, as there is some evidence that it has maintained a 50% award rate going back many years in the scheme. According to Hodges, “The success rate [of claims] in Finland appears to be somewhat higher, at around 50% over the past ten years, and as high as 59% in 2002.” p167.<sup>62</sup>

So, the question arises as to why Finland has been approving more awards for compensation for drug injuries compared to some of its Nordic neighbours, particularly given that Finland operates a similar standard of proof to the one used in Denmark and Sweden, where the proportion of awards approved is approximately 20 percentage points lower than in Finland. As Hodges alludes to, “The standard of proof in the Finnish scheme is stated as being where the ‘injury is likely to have resulted from a drug’. Although there is no local use of percentages, this is intended to be the same as the Swedish ‘preponderant probability’ and to equate to a little over 50%.” p151.<sup>62</sup>

We are inferring that the 50% award approval rate for claimants in Finland is perhaps explained by a more liberal application of the ‘preponderant probability’ standard of proof. What we mean by this is that when Hodges<sup>62</sup> states that in Finland the standard of proof is taken as being when the injury is likely to have resulted from a drug regardless of the severity of the injury, this signals a more liberal application of the same standard that is applied in Sweden. In contrast, the standard of proof adopted in Sweden rests on not just the presence of the injury but also on the severity of the injury in

determining when a claim should be compensated. We further infer that it is this difference in the application of the standard of proof that results in a higher success rate for claims in Finland compared to Sweden. However, of note, more recent data for 2012 and 2013 indicate a decline in the proportion of successful cases to 30% in 2012 and 40% in 2013 which is more in line with trends in the other Nordic countries included in the review.<sup>63</sup>

The second part of our question relates to what features or contextual factors related to the scheme may affect the amount of compensation that is paid out to successful claimants. From our analysis of the data, we infer that it is the wider contextual environment which is made up of a suite of social insurance resources that is predominantly responsible for keeping the total costs of compensation relatively low, and to some extent Hodges supports our inference. He claims that “The low level of the [costs of sums paid] is due particularly to the fact that compensation is paid to injured persons from various sources, with no recourse being taken between the different sources.” p143.<sup>62</sup>

In essence, when it comes to compensating claimants for pain and suffering and disability, the Pharmaceutical Injuries Insurance scheme is viewed primarily as a top-up to the other health and social services that are available in Finland. According to Hodges, “In broad summary, the pharmaceutical schemes make top-up payments for, firstly, pain and suffering and loss of amenity [permanent disability], and, secondly, any shortfall in the provision from other sources of loss of income. Overall, the principle of providing full compensation is observed, but the pharmaceutical schemes merely top-up other extensive sources of compensation, in order to provide what is overall comprehensive cover. The position can be illustrated by recent figures from Finland, which show the percentages of compensation that are paid for pain and suffering, and for permanent handicap.” p162.<sup>62</sup>

Hodges<sup>57</sup> provides data for Finland covering the years of 2003 and 2004 which confirm that approximately 50% of the money paid out in claims compensated for pain and suffering and permanent disability. For example, in 2004, 27% of the total amount of compensation paid was for that of permanent disability and 24% of the total amount of compensation paid was for pain and suffering. p163.<sup>62</sup> Other than a very tiny percentage paid for cosmetic injuries such as scars (2%), the remainder of the compensation paid out was a top-up for the shortfall in loss of income.

The total cost paid out in awards annually reduced from €1,042,000 in 2002 to €891,000 in 2004 p163,<sup>62</sup>.

#### **Key points**

- ***The liberal application of the ‘preponderant probability’ standard of proof and the fact that all injuries receive compensation increases the proportion of successful awards compensated in Finland up to 2011.***
- ***The tax-funded health service pays all healthcare costs and the social insurance funds pay most of the income costs in Finland, which keeps the costs of compensation for the Pharmaceutical Injuries Insurance scheme relatively low.***
- ***The Pharmaceutical Injuries Insurance scheme in Finland makes payments for pain and suffering, permanent disability, and any shortfall in the provision of full income.***

### 3.3.3.6 Question 5: Do no-fault vaccine damage schemes enjoy public acceptance?

We found no mention of public support or approval for vaccine injury compensation in Finland in either of the two papers we reviewed. In addition, we found no explicit attempt to assess public support or approval for the drug injury compensation scheme in general. However, both authors in the papers we reviewed made inferences regarding proxy factors that may be associated with public approval and support for the drug injury compensation scheme.

For example, Urho<sup>64</sup> inferred from the low numbers of appeals to decisions taken in the drug injury scheme that most of the injured claimants to the scheme were satisfied with the decisions regarding their compensation. According to Urho, from an analysis of 130 claims in Finland, “Most of the injured persons were satisfied with the decisions on their compensations judging by the fact that less than 15% of the cases were referred to the Pharmaceutical Injuries Board for review.” p479.<sup>64</sup>

In addition, Hodges<sup>62</sup> used the logic that compensation payments under the scheme are theoretically fair and offer roughly the same level of compensation as the legal system, which he infers as making the scheme attractive to claimants. According to Hodges, “The equation of levels of payments paid under the schemes with those for damages under the tort system satisfies theoretical principles of fairness, and also makes the schemes attractive to claimants, by offering the advantages of the same levels of compensation without the direct transaction costs of the legal system (i.e., having to pay lawyers’ fees).” p63.<sup>62</sup>

#### **Key point**

- ***There was no explicit information in the two papers to assess public support or approval for the drug injury compensation scheme in Finland but there are some indications of public satisfaction with the scheme.***

### 3.3.3.7 Question 6: What cost-control mechanisms covering no-fault vaccine damage schemes are reported in the literature?

The absence of legal costs are regarded as the main cost-control mechanism.

The drug injury insurance scheme in Finland sets a cap on the liability for each injured claimant that successfully proves their case, as well as a cap on the total amount of money for all injuries that the scheme will pay out in the course of one year. Urho outlines the most recent value on both of these caps in the following extract: “According to the terms valid since 1 January 2017: ‘Liability for each injured person is limited to 4 million euro, including the value of annuities capitalised, at the date they are set, in accordance with sound insurance principles, and 30 million euro for all injuries that are reported during one and the same year. Should the amount of compensation in this Clause not be sufficient to satisfy all those entitled to compensation, all compensation paid shall be reduced in an equal proportion.’” p485.<sup>64</sup> These amounts are reiterated in Macleod and Hodges (2017).<sup>63</sup>

Under the exceptional circumstances of the influenza outbreak in 2009, a novel feature was introduced which sees the State covering the funding of the amount of compensation that has exceeded the total cap for all injuries in one year. According to Urho, “According to the estimates, considering that the year 2009 was exceptional, the maximum amount set would not be enough to fully cover the compensations. Therefore, the government submitted a proposal to parliament of partially financing the drug injury insurance from public funds when the compensation level exceeded the 30 million euro limit. The new law came into force on 2 April 2013. The government’s share of covering the compensations is estimated to begin at the turn of 2030, possibly even earlier, and will continue through the lifetime of the injured persons.” p485.<sup>64</sup>

There are also limitations in place for the time it takes for claimants to file a claim. According to Hodges, “Finland followed Sweden in adopting a three-year limitation period [from the date of identification of the injury] with initially a fifteen-year cut-off [from the date when the injured person ceased to use the drug]. However, the cut-off period was subsequently reduced to ten years since it was found that all claims were made well within the shorter period.” p156.<sup>62</sup>

**Key points**

- *There are maximum values on individual awards and the total award expenditure available for injured persons in a single year in Finland; if the total expenditure exceeds the maximum limit, then all awards for that year are reduced by the same percentage so as not to exceed the maximum. More recently, the Government introduced a law to cover excess liability in certain cases.*
- *There are time limitations on claims in Finland: claims must be filed within three years and are barred after 10 years from the date that the medicine was dispensed.*
- *The social services cover a significant portion of lost earnings and the health service covers medical costs as required in Finland.*
- *In Finland, the scheme pays a top-up on lost earnings on an annual basis, so payments are deferred and only paid for as long as the person needs them.*
- *There are no legal expenses in Finland as it is a no-fault scheme.*
- *No cost is paid twice in Finland.*



### 3.3.3.8 Summary

In Finland, it is estimated that the overhead costs involved in operating the Pharmaceutical Injuries Insurance Scheme are relatively low at 11% in 2015. From the point of view of whether claimants to the scheme enjoy timely access to compensation, it is inferred but not proven from the data we analysed that they may do so. We infer that it is the work undertaken in the claims handling and adjudication process that has largely contributed to the finding that claims are handled in an expeditious and flexible manner, which has earned the approval of the three stakeholders to the scheme (the Government, the people, and the pharmaceutical industry). In addition, it is inferred that only 15% of claimants resort to the appeal system for redress, and that this serves as a further signal that people are generally happy that their claims are handled in a timely fashion.

From the limited data we analysed on the number of claimants to the scheme, it would appear that there was a moderate increase in the number of people claiming for compensation up to 2011 and a decrease in 2012. Regarding claims for vaccine injury compensation, the data tell us that following the mass immunisation campaign for the swine flu vaccine, a total of 316 claims were lodged with the scheme for narcolepsy.

Perhaps the most interesting finding of our analysis was the relatively high percentage of awards that were approved for compensation in Finland up to 2011 in contrast with its Nordic neighbours. The data suggest that over many years there has been a 50% approval rate for Finland, which is considerably higher than the 30% approval rate in Sweden and Denmark. The approval rate dropped to 30% in 2012 and 40% in 2013. The 77% approval rate for narcolepsy as a result of the swine flu vaccine indicates that probable vaccine injuries are dealt with generously. From our analysis of the data, we infer that it may be the liberal application of the standard of proof, in contrast to a more strict application of the same standard of proof in Sweden and Denmark, which has primarily contributed to a higher percentage of awards approved in Finland. In addition, there are some data to suggest that the monetary costs paid out for awards are kept at a modest level and, in some cases, have been seen to reduce. We infer that it is the wider context of available social insurance resources that may be primarily responsible for keeping these costs at a modest level. Indeed, in most cases, the drug injury compensation scheme is referred to as merely a top-up resource to the generous financial supports (income replacement and coverage of healthcare costs) available from wider social resources which can be availed of by people claiming injuries from drugs.

It is inferred in the literature that the low levels of appeals of decisions taken internally in the scheme and the fact that the level of compensation paid out is comparable to what one may expect from the legal system are proxy indicators of public support and approval for the scheme.

Finally, in exceptional circumstances, when the financial caps that are set within the scheme to control financial expenditure are exceeded, the State steps in and subsidises the payment of the amount that has exceeded the caps.

There are a number of cost-control mechanisms in Finland's medical injury scheme: no legal fees; maximum values on individual awards and a maximum value on the total award expenditure available for injured persons in a single year; Government subsidies in years where there are an excess number of claims; time limitations on claims; and social services covering a significant portion of lost earnings while the health service covers medical costs as required. The medical injuries scheme pays a top-up on lost earnings on an annual basis, so salary payments are deferred and top-up salary is only paid for as long as the person needs it. One other feature of the scheme is that no cost is paid twice.

### 3.3.4 Norway

#### 3.3.4.1 Introduction

We did not extract any data from the three papers we reviewed on vaccine injury compensation in Norway. However, we did extract data on the wider drug compensation scheme under which compensation for vaccine injuries is covered. According to Hodges, “Drug-related injuries caused by pharmaceuticals and vaccines made available in the particular state are indemnified regardless of whether the producer, importer, or any doctor has been negligent.” p151.<sup>62</sup>

An important feature of the scheme in Norway is that it is mandatory. According to Macleod and Hodges<sup>63</sup> and Urho, “all producers [and importers] of pharmaceuticals are under an obligation to be members of the pharmaceutical association.” p473.<sup>64</sup>

This means that pharmaceutical companies are obliged under legislation to pay levies into the scheme in order to cover compensation for injuries related to vaccines that they produce. According to Hodges, “The medicines scheme in Norway is financed by contributions from industry, in the form of a percentage levy set annually based on pharmaceutical companies’ turnover of sales in the country. Thus the approach is based on the general but unempirical theory that the manufacturers who have larger market shares may be more likely to have products that give rise to the greater percentage of injuries.” p159.<sup>62</sup>

The Pharmaceutical Association appeared to have taken its obligations quite seriously, and it has taken a number of steps to solidify its operations and ensure that it gets the maximum benefit from the levies it pays into the insurance scheme. According to Urho, “in late autumn 2003, the association founded their own new captive insurance company which started its work on 1 January 2004. The association extracts its funds from its members and hands them over to the insurance company who then compensates for the patients’ injuries according to the law.” p474.<sup>64</sup>

In essence, the drug injury compensation scheme appears to satisfy its original intent, which was to compensate persons for drug injuries on a no-fault basis where liability has been ruled out. According to Hodges, “In Norway, it has been estimated that over 95% of all persons who suffer injuries that fall within legal rights to compensation have their loss compensated irrespective of whether the person who caused the injury is legally liable.” p162.<sup>62</sup>

The standard of proof that operates in Norway under the drug injury scheme is similar to that which operates in other Nordic countries, in which the principle of preponderant probability applies to the assessment of claims for compensation. We did not identify any data which allow us to draw inferences on how this standard of proof may affect the number of awards that are approved for compensation in Norway. The data that we did identify merely describe how the standard of proof is conceptualised within the Norwegian scheme. According to Hodges, “In Norway, the standard of proof for medicines claims is the same as that under procedural law for civil claims, namely over 50%. The Norwegian Product Liability Law does not specify a specific standard of proof for medicines claims. The standard that is applied in practice is where it is more likely than not that the injury was caused by a drug, and if this were analysed in percentage terms this would equate to 51% probability. The same standard of more probable than not is also the standard that is applied at law for general liability.” p151.<sup>62</sup>

#### **3.3.4.2 Question 1: What design features and/or contextual conditions are thought to impact on the operating costs associated with no-fault vaccine damage schemes?**

We did not extract any data from the three papers we reviewed on the overhead costs of administering vaccine injury compensation in Norway. However, we did extract data on the average overhead costs of administering the wider drug injury compensation scheme, under which vaccine-related injury compensation is covered. The average cost of overhead in Norway is €150,000 per year p172.<sup>62</sup>

In the paper by Hodges, it is inferred that overhead costs are relatively low in Norway. He claims that “The scheme in Norway is administrative/inquisitorial and cheap to operate, both in terms of administration costs and cost of sums paid.” p143.<sup>62</sup> Macleod and Hodges report in a recent book chapter that the cost of running the scheme in 2014 was €200,000 or 11% of the total award costs paid in 2014.<sup>63</sup>

##### **Key point**

- *In 2014, overhead costs were relatively low in Norway, but whether or not design features affect these costs is unclear.*

#### **3.3.4.3 Question 2: What design features and/or contextual conditions are thought to impact on timely access to no-fault vaccine damage schemes?**

From the three papers we reviewed, we extracted only a very small amount of data regarding whether claimants had their claims for compensation resolved in a timely manner. The data we extracted come from the study by Urho,<sup>64</sup> which included the collection of primary data from stakeholders in Norway. Urho claims that there is general approval of the way claims are handled and of the time within which decisions are taken. According to Urho, “The claims handling body has handled claims professionally and in a way that is approved of by the society and by most of the patients. An average time for handling a claim is just over two years.” p475.<sup>64</sup>

##### **Key point**

- *The activities undertaken in the claims handling and adjudication process of the scheme in Norway are not described, but we infer that they may enable claims to be resolved professionally and the claimants appear satisfied that claims are dealt with within circa two years.*

#### **3.3.4.4 Question 3: What design features and/or contextual conditions are thought to impact on the number of applicants seeking redress via no-fault vaccine damage schemes?**

We did not extract any data from the papers we reviewed to tell us about the number of applicants for compensation for vaccine injuries in Norway.

The only data we did identify, in the book chapter by Macleod and Hughes<sup>63</sup> indicated that there were 513 drug injury claims between 2007 and 2014 and the number of claims was 66 in 2014, combine the number of claims for drug injuries with those of medical treatment injuries,

##### **Key point**

- *We did not extract any data from the papers we reviewed about design features that may influence the number of applicants for compensation for drug injuries in Norway but since 2008 there are less than 100 claims each year.*

#### **3.3.4.5 Question 4: What design features and/or contextual conditions are thought to impact on the volume and costs of awards made under no-fault vaccine damage schemes?**

We did not extract any data on the number of awards approved and the costs of awards that may have been paid out to vaccine injury claimants. However, we did extract some data on the number of awards approved for claimants under the wider drug injury scheme. According to Hodges,<sup>62</sup> “In Norway the success rate is also around 40% [up to 2004], with an annual average of around 20 successful individual claims.” p167. The data indicate that there were approximately 60 drug injury claims in 2004. Between 2007 and 2014, there were 182 (36%) successful drug injury claims out of 513 applicants.<sup>63</sup>

##### **Key point**

- ***There are no data on the design features that may affect the volume of costs and awards for Norway, except that the scheme is a no-fault scheme and there are no legal costs. The success rate was 36% between 2007 and 2014.***

#### **3.3.4.6 Question 5: Do no-fault vaccine damage schemes enjoy public acceptance?**

From the two papers that we reviewed, we did not see any mention of public approval or support for VICPs. However, in the paper by Urho, which included primary data collected by stakeholders in Norway, it would appear that there is public acceptance for the wider drug injury scheme, and in general the scheme is thought to be a success. According to Urho, “The interviewees reported that in many respects, the Norwegian solution has proven to be successful. Initially, there were two specific expectations: first, to provide adequate protection for patients concerning the use of pharmaceuticals within the product liability agenda, and secondly, to provide a viable system for resolving claims. From the point of view of the society and the individual claimants, both expectations have been met in full over the 20 years the system has been in operation. The compensation scheme in Norway has handled claims professionally and in a way that is approved of by the society and by most of the patients.” p474-475.<sup>64</sup>

##### **Key point**

- ***The Norwegian drug injury scheme handled claims professionally and in a way that is approved of by the society and by most of the patients.***

### 3.3.4.7 Question 6: What cost-control mechanisms covering no-fault vaccine damage schemes are reported in the literature?

The absence of legal costs are regarded as the main cost-control mechanism.

From the paper by Hodges that we reviewed, there are some data available on the types of financial caps applied to the drug injury scheme in Norway. For example, the upper limit cap is €10.03 million for all injuries ascertained (a claim is ascertained when the injured party either dies of the injury without having consulted a doctor, or consulted a doctor because of the injury for the first time, or filed a claim because of the injury with the drug compensation scheme during a year and €12.54 million for all injuries caused by the same substance in one or more drugs. p153.<sup>62</sup>)

Regarding the time limits imposed on claimants within which they must submit a claim, according to Hodges, “[Norway adopted] the rule that claims must be filed within three years from the date the patient has or should have had knowledge of the injury, and that claims are barred [20 years] from the date that the medicine was dispensed to the patient.” p156.<sup>62</sup>

#### **Key points**

- ***There are maximum values on the total award expenditure available for persons injured by drugs in a single year and a maximum limit on the total award expenditure for an individual substance in Norway.***
- ***There are time limitations on claims in Norway: claims must be filed within three years and are barred after 20 years from the date that the medicine was dispensed.***
- ***There are no legal expenses in Norway, as it is a no-fault scheme.***

### 3.3.4.8 Summary

Overall, there is insufficient data on the drug injury scheme in Norway for us to draw any inferences regarding what features of the scheme or contextual conditions may affect the number of claims or the number of awards given out. There are no legal fees, so this reduces the total cost of the awards. From the data that we did analyse, it would appear that overhead costs are relatively low, and that there is patient approval for the way that claims are handled and perhaps for the decisions taken to resolve claims. Up until 2006, there was an award approval rate of 40%, based on an average of 20 claims per year, which appears to reflect a relatively small number of claims (approximately 50) submitted annually to the drug injury compensation scheme. From the primary data collected from stakeholders in Norway, it would appear that, for some patients who have been involved with the scheme, the overall functioning of the scheme is viewed as satisfactory.

In his review, it would appear that Hodges<sup>62</sup> faced similar difficulties in understanding why the number and percentage of claims in Norway appears to be quite low, particularly when compared with its Nordic neighbours. According to Hodges, “The number and percentage of claims in Norway is, and has been in recent years, particularly low in comparison with the levels of the other states. It is implausible that medicines are safer in Norway than elsewhere, given the global use of most products, or that Norwegians are more healthy – or resistant to medicinal adverse reactions – than all of their neighbours. This may simply reflect the relative newness of the scheme, but may illustrate that there are cultural differences in attitudes towards claiming.” p167.<sup>62</sup>

There are three cost-control mechanisms in Norway’s drug injury scheme: no legal fees, maximum values on the total award expenditure available for injured persons in a single year, and time limitations on claims.

### 3.3.5 Sweden

#### 3.3.5.1 Introduction

Compensation for vaccine injuries in Sweden is administered through the wider pharmaceutical injuries insurance scheme. A notable feature of the wider compensation scheme is that participation in the scheme by pharmaceutical companies trading in Sweden is voluntary. However, it appears that the majority of pharmaceutical companies operating in Sweden choose to participate in the scheme and make their financial contributions as required. According to Hodges, “The voluntary scheme [in Sweden] would obviously collapse if a significant proportion of companies operating in the country did not contribute. Virtually all the relevant pharmaceutical companies in Sweden do contribute to their schemes. However, injuries caused by drugs distributed in Sweden by a manufacturer or importer who is not a member of the scheme are not covered by the insurance.” p159<sup>62</sup>

Pharmaceutical companies that volunteer to join the scheme and make their financial contributions are organised under the umbrella term of the Swedish Pharmaceutical Insurance Association (LFF). During the past 10 years, this body has been responsible for a number of reforms to the scheme, which Urho<sup>64</sup> outlines in some detail; according to Urho, “In 2007, the Swedish pharmaceutical industry adopted a new system characterized as a captive system... The idea is to keep the risks of the parent company in one place and to extract the best insurance terms available based on the parent company’ risk profile...The main incentive for the reform was the increased insurance costs. The most common argument in favour of such a system is the savings gained...the insurance premium is based on each company’s sales but varies depending on size and whether the company or institute conducts clinical trials or not...The next move was to establish the Swedish Pharmaceutical Insurance Service (SLF) of which the Swedish Pharmaceutical Insurance Association has 100% ownership. At the beginning of 2011, the claims handling arrangements were transferred from the Zurich Insurance Company to the Swedish Pharmaceutical Insurance Service in Stockholm. The adoption of the captive system is, so far, the biggest change and considered a major reform in the pharmaceutical injury insurance system in Sweden.” p472.<sup>64</sup> This information is reiterated by Macleod and Hughes in their book.<sup>63</sup>

The drug injury compensation scheme acts as a top-up rather than as the primary source of compensation. Hodges<sup>62</sup> provides detail on the various sources which can provide additional support for persons who suffer medication-related injuries in Sweden. According to Hodges, “A person injured in Sweden would be able to obtain compensation from the following different sources. State healthcare insurance for accidents covers medical costs and loss of income. If the injury were caused by a drug, the Pharmaceutical Insurance Association might make some extra payments for medical expenses that were not covered under the medical insurance, such as for providing a wheelchair or adapting a home for specific disability arrangements. In relation to loss of income, an employee who suffers injury would first claim social security payments from the government. The amount that the government would pay is amended from year to year, and is currently 80% of a prescribed notional salary. Individual employees or employers may make voluntary arrangements to hold extra first party insurance. If there were long-term disability, the loss of income payments would gradually be turned into an early retirement pension. However, where the injury was caused by a drug, the remaining 20% would be filled up by payments from the Pharmaceutical Insurance Association.” p161<sup>62</sup>

### 3.3.5.2 Question 1: What design features and/or contextual conditions are thought to impact on the operating costs associated with no-fault vaccine damage schemes?

From the three papers we reviewed that covered drug injury compensation in Sweden, we did not extract any data that explicitly reported on overhead costs for administering vaccine injury compensation. However, we did extract some data on the administration costs of running the wider pharmaceutical injury compensation scheme, which includes compensating claimants for vaccine injuries.

It would appear that the overhead costs of running the drug injury compensation scheme in Sweden is considered to be low. According to Hodges, “The administration costs of the scheme [in Sweden] are clearly low. The annual administration cost in 2004 was €1.5 million.” p160<sup>62</sup>

This assessment that overhead costs are low in Sweden is given in comparison with legal costs if a claimant pursued an action through the courts. According to Hodges, “The cost of administration of the scheme is low, particularly in relation to the cost that would apply if court proceedings were pursued instead.” p168<sup>62</sup>

However, these overhead costs are much higher than those reported for Denmark, Finland, and Norway for the same period.

The main reason suggested for low overhead costs is the removal of negligence or fault from the scheme, which we infer is a change to the standard of proof that is required for a claimant to successfully prove their case. In moving away from the need to prove negligence, the claimant does not need to prove that the medical professional who prescribed or administered the drug is at fault or that the drug was defective. A claimant merely needs to demonstrate a causal relationship between the drug and the injury. This reduces the overhead costs, as it eliminates the need to investigate negligence. According to Hodges, “In analysing the Swedish medical system and its no fault scheme, the key feature in reducing overhead costs in the medical system is the elimination of provider liability, so that damages paid out are not recharged to individual producers/suppliers, but paid from the aggregated pool. This avoids the costs of investigation into individual fault or other liability, allocation of specific sums to particular individuals, resolution of resulting arguments on fault, and adopts a causation-only test of compensability.” p165.<sup>62</sup> We suspect that this also applies to Denmark, Finland, and possibly Norway, but it was not expressed as such in the papers available.

#### **Key point**

- ***The absence of negligence (fault) from the scheme in Sweden allows a standard of proof based on probable causation only and therefore legal representation is not required, which keeps overhead costs low.***

### 3.3.5.3 Question 2: What design features and/or contextual conditions are thought to impact on timely access to no-fault vaccine damage schemes?

We did not extract any explicit data from the three papers we reviewed to show evidence that compensation claims are resolved in a timely manner or, alternatively, are delayed. However, according to the LFF website, which provides information to the public on the drug injury compensation scheme, the process takes on average about four months from the date on which a claim is submitted to the date on which the claimant receives a decision regarding entitlement to compensation. However, it is noted that cases can vary depending on the degree of complexity. In addition, the time required to assess the amount of the compensation may vary depending on whether the injury can be paid for within the resources of the scheme or whether a decision has to be delayed until matters such as possible invalidity settlement or sickness benefits are addressed, as this is the responsibility of the social insurance programme.<sup>65</sup>

Hodges<sup>62</sup> suggests that the general intent behind the scheme is to improve access to compensation for claimants and that, for the most part, this objective is being met as almost zero claims for drug injury compensation are being pursued through the courts. According to Hodges, “The existence of the scheme [in Sweden] has led to the almost complete absence of any court claims for product liability. Thus, the scheme has satisfied the policy objective of improving the chances of injured

persons obtaining compensation than might obtain under the law of torts and the legal process.” p164.<sup>62</sup> In a more recent book, Macleod and Hughes state that “a very small number of such claims have been brought to court, but as of 2015 all such claims have subsequently been dropped before completion of the court process.” P188<sup>63</sup>

In addition, it is also claimed that the decision to select a lower standard of proof for the scheme based on the notion of preponderant probability was a decision taken mainly to make the scheme attractive to potential claimants so that they would avoid taking claims through the courts. According to Hodges, “The standard of proof stated in the Swedish scheme translates as a ‘preponderant probability’ that the injury was caused by a drug. The standard of proof is that it is more likely than not that the injury was associated with the medication. This ‘preponderant probability’ standard is deliberately lower than the standard of proof that may generally apply to a legal product liability or tort compensation claim. The historical reason for this is that when the drug scheme was first introduced, the Swedish pharmaceutical industry wanted to make the scheme attractive to patients, given that it was voluntary on both sides, so as to avoid patients bringing claims through the courts, so a number of advantageous features were included in the scheme, of which the standard of proof was one.” p150<sup>62</sup>

Furthermore, it would also appear to be the case that the application of the preponderant probability standard is undertaken with a degree of flexibility. According to Hodges, “Under the Swedish medicines scheme, any disease or injury with a ‘preponderant probability’ that it is related to the pharmaceutical is compensable. Those who operate the scheme resist describing the phrase ‘preponderant probability’ in terms of statistics, since this is artificial and does not reflect realities, but it is interpreted to mean ‘slightly more than 50%’.” p150<sup>62</sup>

So, while we cannot say that the decision to adopt a lower standard of proof in the scheme in Sweden has led to timely access to compensation or has delayed access, what we can infer is that the adoption of this lower standard of proof could be making the scheme attractive to potential claimants who may otherwise choose to embark on a long litigious journey through the courts. So indirectly, by choosing a lower standard of proof, the scheme in Sweden may be improving the chances of timely access to compensation.

**Key point**

- *It appears that the Swedish scheme responds quickly (on average within about four months) to claims, but we do not have any details on the process; the factors attributed to timely access are the removal of fault and the use of a standard of proof based on preponderant probability.*

**3.3.5.4 Question 3: What design features and/or contextual conditions are thought to impact on the number of applicants seeking redress via no-fault vaccine damage schemes?**

Regarding claims for vaccine injury compensation, there are data to suggest that there were 550 claims made regarding suspected narcolepsy cases between 2009 and 2018.<sup>64</sup> Regarding claims for drug injuries in general, the average number of claims per year in Sweden is 626 (we are inferring that this average has been calculated from data from 1994–2015, a 22-year period). p89<sup>63</sup>

**Key point**

- *There is no information on design features that may affect the number of applicants to the scheme in Sweden but we do now that there are an average of 625 applicants each years.*



### 3.3.5.5 Question 4: What design features and/or contextual conditions are thought to impact on the volume and costs of awards made under no-fault vaccine damage schemes?

From the data we extracted from the Urho paper,<sup>64</sup> approximately 75% of adjudicated claims for compensation regarding suspected narcolepsy were approved between 2009 and 2018. Narcolepsy is a recognised adverse event related to the H1N1 vaccine which was administered between 2009 and 2010 to minimise the threat of swine flu to public health. According to Urho, “In Sweden, by March 2018 [from when the H1N1 vaccine was introduced in 2009], there were 550 reported claims [regarding suspected narcolepsy cases], of which 403 were accepted and 138 were declined; the rest are under assessment.” p485<sup>64</sup> The approval rate was 73%.

In contrast to the relatively high award approval rate that pertained for H1N1 vaccine injury compensation, it would appear that in Sweden approximately one-third of all claims for general drug injuries are successful, and this rate appears to have remained constant over a long time period. According to Hodges, “In the 26.5 years up to 31 December 2004 in which the Swedish scheme has operated, 10,171 injuries had been reported. Of the total number of claims reported 6,187 were rejected, and 3,462 were compensated [the remainder were pending examination]. Thus, an average of 384 claims per year were reported, of which 35.9% were compensated. The total compensation paid from 1978 to 2004 was SEK560.2 million, i.e., an average of SEK161,814 per injured person (€17,979). The numbers of claims per year, and the percentage compensated, are reported to have been similar for many years, apart from a rise after a television programme and other media interest in 2001 relating to Hepatitis C infection (although for some reason the number of claims paid remained at the normal level of one-third). Around one-third of all claims are successful in Sweden.” p166-167<sup>62</sup> This exact text is reiterated in the book by Macleod and Hughes.<sup>63</sup>

As noted by Hodges in his review of the Swedish scheme, an interesting observation is the capacity within the scheme to manage to keep the proportion of approved awards to one-third of claims, and to consistently keep to this level stretching over a large number of years. How does the scheme manage this? And are there any particular features of the scheme that may help to explain this observation?

This observation gains added interest when the total compensation paid per year is €11.8 million, excluding administration costs [p172<sup>62</sup>], and the overall financial cap on the total amount that could be paid out per year is €21.74 million for all injuries reported during a single year p153,<sup>62</sup>]. These data suggest that the scheme in Sweden carries a surplus of cash for most years, which could potentially be paid out if additional awards merited approval.

One candidate explanation for why the scheme is able to keep the proportion of approved awards of compensation to approximately one-third of claims is that in Sweden, the scheme adjudicators apply a strict interpretation of the preponderant probability standard of proof. What we mean by this is that from our analysis of the data on the application of the same standard of proof in the four Nordic countries, it would appear that in Finland, Denmark, and perhaps also Norway, compensation is approved when sufficient evidence is advanced to show a probable causal relation between an injury and a particular drug. In contrast, in Sweden it would appear that it is not merely the observation of the probable causal relation that is sufficient to approve compensation; it is also the degree of the severity of the injury that is taken into consideration. We therefore infer from this analysis that both preponderant probability and physical injury are required in Sweden, which may primarily contribute to reducing the number of awards compensated in contrast to, for example, Finland. According to Hodges, “99% of medicines claims in Sweden relate to types of injuries that are already warned about in the written information supplied with products (and approved in advance by regulatory authorities) but which have occurred in the individual claimant with disproportionate severity in comparison with what was expected by previously prevailing expert medical or public expectations.” p164<sup>62</sup> Denmark requires that claimants have an unexpected and enduring physical injury as well.

#### **Key points**

- **Both preponderant probability and enduring physical injury are required for a successful claim in Sweden, which reduces the proportion of successful claims.**

### 3.3.5.6 Question 5: Do no-fault vaccine damage schemes enjoy public acceptance?

We did not find any mention of public support or approval for how vaccine injury compensation is administered in Sweden. However, we did extract some data from both of the papers we reviewed to suggest that the wider drug injury compensation scheme is viewed in positive terms in Sweden. For example, according to Urho, who collected primary data from stakeholders in Sweden, "Overall the interviewees estimate that the compensation system has worked according to expectations. The insurance system covers around 99% of all pharmaceutical sales in Sweden." p472.<sup>64</sup>

In addition, it is claimed that the levels of compensation paid out under the drug injury compensation scheme are on principal perceived as fair, and this helps to make the scheme attractive to claimants. According to Hodges, "The equation of levels of payments paid under the scheme [in Sweden] with those for damages under the tort system satisfies theoretical principles of fairness, and also makes the scheme attractive to claimants, by offering the advantages of the same levels of compensation without the direct transaction costs of the legal system." p163.<sup>62</sup>

Furthermore, it is claimed by Hodges that the methods of compensation payment in Sweden are preferable to the claimants: "The Swedes prefer their system [that payments are made on an annual basis], since it equates to the other social security payments that are made to injured individuals, and affords the flexibility that changes in payees' circumstances can be taken into account. They expect that individuals' circumstances will tend to improve rather than the converse, and this will benefit the fund." p160.<sup>62</sup>

Finally, it is implied that in general, public awareness of the scheme in Sweden may be quite low, but that those who are aware of it are grateful that it exists. According to Hodges, "The scheme would be unlikely to fund a major catastrophe, but its existence would provide a mechanism that could be built on to deal with an appropriate response. It is probably true that not many people would know of the existence of the scheme as such, but there is general confidence that something exists to take care of people." p155.<sup>62</sup>

#### **Key point**

- ***Weak evidence indicates that the drug injury compensation scheme is viewed as fair in Sweden.***

### 3.3.5.7 Question 6: What cost-control mechanisms covering no-fault vaccine damage schemes are reported in the literature?

A number of boundaries are set on the scope of the scheme in Sweden, including a financial threshold for claims, caps on total liability, and limitation periods for bringing claims. In addition, payments are spread across institutions and deferred across years. There are no legal expenses, as this is a no-fault scheme.

For example, a cap on the amount of compensation payable to each person approved for an award during a specific year was set at €1.09 million, and a cap for all injuries awarded compensation during a specific year was set at €21.74 million. p153.<sup>62]</sup>

However, in the event that the total amount claimed for all injuries within a specific year exceeds the total allocated under the cap, the Government in Sweden will subsidise the amount that exceeds the threshold outlined. According to Urho, “Just like in Finland, the Government in Sweden intervened to subsidise the amount of compensation that would be paid over and above the caps...in Sweden, the corresponding law came into force on 1 July 2016. According to its provisions the government will guarantee compensations exceeding the set level for the total amount.” p485.<sup>64</sup>

There is also a set time limit within which claims for compensation must be made. According to Hodges,<sup>62</sup> “The Pharmaceutical Scheme adopts a three-year primary limitation period, and adopts a fifteen-year cut-off from the date when the injured person ceased to use the drug. A fifteen-year period was selected deliberately over a ten-year period, in order to make the medicines scheme more attractive and encourage people to use it.” p156

#### **Key points**

- ***There are maximum values on individual awards and on the total award expenditure available for injured persons in a single year in Sweden.***
- ***There are time limitations on claims in Sweden: claims must be filed within three years and are barred after 15 years from the date that the medicine was dispensed.***
- ***The social services cover a significant portion of lost earnings and the health services cover medical costs as required in Sweden.***
- ***In Sweden, the scheme pays a top-up on lost earnings on an annual basis, so payments are deferred and are only paid for as long as the person needs them.***
- ***There are no legal expenses in Sweden, as it is a no-fault scheme.***

### 3.3.5.8 Summary

In Sweden, the removal of negligence (fault) from the scheme allows a standard of proof based on probable causation only and therefore legal representation is not required, which keeps overhead costs low.

It appears that the scheme responds quickly (on average within about four months) to claims, but we do not have any details on the process; the factors attributed to timely access are the removal of fault and the use of a standard of proof based on preponderant probability.

There is no information on design features that may affect the number of applicants to the scheme.

Both preponderant probability and enduring physical injury are required for a successful claim, which reduces the proportion of successful claims (approximately 35%).

Weak evidence indicates that the Swedish public views the drug injury compensation scheme as fair.

It is suggested that, on average, it takes about four months from the date on which a claim is submitted to the date on which the claimant receives a decision regarding entitlement to compensation. The general intent behind setting up the scheme was to provide an alternative means of compensation for claimants instead of them pursuing claims through the cumbersome legal system. In addition, stakeholders of the scheme adopted a lower standard of proof in the form of the preponderant probability standard, a decision that was taken in order to make the scheme more attractive than the courts to potential claimants. So, we infer that choosing a lower standard of proof to persuade claimants to avoid the legal system and choose the scheme may have indirectly improved timely access to compensation for successful claimants.

Overall, the data suggest that the scheme consistently pays out compensation for approximately 35% of claimants. In Sweden, both preponderant probability and enduring physical injury are required for a successful claim.

From the data we analysed, it would appear that most stakeholders involved with the drug injury compensation system feel that the scheme has worked quite well and that it is fulfilling its objectives. For example, it is thought that the levels of compensation are fair and, on balance, are equal to what a claimant may receive if they went through the tort system. In addition, it is claimed that the method of payment of compensation is preferred by members of the public, as it suits their needs.

Finally, it is suggested that there is a degree of public gratitude for the existence of the scheme, and although it is claimed that not everyone in Sweden may know of the scheme, for those who do, it would appear that it is a welcome intervention.

There are a number of cost-control mechanisms in the Swedish medical injuries scheme: no legal fees; maximum values on individual awards and a maximum value on the total award expenditure available for injured persons in a single year; time limitations on claims; and the fact that social services cover a significant portion of lost earnings while the health service covers medical costs as required. The medical injuries scheme pays a top-up on lost earnings on an annual basis, so salary payments are deferred and only paid for as long as the person needs them. Between 1977 and 2004, 35% of medical injury claims were successful; it would be expected that the vaccine injury success rate would be higher, as noted in the VICPs in Asia.

## 3.4 Asia

### 3.4.1 Introduction

We included eight papers that provided data on vaccine injury compensation in four countries in Asia. The papers are Fei and Peng (2017)<sup>6</sup> covering China; Wang, Yang, *et al.* (2013)<sup>36</sup> covering Japan; Kim, Lee, *et al.* (2017),<sup>41</sup> Choe and Bae (2013),<sup>42</sup> Kim, Jo, *et al.* (2008),<sup>66</sup> and Jo and Kim (2013)<sup>67</sup> covering Korea; and Wang (2015)<sup>35</sup> and Wang, Yang, *et al.* (2013)<sup>36</sup> covering Taiwan.

### 3.4.2 China

#### 3.4.2.1 Introduction

We included one paper that provided data on the VICP in China.<sup>6</sup> This paper draws on an analysis of a select body of literature, including legal papers and practice documents, relating to the scheme in China. The aim of this paper was to evaluate the extent to which the scheme has achieved its intended objectives and outline the potential for further development. Overall, we extracted data from the paper to help address five of our six questions. In addition, we extracted data which help to elaborate some of the descriptive features of the scheme in China. In 2005, China introduced an administrative no-fault compensation scheme for adverse events following immunisation. The vaccines that are covered by the scheme are split into Class I vaccines, which are provided by the Government for the general public, and Class II vaccines, which mainly cover those vaccines paid for by the general public themselves. For injury arising out of inoculation with a Class I vaccine, the expenses of compensation are paid by the Government, and for injuries from a Class II vaccine, the expenses for compensation are borne by the vaccine manufacturer. The Chinese compensation scheme was enacted by the central government but is run by local governments; it is at the level of local government that decisions are taken to negotiate with victims over eligibility and decide on whether to reject or award claims for compensation. The claims handling and adjudication process is structured in three stages: (1) the investigation and authentication stage, (2) the compensation application stage, and (3) the review stage. An expert panel, predominantly comprising members of the medical profession, is responsible for deciding on the clinical merits of claims, and the remainder of the claims handling and adjudication process is undertaken by local officials attached to local government at the provincial level. Although the Chinese scheme is claimed to be a no-fault scheme in principle, the standard of proof required is high, with the expert panel insisting that causation between a vaccine and an injury be demonstrated using high-quality scientific evidence from epidemiological studies.

#### 3.4.2.2 Question 1: What design features and/or contextual conditions are thought to impact on the operating costs associated with no-fault vaccine damage schemes?

Fei and Peng's<sup>6</sup> paper does not provide explicit data on the overhead costs of the scheme, either at a national or provincial level. However, from the limited data provided that speak to the funding of the VICP, it would appear that for Government-funded Class I vaccines, overhead costs for a claim are to be paid by the finance department of the local government in the province, town, or city. However, for self-paid Class II vaccines, it would appear that overhead costs are to be funded by the vaccine manufacturer. According to Fei and Peng, the two funding sources for the scheme are as follows:

For injury arising out of inoculation with a Class I vaccine, the expenses of compensation shall be arranged by the public finance department of the people's government of the province, autonomous region, or municipality directly under the central government...If the inoculated person needs to be compensated due to an unusual reaction to vaccination arising from inoculation with a Class II vaccine, the expenses for compensation shall be borne by the relevant vaccine production enterprise. p105.<sup>6</sup>

Furthermore, Fei and Peng point out that there are large disparities across a number of functions pertaining to compensating claimants for vaccine injuries. It may be likely that these disparities include differences in the overhead costs involved in the administration of the scheme across the different provinces. For example, Fei and Peng highlight some of the disparities, including funding,

that are thought to operate across the administration of the scheme in China. They state that “studies reveal that there are large disparities in funding, compensation scope, compensation calculation methods, and procedures among different provinces.” p105.<sup>6</sup>

### **3.4.2.3 Question 2: What design features and/or contextual conditions are thought to impact on timely access to no-fault vaccine damage schemes?**

From our analysis of the paper by Fei and Peng, we infer that the procedures that pertain to handling claims and making decisions regarding the merits of individual claims can delay timely access to compensation for claimants. In other words, it is the procedures undertaken within the feature of the scheme known as the claims handling and adjudication process that can delay timely access to compensation for claimants.

For example, Fei and Peng signal that there are certain features within the process of handling claims and making decisions that tend to slow down the operation of the scheme. According to Fei and Peng,<sup>6</sup> “First, it takes a long time for the local government to persuade and consult with the victim’s family to accept the compensation amount the local government can offer. Second, the administrative process is cumbersome.” p111-112.<sup>6</sup>

This cumbersome, structured process appears to be related to the decision taken by the central government to decentralise claims handling and decision-making around compensation down to district governments within each province. According to Fei and Peng, “unlike in the majority of jurisdictions where the central government funds most or all compensation costs, funding and decision-making under the Chinese compensation scheme is largely decentralized to the lowest levels, namely the districts of a city or township... the Chinese compensation scheme was enacted by the central government but is run by local governments. It is the lowest-level governments that play key roles in negotiating with the victims over eligibility and compensation decisions.” p112.<sup>6</sup>

When the decision was taken to decentralise decision-making within the scheme, it would appear that within the provinces further decisions were taken to give structure to the process of handling claims and making decisions around compensation. Fei and Peng outline the contours of this structure as follows: “The majority of provincial regulations stipulate that victims should go through three steps to receive compensation: (1) investigation and authentication process... (2) compensation application process... (3) review process.” p107.<sup>6</sup>

#### **3.4.2.3.1 Step 1: investigation and authentication process**

In Step 1, an expert panel is assembled to establish whether the claim qualifies for compensation. It would appear that for the most part, the members of this expert panel come from the medical profession. According to Fei and Peng, “For each dispute over the occurrence of serious vaccine injury accidents, an investigation and diagnosis authentication panel is convened, consisting of medical experts drawn from a database administered by the provincial-level medical association; this panel determines whether the [adverse events following immunisation] qualifies for compensation.” p104-5.<sup>6</sup>

If and when the expert panel decides that a claim does not qualify for compensation, the scheme in China has put in place a number of steps that the claimant can take to lodge an appeal. For example, according to Fei and Peng, “The panel’s decision can be appealed, normally once, by the claimant and will be reviewed by an appellant authentication panel whose members are normally selected by a higher city provincial-level medical association. The claimant can seek further litigation to authenticate the nature of the vaccine injury if he does not accept the final decision made by the appellant authentication panel.” p107.<sup>6</sup>

#### **3.4.2.3.2 Step 2: compensation application process**

In the event that the expert medical panel decides that a claim merits compensation, the decision-making process moves to the second stage. At this stage the claimant must formally apply for compensation and submit relevant documentation to support their claim. Fei and Peng describe what the claimant must do as follows: “After receiving a positive authentication report, the victim can submit an application for compensation to the local county-level health bureau. The application

documents normally include the authentication report, interlocution and diagnosis records, evidence of damage, and so forth.” p107.<sup>6</sup>

Following the submission of the formal application for compensation, the claimant then engages in what has been described as a negotiation process with a number of key actors from different bodies within the relevant province. It would appear that this level of negotiation, which seems in part to be about resolving conflicts, moves the scheme from what may be termed primarily administrative into a more contentious realm. Fei and Peng capture the contentious essence of the scheme in the following extract: “although the compensation program is, in theory, based on an administrative review procedure, practical cases show that the process is essentially one of consultation and conflict resolution rather than a unilateral administrative procedure. One party of the consultation is the victim while the other party varies. In the five Shenzhen cases, the consultation process involves the vaccination hospital, the district CDC [Chinese Center for Disease Control and Prevention], the district health board, the judicial bureau of the district government, and the governor of the district government. It is the district governor who makes the final decision, as he has final control over the relevant economic resources.” p110.<sup>6</sup>

As Fei and Peng<sup>6</sup> allude to above in the Shenzhen City, Guangdong, examples cited, it appears to be the relevant district governor who makes the ultimate decision on whether compensation can be granted. Although this is the case in Guangdong province in China, we cannot be sure that this is what pertains in other provinces, as in some cases the ultimate responsibility for decision-making regarding compensation has been attributed to the district-level health bureau. It is not clear if this body includes the relevant district governor.

#### **3.4.2.3.3 Step 3: review process**

In the event that compensation has been approved at this stage, it would appear to be the case that the claimant must continue to wait before they actually receive any monetary payout. This further illustrates the cumbersome nature of the scheme, as alluded to earlier. The following extract provided by Fei and Peng captures the additional steps taken in reviewing the decisions that have been taken before a final decision is arrived at: “if the county- [district-] level health bureau decides to provide compensation, it should submit its decision to be reviewed by the upper city-level and provincial-level health bureau. In at least one province e.g. in Guangdong, there is a double-review procedure which means that both the compensation decision and the final compensation consultation agreement should be reviewed by the upper government.” p107.<sup>6</sup>

The negotiation between the local government and the claimant is nested within the second stage of a three-stage structured process that underpins the entire operation of the scheme. We infer that it is this three-stage structured process which primarily contributes to what Fei and Peng called the cumbersome features of the scheme, and which we claim may contribute to a delay in timely access to compensation for claimants.

#### **Key point**

- ***The cumbersome three-stage claims handling and adjudication process in China appears to delay timely access to compensation for claimants.***

#### **3.4.2.4 Question 3: What design features and/or contextual conditions are thought to impact on the number of applicants seeking redress via no-fault vaccine damage schemes?**

We found no relevant data in the paper by Fei and Peng<sup>6</sup> regarding the number of applicants to the scheme.

#### **3.4.2.5 Question 4: What design features and/or contextual conditions are thought to impact on the volume and costs of awards made under no-fault vaccine damage schemes?**

From our analysis of the data included in the paper by Fei and Peng,<sup>6</sup> we infer that the high standard of proof and the cumbersome claims handling and adjudication process employed by the scheme in China affect the number of compensation awards approved and the amount of money paid out in compensation. In addition, there are some data to suggest that wider contextual factors (such as different socioeconomic profiles across the provinces) can also affect the amount of compensation paid out for the same injuries within different provinces.

The strict standard of proof employed under the scheme in China can reduce the number of awards made for compensation. Indeed, to paraphrase Fei and Peng,<sup>6</sup> establishing causation is the biggest hurdle for claimants to overcome when seeking compensation for vaccine-related injuries. To understand how the strict standard of proof has come to be used within the scheme in China, we need to contextualise this discussion within the three-phase structured process that underpins the handling of claims and the decisions of whether or not to compensate claimants for vaccine-related injuries.

In Step 1 of the three-phase structured process, it is the job of the medical expert panel to adjudicate whether or not a specific injury has been caused by a specific vaccine. In performing its work, the expert panel must use a measure or standard of proof to determine causation. In the case of China, it would appear that there is a division of thought between Government policy and medical experts regarding the most appropriate standard of proof to employ. On the one hand, the Ministry of Health of the People's Republic of China has recommended the use of a hybrid mix of what one might call 'softer options' for determining the standard of proof that a vaccine is responsible for a specific injury. This hybrid mix can include a general analysis of the clinical and medical information that pertains to the case. However, in practice, it would appear that the expert panel adopts a much stricter standard of proof that is closer to that used in science and epidemiology. According to Fei and Peng, "Causation is the most difficult hurdle for vaccine-injured victims to overcome when seeking compensation under Chinese law. Victims who become ill within days of being vaccinated may be told that their injury would probably have occurred anyway and that the temporal proximity of the two events is merely coincidental. The MOH generally specifies that expert panels evaluating adverse events following vaccination should perform their authentications and judgments using general analysis, by following the laws, regulations, ministerial rules and technical rules, using information from clinical manifestations, medical examination results, vaccine quality inspection results, and so forth. But in practice, the expert panel generally deploys the method of establishing causation used in science and epidemiology." p109.<sup>6</sup>

This strict standard of proof and departure from the original intent of the MOH would appear to be strongly associated with a reduced number of awards than might otherwise have been expected if the standards advocated by the MOH were pursued. According to Fei and Peng, "It can be seen that the Chinese compensation scheme uses a strict approach to the standard of proof, an approach that is generally based on epidemiological causation. As the Regulation excludes injuries that occur by coincidence after inoculation or vaccination, the expert panel tends to come to a negative conclusion when there is no solid epidemiological evidence. The evidence from China Centers for Disease Control supports this argument. From 2000 to 2013, 188 cases of deaths suspected to be abnormal reactions to hepatitis B vaccination were reported to the Centers; only eighteen were determined to be adverse reactions while the rest were considered coincident accidents." p109.<sup>6</sup> These data suggest that the expert panel draws a clear distinction between abnormal reactions (not observed in epidemiological studies) and adverse reactions (observed in epidemiological studies) and that the former, even when severe or fatal, are unlikely to pass the strict standard of proof employed in the scheme, as they are not expected to occur. In addition, there is no consideration given to possible flaws in the production, storage, or administration of the vaccine. What makes the drawing of this distinction even more contentious is that the regulation governing the operation of the scheme does allow compensation to be paid in the event of death or severe disability occurring as an undocumented but possible reaction to vaccination. According to Fei and Peng, "the Regulation has threshold injury or disability criteria that need to be met before claiming compensation. Only if an



inoculated person dies or becomes severely disabled, or if any of his organs or tissues is injured due to an unusual response to vaccination, shall he be paid a lump sum of compensation.” p104.<sup>6</sup>

The decentralisation process in China means that the central government delegated the authority to make decisions to the local level in the provinces. We infer from this level of decentralisation that the claims handling and adjudication process thereafter has played a role in determining the amount of financial compensation paid out to claimants. For example, there is some evidence to suggest that provinces have made different decisions on how to calculate the actual amount of compensation paid out in successful awards. Indeed, this is a good illustration of the differences in decision-making that can occur when authority has been delegated among so many geographical locations. What the literature tells us about China is that the scheme adopts different calculation methods to determine the amount paid in compensation awards across the 32 provinces. This means that the same vaccine-related injury may be awarded different amounts based on where the claim is made in China. Fei and Peng capture this diffuse spread of decision-making in the following extract: “The compensation amount to a great extent is dependent on the calculation methods specified by different provinces [16 provinces adopt the fee-based approach and 16 provinces adopt the disability-based approach]...A province adopting fee-based compensation [includes payment for treatment and rehabilitation costs, lost working time, nursing expenses, equipment and accommodation expenses, and funeral and other expenses] would pay more in compensation than a province adopting disability level-based compensation [actual lump-sum payments for the disability suffered].” p108.<sup>6</sup>

Regarding the types of injuries compensated within the scheme, to paraphrase Fei and Peng,<sup>6</sup> most of the total compensation paid out in Guangdong Province between 2012 and 2013 was for that of disabled victims, and the largest awards were made for injuries related to the oral polio vaccine, the measles vaccine, and the group A multi-peptide vaccine (MPV-A). Fei and Peng provide a more detailed breakdown of compensation paid to disabled victims within the Guangdong province of China. They state that “Guangdong Provincial Centers for Disease Control reported that a total of sixty-six cases of adverse events following free preventative vaccination of category 1 vaccines were reported in thirty-five counties or districts of nineteen prefectures in Guangdong province from 2012 to 2013, and the total compensation for the adverse events was [Chinese Yuan ¥]5.02 million. Of this compensation, 63.47% was for disabled victims. The average amount of compensation in each case was approximately [¥]73,500 and the highest average compensation amounts were for adverse events caused by oral polio vaccine, measles vaccine, and group A multi-peptide vaccine.” p108.<sup>6</sup>

In addition to our claims that the volume and costs of awards are affected by the strict standard of proof employed in the scheme and by particular features of the claims handling and adjudication process, we also suggest that wider contextual factors can influence differences in the amount of compensation paid for the same injuries. The wider context within which the scheme operates in China is important to bear in mind when considering the large and diverse spread of claims and related processes that exist. For example, it would appear that the relative economic profile of different provinces can also affect the amount of compensation paid out in these provinces. For example, according to Fei and Peng, “there is also a large difference across one-time compensation amounts. At higher levels of economic development, compensation levels are higher...The poor districts always pay much less than rich districts for the same injuries.” p112-113.<sup>6</sup>

#### **Key points**

- ***The strict standard of epidemiological proof and the injury threshold that requires the injury to be severe or fatal can reduce the number of successful awards for compensation in China.***
- ***The claims handling and adjudication process can affect the amount of compensation paid out in successful claims in China.***
- ***Compensation is calculated using one of two methods in China: a fee-based approach or a disability-based approach.***
- ***The delegation of the scheme to individual provinces in China and the different economic profiles of the provinces influences the amount of compensation paid; poorer provinces pay less than richer provinces for the same injury.***

### 3.4.2.6 Question 5: Do no-fault vaccine damage schemes enjoy public acceptance?

It would appear from the data provided in the paper by Fei and Peng<sup>6</sup> that claimants using the compensation scheme in China are not satisfied with the compensation paid out in awards or with the procedures that underpin the scheme in general. According to Fei and Peng, “Claimants in China are far from satisfied with compensation through the existing process and pursue their remedies by petitioning or through other informal activities.” p114.<sup>6</sup>

Further evidence of the nature of the discontent showed by unhappy claimants sometimes manifests itself in public unrest. To paraphrase Fei and Peng,<sup>6</sup> this public unrest appears to be mainly due to claimants being unhappy with the amount and scope of compensation provided in the scheme. According to Fei and Peng, “due to limited financial and other resources, the amount and scope of compensation are limited. This easily ignites the fury of victims’ families and causes victims and their families to engage in petitioning or disruptive behaviour.” p113.<sup>6</sup>

Furthermore, Fei and Peng<sup>6</sup> claim that the VICP in China operates in a context that lacks the wider social support that a national social welfare system could provide to such a scheme. According to Fei and Peng, “This study shows that the Chinese compensation scheme functions inefficiently because it does not operate alongside a well-established comprehensive national social welfare system... The insufficiency of the vaccine injury compensation programme in China stands out as a gap in the country’s vaccine policy.” p114.<sup>6</sup>

The inefficiencies of the scheme highlighted thus far and the public disapproval of certain features of the scheme would appear to influence some strange occurrences that may only pertain in the context of the Chinese scheme. For example, there is some evidence put forward by Fei and Peng<sup>6</sup> to suggest that the strength of the social unrest which may arise in a province where dissatisfaction with the scheme is high may influence a shift in decision-making by local officers involved in administering the scheme. According to Fei and Peng, “Under political pressure to maintain societal harmony, the local administrative officer aims to pay compensation according to the disturbance or the seriousness of the petitioning rather than according to rule of law. Such a flexible attitude further encourages victims and their families to resort to petitioning and making disturbances. This cycle weakens the authority of the administrative procedure.” p113.<sup>6</sup>

A particular irony of the scheme in China is that the strength of public unrest can effectively overturn decisions to reject claims, even though the scheme appears to only approve claims that carry the strength of scientific evidence. For example, even in the case where the injury claimed was deemed to not be associated with a specific vaccine, the local officer chose to compensate the alleged victim due to the strength of the public unrest. According to Fei and Peng, “Faced with petitioning and political pressure, the local government paid compensation even in cases where the injury was denied as VAPP [vaccine-associated paralytic poliomyelitis] relevant. In one Zhejiang case, the authentication report denied that the injury was caused by OPV [oral polio vaccine] but the local government still provided [¥] 600,000 to the victims after considering their situation.” p111.<sup>6</sup>

#### **Key point**

- ***In China, claimants using the compensation scheme are not usually satisfied with the compensation paid and pursue other actions in order to gain approval for compensation or increase the size of the award.***

### 3.4.2.7 Question 6: What cost-control mechanisms covering no-fault vaccine damage schemes are reported in the literature?

From our analysis of the data, it would appear that there are limitations to the maximum amount of compensation allowable in some provinces. These limitations may act as a cost-control mechanism within the scheme in China. According to Fei and Peng, "Some provinces set maximum compensation amounts. For example, Shanghai provides that the maximum compensation for the most serious injury would be twenty-five times the annual disposable income of urban households in Shanghai. Suppose a victim died (class one-level injury) from a vaccine in 2016, then the victim's family would receive at most [¥]1,246, 675, as the annual urban income of Shanghai in 2015 was [¥]49, 867 yuan." p106-107.<sup>6</sup>

#### **Key points**

- ***The most visible cost-control mechanisms in China are limitations imposed on the maximum amount of compensation allowable in some provinces.***
- ***Two other forms of indirect cost control are that compensation is only provided to severe cases and to cases that meet the strict burden of proof criteria in China.***

### 3.4.2.8 Summary

In 2005, China introduced an administrative no-fault compensation scheme for adverse events following immunisation. The vaccines that are covered by the scheme are split into Class I vaccines, which are provided by the Government for the general public, and Class II vaccines, which mainly cover those vaccines paid for by the general public themselves. For injury arising out of inoculation with a Class I vaccine, the expenses of compensation are paid by the Government, and for injuries from a Class II vaccine, the expenses for compensation are borne by the vaccine manufacturer. The Chinese compensation scheme was enacted by the central government but is run by local governments; it is at the level of local government that decisions are taken to negotiate with victims over eligibility and decide on whether to reject or award claims for compensation.

We found no explicit data to estimate the overhead costs of operating the VICP in China. However, this lack of data may be explained by the disparities that appear to pertain in funding across the 32-province-level scheme. The data would suggest that the three-phase claims handling and adjudication procedure may contribute to delaying timely access to compensation for claimants. In general, it has been claimed that this procedure is cumbersome, as claimants must process their claims through a procedure which involves different agents making different decisions which then need to be reviewed by other agents before a final declaration is issued regarding the success or otherwise of a claim.

It would appear that the strict standard of epidemiological proof, and the injury threshold that requires the injury to be severe or fatal, can reduce the number of successful awards for compensation. Even in the case of fatalities linked to vaccines that do meet the criteria for an adverse event, such fatalities are seen as abnormal reactions and are rejected on the grounds that causation has not been scientifically proven, i.e. such reactions have not been observed in epidemiological studies. It is suggested that claimants to the scheme are unhappy with the scope and amount of compensation that the scheme covers for vaccine-related injuries. In some cases, claimants have protested in their local provinces to such an extent that they have been able to overturn decisions that had previously ruled against their claims. In such events as local protests, it would appear that local officials succumbed to the protesters in order to reduce the potential for further social unrest.

The most visible cost-control mechanism is the limitation imposed on the maximum amount of compensation allowable in some provinces. Two other forms of cost control may be that compensation is only provided to severe cases and to cases that meet the strict burden of proof criteria.

Essentially, the VICP in China is far from a homogenised entity; it operates across 32 provinces which are characterised by diverse economic and cultural features. In conclusion, it would appear that although the objective of setting up the scheme was apparently well-intentioned, in practice the scheme has shown more weaknesses than strengths and is particularly hampered by cumbersome claims handling and adjudication procedures, the application of a strict standard of proof, variations in awards, and public dissatisfaction.

### 3.4.3 Japan

#### 3.4.3.1 Introduction

We included one relevant paper that provided data on the VICP in Japan: Wang, Yang, *et al.*<sup>36</sup> The main objective of the paper was to compare the VICPs in Japan and Taiwan using data derived from a site visit to Japan, plus analysis of administrative data related to both Taiwan and Japan and a brief review of selected literature. Overall, we extracted data from the paper to answer four of our six questions. However, it must be noted that the paper by Wang, Yang, *et al.* contained only minimal data on the VICP in Japan, as the main purpose was to compare the scheme with that in Taiwan; therefore, the paper covered both schemes in a minimal way.

A notable feature of the VICP in Japan is the distinction between funding for injuries linked with publicly funded vaccines and injuries linked with self-paid vaccines. In addition, publicly funded routine vaccines are distinguished into Class I and Class II, with uptake of the former encouraged by Government policy and uptake of the latter merely being advised. There are two stages to the claims handling and adjudication process, and both stages are applied to claims for both publicly funded vaccines and self-paid vaccines. The ultimate decision on whether to approve a claim rests with different bodies; for the publicly funded vaccines, it rests with the Health Service Bureau (HSB), while for claims for self-paid vaccine injuries, the review and approval of compensation is handled by the Pharmaceutical and Food Safety Bureau (PFSB). Japan has a set payment amount for different injuries, and the review committee only needs to determine whether there is an undisputed correlation between a vaccine and an injury claimed to be caused by the vaccine for payment to be awarded.

#### 3.4.3.2 Question 1: What design features and/or contextual conditions are thought to impact on the operating costs associated with no-fault vaccine damage schemes?

We found no explicit data in the paper by Wang, Yang, *et al.* that estimated the overhead costs incurred in operating the two strands of the VICP in Japan. However, from the limited data provided that speak to the funding of the VICP, it would appear that for publicly funded vaccines, overhead costs may be covered by the central government, whereas for self-paid vaccines, it would appear that overhead costs are shared by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) and others. According to Wang, Yang, *et al.*, the two funding sources are as follows:

As for public-funded vaccine relief payments, the national budget covers them with the Ministry of Health, Labour and Welfare (MHLW) sharing 1/2, prefectural government sharing 1/4, and municipal government sharing 1/4. p8.<sup>36</sup>

As for the budget source for the Pharmaceuticals and Medical Devices Agency (PMDA) self-paid vaccine injury relief, the relief payment is levied from the vaccine manufacturer according to their sales volume using a set rate (the current set rate is 0.35% of their sales volume), and 1/4 of the actual relief amount is also levied. As for the PMDA administrative fees, the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) of the Ministry of Health, Labour and Welfare (MHLW) will cover 1/2 of the cost. p9

#### **Key point**

- ***It would appear that for publicly funded vaccines in Japan, overhead costs may be covered by the central and local government, whereas for self-paid vaccines, it would appear that overhead costs are shared by the PAFSC and others.***

### **3.4.3.3 Question 2: What design features and/or contextual conditions are thought to impact on timely access to no-fault vaccine damage schemes?**

We found no data in the paper by Wang, Yang, *et al.*<sup>36</sup> which would allow us to make inferences regarding whether or not claimants receive compensation in a timely fashion. However, we did extract a descriptive account of the procedures undertaken around the handling of claims and the decision-making process regarding the approval of compensation. We have insufficient data to infer that these procedures impact either way on timely access; however, we believe it is useful to elaborate on them to provide some insight into how claims are handled and decisions taken within the VICP in Japan.

It would appear that in Japan, there are two stages to handling claims and deciding on approval or rejection, and both stages are applied in both publicly funded and self-paid claims. According to Wang, Yang, *et al.*, “In Japan, before vaccine injury cases are sent to the Disease and Disability Certification Council (DDCC) and the PAFSC for review, relevant investigation and opinions have been completed. For example, in public-funded vaccine cases, the municipal government has an established specialized committee, formed by internal medical health officials and jurisdictional medical-related experts which make a preliminary judgment according to the situation for each case. As for self-paid vaccines, the preliminary report is provided to MHLW by a relevant committee under the PMDA. In other words, in the review of cases in Japan, whether it is for public-funded vaccines or self-paid vaccines, both are reviewed in two stages by corresponding committees.” p10.<sup>36</sup>

Following the preliminary work, the ultimate decision on whether to approve a claim rests with different bodies for the publicly funded and the self-paid vaccines. In respect of the publicly funded related claims, the results of claims are reviewed and approved by the DDCC of the HSB. p5.<sup>36</sup> For the ultimate decisions approved regarding claims for self-paid vaccine injuries, the review and approval of compensation claims is done by the PAFSC of the PFSB. p5.<sup>36</sup>

### **3.4.3.4 Question 3: What design features and/or contextual conditions are thought to impact on the number of applicants seeking redress via no-fault vaccine damage schemes?**

According to the limited data in the paper, there were approximately 70 annual claims lodged with the publicly funded scheme for compensation up to 2007. According to Wang, Yang, *et al.*, “In the statistics of application and review results, as of 2007, Japan has received approximately 70 vaccine injury relief cases each year for public-funded vaccinations, with a payment rate that reaches about 80%.” p6.<sup>36</sup>

#### **Key point**

- ***Based on the limited data available, we infer that the proportion of claimants who receive awards (80% of applicants) when compared with other countries indicates that the standard of proof is set at a reasonable level in Japan.***

### **3.4.3.5 Question 4: What design features and/or contextual conditions are thought to impact on the volume and costs of awards made under no-fault vaccine damage schemes?**

A notable feature of the VICP in Japan is the distinction between funding for injuries linked with publicly funded vaccines and injuries linked with self-paid vaccines. In addition, publicly funded vaccines are distinguished into Class I and Class II, with uptake of the former being encouraged by Government policy and uptake of the latter being merely advised. As will be inferred later on in this section, these distinctions may affect the number of claims compensated and the amount of money paid out in successful awards. The following extract from Wang, Yang, *et al.*<sup>36</sup> illustrates the distinction made by Government regarding the grading of routine publicly funded vaccines. According to Wang, Yang, *et al.*, “In 2001, public-funded vaccines were separated into routine vaccines and non-routine vaccines, among which routine vaccines are classified into Class I and Class II; the Class I is encouraged (persuaded) to be vaccinated whereas the Class II is only advised.” p4.<sup>36</sup>

Class I vaccines include those for diphtheria, pertussis, acute poliomyelitis, measles, rubella, Japanese encephalitis, tetanus, tuberculosis, and smallpox.

Class II vaccines include influenza. p4.<sup>36</sup>.

From our analysis of the data in the paper by Wang, Yang, *et al.*, we infer that it is the manner in which vaccines are covered in the scheme that may affect the volume of awards and the amount of compensation per award. The decision to grade publicly funded vaccines into Class I (Government encouraged) and Class II (Government advised) affects the number of claims compensated and the amount of money paid out in claims. For example, two of the vaccines graded in Class I were responsible for the highest number of claims compensated from the start of the VICP (in about 1970) to 2010 in Japan. According to Wang, Yang, *et al.*, "In the vaccine injury relief system in Japan, starting from the date of its operation to 2010, a total of 2,751 cases were paid for; among these, the most cases were for the measles, mumps, and rubella (MMR) vaccine, taking up more than 1/3 of all cases. Following are for the BCG vaccine (to prevent tuberculosis) where more than 460 cases were paid for." p6-8.<sup>36</sup>

According to Wang, Yang, *et al.*, "since Class I vaccines are persuaded (encouraged) by the government for inoculation, the Japanese government believes that when the public receives injury after receiving a government policy-encouraged vaccine, the payment should exceed other cases." p6.<sup>36</sup>

In addition, it appears that the amounts paid out in awards for injuries from publicly funded vaccines are higher than the amount for injuries from self-paid vaccines, which may also signal an attempt to reward the public for contributing to the public health. According to Wang, Yang, *et al.*, "In accordance with the national vaccine policy for public-funded vaccine victims, the payment [for publicly funded vaccine victims] is much higher than for victims of self-paid vaccines." p10.<sup>36</sup>

From the data provided by Wang, Yang, *et al.*, it would appear that four out of every five awards paid out for injury from a publicly funded vaccine are to reimburse and/or cover the costs of health benefits and medical expenses. According to Wang, Yang, *et al.*, "By analysing the different types of payment, 80 percent are issued for healthcare benefits [expenses incurred by the claimant excluding any expenses covered by health insurance] or medical allowance [monthly inpatient/outpatient medical expenses paid by the claimant]. As for disability annuities and funeral fees, the number of cases is no more than 10." p6-8.<sup>36</sup>

The data provided on the volume and costs of awards for self-paid vaccines are minimal; however, it is suggested that there was an increase in the number of awards and that most of the awards were for influenza-related injuries, a vaccine graded as Class II and merely advised by Government policy. According to Wang, Yang, *et al.*, "In self-paid vaccine cases, according to PMDA, the numbers resulting in side-effects or injury show an increase in applied cases each year. From 2005 to 2008, a total of 124 side-effect cases were paid for, with 50% for seasonal influenza vaccines and 42% for mumps vaccines." p6-8.<sup>36</sup>

#### **Key point**

- **Decisions taken to grade publicly funded vaccines as Class I (encouraged or persuaded) and Class II (advised) reduces the overall costs of successful awards in Japan.**

#### **3.4.3.6 Question 5: Do no-fault vaccine damage schemes enjoy public acceptance?**

We found no data that speak to this question.

### 3.4.3.7 Question 6: What cost-control mechanisms covering no-fault vaccine damage schemes are reported in the literature?

We found no explicit data that describe the financial caps that may pertain in the VICP in Japan. However, Wang, Yang, *et al.* do signal that there are set payments for different injuries, but the authors do not elaborate further. According to Wang, Yang, *et al.*,<sup>36</sup> “Japan has a set payment amount for different articles [injuries], and the review committee only need to determine whether the case has an undisputed correlation with the vaccine or not, and whether it fits the standards for payment or not.” p11

There are three categories of payments that are made under the Japanese scheme, and two of them carry a time limit for submitting claims:

- The first category includes healthcare benefits and medical allowances, which can be claimed within five years of first receiving medical assistance.
- The second category includes disability childcare pension and disability pension, and there are no time limits on filing a claim.
- The third category includes bereaved family pension, a bereavement lump-sum benefit, and assistance with funeral expenses. These must be claimed within five years of death.<sup>36</sup>

#### **Key points**

- ***For Japan, there are time limits for healthcare and bereavement payments and payment guides for the different injuries, which are likely to control costs. In addition, the class to which the vaccine is assigned may affect the amount of compensation.***

### 3.4.3.8 Summary

Japan has a stand alone VICP. Overall, we found limited data in the paper by Wang, Yang, *et al.* to address our questions and to make any meaningful inferences. However, it must be noted that this paper compared the VICP in Japan to that in Taiwan, and so the paper was not exclusively focused on providing an overview of the scheme in Japan. The main inference that we can draw from this paper is that the volume and costs of awards for vaccine injury compensation would appear to be affected by the Government’s decision to grade publicly funded vaccines as Class I (which are encouraged by government) and to grade other vaccines as Class II (which are advised by the Government). The data suggest that injuries related to vaccines that are encouraged by the Government receive higher compensatory awards. We therefore infer that claimants who become injured due to receipt of these vaccines are prioritised for reward in recognition of their contribution to herd immunity. Based on the limited data available, we also infer that the proportion of claimants who receive awards (80% of applicants) when compared with other countries indicates that the standard of proof is set at a reasonable level.

There are time limits for healthcare and bereavement payments, as well as payment guides for the different injuries, which are likely to control costs. In addition, the class to which the vaccine belongs may control the amount of compensation.



### 3.4.4 Korea

#### 3.4.4.1 Introduction

We included four relevant papers that provide data on the VICP in Korea: Kim, Lee, *et al.*,<sup>41</sup> Choe and Bae,<sup>42</sup> Kim, Jo, *et al.*,<sup>66</sup> and Jo and Kim.<sup>67</sup> Three of the papers primarily analysed secondary data from administrative data routinely collected by the VICP in Korea (Kim, Lee, *et al.*,<sup>41</sup> Choe and Bae,<sup>42</sup> and Kim, Jo, *et al.*,<sup>66</sup>) and one paper was based on survey data that investigated the views of paediatricians on the Korean VICP (Jo and Kim).<sup>67</sup> Kim, Jo, *et al.*<sup>66</sup> examined data covering the period between 1995 and 2006, Choe and Bae<sup>42</sup> covered the period between 1995 and 2010, and the most recent paper, by Kim, Lee, *et al.*,<sup>41</sup> analysed data from 2011 to 2016.

The VICP in Korea is a standalone initiative; this means that, unlike the situation in the Nordic countries, the scheme in Korea is not part of a wider drug injuries compensation scheme. In addition, the scheme in Korea is confined to compensating for a list of injuries related to a list of vaccines that have been recommended by the Korean authorities. According to Choe and Bae, “The Korea National Vaccine Injury Compensation Program (KVICP), which was [legislated for in 1994 and introduced in 1995], compensates individuals who experience certain adverse events following inoculation...for vaccines that are recommended by the government.” p43.<sup>42</sup>

The VICP is grounded in legislation, specifically the Infectious Disease Control and Prevention Act 1988, which facilitates compensation and clearly outlines that compensation will only be paid for injuries associated with vaccines included in the National Immunization Program and, according to Kim, Lee, *et al.*, “other vaccinations voluntarily undergone by individuals are not covered.” p147-148.<sup>41</sup>

Although the compensation scheme is a standalone initiative, it must be noted that the scheme is also embedded within a wider suite of initiatives that cover three other activities: the administration of vaccines, the surveillance of adverse events, and the compensation of injuries. According to Choe and Bae, “Currently, the vaccine safety management system in Korea is composed of four parts: rapid response system, adverse events following immunization surveillance system, adverse events following immunization investigation system, and vaccine injury compensation program (VICP). The Division of Vaccine Preventable Disease Control and National Immunization Program at Korea Centers for Disease Control and Prevention (KCDC) operates routine and ad-hoc surveillance measures on adverse events following immunization in Korea; performs epidemiological investigation on certain adverse events following immunization such as serious adverse reactions or clustered adverse events following immunizations; and operates [administers] the vaccine injury compensation program (VICP).” p41-42.<sup>42</sup>

The claims handling and adjudication process in the Korean scheme appears to follow a two-stage process. The following extract provides an adequate description of this two-stage process from the time a claim is issued to the time a decision is made to approve or reject the claim. According to Choe and Bae “When a patient places a claim for compensation, the [adverse events following inoculation] investigation team jointly operated by Korea Centers for Disease Control and Prevention (KCDC) and local health authority starts an investigation. Determination of causal association between the injury and vaccination is assessed by Korea Advisory Committee on Vaccine Injury Compensation (KACVIC) [which is composed of 15 expert members], who use the simplified World Health Organization (WHO) categories of likelihood of causality: 1) definite, 2) probable, 3) possible, and 4) unlikely. Compensations are made for cases that are classified as definite, probable, or possible. Unlikely cases are rejected.” p44.<sup>42</sup> Please also see Kim, Lee, *et al.*,<sup>41</sup>

#### **3.4.4.2 Question 1: What design features and/or contextual conditions are thought to impact on the operating costs associated with no-fault vaccine damage schemes?**

We found no data that estimated overhead costs in the four papers we identified through our search.

#### **3.4.4.3 Question 2: What design features and/or contextual conditions are thought to impact on timely access to no-fault vaccine damage schemes?**

We found no data in any of the four papers we reviewed to help us understand if any features of the programme either speed up or slow down access to compensation. However, the Act that underpins the scheme suggests that claims should be resolved within 120 days from the date of submission. According to the wording of the Infectious Disease Control and Prevention Act, "The Minister of Health and Welfare shall determine whether a filed case is applicable to a disease, disability or death under paragraph within 120 days from the date on which a claim for compensation...is filed. In such cases, he/she shall hear the opinions of the Committee in advance."<sup>68</sup> None of the four papers evaluates whether or not this deadline is achieved.

#### **3.4.4.4 Question 3: What design features and/or contextual conditions are thought to impact on the number of applicants seeking redress via no-fault vaccine damage schemes?**

Kim, Lee, *et al.*<sup>41</sup> report that when additional vaccines were added to the programme for both children and the elderly, the number of claims for compensation increased. According to Kim, Lee, *et al.*, "Eight types of vaccines for children aged 12 years or less and one type of vaccine, 23-valent pneumococcal polysaccharide vaccine (PPV23), for the elderly aged 65 years and over were introduced from 2011 to 2016. Consequently, the numbers of vaccine types and subjects filing compensation claims has increased." p147.<sup>41</sup>

When we compared the data on the number of claims filed provided by Kim, Lee, *et al.*<sup>41</sup> and Choe and Bae,<sup>42</sup> we found that the number of claims did increase, and it was plausible to infer that this increase was likely to be due to the addition of new vaccines to the scheme post 2010. For example, according to Kim, Lee, *et al.*, "There was a range of 70 to 121 applications for compensation filed each year [from 2011 to 2016], totaling 515 applications over the 6-year period." p149.<sup>41</sup>

In contrast, in the paper authored by Choe and Bae, it can be seen that from 1995 to 2009 there were fewer than 25 claims for compensation per year. p44.<sup>42</sup>

It would also appear to be the case that including vaccines with a high level of scientific consensus regarding associated injuries can also contribute to a high number of claims for compensation. For example, according to Kim, Lee, *et al.*, "[from 2011 to 2016] the highest number of applications filed for injury compensation (235 cases, 50.1%) involved the BCG vaccine (including its simultaneous inoculation with hepatitis B)." p151;<sup>41</sup> this was 50% of the 469 claims analysed by the authors.

It may be the case that the public, and perhaps their medical advisors, are aware that the BCG vaccine is known to be associated with certain injuries, and that when such injuries occur, injured parties are more likely to submit a claim for compensation. This inference is based on the claim that injuries associated with the BCG vaccine are common and well-known. According to Kim, Lee, *et al.*, "The adverse events following BCG vaccination, such as lymphadenitis and abscess or ulcer formation, are common, well-known, and accepted to have definite causal association with the BCG vaccine." p153.<sup>41</sup>

From the data we analysed, we infer that the number of claims being submitted to the compensation scheme in Korea has also been influenced by wider contextual factors. For example, the sudden threat of an outbreak of a pandemic like the H1N1 influenza virus (otherwise known as swine flu) that occurred in 2009 can also increase the number of claims for compensation related to vaccine injuries. The swine flu virus posed a major threat to the population of Korea, and in response the Government ordered a nationwide immunisation campaign using the Pandemrix vaccine to counter the anticipated outbreak. In 2010, there was a significant increase in the number of claims for compensation lodged with the VICP in Korea.

In Table 4 in the paper authored by Choe and Bae, p44<sup>42</sup> it can be seen that from 1995 to 2009 there were fewer than 25 claims for compensation per year. However, this number jumped to 275 claims in 2010, and it would appear to be the case that the main factor in this increase was the nationwide immunisation campaign against the swine flu virus that took place the previous year. Although there is no direct claim in the papers we reviewed that the mass immunisation campaign against the swine flu virus was responsible for the increase in claims, there is some evidence for us to infer that the association is plausible. For example, according to Choe and Bae, “There were two surges [in the reporting of adverse events following inoculation since 1994 in Korea] in 2001 (n=141) and 2009 (n=2,380), when a nationwide immunization campaigns for measles and H1N1 influenza took place, respectively.” p42.<sup>42</sup> With such a spike in the number of adverse events following inoculation reported in 2009, it would be highly likely that the number of claims for compensation related to some of the reported adverse events would occur.

In addition, it may be the case that the effect of the mass immunisation campaign continued to influence the number of claimants even beyond 2010. For example, according to Kim, Lee, *et al.*, “The second most common vaccine in terms of claims made was influenza [90 claims from 2011 to 2016].” p153.<sup>41</sup> Apparently, there was concern at national level that the H1N1 vaccine may have been associated with the development of Guillain–Barré syndrome (GBS), which is a rapid-onset muscle weakness disorder caused by the immune system damaging the peripheral nervous system and an illness associated with the influenza vaccine.<sup>42</sup>

#### **Key points**

- ***The addition of new vaccines to the compensation scheme in 2011 in Korea increased the number of claims for compensation.***
- ***Where there is expert consensus on vaccine-related injuries, this can increase the number of claimants for the specific vaccine and its associated injuries in Korea.***
- ***Mass-immunisation campaigns using newer vaccines can lead to an increase in claims for compensation as in the case of Korea.***

#### **3.4.4.5 Question 4: What design features and/or contextual conditions are thought to impact on the volume and costs of awards made under no-fault vaccine damage schemes?**

From our review of the papers relating to the VICP in Korea, it would appear that the key feature of the programme which affects the volume and costs of awards is the degree of evidence available on vaccine-related injuries, which makes the standard of proof adopted by the expert panel easier to use.

For the most part, the standard of proof rests on the weight of evidence that is available to support or reject a claim for compensation. The weight of evidence in vaccine injury cases primarily requires a certain degree of consensus among the scientific community.

It can be inferred that the volume of claims that receive compensation for vaccine injuries in Korea is related to the scientific consensus on the causal association between a specific vaccine and the injuries claimed. Korea uses a modified version of established standard of proof assessment criteria to determine the merits of claims for compensation. Kim, Lee, *et al.* clearly describe this approach in the following extract: “Our classification of causality assessment is...based on the World Health Organization (WHO) causality assessment criteria, but modified according to our circumstances. The categories are as follows: definitely related, probably related (likely), possibly related, probably not related (unlikely), and definitely not related.” p148.<sup>41</sup> Compensation is not paid for the ‘probably not related (unlikely)’ and ‘definitely not related’ outcomes.

First of all, the majority of claims for compensation made over the period from 2011 to 2016 were successfully compensated. According to Kim, Lee, *et al.*, “From the 469 cases analysed over the six-year period from 2011–2016... 318 cases (67.8%) resulted in compensation and 151 cases (32.2%) resulted in dismissal.” p151<sup>41</sup>

The vast majority of those cases that received compensation were for injuries related to the BCG vaccine, reflecting what appears to be the scientific consensus regarding the adverse events relating

to this vaccine. For example, according to Kim, Lee, *et al.*, “71% (n=225) of the 318 cases compensated [over the period from 2011 to 2016] were for BCG vaccine-related claims... Among the 225 cases of compensation for BCG-related adverse reaction, 217 cases (96.4%) reflected well-known adverse events, such as BCG lymphadenitis, ulcer or abscess formation... [and are] accepted to have definite causal association with the BCG vaccine.” p152-153.<sup>41</sup>

In addition, it would appear that the claimants’ cases for demonstrating causality between the BCG vaccine and their related injuries were strengthened by the overall profile of the claimants as a group and the temporal association between BCG vaccination and the manifestation of the adverse event. For example, among all compensated claimants from 2011 to 2016, which totaled 318 successful claims, according to Kim, Lee, *et al.*, “this group accounted for four-fifths of affected infants under three years old, in line with characteristics of BCG vaccination. The majority of the adverse events in this group occurred more than 2 months after the inoculation, reflecting the characteristics of BCG lymphadenitis.” p152.<sup>41</sup>

From the papers we reviewed, we did not identify any data that speak to the amount of money that is typically paid out in a successful compensation award. However, we did identify an interesting feature about the VICP in Korea, insofar as there appears to be no difference in the amounts paid out to claimants once an award meets one of the three pillars in the standard of proof. Furthermore, it would appear that whatever the amount of money that a claimant specifies in their compensation claim, if successful, this precise amount is paid to the claimant. These notable features are captured quite clearly in the following extract from Kim, Lee, *et al.* “there is no difference in the compensation amounts among cases in the ‘definitely related’, ‘probably related’, and ‘possibly related’ categories; for all of these cases, the claimed amount is fully compensated. In contrast, cases categorized as ‘probably not related’ and ‘definitely not related’ did not constitute causality; thus, compensation for the amount claimed is totally rejected in these instances.” p148.<sup>41</sup>

#### **Key points**

- **Where there is expert consensus on vaccine-related injuries, this can increase the number of successful claimants for the specific vaccine and its associated injuries as in Korea.**
- **The Korean standard of proof is in line with the recommendations of the WHO and awards definite, probable, and possible cases. Almost 68% of claims are successful.**

#### **3.4.4.6 Question 5: Do no-fault vaccine damage schemes enjoy public acceptance?**

There are no direct data on public support for the Korean VICP; however, we identified one paper by Jo and Kim<sup>67</sup> which set out to investigate how paediatricians perceived the VICP in Korea. In this study, data were analysed from a total of 340 paediatricians who responded to a survey, which is estimated to represent around 10% of the total number of primary care paediatricians in Korea.

As part of the survey, respondents were asked if they know of the existence of the VICP. We consider this an important question, as if medical professionals do not know about the programme, we are unable to know if they support or approve of the scheme. In this case, it appears that the results of the survey regarding this question are conflicting. Jo and Kim reported that “16% answered they knew the Korean National Vaccine Injury Compensation Program well, 73% roughly knew, while 11% answered they did not know the program.” p54 and p55.<sup>67</sup> The authors do not explain the difference between knowing the programme well and roughly knowing the programme

On a general note, it has been claimed that the existence of the compensation programme in Korea is associated with engendering a high level of public trust in the entire suite of vaccine-related initiatives, including the VICP. According to Kim, Lee, *et al.*, “Our system is very effective for sustaining a high level of public trust in the NIP [National Immunization Programme] by responding rapidly to serious [adverse events following inoculation], and providing compensation for each serious adverse event resulting from immunizations recommended by the government.” p153.<sup>41</sup> However, the HRB points out that this is only indicitive proof; it would be more reassuring to have the public opinion.

#### 3.4.4.7 Question 6: What cost-control mechanisms covering no-fault vaccine damage schemes are reported in the literature?

From the papers we reviewed on the VICP in Korea, there is scarce information regarding cost-control mechanisms that operate within the scheme. We identified one paper which provided us with limited information regarding the filing deadline (five years) and the requirement that the claimant had spent more than US\$300. It would appear that both of these mechanisms can affect the eligibility criteria within the VICP in Korea. According to Choe and Bae, “In order to be eligible for compensation, a claim must be filed within 5 years after occurrence of [adverse events following inoculation], and the patient must have spent more than [Korean won]300,000 (approximately US\$300) on health care expenses.” p43.<sup>42</sup>

##### **Key point**

- ***In Korea, claimants must file a complaint within five years of the adverse event and must have spent more than US\$300 on healthcare.***

#### 3.4.4.8 Summary

The VICP in Korea is a standalone initiative; this means that, unlike the situation in the Nordic countries, the scheme in Korea is not part of a wider drug injuries compensation scheme. In addition, the scheme in Korea is confined to compensating for a list of injuries related to a list of vaccines that have been recommended by the Korean authorities.

We found no explicit data in the papers we reviewed that estimated the overhead costs involved in operating the scheme in Korea. In addition, we found no data to explain whether the scheme facilitates timely access to compensation for claimants.

Regarding the number of claims made to the scheme, the data would suggest that when new vaccines are added, the number of claims can increase. In addition, it would appear that when certain injuries are known to be associated with a certain vaccine, this knowledge can play a role in increasing the number of successful claims. The number of claims made can also be affected by emergency mass immunisation campaigns, such as that for the H1N1 influenza vaccine, which contributed to a considerable increase in the number of claims.

It would appear that the number of successful claims that receive a compensation award are affected by the degree of consensus on scientific evidence that is available. For example, the data suggest that when there is a high degree of scientific evidence available to support claims that associate certain injuries with certain vaccines, then the number of awards given for these injuries can increase.

The standard of proof is in line with the recommendations of the WHO and awards definitely, probably, and possibly related cases. Almost 68% of claims are successful.

From the data we analysed, it is difficult to determine whether the scheme enjoys public approval and support. However, there are some claims that the scheme does enjoy some level of trust among the general public.

We identified two cost-control mechanisms: claimants must file within five years of the adverse event, and must have spent more than US\$300 on healthcare.

### 3.4.5 Taiwan

#### 3.4.5.1 Introduction

In order to review the vaccine compensation scheme in Taiwan, we drew on two papers. The most recent paper, by Wang,<sup>35</sup> analysed administrative data from the Taiwan VICP. The second paper, by Wang, Yang, *et al.*,<sup>36</sup> drew on data from a site visit to Japan in order to compare its scheme with the scheme in Taiwan. In addition, this second paper also drew on secondary data analysis and a brief review of the literature to capture the main features of the scheme in Taiwan.

In Taiwan, whether vaccines are publicly or self-funded, all injuries related to these vaccines can be compensated through the same system. All claims are made to the relevant jurisdictional health bureaus, then progressed to the Centers for Disease Control within the Ministry of Health and Welfare, and then to the Vaccine Injury Compensation Programme Working Group (VICPWG) for review and deliberation. The claims handling and adjudication process in Taiwan is detailed quite neatly by Wang, Yang, *et al.* They describe that “After the establishment of this compensation system in Taiwan, whether [the vaccine] is public-funded or self-paid, both are under the same system with the same reviewing criteria; all the claims are received by jurisdictional health bureaus from public application, and after gaining access to medical records and preliminary investigation, the claims are sent to CDC [Centers for Disease Control] of Ministry of Health and Welfare for further inspection and compilation. After the preparation of related information, they are then sent to the VICPWG for further review. After administrative sanctions are achieved according to the decision the panel makes, the notification of results and request for payment are conducted.” p2.<sup>36</sup> The standard of proof employed in Taiwan categorises the causal relationship into three types: an injury can either be related, possibly related, or unrelated; only unrelated injuries are rejected. This model is similar to but not the same as the WHO recommendations.

However, if the claimant is not satisfied with the initial decision on their claim, they have the right to appeal within the scheme, and if still unsatisfied with the decision, they may seek recourse outside of the VICP and file a lawsuit against the Ministry of Health and Welfare. This appeals process is described by Wang in the following extract: “If the claimant does not accept the decision, or is not satisfied with the amount of the award compensated, the claimant has the right to file an appeal within 30 days after receiving decision with the Petitions and Appeals Committee, which is an agency responsible for adjudicating appeals of decisions made by the government. If the claimant still does not accept the decision rendered by the Petitions and Appeals Committee, the claimant can file a lawsuit against the Ministry of Health and Welfare. The Petitions and Appeals Committee so far has not overthrown a decision regarding the causation of injury made by VICPWG; however, there was a successful appeal against the decision in which the injured person was not compensated despite the fact that the injury was caused by immunization.” p153.<sup>35</sup>

#### 3.4.5.2 Question 1: What design features and/or contextual conditions are thought to impact on the operating costs associated with no-fault vaccine damage schemes?

We did not find any explicit data in the two papers we reviewed that estimated the overhead costs for the scheme in Taiwan. However, it would appear that overhead costs are included in the Vaccine Injury Compensation Relief Fund that is comprised of money extracted from vaccine manufacturers who pay levies into the fund. According to Wang, “The Compensation Relief Fund...is funded from the premium of NT\$1.5 imposed on each vaccine dose purchased by the government. The premium is paid by vaccine manufacturers or importers after purchased vaccines are approved and certified by Taiwan Food and Drug Administration (TFDA). However the premium rate can be adjusted when the amount of the Fund either exceeds two hundred million [Taiwan dollars] or is less than 1.5 hundred million dollars so that the Compensation Relief Fund is not restricted to compensation payouts only, it also provides funding for operating expenses and researches on adverse events following vaccination.” p150-151 <sup>35</sup>

### 3.4.5.3 Question 2: What design features and/or contextual conditions are thought to impact on timely access to no-fault vaccine damage schemes?

To answer this question, we set out to extract data from both of the papers we reviewed that might tell us what features of the VICP in Taiwan would either delay or speed up timely access to compensation for claimants. From the limited data we extracted from both papers, we infer that what occurs within the claims handling and adjudication process helps speed up timely access to compensation for claimants.

At the outset, it would appear that one of the objectives of setting up the scheme in Taiwan was to provide reasonable and quick compensation for injuries when the criteria for such were satisfactorily met. According to Wang, Yang, *et al.*, "It was hoped that through this compensation mechanism, if any of the public received vaccination that further caused death, physical and mental impairments, serious illness, and adverse reactions, they can receive reasonable compensation quickly after professional review to eliminate the possible doubts the public has for possible side-effects of vaccines, and elevate the vaccination rate." p2.<sup>36</sup>

The intent to exercise a professional review of all claims submitted for compensation has been carried through with the establishment of an expert working group that is tasked with reviewing all claims and making decisions to approve or reject them. The following extract by Wang, Yang, *et al.*<sup>36</sup> provides a good description of the members of this expert working group and the work they undertake in reviewing claims and making decisions to approve or reject them. According to Wang, Yang, *et al.*, "Members of the VICP Working Group (VICPWG) are made up of 19 to 25 infection specialists, neurologists, immunologists, pathologists, health care experts, legal experts, and social justice experts; among these, legal and social justice experts take up approximately one-third of the members, who cautiously, expertly, and justly discuss matters. The VICPWG will make a decision only after reviewing the situations provided by the case applicant, referring to the medical records, test results, medical treatment received, the course of the disease, and vaccine traits and referring to the academic studies, reports, and clinical data in discovering the possible relations between the injury and vaccination." p20.<sup>36</sup>

It would appear to be the case that the general intent to accelerate claims for compensation by members of the public has been facilitated to a large degree by the work of the expert group. In essence, it could be said that the group has made efforts to resolve claims in a timely fashion. According to Wang, "once the experts have finished reviewing the documents, the cases are brought to the VICPWG review meeting regularly arranged by Taiwan CDC. The meeting is held every other month, with a maximum interval of sixty days between two meetings, so as to ensure that the injury cases are solved in a timely fashion." p152.<sup>35</sup>

From the data that Wang<sup>35</sup> analysed, they make the claim that, overall, the programme has a good record in resolving claims in a timely fashion. We infer from this that the good case resolution record is primarily influenced by the efforts to speed up decision-making taken by the working group. According to Wang, "the programme is able to resolve injury claims in a timely fashion. In the year 2013, 98 injuries cases were resolved; with an average processing time of 155 days from the date of acceptance." p154.<sup>35</sup>

However, despite the apparent good efforts by the expert working group to speed up the claims handling and adjudication process, there is another feature of the programme that may potentially slow down timely access to compensation for injured claimants. This feature has been referred to as overly generous eligibility criteria, in that the programme fails to set restrictions on the type or severity of injury that a claimant can request compensation for. If left unattended to, it is alleged by Wang<sup>35</sup> that this feature of the programme can lead to administrative overload, which may adversely impact on any efforts to speed up timely access to compensation. The implications of this feature of the programme are captured in the following extract from Wang. "The filing requirement is too generous. The program only places restrictions on statute of limitations but not types or severity of injury that is eligible for claim. Therefore, the program allows claims for any outcomes following immunization. This has led some irrational individuals to file cases that obviously are ineligible for compensation. For example, a citizen filed a claim because he still contracted tetanus after receiving tetanus immunization. Such cases can cause administrative overhead in the program." p156.<sup>35</sup> In

order to reduce the adverse impact of administrative overload on the scheme, Wang recommends a tightening up of this generous filing system.<sup>35</sup>

**Key points**

- *The claims handling and adjudication process in Taiwan speeds up timely access to compensation for claimants. In the year 2013, 98 injury cases were resolved, with an average processing time of 155 days from the date of acceptance.*
- *An overly broad scope of eligible injuries under the VICP may create administrative overload and slow down timely access to compensation (no measurement provided). The programme places restrictions on the statute of limitations in Taiwan, but not on the type or severity of injury that is eligible for claims.*

**3.4.5.4 Question 3: What design features and/or contextual factors are thought to impact on the number of applicants seeking redress via no-fault vaccine damage schemes?**

From our analysis of the two papers we reviewed, it appears that events external to the operation of the programme in the 2009–2010 period contributed significantly to an increase in the number of claims for compensation. We infer that the mass immunisation programme ordered by the Taiwan Government in 2009 to prevent an epidemic of the H1N1 influenza virus was the main contributory factor to the increase in claimants for compensation in 2010 data.

In 2010, there were slightly more than 600 claims for compensation, compared with fewer than 100 for most other years. This was mainly due to the public claiming a causal link between the H1N1 vaccine for swine flu and Bell's palsy, a condition that causes a temporary weakness or paralysis of the muscles in the face. It can occur when the nerve that controls the facial muscles becomes inflamed, swollen, or compressed.<sup>35</sup>

Following the upsurge in claims for compensation in 2010, Wang states that the number of claims filed continued to be higher after 2010 compared to the number of claims filed in 2008. According to Wang, "After the year of 2010, VICP had approximately 50% of increase in the number of claims filed, compared to the number of claims in the year of 2008. The public awareness over the issue of vaccine safety and the existence of the vaccine injury compensation program was gained largely through the influence of mass media." p155.<sup>35</sup>

One could argue that, as a result of the public call for mass immunisation, the public became more aware of the existence of the VICP in Taiwan. Indeed, we infer that it may have been the role that the mass media played in encouraging people to be vaccinated and in alerting them to the existence of the programme which contributed to the upward trend observed.

**Key points**

- *Mass immunisation campaigns using newer vaccines can increase claims for compensation as in Taiwan.*
- *Improving awareness of the scheme can increase the number of claims for compensation as in Taiwan.*



#### **3.4.5.5 Question 4: What design features and/or contextual conditions are thought to impact on the volume and costs of awards made under no-fault vaccine damage schemes?**

In the paper we reviewed by Wang, Yang, *et al.*,<sup>36</sup> it is claimed that the number and costs of compensation awards under the scheme in Taiwan appear to be affected by the certainty of the causal relationship between the vaccine and the injury, as well as by the severity of the injury. According to Wang, Yang, *et al.*, “in Taiwan, the review decision and payment amount will differentiate in each case according to the high/low relations to the vaccine and severity.” p11.<sup>36</sup> Thus, it is clearly suggested that the standard of proof adopted in the scheme in Taiwan appears to be a factor in determining the number of awards given out and the amount of money paid in compensation.

To explain this in greater detail, the adjudication body can place the results of a claim in one of three categories depending on the strength of the evidence provided to support the claim. For example, it can go into Category 1, where the evidence is strong and the injury is related to the vaccine; Category 2, where the evidence is less strong and the injury is possibly related to the vaccine; or, Category 3 the evidence is nonexistent or judged to be weak, the injury is deemed to be unrelated to the vaccine and does not merit compensation. It is the adjudication body’s choice to designate a claim as directly related, or possibly related, or not related, depending on the level of evidence adduced, that has led some to claim that Taiwan operates a relaxed standard of proof. According to Wang, “The level of causal relationship is categorized into 3 types: [an injury] is related, [an injury] is possibly related and [an injury] is unrelated. This allows the program to offer a more relaxed standard of proof and the benefit of doubt is resolved in the claimants’ favor.” p152.<sup>35</sup>

However, from the data cited by Wang<sup>35</sup> on the number of claims for compensation, it would appear that over a 15-year period, 40% of claims have been judged successful. The question of whether this relatively lower than expected percentage of successful claims is consistent with the application of a relaxed standard of proof or not requires further research.

From our review of the data in the paper by Wang,<sup>35</sup> it would appear that when the degree of scientific evidence connecting a vaccine with certain adverse events is high, those injuries related to that vaccine are likely to be compensated. According to the data put forward by Wang, “the most compensated vaccine-related claim is the BCG vaccine (156 out of 167 were compensated) because of the advent of techniques of BCG strain differential diagnosis and the implementation of active surveillance by Taiwan CDC on BCG related adverse events.” p155.<sup>35</sup> To paraphrase the claim by Wang, the evidence provided by the new understanding of the different strains of BCG, along with the regular adverse events related to the BCG vaccine observed by the surveillance system in Taiwan, have improved the scientific evidence and enabled a more accurate appraisal of compensation claims for BCG-related injuries.

On the other hand, when there is a lack of scientific evidence regarding a specific vaccine and the specific injuries resulting from that vaccine, this may contribute to a lower number of successful awards for compensation. For example, in 2010, 81% of claims submitted for compensation for related to the H1N1 influenza vaccine were rejected in Taiwan. p154.<sup>35</sup> We infer that this high level of rejection is potentially linked to the absence of strong scientific evidence that confirm or refute the link between certain injuries and the H1N1 vaccine.

However, it must be noted that although the number of awards compensated was relatively low in 2010, the cost of compensation awarded was NT\$18.64 million. This was substantially higher than any other year, barring the first year of operation, when NT\$20.82 million was awarded in 1989. p154<sup>35</sup>

In addition to the features of the programme that appear to affect the volume and costs of awards, a notable contextual feature of the scheme in Taiwan is the inclusion of public opinion on the amount of compensation to be paid for certain injuries. From the data we analysed, it is not clear what form this consultation between the public and the claims handling and adjudication bodies in the scheme takes. However, Wang, Yang, *et al.* provide some insight into the role of the public in discussing compensation amounts in the following extract: “After free discussion done by review committee members, different payment results will appear and before the law and justice personnel make the

final decision, they will submit public view opinions, and the payment amount of those cases which have similar medical situations but different social situations will be slightly altered.” p11.<sup>36</sup>

#### **Key points**

- *The standard of proof used appears to limit the number of awards and costs of compensation in Taiwan. Over a 15-year period, 40% of claims were successful.*
- *Where there is expert consensus on vaccine-related injuries, it can increase the number of successful claimants for the specific vaccine and its associated injuries as in Taiwan.*
- *Where there is little evidence available on the injuries associated with a vaccine, there is a high proportion of rejected cases in Taiwan.*
- *There is public involvement in the deliberation of appropriate compensation amounts in Taiwan. (Taiwan)*

#### **3.4.5.6 Question 5: Do no-fault vaccine damage schemes enjoy public acceptance?**

From the two papers that we reviewed, there is very little evidence put forward that the VICP in Taiwan enjoys public support and approval, although members of the public provide input on the amount that should be paid for individual awards. However, in the paper by Wang,<sup>35</sup> there is some evidence that a particular feature of the VICP in Taiwan may contribute to dissatisfaction on the part of some claimants to the scheme. For example, there seems to be potential for dissatisfaction among some claimants with the amount of compensation paid out in some awards. Wang alludes to this state of affairs in the following extract: “The caps on some types of compensation are so high that it sometimes creates a false expectation and it usually turns out to be an unsatisfied result for the claimants. Some claimants with serious injuries often argued the awards are too low to fully compensate for the losses sustained by the victim and the families.” p156.<sup>35</sup>

In his concluding comments on reviewing the VICP in Taiwan, Wang<sup>35</sup> has claimed that the existence of the compensation programme contributes to public confidence in the overall national immunisation programme in Taiwan. However, it must be stated that he does not provide any explicit evidence to support this claim and, given the reservations they highlighted regarding claimants’ dissatisfaction with the amount of compensation received, it may be the case that this claim is not justified. For the record, the author’s actual claim is that the VICP in Taiwan “helps maintain public confidence in the national immunization programme.” p156.<sup>35</sup>

#### **3.4.5.7 Question 6: What cost-control mechanisms covering no-fault vaccine damage schemes are reported in the literature?**

In the two papers we have reviewed, there are limited data describing the cost-control mechanisms that may operate in the VICP in Taiwan. However, there are data on the filing deadline and on the caps set for the amount of compensation paid for certain injuries. For example, in the VICP in Taiwan, there is a filing deadline enforced, where the claim must be filed within two years of the knowledge of the injury and within five years of the date of vaccination. [p6<sup>36</sup>]

There are maximum amounts (caps) of compensation to be paid out in the case of specific adverse events related to certain vaccines approved in the Taiwan VICP. It appears that these caps were increased in 2013 with a specific purpose in mind, which the following extract describes quite clearly. According to Wang, “In 2013, caps on some types of compensation were drastically raised in order to better reflect the impacts from vaccine-related injury on the family and the life of the injured person.” p155.<sup>35</sup> Table 4 presents the types of costs compensated and the relevant caps.

**Table 4 Monetary caps on levels of compensation under the VICP in Taiwan**

Costs compensated	Maximum compensation awarded
Death	NT\$6 million
Physical and mental impairments	NT\$5 million
Serious illness	NT\$1 million
Adverse reaction	NT\$200,000

Source: Modified from Wang, Yang, *et al.* p3.<sup>36</sup>

**Key point**

- ***There is a filing deadline of two years from the onset of the injury and five years from the receipt of the vaccine in Taiwan. In addition, there are maximum amounts that can be paid for a specific injury.***

### 3.4.5.8 Summary

In Taiwan, whether vaccines are publicly or self-funded, all injuries related to these vaccines can be compensated through the same limited no-fault VICP. All claims are made to the relevant jurisdictional health bureaus, then progressed to the Centers for Disease Control within the Ministry of Health and Welfare, and then to the Vaccine Injury Compensation Programme Working Group (VICPWG) for review and deliberation

We did not find any explicit data in the two papers we reviewed that estimated the overhead costs of the scheme in Taiwan. However, it would appear that overhead costs are covered by the vaccine manufacturers' levies, which are paid to the Vaccine Injury Compensation Relief Fund.

Measures taken by the adjudication body to speed up the claims handling and adjudication process appear to have been successful in improving timely access to compensation for claimants. In 2013, 98 injury cases were resolved, with an average processing time of 155 days from the date of filing. However, it is also claimed that because the scheme allows for a very broad scope of injuries to be claimed for, there is a danger of creating an administrative overload which can slow down adjudications and hamper timely access to compensation for claimants.

The data would suggest that the mass immunisation campaign which called on the public to be vaccinated with the H1N1 vaccine in order to counter the threat of swine flu led to an increase in claims for compensation. In addition, we infer that improving public awareness of the scheme can also increase the number of claims for compensation, as in the case of the aftermath of the H1N1 vaccine campaign and the increase in applications to the fund.

The standard of proof used appears to limit the number of awards and costs of compensation. Over a 15-year period, 40% of claims were successful. Where there is expert consensus on vaccine-related injuries, this can increase the number of successful claimants for a specific vaccine and its associated injuries. The degree of scientific evidence can affect the standard of proof and therefore the number of awards. Where there is little evidence available on the injuries associated with a vaccine, there is a high proportion of rejected cases.

Regarding whether the scheme enjoys public support or not, there are mixed claims in the literature we reviewed on this issue. For example, it is claimed that there seems to be the potential for dissatisfaction among some claimants when the amount of compensation paid falls short of the maximum limit (or cap). On the other hand, it is claimed that the existence of the compensation programme contributes to public confidence in the overall national immunisation programme in Taiwan. However, this latter claim is not supported by any explicit evidence.

There is a filing deadline of two years from the onset of the injury and five years from the receipt of the vaccine, which may act as a cost-control mechanism. In addition, there are maximum amounts that can be paid for a specific injury.

## 3.5 United States of America

### 3.5.1 Introduction

We included 12 papers that provided data on the VICP in the United States of America (USA). Nine of the papers we included reviewed data that were already published in the health policy and legal literature. In addition, most of these papers also included an examination of case law. For example, Barnes and Burke (2015)<sup>69</sup> reviewed relevant literature about the VICP in the USA; Macleod (2017)<sup>32</sup> included relevant literature about the VICP in the USA and secondary data analysis as part of a comparison between the USA and UK VICPs; and Meyers (2011),<sup>29</sup> Daniels (2010),<sup>70</sup> Grey (2011),<sup>71</sup> Robertson (2017),<sup>72</sup> Walker *et al.* (2013),<sup>73</sup> and Todd (2014)<sup>74</sup> exclusively reviewed both case law and a selection of relevant literature pertaining to the USA VICP.

We included three papers that collected primary data using different methods relating to the VICP in the USA. For example, the Altarum Institute (2009)<sup>75</sup> collected primary data from applicants to the VICP and used qualitative and quantitative data analyses to assess responses. Davis *et al.* (2004)<sup>76</sup> also collected primary data through a time-motion study in two public health clinics (PHCs) in Kansas and Louisiana. The USA's Government Accountability Office (GAO) (2014)<sup>30</sup> examined administrative data and interviewed stakeholders involved in the administration of the scheme.

Finally, Engstrom (2015)<sup>18</sup> used primary data which included data drawn from freedom of information requests and interviews.

In this introduction to the VICP in the USA, we are not going to outline any of the key features of the programme as we have done for some other jurisdictions. The reason for this is that we were able to use our data on the key features of the programme to draw inferences regarding answers to our questions. Therefore, all relevant information on the key features of the VICP in the USA is contained within the following answers to our six questions.

### 3.5.2 Question 1: What design features and/or contextual conditions are thought to impact on the operating costs associated with no-fault vaccine damage schemes?

By 'operating costs', we mean all overhead costs associated with the scheme, such as administrative costs and legal fees. We are excluding any costs that constitute an award for an injury or for pain, suffering, or death.

The design features and/or contextual conditions that we infer impact on the operating costs associated with the no-fault vaccine damage scheme in the USA are the United States Court of Appeals for the Federal Circuit (contextual factor) and the standard of proof (programme design feature).

The United States Court of Appeals for the Federal Circuit (Federal Circuit) made a decision to award pre-merit fees to attorneys representing claimants. The awarding of pre-merit decision interim attorney's fees are costs that are paid before any decision is rendered on the merits of the petition, either favourably or unfavourably.

From the data we analysed, it appears that the introduction of these pre-merit interim fees has significantly added to the overhead costs of the VICP. According to Todd, "For the first twenty-six fiscal years that the VICP operated, it paid nearly [US]\$180 million in attorney's fees and costs. For the first nineteen of those years, however, not a single dime of interim fees (whether pre- or post-merit) was paid. That all changed, however, with the Federal Circuit's decision [to award interim fees and costs]. Since then [circa 2010 to 2014], the VICP has paid over [US]\$16.5 million in interim fees... In fact, interim attorney's fees and costs account for nearly one-fifth of all fees and costs awarded over that same time period." p12-13.<sup>74</sup>

In addition to increasing the overhead costs of the scheme, it would appear that the introduction of pre-merit fees has also shifted the focus within the scheme from adjudicating on merit-based claims to adjudicating on pre-merit claims. According to Todd, "What can be inferred, in part, from this admittedly small sample size is that, everything else being equal, in 2012 (compared to 2008) less of the court's time was likely spent on adjudicating merit-based claims which is the mission of the VICP.

Time and the fixed resources of the court's staff are being spent away from merit decisions to adjudicate these pre-merit-decision interim award disputes at multiple levels of review." p14-15.<sup>74</sup>

From the data we analysed, there does not seem to be any restrictions on the overhead costs relating to the legal representation of the VICP. This has resulted in some authors stating that the VICP has created perverse incentives to litigate endlessly without any fear of punitive costs. According to Todd, "This statutory scheme, as some have noted, creates perverse incentives. With automatic fees if you win and basically automatic fees if you lose there is no reason to ever stop litigating in the VICP. There are multiple levels of appellate review for both the merit decision and now, on top of that, the pre-merit-decision interim fee decision. Thus, there is little downside(at least no economic downside) for an opportunistic attorney, who can exhaust every option on every issue at the ultimate expense of the taxpayer." p14.<sup>74</sup>

An additional implication to the endless pursuit of legal claims within the VICP is that this can inadvertently delay or obstruct the smooth running of the scheme. Todd claims that "Because there is no financial risk to pursuing these claims, including pre-merit-decision interim fees, this unnecessarily clogs and burdens the special masters' and judges' dockets of the court. For instance, for fiscal year 2012, there were 250 successful VICP awards, and there were 37 interim fee awards, for a ratio of 7:1. In 2008 —just a few years earlier— that ratio was 71:1." p14.<sup>74</sup> MacLeod also noted that "By 2013... [US]\$148.6 million was paid in attorneys' fees and costs." p385.<sup>32</sup>

It would appear that certain decisions taken by the special masters within the United States Court of Federal Claims (USCFC) can lead to an increase in overhead costs for the running of the VICP. For example, when the special masters sought to modify the standard of proof for off-Table claims, some of their decisions were then subject to appeals, which led to legal fees and additional overhead administrative costs being used. Daniels highlights this turn of events quite well: "Special masters are heightening the burden of proof for petitioners by imposing more standards for causation than required by statute and case law and questioning the credibility of petitioners' expert witnesses against precedent. The heightened standards in these cases may have severe ramifications, such as an increase in costs due to more appeals, as well as more cases potentially moving out of the Vaccine Program [VICP], which increase the number of lawsuits against vaccine manufacturers, in direct opposition to the original purpose of the Vaccine Program." p81.<sup>70</sup>

In addition to seeking to modify the burden of proof, when the special masters refuse to compensate petitioners who meet the standard of proof required, this can also lead to cases being appealed and an additional overhead cost being incurred, primarily through legal fees. According to Daniels, "failing to compensate petitioners who meet the requirements of Althen [causally connecting the vaccination and the injury, a logical sequence of cause and effect showing that the vaccination was the reason for the injury, and a proximate temporal relationship between the vaccination and injury] will have the effect of increasing the length of time for each case through the appeals process. This will lead to an increased cost for the government and the Vaccine Program [VICP] because attorneys' fees and costs, such as expert witness fees, are awarded by the government as established by the Vaccine Act [National Childhood Vaccine Injury Act of 1986]. This costs the government and the vaccine fund more money." p97.<sup>70</sup>

#### **Key points**

- ***The United States Court of Appeals for the Federal Circuit, as a contextual factor, increased overhead costs by awarding pre-merit interim legal fees following two cases, one in 2008 and the other in 2010.***
- ***The application of the standard of proof can affect the overhead costs of the scheme in the USA. For example, where close calls regarding causation for off-Table cases are to be resolved in favour of injured claimants, this reduces the legal fees for claims, while where traditional tort standards are applied to off-Table cases, this increases the legal fees for claims.***

### 3.5.3 Question 2: What design features and/or contextual conditions are thought to impact on timely access to no-fault vaccine damage schemes?

#### 3.5.3.1 Timely access and administration

By 'timely access', we mean the 240-day statutory limit that Congress agreed when it enacted the National Childhood Vaccine Injury Act in 1986.

We infer from the data that the following design features appear to impact on timely access: administration, the claims handling and adjudication process, the standard of proof, and the vaccines and associated injuries covered in the VICP.

By 'administration', we mean decisions taken (or not taken when they should be) by the Department of Health and Human Services (DHHS) that relate to the scheme.

It is the obligation of the DHSS to provide generic and detailed information to the public and potential petitioners about the VICP. We infer that failure to provide information to the public or potential petitioners can delay or obstruct timely access because if they do not know about the programme or the requirements for filing a claim, they cannot access the programme.

According to the Altarum Institute, when petitioners were surveyed about their experience with the scheme, "respondents had differing opinions on the perceived ease of obtaining information about the VICP: 35.24% felt that the process was very or somewhat easy, and 37.15% found the process very or somewhat difficult. The remaining respondents (27.62%) felt neutral about the ease of obtaining information about the VICP." p21.<sup>75</sup>

We also infer that if the information provided by the DHHS on filing a claim is seen as unhelpful, this can delay or obstruct timely access. The Altarum Institute claims that "respondents had differing opinions on the perceived helpfulness of the initial information provided by the VICP on filing a claim. 34.65% found the information very or somewhat helpful, and 30.69% found the information very or somewhat unhelpful." p22.<sup>75</sup>

We infer that one of the implications of not providing adequate information on filing a claim is that this can lead to petitioners not being happy with the process of claim filing. According to the Altarum Institute, "Respondents most frequently reported feeling 'very dissatisfied' (32.08%) with the process of filing a claim. A further 14.15% were somewhat dissatisfied. In contrast, 15.09% were somewhat satisfied and 18.87% were very satisfied with the process." p27,<sup>75</sup>

We infer that when access to an attorney is difficult, this can delay or obstruct access to the VICP. We make this inference with the knowledge that many authors have claimed that the programme is now beset by legalism, rather than what Congress thought the programme could be when it first enacted the National Childhood Vaccine Injury Act. According to the Altarum Institute, "Many respondents reported difficulty in finding an attorney: nearly one-quarter (22.43%) replied that finding an attorney was very difficult, and another 19.63% felt that finding an attorney was somewhat difficult. One-fifth of respondents (20.56%) felt that finding an attorney was somewhat easy, and 16.82% replied that the process was very easy." p26.<sup>75</sup>

From the empirical data we analysed, it became clear that the changes to the Vaccine Injury Table in 1995 and 1997, which were made by the DHHS, had many implications for the VICP. One of these implications is that it affected the congressional intent to resolve claims within 240 days statutory limit and therefore obstructed timely access to the scheme. Three papers we drew data from, Meyers,<sup>29</sup> Barnes and Burke,<sup>69</sup> and Engstrom,<sup>18</sup> all outline how these changes affected access to the scheme, primarily by removing conditions from the Vaccine Injury Table, redefining illness, and adding vaccines without injuries.

Barnes and Burke outline in great detail how these changes came about: "Through a rulemaking process in 1995, residual seizure disorder and hypotonic-hypo responsive episode were struck from the [Vaccine Injury] Table, and encephalopathy was more precisely defined...These revisions...were the first and most controversial of many rulemaking processes...[the DHHS] has added nine more vaccines, but has added few injuries associated with those vaccines to the Table. The net effect...was

to vastly reduce claims that could be made under the Table's streamlined administrative procedure, and to increase the number of off-Table claims... Congress originally mandated that the program resolve claims within a year, but the [VICP] met this standard in just 14% of cases, with more than half the claims taking more than two years, and 18% taking more than five years." p169-171.<sup>69</sup>

Engstrom<sup>18</sup> points out that the changes to the Table in 1995 and in 1997 have increased the number of off-Table claims, which means that the process of resolving a claim now takes much longer than the 240-day statutory limit. According to Engstrom, "While 74% of petitions sought compensation for on-Table injuries prior to 1995, only 55% did by 1999, and now, only about 2% of VICP petitions proceed down the on-Table path... This migration away from the Table has had ripple effects, touching every corner of VICP administration. Compared to on-Table petitions, off-Table petitions... are more likely to be contested, rather than conceded, and once contested, take longer to prepare, longer to present and longer to decide." p1702-1706.<sup>18</sup>

Meyers also points out that the off-Table claims now seem to delay and obstruct timely access; for example, "These changes in the Table have resulted in other major changes in the operation of the program. The cases are now substantially more difficult, complex, and time-consuming to litigate. The science is less clear, and the special masters have much more difficult and complex scientific disputes to resolve than they did for the relatively simpler Table injury claims. Both petitioners' counsel and government counsel now need to search for experts in cutting-edge medical areas, such as genetics and neurology, where a great deal of uncertainty still exists." p790.<sup>29</sup>

As Meyers<sup>29</sup> points out, one of the implications of the 1995 changes has been the shift to off-Table claims. According to Meyers, "These off-Table cases often involve complex medical questions about which there is likely to be no definitive consensus among experts. This has become a particular problem for the Vaccine Program [VICP] because of the dramatic shift from the early years of the program, 1989 to 1992 when more than 90% of the petitions filed asserted Table injuries, to the most recent years, 2007 to 2010, when almost 90% of the petitions filed assert only non-Table injuries." p798.<sup>29</sup>

### **3.5.3.2 Claims handling and adjudication process**

What we mean by 'claims handling and adjudication process' is the work and the decisions taken in the USCFC, including the work and decisions taken by the special masters. Central to this work are all the efforts that go into resolving claims. Our analysis of the data suggests that there are many impediments to the speedy resolution of claims.

The congressional intent behind the scheme was that all claims would be resolved within the 240 day statutory limit. Walker *et al.* (2013) outline the principles underpinning this intent: "The legislative history of the statute states as a goal the establishment of 'a Federal no-fault compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity'. Congress intended the VICP to be 'fair, simple, and easy to administer', and hoped that 'a more stable childhood vaccine market will evolve'." p193.<sup>73</sup>

Engstrom<sup>18</sup> and Meyers<sup>29</sup> provide us with empirical data to suggest that the 240-day limit is not being adhered to. According to Engstrom, "despite Congress's high hope and clear demand, the VICP in action is notable not for its speed but rather for its long times to decision. Few petitions (less than 5%) satisfy the statutory 240-day deadline. Most exceed it by a wide margin... Of petitions filed between 1999 and March 31, 2014, the Program's average adjudication time clocked in at about five-and-a-half years, while most petitions (51%) remained pending for over a half-decade." p1685.<sup>18</sup>

According to Meyers, "The adjudications today are typically not informal at all, virtually no cases are concluded within the 240-day deadline, and the Vaccine Injury Table, which was originally a central feature of the Vaccine Act and a key innovative provision of the Act, has been significantly changed and narrowed over the years so that today it plays only a limited role in Vaccine Act cases." p789.<sup>29</sup>

When Congress enacted the programme, part of the rationale was to move compensation claims away from the tort system, as it would speed up the resolution of claims. However, according to Engstrom,<sup>18</sup> it appears that the scheme is not delivering on this objective. Engstrom points out that "Critically, it takes more time, on average, to process claims within the Program than it does to process claims within the traditional tort system: approximately 66 months within the VICP, as

compared to 25.6 months for tort cases that terminate in a judgment or verdict...And, VICP petitions appear to take substantially more time to resolve than medical malpractice claims, which, in terms of injury severity and scientific complexity, probably offer the closest comparator.” p1686-1687.<sup>18</sup>

However, there may be unique reasons as to why the scheme seems to be very slow in resolving claims. According to Engstrom, “There is an argument that the above delays are unique to the VICP... that the VICP has twice been hit by an onslaught of unanticipated filings... (i.e., claims for vaccine injuries sustained prior to the Act’s October 1988 effective date). Exactly 4,500 such claims were filed [and] created a backlog...Then, just as the VICP dug itself out from that mountain of retrospective cases, the Program got hit a second time by a barrage of petitions (over 5,500 in all) alleging a link between [measles] vaccines and autism.” p1688.<sup>18</sup>

The GAO, in its 2014 review of the scheme, presented additional empirical data to support the claim that the 240-day limit is not being adhered to: “VICP claims filed since fiscal year 1999 took an average of about 5-and-a-half years to adjudicate, according to data for the nearly 8,800 claims filed since fiscal year 1999 that were adjudicated as of March 31, 2014... For claims filed since fiscal year 2009, a greater percentage of claims were resolved within 1 or 2 years. One possible reason is that the vast majority of claims alleging autism as the injury were filed prior to fiscal year 2009... According to data, for the more than 1,400 claims filed since fiscal year 2009 that were adjudicated as of March 31, 2014, the average amount of time to adjudicate a claim was 587 days (about 1.6 years). More than 900 (40 per cent) of the claims filed since fiscal year 1999 were still pending, which could cause this average to increase over time as these pending claims are resolved.” p9-11.<sup>30</sup>

The GAO also provides us with a number of reasons why it takes quite a long time to process and resolve claims. According to the GAO, “Officials at USCFC and DOJ [Department of Justice] told us that the time petitioners spend gathering supporting documentation or evidence can add significantly to the amount of time required to process a claim. These delays may occur at multiple points in the claims process, from petitioners needing to gather sufficient documentation for the court to begin an initial review, to the court needing documentation to determine the amount of compensation that a successful petitioner will receive. According to HRSA [Health Resources and Services Administration], for claims adjudicated as of March 31, 2014, its medical review process averaged over 700 days for claims filed in fiscal year 2010. HRSA attributes the length of time for medical review primarily to time spent waiting for petitioners to submit requested documentation. During the medical review, HRSA may also consult with external experts, who require additional time to review the details of the case; HRSA’s data indicate that over 1,200 outside reviews were conducted from fiscal years 2009 to 2014. Additionally, when special masters are reviewing the claim, a party may request that the special master delay a decision until additional documentation is available. Special masters may also request additional information from petitioners—such as a specialist physician’s opinion.” p12-13.<sup>30</sup>

Part of the reason for the delay in resolving claims seems to be the large amount of discretion given to the special masters, which allows them to request additional information from the claimants. According to Robertson, “Requesting scientific evidence beyond what the expert has already researched and posited adds even more time to the litigation process...but the discretion granted to the special masters allows them to place additional time-consuming burdens on petitioners, and, ultimately, the Program as a whole. A lack of uniformity stems from the high level of discretion granted to special masters in the Program.” p526.<sup>72</sup>

The empirical data suggest that the length of the claims process is way beyond the 240 days statutory limit endorsed by Congress, thus delaying timely access to the scheme. According to the Altarum Institute, “In 2007, the average claim processing time was 1,337 days or nearly three-and-a-half years. The majority of respondents were dissatisfied with the length of the claims process. Almost half of the respondents (46.60%) were very dissatisfied with the length of the process, and a further 17.48% were somewhat dissatisfied with it.” p31.<sup>75</sup>

We infer that if petitioners are dissatisfied with the hearing process, it could suggest that timely access is adversely affected. The Altarum Institute claimed that “Almost one-third of respondents (30.48%) were very dissatisfied with the hearing process and an additional 6.67% were somewhat dissatisfied. In contrast, only 17.14% were very satisfied and 13.33% were somewhat satisfied.” p28.<sup>75</sup>



One of the few ways that timely access can be improved depends on the type of adjudication carried out in the VICP. There seem to be three types of adjudication that the Court of Federal Claims can choose to undertake. According to the GAO, “For claims that are compensated, there are three adjudication categories:

- Concession. In a concession, the [D]HHS’s review of medical records, scientific literature, and other documents finds that the petitioner is entitled to compensation, because the evidence meets the criteria of the Vaccine Injury Table or because it is more likely than not that the vaccine caused the injury.
- Negotiated settlement. In a negotiated settlement, the petition is resolved via negotiation between the [D]HHS (represented by DOJ) and the petitioner.
- Contested decision in favor of the petitioner. If the [D]HHS does not concede that a petition should be compensated or if both parties do not agree to settle, the special master issues a decision after weighing the evidence presented by both sides, which may involve conducting a hearing.” p7.<sup>30</sup>

From these three types of adjudication, there is some evidence that suggests that negotiated settlements can speed up timely access. According to the GAO, “Most of the VICP claims filed since fiscal year 1999 have taken multiple years to adjudicate, but those filed since fiscal year 2009 have taken less time. For many claims, the parties have concluded the proceeding through a negotiated settlement, rather than a contested decision adjudicated by a special master or the courts. Additionally, certain claims were addressed along with similar claims as part of an omnibus proceeding or informal grouping.” p9.<sup>30</sup>

### **3.5.3.3 Standard of proof**

By ‘standard of proof’, we mean two separate dimensions. Traditionally in the USA’s VICP, dimension one is the Vaccine Injury Table with associated injuries included in the Table for each vaccine. The second dimension is the standard of proof for determining off-Table injuries which are related to vaccines in the Table but which do not have the scientific consensus regarding the injuries claimed for. From the data we analysed, it would appear that the Althen (causation) ruling, which derived from the Federal Circuit, is the standard of proof required for off-Table claims.

We will now make a case for the claim that the difficulties observed in determining standard of proof, particularly for off-Table claims, can greatly delay and obstruct timely access for claimants. For example, Grey provides us with empirical data to suggest that the overwhelming amount of claims in the current context are made for off-Table injuries. According to Grey, “the number of off-Table claims has come to far surpass the number of Table claims. They now likely account for 90% of all claims.” p345.<sup>71</sup>

From our analysis of the data, it would appear that the issue of determining the standard of proof for off-Table claims continues to beset the VICP. One of the reasons for this is that the original National Childhood Vaccine Injury Act does not provide clear direction to help deal with this issue, and Grey provides us with empirical observations to support this claim. According to Grey, “The Vaccine Act itself does not supply a standard, nor has precedent under the Act clarified the issue. The primary question is whether the program should, or could, require the same sufficiency of evidence standard used in the common law tort context and still promote the goals of the program. Striking the appropriate balance on the causation issue is critical because requiring too high a standard would leave worthy victims uncompensated and potentially threaten the vaccine manufacturing market, while too low a standard could open the floodgates to unworthy claims and suggest to the public that vaccines present risks that outweigh their benefits.” p346.<sup>71</sup>

In addition to the deficiencies in the earlier draft of the Vaccine Act, the role of science has not helped to resolve this issue either. As Grey draws our attention to, “Congress apparently expected that as evidence developed, the [D]HHS would expand the Table to list additional combinations of injuries and vaccines, and the need for off-Table claims would be reduced or eliminated. Congress’s assumptions have not been realized, however, because the science has not developed as anticipated—mostly because vaccine side effects are so rare that they are hard to study.” p346.<sup>71</sup>

One of the implications arising from this dispute on the standard of proof required for off-Table claims is that the decision-making process can be greatly slowed down to allow the various actors to advance their cases. According to Barnes and Burke, “The parties and their lawyers in off-Table cases frame the issues and gather the evidence, which is presented to the special master. In these respects, the VICP today roughly parallels the tort law system it replaced, although the process is far more centralized than ordinary tort litigation.” p169-171.<sup>69</sup>

A key contextual element (empirical observation) that has recently entered this debate has been the intervention of the Federal Circuit, which has been called upon to provide some direction in determining the standard of proof for off-Table claims. According to Meyers, “The present focus of the Vaccine Program [VICP] on virtually all off-Table cases has also resulted in a series of recent decisions from the U.S. Court of Appeals for the Federal Circuit, purportedly clarifying but sometimes confusing the standards that the special masters are required to apply in deciding off-Table cases. A number of the Federal Circuit’s recent rulings have observed that Congress intended compensation to be provided generously, and that close calls regarding causation are [to be] resolved in favor of injured claimants. To the contrary, other recent Federal Circuit rulings have emphasized the importance of strict compliance with traditional tort standards of causation. Such inconsistencies have illuminated the need for clear standards.” p790-791.<sup>29</sup>

The lack of agreement on clear standards for determining standard of proof for off-Table injuries appears to also impact on the decision-making by the special masters in the USCFC. According to Meyers, “In vaccine cases where no Table injury claim can be made the special masters have much more difficult and complex issues to decide. In such off-Table cases, the special masters must base their decisions on medical opinions or published articles linking the vaccine to the injury involved in the case. These off-Table cases often involve complex medical questions about which there is likely to be no definitive consensus among experts. This has become a particular problem for the Vaccine Program [VICP] because of the dramatic shift from the early years of the program, 1989 to 1992 when more than 90% of the petitions filed asserted Table injuries, to the most recent years, 2007 to 2010, when almost 90% of the petitions filed assert only non-Table injuries.” p798.<sup>29</sup>

The ultimate impact of the above issues relating to determining the standard of proof is that timely access to the scheme has been greatly affected. Indeed, Meyers adequately captures the true effect on the programme as follows: “The cases are now substantially more difficult, complex, and time-consuming to litigate. The science is less clear, and the special masters have much more difficult and complex scientific disputes to resolve than they did for the relatively simpler Table injury claims.” p790.<sup>29</sup>

The implication of the lack of scientific consensus has also been highlighted by Engstrom, who posits the claim that this is one of the central reasons why the VICP has failed to deliver timely access to awards for applicants. According to Engstrom, “when assessing why the VICP has stumbled, some of the blame ought to be laid here: at the elemental scientific uncertainty at the root of the causal inquiry...This yields a pair of crucial insights: (1) If particular injuries are not traumatic, visible, or otherwise obvious, causation questions are unlikely to be easily resolved, and (2) in such cases, adjudications are unlikely to be predictable, simple, or swift. Indeed, many of a no-fault system’s supposed benefits appear to dissipate the moment those systems confront causation questions steeped in scientific uncertainty.” p1699-1701.<sup>18</sup>

One of the empirical decisions taken by the special masters and arising from the lack of scientific consensus linking injuries with vaccines was to heighten the standard of proof. According to Daniels, “Instead of using the standards set forth in the Vaccine Program [VICP], special masters heightened the burden for petitioners by: (1) imposing more standards of causation than required by statute and case law, and (2) questioning the credibility of petitioners’ expert witnesses in certain cases in opposition to established precedent.” p89.<sup>70</sup>

This empirical decision by the special masters was subsequently overturned by the Federal Circuit when it instituted what has become known as the Althen causation ruling. According to Daniels, “The three-prong test from Althen resulted from a special master’s decision to impose a five-prong test for petitioners to meet in order to receive compensation in the Program...The special master determined that because the petitioner did not provide peer-reviewed literature, she did not qualify for compensation. Upon review, the Federal Circuit determined that the application of the five-prong

test was contrary to law, stating that both prongs two and three of the test ‘contravene the plain language of the statute’. The Federal Circuit held that requiring medical literature ‘impermissibly’ raised petitioner’s burden and was in direct conflict with the statute’s allowance of medical opinion as proof. Finally, the Federal Circuit noted that the role of the special master is ‘not to craft a new legal standard’.” p90.<sup>70</sup>

The implication of the USCFC setting forth its own requirements for establishing the burden of proof for off-Table claims is that this can delay or impede timely access. Indeed, some authors have argued that the implications can go even wider than delaying timely access. For example, according to Daniels, “Special masters recently drifted from using established precedent and documented congressional intent, heightening the burden on petitioners in the Vaccine Program [VICP]. If this trend continues, the ramifications will extend beyond simply making compensation in the Vaccine Program more difficult and could jeopardize the very foundation of the Vaccine Program itself.” p96.<sup>70</sup>

From our analysis of the data, it would appear that changes to the number and types of vaccines and associated injuries covered by the VICP can impact timely access. In particular, a number of changes made to the Vaccine Injury Table by the DHHS in 1995 and 1997 seem to have had a detrimental impact on timely access to awards for claimants. Barnes and Burke neatly encapsulate these events in the following empirical observation: “Through a rulemaking process in 1995, residual seizure disorder and hypotonic-hypo responsive episode were struck from the Table, and encephalopathy was more precisely defined...These revisions...were the first and most controversial of many rulemaking processes...[the DHHS] has added nine more vaccines, but has added few injuries associated with those vaccines to the Table. The net effect...was to vastly reduce claims that could be made under the Table’s streamlined administrative procedure, and to increase the number of off-Table claims... Congress originally mandated that the program resolve claims within a year, but the [VICP] met this standard in just 14% of cases, with more than half the claims taking more than two years, and 18% taking more than five years.” p169-171.<sup>69</sup>

The implications of removing these injuries from the Table are neatly encapsulated in the following empirical extract from Engstrom: “Because the Department of Health and Human Services ([D]HHS) removed the injuries that had been the most frequently utilized by petitioners, the practical effect of these additions and subtractions was to shrink the Table’s scope, and importance, dramatically. While 74% of petitions sought compensation for on-Table injuries prior to 1995, only 55% did by 1999, and now, only about 2% of VICP petitions proceed down the on-Table path.” p1702-1706.<sup>18</sup>

In addition to removing the injuries listed from the Table, the DHHS also has the power to add new vaccines to the Table. Since 1988, the DHHS has added a number of new vaccines to the Table, but did not have the scientific evidence to add associated injuries. This meant that claims for injuries relating to these vaccines had to proceed off-Table and, as many authors have pointed out, this has implications on timely access to awards for claimants. For example, according to Meyers in the following empirical extract, “the nine vaccines added to the Table by the Secretary of [D]HHS since 1988 generally have no specified Table injuries at all or have the immediate onset of anaphylactic shock as the only listed Table injury. These changes in the Table have resulted in other major changes in the operation of the program. The cases are now substantially more difficult, complex, and time-consuming to litigate. The science is less clear, and the special masters have much more difficult and complex scientific disputes to resolve than they did for the relatively simpler Table injury claims. Both petitioners’ counsel and government counsel now need to search for experts in cutting-edge medical areas, such as genetics and neurology, where a great deal of uncertainty still exists. This contributes to a much more adversarial process than was supposed to exist in a program that was designed to be less adversarial.” p790.<sup>29</sup>

As Meyers has pointed out above, moving deliberations into a more adversarial process means that applicants are now obliged to demonstrate that the vaccine caused the alleged injury. This is a further implication of the DHHS decision to add vaccines to the Table without associated injuries. According to the GAO, “Since fiscal year 1999, [D]HHS has added six vaccines to the Vaccine Injury Table, but it has not added covered injuries associated with these vaccines to the Table. This means that while individuals may file VICP claims for these vaccines, each petitioner must demonstrate that the vaccine that was administered caused the alleged injury.” p1.<sup>30</sup>

Another implication of the decision by DHHS to include vaccines on the Table without associated injuries is that this can delay the process whereby the special masters can make decisions about awarding claims. For example, Meyers speculated that “In vaccine cases where no Table injury claim can be made the special masters have much more difficult and complex issues to decide. In such off-Table cases, the special masters must base their decisions on medical opinions or published articles linking the vaccine to the injury involved in the case. These off-Table cases often involve complex medical questions about which there is likely to be no definitive consensus among experts. This has become a particular problem for the Vaccine Program [VICP] because of the dramatic shift from the early years of the program, 1989 to 1992 when more than 90% of the petitions filed asserted Table injuries, to the most recent years, 2007 to 2010, when almost 90% of the petitions filed assert only non-Table injuries.” p798.<sup>29</sup>

The changes to the Vaccine Injury Table in 1995 and 1997, which included the removal of injuries and addition of new vaccines without associated injuries, are said by some authors to be tantamount to creating a new and second VICP. Meyers speculated that “The National Vaccine Injury Compensation Program changed substantially in 1995, when the Secretary of [D]HHS announced modifications to the Vaccine Injury Table that would drastically change not only the Table, but also the nature of the Vaccine Compensation Program. The Table changes have in effect created a new and different vaccine compensation program.” p799-800.<sup>29</sup>

#### **Key points**

- ***When administration fails to provide adequate information about the VICP, this can affect timely application for compensation in the USA.***
- ***The lack of clear guidelines on what vaccine-related injuries can be compensated also delays timely access to compensation in the USA.***
- ***The claims handling and adjudication process delays timely access to compensation through its tort-like approach and the definitive scientific information requirements of some special masters in the USA.***
- ***The application of an unclear standard of proof due to not describing the standard of proof in legislation and varying interpretation of court guidance by special masters can affect timely access to compensation in the USA.***
- ***How vaccines and vaccine-related injuries are covered in the VICP can affect timely access to compensation in the USA; for example, on-Table versus off-Table injuries.***
- ***Adding vaccines to the Vaccine Injury Table without the associated injuries shrinks the Table’s scope and the VICP’s ability to deal with injuries in a timely manner in the USA.***

#### **3.5.4 Question 3: What design features and/or contextual conditions are thought to impact on the number of applicants seeking redress via no-fault vaccine damage schemes?**

We claim that the design features and/or contextual conditions that in some way affect the number of applicants seeking redress via no-fault vaccine damage schemes are administration and the vaccines and vaccine-associated injuries named in the Vaccine Injury Table.

It is the responsibility of DHHS administration to provide adequate information about the VICP to make the public aware of its existence. The following extract neatly encapsulates the precise responsibilities of the DHHS in this regard. According to the report by the GAO “[D]HHS is required to include a statement of the availability of VICP in the vaccine information materials that health care providers are to distribute to the parent or legal representatives of a child or to any other individual to whom the provider intends to administer a covered vaccine... HHS is also required to undertake reasonable efforts to inform the public of the availability of the program.” p9.<sup>30</sup>

However, a relatively recent review of the VICP suggests that the DHHS is failing to meet its responsibility of making the public aware of the scheme, and it appears that this failure can impact on the number of applicants making claims to the scheme. According to the GAO “Even with the requirement to provide these vaccine information materials stakeholders claim that the public are largely unaware of the programme and ‘this lack of awareness contributes to missing filing deadlines and individuals being denied the opportunity for compensation’.” p32.<sup>30</sup>

When vaccines are added to the Vaccine Injury Table without associated injuries, this can lead to an increase in the number of claims going off-Table. According to the GAO, “[D]HHS has added vaccines to the Vaccine Injury Table without adding covered injuries associated with those vaccines. Following their addition to the Table, more claims were filed for off-Table injuries. Since fiscal year 1999, HHS has added six vaccines to the Vaccine Injury Table but has not added covered injuries associated with these vaccines to the Table.” p16-17.<sup>30</sup>

When vaccines are recommended for adult use, as in the case of vaccines to prevent influenza, this is also seen in the number of claims alleging injuries associated with these vaccines. According to the GAO, “Claims alleging injuries to adults also increased as a result of the addition of vaccines that are recommended for administration in adults (as well as children) to the Vaccine Injury Table.” p20.<sup>30</sup>

#### **Key points**

- ***How administration informs the public about the VICP can affect the number of claims for compensation; failure to inform the public leads to a reduction in claims in the USA.***
- ***How vaccines and their associated injuries are covered under the VICP can increase or reduce the number of approved claims for compensation in the USA; removing vaccines and their associated injuries and not listing vaccine injuries leads to a reduction in approved claims. Alternatively, adding new vaccines leads to an increase in claims.***
- ***The application of an unclear standard of proof due to not describing the required standard of proof in legislation and varying interpretations of court guidance by the special masters in the USA can affect timely access to compensation.***

### **3.5.5 Question 4: What design features and/or contextual conditions are thought to impact on the volume and costs of awards made under no-fault vaccine damage schemes?**

By ‘volume’, we mean the number of awards made, and by ‘cost’, we mean the amount of money paid out to claimants for any or all of the following: a) for actual injury related to the vaccine, b) for death of claimant, c) for medical bills, and/or d) for pain and suffering. We exclude overhead costs, including legal costs, which we have covered in Question 1. However, we do acknowledge that some authors may not have made this distinction explicit and, where necessary, we will seek to draw attention to this in the text.

The design features and/or contextual conditions that we, the review authors, claim affect the volume and costs of awards are scheme administration and standard of proof.

The DHHS has primary responsibility for looking after administrative aspects of the VICP. Part of this responsibility is its power to add new vaccines to the Table. From the data we analysed, it would appear that the addition of new vaccines to the Table can lead to an increase in the number of awards given to adult claimants but not to children. According to Meyers, “In the Vaccine Compensation Program’s early years, the overwhelming majority of the cases brought, and compensation awarded, involved injuries to children. This has changed dramatically, and in the past few years the majority of cases brought, and awards made, have involved adults...The principal reason for this change appears to be the addition of seasonal flu vaccines to the Vaccine Act in 2005, and the widespread use of these vaccines by adults. A total of 2,713 awards [to adults] have been made in the Vaccine Compensation Program through to September 9, 2011.” p795.<sup>29</sup>

The empirical observations outlined by Meyers above are also supported by empirical data from the report by the GAO regarding the increase in awards made to adult petitioners: “According to the Office of Special Masters, the increase in the total amount paid to petitioners in compensation and number of compensated claims is related to the addition of the influenza vaccine to the Vaccine Injury Table. The influenza vaccine, which is administered to millions of people each year, was added to the injury table in fiscal year 2005.” p25.<sup>30</sup>

In the absence of explicit data showing a relationship between a distinct feature of the programme and changes to the overall volume of awards and costs incurred therein, we are using an inferential claim put forward by Grey to suggest that legal interpretations by the Federal Circuit may be associated with an increase in the pool of claimants compensated under the VICP. According to Grey,

“the increased frequency of [off-Table] claims, combined with Congress’s lack of direction regarding their resolution, have left the special masters and courts in charge of implementing the program to struggle with the sufficiency of evidence question and how much to be influenced by traditional tort law. The Federal Circuit, in interpreting the sufficiency of evidence for causal proof in off-Table claims, has leaned toward lower sufficiency standards, thereby increasing the pool of claimants compensated under the program and reducing the potential number of claimants who could later seek redress in court.”<sup>71</sup>

However, this inferential claim by Grey may not represent the full picture of interpretation arising in the Federal Circuit. According to Meyers, there are two streams of thought relating to the interpretation of the standard of proof for off-Table decisions that arise in the Federal Circuit. It may well be the case that either or both of these streams of thought can impact on the volume of awards given out under the VICP. As Meyers has pointed out, “These legal standards are noncontroversial and widely accepted. However, a controversy emerged from a line of Federal Circuit cases... In these cases, the Federal Circuit emphasized that close calls regarding causation are [to be] resolved in favor of injured claimants. Such a rule is consistent with Congress’s intent that the vaccine law create a generous compensation program that was to be liberally construed in favor of compensating injured petitioners. However, a second line of cases... takes a very different perspective, emphasizing that traditional tort standards should be strictly applied to off-Table cases.” p802-803. <sup>29</sup>

From the papers we reviewed, the work by Macleod is the only paper that provided us with an overall amount of the costs of awards awarded to victims. Macleod states that “By 2013, [US]\$2.24 billion had been awarded to vaccine victims in 14,214 claims, [US]\$148.6 million paid in attorneys’ fees and costs, and there was a surplus of [US]\$3.404 billion in the VICP Trust Fund. Roughly two out of three plaintiffs are denied compensation (31%).” p385. Of note, by 2013, 69% of claims were successful. The average individual award was US\$157,591, excluding legal costs. The legal costs paid by the scheme consumed 6.2% of the total award budget.<sup>32</sup>

#### **Key points**

- ***When the USA administration makes changes to the Vaccine Injury Table, this can affect the number of awards for compensation; there was an increase in awards to adults as a result of adding the influenza vaccine to the Vaccine Injury Table, and a decrease in awards is seen when vaccines and/or injuries are removed from the table.***
- ***The interpretation of the standard of proof positively or negatively affects the number of awards compensated in the USA. For example, the Federal Circuit emphasised that close calls regarding causation for off-Table cases are to be resolved in favour of injured claimants. However, a second line of cases adjudicated by some special masters indicates that traditional tort standards were applied to their cases.***

#### **3.5.6 Question 5: Do no-fault vaccine damage schemes enjoy public acceptance?**

We did not locate any papers that sought to directly measure or report on the actual level of public acceptance that the VICP in the USA enjoys. Therefore, we have decided to use what we are calling a number of proxy fits to make some inferences regarding how stakeholders and the public feel about the VICP in general.

One paper that we drew data from suggests that there are concerns with delays in resolving claims and with the overly adversarial nature of the cases. In addition, there are also concerns about the level of attorney’s fees. According to Grey, “After the Vaccine Compensation Program had been operating for a decade, three major US[A] government organizations evaluated and published reports on the program—the Federal Judicial Center, the U.S. Government Accountability Office (GAO) [the 1999 review], and the House Subcommittee on Criminal Justice, Drug Policy, and Human Resources. The three reports raised similar concerns about the operation of the Vaccine Program, including delays in resolving cases that stretched far beyond the statutory 240-day statutory limit, and the overly adversarial nature of the cases in a compensation program intended to be less adversarial. All three reports also noted concerns about payment of attorneys’ fees, including concerns that the fees were too low, took too long to process, and were subject to unnecessarily adversarial review by Department of Justice (DOJ) attorneys. These same concerns have continued to be raised by others, and they remain valid today. Problems with delays and the overly adversarial

nature of the program have been exacerbated by the change in the Vaccine [Injury] Table and the related developments described above.” p804-805.<sup>71</sup>

We would expect that in order for the public to express their confidence – or lack thereof – in the VICP, it would be necessary for them to be aware of the scheme’s existence. As we have already noted, it is the DHHS’s responsibility, under the Vaccine Act, to provide adequate information about the VICP to the public. However, there appear to be some deficits in fulfilling this responsibility, as reported in some of the papers we have reviewed. According to the GAO, “HRSA has acknowledged being criticized for years for not adequately promoting public awareness of VICP, and has recently taken some steps...to improve its efforts to reach out to providers and the public... HRSA noted that one of the critical issues facing the program from 2005 to 2010 was that many parents, the general public, attorneys, and health care professionals were not aware VICP existed... In each of HRSA’s annual justification of estimates for appropriations committees for fiscal years 2011–2014, HRSA noted that the agency has been criticized for not adequately promoting public awareness of the VICP. HRSA officials also noted the need to carefully balance messages that increase awareness of VICP with public health messages that encourage and promote immunizations.” p31.<sup>30</sup>

One of the implications of not providing adequate information to the public is that potential claimants may fail to submit a claim within the statutory three-year limit that is imposed. According to the GAO, “Without awareness of the program, individuals who might otherwise receive compensation for a vaccine-related injury or death could be denied compensation because of a failure to file their claim within the statutory deadlines. One stakeholder commented that the public is largely unaware of the program, and this lack of awareness contributes to missing filing deadlines and individuals being denied the opportunity for compensation. Members of the Advisory Commission on Childhood Vaccines also told us that many individuals may not know there is a statute of limitations on filing a claim and many miss the opportunity to file a claim because of the statute of limitations.” p32-33.<sup>30</sup>

We know from the data analysed that it is an obligation to provide information about the VICP in vaccine clinics when children or adults are receiving a vaccination. However, yet again there appears to be deficit in the fulfilment of this obligation. According to Davis *et al.*, “United States law requires that immunization providers use Centers for Disease Control Vaccine Information Statements (VISs) and inform parents about vaccine risks and benefits prior to every childhood immunization. A recent national survey found that public health clinics (PHCs) reported high compliance with this law. To further investigate these findings, we [Davis *et al.*] conducted an immunization time-motion study in two PHCs in Kansas and Louisiana... The national Vaccine Injury Compensation Program (VICP) was never discussed.” p228.<sup>76</sup>

Notwithstanding the deficits above in the information provided to the public about the VICP, there is some evidence available to suggest how the public does actually learn about the scheme. According to the Altarum Institute, “Many respondents learned about the Program through unofficial sources. One-quarter of respondents (25.23%) learned about the Program from a Web site other than the one maintained by the VICP. However, the VICP Web site was the second most frequently reported source (17.76%).” p20.<sup>75</sup>

In addition to learning about the VICP through unofficial sources, there is evidence that members of the public also receive information through official sources. According to the Altarum Institute, “Common health care-related sources of VICP information included the health care provider who gave the vaccine (12.15%), another health care provider (13.08%), and the Vaccine Information Statement (VIS) (7.48%) that is given to the patient or parent/guardian with each vaccination. Relatively few respondents found out about the Program through advertising: 6.54% read about it in a newspaper or magazine, 5.61% heard about it on the radio or television, and 2.80% saw a flyer or brochure from the VICP. Four respondents (3.74%) found out about the VICP when they were contacted by the CDC [Centers for Disease Control and Prevention]. Other sources of information included other parents or adults who had been involved with the VICP (12.15%), attorneys (11.22%), and the National Vaccine Information Center (2.80%), a private advocacy organization.” p20.<sup>75</sup>

One of our proxy fits is to infer that satisfaction with the VICP may be an indication of public acceptance. Drawing on a small survey of petitioners, we have some data to show that respondents were satisfied with some elements of the VICP. For example, according to the Altarum Institute,

“Receipt of a financial award is associated with increased satisfaction with all relevant elements of the claims process addressed in the survey.” p36.<sup>75</sup>

When it comes to assessing satisfaction with the process of determining damages, survey respondents were less satisfied with this element of the VICP. According to the Altarum Institute, “Respondents tended to be dissatisfied with the process for determining damages; nearly one-third (30.77%) were very dissatisfied and 12.31% were somewhat dissatisfied. Only 9.23% were very satisfied and 23.08% were somewhat satisfied. Almost one-quarter of respondents (24.62%) were neither satisfied nor dissatisfied with the process.” p29.<sup>75</sup>

In contrast, survey respondents seemed to be more satisfied with how awards are paid out. According to the Altarum Institute, “Respondents were generally satisfied with how the awards are paid, but feel that the compensation is inadequate... In general, they were satisfied with the method [of payment]. More than half of the respondents were very satisfied (37.70%) or somewhat satisfied (18.03%), while less than one-fifth were very dissatisfied (9.84%) or somewhat dissatisfied (8.20%). About one-quarter of respondents (26.23%) were neither satisfied nor dissatisfied.” p33.<sup>75</sup>

When respondents were asked whether they were satisfied that the amounts paid out in awards were adequate, they tended to express dissatisfaction. The Altarum Institute claimed that “Respondents were asked whether the amount of the award was adequate to cover past and future medical care not reimbursed by other sources. In contrast to respondents’ general satisfaction with the method of payment, most respondents felt that the award amount was inadequate. Nearly one-third felt that the award amount was very inadequate (31.75%) and 19.05% felt that it was somewhat inadequate. Only 6.35% of respondents felt that the award amount was very adequate and 23.81% felt it was somewhat adequate.” p34.<sup>75</sup>

From the data we analysed, it would appear that certain decisions taken within the USCFC did not receive public acceptance. This may be an indirect means of assessing how members of the public feel about the internal workings of the VICP. According to Daniels, “Consumers injured from vaccines have a statutory right to be compensated for their losses. By denying compensation for claims that satisfy the three-prong Althen test [of causation], petitioners continue to wait for compensation to take care of medical bills, lifestyle changes (such as necessary physical, occupational, and speech therapy), or expenses related to death injuries. Petitioners are waiting longer to be compensated, if at all, and experience a longer, more stressful, and litigious process than the legislatively directed ‘quick’ and ‘generous’ process.” p103.<sup>70</sup>

An additional indirect measure of public acceptance within the scheme can be inferred from recent events outlined by Daniels. Daniels posits the claim that if the scheme continues to overly rely on the legal route, there may be a threat to public health by vaccine manufacturers who withdraw their vaccines from public use or stop making vaccines altogether. According to Daniels, “The primary goal of the Act [National Childhood Vaccine Injury Act of 1986] was to limit lawsuits against vaccine manufacturers and Congress believed this would best be accomplished by directing potential lawsuits into a generous forum: the Vaccine Program [VICP].”<sup>70</sup>

Certain decisions taken by the DHHS in 1995 that changed the Vaccine Injury Table appear not to have been well received by members of the public. The following extract from Barnes and Burkeneatly encapsulates the effects of the 1995 changes on the public: “The amendments to the Table [in 1995] also changed the politics of the program. Not surprisingly, as in the case of Social Security Disability Insurance (SSDI), agency efforts to make claims harder to prove angered claimants. The parents’ group, Dissatisfied Parents Together (DPT)\*, had by the late 1990s become the National Vaccine Information Center (NVIC), and the leader of the Center, Barbara Loe Fisher, was outspoken in her criticism of the program. The main target for her criticisms was the changes made to the Table of Injuries [in 1995]. Fisher was not alone. Beginning in the 1990s, claimants’ criticisms of the [Vaccine Injury] Compensation Program were aired in the media and in congressional hearings. From the perspective of parents and their lawyers, there were a bunch of problems that needed fixing... The original law had limited pain and suffering and death damages at [US]\$250,000, but had not included a provision for inflation, so the parents’ groups wanted the amount to be raised. Probably the most important proposal, though, was to increase the three-year statute of limitations on claims made to the program. The parents and lawyers argued that because the VICP was so obscure, would-



be claimants sometimes learned about the right to file for compensation after the time limit had expired.” p171-172.<sup>69</sup>

However, despite the many criticisms of the VICP outlined above, there is still some merit to the operations of the scheme highlighted by some authors. For example, according to Barnes and Burke, “No public policy could possibly resolve the differences among parents, their lawyers, vaccine manufacturers, public health officials, and doctors over vaccines, but the [Vaccine Injury] Compensation Program has had the net effect of diminishing those differences rather than widening them.” p182.<sup>69</sup>

#### **Key points**

- ***Delays in claims handling and the adjudication process negatively affect public support for the VICP in the USA.***
- ***A lack of public awareness of the VICP reduces public support for the scheme in the USA.***
- ***Satisfaction with the VICP in the USA is mixed, and tends towards dissatisfaction.***
- ***How the standard of proof is interpreted within the VICP can affect public support for the scheme in the USA. If courts continue to narrowly interpret symptom(s) or manifestation of onset, this may have the effect of pushing claimants out of the VICP and the claimants bringing suit against vaccine manufacturers.***
- ***How vaccines and related injuries are covered under the VICP can affect public approval of the scheme in the USA, such as the changes to the Vaccine Injury Table in 1995 and to the cost-control mechanisms within the scheme, such as compensation caps on pain and suffering or death and the three-year filing deadline.***

#### **3.5.7 Question 6: What cost-control mechanisms covering no-fault vaccine damage schemes are reported in the literature?**

From the data we analysed, there appear to be two caps on awards made within the scheme. According to the Altarum Institute, “For an injury, the petitioner may be paid for past and future non-reimbursable medical and custodial care, rehabilitation costs, up to [US]\$250,000 for actual and projected pain and suffering, lost earnings, and reasonable legal costs. In the case of a death, the petitioner may be paid up to [US]\$250,000 as a death benefit and for reasonable legal costs. Compensation is paid through a lump sum and/or annuity. Attorneys’ fees and costs are paid whether or not compensation is awarded if the claim was filed on good faith and reasonable basis.” p33.<sup>75</sup>

In addition to the caps on certain payments that act as a cost-control mechanism within the VICP, it can also be inferred that the three-year statute of limitations which is imposed on claimants, within which they must file their claim, can also act as a cost-control mechanism. Indeed, this statute of limitations requirement has also come under some criticism. According to Grey, “Other problems that have been noted with the Vaccine Program [VICP] include the short, inflexible three-year statute of limitations to file a claim in the program.” p804-805.<sup>71</sup>

An additional feature of the VICP which can be construed as a cost-control mechanism is the use of life care planners. The following description provides insight into how the life care planners can operate within the VICP. According to the Altarum Institute, “If a financial award is granted, life care planners help the petitioner to develop a plan for acquiring and funding services and any equipment required for the injured individual. Life care planners review medical records, collaborate with health care providers and experts, identify patient needs, and calculate costs of care... Among respondents who had a life care planner, the most common arrangement was to have two life care planners, one hired by the petitioner or the petitioner’s attorney and one hired by [D]HHS (54.54%).” p23.<sup>75</sup>

Petitioners who availed of the use of life care planners within the VICP expressed different views regarding their satisfaction with the life care planners. According to the Altarum Institute, “Respondents had differing, yet strongly-held opinions about their satisfaction with the role of the life care planners. There were slightly more satisfactory responses than unsatisfactory ones, with almost one-third (32.14%) reporting being very satisfied with their life care planner(s) and 3.57% reporting being somewhat satisfied. Twenty-eight per cent (28.57%) reported feeling very

dissatisfied. This distribution must be interpreted with caution, however, given the small number of respondents to this survey item (n=28).” p24.<sup>75</sup>

#### **Key points**

- ***There are a number of cost-control mechanisms in the USA’s VICP: a maximum limit on pain and suffering awards, the three-year filing deadline, life planners for petitioners, and the DHHS. In addition, the current Vaccine Injury Table may act as a proxy cost-control measure in the USA, as it restricts the number of applications and increases off-Table applicants costs.***

### **3.5.8 Summary**

The USA operates a standalone VICP. From the data we analysed, it appears that certain decisions taken outside of the vaccine injury compensation programme (VICP) by the Federal Circuit led to an increase in overhead costs. For example, the Federal Circuit ruled that pre-merit fees be paid to attorneys representing claimants to the VICP. These fees were then added to the administrative costs of the scheme. In addition, decisions taken by the special masters in the VICP to raise the burden of proof to comply with all five epidemiological causality criteria also led to an increase in overhead costs, as this led to an increase in applicants appealing decisions and requiring further legal representation, which was covered by the scheme.

Our analysis of the data suggests that there was inadequate information about the scheme provided to the general public, that the congressional intent that all claims be resolved within a 240 day statutory limit was being frustrated by the 1995 and 1997 changes to the Vaccine Injury Table, that there were inconsistencies in determining the standard of proof for off-Table claims for vaccine compensation, and that there were changes to the way in which vaccines and related injuries were covered by the VICP, all of which were associated with reducing timely access to compensation for claimants. Failure to inform the public of the deadline for filing a claim and adding vaccines to the Vaccine Injury Table without associated injuries affected the numbers of people who were able to make claims to the VICP.

Adding new vaccines to the Vaccine Injury Table led to an increase in the number of awards for compensation, and how the standard of proof was interpreted also affected the number of awards. For example, when the special masters used a higher standard of proof, this led to a decrease in the number of awards, whereas when the Federal Circuit employed a lower standard of proof to give the claimant the benefit of the doubt, this led to an increased number of awards of compensation.

A lack of public awareness of the scheme can affect public approval; if the general public does not know about the VICP, they cannot offer a judgement on whether they approve or not. Generally, claimants’ satisfaction with the VICP and its constituent parts was mixed and tended towards dissatisfaction. For claimants, delays in the claims handling and adjudication process has led to general dissatisfaction. If claimants deem the interpretation of the standard of proof or causation criteria applied to be too strict, they expressed doubts about the VICP. When the vaccines that were responsible for the majority of claims were removed from the Vaccine Injury Table, this decision was met with public disapproval, as claimants then had to pursue their claims off-Table, which meant engaging with the courts and embarking on an adversarial encounter which the VICP was set up to avoid.

There are a number of cost-control mechanisms in the USA’s VICP: a maximum limit on pain and suffering awards, the three-year filing deadline, life planners for petitioners, and the DHHS. In addition, the current Vaccine Injury Table acts as a proxy cost-control measure in the USA, as it restricts the number of applications.

## 3.6 United Kingdom

### 3.6.1 Introduction

We drew on five papers that provided data on the Vaccine Damages Payment Scheme (VDPS) in the United Kingdom (UK). Fairgrieve (2018)<sup>45</sup> cited data retrieved via the Freedom of Information Act and a selection of relevant legal papers and material related to the VDPS. Macleod (2017)<sup>32</sup> drew on a review of relevant documentation and data provided under the Freedom of Information Act in order to document key features of the VDPS in the UK and provide an update on the number of claims and successful awards provided under the scheme. Tindley (2008)<sup>77</sup> and Pywell (2000)<sup>78</sup> drew on a mix of data sources they had used as part of their doctoral work which sought to review the scheme at different points in its existence. We also used data from Raine (2011),<sup>79</sup> who analysed paediatric data from the then National Health Service Litigation Authority (NHSLA) to determine the commonest events that result in litigation, their causes and consequences, and the cost to the National Health Service (NHS). The data analysed by Raine<sup>79</sup> were retrieved for analysis via a Freedom of Information request to the NHSLA and covered claims submitted from 1 April 2005 to 31 March 2010.

The VDPS was created under the Vaccine Damage Payments Act 1979. An important feature to note about the VDPS in the UK is that from the beginning, the scheme was not designed to be a no-fault scheme, nor did it claim to provide compensation for vaccine injuries. In an early review of the VDPS, Pywell noted that “The Secretary of State reiterated that the VDPS is not a no-fault liability scheme, nor is it a compensation scheme.” p252.<sup>78</sup> This means that the scheme in the UK was not designed to prevent people from going to the courts for compensation and redress, unlike in other jurisdictions examined in this report. Nor can it be said that the VDPS was designed to protect manufacturers from facing liability in the courts. Although the scheme from the outset did make a one-off payment to successful claimants, according to Pywell, “such a payment is not an admission of negligence, nor does it result from strict liability...a VDPS payment thus appears to defy convenient classification.” p252.<sup>78</sup>

Coverage of the VDPS in more up-to-date literature suggests that the scheme continues to be non-negligence based, and no proof of fault is necessary. The VDPS provides a single, tax-free payment of up to GB£120,000 made by the Government to a person who has suffered severe mental and/or physical disablement as a result of vaccination against one or more specified diseases. According to Macleod, “the payment is not regarded as compensation, or as tailored to the financial needs of the individual, but is designed to ease the present and future burdens of those suffering vaccine damage, and their families.” p396.<sup>32</sup>

A claim must be submitted to the Secretary of State via the Vaccine Damage Payment Unit, which will then obtain relevant medical evidence from the doctors or hospitals involved in the applicant’s treatment. In the event that the claimant is unsuccessful, they can request a review by the Vaccine Damage Payment Unit or can appeal to the First-tier Tribunal and the Upper Tribunal. According to Macleod, “legal representation is very rare during the initial stages: of the 1,551 claims registered between April 2000 and August 2013, only 2 are noted as having legal representation.” p398.<sup>32</sup>

Since 1 May 2014, the VDPS has been the joint responsibility of the Department for Work and Pensions and the Department of Health. As set out in the Vaccine Damage Payments Act 1979, the Department of Health is responsible for policy – for example, changes to the list of infectious diseases covered by the Act in line with changes to the immunisation programme. The Department for Work and Pensions is responsible for assessing claims for compensation.

Perhaps the most contentious feature of the VDPS in the UK is the requirement that a claimant must demonstrate that they have incurred a severe disability as a result of being vaccinated. This means that a host of less serious injuries are not considered to merit compensation. According to Tindley, “the method of assessing percentage disablement in vaccine-damage cases remains problematic. The prescribed degrees of disablement set out in the schedules to the relevant legislation do not cover every conceivable impairment, relate to physical disabilities in adults, and are more suited to injuries caused by industrial accidents or in battle than as the result of vaccination.” p338-339.<sup>77</sup>

Historically, the level of disablement that a claimant had to demonstrate was set to at least 80%, but this was reduced to a contemporary level of at least 60%. According to Macleod, “the term ‘severely

disabled' is defined to mean at least 60% disabled, as assessed under the separate industrial injuries compensation scheme." p397.<sup>32</sup> Tindley<sup>77</sup> outlines quite clearly what this level could mean in practice. According to Tindley, "60 per cent disablement corresponds to amputation of one hand or [of one leg] at the knee, or to hearing loss of 73-79db, at which speech would be incoherent." <sup>77</sup>

### **3.6.2 Question 1: What design features and/or contextual conditions are thought to impact on the operating costs associated with no-fault vaccine damage schemes?**

We did not locate any data which estimated the level of overhead costs associated with the VDPS.

### **3.6.3 Question 2: What design features and/or contextual conditions are thought to impact on timely access to no-fault vaccine damage schemes?**

We did not locate any data to estimate the length of time it takes for claimants to receive compensation.

### **3.6.4 Question 3: What design features and/or contextual conditions are thought to impact on the number of applicants seeking redress via no-fault vaccine damage schemes?**

We did not locate sufficient data to examine what features of the VDPS may either increase or decrease the number of claims for compensation. The limited amount of data on the number of claimants included in the papers we reviewed is contextualised in our discussion of the data relating to the volume and costs of awards in Question 4.

### **3.6.5 Question 4: What design features and/or contextual conditions are thought to impact on the volume and costs of awards made under no-fault vaccine damage schemes?**

It would appear that in the early years of the VDPS, the award approval rate was relatively high, which was likely due to handling a backlog of claims that predated the scheme. However, since those early years, all the data cited in the papers we reviewed suggest that the award approval rate has declined, and it is claimed that failure to prove causation is the main reason for this decline. For example, data cited by Macleod<sup>32</sup> suggest that the number of awards fell from 272 in 1979–1980 to five in 1999–2000. According to Macleod, "the number of accepted claims (awards) peaked between 1979 and 1983; since then numbers have fallen to very low levels. Proof of causation is usually the problem." p398.<sup>32</sup>

Despite the decline in the number of approved awards, the number of claims made to the VDPS over the 10-year period that followed the year 2000 remained relatively high, but the approval rate remained low. According to Macleod, "Between 1 January 2000 and 31 December 2010 the Vaccine Damages Payment Unit received 1,483 claims; of these, 26 resulted in an award. The total amount paid out for those awards was £2,600,000." p401.<sup>32</sup> or a 1.7% approval rate

An examination of the data on approval rates over a five- to six-year period also shows a substantial decline in the approval rate compared to the very early days of the VDPS. According to Macleod, "for the period 2006/07-2011/12 a total of 38 awards were approved and 407 were rejected, a success rate of 8.5%." p402.<sup>32</sup> Indeed, the most recent data cited in the papers we reviewed suggest that the approval rate has decreased to zero. For example, data cited by Macleod show that in 2010–2011, one award was made and in 2011–2012, zero awards were made. p399.<sup>32</sup>

Proving causation appears to be the main stumbling block that faces claimants, and from the data cited in the papers we reviewed, failure to demonstrate causation is the main reason provided for rejecting a claim. For example, data cited by Macleod<sup>32</sup> which capture the reasons for refusing a claim up to August 2013 show that out of 5,333 refusals, 4,403 [or 83%] were due to causation not being accepted, while 551 [or 10%] were deemed to have been made after the statutory time limit for making a claim. p400.<sup>32</sup>

In addition, data cited by Fairgrieve that were retrieved via a Freedom of Information request suggest that, "since 1979 [to May 2017], there had been 6,196 claims, of which 936 [or 6%] resulted in

awards. There have been 4,177 [79% out of 5,260] rejections on the basis that ‘causation due to vaccination has not been accepted’, and 125 [2%] where ‘causation [is] accepted but resulting disablement [is] not severe (less than 60%)’. The other main reason for rejection was claims were received outside the statutory time limit for making a claim, with 587[11%] thereby rejected.” p87-88.<sup>45</sup>

The steady decline in the approval rate suggests that potential claimants may be inclined to pursue compensation through an alternative route. Data cited by Raine<sup>79</sup> may provide some insight into what potential claimants may be doing regarding seeking compensation. Raine analysed paediatric data from the NHSLA in order to determine the commonest events that result in litigation, their causes and consequences, and the cost to the NHS. The data were retrieved for analysis via a Freedom of Information request to the NHSLA and covered claims submitted from 1 April 2005 to 31 March 2010. In total, Raine examined 195 closed cases and reported that the commonest cause of litigation were medication or vaccination errors. Raine does not elaborate on what is meant by vaccination errors; however, it may be the case that these are claims that relate to vaccine injuries which are claimed to result from errors associated with the preparation or administration of vaccines.

#### **Key points**

- *Since the mid-eighties, the award approval rate has declined in the UK, and it is claimed that failure to prove causation is the main reason for this decline at 79% of rejections.*
- *The overall approval rate in the UK from the most recent data is just over 6%. Despite the decline in the number of approved awards, the number of claims made to the VDPS over the between 2000 and 2010 remained relatively high, but the approval rate remained low. In total, there were 6,196 claims between 1979 and May 2017.*

### **3.6.6 Question 5: Do no-fault vaccine damage schemes enjoy public acceptance?**

We did not locate any data which explicitly speak to levels of public approval or support for the VDPS, but the decreasing number of applicants to the scheme indirectly indicates that it is not used by the public.

#### **Key point**

- *Decreasing numbers of applicants in the UK indicate reduced public acceptance*

### **3.6.7 Question 6: What cost-control mechanisms covering no-fault vaccine damage schemes are reported in the literature?**

The data relating to cost-control mechanisms concerns the maximum GB£120,000 lump-sum payment for approved awards and the limitation of payment to those with a 60% or more disability. There is also a filing deadline.

#### **Key point**

- *The cost control mechanisms for paying damages in the UK are: a maximum award, a filing deadline, and only severely disabled cases are paid damages*

### 3.6.8 Summary

The Vaccine Damages Payment Scheme (VDPS) was created under the Vaccine Damage Payments Act 1979. The scheme was not designed to be a no-fault scheme, nor did it claim to provide compensation for vaccine injuries. The scheme sets a high injury threshold, requiring that for compensation to be awarded, a claimant must demonstrate that his or her injury meets the criteria of the person being at least 60% disabled (equivalent to amputation or severe hearing loss). The VDPS provides a single tax-free payment of up to GB£120,000 made by the Government to a person who has suffered such severe mental and/or physical disablement. Up to the end of 2013, a claim must be submitted to the Secretary of State via the Vaccine Damage Payment Unit, which would then obtain relevant medical evidence from the doctors or hospitals involved in the applicant's treatment. In the event that the claimant is unsuccessful, the applicant could request a review by the Vaccine Damage Payment Unit or could appeal to the First-tier Tribunal and the Upper Tribunal. Legal representation was very rare between 2000 and 2013. Since 1 May 2014, the VDPS has been the joint responsibility of the Department for Work and Pensions and the Department of Health. The Department of Health is responsible for policy, for example, changes to the list of vaccines covered by the Act. The Department for Work and Pensions is responsible for assessing claims for compensation. Since the mid-eighties, the award approval rate has declined in the UK, and it is claimed that failure to prove causation is the main reason for this decline. In total, there were 6,196 claims between 1979 and May 2017. Since the schemes inception to May 2017, 79% of claims were rejected based on the claimants' inability to prove causation and the overall approval rate from the same period was just over 6%. There has been a serious decline in the number of approved awards overtime, currently single digit numbers. These average numbers, presented in the research used in this review, hide the decreasing numbers of applicants each year and also are a proxy indicator of reduced public acceptance. The cost-control mechanisms for paying damages are: a maximum award of GB£120,000, a filing deadline of 6 years, and damages are only awarded to severely disabled cases.

## 4 Data synthesis and overall conclusions

### 4.1 Introduction

Throughout this review, we had hoped to be able to assemble a final synthesis of the data that would capture some of the main commonalities and differences that characterise the various VICPs we reviewed. However, on closer scrutiny of our findings, we have decided that such a synthesis is not feasible given the range and types of questions we asked of the data, the diverse and complex nature of the data, and the distinctive design features and contextual conditions that underpin the different VICPs. Therefore, we have decided to let the findings speak for themselves and instead concentrate on producing a distilled version of our synthesis with some general conclusions. We have chosen to use a modified version of the framework developed by Morestin *et al.*<sup>55</sup> to structure this section, as the framework contains a number of key questions that we can apply to the data we collected on the effectiveness and the implementation of the various VICPs. The three questions we have chosen from the framework are: (1) Are VICPs effective? (2) What are the costs involved in implementing such schemes? and (3) Are these schemes acceptable to the relevant stakeholders? We view these three questions as being highly pertinent to policy-makers when they consider the pros and cons of introducing such a scheme.

### 4.2 Effectiveness

#### 4.2.1 What effects do VICPs have on the targeted problem?

According to Morestin *et al.*, “the first element used to assess the success of a public policy is its effectiveness or, in other words, the degree to which it has achieved its objectives.” p5.<sup>55</sup> So, what are the objectives of a VICP, and have these objectives been achieved? It would appear that two key objectives for setting up a VICP are to avoid litigation being taken against vaccine manufacturers and to alleviate public fears about the risks of vaccination, with the ultimate objective being to maintain public health and the public’s confidence in vaccines. Macleod elaborates on the rationale underpinning these objectives in the following extract:

The history of a succession of vaccine schemes shows consistently that a principal motivation was to create them so as to avoid litigation against the manufacturers, since the potential litigation cost risk...was both high and uncertain. That commercial risk, manifested in the unavailability of insurance and a drastic fall in the number of manufacturers who were willing to make vaccines, threatened the continued supply of vaccines after the number of manufacturers had fallen dramatically as a result of litigation. Further, considerations of compensating patients post harm through the litigation system were not thought to be adequate to overcome families’ and parents’ concerns over the risk of being vaccinated against very unpleasant diseases. That fear...created a serious risk to the safeguarding of public health should the vaccination rate fall. Creating a compensation scheme was a means of both limiting the liability exposure of manufacturers and maintaining public confidence in vaccination programmes. In short, the real consideration driving the vaccine schemes was to maintain public health and confidence in the safety of vaccines in order to maintain a high vaccination rate by the general population. p620.<sup>32</sup>

As Morestin *et al.* accurately point out, when seeking to assess the effectiveness of public policies, “analysts are frequently confronted with a lack of literature on the links between policies and their ultimate effect on the problem they target.” p5.<sup>55</sup> This was our experience in this review, as we did not locate any empirical evidence that assessed whether VICPs have an impact on vaccine confidence. Similar experiences in failing to find empirical studies that assessed the impact of compensation schemes on vaccine confidence have been reported by Wilson and Keelan<sup>12</sup> and Hapuhennedige.<sup>49</sup>

When there is a lack of empirical literature assessing the ultimate effectiveness of a policy, Morestin *et al.* suggest “opening up the analysis to other types of data on effectiveness: [perhaps] those focused on the link between a public policy and its intermediate effects.” p5.<sup>55</sup> We have chosen to follow this advice by asking the data: Is there evidence that VICPs improve timely access to compensation for claimants?

It could be argued that one of the intermediate effects that VICP designers hope to achieve is to improve timely access to compensation for claimants. If claimants believe they can access compensation quicker and with much less effort than would pertain if they pursued action through the courts, then they are more likely to use the VICP. For example, it would appear that one of the objectives of setting up the VICP in Taiwan was to provide reasonable and quick compensation for injuries when criteria for such were satisfactorily met. According to Wang, Yang, *et al.*, “It was hoped that through this compensation mechanism, if any of the public received vaccination that further caused death, physical and mental impairments, serious illness, and adverse reactions that they can receive reasonable compensation quickly after professional review to eliminate the possible doubts the public has for possible side-effects of vaccines, and elevate the vaccination rate.” p2.<sup>36</sup> Similar objectives underpinned the establishment of the VICP in the USA where, according to Walker, “the legislative history of the statute [in the USA] states as a goal the establishment of a Federal no-fault compensation programme under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity.” p193<sup>73</sup>

Our analysis of the data we collected suggests that only some of the schemes we reviewed have made progress on improving timely access to compensation for claimants. It is these schemes and the likely features that have contributed to improving access that we shall turn to first.

#### **4.2.1.1 Assessing timely access to vaccine injury compensation**

##### **4.2.1.1.1 New Zealand**

There is broad agreement in the literature we reviewed that the VICP in New Zealand has met the primary objective of improving injured patients’ access to compensation.<sup>27 56 59</sup> The key feature of the VICP that has contributed to improving access to compensation is the 2005 reforms, which included the removal of the need for claimants to prove negligence. It would appear that one of the reasons for removing negligence from the VICP was to improve the therapeutic relationship between patients and their healthcare professionals and to encourage healthcare professionals to assist patients to submit claims for compensation and assist the VICP with processing such claims. There is a consensus in the literature we reviewed that since the reforms in 2005, healthcare professionals are more actively involved in assisting claimants to submit claims for compensation and in assisting the VICP to streamline the handling of claims, and this development has been a major contributory factor in improving timely access to compensation.<sup>28 58</sup>

##### **4.2.1.1.2 Nordic countries**

In the four Nordic countries we reviewed, where compensation for vaccine injuries is part of a wider drug injury compensation scheme and the wider drug injury scheme is part of or a sister to a medical treatment scheme, the objective of improving timely access to compensation seems to have progressed quite well. For example, data provided by Hodges<sup>62</sup> suggest that in Denmark, Norway, and Sweden, the VICPs have led to the almost complete absence of any legal claims for product liability. Thus, the VICPs have satisfied the policy objective of improving the chances of injured persons obtaining compensation than might have pertained if claimants were obliged to pursue their actions through the legal process. In Finland, data provided by Urho<sup>64</sup> suggest that the VICP consistently processes claims expeditiously and flexibly, and thus far the scheme does not appear to exhibit any major flaws. Similarly to what pertains in Denmark, Norway, and Sweden, the scheme in Finland avoids time-consuming and expensive litigations.

In the four Nordic countries, the VICPs are based on the principle of finding no fault regarding negligence, which means that applicants do not have to incur any legal expenses or engage in adversarial proceedings. The removal of adversarial disputes and the delegation of the claims handling and decision-making to an expert panel would appear to be key features in satisfying the original intent of the VICPs to improve timely access to compensation.

An additional contributory feature of the VICPs in the Nordic countries which can play a role in improving timely access to compensation is the decision in all four countries to employ a low standard of proof, in contrast to what may pertain in a legal court hearing on such claims. Data provided by Hodges<sup>62</sup> suggests that the decision to select a lower standard of proof for the schemes in all four Nordic countries, based on the notion of preponderant probability, was a decision taken



mainly to make the VICPs attractive to potential claimants so that they would avoid taking claims through the courts. The preponderant probability standard accepts that it is more likely than not that an injury is associated with a drug. This renders the preponderant probability standard much lower than the standard of proof that is generally required to demonstrate causation in a court of law. In percentage terms, the concept means that the injury claimed for is more likely than not (at least 51% likely) a result of a vaccine.

#### **4.2.1.1.3 Asian countries**

The data in the papers on the four Asian countries we reviewed are mixed. First of all, there were insufficient data available on the VICPs in both Japan and Korea to draw inferences on whether either scheme improves timely access to compensation for claimants. In the paper by Fei and Peng<sup>6</sup> which documents the features of the scheme in China, the data suggest that the cumbersome three-stage claims handling and adjudication process delays timely access to compensation for claimants. In stage one of the process, an expert panel is assembled to establish whether the claim qualifies for compensation; in stage two, if the claim has been authenticated, the victim can submit an application for compensation; and in stage three, there is a double-review procedure which means that both the compensation decision and the final compensation consultation agreement are reviewed by bodies higher up in Government. Although the VICP is, in theory, based on an administrative review procedure, practical cases show that the process is essentially one of consultation and conflict resolution rather than a unilateral administrative procedure. This cumbersome procedure slows down the claims handling and adjudication process and makes timely access to compensation less likely.

An additional impediment to timely access to compensation in the VICP in China and one highlighted by Fei and Peng<sup>6</sup> is the difficulties claimants encounter in demonstrating causation between their injuries and a vaccine. When adjudicating on matters relating to causation, the expert panel generally deploys the method of establishing causation that is used in science and epidemiology. This means that the panel draws a clear distinction between abnormal reactions (not observed in epidemiological studies) and adverse reactions (observed in epidemiological studies); the former, even when severe or fatal, are unlikely to pass the strict standard of proof employed in the VICP, as they are not expected to occur.

In contrast to the cumbersome claims handling process and the high standard of proof required in the Chinese VICP which slow down timely access to compensation for claimants, the VICP in Taiwan has a good record in resolving claims in a timely fashion. From the data provided by Wang,<sup>35</sup> it would appear that it is the efforts of the expert working group in the Taiwan scheme that are responsible for speeding up the processing of claims in a timely manner. The expert working group meets regularly to review claims, with a maximum interval of 60 days between two meetings, so as to ensure that the injury cases are resolved in a timely fashion. It is estimated that in the year 2013, 98 injuries cases were resolved, with an average processing time of 155 days from the date of acceptance.

In addition, access to compensation in the VICP in Taiwan is helped by the scheme's employment of a relaxed standard of proof regarding causation. The standard of proof employed allows for a causal relationship between a vaccine and an injury to be categorised into one of three categories: (i) an injury is related to the vaccine, (ii) an injury is possibly related to the vaccine, or (iii) an injury is unrelated; compensation is paid for injuries that are related or possibly related to the vaccine. This categorisation allows the adjudicating panel to accept a relaxed standard of proof and provides a mechanism where the benefit of the doubt can be decided in favour of the claimant.

#### **4.2.1.1.4 USA**

One of the key objectives of introducing the VICP in the USA was to compensate vaccine-injured persons quickly, easily, and with certainty and generosity. To this end, it was the congressional intent that all claims would be resolved within a 240 day statutory limit. From the data we analysed, it would appear that most authors do not believe that the programme has met this objective<sup>18 29 30 75 80</sup> with some claiming that it takes more time, on average, to process claims within the VICP than it does to process claims within the traditional tort system.

One of the key features of the USA's VICP which has contributed significantly to reducing timely access to compensation for claimants was the changes made to the vaccine table in 1995. These changes reduced the number of claims that could be made under the table's streamlined administrative procedure and increased the number of off-Table claims, which are more likely to be contested; off-Table claims take longer to prepare, longer to present, and longer to decide, which means that the vast majority of claims take much longer than the 240 days outlined by Congress.<sup>18 29</sup>  
69

The changes made to the table in 1995 included the removal of vaccines with associated injuries that had previously been largely uncontested regarding causation. New vaccines were added to the table without associated injuries, which meant that injured claimants now had to produce adequate scientific evidence to demonstrate causation between the vaccine and the injury. The special masters who are responsible for the claims handling and adjudication process applied inconsistent requirements to the standard of proof required to demonstrate causation, with some special masters demanding a high level of proof based on scientific epidemiological causation criteria. These decisions by the special masters were subsequently challenged in the courts, and the Federal Circuit ruled in the *Althen* case that such high standards of causation were not in line with the congressional intent to give sufficient weight to the evidence produced by medical opinion and, in cases of doubt, to consider ruling in the claimant's favour. The data suggest that the special masters continue to exercise their own discretion when demanding evidence of causation in off-Table cases, and that such requirements delay timely access to compensation for claimants.

#### **4.2.1.1.5 UK**

We have no data on timely access for the UK.

## **4.3 Implementation**

### **4.3.1 What are the financial costs of implementing VICPs?**

#### **4.3.1.1 New Zealand**

In New Zealand, it would appear that the removal of negligence in the 2005 reforms which reframed the standard of proof has contributed to keeping overhead costs low, in particular dispensing with the need for legal costs. For example, it is claimed by Mello *et al.*<sup>59</sup> that overhead costs account for approximately 17% of the total cost of the VICP, compared to an estimated 55% to 60% in the USA. In addition, claimants to the VICP can also claim from the wider social insurance resources for a variety of losses and expenses. This means that they do not need to submit these claims to the VICP, which means that the average cost of claims for compensation can be kept low. There are also caps on lump-sum monetary awards for permanent disability, and a 12-month filing deadline.

#### **4.3.1.2 Nordic countries**

The data provided by Hodges<sup>62</sup> suggest that the overhead costs of administering the drug injury compensation schemes in Denmark, Finland, Norway, and Sweden are low when compared with the costs that would apply if court proceedings were pursued instead. The main reason suggested for low overhead costs is the removal of negligence or fault from the VICPs, which means that legal costs that may pertain in more adversarial proceedings are virtually omitted from the schemes.

Furthermore, both Hodges<sup>62</sup> and Urho<sup>64</sup> claim that Denmark and Sweden have managed to keep the percentage of medication-related compensation claims they approve at about 30% over a long period, despite both countries operating the same standard of proof based on the preponderant probability criteria. In contrast, the percentage of approval for successful claims in Finland is 50% up to 2011 but in 2012-13 was between 30% and 40%. This difference in earlier years is most likely due to the differences in application; in Denmark and Sweden, it is required that the injury is a serious and/or enduring injury, which may control the number of awards that are compensated, whereas in Finland it would appear that all injuries, regardless of their severity, receive compensation, which increased the percentage of successful awards compensated.

In addition, the wider contextual influence of social security and healthcare measures, which cover the majority of lost earnings and provide free medical care when required, also helps to keep the costs of direct compensation relatively low in the four Nordic countries examined. The drug injury compensation schemes make top-up payments for, firstly, pain and suffering and loss of amenity and, secondly, any shortfall in provisions from other sources, such as income. Data provided by Hodges<sup>62</sup> suggest that the drug injury compensation schemes merely top up other extensive sources of compensation in order to provide comprehensive cover to claimants for injuries related to drugs, including vaccines.

In all four Nordic VICPs examined, direct cost-control mechanisms include minimum and maximum values on individual awards and a maximum value on the total award expenditure available for injured persons in a single year. In all four Nordic VICPs, there are time limitations on claims: in Denmark and Finland, claims must be filed within three years and are barred after 10 years from the date that the medicine was dispensed; in Norway, claims must be filed within three years and are barred after 20 years from the date that the medicine was dispensed; and in Sweden, claims must be filed within three years and are barred after 15 years from the date that the medicine was dispensed.

#### **4.3.1.3 Asian countries**

From the papers we reviewed that provided data on the VICPs in China, Japan, Korea, and Taiwan, we found no explicit data that estimated the overhead costs involved in operating the VICPs. However, we collected some data on features of the schemes that include both direct and indirect cost controls and which may have some bearing on financial costs; we have summarised these data here in order to provide insight for policy-makers.

Fei and Peng<sup>6</sup> point out that in China, injuries incurred by Class I vaccines that are routinely provided by the Government for the general population are compensated by the Government, and injuries incurred by Class 2 vaccines, which are privately paid for by the citizens, are compensated by the vaccine manufacturers. Similar funding distinctions operate in Japan, as Wang, Yang, *et al.*<sup>36</sup> point out that administration and compensation costs incurred by injuries caused by routine vaccines are funded from central government. On the other hand, costs incurred for injuries caused by vaccines that citizens voluntarily pay for themselves are shared between the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) and others. This distinction between compensating injuries caused by routine vaccines and self-paid vaccines may help the State to control both operating costs and compensation costs by only compensating injuries incurred by State-sponsored routine vaccines. The VICP in Korea is confined to providing compensation for a list of injuries related to a list of vaccines that have been recommended by the Korean authorities,<sup>42</sup> and in Taiwan the VICP is funded through a premium paid by vaccine manufacturers or importers after purchased vaccines are approved and certified.<sup>35</sup> In Taiwan, the VICP provides funding for compensating claims and for operating expenses and research on adverse events following inoculation.

In China, the application of a strict standard of proof that requires epidemiological evidence to substantiate a claim for compensation, and a high injury threshold that requires the injury to be severe or fatal, would appear to be an indirect mechanism to control the number of claims that are successfully compensated, and thus to control the costs of compensation. In addition, compensation is calculated in different provinces using one of two methods: a fee-based approach, which includes payment for treatment and rehab costs and awards higher amounts of compensation, and a disability-based approach, which pays a lower amount of compensation via a lump-sum payment.

In contrast, in both Korea and Taiwan, it would appear that the VICPs operate a more relaxed standard of proof, which may relax controls on the amount of compensation paid out to successful claimants. For example, data provided by Kim, Lee, *et al.*<sup>41</sup> about the scheme in Korea suggest that claims are approved for compensation if the injuries claimed for are a) definitely related, b) probably related, or c) possibly related to a vaccine. In all three categories, the amount claimed for is fully compensated. This means that there is no difference in the amounts paid out to claimants once an award meets one of the three pillars in the standard of proof. Furthermore, it would appear that whatever the amount of money a claimant specifies in their compensation claim, if successful, this precise amount is paid to the claimant. In suggesting a similar relaxed application in Taiwan, Wang<sup>35</sup> shows that the level of causal relationship is categorised into three types: an injury is related, an

injury is possibly related, and an injury is unrelated. Applying a relaxed standard of proof allows the adjudicating panel to consider the merits of different levels of evidence, and the benefit of the doubt tends to be resolved in the claimant's favour.

In all four Asian countries that operate a VICP, there are a variety of direct cost-control mechanisms implemented to contain costs. For example, in China, there are cost controls imposed via the maximum amount of compensation allowable in some provinces. In Japan, there are time limits for healthcare and bereavement payments, as well as payment guides for the different injuries, which are likely to control costs. In addition, the class to which the vaccine is assigned may affect the amount of compensation. In Korea, claimants must file a complaint within five years of the adverse event and have spent more than US\$300 on healthcare. In Taiwan, there is a filing deadline of two years from the onset of the injury and five years from the receipt of the vaccine. In addition, there are maximum amounts that can be paid for a specific injury.

#### **4.3.1.4 USA**

One of the key differences between the VICP in the USA and those in the other jurisdictions we examined in the literature is the high level of legal representation that is employed and funded by the scheme in the USA. This feature of the USA VICP contributes significantly to higher overhead costs compared to those reported in other jurisdictions. Data provided by Todd<sup>74</sup> suggest that fees and costs paid to attorneys to cover pre-merit interim payments account for nearly one-fifth of all fees and costs in the scheme. In addition, it is noted that the VICP does not restrict the costs incurred for legal representation; there are automatic legal fees whether a lawyer wins or loses, so there is no reason to ever stop litigating in the scheme.

Data reviewed suggest that discretionary decisions taken by the special masters in the VICP in the USA can impact greatly on overhead costs.<sup>29 70 71</sup> For example, when the special masters follow the ruling from the Federal Circuit which emphasised that close calls regarding causation for off-Table cases are to be resolved in favour of injured claimants, this can reduce the need for legal representation and reduce overhead costs. However, when special masters ignore the court's ruling and require a higher standard of proof to demonstrate causation in off-Table claims, this can necessitate legal representation and increase overhead costs. The Altarum Institute<sup>75</sup> and Grey<sup>71</sup> document a number of direct cost-control mechanisms that operate in the USA's VICP. These include a maximum limit payment for pain and suffering awards and a three-year filing deadline for claims. In addition, there are life planners required for petitioners and the DHSS.

#### **4.3.1.5 UK**

We do not know what the administration aspects of the scheme costs but we do know that the VDPS provides a single tax-free payment of up to GB£120,000 to a small number of successful applicants (maximum 5).

### **4.3.2 What is the public's level of acceptance of vaccine compensation schemes?**

#### **4.3.2.1 New Zealand**

In New Zealand, data collected from interviews with stakeholders by Kachalia *et al.*<sup>58</sup> suggest that claimants are reassured that the VICP adjudicates on claims in a fair and consistent manner. Kachalia *et al.*<sup>58</sup> and Mello<sup>59</sup> report that since the reforms to the scheme in 2005, which removed the need to prove negligence, physicians have bought into the scheme and assist claimants to submit claims. Physicians also actively cooperate with the claims handling process by submitting relevant documentation to support claims when required. It could be inferred from the active engagement by physicians that they approve of the scheme. Keelan *et al.*<sup>27</sup> suggest that unlike most other jurisdictions, where public awareness of such schemes tends to be inadequate, in New Zealand, most of the general population is aware that compensation is available for injuries related to immunisation.

#### 4.3.2.2 Nordic countries

In the two papers<sup>62 64</sup> we reviewed on the VICPs in the four Nordic countries, the authors make a number of inferences regarding judgements of the schemes by stakeholders. For example, Hodges,<sup>62</sup> commenting on the schemes in Denmark, Finland, Norway, and Sweden, claims that in each case, the payment of compensation comparable to what would be expected in the courts without having to incur excessive legal fees renders each of the VICPs attractive to claimants. Data provided by Urho<sup>64</sup> suggest that in Finland, claimants appear to be satisfied with decisions taken regarding their compensation, and that in Norway, most of the claimants and the general public appear to approve of the VICP. However, Urho<sup>64</sup> highlights a lack of information among the general public in Denmark regarding the existence of the VICP, and Hodges<sup>62</sup> alludes to a similar situation in Sweden; inadequate information about the scheme can reduce the level of public awareness and use of the scheme.

#### 4.3.2.3 Asian countries

From the four papers we reviewed on the VICPs in Asia, we found no explicit data that directly captured the views of stakeholders regarding their judgement of the schemes. However, in some cases, the authors of the papers did make some inferences from their analyses to suggest how stakeholders judged the schemes. For example, data provided by Fei and Peng<sup>6</sup> highlighted the dissatisfaction among claimants and their families in China regarding the limited amount and scope of compensation that the VICP sometimes pays out. In some cases, this dissatisfaction with the scheme leads to public unrest and informal lobbying to change decisions in favour of claimants.

Kim, Lee, *et al.*<sup>41</sup> make the claim that the scheme in Korea helps to engender trust among the general public in the National Immunization Program, and Wang<sup>35</sup> claims that the scheme in Taiwan helps to maintain public confidence in its national immunization programme. At first glance, the claims by Kim, Lee, *et al.* (Korea)<sup>41</sup> and Wang (Taiwan)<sup>35</sup> come close to inferring an association between the VICPs and vaccine confidence among the general public. However, both claims are presented as unsubstantiated inferences and neither author presents any direct evidence to support either claim. We found no data that could infer stakeholder judgement of the scheme in Japan.

#### 4.3.2.4 USA

In the USA, the Altarum Institute,<sup>75</sup> reporting on the findings from a survey with a small number of claimants to the VICP, suggested that some respondents were dissatisfied with the process for determining damages, and that in some cases claimants felt that the amount of compensation paid out was inadequate. On the other hand, there was some satisfaction among claimants with the method of payment, and claimants who received compensation appeared to be satisfied with the scheme in general. Barnes and Burke<sup>69</sup> highlighted the public dissatisfaction with the changes made to the Vaccine Injury Table in 1995, when vaccines responsible for the most compensable injuries up to that point in time were removed, which meant that subsequent claims for these injuries were adjudicated on by using the off-Table mechanism, which was viewed as being more adversarial than what had previously pertained. In addition, parents' groups were unhappy with the financial cap that limited pain and suffering and death damages to [US]\$250,000, but which had not included a provision for inflation. The GAO<sup>30</sup> pointed out that efforts to promote public awareness of the VICP were seen as inadequate, and in general it was felt that the general public was largely unaware of the scheme. This had implications for would-be claimants, as they sometimes learned about the right to file for compensation after the time limit to file had expired. Davis *et al.*<sup>76</sup> reported that in public health clinics where parents brought their children to be immunised and where it was required that the service provide information on the scheme to the visiting public, the VICP was rarely discussed with parents.

#### 4.3.2.5 UK

We did not locate any data which explicitly speak to levels of public approval or support for the UK's VDPS, but the decreasing number of applicants to the scheme indirectly indicates that it is rarely used by the public.



## 5 Conclusions

We provide a brief overview of some of the key features of the compensation schemes we reviewed and how these features relate to our key parameters of interest. We do not replicate the summary findings for each of our included countries as summaries for each country are presented at the end of the country sub-section in the report and are clearly labelled in the table of contents. The summary findings related to VICPs in Denmark, Finland, Norway, and Sweden are grouped under in the title 'Nordic countries'. Also, findings related to the schemes in China, Japan, Korea, and Taiwan are grouped under the title 'Asian countries'. Findings related to the schemes in New Zealand, the United States of America (USA), and United Kingdom (UK), are presented individually as they are very different to other schemes.

### 5.1 New Zealand

In New Zealand in 2005, medical mishap and medical error were replaced with a new concept of treatment injury. In effect, this reform to the New Zealand injury compensation programme meant that the need to prove negligence by a health professional was removed and the programme became a full no-fault administrative intervention redesigned to improve the chances of compensation for claimants. In addition, vaccine injuries were included as medical injury. There is broad agreement that the compensation scheme in New Zealand has met the primary objective of improving injured patients' access to compensation. The 2005 reforms to the scheme, which included the removal of the need for claimants to prove negligence, have been key to speeding up access to compensation. Since these reforms, health professionals are more actively involved in assisting claimants to submit claims for compensation which assists the scheme to streamline the handling of claims, and this development has been a major contributory factor in improving timely access to compensation. It is estimated that the administrative costs and overhead costs represent approximately 10% to 17% of total expenditures, compared with 50% to 60% among malpractice systems in other countries. Contextually speaking, the scheme is embedded in a wider suite of social and employment insurance resources, and these external supports for claimants seem to keep both the overhead running costs and the compensation costs to a manageable level. Unlike most of the other schemes we reviewed, there is a high level of public awareness of the scheme in New Zealand, and it appears to enjoy support from the public and has buy-in from physicians and health professionals in general. We identified three cost-control mechanisms in New Zealand: no legal fees, caps on lump-sum monetary awards for permanent disability, and a 12-month filing deadline. In addition the scheme does not provide compensation for pain and suffering only for permanent disability.

### 5.2 Nordic countries

In the four Nordic countries – Denmark, Finland, Norway, and Sweden – compensation for vaccine injuries is handled as part of a wider drug injury compensation scheme; the wider drug injury scheme is part of or a sister to a medical treatment scheme. The overhead costs of administering the drug injury compensation schemes in the four Nordic countries are low when compared with the costs that would apply if legal actions were pursued instead. In all four countries' schemes, the objective of improving timely access to compensation seems to have progressed quite well. The removal of negligence or fault from the schemes has greatly contributed to keeping costs low (by removing legal costs) and improving access to compensation. All four schemes employ a more relaxed standard of proof based on the principle of preponderance of probability (or the principle that the medicine more likely than not caused the injury) is more favourable for claimants than the rigorous causation requirements that would pertain in the courts. However, there are variations in how some of the Nordic countries apply the standard of proof; for example, Finland approves 30-40% of claims for compensation, compared with 36% in Norway and circa 30% in Denmark and 35% in Sweden, which suggests a more liberal application in the case of Finland. The four schemes are embedded in societies that provide substantial social security, employment insurance, and healthcare measures to assist injured persons. The drug injury compensation schemes are a 'top-up' to other sources of Government-based compensation in order to provide comprehensive cover to claimants for injuries related to drugs, including vaccines. This wider contextual assistance helps to keep the costs of compensation from the scheme at modest levels. There are three cost-control mechanisms common

to all Nordic countries' drug injury schemes: no legal fees, maximum values on the total award expenditure available for injured persons in a single year, and time limitations on claims. We have very limited data on Norway, but the data from Denmark, Finland, and Sweden indicate that the schemes act as a top up to payments through social and health care services. Of note, these schemes do compensate for pain and suffering.

### 5.3 Asian countries

Four countries in Asia – China, Japan, Korea, and Taiwan – operate a standalone VICP. In China, a highly structured three-stage claims handling and adjudication process, which involves cumbersome and repetitive procedures, delays timely access to compensation for claimants. The scheme employs a strict standard of proof which normally requires the claimant to demonstrate that a vaccine has caused the injury claimed for by drawing on evidence from rigorous epidemiological studies. The decision to require such a high standard of proof appears to keep the approval rate for compensating claimants quite low. Claimants to the scheme are unhappy with the scope and amount of compensation that is paid out, and have often engaged in public protest in an attempt to overturn decisions that ruled against their claims. The programmes in both China and Japan distinguish between Class I and Class II vaccines; Class I are routine and encouraged by the Government, and Class II vaccines are advised and non-routine. In Japan, injuries incurred by claimants in receipt of Class I vaccines receive higher amounts of compensation for their contribution to protecting society (known as 'herd immunity') than their Class II vaccine counterparts. Otherwise, data on the VICP in Japan are scant. Both Korea and Taiwan operate a more relaxed standard of proof, which is in line with WHO recommendations. In Korea, claims are approved for compensation if the injuries claimed for are a) definitely related, b) probably related, or c) possibly related to a vaccine, and almost 68% of vaccine compensation claims are successful. In Taiwan, the level of causal relationship is categorised into three classes: an injury is related, an injury is possibly related, or an injury is unrelated. The first two classes of injury are compensated and, over a 15-year period, 40% of claims were successful. The scheme in Taiwan has a good record of resolving claims in a timely fashion, and it appears that the consistent efforts of the expert working group are primarily responsible for speeding up the processing of claims in a timely manner.

### 5.4 USA

The USA operates a standalone VICP. The scheme incurs a high level of overhead running costs, mainly due to the high level of legal representation that claimants require in order to navigate the scheme. Up until 1995, the scheme relied mainly on the Vaccine Injury Table to decide whether injuries claimed for were caused by certain vaccines; the table contained a number of vaccines and associated injuries that had scientific consensus. In 1995 and (again in 1997), a number of vaccine injuries were removed from the table and a number of vaccines were added without all associated injuries; these revisions narrowed the size and scope of the Vaccine Injury Table and the number of off-Table claims increased. Subsequently, the special masters who handle all claims and adjudications in the scheme required that claimants submit high levels of epidemiological evidence to demonstrate causation for their off-Table claim. This resulted in the federal courts ruling against the special masters and recommending that a lower standard of evidence, perhaps based on medical opinion, could suffice in most off-Table cases. However, the discretionary deliberations on the part of the special masters around what constitutes causation appear to continue in the scheme, which means that most claimants require legal representation to assist them, which in turn keeps the costs of running the scheme higher than was initially intended. Initially, Congress intended that the scheme would resolve all claims in less than the statutory 240 days limit. However, the evidence strongly suggests that the scheme has rarely met this objective and that timely access to compensation is consistently slowed down by the long-drawn-out claims handling and adjudication process on behalf of the special masters and the ever-increasing level of legal representation that claimants seem to rely on to navigate the scheme. The literature suggests that the public's awareness of the VICP is low and that the Department of Health and Human Services do not make the adequate efforts to advertise the programme and inform the public about it. In addition, research suggests that the satisfaction of the VICP users is mixed and tends towards dissatisfaction. There are cost-control mechanisms in the USA's VICP documented in the literature: a maximum limit on pain and suffering awards, a three-year filing deadline, life planners for petitioners, and for the DHHS. In addition, the



current Vaccine Injury Table may acts as a proxy cost-control measure in the USA, as it restricts the number of applications and increases the claimants' costs through an off-Table adjudication process.

## 5.5 UK

The Vaccine Damages Payment Scheme (VDPS) was created under the Vaccine Damage Payments Act 1979. The scheme was not designed to be a no-fault scheme, nor did it claim to provide compensation for vaccine injuries so it is quite different to other schemes which seek to protect vaccine production and compensate vaccine users who suffer harm. The scheme sets a high injury threshold, requiring that for compensation to be awarded, a claimant must demonstrate that his or her injury meets the criteria of the person being at least 60% disabled (equivalent to partial limb amputation or severe hearing loss). The VDPS provides a single tax-free payment of up to GB£120,000 made by the Government to a person who has suffered such severe mental and/or physical disablement. Up to the end of 2013, a claim must be submitted to the Secretary of State via the Vaccine Damage Payment Unit, which would then obtain relevant medical evidence from the doctors or hospitals involved in the applicant's treatment. In the event that the claimant is unsuccessful, the applicant could request a review by the Vaccine Damage Payment Unit or could appeal to the First-tier Tribunal and the Upper Tribunal. Legal representation was very rare between 2000 and 2013. Since 1 May 2014, the VDPS has been the joint responsibility of the Department for Work and Pensions and the Department of Health. The Department of Health is responsible for policy, for example, changes to the list of vaccines covered by the Act. The Department for Work and Pensions is responsible for assessing claims for damages. Since the mid-eighties, the award approval rate has declined in the UK, and it is claimed that failure to prove causation is the main reason for this decline. In total, there were 6,196 claims between 1979 and May 2017. Since the schemes inception to May 2017, 79% of claims were rejected based of the claimants' inability to prove causation and the overall approval rate from the same period was just over 6%. There has been a serious decline in the number of approved awards overtime, currently at single digit numbers. These average numbers, presented in the research used in this review, hide the decreasing numbers of applicants each year and also are a proxy indicator of reduced public acceptance. The cost-control mechanisms for paying damages are: a maximum award of GB£120,000, a filing deadline of 6 years, and damages are only awarded to severely disabled cases.

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## Appendix 1: Medline search strategy

**Database provider:** Ovid SP Medline (Wolters Kluwer) Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R)  
**Coverage:** 1946-present  
**Date of final searches:** 13 July 2018

Medline search summary		
1	#1 Vaccines	585497
2	#2 Redress	48055
3	#3 No-fault	3302
4	Vaccines AND Redress (#1 AND #2)	655
5	Vaccines AND no fault (#1 AND #3)	87
6	No-fault AND redress (#2 AND #3)	361
7	Vaccines AND (redress OR no-fault)	708
8	#6 or #7	1135
	<b>Total exported to Endnote</b>	<b>1135</b>

#1 Vaccine Search terms and results		
1	exp Vaccines/	211846
2	exp VACCINATION/	76773
3	exp IMMUNIZATION/	162538
4	exp Immunization Programs/	12046
5	exp Vaccine Potency/	275
6	exp Immunogenicity, Vaccine/	482
7	exp Vaccination Refusal/	97
8	exp THIMEROSAL/	1231
9	exp TOXOIDS/	14952
10	vaccin\$.af.	357294
11	revaccin\$.af.	2066
12	(post-vacc\$ or postvacc\$).af.	6811
13	immuniz\$.af.	175858
14	immunis\$.af.	13501
15	inocul\$.af.	122246
16	variolat\$.af.	111
17	(booster shot\$ or booster dos\$ or booster response\$).af.	2835
18	(vicp or nvicp or kvicp).af.	22
19	vaers.af.	267

	#1 Vaccine Search terms and results	
20	aefi.af.	276
21	(BCG or bacillus Calmette-Guerin or immucyst).mp.	28872
22	(DTap or dtp or dtwp or tdap or revaxis or daptacel or infanrix or quadracel or kinrix or pediarix).mp.	2904
23	(rotarix or rotateq or rotavac or rotavin or rotashield).mp.	606
24	Celvapan.mp.	6
25	pandemrix.mp.	183
26	arepanrix.mp.	24
27	focetria.mp.	34
28	(Menacwy or 4CMenB or MenB or Menactra or menveo or trumenba or Bexsero).mp.	682
29	(mmr or mmrv or mmrvaxpro or Proquad or priorix or tresivac or trimovax).mp.	6802
30	mumpsvox.mp.	5
31	meruvax.mp.	10
32	attenuvax.mp.	16
33	(ty21a or vivotif).mp.	268
34	(zostavax or shingrix).mp.	116
35	(varilvax or varivax).mp.	81
36	(pneumovax or prevnar or prevenar or synflorix or pcv13).mp.	1357
37	arilvax.mp.	7
38	gardasil.mp.	427
39	cervarix.mp.	252
40	(thiomersal or thimerosal).mp.	1867
41	Dengvaxia.mp.	39
42	(PedvaxHIB or ActHIB or Hiberix).mp.	77
43	(Boostrix or adacel).mp.	87
44	(Fluzone or fluarix or flulaval or flucelvax or afluria).mp.	127
45	vax.mp.	480
46	(antivax or anti-vax).mp.	4
47	(antivacc\$ or anti-vacc\$).mp.	527
<b>48</b>	<b>or/1-47</b>	<b>585497</b>



#2 Redress search terms and results (MEDLINE)		
1	exp "Compensation and Redress"/	2825
2	exp Workers' Compensation/	7265
3	((Redress or recompens\$ or restitution or reimburs\$ or reparation\$ or compensat\$) dj10 (Financial or judicial or legislat\$ or claim\$ or legal or courts)).mp.	6292
4	(Redress or recompens\$ or restitution or reimburs\$ or reparation\$ or compensat\$).ab. and (lj or es or ec).fs.	15742
5	(Redress or recompens\$ or restitution or reimburs\$ or reparation\$ or compensat\$).ti.	28379
6	((claims or legal or courts) adj5 (indemnity or damages or allocat\$ or settlement\$)).mp.	487
7	("Compensación" or "compensé" or "réparation" or "indemnités" or "indemnisation" or "indemniser" or compensazione or felkompensation or kompensasjon or ei-vikakompensointi).mp	50
8	or/1-7	50657
9	(risk compensat\$ or moral compensat\$ or error compensat\$ or charge compensat\$ or genetic compensat\$ or dosage compensat\$ or differential compensat\$ or central compensat\$ or energy compensat\$ or metabolic compensat\$ or functional compensat\$ or respiratory compensat\$ or neural compensat\$ or renal compensat\$ or vestibular compensat\$ or developmental compensat\$ or ecologic\$ compensat\$ or flow compensat\$ or phase compensat\$ or magnific\$ compensat\$ or compensat\$ mutation\$ or kernel compensat\$ or restitution compensat\$ or compensat\$ cirrho\$ or compensatory lung or gait compensat\$ or compensat\$ hypogonad\$ or compensat\$ behav\$).mp.	11091
<b>10</b>	<b>8 not 9</b>	<b>48055</b>

	#3 No-fault search terms (MEDLINE)	
1	(no fault or no-fault or nofault or blame-free or blameless or no-blame or no blame).mp.	685
2	(burden adj3 (evidence or proof)).mp.	780
3	(proof adj3 (injur* or fault)).mp.	73
4	Fault-based.mp.	38
5	Fault.ti	1864
6	evidentiary standard*.mp.	91
7	((("Compensación" or "réparation" or indemni\$ or compensazione) adj3 ("sin culpa" or "sans faute" or "non fautif" or "senza colpa")) or (ingen felkompensation or ingen feil kompensasjon or eivikakompensointi or ingen fejl compensation or ONIAM or "Office National d'Indemnisation des Accidents Médicaux" or "án bilunar bætur")).mp.	6
8	Non-tort	2
9	(administrative adj2 compensation).mp.	44
10	Health court\$.mp.	176
11	or/1-10	3302

Search strategies are listed for Ovid Medline. Other search strategies are available on request (cle@hrb.ie).

## Appendix 2: Databases used and search parameters

Search Database	Platform/Publisher	Coverage	Date of final search
MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) 1946 to present (Wolters Kluwer)	Ovid	1946-present	13 July 2018
CINAHL with Full Text	EBSCO	1946-present	10 July 2018
Cochrane Library	John Wiley & Sons Inc.	1996-present	10 July 2018
Scopus	Elsevier	1823-present (34 million records dating back to 1996, 21 million pre-1996 records going back as far as 1823)	13 July 2018
Web of Science	Thomson Reuters Corporation	1900-present	13 July 2018
HeinOnLine	Hein	Various, back to 1754	08 July 2018
Legal Trac	Gale	Approx. 1980-present	08 July 2018

Disclaimer: Search terms were selected and included based on likelihood of returning published material relevant to the search. Use of the terms does not imply these terms are linked to the topic requested, only that they may have been used in previous works that may include material relevant to the topic.

## Appendix 3: Non-English databases searched

Database	Address	Country
Airiti Library	<a href="http://www.airitilibrary.com/">http://www.airitilibrary.com/</a>	Taiwan
DBpia	<a href="http://www.dbpia.co.kr">http://www.dbpia.co.kr</a>	Korea
KoMCI Web	<a href="https://komci.org/KoMCIWeb_gs.php">https://komci.org/KoMCIWeb_gs.php</a>	Korea
KoreaScience	<a href="http://www.koreascience.or.kr/MainPage.jsp">http://www.koreascience.or.kr/MainPage.jsp</a>	Korea
KoreaMed Synapse	<a href="https://synapse.koreamed.org/AdvancedSearch.php">https://synapse.koreamed.org/AdvancedSearch.php</a>	Korea
CiNii	<a href="https://ci.nii.ac.jp/en">https://ci.nii.ac.jp/en</a>	Japan
J-Stage	<a href="https://www.jstage.jst.go.jp/search/global/search/-char/en">https://www.jstage.jst.go.jp/search/global/search/-char/en</a>	Japan
CNKI Overseas	<a href="http://oversea.cnki.net/kns55/brief/result.aspx?dbPrefix=CJFD">http://oversea.cnki.net/kns55/brief/result.aspx?dbPrefix=CJFD</a>	China
Scielo	<a href="http://www.scielo.org/php/index.php?lang=en">http://www.scielo.org/php/index.php?lang=en</a>	South America/International
Helsebiblioteket	<a href="https://www.helsebiblioteket.no/">https://www.helsebiblioteket.no/</a>	Norway
Arianna	<a href="http://www.anagrafenazionale.ricerche.it/arianna/contentpages/consultazione.aspx">http://www.anagrafenazionale.ricerche.it/arianna/contentpages/consultazione.aspx</a>	Italy

## Appendix 4: Supplementary websites searched

Search Engine	Address	Region
Google	<a href="http://www.google.com">www.google.com</a>	International
DuckDuckGo	<a href="http://www.duckduckgo.com">www.duckduckgo.com</a>	International
Google Scholar	<a href="http://scholar.google.com">scholar.google.com</a>	International

## Appendix 5: References used in findings

<i>New Zealand (7)</i>
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57. Wilson R, Derrett S, Hansen P, et al. Costs of injury in New Zealand: Accident Compensation Corporation spending, personal spending and quality-adjusted life years lost. <i>Injury Prevention</i> 2013;19(2):124-9. doi: <a href="https://dx.doi.org/10.1136/injuryprev-2011-040252">https://dx.doi.org/10.1136/injuryprev-2011-040252</a>
<i>Nordic countries (2)</i>
58. Hodges C. Nordic compensation schemes for drug injuries. <i>Journal of Consumer Policy</i> 2006;29(2):143-75. doi: 10.1007/s10603-006-9003-4
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<i>Asia (7)</i>
6. Fei L, Peng Z. No-fault compensation for adverse events following immunization: A review of Chinese law and practice. <i>Medical Law Review</i> 2017;25(1):99-114. doi: 10.1093/medlaw/fwx001
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62. Jo DS, Kim JS. Perspectives on vaccine injury compensation program in Korea: The pediatricians' view. <i>Clinical &amp; Experimental Vaccine Research</i> 2013;2(1):53-7. doi: <a href="https://dx.doi.org/10.7774/cevr.2013.2.1.53">https://dx.doi.org/10.7774/cevr.2013.2.1.53</a>

<b>USA (11)</b>
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64. Barnes J, Burke TF. Chapter 5: Vaccine injury compensation: shifting policies, shifting politics. <i>How Policy Shapes Politics: Rights, Courts, Litigation, and the Struggle Over Injury Compensation</i> . Oxford, UK: Oxford University Press 2015:152-89.
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67. Robertson M. Molecular mimicry: Exemplifying the procedural insufficiencies of the Vaccine Injury Compensation Program. <i>Federal Circuit Bar Journal</i> 2017;26(4):513-34.
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<b>UK (4)</b>
43. Fairgrieve D. Compensation for vaccine damage in the United Kingdom. <i>Journal de Droit de la Santé et de l'Assurance Maladie</i> 2018;19:87-9.
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73. Pywell S. A critical review of the recent and impending changes to the law of statutory compensation for vaccine damage. <i>Journal of Personal Injury Law</i> 2000(4):246-56.
74. Raine J. An analysis of successful litigation claims in children in England. <i>Archives of Disease in Childhood</i> 2011;96:838-40.
<b>Reviews of multiple countries (2)</b>
26. Keelan J, Wilson K. Designing a No-Fault Vaccine Injury Compensation Scheme for Canada: Lessons Learned from an International Analysis of Programmes. Toronto, Ontario: Munk School of Global Affairs, University of Toronto, 2011:47.
35. Macleod S and Hodges C, editor. Redress Schemes for Personal Injuries. Oxford, England: Hart 2017.

## Appendix 6: Example of bespoke data extraction sheet used in the review

Paper under review	Kim et al. (2017) Korea
Reviewer	Martin Keane
Date(s) of review	5 -7 2018

Review question	Authors claims and evidence provided	Reviewers inferences and/or notes
Q1> What design features and/or contextual conditions are thought to impact on the <b>operating costs</b> associated with no-fault vaccine damage schemes?		
Q2> What design features and/or contextual conditions are thought to impact on <b>timely access</b> to no-fault vaccine damage schemes?		
Q3> What design features and/or contextual conditions are thought to impact on the <b>number of applicants</b> seeking redress via no-fault vaccine damage schemes	<p>'...However the NIP recently introduced new vaccines every year. Eight types of vaccines for children aged 12 years or less and one type of vaccine, 23-valent pneumococcal polysaccharide vaccine (PPV23), for the elderly aged 65 years and over have been introduced from 2011 to 2016. Consequently, the numbers of vaccine types and subjects filing compensation claims has increased...' p147</p> <p>They authors then go on say that '...There was a range of 70 to 121 applications for compensation filed each year, totaling 515 applications over the 6-year period. Most of these were compensation claims for illness (487 cases, 94.5%), and two-thirds of them were awarded...' p149</p>	<p>This relates to 'vaccines covered in the conceptual scheme</p> <p>However, when we examine the breakdown of total claims per year we see the following;</p> <p>2011 = 71 2012 = 70 2013 = 81 2014 = 121 2015 = 99 2016 73</p>



Review question	Authors claims and evidence provided	Reviewers inferences and/or notes
	<p>‘...The BCG vaccine comprised half of the total claims made and two-thirds of the total compensated cases. The adverse events following BCG vaccination, such as lymphadenitis and abscess or ulcer formation, are common, well-known, and accepted to have definite causal association with the BCG vaccine...’ p153</p> <p>‘...The second most common vaccine in terms of claims made was influenza. Compared to the BCG vaccine, various age groups and classifications of adverse reactions were included in influenza vaccine-related cases, and less than one-third received compensation. In particular, most non-specific systemic, gastrointestinal, or respiratory symptoms were dismissed...’ p153</p>	<p>So the increase noted in 2014 has plateaued out and back to 2011 figures in 2016</p> <p>Here, the author is inferring that clinical evidence on causal link between the BCG vaccine and adverse events is related to the number of claims made</p>
<p><b>Q4&gt; What design features and/or contextual conditions are thought to impact on the volume and costs of awards made under no-fault vaccine damage schemes</b></p>	<p>There were 515 applications filed for compensation over the 6-year period... we reviewed 469 cases in total for this study. Out of these, 318 cases (67.8%) resulted in compensation and 151 cases (32.2%) resulted in dismissal...’ p151</p> <p>‘...Several distinct differences exist between the compensated and the dismissed groups. The compensated group accounted for 71% of BCG vaccines, while the dismissed group accounted for 41% of influenza vaccines and 19% of PPV23 vaccines, respectively. The compensated group accounted for more than 80% of infections, including lymphadenitis and abscess due to the BCG vaccine. Additionally,</p>	<p>This could suggest that the number of compensated claims is associated with the type of vaccine, i.e. the link between vaccine and adverse event is more established; the age of the claimant i.e. children are more likely to be compensated; the length of time between vaccination and adverse event.</p>

Review question	Authors claims and evidence provided	Reviewers inferences and/or notes
	<p>this group accounted for four-fifths of affected infants under three year old, in line with characteristics of BCG vaccination. The majority of the adverse events in this group occurred more than 2 months after the inoculation, reflecting the characteristics of BCG lymphadenitis. In contrast, the dismissed group consisted of subjects in various age groups, including 42% of elderly people and 30% of children aged 3 years or younger. In particular, dismissed claims had noticeably shorter time intervals between vaccination and adverse event than did the compensated claims...' p152</p> <p>'...Among 235 applications filed for BCG vaccination, 225 cases (95.7%) were compensated. Compensation for the BCG vaccine accounted for 71% of the 318 compensated cases. Among the 225 cases of compensation for BCG-related adverse reaction, 217 cases (96.4%) reflected well-known adverse events, such as BCG lymphadenitis, ulcer or abscess formation.</p> <p>'...Among 90 applications filed for influenza vaccine injury, 28 cases (31.1%) were approved for compensation. Of these, 18 cases concerned neurological diseases (nine cases of Guillain–Barré syndrome, six cases of encephalomyelitis, one case of peripheral neuropathy, one case of brachial plexus inflammation, and one case of narcolepsy), four cases concerned infections, and four cases concerned skin, soft tissue, and musculoskeletal diseases. Regarding age distribution, the elderly and adults comprised 80% of</p>	<p>Again this would suggest that the compensated awards appear to be associated with the type of vaccine, well known adverse events</p> <p>Potential association with awards and serious adverse events,</p> <p>Here, the author is inferring that clinical evidence on causal link between the BCG vaccine and adverse events is related to volume of awards made</p> <p>Less awards for influenza vaccine</p>

Review question	Authors claims and evidence provided	Reviewers inferences and/or notes
	<p>influenza-related cases. For PPV23-related cases, 27 of 55 applications (49.1%) were compensated, demonstrating a higher compensation ratio for PPV23 than for influenza. Regarding classification of adverse reaction type, 30 out of the 55 PPV23 cases were considered infections, 23 cases (76.7%) of which were compensated...’ p152</p> <p>‘...The BCG vaccine comprised half of the total claims made and two-thirds of the total compensated cases. The adverse events following BCG vaccination, such as lymphadenitis and abscess or ulcer formation, are common, well-known, and accepted to have definite causal association with the BCG vaccine...’ p153</p> <p>‘...The second most common vaccine in terms of claims made was influenza. Compared to the BCG vaccine, various age groups and classifications of adverse reactions were included in influenza vaccine-related cases, and less than one-third received compensation. In particular, most non-specific systemic, gastrointestinal, or respiratory symptoms were dismissed...’ p153</p>	
<p><b>Q5&gt; Do no-fault vaccine damage schemes enjoy public acceptance?</b></p>	<p>‘...Our system is very effective for sustaining a high level of public trust in the NIP [National Immunization Programme] by responding rapidly to serious AEFI, and providing compensation for each serious adverse event resulting from immunizations recommended by the government...’ p153</p>	<p>This would seem to count as an inference made by the author but not grounded in empirical evidence, but it could be true.</p>
<p><b>Q6&gt; What cost control mechanisms covering no-fault vaccine damage schemes are</b></p>		

Review question	Authors claims and evidence provided	Reviewers inferences and/or notes
<b>reported in the literature?</b>		

Additional reviewer notes

Does the introduction of a national surveillance system to capture the outbreak of adverse events associated with vaccines act as a 'wider contextual factor'? In other words, what impact does such a system have on public confidence in vaccines?

Can we consider the addition of new vaccines a contextual factor that is associated with an increase in claims? No, new vaccines comes under our conceptual codes of 'vaccines covered'.

BCG Vaccine

Bacillus Calmette–Guérin vaccine is a vaccine primarily used against tuberculosis. In countries where tuberculosis (TB) or leprosy is common, one dose is recommended in healthy babies as close to the time of birth as possible

HPV Vaccine

The HPV – or human papilloma virus – vaccine, marketed as Gardasil, protects against cervical and other forms of cancer. HPV is one of the common sexually-transmitted diseases. Most infections do not cause symptoms and go away on their own, but when the immune system does not clear the virus, persistent HPV infection can cause abnormal cervical cells. These pre-cancerous lesions can progress to cervical cancer if left untreated.

PPV23 Vaccine

Pneumococcal polysaccharide vaccine (PPV23) which is for those aged 65 years and older and those over 2 years with long term medical conditions. This vaccine protects against 23 types of pneumococcal disease including those most likely to cause severe disease.

## Appendix 7: List of sub-questions developed to interrogate the data from the scheme in the USA

Primary Review question	Secondary Review question	Candidate Design Feature of the scheme
<b>Q1: What design features of the VICP affect overhead costs?</b>	How do decisions by the Special masters to change the burden of proof affect the overhead costs of the scheme?	Standard of Proof
		Funding source for scheme
	How does the funding source for the scheme affect the overhead costs?	Administration of the scheme
	How does the allowance for pre-merit-decision interim attorney's fees affect the overhead costs of the scheme?	
<b>Q2: What design features of the VICP affect timely access?</b>	How does generic information about the scheme provided to the public affect timely access to the scheme?	Administration of the scheme
		Administration of the scheme
	How does information provided to the public regarding the claim process affect timely access to the scheme?	Administration of the scheme
		Administration of the scheme
	How does getting access to an attorney affect timely access to the scheme?	Process and decision-making
	How does the experience of the hearing/adjudication process affect timely access to the scheme?	Process and decision-making
	How does the length of the claims process affect timely access to the scheme?	Vaccines Covered
	How did the amendment to table of injuries in 1995 affect timely access to the scheme?	Standard of Proof
	How does the decision to set standards for showing causation	

Primary Review question	Secondary Review question	Candidate Design Feature of the scheme
	for off-table injuries affect timely access to the scheme?	Standard of Proof
	How do the decisions by the Special masters to heighten the standard for burden of proof required for off table injuries, affect timely access to the scheme?	Vaccines covered Deadline for filing complaint
	How do the types of vaccines covered on the table and off table affect access to the scheme?	Process and decision-making
	How does the deadline for filing complaints affect access to the scheme?	Standard of Proof
	How does the delay in resolution of claims affect timely access to the scheme?	Standard of Proof
	How does the lack of scientific certainty, linking injuries with vaccines, affect timely access to the scheme?	Administration of scheme
	How does the standard of proof required for off table claims affect timely access to the scheme?	Administration of scheme
	How does the three agents; Congress, HHS and Federal Circuit affect timely access to the scheme?	Process and decision making
	How does the filing fee of \$400 affect timely access to the scheme?	Standard of Proof
	How does the failure to meet the 240 day deadline for resolution of claims affect timely	

Primary Review question	Secondary Review question	Candidate Design Feature of the scheme
	access to the scheme?	Process and decision making
	How do the decisions by the Court of Appeals of the Federal Circuit regarding off table claims affect timely access to the scheme?	Process and decision making
	How do the deliberations by the Special Masters regarding off table claims affect timely access to the scheme?	Administration of scheme
	How does the discretion given to the Special Masters affect timely access to the scheme?	Process and decision making
	How does the absence of a financial risk to pursuance of claims affect timely access to the scheme?	Process and decision making
	How do negotiated settlements between petitioner and DoJ attorneys affect timely access to the scheme?	Administration of scheme
	How do delays in resolution of claims affect timely access to the scheme?	Vaccine Covered
	How does the demand for petitioners to submit supporting documentation affect timely access to the scheme?	Process and decision making
	How does adding vaccines to table without associated injuries affect timely access to the scheme?	Administration of the scheme
	How does the form of adjudication taken; 1) Concession 2) Negotiated Settlement 3) Contested	

Primary Review question	Secondary Review question	Candidate Design Feature of the scheme
	<p>decision, affect timely access to the scheme?</p> <p>How does the congressional intent via the Vaccine Act i.e. (240 days) affect timely access to the scheme?</p> <p>How does the role of congress affect timely access to the scheme?</p>	Administration of the scheme
<b>Q3: What design features of the VICP affect the number of applicants?</b>	<p>How does the number and type of Vaccines covered in off table claims affect the number of applicants to the scheme?</p> <p>How does the number and type of vaccines added to the table affect the number of applicants to the scheme?</p> <p>How does the deadline for filing complaints affect the number of applicants to the scheme?</p> <p>How does the lack of awareness of the scheme affect the number of applicants to the scheme?</p>	<p>Vaccines Covered</p> <p>Vaccines Covered</p> <p>Deadline for filing complaints</p> <p>Administration of the scheme</p>
<b>Q4: What design features of the VICP affect the volume awards and the costs of awards?</b>	<p>Are claimants satisfied with the process of determining damages?</p> <p>Are claimants satisfied with how awards are paid?</p> <p>Are claimants satisfied that awards are adequate?</p> <p>Are claimants satisfied with the volume of awards?</p> <p>How do the decisions of the Court of Federal Claims to</p>	<p>Process and decision making</p> <p>Process and decision making</p> <p>Process and decision making</p> <p>Process and decision making</p> <p>Process and decision making</p>



Primary Review question	Secondary Review question	Candidate Design Feature of the scheme
	amend the findings of the special masters affect the volume and costs of awards?	
	How does the Althen ruling on deciding burden of proof affect the volume and cost of awards?	Standard of Proof
	How do the Special Masters and the Vaccine Injury table affect the volume and costs of awards?	Process and decision making Vaccines Covered
	How do efforts to calculate damages affect the volume and costs of awards?	Process and decision making
	How do changes to the standard of proof for off table claims affect the volume and costs of awards?	Standard of Proof
	How does the Vaccine Act affect the volume and costs of awards?	Administration of the scheme
	How does the addition of new vaccines to the Vaccine Act affect volume and costs?	Vaccines covered
	How do changes to the standard of proof affect volume and costs?	Standard of Proof
	How do rulings by the Federal Circuit Court of Appeals regarding standard of proof affect volume and costs?	Standard of Proof
	How do delays in the processing of claims affect volume and costs?	Process and decision making
	How do negotiated settlements affect volume and costs?	Process and decision making

Primary Review question	Secondary Review question	Candidate Design Feature of the scheme
	How do changes to the number and type of vaccines covered affect volume and cost?	Vaccines covered
	How do decisions taken by Congress, HHS, and Supreme Court, Court of Appeals of the Federal Circuit and the Court of Federal Claims and Special Masters affect volume and costs?	Needs unpacking!
<b>Q5: Does the VICP enjoy public acceptance?</b>	In what way is satisfaction in receiving a financial award associated with public acceptance of the scheme?	Process and decision making
	In what way is learning about the programme through official and unofficial channels associated with public acceptance of the scheme?	Administration of the scheme
	In what way are the changes in 1995 to the Vaccine Injury Table associated with public acceptance of the scheme?	Vaccines covered
	In what way were the initial years of the scheme associated with public acceptance of the scheme and how did this change when legalism crept in (1995)?	Vaccines covered
	In what way is the Special masters going against congressional intent and not adhering to the Althen ruling associated with public acceptance of the scheme?	Standard of Proof
	In what way is the lack of discussion about the scheme in vaccination clinics associated with public acceptance of the	Administration of the scheme

Primary Review question	Secondary Review question	Candidate Design Feature of the scheme
	<p>scheme?</p> <p>In what way are changes to the vaccine table associated with public acceptance of the scheme?</p> <p>In what way is the time it takes to resolve claims associated with public acceptance of the scheme?</p>	<p>Vaccines covered</p> <p>Process and decision making</p>
<b>Q6: What cost control measures does the VICP operate?</b>	<p>How do life care planners act as a cost control mechanism to the scheme?</p> <p>How do caps on certain payments act as a cost control mechanism to the scheme?</p> <p>How does the limitation on time to file a claim (3 years) act as a cost control mechanism to the scheme?</p> <p>How does the limitations (caps) on vaccine related deaths, medical expenses and care act as cost control mechanisms to the scheme?</p>	<p>Administration of the scheme</p> <p>Types of costs compensated</p> <p>Deadline for filing a complaint</p> <p>Types of costs compensated</p>

## Appendix 8: List of secondary questions and data collected per question on scheme in the USA

Secondary question	Evidence	Comments on the nature of the evidence
<p>Q1: How do decisions by the Special masters to modify the burden of proof affect the overhead costs of the scheme?</p>	<p>'...Special masters are heightening the burden of proof for petitioners by imposing more standards for causation than required by statute and case law and questioning the credibility of petitioners' expert witnesses against precedent. The heightened standards in these cases may have severe ramifications, such as an increase in costs due to more appeals, as well as more cases potentially moving out of the Vaccine Program, which increase the number of lawsuits against vaccine manufacturers, in direct opposition to the original purpose of the Vaccine Program...' p81 (Daniels: 2010)</p> <p>'...failing to compensate petitioners who meet the requirements of Althen will have the effect of increasing the length of time for each case through the appeals process. This will lead to an increased cost for the government and the Vaccine Program because attorneys' fees and costs, such as expert witness fees, are awarded by the government as established by the Vaccine Act. This costs the government and the vaccine fund more money...' p97 (Daniels: 2010)</p> <p>'...By denying requisite compensation at the special master level, the special masters are effectively costing the Vaccine Program more money in attorneys' fees and costs, as well as the cost of the appellate process...' p 103 (Daniels: 2010)</p>	<p>Decisions by the Court of Federal Claims – Special Masters.</p> <p>NB: These are prospective claims made by Daniels but they are not supported by explicit evidence.</p>
	<p>'...By 2013... \$148.6 million was paid in attorneys' fees and costs...' p385 (McLeod:</p>	
<p>Q1: How does the allowance for pre-merit-decision interim attorney's fees affect the overhead costs of the scheme?</p> <p>The allowance of pre-merit-decision interim attorney's fees— are, fees and costs that are paid— before any decision is rendered on the merits of the petition, either favourably or unfavourably.</p>	<p>'...For the first twenty-six fiscal years that the VICP operated, it paid nearly \$180 million in attorney's fees and costs. For the first nineteen of those years, however, not a single dime of interim fees (whether pre- or post-merit) was paid. That all changed, however, with the Federal Circuits decisions [to award interim fees and costs]. Since then, the VICP has paid over \$16.5 million in interim fees... In fact, interim attorney's fees and costs account for nearly one-fifth of all fees and costs awarded over that same time period...' p12-13 (Todd: 2014)</p> <p>'...Because there is no financial risk to pursuing these claims, including pre-merit-decision interim fees, this unnecessarily clogs and burdens the special masters' and judges dockets of the court. For instance, for fiscal year 2012, there were 250 successful VICP awards, and there were 37 interim fee awards, for a ratio of 7:1. In 2008 —just a few years earlier that ratio was 71:1. <b>What can be inferred, in part, from this admittedly small sample size is that, everything else being equal, in 2012 (compared to 2008) less of the courts time was likely spent</b></p>	

Secondary question	Evidence	Comments on the nature of the evidence
<p>NB – this data in red can also speak to delay in Timely Access</p>	<p>on adjudicating merit-based claims which is the mission of the VICP. Time and the fixed resources of the courts staff are being spent away from merit decisions to adjudicate these pre-merit-decision interim award disputes at multiple levels of review...' p14-15 (Todd: 2014)</p> <p>'...This statutory scheme, as some have noted, creates "perverse incentives. With automatic fees if you win and basically automatic fees if you lose there is no reason to ever stop litigating in the VICP. There are multiple levels of appellate review for both the merit decision and now, on top of that, the pre-merit-decision interim fee decision. Thus, there is little downside at least no economic downside for an opportunistic attorney, who can exhaust every option on every issue at the ultimate expense of the taxpayer...' p14 (Todd: 2014)</p>	
<p>Q2: How does generic information about the scheme provided to the public affect timely access to the scheme?</p>	<p>'...[survey] respondents had differing opinions on the perceived ease of obtaining information about the VICP.(35.24%) felt that the process was very or somewhat easy, and (37.15%) found the process very or somewhat difficult. The remaining respondents (27.62%) felt neutral about the ease of obtaining information about the VICP...' p21 (Altarum: 2009.)</p>	
<p>Q2: How does information on filing a claim provided to the public affect timely access to the scheme?</p>	<p>'... [Survey] respondents had differing opinions on the perceived helpfulness of the initial information provided by the VICP on filing a claim. (34.65%) found the information very or somewhat helpful, and (30.69%) found the information very or somewhat unhelpful...' p22 (Altarum: 2009)</p> <p>'... Many respondents found the claims process unsatisfactory, giving particularly low ratings to the process of filing a claim, providing additional requested information after the claim was filed, and determination of damages. Respondents reacted most negatively to the length of the process, with which 64.08% were dissatisfied...' p23 (Altarum: 2009)</p> <p>'...Respondents most frequently reported feeling "very dissatisfied" (32.08%) with the process of filing a claim. A further 14.15% were somewhat dissatisfied. In contrast, 15.09% were somewhat satisfied and 18.87% were very satisfied with the process...' p27 (Altarum: 2009)</p> <p>'...If further information was requested after the claim had been filed, a plurality of respondents found it very difficult (18.27%) or somewhat difficult (32.69%) to do so. In contrast, only one-fifth of respondents found it somewhat (14.42%) or very easy (6.73%) to provide additional requested information...' p27 (Altarum: 2009)</p>	

Secondary question	Evidence	Comments on the nature of the evidence
Q2: How does getting access to an attorney affect timely access to the scheme?	'...Many respondents reported difficulty in finding an attorney: nearly one-quarter (22.43%) replied that finding an attorney was very difficult, and another 19.63% felt that finding an attorney was somewhat difficult. One-fifth of respondents (20.56%) felt that finding an attorney was somewhat easy, and 16.82% replied that the process was very easy...' p26 (Altarum: 2009)	
Q2: How does the hearing/adjudication process affect timely access to the scheme?	'...Almost one-third of respondents (30.48%) were very dissatisfied with the hearing process and an additional 6.67% were somewhat dissatisfied. In contrast, only 17.14% were very satisfied and 13.33% were somewhat satisfied...' p28 (Altarum: 2009)	
Q2: How does the length of the claims process affect timely access to the scheme?	'...In 2007, the average claim processing time was 1,337 days or nearly three and one-half years. The majority of respondents were dissatisfied with the length of the claims process. Almost half of the respondents (46.60%) were very dissatisfied with the length of the process, and a further 17.48% were somewhat dissatisfied with it...' p31 (Altarum: 2009)	
Q2: How did the amendment to table of injuries in 1995 affect timely access to the scheme?	<p data-bbox="587 913 1023 1507">"...Through a rulemaking process in 1995, residual seizure disorder and hypotonic-hypo responsive episode were struck from the Table, and encephalopathy was more precisely defined. This was a significant change in policy...The revisions on residual seizure disorder and hypotonic-hypo responsive episode were the first and most controversial of many rulemaking processes...HHS was also granted the power to add any vaccine routinely given to children for coverage under the program, and so has added nine more, but has added few injuries associated with those vaccines to the Table. The net effect of HHS's actions, starting in 1995, was to vastly reduce claims that could be made under the Table's streamlined administrative procedure, and to increase the number of off-Table claims... Congress originally mandated that the program resolve claims within a year, but the 1999 report found that it met this standard in just 14 % of cases, with more than half the claims taking more than two years, and 18% taking more than five years... p169-171</p> <p data-bbox="587 1525 1023 1630">"...The most obvious cause of rising adversarial legalism was the amendment to the Table of Injuries and the rising number of "off-Table" cases..." p180, (Barnes and Burke: 2015)</p> <p data-bbox="587 1727 1023 2027">'...Because the Department of Health and Human Services (HHS) removed the injuries that had been the most frequently utilized by petitioners, the practical effect of these additions and subtractions was to shrink the Table's scope, and importance, dramatically. While 74% of petitions sought compensation for on-Table injuries prior to 1995, only 55% did by 1999, and now, only about 2% of VICP petitions proceed down the on-Table path. Thus, the Table, which at enactment was viewed as the VICP's most important feature has, in the words of one</p>	<p data-bbox="1045 913 1326 987">Data on changes to the vaccine table came from administrative data.</p> <p data-bbox="1045 1048 1326 1122">Data on impact of changes from the vaccine table came from the 1999 GAO report.</p>

Secondary question	Evidence	Comments on the nature of the evidence
	<p>lawyer for petitioners, morphed into “a meaningless thing. This migration away from the Table has had ripple effects, touching every corner of VICP administration. Compared to on-Table petitions, off-Table petitions (where causation is determined by reference to traditional tort principles) are more likely to be contested, rather than conceded, and once contested, “take longer to prepare, longer to present and longer to decide. “Off-Table petitions are also, quite importantly, far less likely to result in compensation for the petitioner. This means that much of the trouble identified above can be traced, directly, to the Table amendments.’ p1702-1706 (Engstrom:2015)</p> <p>“the Table was substantially modified and narrowed by the Secretary of HHS in 1995 through an administrative rulemaking proceeding. In addition, the nine vaccines added to the Table by the Secretary of HHS since 1988 generally have no specified Table injuries at all or have the immediate onset of anaphylactic shock as the only listed Table injury. These changes in the Table have resulted in other major changes in the operation of the program. The cases are now substantially more difficult, complex, and time-consuming to litigate. The science is less clear, and the special masters have much more difficult and complex scientific disputes to resolve than they did for the relatively simpler Table injury claims. Both petitioners' counsel and government counsel now need to search for experts in cutting-edge medical areas, such as genetics and neurology, where a great deal of uncertainty still exists. This contributes to a much more adversarial process than was supposed to exist in a program that was designed to be less adversarial...’ p790, Meyers</p> <p>‘...The present focus of the Vaccine Program on virtually all off-Table cases has also resulted in a series of recent decisions from the U.S. Court of Appeals for the Federal Circuit, purportedly clarifying but sometimes confusing the standards that the special masters are required to apply in deciding off-Table cases. A number of the Federal Circuit's recent rulings have observed that Congress intended compensation to be provided generously, and that "close calls regarding causation are [to be] resolved in favor of injured claimants. To the contrary, other recent Federal Circuit rulings have emphasized the importance of strict compliance with traditional tort standards of causation. Such inconsistencies have illuminated the need for clear standards...’ p790-791, Meyers</p> <p>‘...In vaccine cases where no Table injury claim can be made the special masters have much more difficult and complex issues to decide. In such off-Table cases, the special masters must base their decisions on medical opinions or</p>	

Secondary question	Evidence	Comments on the nature of the evidence
	<p>published articles linking the vaccine to the injury involved in the case. These off-Table cases often involve complex medical questions about which there is likely to be no definitive consensus among experts. This has become a particular problem for the Vaccine Program because of the dramatic shift from the early years of the program, 1989 to 1992 when more than 90% of the petitions filed asserted Table injuries, to the most recent years, 2007 to 2010, when almost 90% of the petitions filed assert only non-Table injuries...' p798 Meyers</p> <p>'...The National Vaccine Injury Compensation Program changed substantially in 1995, when the Secretary of HHS announced modifications to the Vaccine Injury Table that would drastically change not only the Table, but also the nature of the Vaccine Compensation Program. The Table changes have in effect created a new and different vaccine compensation program...' p799-800, Meyers</p>	
<p>Q2: How do the decisions by the Special masters to heighten the standard for burden of proof required for off table injuries, affect timely access to the scheme?</p>	<p>'...Instead of using the standards set forth in the Vaccine Program, special masters heightened the burden for petitioners by: (1) imposing more standards of causation than required by statute and case law, and (2) questioning the credibility of petitioners' expert witnesses in certain cases in opposition to established precedent...' p89 (Daniels: 2010)</p> <p>'...The three-prong test from Althen resulted from a special master's decision to impose a five-prong test for petitioners to meet in order to receive compensation in the Program...The special master determined that because the petitioner did not provide peer-reviewed literature, she did not qualify for compensation. Upon review, the Federal Circuit determined that the application of the five-prong test was contrary to law, stating that both prongs two and three of the test "contravene the plain language of the statute. The Federal Circuit held that requiring medical literature "impermissibly" raised petitioner's burden and was in direct conflict with the statute's allowance of medical opinion as proof. Finally, the Federal Circuit noted that the role of the special master is "not to craft a new legal standard..." p90 (Daniels: 2010)</p> <p>"Special masters recently drifted from using established precedent and documented congressional intent, heightening the burden on petitioners in the Vaccine Program. If this trend continues, the ramifications will extend beyond simply making compensation in the Vaccine Program more difficult and could jeopardize the very foundation of the Vaccine Program itself..." p96 (Daniels: 2010)</p>	<p>This data would appear to come from an analysis from the rulings of the Federal Circuit Court.</p>
<p>Q2: How do the type and numbers of vaccines covered affect access to the scheme?</p>	<p>"Since fiscal year 1999, HHS has added six vaccines to the Vaccine Injury Table, but it has not added covered injuries associated with these</p>	



Secondary question	Evidence	Comments on the nature of the evidence
	<p>vaccines to the table. This means that while individuals may file VICP claims for these vaccines, each petitioner must demonstrate that the vaccine that was administered caused the alleged injury." First page, 'highlights', but not technically pg 1. United States Government Accountability Office, 2014.</p>	
<p>Q2: How does the deadline for filing complaints affect access to the scheme?</p> <p>NB – we need to collect data to show that a lack of awareness of the scheme can delay the filing of a complaint.</p> <p>The data we have here, does not speak to the question.</p>	<p>"In order to be eligible for compensation, a petitioner must file his or her petition with the court within three years from the onset of symptoms. The Federal Circuit held that the first symptom or manifestation of onset is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." P89 Daniels M, 2010</p> <p>NB – we must check when the Federal Circuit Court made this ruling and why.</p>	
<p>Q2: How does the delay in resolution of claims affect timely access to the scheme?</p>	<p>'The legislative history of the statute states as a goal the establishment of 'a Federal "no-fault" compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity'. Congress intended the VICP to be 'fair, simple, and easy to administer', and hoped that 'a more stable childhood vaccine market will evolve'.' p193 Walker VR, 2013.</p> <p>'The process of creating legal rules began when the U.S. Congress, the legislative branch of the U.S. government, established the basic legal rules for causal inference in the National Childhood Vaccine Injury Act of 1986, which established the VICP.12 Congress was responding in part to an increase in litigation over vaccine-related injuries, which helped cause prices of vaccines to increase and vaccine manufacturers to leave the market.' p193 Walker VR, 2013.</p> <p>'At this foundational level for the programme, Congress tried to set a politically acceptable balance of the competing policy objectives by establishing the basic procedural and substantive legal rules that would govern the VICP...' p193 Walker VR, 2013.</p> <p>'...despite Congress's high hope and clear demand, the VICP in action is notable not for its speed but rather for its long times to decision. Few petitions (less than 5%) satisfy the statutory 240-day deadline. Most exceed it by a wide margin... Of petitions filed between 1999 and March 31, 2014, the Program's average adjudication time clocked in at about five-and-a-half years, while most petitions (51%) remained pending for over a half-decade...'</p>	

Secondary question	Evidence	Comments on the nature of the evidence
	<p>p1685 (Engstrom: 2015)</p> <p>'...Critically, it takes more time, on average, to process claims within the Program than it does to process claims within the traditional tort system: approximately 66 months within the VICP, as compared to 25.6 months for tort cases that terminate in a judgment or verdict...And, VICP petitions appear to take substantially more time to resolve than medical malpractice claims, which, in terms of injury severity and scientific complexity, probably offer the closest comparator...' p1686-1687 (Engstrom: 2015)</p> <p>'...There is an argument that the above delays are unique to the VICP... that the VICP has twice been hit by an onslaught of unanticipated filings. .. (i.e., claims for vaccine injuries sustained prior to the Act's October 1988 effective date). 4500 such claims were filed [and] created a backlog...Then, just as the VICP dug itself out from that mountain of retrospective cases, the Program got hit a second time by a barrage of petitions (over 5500 in all) alleging a link between vaccines and autism...' p1688 (Engstrom: 2015)</p> <p>'...The adjudications today are typically not informal at all, virtually no cases are concluded within the 240-day deadline, and the Vaccine Injury Table, which was originally a central feature of the Vaccine Act and a key innovative provision of the Act, has been significantly changed and narrowed over the years so that today it plays only a limited role in Vaccine Act cases...' p789 (Meyers: 2011)</p> <p>'...VICP claims filed since fiscal year 1999 took an average of about 5 and a half years to adjudicate, according to data for the nearly 8,800 claims filed since fiscal year 1999 that were adjudicated as of March 31, 2014... For claims filed since fiscal year 2009, a greater percentage of claims were resolved within 1 or 2 years. One possible reason is that the vast majority of claims alleging autism as the injury were filed prior to fiscal year 2009... According to data, for the more than 1,400 claims filed since fiscal year 2009 that were adjudicated as of March 31, 2014, the average amount of time to adjudicate a claim was 587 days (about 1.6 years). More than 900 (40 percent) of the claims filed since fiscal year 1999 were still pending, which could cause this average to increase over time as these pending claims are resolved...' p9-11</p> <p>'...Officials cite certain delays within the process as factors that can increase average claims processing times. Officials at USCFC and DOJ told us that the time petitioners spend gathering</p>	

Secondary question	Evidence	Comments on the nature of the evidence
	<p>supporting documentation or evidence can add significantly to the amount of time required to process a claim. These delays may occur at multiple points in the claims process, from petitioners needing to gather sufficient documentation for the court to begin an initial review, to the court needing documentation to determine the amount of compensation that a successful petitioner will receive. According to HRSA, for claims adjudicated as of March 31, 2014, its medical review process averaged over 700 days for claims filed in fiscal year 2010. HRSA attributes the length of time for medical review primarily to time spent waiting for petitioners to submit requested documentation. During the medical review, HRSA may also consult with external experts, who require additional time to review the details of the case; HRSA's data indicate that over 1,200 outside reviews were conducted from fiscal years 2009 to 2014. Additionally, when special masters are reviewing the claim, a party may request that the special master delay a decision until additional documentation is available. Special masters may also request additional information from petitioners—such as a specialist physician's opinion...' p12-13 United States Government Accountability Office, 2014.</p> <p>"Officials from the U.S. Court of Federal Claims (USCFC), where VICP claims are adjudicated, report that delays may occur while petitioners gather evidence for their claims." First page, 'highlights', but not technically pg 1. United States Government Accountability Office, 2014.</p> <p>'...Officials cite certain delays within the process as factors that can increase average claims processing times. Officials at USCFC and DOJ told us that the time petitioners spend gathering supporting documentation or evidence can add significantly to the amount of time required to process a claim. These delays may occur at multiple points in the claims process, from petitioners needing to gather sufficient documentation for the court to begin an initial review, to the court needing documentation to determine the amount of compensation that a successful petitioner will receive. According to HRSA, for claims adjudicated as of March 31, 2014, its medical review process averaged over 700 days for claims filed in fiscal year 2010. HRSA attributes the length of time for medical review primarily to time spent waiting for petitioners to submit requested documentation. During the medical review, HRSA may also consult with external experts, who require additional time to review the details of the case; HRSA's data indicate that over 1,200 outside reviews were conducted from fiscal years 2009 to 2014. Additionally, when special masters are reviewing the claim, a party may request that the special master delay a decision until additional documentation is available. Special masters may also request additional information from petitioners—such as a specialist physician's</p>	

Secondary question	Evidence	Comments on the nature of the evidence
	opinion...’ P12-13, United States Government Accountability Office, 2014.	
Q2: How does the lack of scientific certainty, linking injuries with vaccines, affect timely access to the scheme?	‘...when assessing why the VICP has stumbled, some of the blame ought to be laid here: at the elemental scientific uncertainty at the root of the causal inquiry...This yields a pair of crucial insights: (1) If particular injuries are not traumatic, visible, or otherwise obvious, causation questions are unlikely to be easily resolved, and (2) in such cases, adjudications are unlikely to be predictable, simple, or swift. Indeed, many of a no-fault system’s supposed benefits appear to dissipate the moment those systems confront causation questions steeped in scientific uncertainty...’ p1699-1701 (Engstrom: 2015)	The author is drawing on a mix of anecdotal information, surveys of 786 decisions in VICP and some administrative data.
Q2: How does the standard of proof required for off table claims affect timely access to the scheme?	<p>‘...How off-Table claims are resolved has huge consequences for the claimants and the fund. Although Congress intended the Table to be the centrepiece of the program, the number of off-Table claims has come to far surpass the number of Table claims. They now likely account for 90% of all claims, and off-Table claimants have received billions of dollars in compensation...’ p345 (Grey: 2011)</p> <p>"Off-Table claims, the critical question—and the focus of this Article—is defining the level of proof sufficient to show causation. The Vaccine Act itself does not supply a standard, nor has precedent under the Act clarified the issue. The primary question is whether the program should, or could, require the same sufficiency of evidence standard used in the common law tort context and still promote the goals of the program. Striking the appropriate balance on the causation issue is critical because requiring too high a standard would leave worthy victims uncompensated and potentially threaten the vaccine manufacturing market, while too low a standard could open the floodgates to unworthy claims and suggest to the public that vaccines present risks that outweigh their benefits...’ p346 (Grey: 2011)</p> <p>‘...Congress apparently expected that as evidence developed HHS would expand the Table to list additional combinations of injuries and vaccines, and the need for off-Table claims would be reduced or eliminated. Congress’s assumptions have not been realized, however, because the science has not developed as anticipated—mostly because vaccine side effects are so rare that they are hard to study...’ p346 (Grey: 2011)</p> <p>‘...The standard for demonstrating causation in off-Table injuries was left quite open in the legislation, providing lots of opportunity for the parties to argue its proper interpretation and application. The parties and their lawyers in off-Table cases frame the issues and gather the evidence, which is presented to the special</p>	

Secondary question	Evidence	Comments on the nature of the evidence
	<p>master. In these respects, the VICP today roughly parallels the tort law system it replaced, although the process is far more centralized than ordinary tort litigation...' p169-171 (Barnes and Burke: 2015)</p> <p>'...The present focus of the Vaccine Program on virtually all off-Table cases has also resulted in a series of recent decisions from the U.S. Court of Appeals- for the Federal Circuit, purportedly clarifying but sometimes confusing the standards that the special masters are required to apply in deciding off-Table cases. A number of the Federal Circuit's recent rulings have observed that Congress intended compensation to be provided generously, and that "close calls regarding causation are [to be] resolved in favor of injured claimants. To the contrary, other recent Federal Circuit rulings have emphasized the importance of strict compliance with traditional tort standards of causation. Such inconsistencies have illuminated the need for clear standards...' p790-791 (Meyers: 2011)</p> <p>'...In vaccine cases where no Table injury claim can be made the special masters have much more difficult and complex issues to decide. In such off-Table cases, the special masters must base their decisions on medical opinions or published articles linking the vaccine to the injury involved in the case. These off-Table cases often involve complex medical questions about which there is likely to be no definitive consensus among experts. This has become a particular problem for the Vaccine Program because of the dramatic shift from the early years of the program, 1989 to 1992 when more than 90% of the petitions filed asserted Table injuries, to the most recent years, 2007 to 2010, when almost 90% of the petitions filed assert only non-Table injuries...' p798 (Meyers: 2011)</p> <p>'...These changes in the Table have resulted in other major changes in the operation of the program. The cases are now substantially more difficult, complex, and time-consuming to litigate. The science is less clear, and the special masters have much more difficult and complex scientific disputes to resolve than they did for the relatively simpler Table injury claims...' p790 (Meyers: 2011)</p>	
<p>Q2: How does the three agents; Congress, HHS and Federal Circuit affect timely access to the scheme?</p>	<p>'...Three entities can control the sufficiency of causal proof required in off-Table claims: (1) Congress, in its ability to amend the statute; (2) HHS, indirectly in its ability to amend the Table; and (3) the Federal Circuit, in its interpretation of the Act and oversight of implementation of the program...' p346 (Grey: 2011)</p>	
<p>Q2: How does the filing fee of \$400</p>	<p>'...A claim for vaccine-related injury or death is filed with a petition for compensation at the</p>	

Secondary question	Evidence	Comments on the nature of the evidence
affect timely access to the scheme?	Court of Claims, copied to the HHS/Director to the Division of Vaccine Injury Compensation. Claims can be in person or represented by an attorney. Claims must be filed within 24 months of a death and 36 months of an injury. There is a filing fee of \$400...' p386 (McLeod: 2017)	
Q2: How does the discretion given to the Special Masters affect timely access to the scheme?	'...Requesting scientific evidence beyond what the expert has already researched and posited adds even more time to the litigation process...but the discretion granted to the special masters allows them to place additional time-consuming burdens on petitioners, and, ultimately, the Program as a whole. A lack of uniformity stems from the high level of discretion granted to special masters in the Program....' p526 (Robertson: 2016)	
Q2: How does the form of adjudication taken; 1) Concession 2) Negotiated Settlement 3) Contested decision, affect timely access to the scheme?	<p>An aspect of the US system's process and decision making; the three adjudication categories - 1. Concession, 2. Negotiated settlement and 3. Contested decision in favour of the petitioner - can affect the length of time it takes to adjudicate the claim.</p> <p>"For claims that are compensated, there are three adjudication categories:</p> <ul style="list-style-type: none"> <li>• Concession. In a concession, HHS's review of medical records, scientific literature, and other documents finds that the petitioner is entitled to compensation, because the evidence meets the criteria of the Vaccine Injury Table or because it is more likely than not that the vaccine caused the injury.</li> <li>• Negotiated settlement. In a negotiated settlement, the petition is resolved via negotiation between HHS (represented by DOJ) and the petitioner.</li> <li>• Contested decision in favor of the petitioner. If HHS does not concede that a petition should be compensated or if both parties do not agree to settle, the special master issues a decision after weighing the evidence presented by both sides, which may involve conducting a hearing." Pg 7, United States Government Accountability Office, 2014.</li> </ul> <p>'...Most of the VICP claims filed since fiscal year 1999 have taken multiple years to adjudicate, but those filed since fiscal year 2009 have taken less time. For many claims, the parties have concluded the proceeding through a negotiated settlement, rather than a contested decision adjudicated by a special master or the courts. Additionally, certain claims were addressed along with similar claims as part of an omnibus proceeding or informal grouping...' p9 (United States Government Accountability Office: 2014.</p>	
Q3: How does the number and type of vaccines covered in the table affect the number of applicants to the scheme?	'...HHS has added vaccines to the Vaccine Injury Table without adding covered injuries associated with those vaccines. Following their addition to the table, more claims were filed for off-table injuries. Since fiscal year 1999, HHS has added six vaccines to the Vaccine Injury Table (but has	

Secondary question	Evidence	Comments on the nature of the evidence
	<p>not added covered injuries associated with these vaccines to the table)...' p16-17 GAO, 2014.</p> <p>'...While the injuries Health Resources and Services Administration (HRSA) is considering have not yet been added to the table, HRSA and DOJ officials report that many claims alleging these injuries that HRSA is considering adding to the table have been conceded or settled. For example, according to DOJ officials, there have been numerous settlements for cases alleging Guillain-Barré Syndrome as an injury associated with the influenza vaccine...' p20 GAO, 2014.</p> <p>"Claims alleging injuries to adults also increased as a result of the addition of vaccines that are recommended for administration in adults (as well as children) to the Vaccine Injury Table." Pg 20 GAO, 2014</p>	
<p>Q3: How does the lack of awareness of the scheme affect the number of applicants to the scheme?</p>	<p>"HHS is required to include a statement of the availability of VICP in the vaccine information materials that health care providers are to distribute to the parent or legal representatives of a child or to any other individual to whom the provider intends to administer a covered vaccine... HHS is also required to undertake reasonable efforts to inform the public of the availability of the program." Pg 9 GAO, 2014</p> <p>However, even with the requirement to provide these vaccine information materials stakeholders claim that the public are largely unaware of the programme and</p> <p>"this lack of awareness contributes to missing filing deadlines and individuals being denied the opportunity for compensation" Pg 32 GAO , 2014</p>	
<p>Q4: Are claimants satisfied with the process of determining damages?</p>	<p>'...Respondents tended to be dissatisfied with the process for determining damages; nearly one-third (30.77%) were very dissatisfied and 12.31% were somewhat dissatisfied. Only 9.23% were very satisfied and 23.08% were somewhat satisfied. Almost one-quarter of respondents (24.62%) were neither satisfied nor dissatisfied with the process...' p29 Altarum, 2009</p>	
<p>Q4: Are claimants satisfied with how awards are paid?</p>	<p>'...Respondents were generally satisfied with how the awards are paid, but feel that the compensation is inadequate...' p33 Altarum, 2009.</p> <p>'... In general, they were satisfied with the method [of payment]. More than half of the respondents were very satisfied (37.70%) or somewhat satisfied (18.03%), while less than one-fifth were very dissatisfied (9.84%) or</p>	

Secondary question	Evidence	Comments on the nature of the evidence
	somewhat dissatisfied (8.20%). About one-quarter of respondents (26.23%) were neither satisfied nor dissatisfied...' p33 Altarum, 2009.	
Q4: Are claimants satisfied that awards are adequate?	<p>'...Respondents were asked whether the amount of the award was adequate to cover past and future medical care not reimbursed by other sources. In contrast to respondents' general satisfaction with the method of payment, most respondents felt that the award amount was inadequate. Nearly one-third felt that the award amount was very inadequate (31.75%) and 19.05% felt that it was somewhat inadequate. Only 6.35% of respondents felt that the award amount was very adequate and 23.81% felt it was somewhat adequate...' p34 Altarum, 2009.</p> <p>NB – The average amount paid out for injury/disability is \$933,000</p> <p><a href="http://www.richardgage.net/Compensation.html">http://www.richardgage.net/Compensation.html</a></p> <p>Accessed 27/09/2018</p>	
Q4:	<p>'...Two-fifths of respondents (40.57%) received compensation; 59.43% did not.' p33 Altarum, 2009.</p> <p>NB - we must decide what to do with this data</p>	
Q4: How do the decisions of the Court of Federal Claims to amend the findings of the special masters affect the volume and costs of awards?	<p>"Special masters recently drifted from using established precedent and documented congressional intent, heightening the burden on petitioners in the Vaccine Program. If this trend continues, the ramifications will extend beyond simply making compensation in the Vaccine Program more difficult and could jeopardize the very foundation of the Vaccine Program itself. The above-mentioned cases may have deeper ramifications, for example, an increase in costly appeals." Pg 96 - thus affecting the overall costs of awards in the US scheme, Daniels M, 2010.</p> <p>NB – need more data to answer this question.</p>	
Q4: How does the Althen ruling on deciding burden of proof affect the volume and cost of awards?	Return to this again.	
Q4: How do the Special Masters and the Vaccine Injury table affect the volume and costs of awards?	NB –We need to seek out data that speaks to these components directly.	
Q4: How do efforts to calculate damages affect the volume and costs of awards?	"while the VICP does formally take numerous steps to simplify damage calculations, those efforts have, once again, fallen short of expectations... In 2002, for example, a median of 533 days elapsed between when a victim was found to be eligible for compensation and the	



Secondary question	Evidence	Comments on the nature of the evidence
	<p>time when damages were actually awarded; in 2003, a median of 564 days elapsed; in 2004, a median of 529 days elapsed; and in 2005, a median of 484 days elapsed. This means that it often takes the VICP twice as long to calculate damages as Congress—which, recall, imposed a 240-day statutory deadline on vaccine adjudications—thought it would take to resolve cases from start-to-finish...' p1691-1692, Engstrom NF, 2015.</p>	
<p>Q4: How do changes to the standard of proof for off table claims affect the volume and costs of awards?</p>	<p>"the increased frequency of (Off-table) claims, combined with Congress's lack of direction regarding their resolution, have left the special masters and courts in charge of implementing the program to struggle with the sufficiency of evidence question and how much to be influenced by traditional tort law. The Federal Circuit, in interpreting the sufficiency of evidence for causal proof in off-Table claims, has leaned toward lower sufficiency standards, thereby increasing the pool of claimants compensated under the program and reducing the potential number of claimants who could later seek redress in court." - affecting the overall volume and costs of awards. Grey BJ, 2011.</p>	
<p>Q4: How does the Vaccine Act affect the volume and costs of awards?</p>	<p><b>"The Vaccine Act thus grants the special master great control over how much weight to accord the evidence proffered by the parties subject to review only for abuse."</b> Grey BJ, 2011.</p> <p><b>NB – need to collect more data to answer this question.</b></p>	
<p>Q4: How does the addition of new vaccines to the Vaccine Act affect volume and costs?</p>	<p>'...In the Vaccine Compensation Program's early years, the overwhelming majority of the cases brought, and compensation awarded, involved injuries to children. This has changed dramatically, and in the past few years the majority of cases brought, and awards made, have involved adults...The principal reason for this change appears to be the addition of seasonal flu vaccines to the Vaccine Act in 2005, and the widespread use of these vaccines by adults. A total of 2,713 awards have been made in the Vaccine Compensation Program through September 9, 2011.' p795, Meyers PH, 2011.</p> <p>NB – need to collect more data to answer this question regarding adding vaccines to the Vaccine Act itself.</p>	
<p>Q4: How do changes to the standard of proof affect volume and costs?</p>	<p>'...The recent focus on causation-in-fact cases has also generated other major changes in the nature of the Vaccine Injury Program. First, the cases are substantially more difficult and complex to litigate. The special masters have much more challenging scientific disputes to resolve in these cases than they do for Table</p>	

Secondary question	Evidence	Comments on the nature of the evidence
	<p>claims. Second, both sides need to locate experts in cutting-edge areas, where substantial uncertainty still exists... The complex off-Table cases that now predominate in the Vaccine Compensation Program also proceed more slowly than the simpler Table injury cases, and typically result in more adversarial litigation than Table cases because the parties and their experts usually begin from polar opposite positions... These changes have encouraged the type of adversarial litigation that the Vaccine Act was designed to minimize...Instead, it is a much slower and more adversarial process that focuses on formally adjudicating non-Table causation-in-fact cases...' p801-802 Meyers PH, 2011.</p> <p>NB, we must return to Meyers' cells on this question to get additional data.</p>	
<p>Q4: How do rulings by the Federal Circuit Court regarding standard of proof affect volume and costs?</p>	<p>'...A final important consequence of the massive switch to off-Table cases has been a series of decisions from the U.S. Court of Appeals for the Federal Circuit, beginning in 2005, which have attempted to clarify the legal standards for proving causation-in-fact cases." Under the principles enunciated in these cases, petitioners' burden in off-Table cases is to demonstrate that a vaccine was a substantial factor in causing an injury, but not necessarily the sole or even the predominant factor causing the injury. Petitioners must also demonstrate that the vaccine was a "but for" cause of the injury, in that the injury would not have occurred except for the administration of the vaccine. Petitioners are not required to prove that a specific biological mechanism was the means by which the vaccine caused the injury, and are also not required to show that all other possible causes for the injury have been eliminated. In <i>Althen v. Secretary of Health &amp; Human Services</i>, the Federal Circuit specified that to satisfy these burdens, petitioners must demonstrate: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury...' p802 Meyers PH, 2011.</p> <p>NB – proposal to use above as a good description of the role of the Federal Circuit Court.</p> <p>'...These legal standards are noncontroversial and widely accepted. However, a controversy emerged from a line of Federal Circuit cases... In these cases, the Federal Circuit emphasized that "close calls regarding causation are [to be] resolved in favor of injured claimants. Such a rule is consistent with Congress's intent that the vaccine law create a generous compensation program that was to be liberally construed in</p>	

Secondary question	Evidence	Comments on the nature of the evidence
	<p>favor of compensating injured petitioners. However, a second line of cases... takes a very different perspective, emphasizing that traditional tort standards should be strictly applied to off-Table cases.' p802-803 Meyers PH, 2011.</p>	
<p>Q4: How do delays in the processing of claims affect volume and costs?</p>	<p>'...Another reason for delay in Vaccine Act cases is that they are generally bifurcated into two separate stages. In the first stage, the sole issue is whether the petitioner has proven entitlement to receive compensation for a vaccine injury. If petitioner is successful at this stage, the case then proceeds to the second stage, which involves a determination of the amount of compensation to be awarded. The damages stage is often complex and protracted and commonly exceeds, by itself, the 240-day statutory deadline for final resolution of the entire case...' pp809 Meyers PH, 2011.</p> <p>NB – the above are just two of the many delays mentioned throughout the data. We need to collect data on other delays.</p>	
<p>Q4: How do negotiated settlements affect volume and costs?</p> <p>NB – must define negotiated settlements</p>	<p>'...According to HRSA data for claims filed since 2006, most compensated claims were adjudicated through negotiated settlement rather than a concession or a contested decision. HRSA's data indicated that about 80 percent of the more than 1,500 non-autism VICP claims filed since 2006 for which compensation was awarded were adjudicated through a negotiated settlement between the parties, compared to about 10 percent involving a contested decision in favor of the petitioner and about 10 percent conceded by HHS... According to HRSA, claims which HHS does not concede may be resolved via a negotiated settlement for several reasons, including a desire by both parties to resolve a case quickly and efficiently. According to the Office of Special Masters, a special master may recommend parties settle as an expeditious and efficient method of resolving certain claims...' p13-14 GAO, 2014.</p>	
<p>Q4: How do changes to the number and type of vaccines covered affect volume and cost?</p> <p>NB – reframe relevant question above</p>	<p>'...According to the Office of Special Masters, the increase in the total amount paid to petitioners in compensation and number of compensated claims is related to the addition of the influenza vaccine to the Vaccine Injury Table. The influenza vaccine, which is administered to millions of people each year, was added to the injury table in fiscal year 2005...' p25 GAO, 2014.</p> <p>NB – when we are considering the other questions about the number and type of vaccines, let's remember the 2005 addition of the influenza vaccine.</p>	

Secondary question	Evidence	Comments on the nature of the evidence
Q4: How do decisions taken by Congress, HHS, and Supreme Court, Court of Appeals of the Federal Circuit and the Court of Federal Claims and Special Masters affect volume and costs?	<p>“...The issue of whether a particular vaccination caused an injury is decided through a process involving numerous decision-makers acting on various logical constituents of the causal inference. The major decision-makers include the U.S. Congress, the Secretary of the Department of Health and Human Services (HHS), the Supreme Court of the USA, the U.S. Court of Appeals for the Federal Circuit, the U.S. Court of Federal Claims and special masters attached to the Court of Federal Claims. The major logical constituents are /KUG rules, policy objectives, presumptions, evidentiary elements and findings of fact...’ p189 Walker VR, 2013.</p> <p><b>NB – must return to unpack the cells of Walker VR.</b></p>	
Q5: In what way is satisfaction in receiving a financial award associated with public acceptance of the scheme?	<p>‘...Receipt of a financial award is associated with increased satisfaction with all relevant elements of the claims process addressed in the survey...’ p36 Altarum, 2009.</p>	
Q5: How do petitioners to the programme learn of the scheme and what can we infer from this regarding public support for the programme?	<p>‘...Many respondents learned about the Program through unofficial sources. One-quarter of respondents (25.23%) learned about the Program from a Web site other than the one maintained by the VICP. However, the VICP Web site was the second most frequently reported source (17.76%)...’ p20 Altarum, 2009.</p> <p>‘...Common health care-related sources of VICP information included the health care provider who gave the vaccine (12.15%), another health care provider (13.08%), and the Vaccine Information Statement (VIS) (7.48%) that is given to the patient or parent/ guardian with each vaccination. Relatively few respondents found out about the Program through advertising: 6.54% read about it in a newspaper or magazine, 5.61% heard about it on the radio or television, and 2.80% saw a flyer or brochure from the VICP. Four respondents (3.74%) found out about the VICP when they were contacted by the CDC. Other sources of information included other parents or adults who had been involved with the VICP (12.15%), attorneys (11.22%), and the National Vaccine Information Center (2.80%), a private advocacy organization...’ p20 Altarum, 2009.</p>	
Q5: How does public awareness of the programme affect public support of the scheme?	<p>‘...HRSA has acknowledged being criticized for years for not adequately promoting public awareness of VICP, and has recently taken some steps...to improve its efforts to reach out to providers and the public... HRSA noted that one of the critical issues facing the program from 2005 to 2010 was that many parents, the general public, attorneys, and health care professionals were not aware VICP existed... In each of HRSA’s annual justification of estimates for appropriations committees for fiscal years</p>	

Secondary question	Evidence	Comments on the nature of the evidence
	<p>2011-2014, HRSA noted that the agency has been criticized for not adequately promoting public awareness of the VICP. HRSA officials also noted the need to carefully balance messages that increase awareness of VICP with public health messages that encourage and promote immunizations...' p31, GAO, 2014.</p> <p>'...Without awareness of the program, individuals who might otherwise receive compensation for a vaccine-related injury or death could be denied compensation because of a failure to file their claim within the statutory deadlines. One stakeholder commented that the public is largely unaware of the program, and this lack of awareness contributes to missing filing deadlines and individuals being denied the opportunity for compensation. Members of the Advisory Commission on Childhood Vaccines also told us that many individuals may not know there is a statute of limitations on filing a claim and many miss the opportunity to file a claim because of the statute of limitations...' p32-33 GAO, 2014.</p>	
<p>Q5: In what way are the changes in 1995 to the Vaccine Injury Table associated with public acceptance of the scheme?</p>	<p>'...The amendments to the Table [in 1995] also changed the politics of the program. Not surprisingly, as in the case of Social Security Disability Insurance (SSDI), agency efforts to make claims harder to prove angered claimants. The parents' group, Dissatisfied Parents Together (DPT)*, had by the late 1990s become the National Vaccine Information Center (NVIC), and the leader of the Center, Barbara Loe Fisher, was outspoken in her criticism of the program. The biggest target of her criticisms were the changes made to the Table of Injuries [in 1995]. Fisher was not alone. Beginning in the 1990s, claimants' criticisms of the Compensation Program were aired in the media and in congressional hearings. From the perspective of parents and their lawyers, there were a bunch of problems that needed fixing... The original law had limited pain and suffering and death damages at \$250,000, but had not included a provision for inflation, so the parents' groups wanted the amount to be raised. Probably the most important proposal, though, was to increase the three-year statute of limitations on claims made to the program. The parents and lawyers argued that because the VICP was so obscure, would-be claimants sometimes learned about the right to file for compensation after the time limit had expired...' p171-172</p> <p>*For more information on the history of the DPT Group, see pg 163-165 Barnes and Burke, 2015.</p>	

Secondary question	Evidence	Comments on the nature of the evidence
	<p>NB – caps about payments and statute of limitations have been confirmed to remain the same, as of Sept 2018. MK saved booklet in Data Analysis folder.</p> <p>'...No public policy could possibly resolve the differences among parents, their lawyers, vaccine manufacturers, public health officials, and doctors over vaccines, but the Compensation Program has had the net effect of diminishing those differences rather than widening them...' p182 Barnes and Burke, 2015.</p>	
<p>Q5: In what way is the Special masters going against congressional intent and not adhering to the Althen ruling associated with public acceptance of the scheme?</p>	<p>Daniels claimed that "Consumers injured from vaccines have a statutory right to be compensated for their losses. By denying compensation for claims that satisfy the three-prong Althen test, petitioners continue to wait for compensation to take care of medical bills, lifestyle changes (such as necessary physical, occupational, and speech therapy), or expenses related to death injuries. Petitioners are waiting longer to be compensated, if at all, and experience a longer, more stressful, and litigious process than the legislatively directed "quick" and "generous" process." Pg 103</p> <p>Further, Daniels mention that there is a need for concern regarding public health:</p> <p>"The primary goal of the Act was to limit lawsuits against vaccine manufacturers and Congress believed this would best be accomplished by directing potential lawsuits into a generous forum: the Vaccine Program.</p> <p>If courts continue to narrowly interpret first symptom or manifestation of onset, it may have the effect of pushing petitioners out of the Vaccine Program, giving petitioners the opportunity to sue vaccine companies... If petitioners are pushed out of the Program and bring suit against vaccine manufacturers, vaccine supplies and public health may once again be jeopardized." Pg 106 Daniels M, 2010</p> <p>NB – Special masters not explicitly mentioned, so we must draw inferences from the above.</p>	
<p>Q5: In what way is the lack of discussion about the scheme in vaccination clinics associated with public acceptance of the scheme?</p>	<p>'...United States law requires that immunization providers use Centers for Disease Control Vaccine Information Statements (VISs) and inform parents about vaccine risks and benefits prior to every childhood immunization. A recent national survey found that public health clinics (PHCs) reported high compliance with this law. To further investigate these findings, we conducted an immunization time-motion study in two PHCs in Kansas and Louisiana... The national Vaccine Injury Compensation Program (VICP) was never discussed...' p228 Davis TC, 2004.</p>	

Secondary question	Evidence	Comments on the nature of the evidence
Q5: In what way is the time it takes to resolve claims associated with public acceptance of the scheme?	<p>"...After the Vaccine Compensation Program had been operating for a decade, three major U.S. government organizations evaluated and published reports on the program—the Federal Judicial Center, the U.S. Government Accountability Office (GAO), [the 1999 review] and the House Subcommittee on Criminal Justice, Drug Policy, and Human Resources. The three reports raised similar concerns about the operation of the Vaccine Program, including delays in resolving cases that stretched far beyond the statutory 240-day limit, and the overly adversarial nature of the cases in a compensation program intended to be less adversarial. All three reports also noted concerns about payment of attorneys' fees, including concerns that the fees were too low, took too long to process, and were subject to unnecessarily adversarial review by Department of Justice (DOJ) attorneys. These same concerns have continued to be raised by others,' and they remain valid today. Problems with delays and the overly adversarial nature of the program have been exacerbated by the change in the Vaccine Table and the related developments described above." p804-805 Grey BJ, 2011.</p>	
Q5: Are claimants satisfied with the process of determining damages?	<p>'...Respondents tended to be dissatisfied with the process for determining damages; nearly one-third (30.77%) were very dissatisfied and 12.31% were somewhat dissatisfied. Only 9.23% were very satisfied and 23.08% were somewhat satisfied. Almost one-quarter of respondents (24.62%) were neither satisfied nor dissatisfied with the process...' p29 Altarum, 2009</p>	
Q5: Are claimants satisfied with how awards are paid?	<p>'...Respondents were generally satisfied with how the awards are paid, but feel that the compensation is inadequate...' p33 Altarum, 2009.</p> <p>'... In general, they were satisfied with the method [of payment]. More than half of the respondents were very satisfied (37.70%) or somewhat satisfied (18.03%), while less than one-fifth were very dissatisfied (9.84%) or somewhat dissatisfied (8.20%). About one-quarter of respondents (26.23%) were neither satisfied nor dissatisfied...' p33 Altarum, 2009.</p>	
Q5: Are claimants satisfied that awards are adequate?	<p>'...Respondents were asked whether the amount of the award was adequate to cover past and future medical care not reimbursed by other sources. In contrast to respondents' general satisfaction with the method of payment, most respondents felt that the award amount was inadequate. Nearly one-third felt that the award amount was very inadequate (31.75%) and 19.05% felt that it was somewhat inadequate. Only 6.35% of respondents felt that the award amount was very adequate and 23.81% felt it</p>	

Secondary question	Evidence	Comments on the nature of the evidence
	<p>was somewhat adequate...' p34 Altarum, 2009.</p> <p>NB – The average amount paid out for injury/disability is \$933,000</p> <p><a href="http://www.richardgage.net/Compensation.html">http://www.richardgage.net/Compensation.html</a></p> <p>Accessed 27/09/2018</p>	
<p>Q6: How do life care planners act as a cost control mechanism to the scheme?</p>	<p>'...If a financial award is granted, life care planners help the petitioner to develop a plan for acquiring and funding services and any equipment required for the injured individual. Life care planners review medical records, collaborate with health care providers and experts, identify patient needs, and calculate costs of care. In general, the petitioner and HHS each retain a life care planner, but in some cases, a single life care planner is agreed upon...' p23</p> <p>'...Among respondents who had a life care planner, the most common arrangement was to have two life care planners, one hired by the petitioner or the petitioner's attorney and one hired by HHS (54.54%)...' p23</p> <p>'...Respondents had differing, yet strongly-held opinions about their satisfaction with the role of the life care planners. There were slightly more satisfactory responses than unsatisfactory ones, with almost one-third (32.14%) reporting being very satisfied with their life care planner(s) and 3.57% reporting being somewhat satisfied. Twenty-eight percent (28.57%) reported feeling very dissatisfied. This distribution must be interpreted with caution, however, given the small number of respondents to this survey item (n=28)...' p24</p>	
<p>Q6: How do caps on certain payments act as a cost control mechanism to the scheme?</p>	<p>'...After the court proceedings, a special master decides if an award will be paid, and if so, the amount. For an injury, the petitioner may be paid for past and future non-reimbursable medical and custodial care, rehabilitation costs, up to \$250,000 for actual and projected pain and suffering, lost earnings, and reasonable legal costs. In the case of a death, the petitioner may be paid up to \$250,000 as a death benefit and for reasonable legal costs. Compensation is paid through a lump sum and/or annuity. Attorneys' fees and costs are paid whether or not compensation is awarded if the claim was filed "on good faith and reasonable basis..." p33 Altarum, 2009.</p> <p>'Other problems that have been noted with the Vaccine Program include the short, inflexible three-year statute of limitations to file a claim in the program; the low \$250,000 award for death cases; the low \$250,000 cap on pain and suffering in injury cases; and the burden of proof</p>	



Secondary question	Evidence	Comments on the nature of the evidence
	<p>imposed on petitioners in off-Table cases...' p804-805 Grey BJ, 2011.</p> <p>"If the US Court of Claims awards compensation to the vaccine-injured person: The VICP will offer to pay up to \$250,000 for a vaccine associated death. The VICP will offer to pay for all past and future unreimbursed medical expenses, custodial and nursing home care; and up to \$250,000 pain and suffering as well as loss of earned income. If an individual rejects the award or is denied compensation, a lawsuit may be filed in civil court but with certain restrictions." Pg 386, McLeod 201?</p>	
<p>Q6: How does the limitation on time to file a claim (3 years) act as a cost control mechanism to the scheme?</p>	<p>'... Other problems that have been noted with the Vaccine Program include the short, inflexible three-year statute of limitations to file a claim in the program...' p804-805 Grey BJ, 2011</p>	

## Appendix 9: Articles excluded as not relevant from 2nd stage full text screen (n= 23)

Citation	
1.	Bakker C, and Honig N. (2018). Addressing Pharmaceutical Injuries: The US Landscape. <i>Clinical Pharmacology and Therapeutics</i> , 103(3), pp.384-385.
2.	Bismark M, Dauer E, Paterson R, and Studdert D. (2006). Accountability sought by patients following adverse events from medical care: the New Zealand experience. <i>Canadian Medical Association Journal</i> , 175(8), pp.889-894.
3.	Boxler Brandon L. (2010). What to Do with Daubert: How to Bring Standards of Reliable Scientific Evidence to the National Vaccine Injury Compensation Program Note. <i>William and Mary Law Review</i> , 52, pp.1319-1368.
4.	Chen Yu-Ling, Huang Angela Song-En, Cheng An-Hua, and Chien Ta-Jen. (2015). A comparison of vaccine injury compensation scheme in Germany, Finland and Taiwan. <i>Taiwan Epidemiology Bulletin</i> , 31(18), pp.159-164.
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