Policy Briefing: NFCS for Vaccine injuries

Covid-19 Vaccine No Fault Compensation Schemes

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https://www.law.ox.ac.uk/home-no-fault-compensation-schemes-covid-19-vaccines

This Briefing draws on the existing literature and our own findings on Compensation Schemes for injuries following Covid-19 vaccination and sets out policy proposals to improve provision and aid future pandemic preparedness.

These findings arose from a project looking at No-Fault Compensation Scheme carried out at the Centre for Socio-Legal Studies, University of Oxford.

This Briefing can stand alone or can be read in conjunction with other outputs from this project.

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Covid-19 Vaccine NFCS – Policy Briefing

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Executive summary

While Vaccine compensation schemes are not new the covid pandemic has dramatically shifted the landscape. Previous schemes have been national schemes, usually created as a policy response to particular demands made to the national government. These schemes predominantly cover childhood vaccines introduced and well-characterised vaccines against known diseases. Pandemics are very different in several ways. The covid pandemic potentially risked a perfect storm; a previously uncharacterised virus, vaccines developed using novel RNA technology, and global mass vaccination rolled out at speed. Each of these elements adds an additional layer of uncertainty.

We know there will be another pandemic, but we do not know which disease will cause it. While greater disease familiarity can reduce the risks associated with pandemic vaccines, it cannot eliminate them. The 2009 H1N1/Swine flu pandemic was a very well characterised pathogen and flu vaccines like Pandemerix have been manufactured in the same way for decades. Even with this far higher baseline knowledge the link between the Pandemerix vaccine and narcolepsy was unforeseen. Whatever disease causes the next pandemic, even if it is a familiar pathogen, any vaccine development will be accompanied by considerable uncertainty.

This uncertainty differentiates pandemic vaccinations from standard vaccinations, and this uncertainty must be taken into account when planning vaccine-related pandemic responses. Well designed, properly functioning no-fault compensation schemes can provide security. For individuals who are being vaccinated there is a promise that if they suffer an adverse event they will be compensated. For governments these schemes can help, alongside other measures such as indemnity agreements, to facilitate vaccine supply by providing reassurance to the pharmaceutical industry.

Potential claimants to vaccine compensation schemes have a legitimate expectation that they will do what they say; that will deliver compensation for vaccine injuries. Our research has found huge variation in the effectiveness of the delivery of compensation. We have observed some highly effective examples of best practice, but too often we have found that schemes are falling short. There will be further pandemics and there is a need for greater pandemic preparedness. We have set out a series of recommendations to improve no-fault compensation schemes which are applied in a pandemic context.

Introduction to vaccine compensation schemes

No fault compensation schemes for vaccine injury

Vaccine injury compensation scheme have existed in some countries for many decades. They have tended to be located in high income countries, see figure 1. The national scheme that predated the pandemic predominantly cover childhood vaccines, although some also cover vaccinations administered to adults.

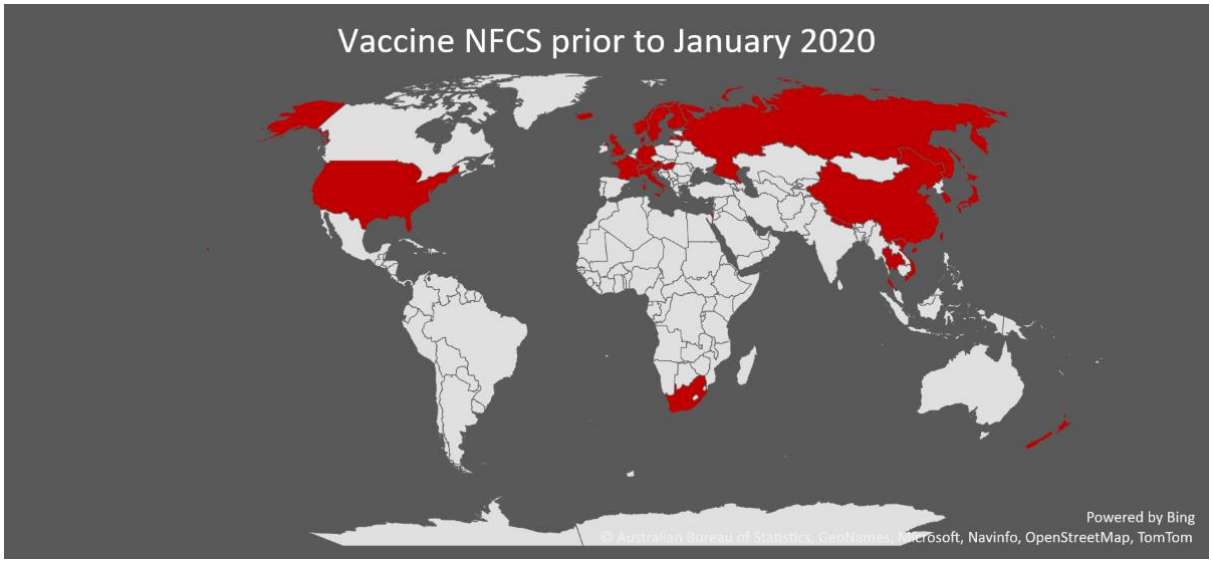

Figure 1. Countries with a vaccine NFCS operational prior to January 2020.

The advent of the covid pandemic created seismic shift in vaccine compensation coverage, figure 2 shows countries with coverage for at least some of the covid vaccines administered in that jurisdiction. There were a few countries, such as Hungary, that had an existing vaccine NFCS but chose not to include covid vaccinations under it.

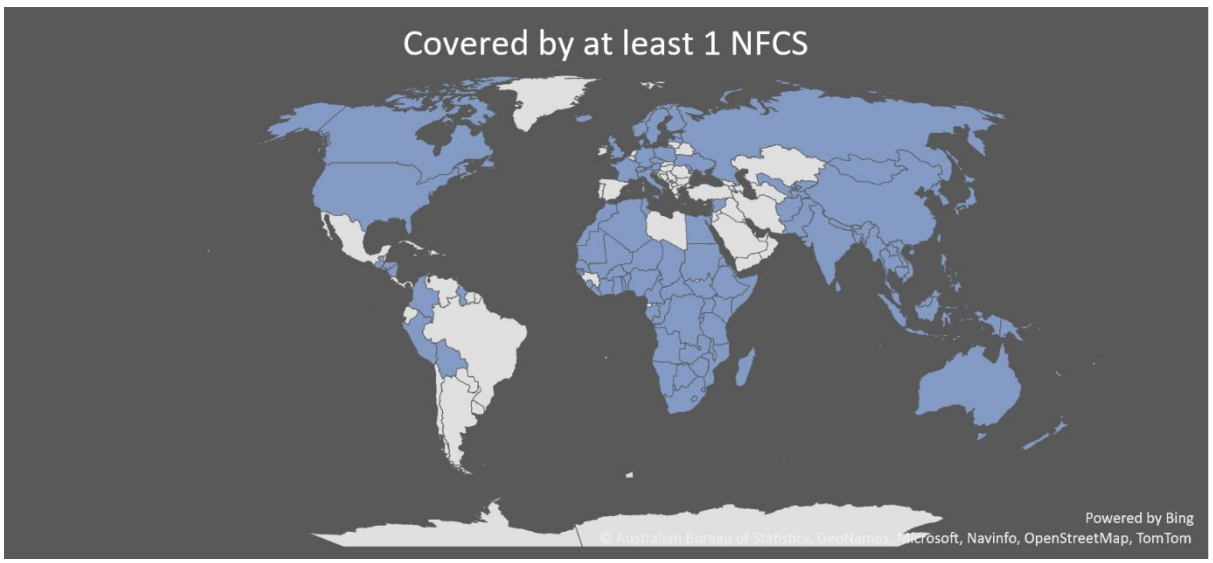

Figure 2. Countries with at least one No-fault compensation Scheme covering covid vaccines

While it may be tempting to consider vaccine schemes in totality covid vaccination schemes have some distinct features. Firstly, covid vaccines were primarily used in healthy adults. Although vaccination policies varied by country it was often older adults that were early vaccine recipients.

This meant the vast majority of vaccine recipients were able to consent for themselves, albeit with more limited information on the risks being consented to than would be available in a standard medical setting. Secondly covid vaccines were created to counter a novel disease; childhood vaccines protect against known and well characterised diseases. Thirdly, some of the covid vaccines were based on novel RNA technology; all of the commonly used childhood vaccines rely on tried and tested techniques for manufacturing vaccines and driving immunity. Finally, covid vaccines were rolled out during a pandemic, which created a plethora of deviations from social and political rules and norms. Many governments enacted some form of vaccine mandate, with varying consequences for non-compliance.[1]

This project

This policy briefing is an output from the third and final phase of a project carried out at the Centre for Socio-Legal Studies, University of Oxford. This briefing can stand alone or be read in conjunction with other outputs from this project.

In phase one we identified 29 national schemes that were offering no-fault vaccine compensation at the start of the pandemic in January 2020. A rapid proliferation in NFCS was triggered by the pandemic, the number of jurisdictions with a no-fault compensation scheme which covers at least some of the Covid-19 vaccines given in that jurisdiction increased almost five-fold in under two years.

The first stage of our research mapped the NFCS landscape, with our findings set out on the project website and in a series of reports.

Phase 2 of this project has sought to research the performance of a selection of these schemes in more detail, looking at a range of key performance indicators. These are described in this report.

Phase 3 of the project involved literature reviews of eight countries, Canada, Estonia, Finland, Japan, Poland, New Zealand, the UK and Hungary. These were selected as the phase two research indicted interesting elements to each of them. Summary reports for these countries are available on the project website. In depth follow up surveys and interviews were carried out in five of these countries, Canada, Estonia, Finland, New Zealand and the UK. The surveys and interviews have enabled a qualitative analysis of experiences of these NFCSs which have informed this briefing and other publications.

Why set up a scheme?

A number of reasons have been proposed for establishing vaccine compensation schemes. Clearly the rationales for earlier national schemes were not proposed in a pandemic context. The multinational schemes are distinct; they sit within a much wider organisational aim of providing vaccines to low and middle income countries which is very different to all other NFCSs. Aurelia Nguyen, Deputy CEO of CEPI and formerly Managing Director of COVAX outlines the motives behind COVAX of delivering world-wide vaccinations and learnings from Swine Flu[2]

[1] Institute for Government 'Vaccine Mandates' (23 December 2021) https://www.instituteforgovernment.org.uk/article/explainer/vaccine-mandates

[2] CEPI Covax: The "world first" vaccine sharing scheme that saved millions.

"It was also clear that we needed to avoid the terrible failings of the 2009 Swine Flu pandemic when a small number of rich countries bought up almost the entire global supply of H1N1 vaccines. COVAX was a way of trying to get all of the world's most vulnerable people vaccinated, not just some of them."

The multinational NFCSs are part of an architecture with an overarching goal of achieving a more equitable global supply of vaccines. This is not seen in national schemes, which meet the needs within that State. But it is worth briefly exploring and contextualising similarities and differences between the rationales proposed for earlier schemes and those that were created in response to the pandemic. Rationales can be broadly defined into utilitarian and non-consequentialist arguments.[3]

Protecting the supply of vaccines has been suggested as utilitarian rationale behind national NFCSs. Historically there are clear examples of no-fault compensation schemes being introduced in response to vaccine manufacturers leaving the market and/or raising prices when confronted with escalating liability costs.[4] This has led to proposals that protecting the supply of vaccines by increasing the security of vaccine manufacturers is a driver of NFCS creation.[5] Our research indicates that the degree of protection from liability that schemes offer varies according to how the scheme sits in the wider legal landscape. For example, in the UK, whatever the intentions behind it were, the current NFCS has almost no impact on the claimant's decision to litigate or not. Our findings indicate that a more holistic view incorporating the wider social and legal contexts is needed. This would include the relative degree of liability protection afforded to suppliers (including but not limited to, access to and impacts on litigation, indemnity agreements, etc) and the availability of other forms of support (including potential awards from litigation, provisions of healthcare, social security payments, housing support, etc) for injured individuals. We would favour the more nuanced argument put forward by Michele Mello that liability limitations for manufacturers are likely to be more important for a positively impact on vaccine supply than the creation of a NFCS in isolation.[6]

The multinational schemes suggest that the vaccine supply rationale can be glossed with an argument over more equitable access to vaccines globally and the countering of potential 'vaccine nationalism' during a global pandemic.

Another proposed rationale for national NFCSs is protecting the uptake of vaccines. Vaccines offer protection to individual recipients, but (unlike other pharmaceuticals) when their uptake is sufficiently high they also confer the wider social benefit of herd immunity. Herd immunity is particularly important in protecting key vulnerable groups who cannot be vaccinated:- very young babies, individuals whose treatment leaves them immunocompromises (some cancer patients, transplant recipients, etc), those with autoimmune conditions, etc. Each vaccine will have a different level of population coverage required to deliver herd immunity. Vaccine hesitancy has a dual impact, it leaves unvaccinated individuals more vulnerable to the disease (with implications both for themselves and for healthcare systems) and it is a potential threat to achieving sufficient coverage for herd immunity. In 2019, prior to the pandemic, the WHO named vaccine hesitancy[7] as one of the

[3] Mello MM. Rationalizing vaccine injury compensation. Bioethics. 2008 Jan;22(1):32-42, 33.
[4] R Manning Changing Rules in Tort Law and the Market for Childhood Vaccines (1994) 37 Journal of Law and Economics 247-275.
[5] Mello, see FN 3, Wilson K, Keelan J. The case for a vaccine injury compensation program for Canada. Canadian journal of public health. 2012 Mar;103(2):122-4
[6] Mello, see FN 3
[7] We have adopted the following definition 'vaccine hesitancy refers to delay in acceptance or refusal of vaccination despite availability of vaccination services' taken from MacDonald NE; SAGE Working Group on

top ten threats to global health.[8] Vaccine scepticism and vaccine hesitancy[9] have come to the fore recently, but they are not new phenomena. Vaccines have always attracted some degree of controversy, and there have always been people who are highly sceptical of vaccine safety and/or efficacy.[10] Uptake of vaccines and maintaining public confidence in vaccines have been proposed as arguments for the introduction of a NFCS.[11] This rationale for creating a NFCS has not received universally support, [12] and there is no empirical evidence of a link between the existence of a NFCS and willingness to undergo vaccination.[13] If a NFCS can, as has been proposed, increase vaccine confidence this may become an increasingly role in a backdrop of rising global vaccine hesitancy. Our research was on claimant experience of claiming from a vaccine injury compensation scheme, by definition our research participants had been vaccinated. Our results do not add to the discourse on the proposed linkage between creation of a NFCS and vaccine confidence. What our research has indicated is that the UK redress system, which is perceived as non-functional by claimants, can reduce trust in the government.[14] Global analysis shows that trust in Government it is a strong predictor of vaccine hesitancy during the pandemic.[15] **Given the global importance of vaccine confidence these issues urgently need to be addressed by further research.**

An alternative explanation for the establishment of NFCS can be found in the more morally focussed non-consequentialist rationales. Although fairness has been raised as a potential rationale for NFCS creation,[16] most of the non-consequentialist arguments have focussed on solidarity and ethical arguments.[17] This was clearly stated by the Pearson Commission in the UK in 1978 when advocating for a compensation scheme, when they set out that there is a special case for vaccine injury compensation when '….vaccination is recommended by a public authority and is undertaken to protect the community.' These rely on the presumption that by being vaccinated against a communicable disease an individual is contributing to the common good of herd immunity. Applying

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Vaccine Hesitancy. Vaccine hesitancy: Definition, scope and determinants. Vaccine. 2015 Aug 14;33(34):4161-4. doi: 10.1016/j.vaccine.2015.04.036. Epub 2015 Apr 17. PMID: 25896383.

[8] https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019

[9] A new form of vaccine scepticism was seen during the covid pandemic, where claims were made that certain covid vaccines were inferior and were not in fact vaccines, see Demjén Z, Elena Semino, Gleave R. A jab is not a vaccine; it's a 'shot'. Public Health. 2025 Aug;245:105815. doi: 10.1016/j.puhe.2025.105815. Epub 2025 Jun 9. PMID: 40494211.

[10] For example see Kirkland A Vaccine Court: The Law and Politics of Injury (New York, New York University Press, 2016); Colgrove JK State of Immunity: The Politics of Vaccination in Twentieth Century America (Berkeley: University of California Press, 2006); Durbach N Bodily Matters: The Anti-Vaccination Movement in England 1853-1907 (Durham NC, Duke University Press. 2005)

[11] Fairgrieve D, Borghetti JS, Dahan S, et al. Comparing no- fault compensation systems for vaccine injury. Tulane J Int Comp Law 2023;31:75–118. Benbow DI. Virtue ethics and the United Kingdom (UK) vaccine damage payment scheme (VDPS). J Soc Wel & Fam L 2022;44:391–410

[12] Benbow ibid

[13] Mello see FN 3, Wilson & Keelan see FN5

[14] Gyurko F and Macleod S The 'unheard scandal': Covid-19 vaccine-injured people's perceptions of the national redress scheme, and trust in the government in the UK. Accepted for a Special edition of Law and Society, awaiting citation

[15] D'Silva C, Fullerton MM, Hu J, Rabin K, Ratzan SC. A global survey to understand general vaccine trust, COVID-19 and influenza vaccine confidence. Front Public Health. 2024 Nov 20;12:1406861. doi: 10.3389/fpubh.2024.1406861. PMID: 39635221; PMCID: PMC11615073; Jennings W, Valgarðsson V, McKay L, Stoker G, Mello E, Baniamin HM. Trust and vaccine hesitancy during the COVID-19 pandemic: A cross-national analysis. Vaccine X. 2023 Aug;14:100299. doi: 10.1016/j.jvacx.2023.100299. Epub 2023 Apr 6. PMID: 37063307; PMCID: PMC10079319.

[16] Mello FN 3

[17] Report of the Royal Commission on Civil Liability and Compensation for Personal Injury (Pearson Commission), Chairman Lord Pearson, Cmnd 7054- 1 1978, para. 1398.

this rationale is straightforward when all vaccinated individuals in a State are covered by the NFCS. There is a particular conceptual difficulty in applying these rationales to the multinational compensation schemes, which only afford protection to individuals vaccinated under their framework, even though all individuals who are vaccinated contribute to herd immunity.[18]

This narrower construction of social solidarity rests on a contribution to the common good of herd immunity. A wider construction is possible, which just requires that the broader societal judgment is that medical risks should be shared.[19] This is particularly relevant when considering novel vaccines, where the risk profile for rarer events, which are unlikely to be detected in clinical trials, is initially uncertain. Early vaccine recipients cannot fully appreciate or assume the risks early in a pandemic due to lack of knowledge of real-world context. This more limited opportunity for fully informed consent feeds into this broader social solidarity argument.

Historically the establishment of national NFCS have been reactive, follow national campaigns around known, existing concerns over the safety of a particular vaccine or vaccines.[20] The national schemes have tended to be retrospective and to compensate (at least some of) the individuals who have already been injured as well as being prospective and covering against known future harms. The multinational schemes created during the pandemic were quite distinct, they were not created in response to safety concerns, but in advance of them. This prospective coverage was created before the full risk profile of the vaccines had been established. These schemes were also created as part of a drive for more equitable worldwide access to vaccines. This is global social solidary focussed on sharing positive impacts of vaccinations is novel and extends the established arguments on solidarity and the sharing of the risks of medical treatments.

We agree with Michelle Mello that there has not been an overarching set of principles '…policies in this area reflect political pressures and economic considerations more than any cognizable set of principles'. We have set out a framework for best practice for vaccine NFCS with our rationales for pandemic schemes, which differ from the rationales underpinning national schemes.

Who establishes schemes and how are they created?

Prior to the pandemic establishing NFCS had generally only been created by national governments. The response to the Covid pandemic has changed this. National governments have tended to use legislation to create these schemes, though not always, see figure 3. Canada has both statutory models in Quebec a non-statutory scheme for the remainder of the country.

[18] Macleod S, Uberti F, Kameni E. No-fault compensation schemes for COVID-19 vaccine injury: a mixed bag for claimants and citizens. J Med Ethics. 2025 Jan 23;51(2):115-120. doi: 10.1136/jme-2024-109900. PMID: 38889950.

[19] Mello, FN 3

[20] Macleod, Uberti & Kameni see FN18

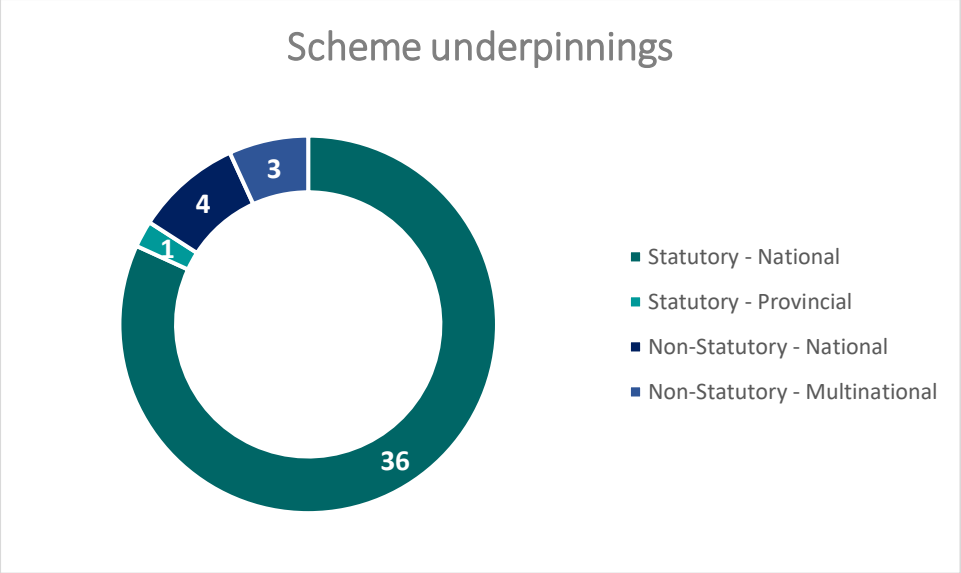

Figure 3. Underpinnings of the different schemes.

Schemes that cover more than one jurisdiction tend to be contractual rather than statutory, probably because of the difficulties that would be involved in co-ordinating legislation across multiple countries with differing legal systems. There had been some earlier examples of a multi-country responses to outbreaks of disease and pandemics, and consideration of liability protection and of no-fault compensations schemes. Liability protection provides manufacturers with security, but leaves injured individuals still reliant on litigation to obtain compensation. No-fault schemes have the advantage that they provide claimants with a route to redress that does not involve litigation. These two elements can be complimentary, but they have not always been applied together.

In 2014 an Ebola outbreak began that affected Guinea, Liberia and Sierra Leone. Ebola is a serious illness, on average it kills half of infected individuals. Until 2014 outbreaks had been contained within sparsely populated rural areas, and the limited numbers enabled the manufacturers to self-insure. What differentiated the 2014 outbreak from previous outbreaks was its progress into populous urban areas. Vaccines were developed, and exploration was undertaken over how to provide compensation for participants in the Partnership for Research on Ebola Vaccines in Liberia (PREVAIL) vaccine trial.[21] This included considering commercial insurance, and a self-insurance fund in Liberia capitalised by the US Government and the Pharmaceutical manufacturers. Differences existed between Liberia and the US on the amount and source of capitalisation, the claims process and the scope of coverage; the PREVAIL trial concluded before these could be resolved. Separately there were discussions with the World Bank over emergency indemnification. In 2017 the World Bank launched the Pandemic Emergency Funding Facility, which was intended to provide risk sharing and insurance funds. In actuality, the funding was used to provide responsive care to later outbreaks, and not for compensation and/or liability protection.

[21] Larson G. In Focus: Clinical Trial Insurance and Indemnification. 2024 Aug 31. In: Sorenson RA, Higgs ES, Fallah MP, et al., editors. Principles and Practice of Emergency Research Response [Internet]. Cham (CH): Springer; 2024. Chapter 32.2. Available from: https://www.ncbi.nlm.nih.gov/books/NBK613988/ doi: 10.1007/978-3-031-48408-7_49

A potential alternative route to compensation could be found in the immunity from legal processes held by the UN[22] and by extension the WHO.[23] While the New York Convention affords the UN and the WHO immunity from all forms of legal process, there is still a requirement to make provision for alternative modes of settlement, which could comprise a compensation scheme. This immunity was used as a liability shield for vaccine manufacturers during the H1N1 pandemic.[24] Passing vaccines from the manufacture to the WHO then to the recipient country effectively activated the liability shield over those vaccines, protecting manufactures and making the WHO responsible for making provision for settlement of claims relating to vaccine injuries. For this approach to be effective recipient countries have to be confident that the WHO will assume responsibility for compensation. Following the 2010 earthquake in Haiti UN peacekeepers imported a virulent strain of cholera, and then the UN both failed to establish an alternative mode of settlement and invoked its immunity to have legal proceedings dismissed. Attaran and Wilson argue persuasively that these actions made this approach untenable for future pandemics.[25]

The Covid Pandemic saw three multinational compensation schemes created. COVAX, AVAT and UNICEF. These covered low and middle income countries, with the COVAX scheme extending coverage to nations all over the globe, AVAT covering participating African Union and the CARICOM states, with UNICEF operating in member states in Asia.

COVAX was a unique multilateral effort which was co-led Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) the WHO and UNICEF. The NFCS was developed by WHO on behalf of COVAX partners.

AVAT was an African Union initiative set up to secure vaccines for Africa. It was a collaboration between several key partners including The African Union, The African Export-Import Bank (Afrexim Bank) Africa CDC, and the World Bank. As part of this initiative a No-Fault compensation Scheme was set up, with the funds held in a Trust in Mauritius and administered by ESIS Inc.

Interestingly both the UNICEF scheme and the COVAX schemes could have potentially utilised the liability protection that stems from being WHO agencies, but they did not, suggesting that the presumption put forward by Attaran and Wilson in 2015 was correct.

While the multinational schemes will offer coverage in member states, this is limited coverage. It only applies to vaccines supplied under their framework. Vaccines given under bilateral agreements, as donations, etc will not be covered.

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[22] UNGA 'Registration No. 4 in the United Nations Treaty Series: Conventions on the privileges and immunities of the United Nations.' (Adopted by the General Assembly 13 February 1946 https://www.un.org/en/ethics/assets/pdfs/Convention%20of%20Privileges-Immunities%20of%20the%20UN.pdf

[23] UNGA 'Resolution 179 (II): Convention on the privileges and Immunities of the Specialised Agencies' (adopted on 21 November 1947) https://apps.who.int/gb/bd/PDF/bd47/EN/convention-on-the-privi-en.pdf

[24] World Health Organization. Main operational lessons learnt from the WHO pandemic influenza A (H1N1) vaccine deployment initiative. A report of a WHO meeting held in Geneva, Switzerland 13–15 December 2010. Report. 2011. https://iris.who.int/bitstream/handle/10665/44711/9789241564342_eng.pdf

[25] Attaran A, Wilson K. The Ebola Vaccine, Iatrogenic Injuries, and Legal Liability. PLoS Med. 2015 Dec 1;12(12):e1001911. doi: 10.1371/journal.pmed.1001911. PMID: 26625163; PMCID: PMC4666648.

What do NFCS schemes offer?

There is no uniformity across different schemes. Schemes have developed in a piecemeal way, which has been highly influenced by local context. Key elements of an NFCS offer are explored below.

Temporary or permanent injury

Some schemes cover temporary injuries, others will only cover permanent injuries/death, see table X. This is a significant policy question as it has wider societal and financial implications. Clearly including temporary injuries will increase the potential claimant pool.

Figure 4 shows the injuries covered by the 26 pre-pandemic schemes and the 15 post pandemic schemes (including the three multinational schemes), and there seems to be no real difference between them.

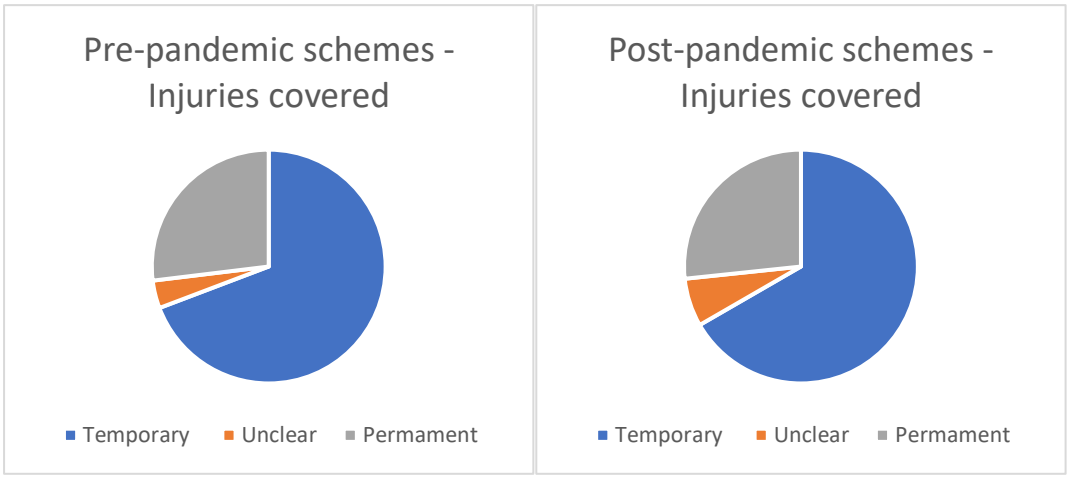

Figure 4. Injuries covered by NFCSs created pre and post pandemic

Eligibility to make a claim

There are variations in who can make a claim. Every scheme we have studied allows an injured claimant to claim and allows a representative to claim for a deceased individual. There are differences in who qualifies as a representative across different schemes, in some cases this is the estate in others it is an individual from a specified list, often with an assigned priority. Some schemes also allow dependents of the injured/deceased individual to make a claim in their own right separate from a claim by the estate.

The eligibility thresholds for payments are very different between the schemes. This will be explored in the framework section. This inconsistency, which is combined with a lack of public information on performance metrics for a large number of schemes, makes comparisons across schemes difficult.

Payments made under the NFCS

It is notable the only example we have found of a scheme which awards a fixed capped sum with no reference to the individual claimant's circumstances is the UK.

There is no consistent approach to quantification across schemes, some use tariffs while others adopt a fully individualised approach. A number of schemes will quantify against a national benchmark, the Scandinavian schemes, the multinational schemes and some other use this approach. All the NFCS we have studied have limits on payments. In some cases this is a cap on the overall payment, in other schemes particular elements of the payment are capped.

Awards made under vaccine NFCS vary. Some schemes (including the multinational schemes) make payments as capitalised lump sums, some using periodic payments, and other scheme using combinations of both of these, see figure 5 for the different national NFCS payment types.

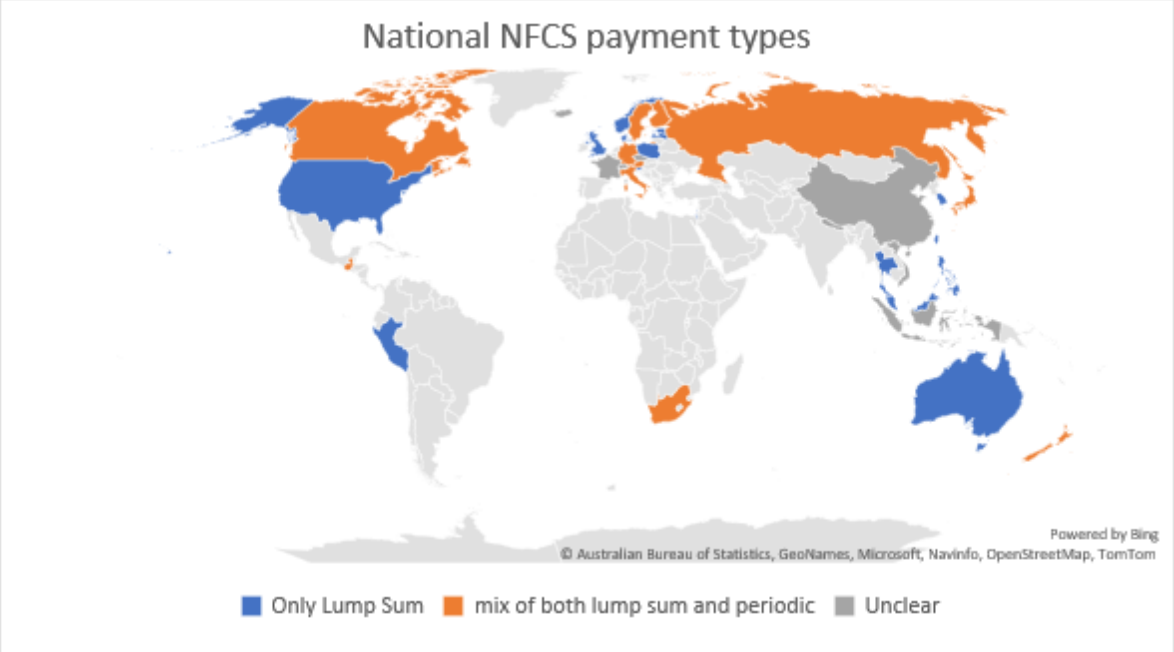

Figure 5 Different payment types for National NFCSs

Where is covered?

Prior to the pandemic vaccine NFCS coverage was limited to a subset of medium and higher income countries. The multinational NFCSs vastly expanded coverage into low and middle income countries.

All schemes have geographical restriction, these usually relate to where the vaccine was administered, for example the US CICP will only cover vaccines administered in the US. There are some exceptions to this, for example the UK VDPS will cover vaccines that were given as part of armed forces medical treatment wherever they were administered, as well as vaccines that were given in the UK or the Isle of Man.

For the multinational schemes there is a dual requirement the vaccine must have been administered in a participating member state and the vaccine must have been procured through the relevant program.

When did coverage apply

Timeline of start of coverage and end of coverage for schemes vary. Some of the schemes pre-dated the pandemic added the covid vaccines to the list of eligible vaccines and will continue coverage. Other schemes which were created as emergency responses, such as the multinational schemes, are

time limited pandemic responses. The COVAX NFCS's application process will end on 30 June 2027.[26] The AVAT NFCS applications must be received by 03 August 2026.[27] The coverage end points are different for each vaccine, the final vaccine to close is NUVAXOVID which closes on 19 December 2023.

The majority of schemes we have studied have a time limit on when claims can be made. These vary from 30 days to notify of an adverse event in South Africa and Guatemala up to six years in the UK and Slovenia. There is no 'correct' time period, the selected timeframe will be a policy decision.

Findings relevant to best practice for NFCS

We have identified a number of findings that are relevant to best practice for pandemic NFCS. These recognise the inherent differences between a 'standard' vaccine injury compensation system, and a pandemic context which has far higher levels of uncertainty. In a pandemic the underlying disease may be uncharacterised, and if so the risks of both the disease and any vaccines developed against it are initially unascertained. During a pandemic vaccine development and testing may be expedited and approvals based on emergency protocols rather than the standard authorisation pathways, with more limited opportunities to detect rare side effects prior to mass roll out. At the start of their usage, vaccines developed used novel technology, such as the RNA vaccines that were developed and deployed during the covid pandemic, do not have an established risk profile for real world usage. These factors all impinge upon an individual's ability to understand and to voluntarily assume the risks associated with vaccination, particularly for those vaccinated early in a pandemic. All of these uncertainties are set against a backdrop of increased importance of vaccination as a means of reducing the spread and/or severity of a pandemic. A well-functioning NFCS cannot reduce these risks, but it can aid early signal detection and provide protection for individuals who are unfortunate and suffer an adverse vaccine event.

There are two main potential funding models for pandemic NFCSs. These are using a levy or payment per dose (which could be from manufacturers, suppliers, donors, etc) or government funding. The levy model has been successfully used in national vaccine compensation schemes for decades, for example the US VICP and the Scandinavian pharmaceutical compensation schemes. This model was adapted for the multinational schemes, which is provides a practical solution for schemes that covered multiple member States. This is not the predominant model for national pandemic vaccine schemes, the vast majority of which are government funded. As NFCSs are generally funded by governments, there is a strong argument they should be accountable to governments and the wider public.

Based on our findings we have developed a framework for NFCSs. This is not intended to be rigid and inflexible and must be tailored to the requirements of each scheme. In our view it is particularly important that scheme design and development is undertaken as part of pandemic preparation, not during the emergency phase of a pandemic. This process should take into account the viewpoints of multiple stakeholders; as the public are both the funders (via taxation) and the ultimate end users these schemes strong public input should be a must in the co-design process.

[26] Schedule 1(i) of the COVAX Program Protocol available at https://covaxclaims.com/program-protocol/
[27] Schedules 1 and 7 of the Program Protocol available at https://avatclaims.com/program-information/schedules-and-other-documents/

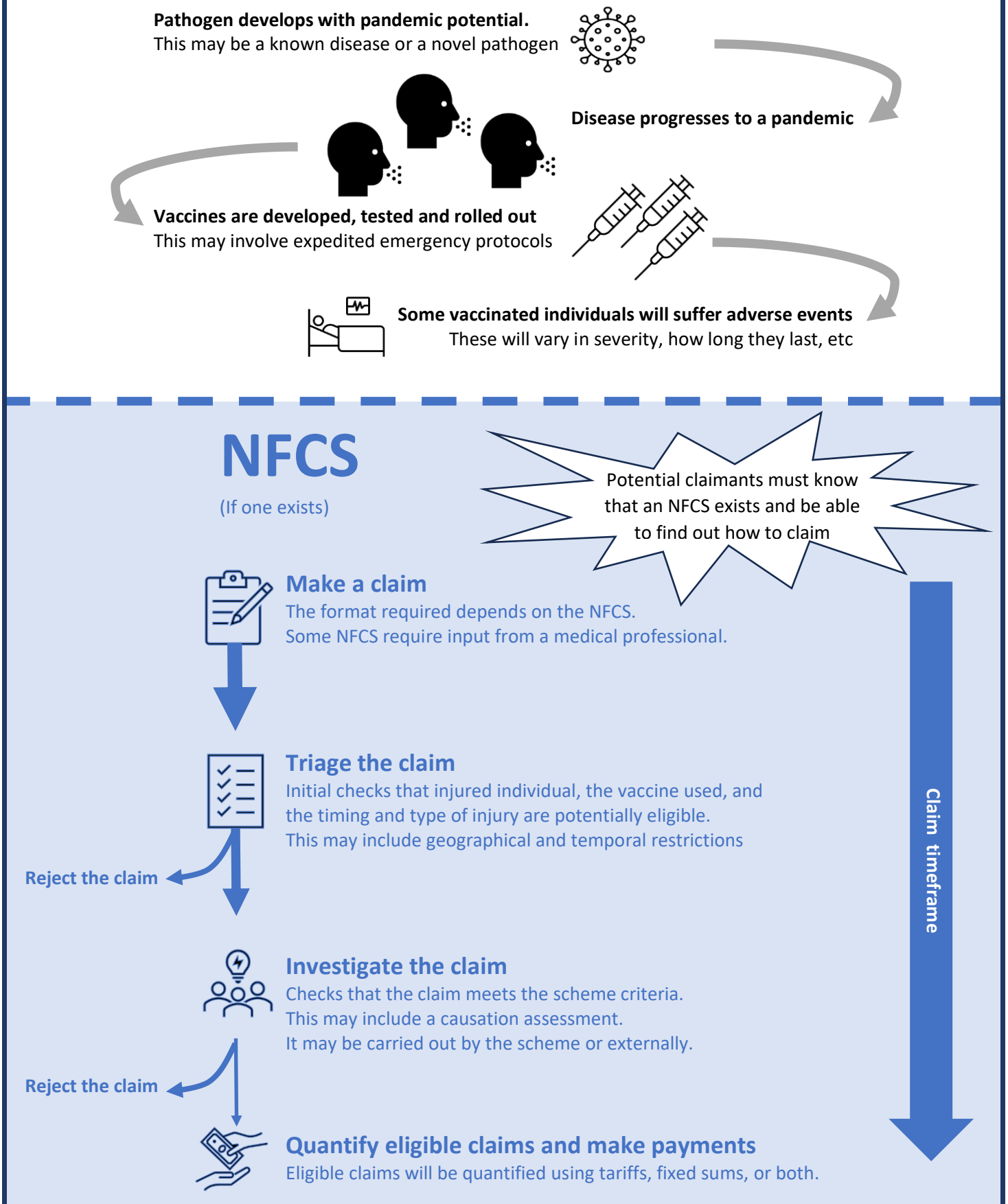

Figure 6. Schematic of pandemic NFCS processes

Framework for NFCS

Figure 6 provides a schematic of the key processes for a pandemic NFCS. There are four stages that are common to the majority of NFCSs:-

- Making the claim
- Triaging the claim
- Assessing the claim
- Quantifying and paying the claim

Clearly the first stage, making a claim, is completed by the claimant, rather than by the scheme. However, we have included this stage as we have found that scheme design can influence the making of claims. All schemes have a triage function, this is a fairly light touch check that the claim could potentially be eligible. The more detailed assessment of the claim occurs in the next stage. Once a claim has been accepted then quantification and payment follow. There is one scheme which does not have a quantification stage, the UK VDPS awards a fixed sum so there is no requirement for quantification.

The right to an appeal or reconsideration mechanism is not consistently found across all NFCSs. When it exists it may be carried out by an external body, such as a court or tribunal, so we have not included it in the infographic, but it is an important element and will be addressed later.

We have identified a number of key aspects that contribute to the effective functioning of a NFCS.

Awareness, accessibility and triage

We have found that there appears to be a correlation between the time a scheme has been in existence and the rate of claims per vaccine does, see figure 7.

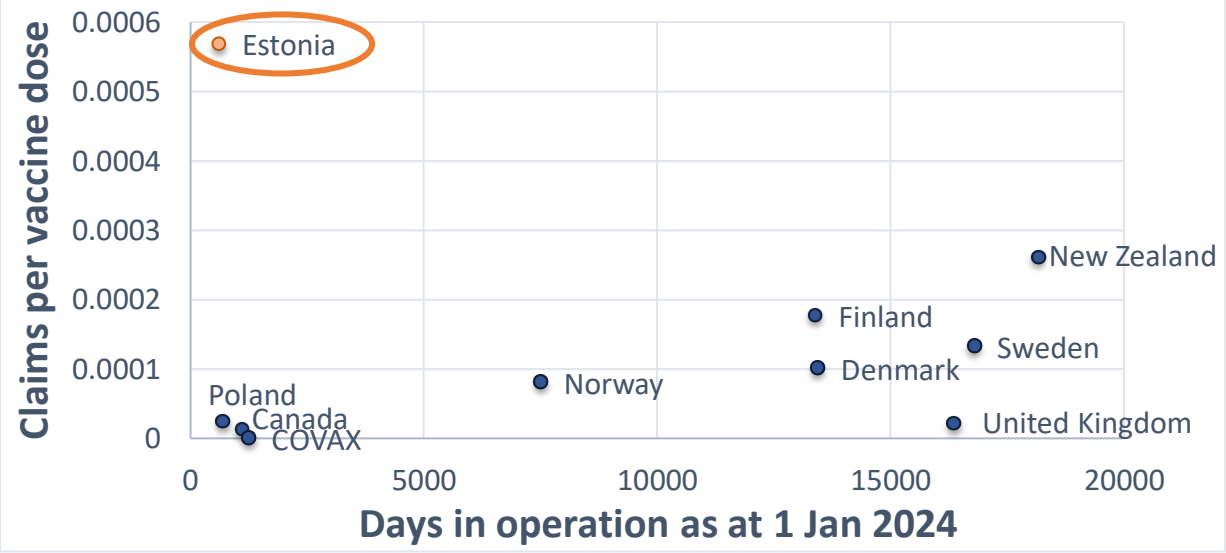

Figure 7. Claims made 2020-2022 per vaccine dose plotted against time in operation. Including Estonia there is no significant correlation; excluding Estonia as an outlier a significant correlation is seen using the Spearman's Rank Correlation test; Just national schemes ($r_s = 0.62$, $n = 8$, $p < 0.1$), Including COVAX ($r_s = 0.67$, $n = 9$, $p < 0.05$)

A NFCS is of no use to a potential claimant if they do not know it exists. Where the NFCS is embedded in the national consciousness, such as NZ and the Scandinavian countries, our

participants reported existing knowledge of the scheme prior to their injury. In the UK, even though the VDPS has been in existence since 1979 the general level of awareness appeared to be much lower. One participant described how she was only aware of it because her doctors and then her parliamentary representative informed her about it. Another of our interviewees described how:-

> 'It's not well publicised, I don't think most people know about it.'

In her witness statement to the Covid-19 Public Inquiry dated 21 October 2024 Ms Sarah Moore, a solicitor, describes how there is a low level of public awareness of the VDPS.[28] This demonstrates that even a long-standing schemes may not be familiar to the majority of potential scheme users.

For new schemes this problem is even more acute. It can be difficult to find information about some of the schemes/coverage, for example the AVAT NFCS list of member states is not obvious. We have also found examples of mixed (and incorrect) messaging in relation to the AVAT scheme. On 30 August 2021 the Jamaica Observer reported that the Health Minister had stated that Jamaicans can get vaccine injury compensation.[29] A week later on 7 September 2021 the Phoenix Newspaper reported that the Health Minister had said that Jamaica has no vaccine compensation program.[30] Jamaica had been a member of the AVAT NFCS since June 2021. These difficulties might explain the low application rate made to the AVAT NFCS, which had not received any applications as at February 2024.[31] The other multinational schemes have also had low application rates. The COVAX program delivered 1.75 billion vaccines, as at 31 May 2024 a total of 172 claims or enquiries had been received by the NFCS, with 23 of those relating to an COVAX vaccine.

Estonia provides a striking example of a new scheme with a high claim rate. It was established 1 May 2022 and covered vaccines administered from 27 December 2020. There was an accompanying public awareness campaign. Estonia has a centralised social health insurance system covers over 94% of the population, with the Estonian Health Insurance Fund (EHIF) organising the majority of the health care provision.[32] Estonia is also a highly digitised society, with all health information, including vaccination history available on the EHIF Health Portal. Submitting a claim for vaccine compensation involves signing in to the Health Portal and simply selecting a button to make a claim for a vaccine injury. The potential claimant is then given the option to upload up to 10 additional documents, if they wish to. There is no requirement to upload additional information, the scheme will access the claimant's vaccination record and their health records. This application process reduces the burden on the applicant compared to most other NFCSs. It appears to work well in a highly digitised society where the vast majority of the population have coverage. In a society where digital poverty and/or digital literacy are more prevalent this model is likely to need modification to ensure accessibility for all.

There is a sharp contrast between the easy accessibility Estonian claimants told us about and the experiences of claimants under other schemes. In New Zealand a claim has to be submitted by a

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[28] https://covid19.public-inquiry.uk/wp-content/uploads/2025/01/29165813/INQ000474459.pdf
[29] Jamaicans can get vaccine injury compensation - Ennis [Jamaica Observer]. 30 August 2021. Available: https://www.jamaicaobserver.com/news/Jamaicans-can-get-vaccine-injury-compensation-ennis/
[30] Unlike programmes for other countries, Jamaica has no vaccine injury compensation program even as adverse events rise [The Phoenix Newspaper]. 7 September 2021. Available: https://thephoenixnewspaper.com/unlike-programmes-for-other-countries-jamaica-has-no-vaccine-injury-compensation-program-even-as-adverse-events-rise
[31] Macleod, Uberti & Kameni see FN 18
[32] https://eurohealthobservatory.who.int/publications/i/estonia-health-system-summary-2024-updated

health care practitioner. This has been raised as a particular difficulty by claimants. Similarly, an application in Canada must include a form completed by a registered doctor. Clearly these requirements restrict access to the schemes, with the healthcare professionals effectively act as 'gatekeepers'. One of the major concerns that has been raised is that there is a lack of medical knowledge and/or consensus around vaccine injuries in a pandemic, which inhibits the making of claims.

This filtering effectively outsources some aspects of the triage stage. However, checks will still be required by the NFCS. The triage stage is not a full examination of the merits of the claim. It should be an assessment of whether the claim contains sufficient information to determine if:-

- the affected individual is potentially eligible, eg if they meet any geographic or citizenship eligibility criteria such as residency, if it is an estate claim whether they fall within a category of people entitled to make a claim
- a vaccine was given and whether that vaccine is eligible under the NFCS
- the claim has been made within any time limits specified by the NFCS
- the injury claimed for is within the type or injury that the NFCS compensations, for example

The criteria used at the triage stage are generally straightforward and a prompt answer should be provided to potential claimants. The use of factual criteria allows the triage stage to be carried out by non-experts. This is potentially more cost effective for schemes than the use of highly qualified, and more costly, gatekeepers.

There is a policy decision for schemes. A fully accessible claims process will not 'filter' claims in any way. There are potential advantages to this. It is well recognised that spontaneous reporting of adverse events is low and there is no benefit to the individual in making a report. An application for compensation offers a potential benefit to the applicant, which potentially incentivises reporting. Claims data could provide an additional data source for identifying patterns of adverse events.

The alternative approach is that the scheme does a more substantial initial triage for eligibility. This can be done by administrators within the scheme. Administrators are usually perceived as less expert than healthcare professionals, but in a pandemic context where knowledge is developing this gap is likely to be reduced because less expertise exists in total. The approach taken by New Zealand and Canada will restrict the number of claims coming in, but there is a cost. The scheme pays for the doctor for the cost of filing the claim. In New Zealand we heard from individuals who wanted to file a claim, but were unable to find a doctor willing to do this for them. This is a particularly difficult early in a vaccination campaign when there is limited awareness of adverse events associated with the vaccine. This filtering limits the centralisation of awareness of adverse events.

The Canadian scheme requires medical evidence to be submitted by the claimant with the claim. This should, in theory, reduce the claim processing time. However, we have heard from Canadian claimants that there is a severe backlog before a claim is assigned to a case manager. This is clearly not acceptable.

'They assigned it a case number and they said thank you for submitting your application to the Vaccine Injury Support program. We've received your application and it's in a queue to be assigned to a case manager. Once a case manager has been assigned, they will review your eligibility of your claim and they'll reach out to you…

So that was June of 2024 and now today we're into March. So we're almost 10 months to 11 months and they're saying it's in a queue.' Canadian Claimant

Awareness, Accessibility and Triage Recommendations

- **NFCS must ensure that potential claimants are aware of their existence and how to claim.** Estonia has demonstrated that this can be achieved digitally where electronic health records exist. Non-digital options include providing information on the NFCS on the physical vaccination card. In the UK the vaccination card contained details of how to report an adverse event via the yellow card system, but no information on the VDPS.
- **Schemes should be made as accessible as possible so claims information can be useful as part of the overall post-market surveillance system.** The usefulness of data from NFCSs vary, the less filtering a scheme has the more centralised, and potentially useful, its data pool will be.
- **The triage function carried out by a Scheme should use factual criteria to enable prompt decision making.** Claimants who are ineligible should be rejected quickly and with a clear reason given based on the factual criteria.
- **A scheme should be sufficiently resourced to be able to triage and assign claims to a case manager in timely way.**

Investigating the claim

Schemes operate to provide redress, they are part of a wider justice landscape. While the majority of scholarship has focussed on traditional judicial processes there is a clear applicability of the requirements for procedural justice, transparency and openness in NFCS.

Procedural justice, Transparency and openness in NFCS processes

The Canadian scheme has not published any scheme rules, making it impossible to judge this scheme. Even where scheme rules have been published, for a number of the schemes we studied it is very difficult to ascertain how claims are handled and what processes are used to determine the

'…the whole process [is] impersonal and humiliating. And that was the really upsetting thing is that you've got someone who can't advocate on behalf of themselves anymore because they can't speak, and you have people who are treating them, you know, as if they're just nothing' UK Claimant

claim. This is clearly not satisfactory for claimants and fails to meet the most basic of procedural justice standards. This is important as there is a growing literature that links perceptions of injustice in a compensation system with worse health outcomes for claimants.[33] Claimants to the UK scheme clearly described the 'intensive and stressful' and anti-therapeutic impact of making a VDPS claim.

We fully recognise Thomas and Tomlinson's proposition that administrative processes can be seen from two distinct perspectives.[34] The legal perspective considers justice and fairness in that individual case; the governmental perspective is concerned with whether the system provides adequate, timely and proportionate redress within the limits of the available resources. It requires the delivery of the best justice within the limits of what is possible.

Each scheme will have to take a policy decision on whether to prioritise the legal or the governmental perspective. The 'best justice' will depend on the context of each scheme, but we have identified some key aspects which span both of the legal and perspectives.

The administrator.

NFCS use a number of different administers, from private companies to the government itself. If the decision maker is not perceived as neutral and trust-worthy then the scheme will not meet key elements required for procedural justice.

> 'I understand the vaccine was introduced in unprecedented circumstances, but novel ways were found to roll out the vaccine. The novelties stopped there though, and the same effort or urgency has been disregarded when dealing with the people injured through this vaccine.' UK claimant

This is a particular difficulty for schemes that are run by or under the control of governments who are felt to be responsible for the harm.

Administrator Recommendations

- **NFCS administrators must be neutral and demonstrate that they are trust-worthy.** If a scheme cannot demonstrate these then it will fail to meet the procedural justice norms. This is likely to erode trust in the scheme, and, potentially the government. A regular breakdown of the structure, oversight and funding of the administrator should be published.

[33] C. Orchard et al., 'How Does Perceived Fairness in the Workers' Compensation Claims Process Affect Mental Health Following a Workplace Injury?' (2020)30(1) *Journal of Occupational Rehabilittaion*.40.; K.R. Monden et al., 'The unfairness of it all: Exploring the role of injustice appraisals in rehabilitation outcomes' (2016) 61(1) *Rehabilitation Psychology*. 41.; M.J.L. Sullivan et al., 'Perceived Injustice and Adverse Recovery Outcomes' (2014) 7 (4) *Psychological Injury and Law*. 325.; E. Yakobov et al., 'The role of perceived injustice in the prediction of pain and function after total knee arthroplasty' (2014) 155(10) *Pain*. 2040.; N.A. Elbers et al., 'Procedural justice and quality of life in compensation processes' (2013) 44(11) I*njury*. 1431.

[34]Thomas, R., & Tomlinson, J. (2017). Mapping current issues in administrative justice: austerity and the 'more bureaucratic rationality' approach. Journal of Social Welfare and Family Law, 39(3), 380–399. https://doi.org/10.1080/09649069.2017.1363526

Scheme process types.

Isreal is the only example of an adversarial covid vaccine NFCS we have found. This is likely to be due to the fact that adversarial schemes have higher legal costs associate and usually take longer to determine claims. The US VICP which covers childhood vaccines is adversarial quasi-litigation vaccine NFCS, so there is no doubt that this model can be sustainable and function in the long term However, we would strongly agree with Akkermans in his assessment that addressing the claimant's emotional needs within the claims process is more important than the type of process or whether payment is based on a fault or no-fault trigger for payment. [35] We got a very clear sense of failure to address emotional needs and feelings of abandonment from some scheme claimants.

'I say that we're like discarded people. We've just been discarded and we're not useful. We've just been thrown away people.' Canadian Claimant

'What I can't truly accept, and I'm still in a place of non-acceptance, is how everybody in the society at the time they all went in line. Like, not all, but a high percentage of people were all in this together. And now we're not together anymore…'' Canadian Claimant

We have seen clear examples of administrative processes across different schemes all being described as stressful, traumatising, degrading. The process of claiming is felt to compound the harm that has been suffered.

Recommendations on scheme process

- **The process a scheme uses should not compound the harm already suffered.** All schemes, regardless of whether they are adversarial or administrative, should consider how to reduce compounded harm. This could be through modifications to the process, including more restorative processes, increasing 'human' contact, etc.
- **Adequate training must be provided for claims handing staff.** This should include vaccine specific elements on how to apply the scheme criteria to pandemic vaccine injuries, as well as general training on addressing the emotional needs of claimants and avoiding compounding harm

Scheme eligibility criteria.

All schemes allow injured individuals and representatives to make a claim on behalf of a deceased individual. The vast majority of schemes clearly set out who can claim.

Where there are time limits on making a claim these should be easy to ascertain for claimants. There is a balance between giving discretion to individuals and having firmer rules that allow a scheme to run in a predictable way and have confidence in financial forecasts. The vast majority of schemes we have looked at set out time limits in a manner that is clear for potential claimants.

[35] Arno Akkermans *'Chapter 2: Achieving Justice in Personal Injury Compensation: The Need to Address the Emotional Dimensions of Suffering a Wrong'* in Prue Vines & Arno Akkermans *Unexpected Consequences of Compensation Law* (Hart 2022)

NFCS coverage of temporary injuries varies. Paying temporary injuries as well as permanent ones has obvious financial implications. In an interview we conducted with a stakeholder from the Finnish NFCS the wider societal implications of paying compensation for temporary injuries was highlighted:-

> *''…in Finland the first persons to be vaccinated were the healthcare personnel. So, of course, we saw a bit more cases where people had short sick leaves. When you got a fever and so on, you couldn't go to work.'* Finnish NFCS representative

Healthcare workers were prioritised for vaccination because they were higher risk for both getting and spreading the illness. When these initial claims were made covid vaccinations for healthcare workers were not mandatory in Finland.[36] When vaccinations are voluntary there is a clear policy rationale behind covering temporary injuries to incentivise vaccine uptake in groups who are higher risk. Schemes need to assess the potential cost savings from lowered transmission and disease severity against the additional cost of covering temporary injuries.

Recommendations on scheme eligibility criteria

- **Schemes should clearly set out who can make a claim**
- **NFCS should clearly set out the time limits for making a claim.**
- **Schemes should be clear on whether temporary injuries are covered, and if so in what circumstances.**

Transparency and voice within the claims process

There have been highly unfavourable comparisons of the US CICP which covers covid vaccines, with the VICP. Critics have highlighted the CICPs lack the openness and accountability, and contrasting it to the evidential disclosure requirements and open court conduct of the VICP.[37]

We have seen examples of administrative schemes that are in effect a 'black box' where claimants have little notion of how decisions are made, what evidence is used, etc.

> *''…because I have no way of knowing what's going on in this program, because there's just no, there's no transparency. It's just sort of like, who knows?'* Canadian NFCS claimant

[36] From February 1st, 2022 covid vaccination has been mandatory for health and social care workers who are in close contact with patients or customers who at high risk of severe disease from covid infection

[37] Zhao J, Demir F, Ghosh PK, et al. Reforming the countermeasures injury compensation program for COVID-19 and beyond: an economic perspective. J Law Biosci 2022;9:lsac008

A particular concern has been the lack of 'voice' within the process, which runs contra to procedural justice theory which has long highlighted the importance of opportunities for claimants to explain their situation and be 'heard' within the claims process.[38] One of the issues that we have found is that participants can find describing events traumatising.

> *'…the whole process [is] impersonal and humiliating. And that was the really upsetting thing is that you've got someone who can't advocate on behalf of themselves anymore because they can't speak, and you have people who are treating them, you know, as if they're just nothing.'* UK Claimant

Our findings suggest that administrate models can deliver transparency, openness and voice. The Danish scheme which is administered by the Danish Patient Compensation Association have a much more transparent approach. Their online case management system gives claimants access to and the ability to comment on every document added to their case file. Claimants are involved directly rather than through a legal representative, facilitating the claimant voice throughout the claim process.

This contrast with the narratives we heard over the free-text box in the VDPS application. This could serve as a platform for claimants to 'have a voice'. Participants said they were unclear what to include. In addition, some claimants have expressed that they feel under a burden to go to private specialists and 'find medical evidence' which won't necessarily be considered by the case workers. When the free text they wrote was incorporated into the rejection of their claim they perceived this as detrimental.

> *'…the whole process [is] impersonal and humiliating. And that was the really upsetting thing is that you've got someone who can't advocate on behalf of themselves anymore because they can't speak, and you have people who are treating them, you know, as if they're just nothing.'* UK Claimant

> *'[in the rejection letter] They used parts of my sentences but they weren't very well formed anyway because I was ill.'* UK claimant

This perception is not surprising as the literature distinguishes a 'voice effect' from the 'fair process effect'. Having a voice is not, in itself, sufficient, and the voice effect is context specific. NFCSs should give the opportunity for ongoing dialogue, a single opportunity to comment without a clear frame of reference, is not sufficient and can lead to claimants perceiving the process as unfair

[38] J.W. Thibaut and L.J. Walker, *Procedural Justice: A Psychological Analysis* (1975).; T.R. Tyler, *Why People Obey the Law* (1990).

Transparency and Voice Recommendations

- **Scheme processes should be transparent and open.** All scheme should publish information that explains their processes, including how decisions are made and what evidence is required and statistics on key indicators, such as application numbers, decision timeframes, acceptance rates, rates of appeals.
- **Claimant voice should be prioritised in the claims process.** Schemes should enable claimants to have a meaningful voice in the process with an ongoing ability to contribute

Thresholds used for payment

The threshold a scheme uses to determine eligibility for payments will depend on the social and legal context behind the scheme. This is very obvious with the UK VDPS scheme, which has several quirks that are likely to be a reflection of the fact that this scheme was hastily pushed through in 1978/9 in the last days of the Callaghan Labour government. The Labour government were explicit that this Act was an interim measure, and they were intending to return and develop and more comprehensive approach to vaccine damage after the general election, which they then lost.[39] The scheme makes payments that are ex gratia. The Pearson Commission set out the rationale for the VDPS in 1978 stating that there is a 'special case' for vaccine injury compensation when '…vaccination is recommended by a public authority and is undertaken to protect the community'. This rationale indicates that this payment sits outside the standard approach to compensation. Interestingly, in the UK an ex gratia payment made by the NFCS (and funded by the government) is recoverable from any subsequent litigation award. The doctrine of preventing double recovery is well established at common law, but its application is tenuous in this context. The alternative is to view the UK scheme as an adjunct to litigation making additional payments over and above those offered by litigation. This highlights how the prevailing political context can influence scheme design, in this case the rushed 'interim' solution has led to both conceptual and practical difficulties with the NFCS.

In countries where the NFCS replaces the right to litigate it is often the only way for an injured claimant to obtain compensation. Traditional litigation has a strong focus on the causation requirements, which is important when attributing liability. In order to facilitate access to justice in countries where the NFCS replaces litigation the approach the scheme takes to causation should be no more stringent than the legal test applicable to product liability cases in that jurisdiction.

Where a scheme does not impact on the right to litigate the threshold for payment is a more open question. A policy decision could be taken to draw it more widely or to make it more restrictively. However, if the scheme is intended to act as an alternative to litigation, then the scheme has to be a more attractive option for claimants. This is likely to require that the process is at least as quick as and no more onerous/costly than litigation, that the thresholds used for payment are no more stringent and that there is parity in the awards given by the scheme and litigation.

NFCSs use multiple different approaches to causation and to the standard that is required to demonstrate it. One solution to this is to have a 'table' where causation is presumed for the injuries listed in the table. This reduces the burden on the claimant and facilitates a swifter delivery of redress in a way that is akin to strict liability. Injuries are added to the table once it has been ascertained that the injury is caused by the vaccine. The scheme will set out what is required for

[39] Millward G. A Disability Act? The Vaccine Damage Payments Act 1979 and the British Government's Response to the Pertussis Vaccine Scare. Soc Hist Med. 2017 May;30(2):429-447. doi: 10.1093/shm/hkv140. Epub 2016 Aug 4. PMID: 28473731; PMCID: PMC5410922.

demonstrating causation as there are different approaches. It may be that the scheme administrators are authorised to do this, or it may be 'outsourced' and either a panel of medical experts and/or legal experts or representative actions in a litigation setting determine this. All of these processes for determining causation will take time and should require biological and epidemiological evidence. The covid pandemic was a novel virus with novel vaccines, so there could not be a table as there were no well-established adverse effects. In a pandemic with a novel disease there is, at least initially, very little prospect of a table either existing or containing enough of the adverse events to be useful.

Taiwan has taken an interesting approach to dealing with uncertainty in their causality assessment. They have three different categories of causation:-

Unassociated: The assessment result will be "unassociated" if any of the following situations applies:

1. Clinical examination or the laboratory test result substantiates that the injury was caused by something other than vaccination.
2. Medical evidence shows no causality or medical evidence does not support causality.
3. Medical evidence supports causality. However, the injury did not occur during a reasonable period of time following vaccination.
4. It is determined in consideration of medical principles and following a comprehensive review that there is no support for causality between the alleged injury and vaccination.

Associated: The assessment result will be "associated" if the following situations all apply:

1. Medical evidence, clinical examination or the laboratory test result supports causality between vaccination and the alleged injury.
2. The alleged injury occurred within a reasonable period of time following vaccination.
3. After a comprehensive review, it is determined that a significant association exists.

Indeterminate: The case is free of the situations described in the preceding two subparagraphs and causality cannot be determined following a comprehensive review.

"Medical evidence" referred to in the preceding paragraph is defined as evidence from a population-based study or pathogenesis study that is published in a domestic or foreign journal.

"Determined following comprehensive review" is defined as professional medical judgment made after giving considerations to the medical history of the alleged victim before and after vaccination, the alleged victim's family history, adverse reactions experienced by the alleged victim in the past after receiving analogous vaccines, medications taken by victim, victim's exposure to toxins, biologic coherence and other relevant factors.

If an injury is unassociated no payment will be made. Full payment is made for associated injuries, determined using a tariff. Indeterminate injuries receive a lower level of payment, again calculated using a tariff. This approach allows more flexibility than the standard binary causality tests.

Determining causation is one of the most complex and time consuming processes for a NFCS. There are schemes which do not include causation in their eligibility test. Poland and Latvia use the Summary Product Characteristics (SmPC) as a 'table'. This is interesting as the SmPC consists of side effects that have been associated with a pharmaceutical, it is based on correlation not causation. This is a clear example of the simplification of the claims process and the 'governmental perspective' being preferred over the 'legal perspective'. Using the SmPC as a 'table' reduces the administrative

burden on these schemes as the SmPC provides a clear and definite set of criteria, which can be determined with a lower level of expert input.

Australia has applied a more stringent approach to using the SmPC. An injury will only be eligible if it fulfils **all** three of these requirements:-

a. Diagnosed by a treating practitioner, and

b. Included in

i. The product information; and

ii. Table 1 where the condition in column 1 results from a vaccine listed in column 2, and,

c. was most likely caused by the COVID-19 Vaccine and less likely caused by any of the COVID-19 Vaccine Recipient's other circumstances

This provides a clear fact-based framework for case handlers, the only determination they are required to make is whether the injury was more likely to have been caused by the vaccine or by other circumstances.

In our surveys of NFCS caseworkers in New Zealand generated some interesting insights into the practical difficulties in administering a scheme that does not have clear definitions/guidelines. There is understandably a strong reliance on expert medical input by the caseworkers, at a time when this knowledge has not been established or agreed. This creates considerable difficulties: we obtained the following quotes from caseworkers in New Zealand who were asked to describe the challenges they face when handling covid vaccine injury claims.

'Lack of knowledge from our medical advisors and technical specialist on the symptoms and incapacity due to covid vaccinations.' New Zealand NFCS Caseworker

''…Lack of clear guidelines, and uncertainty around the mechanism of injury. Most are autoimmune concerns that are not specific with their symptoms, so harder to manage. New Zealand NFCS caseworker

'Acceptance by the medical profession that an injury has occurred as a result of a covid-19 vaccination and in some cases, confirming what injury has occurred.' New Zealand NFCS Caseworker

The UK VDPS provides another stark example of difficulties in understanding both causation and injury eligibility thresholds. It is clear from our interviews that the causation requirements and the 60% disablement threshold used by the UK VDPS is difficult for claimants (and lawyers) to understand. In our survey we asked vaccine injured individual if they felt their injury was caused by

the covid vaccine and 99% of respondents felt it was. When asked if their injury was eligible under the VDPS all respondents felt it was. When asked if they felt their level of disablement was eligible under the VDPS all of our UK survey respondent felt it was. This is not reflected in the VDPS decisions up to 25 September 2024.[40] Of the 7,936 claimants 7,748 claims were rejected, with a further 716 claims failing to meet the criteria for medical assessment. Of the total claims made 7,357 (93%) were rejected because the independent medical assessor recommended that, on the balance of probabilities, the vaccine did not cause the disability in question (causation). Just 579 claims (7%) passed the causation threshold. Of these 188 claimants (32%) have been notified that they are entitled to a Vaccine Damage Payment. 391 (68%) of the claims where causation had been accepted were unsuccessful because, although the claims met the criteria for causation, the independent medical assessor recommended that the vaccine has not caused severe disablement. When we asked our participants if they believed their claim would result in a payment from the VDPS 72% felt it would. In reality just 2.4% of claims made to the VDPS result in a payment. There is a clear mismatch of expectation and a lack of understanding of what causation and the 60% disability threshold means.

Thresholds for payment Recommendations

- **An NFCS should consider how to best balance delivering justice with the need for administrative efficiency and timely determination of claims.** If the criteria used by a scheme to establish eligibility are complex, uncertain, and/or require high levels of expert input this will slow the processing of claims. The use of a table facilitates quick efficient claims handling, but novel vaccines will not have a ready to go table. The use of alternatives, such as the SmPC, reduces the administrative burden on the NFCS, while potentially providing a more generous approach to payment. Schemes need to consider how to best balance the need for administrative efficiency and prompt claim resolution with the need to deliver just outcomes and decisions.
- **Each NFCS should explain the threshold it uses for payment** The threshold choice is a policy decision. The rationale for the scheme and the underlying legal landscape and relationship with litigation should be considered when determining the threshold. The threshold and the reasons for the threshold choice should be set out by the NFCS.
- **The approach to causation should be clearly set out for each NFCS**. Schemes do not have to determine legal causation, and can opt for a more relaxed test. If a scheme decides to consider causation it should clearly explain how the decision is made, including who makes the decision and what evidence they use. Schemes should publish claims acceptance rates for causation.
- **If an injury severity threshold is used this should be clearly explained in accessible language with appropriate examples**. The potential for significant mismatches between claimant expectation and scheme performance can be seen. Schemes should publish clear accessible explanations of the degree of disability using relevant examples, for example where adverse effects are often systemic neurological impacts the degree of disability caused by amputation is not particularly helpful.

[40] https://opendata.nhsbsa.net/dataset/foi-02252

Quantification and payment and scheme funding.

We have only found one scheme that does not have a quantification function. The UK VDPS makes a fixed sum award, so there is no requirement for quantification. The VDPS awards a fixed payment of £120,000 for death or an injury that results in over 60% disablement. Clearly removing the quantification stage simplifies the scheme design and administration, but the flip side is that it is unlikely that the level of payment will correspond to the level of injury experienced. As there is a high threshold of 60% disablement it is highly unlikely that the fixed payment would result in overpayment when compared to the value that would be awarded following successful litigation. We have heard considerable dissatisfaction from UK claimants.

The US CICP effectively prevents a claimant from litigating, but the value of compensation offered is not comparable to the level that would accompany a successful litigation award. This has caused considerable dissatisfaction. This is the US pandemic scheme, and illustrates the different policy decisions that were made around standard situations and pandemic circumstances.

NFCS use a range of quantifications, including tariff-based systems, fixed value awards and periodic payments. This is a policy decision for the scheme to make and there are advantages and disadvantages to each option which have been widely explored in the literature. Briefly individualised payments are likely to be more reflective of individual circumstances, but tariffs offer a more streamlined mechanism for a scheme and can deliver greater consistency between claimants.

The level of payments are likely to reflect the underlying scheme rationale. If the NFCS is intended to provide an alternative route to compensation rather than litigation then there should be parity with the value of awards under each system. This is seen in the Scandinavian countries. The combination of an administrative scheme with parity of awards should be more cost effective than litigation.

All the multi-national schemes are funded by some form of payment per dose. This may be paid by donors or by recipient governments. For multinational schemes this seems to be the most straightforward solution. The majority of national pandemic NFCS are funded by governments. There are some schemes which operate on a mix funding sources, for example Poland. The only schemes we have found that were exclusively levy based were Finland, Norway, Sweden, and Taiwan. The difficulties in predicting the potential cost of a pandemic vaccination campaign prevented the purchasing of commercial reinsurance and both the Finnish and Swedish scheme were effectively indemnified by national governments. Even in countries were there is a relatively small populations there are issues with the reserves held by schemes being insufficient. We understand that there these difficulties have led to a change in policy in Finland, and in future they will fund pandemic vaccine compensation from government funding.

The US VICP has utilised levy funding and has been financially stable for many years. This is clearly a viable model for well characterised and more predictable claim flows that arise from childhood vaccines. Among the new schemes it is interesting to note that Estonia distinguishes between covid vaccination compensation, which is funded by the government and standard childhood vaccinations which are funded via a levy.

How a scheme is funded does not appear to impact on the claims approval rates, which vary hugely between scheme and are more likely to be due to the assessment criteria and thresholds that a scheme applies.[41]

Recommendations on Quantification

- **If a fixed sum is awarded it should be clear what this is for** The rationale for this payment and how it fits within the wider compensation landscape should be explained. Fixed sums are not the preferred option for NFCS quantification.
- **If a NFCS prevents litigation the policy decisions around quantum should be clearly set out**. This applies whether the quantum is more or less generous than a non-pandemic award would be.
- **The approach a scheme takes to quantification should be available to the public**. This aids transparency and builds trust in the NFCS. Ideally a calculator should be available so potential claimants are able to estimate the value of an award if they are successful
- **The quantum awarded should be contextualised against other compensation mechanisms to enable informed decision making by potential claimants.** Schemes should provide information for potential claimants that contextualises their offer in the wider compensation landscape. This could include examples of the net amount a claimant would obtain from litigation compared to the net award from the NFCS for the same injury.

Appeals and reconsiderations.

There are a number of different options for reviewing or reconsidering an NFCS decision, both internally within the organisation or by an external body. In a context where the knowledge base is being built it is particularly important that there is a mechanism to reconsider claims when there is new evidence. We know that if there is new evidence about a particular adverse vaccine impact some schemes, such as Finland, will automatically reconsider all claims relating to that particular adverse vaccine impact. Other schemes require that the claimant resubmits or asks for their claim to be reconsidered.

There are a number of schemes where the NFCS decision is reviewed, not on the merits of the decision, but on the way in which the decision was reached.

The relative importance of each of these mechanisms for reconsideration and or appeals will depend on the wider legal context and what other options are available to rejected/dissatisfied claimants, and the relative costs and timeframes for these options.

Recommendations on Reconsiderations and Appeals

- **All NFCS should have a mechanism to reconsider decisions in the light of new evidence.** The best practice is for schemes to proactively review affected past decisions when new evidence comes to light

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- **Schemes should set out clear rules on what will happen if a claimant requests a re-examination of their claim** This should include who will conduct the re-examination, what criteria will be used and expected timeframes.
- **A scheme should consider whether the options available to rejected/dissatisfied claimants are adequate.** This will involve examining the wider legal context and what other options are available. If the available options are not satisfactory the scheme should consider what is needed and either implement or lobby for this.

Conclusions

The NFCS coverage globally changed significantly in response to the covid pandemic. There was an almost five-fold increase in the number of countries covered, predominantly in low- and middle-income nations. The coverage under the multinational schemes was a time limited response and is heading towards its end point.

One of the arguments that is often put forward are that such schemes only work well in countries with smaller populations, such as the Scandinavian countries and New Zealand. There are potential issues with the rapid scaling up of claims handling, however a number of these can be overcome by good scheme design. Reducing the bottlenecks within a scheme and using factual rather than subjective criteria will facilitate claims handling. One of the most difficult elements of claims handling for the majority of schemes is establishing causation. A traditional approach to causation requires considerable medical and legal expert input and creates a complex claims process. This is particularly so in a pandemic context when there is often very limited information on the potential side effects of novel vaccines.

The use of a table greatly eases the burden on claimants. It also provides claims handlers with more guidance. In a pandemic situation there will be a novel virus and potentially a large increase in claims numbers due to mass vaccinations and it is very unlikely there will be an established table. Using the SmPC effectively as a table provides practical guidance for claims handlers: it is administratively much simpler to establish if an individual has a condition on a defined list than it is to establish if the condition they have is causally related to the vaccine. This is a more relaxed approach than traditional legal causation as the SmPC works on correlation rather than causation. However, it allows a much simpler claims handling process which can be more easily scaled. If a claim is for a condition listed on the SmPC it would still need to be temporally appropriate, conditions that occurred prior to vaccination would not be eligible. For the majority of claims this analysis would not complex, and it could be carried out by case workers with additional training rather than by medical experts. This type of approach would create a simplified claims handling process that is scalable, albeit potentially more generous. Australia adopts a more restrictive modified version of this and has an approval rate (~13.5%) that is at the lower end when compared to other jurisdictions.[42]

We are now in a position to evaluate pandemic NFCS and to establish what best practice looks like and what needs to be done better when the inevitable next pandemic arrives. Each and every NFCS will have lessons to learn and improvements to make. It is imperative that this is done prior to next pandemic. This briefing sets out some overarching suggestions which have arisen from our research. It is only intended to be the start of a wider conversation, involving multiple stakeholders, including

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vaccine injured individuals, policy makers, healthcare professionals, legal representatives, vaccine manufactures and NFCS scheme administrators.

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Finally, I have been supported by wonderful colleagues at CSLS and in particular I want to thank my post-doctoral researchers, Francesca Uberti and Fanni Gyurko, who have been remarkable.

Recommendations

Taken together our recommendations are intended to provide guidance for NFCS design, but each scheme will need to be adapted to the context in which it operates.

Awareness, Accessibility and Triage Recommendations

- **NFCS must ensure that potential claimants are aware of their existence and how to claim.** Estonia has demonstrated that this can be achieved digitally where electronic health records exist. Non-digital options include providing information on the NFCS on the physical vaccination card. In the UK the vaccination card contained details of how to report an adverse event via the yellow card system, but no information on the VDPS.
- **Schemes should be made as accessible as possible so claims information can be useful as part of the overall post-market surveillance system.** The usefulness of data from NFCSs vary, the less filtering a scheme has the more centralised, and potentially useful, its data pool will be.
- **The triage function carried out by a Scheme should use factual criteria to enable prompt decision making.** Claimants who are ineligible should be rejected quickly and with a clear reason given based on the factual criteria.
- **A scheme should be sufficiently resourced to be able to triage and assign claims to a case manager in timely way.**

Administrator Recommendations

- **NFCS administrators must be neutral and demonstrate that they are trust-worthy.** If a scheme cannot demonstrate these then it will fail to meet the procedural justice norms. This is likely to erode trust in the scheme, and, potentially the government. A regular breakdown of the structure, oversight and funding of the administrator should be published.

Recommendations on scheme process

- **The process a scheme uses should not compound the harm already suffered.** All schemes, regardless of whether they are adversarial or administrative, should consider how to reduce compounded harm. This could be through modifications to the process, including more restorative processes, increasing 'human' contact, etc.
- **Adequate training must be provided for claims handing staff.** This should include vaccine specific elements on how to apply the scheme criteria to pandemic vaccine injuries, as well as general training on addressing the emotional needs of claimants and avoiding compounding harm.

Recommendations on scheme eligibility criteria

- **Schemes should clearly set out who can make a claim**
- **NFCS should clearly set out the time limits for making a claim.**
- **Schemes should be clear on whether temporary injuries are covered, and if so in what circumstances.**

Transparency and Voice Recommendations

- **Scheme processes should be transparent and open.** All scheme should publish information that explains their processes, including how decisions are made and what evidence is required and statistics on key indicators, such as application numbers, decision timeframes, acceptance rates, rates of appeals.
- **Claimant voice should be prioritised in the claims process.** Schemes should enable claimants to have a meaningful voice in the process with an ongoing ability to contribute.

Thresholds for payment Recommendations

- **An NFCS should consider how to best balance delivering justice with the need for administrative efficiency and timely determination of claims.** If the criteria used by a scheme to establish eligibility are complex, uncertain, and/or require high levels of expert input this will slow the processing of claims. The use of a table facilitates quick efficient claims handling, but novel vaccines will not have a ready to go table. The use of alternatives, such as the SmPC, reduces the administrative burden on the NFCS, while potentially providing a more generous approach to payment. Schemes need to consider how to best balance the need for administrative efficiency and prompt claim resolution with the need to deliver just outcomes and decisions.
- **Each NFCS should explain the threshold it uses for payment** The threshold choice is a policy decision. The rationale for the scheme and the underlying legal landscape and relationship with litigation should be considered when determining the threshold. The threshold and the reasons for the threshold choice should be set out by the NFCS.
- **The approach to causation should be clearly set out for each NFCS**. Schemes do not have to determine legal causation, and can opt for a more relaxed test. If a scheme decides to consider causation it should clearly explain how the decision is made, including who makes the decision and what evidence they use. Schemes should publish claims acceptance rates for causation.
- **If an injury severity threshold is used this should be clearly explained in accessible language with appropriate examples**. The potential for significant mismatches between claimant expectation and scheme performance can be seen. Schemes should publish clear accessible explanations of the degree of disability using relevant examples, for example where adverse effects are often systemic neurological impacts the degree of disability caused by amputation is not particularly helpful.

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