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# Economic and immunisation safety surveillance characteristics of countries implementing no-fault compensation programmes for vaccine injuries

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ABSTRACT

Improvements in vaccine safety surveillance and investigative capacity lead to identification of rare reactions attributable to vaccination. As a result, the issue of fair compensation for those who experience vaccine injuries is gaining growing attention. Although vaccine injury compensation programmes (VICP) have been developed in a few countries for more than 50 years, no global policy guidance to guide vaccine injury compensation in all countries wishing to adopt such compensation schemes is currently available. To update the landscape analysis of no-fault compensation programmes and characterize VICP implementing countries, we conducted a survey of all 194 Member States from the World Health Organization and received feedback from 151. This analysis describes the economic and vaccine safety surveillance characteristics of Member States implementing VICPs. This analysis describes the characteristics of 25 Member States implementing a compensation programmes. Characteristics examined include economic, vaccination and safety surveillance indicators. Twenty of the 25 Member States (80%) with compensation programmes are categorized as high-income countries, 20/25 (80%) met the Global Vaccine Action Plan (GVAP) safety indicator of reporting at least ten annual reports of adverse events following immunization per 100,000 population, 21/25 (84%) met the GVAP coverage indicator by achieving greater than 90% third dose of Diphtheria, Tetanus and Pertussis vaccine (DTP3) and 17/25 (68%) assessed vaccine hesitancy in 2017. All Member States with VICP have a national immunization technical advisory group. This study identified growing interest in the implementation of no-fault compensation programs beyond high-income countries. Global policies guiding compensation should be developed for countries regardless of the maturity of their immunization programmes.

*Research in context:* As a result of improved vaccine safety surveillance, World Health Organization (WHO) Member States are facing situations where known untoward serious vaccine reactions are documented, including in low- and middle-income settings. This has led to increased interest for the development of national no-fault compensation policies for vaccine injuries. As of 2010, compensation schemes for vaccine related injuries had been identified and characterized in 19 out of 194 WHO member states. All these programmes were in the industrialized world with none in low- and middle-income countries. Previous reviews have described the characteristics of the existing programmes based on the six common elements identified by Evans in 1999 with less emphasis on characteristics from countries implementing these no-fault compensation programmes.

This manuscript aimed to identify predictors of countries implementing no-fault compensation programmes for vaccine injuries and update the inventory of existing programmes as part of a more comprehensive global landscape evaluation of existing programmes. This information will be useful for country self-evaluation and future compensation policy formulation as discussion to develop policies guiding the implementation of vaccine injury compensation continues to gain growing attention.



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## 1. Introduction

Vaccines are widely used in healthy populations to prevent diseases. While extremely safe, vaccines on rare occasions have been shown to be associated with serious adverse reactions [1–3]. These adverse reactions may result in physical injuries, illnesses, disabilities, other serious medical conditions or death [1–3]. Considering the societal benefits of vaccination beyond protection of individuals from diseases [4], deliberate efforts by policy makers as custodians of public health are warranted, to address societal concerns about vaccine injuries and to maintain confidence in vaccination programmes [5].

Vaccine injury compensation programmes are no-fault compensation programmes established to compensate individuals who experience a rare vaccine related injury due to the inherent risk of vaccination. These rare reactions include neurological disorder in a child following vaccination with a well-manufactured and administered vaccine or paralysis following nerve injury due to poor injection technique [6–8]. The term ¨no-fault¨ implies a measure put in place by public health authorities, private insurance companies, manufacturers and other stakeholders to compensate individuals inadvertently harmed by vaccines [8,9]. Vaccine injury compensation programmes do not require the injured party or their legal representative to prove negligence or fault by the vaccine provider, health care system or the manufacturer prior to compensation [10]. They serve to waive the need for accessing compensation through litigation processes [8,10]. No-fault compensation systems which are mostly administrative procedures are considered a fair approach to both the victims of vaccine injuries and manufacturers by reducing the financial burden of compensation [11].

With the global efforts to improve vaccine safety surveillance including low- and middle-income settings [12,13], World Health Organization (WHO) member states are facing situations where adverse reactions associated with vaccines are documented. This has led to increased interest and discussion for national no-fault compensation policies for vaccine injuries [10]. As of 2010, compensation schemes for vaccine related injuries had been identified and characterized in only nineteen out of 194 WHO member states [8]. The majority of these programmes have been implemented in the industrialized world with none in low- and middle-income countries. Previous reviews have described the characteristics of the existing programmes based on the six common elements identified by Evans in 1999 with less emphasis on economic and vaccine safety surveillance characteristics of countries implementing these no-fault compensation programmes [7,8]. The six common elements include; administration and funding, eligibility, process and decision making, standard of proof, element of compensation, and litigation rights.

Therefore, we conducted a global survey of the status of vaccine injury no-fault compensation programmes with the aim to update the inventory of such programmes and analyse characteristics of countries implementing no-fault compensation programmes. This analysis seeks to forecast the next segment of VICP adopters and guide vaccine injury compensation policy formulation. The characteristics of the existing compensation programmes are described in a separate manuscript. This publication is reporting on the characteristics of implementing countries including economic profiles and immunization safety surveillance indicators.

## 2. Methods

The study included three parts. Initially a landscape analysis and scoping review of published and unpublished literature was conducted to update the inventory of countries that are currently implementing a no-fault compensation programme for vaccine injuries. Published data were supplemented with official documents accessed from government websites (where available). A review of these documents was conducted to evaluate current policies and practices of no-fault compensation programmes implemented in all WHO member states.

Secondly, all 194 WHO Member States were screened to identify those with a no-fault compensation programme for vaccine injuries. We approached several professional networks. These included immunization programme focal points in WHO regional or country offices and local Ministry of Health in member states. Screening for programmes was also conducted amongst current and past members of the WHO Global Advisory Committee on Vaccine Safety (GACVS) [14], conference attendants (Global Immunization 2018 Meeting [15], Vaccine Safety Net 2018 meeting [16] and International Conference of Drug Regulatory Authorities 2018 [16]). During the same period (June to November 2018), information on the presence of systematic compensation programmes for vaccine injuries was being collected through the WHO Immunization, Vaccines and Biologicals Department repository and a global survey of national immunization technical advisory groups (NITAGs). All this data were used to triangulate the presence or absence of programmes for compensating vaccine injuries. For each country with a no-fault compensation programme for vaccine injuries, an expert with in-depth knowledge of their national immunization programme was identified to complete a structured online survey. To ensure accuracy of the data, survey respondents were encouraged to seek clarification and the survey tool was available in English and French. The detailed characterization of current no-fault compensation programmes for vaccine injuries is reported separately.

Thirdly we assessed the profile of no-fault compensation programme implementers with administrative data from the WHO-UNICEF-joint reporting form (JRF) and the World Bank repository [17]. These data were used to summarize selected characteristics of countries implementing compensation programmes for vaccine injuries. The characteristics were selected based on their relevance in implementing vaccine safety measures, monitoring and evaluation and financial capacity for programme sustainability. The characteristics were considered in three categories including: country s economic status, geographic distribution (according to WHO regions), and selected immunisation programme indicators. The selected indicators included presence of: a National immunization Technical Advisory Group (NITAG) and Adverse Event Following Immunization (AEFI) reviewing committee, an AEFI monitoring system, mandatory vaccination, vaccine hesitance assessment, achievement of the Global vaccine Action Plan (GVAP) indicators for vaccine coverage and safety. A descriptive analysis of the selected indicators is presented below.

## 3. Ethical consideration and scientific oversight

Scientific review of the protocol was conducted in collaboration with the academic and scientific committee from the University of Siena, Master of Vaccinology and Pharmaceutical Clinical Development programme. An independent scientific committee consisting of selected members of the GACVS, and additional immunization experts was set up to oversee the conduct of the study and ensure scientific rigor. The study was granted exemption from full ethical review by the WHO ethics committee since it only included human subjects participating in their professional capacity (as staff or affiliates of WHO regional or country offices and/or Ministry of Health) and sharing information available in the public domain. Informed consent was sought from all participants prior to collecting any study related data.

## 4. Results

We identified 25 of the 194 WHO Member States implementing VICP from our triangulation of information using literature search and approaching immunization programme experts. The existing programmes cover just approximately 30% of the total population of all 194 WHO Member States. This represents a 30% increase in the number of programmes from the last review by Kelly and Looker which identified 19 countries. These include; USA and Province of Quebec in Canada representing 6% of the region's 35 Member States in the WHO region of the Americas. The European region has the highest number of compensation programmes with 17 of the 53 (32%) member states. These include: Austria, Denmark, Finland, France, Germany, Hungary, Iceland, Italy, Latvia, Luxembourg, Norway, Russia, Slovenia, Sweden, Switzerland and United Kingdom. Five of the 27 (19%) member states from the Western Pacific region also implement vaccine injury compensation programmes. These include: China, Japan, New Zealand, Republic of Korea and Viet Nam. Nepal and Thailand are the only member states implementing a vaccine injury compensation programme in South East Asia region. There are no countries from African and Eastern Mediterranean region nor from Latin America identified as implementing no-fault compensation schemes (Fig. 1).

Since Germany implemented the first no-fault compensation programme in 1961, the number of countries with such programmes has slowly but steadily increased. During the 70's and 80's 11 countries implemented one [8]. Interestingly, the number of new countries has not accelerated during the twenty first century, with only three new countries during the first decade and three during the current one (Fig. 2).

Twenty of 25 countries (80%) with a no-fault compensation programme for vaccine injury are classified by the World Bank as high-income countries (Table 1). This represents 36% of the 56 high income countries. However, of those 20 countries, 19 belong to the 33 countries under the Organization for Economic Co-operation and Development (OECD), representing 58% of OECD countries whilst only one (4%) of the 23 non-OECD countries have regulations guiding compensation for vaccine injuries (Latvia). Unlike previous reports [7,8], implementation of no-fault compensation programmes were not restricted to high-income countries. The other countries are classified as follows; three upper middle-income countries (China, Russia and Thailand), one lower middle-income country (Vietnam) and one low-income country (Nepal).

According to data reported in the WHO-UNICEF joint reporting form for the year 2017 [17], all 25 Member-States with VICP have a National Immunization Technical Advisory Group (NITAG) or a group of experts who provide scientific recommendations to guide evidence-based immunization policy formulation and programme decisions (i.e. Norway). In those without VICP, 109 out of 169 Member States (64%) have a NITAG. All 25 Member States with VICP have a National Adverse Event Following Immunization (AEFI) monitoring system and 20 (80%) had a national AEFI surveillance system achieving the GVAP safety indicator (reported at least 10 AEFIs per 100,000 surviving infants) [13]. Four of the high income, OECD countries from EURO region were yet to report this data in the WHO/UNICEF JRF, whilst one country from lower-middle income country category did not meet this indicator. Twenty-one Member States (84%) with VICP met the GVAP coverage indicator of 90% DTP3 coverage compared to 63% of Member States without VICP. The coverage ranged from 89% to 99% in implementing Member States compared to 33% – 99% in non-implementing countries [18]. Sixteen out of 25 MS (64%) with VICP had a National AEFI Review Committee that conducts causality assessment of serious AEFIs. However, all the Member States implementing VICP who responded to our survey indicated utilizing a selected group of medical experts to establish causal link between vaccine and injury prior to compensation. Ten of the 25

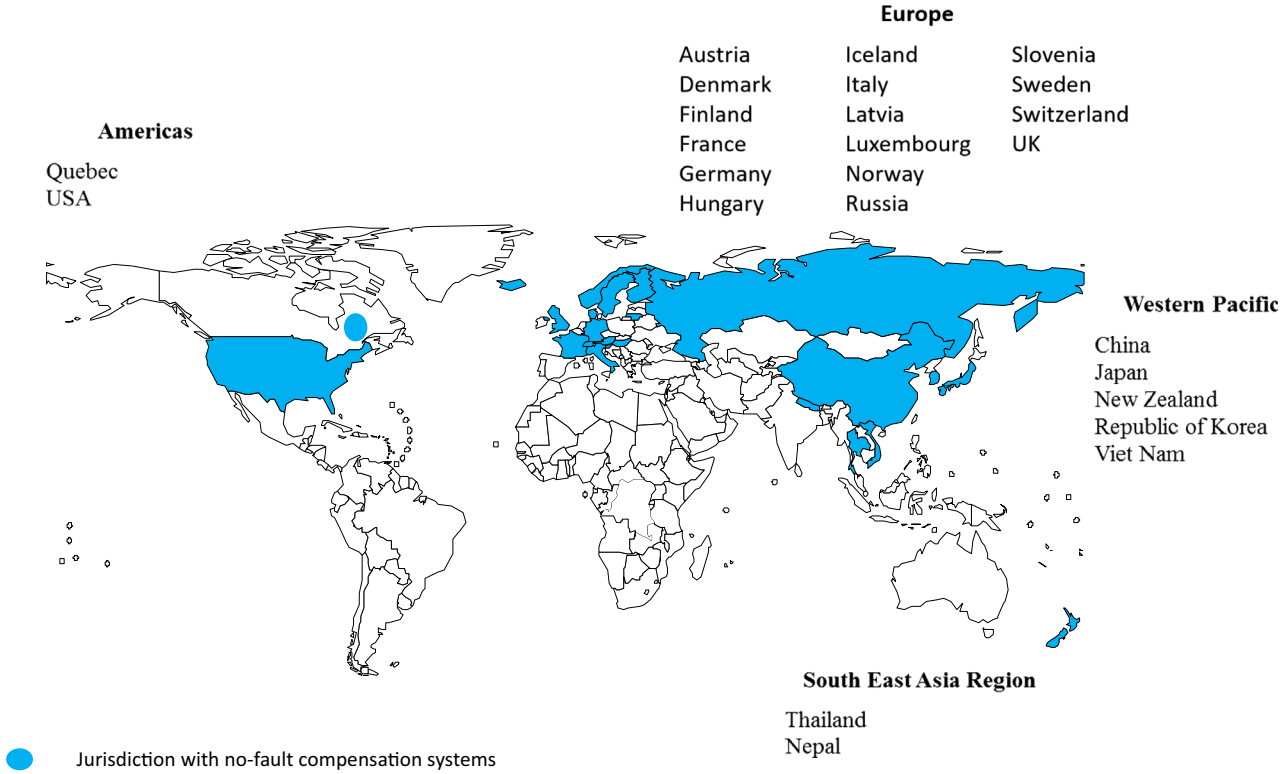


**Fig. 1.** Jurisdictions implementing vaccine injury no-fault compensation schemes in 2018.

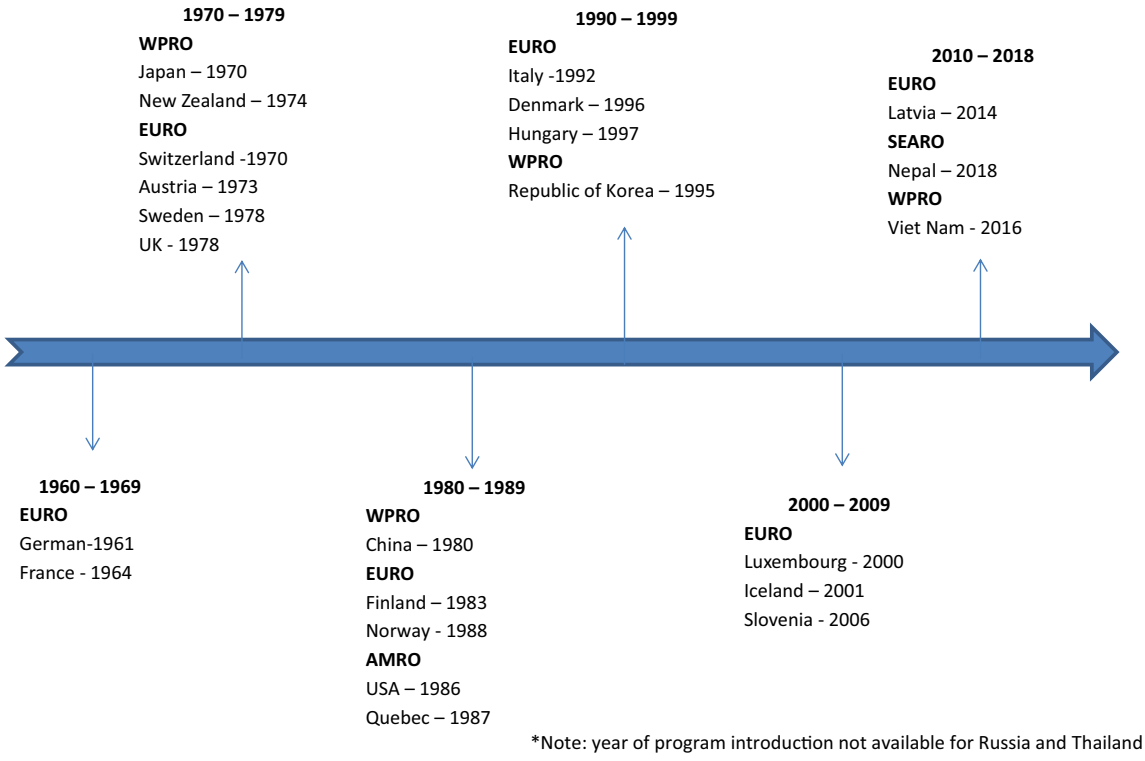


**Fig. 2.** Evolution of no-fault vaccine injury compensation programmes in six decades.

**Table 1**
Summary of country profiles for VICP implementers and non-implementers.

| Variable | Number of MS | MS with VICP (n = 26) | MS with no VICP (n = 168) | Proportion of all MS (N = 194) |
|---|---|---|---|---|
| Economic category | | | | |
| LIC | 31 | 1 (3%) | 30 (97%) | 16% |
| LMIC | 50 | 1 (2%) | 49 (98%) | 26% |
| UMIC | 55 | 3 (5%) | 52 (95%) | 28% |
| HIC: OECD | 33 | 19 (58%) | 14 (42%) | 17% |
| HIC: non-OECD | 23 | 1 (4%) | 22 (96%) | 12% |
| No information | 2 | 0 | 2 (N/A)* | 1% |
| WHO region | | | | |
| AFRO | 47 | 0 | 47 (100%) | 24% |
| AMRO | 35 | 2 (6%)** | 33 (94%) | 18% |
| EMRO | 21 | 0 | 21 (100%) | 11% |
| EURO | 53 | 16 (30%) | 37 (70%) | 27% |
| SEARO | 11 | 2 (18%) | 9 (82%) | 6% |
| WPRO | 27 | 5 (19%) | 22 (81%) | 14% |

HIC – high income countries; LIC – low income countries; LMIC – lower middle-income countries; MS – member states; OECD – Organization for Economic Co-operation and Development; UMIC – upper middle-income countries; VICP – vaccine injury compensation programme.
* 2 blank (Cook Island and Niue).
** None in Latin America.

Member States (40%) with VICP had mandatory vaccination requirements (Table 2).

In 2017, 72 of the 194 (37%) Member States reported assessing for vaccine hesitancy (18). Of these, 17 of the 25 Member States (68%) with VICP assessed vaccine hesitancy compared to 55 of 169 (33%) Member States without VICP. Sixty-four of the 72 Member States (89%) that assessed vaccine hesitancy had supporting evidence of the assessment including 15 of 25 (60%) member states with no-fault compensation programmes and 49 of 169 (29%) with no compensation (Table 2).

## 5. Discussion

The number of countries with no-fault injury compensation is slowly increasing over time and in recent years, one low-income and one lower middle-income country initiated such programs. However, only a minority of countries, 25 (13%), currently have such program. Of all income categories studied, except for 19 of 33 (58%) OECD members, less than 10% of the countries have no-fault injury compensation. Of note no countries from Africa, Latin America and the WHO Eastern Mediterranean region have such program.

The implementation of no-fault compensation programmes beyond richest countries is encouraging and demonstrates the feasibility of developing policies guiding compensation in limited resource settings. With increasing number of vaccines available including products for disease of regional significance, the decrease of vaccine-preventable diseases leads to more attention to adverse events following immunization and possible untoward vaccine reactions [12,19]. This combined with strengthening of vaccine

**Table 2**
Summary of country vaccination indicators for VICP implementers and non-implementers.

| Vaccination indicator | Status | VICP (n = 25) | No VICP (n = 169) |
|---|---|---|---|
| Mandatory vaccination | Yes | 10 (40%) | No information* |
| | No | 15 (60%) | No information* |
| Achieved GVAP safety indicator 2017 | Yes | 20 (80%) | 94 (56%) |
| | No | 5 (20%) | 75 (44%) |
| AEFI committee | Yes | 16 (64%) | 113 (67%) |
| | No | 9 (36%) | 56 (33%) |
| AEFI monitoring system | Yes | 25 (100%) | 145 (86%) |
| | No | 0 | 24 (14%) |
| NITAG | Yes | 25 (1 0 0) | 109 (64%) |
| | No | 0 | 60 (36%) |
| Vaccine hesitancy assessment in 2017 | Yes | 17 (68%) | 55 (33%) |
| | No | 8 (32%) | 114 (67%) |
| Vaccine hesitancy evidence | Yes | 15 (60%) | 49 (29%) |
| | No | 10 (40%) | 120 (71%) |
| DTP3 Vaccine coverage >90%** | Yes | 21 (84%) | 106 (63%) |
| | No | 2 (8%) | 60 (36%) |

AEFI – adverse events following immunization; GVAP – Global vaccine action plan; NITAG – National Immunization Technical Advisory Committee; VICP: vaccine injury compensation programs.
* Information not available for all member states without VICP.
** information not reported for 2 countries with VICP and 3 countries without VICP.

safety surveillance activities in all WHO member states, increases the likelihood of observing the extremely rare true serious reactions to vaccination [13].

Noteworthy, most countries with no-fault compensation programmes have a mature and efficient immunization programme. These countries achieved the GVAP vaccine safety indicator of reporting more than 10 AEFI cases per 100,000 surviving infants, had a NITAG in place, had assessed vaccine hesitancy and had high immunization coverage, which are important components of immunization programs [20–22]. Despite 4 of the 25 VICP implementing countries did not meet the GVAP coverage indicator (achieving 90% of DTP3), all of them had high coverage. There were differences (though minor) in the existence of a national AEFI committee or national AEFI monitoring system between countries with or without a no-fault compensation programme. This may imply that the relationship between VICP and vaccine safety reporting and surveillance programs needs to be studied further in detail. Countries may benefit from strengthening their vaccine safety reporting, having a functional AEFI committee and NITAG, and put in place vaccine hesitancy assessment measures prior to implementing vaccine injury compensation policies. However, development of such system does not seem to be motivated by the mandatory vaccination, as only 42% of implementing countries have mandatory vaccination requirement. Information is scanty on the resources required for implementation of VICPs, but different countries with compensation policies have a variety of approaches. The analysis of different characteristics of existing VICPs is presented in a different manuscript.

Our approach of evaluating the status of no-fault compensation programmes has some limitations because we could not reach out individually to all 194 WHO member states. To correct this limitation in the screening process we used indirect approaches to triangulate the presence or absence of compensation programmes and are confident this offered us a close to accurate estimation of existing programmes. Some Member States may have other types of medical injury compensation that could, on occasion, cover for vaccine-related events. The limitation of our work is that this has not been examined.

## 6. Conclusion

As countries keep expanding vaccines use and strengthen their vaccine safety surveillance and investigative capacity, occasional severe vaccine reactions are increasingly being identified. Subsequently, the question of fair and equitable compensation of identified vaccine injuries is more frequently raised. Findings from this survey demonstrate that interest in vaccine injury compensation policies is no longer limited to high-income countries. Therefore, it is essential that global policies to guide implementation of vaccine injury compensation programmes in different economic settings be developed.

## Author contribution

RGM, PZ and CM contributed to protocol development, conducting the landscape analysis, manuscript development. All the authors reviewed and approved the final version of this manuscript.

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## Declaration of Competing Interest

None declared.

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## Disclaimer

The authors alone are responsible for the views expressed in this article and they do not necessarily represent the views, decisions or policies of the institutions with which they are affiliated.

## Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2019.06.018.

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