



Mandatory vaccination and no fault vaccine injury compensation schemes: An identification of country-level policies

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ABSTRACT

Background: To prevent the spread of infectious diseases, governments have implemented a number of policies, including a range of mandatory vaccination policies. In addition, some governments have implemented no fault vaccine injury compensation schemes as a legal mechanism of recourse for individuals experiencing adverse events following vaccination. We aimed to identify countries with mandatory vaccination policies that also have no fault compensation schemes.

Methods: To identify countries with mandatory childhood vaccination policies, we utilized existing publications, lists and databases, also conducting multiple country searches and policy detail verification. We then investigated compensation schemes for each country with childhood vaccination mandates, using an existing study and database/internet searches.

Results: Of the 62 countries we identified with mandatory childhood vaccination policies, we found evidence that only 7 (11%) had also implemented no fault compensation schemes.

Conclusions: No-fault compensation schemes are one government approach to address unintended consequences of vaccination. Few countries have implemented these schemes, including those with mandatory vaccination policies. Mandatory vaccination invokes a strong need to protect those who fall victim to extremely rare cases of provable no-fault vaccine injury. Countries that mandate childhood vaccination without providing no fault compensation schemes could be seen as abrogating the social contract. This is particularly important when public policies limit parental choice regarding whether to vaccinate.

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1. Introduction

Vaccination brings both individual and societal benefits. Limiting the risk and spread of infectious diseases such as measles, influenza and whooping cough (pertussis) reduces suffering, death and economic costs to governments [1]. Since vaccination was first demonstrated as an effective means of disease control, governments have employed multiple means to improve uptake. Mandatory childhood vaccination is one such means: a legislative lever whereby governments require individuals to vaccinate their children, and may impose consequences when parents do not comply [2]. Mandatory childhood vaccination is defined variably in the literature [3,4]. Here, we define it as a policy officially established by a governing body that specifies EITHER that at least one vaccination is required for an entire subset of the resident population

based on age alone, OR that at least one vaccination is required to access, obtain, or receive a fundamental service or societal benefit, such as enrolment in school. Governments typically justify mandatory childhood vaccination through recourse to the undeniable and significant benefits of vaccination.

Despite their enormous benefits, vaccines – like any medical intervention – also bring risks. Primarily these are temporary and minor side effects, such as pain at the injection site or fever. Serious adverse events following immunization (AEFIs) are exceedingly rare; the World Health Organisation (WHO) observes that serious adverse events following immunisation that are assessed to be causal are generally experienced at a rate of less than 1 in 10,000 cases for commonly used vaccines [5]. WHO also provides detailed analysis of the risk of all identified adverse effects associated with specific vaccines in its information sheets on Observed Rates of Vaccine Reactions; these rates typically align with the broader statement of >1 in 10,000 [6].

Since the risk of serious vaccine injury is so small, and high rates of vaccine coverage benefit everyone through community protec-

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tion, some people believe that governments need not concern themselves with the hardships of those afflicted with vaccine injuries. Such an approach is referred to by Halabi and Omer as “an extreme utilitarian version of the fundamental social contract supporting immunization,” whereby victims of adverse effects are expected to bear the costs of injury themselves for the good of the wider community [7]. However, we argue that when a state mandates vaccination, a social contract is created that should *protect* the individual. The state has a responsibility to address unanticipated harms that result when individuals comply with mandatory vaccination policies. By extension, the more strictly mandatory vaccinations are enforced – and the more difficult it is for parents to access exemptions – the stronger this social contract becomes [8]. In those rare instances where the individual's contribution to protecting public health results in their being harmed, governing bodies should ensure that those individuals are compensated and supported. Verweij and Dawson [9] refer to this as “just distribution of benefits and burdens of vaccination”. Moreover, the social contract arguably extends to the community at large, as the individual was contributing to the public good by being vaccinated and thus averting a potential tragedy of the commons [10]. From this perspective, society bears an interest in assisting a member of the ‘collective’ who is harmed [8].

No fault vaccine injury compensation schemes (hereafter called “no fault compensation schemes”) are a key way for governments to explicitly respond to the responsibility that mandatory vaccination policies generate. Such schemes compensate a person or family who has experienced a serious injury or death caused by a vaccine when there has been no fault in the manufacturing or administration of the vaccine. The process of deciding whether compensation can be awarded requires systems for assessing the causal link between the vaccine and the injury or death.

No fault compensation addresses the limitations of the litigation system that must establish negligence or liability for the injury or death. Other pragmatic benefits contribute to effective national vaccination programmes, and consequently to public health. For example, as Keelan and Wilson note, no fault compensation schemes encourage vaccine innovation and production, as researchers and manufacturers are not left to bear the financial burden of those harmed by adverse effects submitting personal injury claims for compensation; indeed, this was one of the key drivers behind the introduction of a federal vaccine injury compensation scheme in the United States in 1986. Relatedly, litigation does not ensure fairness for victims of adverse effects. The cost of litigation can be prohibitive, awards of damages are variable and unpredictable, and because many vaccine injuries are not the result of negligence, many claimants will fail to satisfy the requirements of personal injury law and their claims will not succeed [11,12]. A further rationale is that compensation schemes contribute to a more robust and comprehensive vaccination programme overall. Finally, they can provide health care workers and the general public with confidence that individuals potentially harmed by a vaccine have support available to them [13].

A recent paper in this journal notes a knowledge gap regarding what percentage of countries have both mandatory vaccination policies and no fault compensation schemes for vaccine injuries [2]. Our paper examines country-level vaccination policies to identify which countries have evidence of mandatory vaccination policies and whether these countries have in place a no fault compensation scheme.

2. Materials and methods

To identify countries with mandatory vaccination policies, we utilized multiple strategies and sources. First, we compiled a list

of countries known to have at least one mandatory childhood vaccination according to the VENICE study of European countries [3]. Then PubMed was searched using the terms: ((compulsory[All Fields] OR (“mandatory”[All Fields] AND (“vaccination”[MeSH Terms] OR “vaccination”[All Fields])) NOT (“united states”[MeSH Terms] OR (“united”[All Fields] AND “states”[All Fields]) OR “united states”[All Fields])) without any restrictions. (We excluded the U.S. in the search given the large number of publications on this topic). When additional evidence for a country scheme was needed, searched the World Legal Information Institute Database for vaccine mandate policy copies. A search engine then was then used to complement the above, with the following key words in combination with variations of each country's name: “mandatory vaccine policy”, “mandatory immunization policy”, “mandatory vaccine law”, “mandatory immunization law”, and “compulsory vaccination”. We also searched using specific mandatory vaccination policy details (for example, dates, vaccines mandated) along with specific policy titles, if known.

Separately, we obtained from the World Health Organization information from the Joint Reporting Form on school entry vaccination requirements in Europe (2016), the Western Pacific Region (2016) and the Pan American Health Organisation (2013) [14]. For countries included in these datasets but not identified through our initial searches, we obtained further policy information using a search engine with the following key words in combination with variations of each country's name: “vaccination school entry” and “immunization school entry.” We also obtained a summary database compiled by the Sabin Institute for Vaccines and available online [15], the Sabin Institute report on vaccination policies in Europe [4], and a searchable European database [16]. We used an internet search engine to obtain more information on the policies we found through these methods.

Titles, abstracts, and links resulting from these searches were reviewed for relevance and, if possibly relevant, the full text was reviewed. Throughout each stage of the search, we followed leads and triangulated evidence until we obtained specific policy details, could verify a policy's existence, and could confirm that it met our definition of a mandate. Whenever this search led to potential evidence that other countries had vaccine mandates, we expanded the search and repeated the strategy for those countries. To be included, a mandatory vaccination policy had to be described in the official government-issued vaccination policy document itself, or outlined in a well-established news source or NGO document.

From the final list of countries with sufficient evidence of a mandatory childhood vaccination policy, we determined whether each country had a no-fault compensation scheme. This included examining Looker and Kelly's 2011 review of no fault compensation schemes globally, then database searches to identify relevant literature using keywords (vaccine AND injury; vaccine AND damage; vaccine AND adverse effects OR adverse events; vaccine AND compensation) in combination with each remaining country name. Databases included PubMed, Proquest, and EBSCO (Academic Search Premier, CINAHL Plus, Medline, Political Science Complete). Results were scanned for potentially relevant titles, and abstracts and/or content was read where titles suggested relevance. We repeated this search pattern as an internet search and again scanned for relevant results, including grey literature and national government documents. We also used the Sabin Institute report [4] and the Sabin searchable database of country policies [17] to search for references to compensation schemes in the policies of European countries identified in our table. Where our searches turned up no reference to countries having a no fault compensation scheme for vaccine injury, we concluded that such a scheme has not been implemented. Searches were restricted to information available online, in electronic format, and in English or in a format that could be translated electronically.

For each country identified as having a mandatory scheme, we identified its Organisation for Economic Co-operation and Development (OECD) income classification, the number of vaccines required, the availability of exemptions, and whether the country has implemented a no-fault compensation scheme, and the year that scheme was introduced. With regard to the assessment that a country does not have a no-fault compensation scheme, we distinguished between outcomes where a) we found evidence that no scheme exists (denoted with asterisk), and b) those where no evidence of a scheme has been found.

3. Results

Table 1 presents a list of the 62 countries for which we found evidence of mandatory childhood vaccination according to our definition. Table 2 presents countries that our source documents had identified as having mandatory childhood vaccination, but which we excluded. Of the 62 countries with mandatory schemes, we identified 7 with evidence of no fault vaccine injury compensation schemes (11%). These were France, Hungary, Italy, Slovenia, The Republic of Korea, Taiwan, and the United States – all high-income countries according to the OECD classification. The evidence from our searches suggests that none of the other 55 countries had a no-fault compensation scheme. Looker and Kelly (2011), in their review of no-fault compensation schemes, identified 19 countries that do have such schemes. No further countries were identified via our search. Twelve of the countries with no fault compensation schemes identified by Looker and Kelly have no mandates at present.

4. Discussion

The majority of countries that mandate at least one vaccine for children have no official policy for compensating rare instances of serious adverse events following immunisation requiring compensation through a no-fault scheme. Twelve of the nineteen countries with no fault vaccine injury schemes have no mandates. This suggests that compensation schemes arise independently of mandatory vaccination. As noted by Looker and Kelly (2011), no fault compensation schemes arise from political and economic pressures, litigation threats, increasing confidence in population-based vaccine programmes and an imperative to ensure an ongoing vaccine supply. Meanwhile, the fifty-five countries that have mandatory childhood vaccination policies but lack no fault vaccine injury compensation schemes are at risk of abrogating the social contract. Implementing stricter requirements for individuals to vaccinate, as Australia has recently done [18], provides an opportunity for countries to address their obligations towards the vaccine-injured. We suggest that any state contemplating moving along the continuum towards more restrictive mandates [19] ought, as a matter of course, to review its options for setting up a no fault vaccine injury compensation scheme.¹

Other means exist for addressing a country's obligations to the (potentially) vaccine injured. A comprehensive disability welfare scheme could also assist individuals who suffer ongoing or permanent disability due to a vaccine injury. For example, in Australia the National Disability Insurance Scheme offers comprehensive support, services and individualised funding to people with disabilities to assist with day to day needs and ongoing well-being [20,21]. A

further mechanism for addressing a country's obligations is through a robust health care system that addresses any medical needs of an individual who suffered a vaccine adverse effect, without any cost being borne by the individual. The National Health Service in the United Kingdom is an example of this type of health system.

However, these systems do not apply to those without permanent, ongoing and qualifying harms (disability insurance) or provide ongoing services to improve an individual's capacity and welfare (robust public health system). Moreover, they do not compensate for death in the extremely rare instance where this occurs, nor for serious but non-permanent disability. Furthermore, neither alternative offers expert review and assessment of affected individuals that would be part of an effective compensation program. Such a review system brings the benefit of follow-up for those who report serious vaccine adverse events. We therefore argue that, owing to the special nature of vaccine injuries [22], in particular where they are the result of a mandate, a dedicated compensation scheme is the most appropriate approach.

The administration of no fault compensation schemes is not without cost. However, as in the US, it is possible to finance the scheme via a levy on each vaccine, thus passing the cost on to vaccine manufacturers [23]. Halabi and Omer [7] suggest implementing a global vaccine injury compensation system that could operate either by countries undertaking to establish their own national compensation scheme in compliance with an overarching, international agreement, or by participating in a regional or a WHO-administered scheme. They suggest options to finance a global-scale system could include adding an excise to the cost of vaccines, which would in turn fund a compensation system; that GAVI (Global Alliance for Vaccines and Immunization) could require countries to establish a compensation scheme that would continue after they graduate from receiving GAVI support; or that networks developed between governments and vaccine manufacturers as part of GAVI's involvement might facilitate an independent basis for them to reach agreement on funding a no fault compensation scheme.

There are also risks and problems attached to no fault compensation schemes. In some countries, parents have utilized the schemes to seek financial recompense for disability or disease of children that is not caused by vaccination, and sometimes compensation is awarded in a way that does not accord with robust medical nor epidemiological evidence [24,25]. Anti-vaccination activists can also use schemes to emphasise vaccine injuries, ignoring the fact that passive surveillance systems for adverse events following immunisation list adverse events prior to the establishment of causation [26]. Therefore, schemes should adhere to the WHO recommendations regarding establishing causality for AEFIs [27], with mechanisms for expert assessment and agreed criteria for compensation.

5. Limitations

The search to identify countries with mandatory vaccination schemes was limited due to incomplete availability of information. We did not seek to describe the detailed characteristics of how each country's mandatory and/or no-fault scheme operates, nor to explore the construction and operation of existing alternatives to no-fault vaccine injury compensation schemes (eg. medical accident compensation schemes). We were also not able to evaluate or describe any patterns in the countries with no fault compensation schemes beyond all of them being high income countries. Questions such as what specific factors led to their adoption would require different methodologies than those employed here. Likewise, we could not make any claims about why countries have

¹ Although it is beyond the scope of this study, we also note the utility and importance of no fault compensation schemes in the context of mandatory adult vaccinations, which several jurisdictions are also implementing. This is particularly pertinent for healthcare workers, whose lives and earnings might be disrupted in the event of acquiring a vaccine injury whilst receiving an influenza (or other) vaccine required for their employment.

Table 1
Countries with mandatory vaccination policies identified by our search strategies; characteristics of the countries including income group and the whether a no-fault vaccine injury compensation scheme has been implemented¹.

Country/Jurisdiction (World Bank Classification)	World Bank Classification Income Group (High, low, middle)	One or More than One Vaccination Required	Exemptions Allowed	No-Fault Compensation Scheme	Year NFC Introduced
Albania [4]	Upper middle	More than one	Unknown	No	N/A
Andorra [4]	High	More than one	Unknown	No	N/A
Antigua [14,28]	High	Unknown	Unknown	No	N/A
Argentina [14,29,30]	Upper middle	More than one	Unknown	No	N/A
Australia [31]	High	More than one	Medical or Secretary	No* [32]	N/A
Azerbaijan [4]	Upper middle	More than one	Unknown	No	N/A
Barbados [14,33]	High	More than one	Unknown	No	N/A
Belgium [3,4]	High	One (and more in some regions [4])	Medical	No* [34]	N/A
Belize [35]	Upper middle	More than one	Medical	No	N/A
Bhutan [36]	Lower middle	More than one	Unknown	No	N/A
Brunei [37]	High	More than one	Medical	No	N/A
Bulgaria [4]	Upper middle	More than one	None listed in official policy	No* [34]	N/A
Canadian Provinces: Ontario, New Brunswick [38]	High	More than one	Religious, Medical, or Out of Conscience	No* [38,39]	N/A
Costa Rica [14,15]	Upper middle	More than one	Not Conscience or Religion [40]	No	N/A
Croatia [41]	Upper middle	More than one	Unknown	No* [39]	N/A
Cyprus [3,4,14]	High	More than one	Unknown	No	N/A
Czech Republic [3,4,33]	High	More than one	Medical	No* [34]	N/A
Dominica [14,42]	Upper middle	More than one	Unknown	No	N/A
Egypt [43]	Lower middle	More than one	Unknown	No	N/A
Federated States of Micronesia [14,44]	Lower middle	More than one	Unknown	No	N/A
France [3,4,45]	High	More than one	Medical	Yes* [13]	1963
Greece [3,4,14]	High	More than one	Unknown	No	N/A
Grenada [14,46,47]	Upper middle	More than one	Religious	No	N/A
Guyana [14,17]	Upper middle	More than one	Medical	No	N/A
Honduras [15]	Lower middle	More than one	Unknown	No	N/A
Hungary [3,4]	High	More than one	Medical	Yes* [13]	2005
India (Tamil Nadu) [33,48]	Lower middle	More than one	Unknown	No	N/A
Italy [3,4,19]	High	More than one	Medical	Yes* [13]	1992
Jamaica [14,49]	Upper middle	More than one	Medical	No	N/A
Kazakhstan [4,14]	Upper middle	More than one	Unknown	No	N/A
Korea (Republic of) [14,50]	High	More than one	Unknown	Yes* [13]	1994
Kosovo [15]	Lower middle	More than one	None listed in legislation[51]	No	N/A
Kuwait [33,52]	High	More than one	Unknown	No	N/A
Latvia [3,4]	High	More than one	Medical	No* [4,34]	N/A
Macedonia [4]	Upper middle	More than one	Unknown	No	N/A
Malta [3,4,14]	High	More than one	By permission of Superintendent	No	N/A
Marshall Islands [14,53]	Upper middle	More than one	Medical, Religious, Personal Belief, Minister of Health	No	N/A
Moldova [4,15]	Lower middle	More than one	Not conscience[54]	No	N/A
Monaco [4]	High	More than one	Unknown	No	N/A
Mongolia [15,55]	Lower middle	More than one	Unknown	No	N/A
Montenegro [4]	Upper middle	More than one	Unknown	No	N/A
Nepal [56]	Low	More than one	Medical	No	N/A
Pakistan [57]	Lower middle	One	Unknown	No	N/A
Palau [14,58]	High	More than one	Unknown	No	N/A
Paraguay [14,15]	Upper middle	More than one	Unknown	No	N/A
Poland [3,4]	High	More than one	Unknown	No* [34]	N/A
San Marino [4,14,59]	High	More than one	Medical; Right to refuse	No* [60]	N/A
Serbia [4,61]	Upper middle	More than one	Medical	No	N/A
Singapore [62]	High	More than one	Unknown	No	N/A
Slovakia [3,4,63]	High	More than one	Medical	No* [34]	N/A
Slovenia [3,4]	High	More than one	Medical	Yes* [34,64]	2004
St Kitts [14,65]	High	More than one	Unknown	No	N/A
St Vincents [14,46]	Upper middle	More than one	None listed in legislation	No	N/A
Suriname [14,66]	Upper middle	More than one	Unknown	No	N/A
Taiwan [67]	High	More than one	Medical	Yes* [13]	1988
Tajikistan [4]	Low	More than one	Unknown	No	N/A
Trinidad [14,68]	High	More than one	Medical; immunity	No	N/A
Uganda	Low	More than one	Medical	No	N/A
Ukraine [4]	Lower middle	More than one	Medical	No	N/A
Uruguay [69]	High	More than one	Unknown	No	N/A
U.S. states [70,71]	High	More than one	Medical, Religious, Philosophical; Varies by State	Yes (Federal Scheme)* [13]	1988
Uzbekistan [4,14]	Lower middle	More than one	Unknown	No	N/A

¹ Our first reference in column 1 is the VENICE study [3], and/or the WHO list [18] and/or the Sabin report on European vaccination policy [4] or the Sabin global database (for non-European countries) [19]. This allows readers to see the basis of our initial classification. We then augment this with additional references where possible. We cite our sources for the verified presence or absence of no fault compensation schemes in the fifth column.

Table 2

Countries listed in source documents as having mandatory vaccination but excluded in this assessment.

Study/Document	Year undertaken	Countries listed as mandatory that we excluded	Why we excluded
VENICE	2010	Romania	Lack of sufficient evidence that policies are in place presently. Sabin European report also classified as 'recommended' [4]
WHO list	2013–2016	Belarus, Bolivia, China, Colombia, Kyrgyzstan, Russia, St Lucia,	Lack of sufficient evidence, or evidence of no mandate.
Sabin database	N.D.	Bolivia and Bangladesh	Bolivia: we interpreted the wording of the “mandate” claim as placing obligation on government to deliver vaccines rather than on citizens to accept them. Bangladesh: we found evidence that the law was repealed.

not implemented no fault compensation schemes. These questions inform our current and future research projects.

6. Conclusion

Despite their costs and problems, no fault compensation schemes provide considerable benefits. Not only do they fulfil the social contract, they also have the potential to contribute to public and health care worker confidence in vaccination programs. If individuals are expected to accept the risks inherent with adhering to vaccine mandates, they should be confident that they will be cared for in the rare case that they suffer an adverse event. No-fault compensation schemes can also mitigate against negative publicity which can occur when a child or adult receives an injury that appears to satisfy conditions of causality, but where families must take the matter to court. Such cases sometimes receive sustained coverage in the media, thereby perpetuating public exposure to potent testimony amplifying the risks of vaccination. Finally and more broadly, when NFC schemes are in place, public discourse can emphasize that resources have been devoted to ensuring that this happens, and that governments are ensuring that they meet their responsibly to support those harmed. Whilst alternative policies and institutional mechanisms can fulfil the social contract in terms of protecting the vaccine-injured (such as more general medical accident compensation schemes), only policies that specifically pertain to vaccination can directly address public confidence in vaccines, helping to generate consent for mandatory vaccination. Hence, vaccine injury compensation schemes (with appropriate mechanisms for assessing causality) can both satisfy the social contract and help build confidence in vaccines in countries that mandate vaccination.

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