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Sam F. Halabi
University of Missouri School of Law, halabis@missouri.edu

Saad B. Ommer

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VIEWPOINT

A Global Vaccine Injury Compensation System

Sam F. Halabi, JD, MPhil
O'Neill Institute for National and Global Health Law, Georgetown University, Washington, DC; and University of Missouri School of Law, Columbia.

Saad B. Omer, MBBS, MPH, PhD
School of Medicine, Emory University, Atlanta, Georgia.

Supplemental content

Vaccines are extremely safe and harm is rare. Worldwide, more than 30 000 vaccine doses are delivered per second through routine immunization programs, which, in turn, prevent an estimated 2 million to 3 million deaths annually.[1] The occurrence of serious adverse events, such as those that result in death, threaten life, require inpatient hospitalization, or result in significant disability, are rare (eg, <1 adverse event occurs per 10 million doses for tetanus toxoid vaccines, 1-2 adverse events per 1 million doses for inactivated influenza vaccine, and none for hepatitis A).[2]

Yet the specter of vaccine injury plays a central role in vaccine access and will continue to do so as vaccine technologies evolve. The public health emergencies involving influenza A(H1N1), Ebola, and Zika illustrate the relationship between vaccine access and vaccine injury. An H1N1-specific vaccine was developed within 4 months of the virus being isolated by the Centers for Disease Control and Prevention, but the demands of vaccine manufacturers and donating governments for comprehensive release of liability delayed distribution of vaccines to low-resource countries by at least 5 months.[3] Governments and international organizations prioritized vaccine injury liability when considering whether promising Ebola vaccine candidates, which incorporated technologies unused in any licensed vaccine worldwide, might be used to address the outbreak. Because the teratogenic effects of Zika virus may occur at all stages of pregnancy, candidate Zika vaccines would be most beneficial if administered prior to or during pregnancy—the condition most likely to affect both research and immunization because of liability concerns.[4]

> There is a strong public health justification for a system that compensates those who experience vaccine injury, especially when the system is supported by all responsible parties.

There are 3 types of approaches to addressing vaccine injury: patients with adverse events may bear the costs associated with their injuries; they may seek compensation through litigation against private-sector actors (principally manufacturers); or they may seek compensation from publicly supported systems that draw from public-sector and private-sector contributions. Each type of approach is supported by an ethical rationale. The first approach, requiring individuals with vaccine injury to bear their own costs, is an extreme utilitarian version of the fundamental social contract supporting immunization. The benefits of vaccination so outweigh the risks that communities accept that some individuals will experience adverse events in return for herd immunity.

The second approach, requiring manufacturers to pay, is based on the integrity and dignity of the individual person—those whose products cause injury should make whole those individuals who experienced an adverse event. These types of approaches are representative of the common approach worldwide, yet they destabilize the effort to promote immunization by failing fundamental tests for fairness by asking people with few resources to pay for serious (if rare) injuries with the first approach vs introducing economic uncertainty with the second.

The third approach, a no-fault compensation system for adverse events attributed to vaccination, balances these competing principles. Under a no-fault vaccine injury compensation system, governments compensate individuals who are harmed by properly manufactured vaccines instead of requiring them to use legal or other processes against manufacturers. A no-fault system acknowledges that a community that promotes immunization, knowing individuals will be injured, must share the burden of the cost of injuries. This approach also acknowledges that manufacturers are a critical part of vaccine access and that they must have a basic level of economic certainty. It fulfills the utilitarian and communitarian expectations of a democratic society. Yet no-fault compensation systems for vaccine injury prevail in only 19 jurisdictions worldwide including the United States.[5]

A global vaccine injury compensation system to bring economic certainty would represent a substantial advance to this critical component of the global public health system and build trust necessary for vaccines—especially in emergency contexts. Such a system would address barriers to vaccine manufacturers' participation as well as perceptions that contribute to vaccine hesitancy in low-resource countries. A prominent perception shared by persons in low-resource settings is that diseases with pandemic potential that affect the global poor are neglected by the world's major medical research institutions. When one of those diseases threatens Europe or North America, those institutions and their sponsoring governments invest in relevant medical research but do so using the global poor as relatively unprotected human research subjects.[6] A global vaccine injury compensation system may reduce the hesitancy among those making the decision to receive a candidate vaccine with a limited safety profile.

The ethical and policy rationales behind no-fault compensation systems for adverse events attributable to vaccination are clear. Principles of fairness justify compensation to those who are injured and remedy

Corresponding Author: Sam F. Halabi, JD, MPhil, O'Neill Institute for National and Global Health Law, 600 New Jersey Ave NW, Washington, DC 20001 (sfh9@georgetown.edu).

inequities that inhere in litigation, and few who are injured have the resources to formally complain to administrative or judicial authorities. Moreover, the overwhelming consensus in the public health literature suggests that no-fault compensation systems increase public confidence in vaccination.[7]

Some examples under international law may inform such a system. It begins with an agreement recognizing the overwhelming, evidence-based consensus that community-wide immunization provides an immense public health benefit and that the benefit should not accrue to the uninjured at the expense of the injured.[8] There is precedent for such a fairness-oriented public health agreement. The 2011 World Health Organization (WHO) Pandemic Influenza Preparedness Framework[9] allows vaccine manufacturers to access biological materials from the Global Influenza Surveillance and Response System in return for donated or discounted contributions of resulting vaccines. Manufacturers also contribute toward the cost of running the facility.

Once the agreement is formed, member states could borrow the principle of complementarity from other international legal regimes. Under complementary systems, states agree to either manage the subject matter of the agreement internally or participate in a regional or international system of administration. In the vaccine context, states would agree to establish their own national systems for no-fault compensation or agree to participate in a regional or a WHO-administered scheme accomplishing the same objective. Models exist for national implementation even in low-resource settings. For example, the WHO already provides assistance to many national technical immunization advisory groups and may have a primary role in developing adverse event and compensation tables analogously to the US Department of Health and Human Services' Health Resources and Services Administration. In New Zealand, vaccine injury is under the same administrative authority as other injuries caused by accident (ie, unintentional events); the program may be a model for low-resource countries in which worker compensation claims systems are more developed.

Several policy options for funding and eligibility and administration for WHO, regional, and national systems are shown in the eTable in the Supplement. The Pan American Health Organization (PAHO) Revolving Fund, for example, might add an excise tax to the price it currently pays for vaccine doses to fund a regional compensation plan. Gavi (Global Alliance for Vaccines and Immunization), the vaccine financing organization for the poorest countries, could require that finance ministries plan (including consideration of public or private insurance alternatives) a compensation scheme that would create a path to ensure those schemes persist after countries have graduated from receiving Gavi support. The relationships Gavi facilitates between governments and vaccine manufacturers may provide an independent basis for those parties to reach agreements on no-fault systems.

There is a strong public health justification for a system that compensates those who experience vaccine injury, especially when the system is supported by all responsible parties (governments that compel immunization and manufacturers that produce the vaccines). Establishing a global compensation system could build confidence in the processes that lead to the development of vaccines deployed in low-resource settings, relieve vaccine manufacturers of liability concerns that impede vaccine investments, and facilitate effective responses to global public health threats like Ebola and Zika.

ARTICLE INFORMATION

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