The NEW ENGLAND JOURNAL of MEDICINE

Perspective

No-Fault Compensation for Vaccine Injury — The Other Side of Equitable Access to Covid-19 Vaccines

Sam Halabi, J.D., Andrew Heinrich, J.D., and Saad B. Omer, M.B., B.S., Ph.D., M.P.H.

The Covid-19 pandemic has triggered a global vaccine race. As of September 27, 2020, there were more than 200 vaccine candidates in preclinical and clinical development, including 11 in phase 3 trials. Wealthy governments that have invested in vaccine candidates have made bilateral agreements with developers that could result in vaccine doses being reserved for the highest-income countries — a phenomenon known as "vaccine nationalism" — potentially leaving people in poor countries vulnerable to Covid-19.

The response to vaccine nationalism has been the creation of the COVAX Facility, an international partnership that aims to financially support leading vaccine candidates and ensure access to vaccines for lower-income countries. Seventy-nine higher-income countries are COVAX members. Their governments will help support 92 countries that couldn't otherwise afford Covid-19 vaccines.

But large, up-front financial commitments to manufacturers are only half the solution when it comes to ensuring that companies will be willing to participate in the COVAX mechanism for vaccine distribution. Equally important is offering companies protection against potentially substantial liability should Covid-19 vaccines cause real or perceived injuries to recipients. Manufacturers won't agree to procurement contracts or ship vaccine without liability protection. According to an AstraZeneca executive, for example, in the company's bilateral contracts, it has been granted protection against legal claims arising from the use of its vaccine products, since it "cannot take the risk" of liability.[1] As early as 2006, the International Federation of Pharmaceutical Manufacturers and Associations, the global pharmaceutical-industry lobbying group, publicly demanded that manufacturers be granted protection from lawsuits associated with vaccine-related adverse events if they were going to participate in pandemic responses. In the United States, the Public Readiness and Emergency Preparedness Act provides manufacturers immunity from lawsuits related to injuries caused by vaccines, with narrow exceptions. People injured by Covid-19 vaccines must file claims with a fund administered by the Department of Health and Human Services.

For a vaccine that will most likely be distributed worldwide,

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there is an inevitable risk of serious adverse events, such as seizures and allergic reactions, even with a very safe product. Such events might not begin surfacing until a substantial number of people have been vaccinated. During the 2009 H1N1 influenza pandemic, the incidence of serious adverse events after immunization varied by country. In the United States, the Vaccine Adverse Event Reporting System received reports of such events at a rate of 2.45 per 100,000 doses. China's equivalent surveillance system found that 1083 of the 8067 adverse events recorded (1.21 per 100,000 doses) were serious. Compensation costs also varied. One H1N1 vaccine that contained an adjuvant was associated with an increased risk of narcolepsy, which resulted in substantial compensation claims in Northern European countries.

For most countries, offering pharmaceutical companies indemnity or complete immunity from lawsuits is constitutionally or financially impossible. Some governments will refuse to make such offers because of basic fairness principles: manufacturers should pay for the injuries their products cause. During the Ebola emergency in West Africa, for example, the government of one of the most affected countries refused to accept liability related to vaccines that were considered for deployment under emergency use authorizations. The dilemma for low- and middle-income countries, therefore, involves whether to refuse to offer manufacturers protection against liability and go without Covid-19 vaccines or to extend liability protections (if doing so is constitutionally possible) and risk having a large number of people injured to whom the government is unable to offer compensation.

We believe that the solution to this problem involves leveraging two existing no-fault vaccine-injury regimens and constructing a third regimen under COVAX's authority. Countries could, of course, opt out of these programs or design their own national or regional compensation systems, but such systems would have to be created fairly quickly.

First, 24 countries and the Canadian province of Quebec have no-fault vaccine-injury compensation systems for routine immunizations.[2] Although these systems generally aren't designed to cover injuries related to vaccine administration during public health emergencies, they could quickly be adapted to do so. Changes could be made to policies related to funding, proving injury, and distributing compensation. These systems tend to exist in wealthier countries, but Nepal and Vietnam also have such systems. Countries with existing no-fault vaccine-injury compensation systems could incorporate Covid-19 vaccines into these programs.

Second, the World Health Organization (WHO) has an insurance mechanism for vaccines deployed under emergency use authorizations. This mechanism requires that the recipient country agree to indemnify the WHO, donors, manufacturers, and health care workers who vaccinate people; the WHO then provides compensation to people who have a serious adverse event. The program is necessarily small in scale, but it could be a useful option for small countries.

Although these components are part of the answer, there also needs to be a mechanism for efficiently handling a high volume of claims from throughout the world. To meet this need, we believe that the COVAX Facility should establish a procedure for compensating people who have a severe adverse event after immunization. Because COVAX will require national deployment plans for vaccines, it could make countries include plans for postmarketing safety surveillance.

Scholars, economists, and representatives from international organizations have asserted that it's impossible to accurately identify people who have been seriously injured, verify their claims, and directly distribute compensation. Existing mass-claim models, however, show that similar claims can be processed accurately and efficiently.

Compensation funds have served large groups of people, including in low- and middle-income countries. After the Iraqi invasion of Kuwait, the United Nations created the United Nations Compensation Commission in 1991. The commission evaluated nearly 2.7 million claims and issued 1.5 million awards with an aggregate value of more than $50 billion and was an early and lauded model for accurate and efficient mass-claims processing.[3] The Trust Fund for Victims is another applicable model. This fund was created to provide support to victims of crimes perpetrated by people convicted in the International Criminal Court. It has routinely made payments to more than 100,000 people per year, including those in rural regions of the Democratic Republic of Congo, Uganda, and the Central African Republic. According to external evaluations, the fund makes such payments "in an effective and efficient way."[4] These compensation systems demonstrate

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Funding, Eligibility, and Administration Options for No-Fault Compensation for Injuries Attributable to Covid-19 Vaccines.*

Factor	World Health Organization	COVAX Facility	National or Provincial System
Funding	Insurance premium paid from general WHO revenues	Per-dose or per-volume fee	Tax on manufacturers (based either on a percentage of manufacturers' annual sales or number of doses sold), distributors, or suppliers; general revenues
Eligibility	Based on temporal relationship between immunization and serious adverse event	Criteria jointly developed by CEPI; Gavi, the Vaccine Alliance; and the WHO that could include temporal association or tables of injuries based on phase 3 trial data	Existing criteria for other vaccines that are eligible for compensation programs, including vaccines deployed under criteria for a national public health emergency, e.g., "balance of probabilities" or "compelling" evidence of a relationship between immunization and serious adverse event
Administration	WHO compensation-claims personnel and insurance-claims administrators	Third-party claims administrator, including claims-administration services available from global insurers	Designated national judicial or administrative authorities
Elements of compensation	Lump-sum payment based on weighted average of claims histories for injury compensation in national systems adjusted for relative purchasing value	Lump-sum payment based on weighted average of claims histories for injury compensation in national systems adjusted for relative purchasing value	Nationally determined compensation (based on lost wages, nonreimbursed medical expenses, disability pension, and noneconomic loss, and including death benefits)

* CEPI denotes Coalition for Epidemic Preparedness Innovations, and WHO World Health Organization.

that it would be possible to create a global, centralized compensation commission for injuries related to Covid-19 vaccines.

A COVAX compensation system could be funded by earmarking committed resources from higher-income countries or by charging manufacturers a per-dose tax to support its purpose. Given that billions of doses of Covid-19 vaccine will probably be administered, a 5- or 10-cent charge per dose would be enough to build a pool of resources for compensation. The table outlines the funding, eligibility, and administrative features of this proposal.

Creating a comprehensive system for no-fault vaccine-injury compensation would be feasible and would promote justice. Excluding countries that are unable to provide indemnity or immunity to manufacturers could deprive billions of people of the protection that vaccines will afford. Allowing access to Covid-19 vaccines without ensuring that people who have serious adverse events will be compensated would benefit uninjured people at the expense of injured people.[5] We believe that the global community that promotes immunization as a collective interest, knowing that people will be injured, must share the burden of these injuries' costs. Furthermore, manufacturers are essential to vaccine development and access and should be extended a minimum level of economic certainty. A global commission for compensation based at the COVAX Facility is a realistic, achievable solution that would facilitate the procurement of Covid-19 vaccines while ensuring that vulnerable people are able to seek compensation for injuries, and it could set a precedent for future vaccination campaigns.

Disclosure forms provided by the authors are available at NEJM.org.

From the O'Neill Institute for National Global Health Law, Washington, DC (S.H.); and the Yale School of Public Health (A.H.) and the Yale Institute for Global Health (S.B.O.) — both in New Haven, CT.

This article was published on October 28, 2020, at NEJM.org.

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DOI: 10.1056/NEJMp2030600
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