A REPORT OF THE CSIS
GLOBAL HEALTH POLICY CENTER

Role(s) of Vaccines and Immunization Programs in Global Disease Control

MIND THE NITTY-GRITTY DETAILS

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Center for Strategic and International Studies
1800 K Street, N.W., Washington, D.C. 20006
Tel: (202) 887-0200
Fax: (202) 775-3199
Web: www.csis.org

ROLE(S) OF VACCINES AND IMMUNIZATION PROGRAMS IN GLOBAL DISEASE CONTROL

MIND THE NITTY-GRITTY DETAILS

Phillip Nieburg and Nancy M. McLaren[1]

Introduction and Background

A good deal of the substantial progress seen in global health over the past several decades can be ascribed to the beneficial impacts of various vaccines and immunization programs on the control of serious disease among both individuals and populations. In just the first decade of the 21st century, an estimated 2.5 million deaths of children younger than five were prevented worldwide by vaccines.[2] The population coverage of many childhood vaccines has risen sharply in recent years, along with the number of countries using the more recently arrived vaccines. For example, the number of countries providing *Haemophilus influenzae* type B (Hib) vaccine increased from 62 to 161 from 2000 to 2009, preventing an estimated 130,000 deaths in the process.

Given the relative successes of the *GAVI* Alliance (formerly, the Global Alliance for Vaccines and Immunisation) and the recent call by the World Health Assembly for a global vaccine action plan to guide the world for the next 10 years, the world is focusing much attention, justifiably, on various aspects of macropolicy and planning for the progressive expansion of global vaccine efforts.

Although the global consensus on which vaccines generally offer benefits that outweigh their risks and their costs is relatively strong, recommendations for specific vaccine use and for the priority target groups for national immunization programs are not yet consistent across countries. This brief report focuses on the "nuts and bolts" of the complex biological, epidemiologic, and risk management concepts that are the foundations of global and national "expert group" recommendations for specific target groups for currently available childhood vaccines and others. Using examples of specific vaccine successes and disease challenges, this report highlights the ongoing attention to detail required for the success of local, national, and global immunization efforts.

The key lessons and recommendations for those organizations and individuals who fund and direct immunization programs include: (1) the need to learn the eradication and disease-control lessons of past successes and failures and to incorporate those lessons into current programs; (2) the need to put enough surveillance resources into the monitoring of adverse effects of vaccines and the changing epidemiology of target diseases to allow for the accurate balancing of benefits

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1. Phillip Nieburg is a senior associate at the CSIS Global Health Policy Center and visiting associate professor in the Department of Pediatrics at the University of Virginia in Charlottesville, Virginia. Nancy M. McLaren is assistant professor and director of the Division of Adolescent Medicine in the Department of Pediatrics at the University of Virginia.

2. Centers for Disease Control and Prevention, "Ten Great Public Health Achievements," *Morbidity Mortality Weekly Report* 60 (24) (August 2011): 814–18.

and risks of vaccine-based disease-control programs; (3) the need to keep attention on the role of equity in providing access to the benefits of immunization programs; and (4) the importance of transparency, trust, and listening in preparation and operation of immunization programs.

Basic Concepts of Vaccines and Immunizations

Vaccination is the process of administering a vaccine, i.e., a biological substance intended to stimulate a recipient's immune system to produce antibodies or to undergo other changes that provide future protection against specific infectious diseases. *Immunization* is the stimulation of changes in the immune system through which that protection occurs. These two concepts differ slightly in that administration of a vaccine may not always result in satisfactory immunization (protection) and that immunization may sometimes occur as a result of processes other than administration of a vaccine, e.g., through the body's immunologic response to natural illness or through injection of preformed antibodies from an external source (such as gamma globulin for protection against hepatitis A).

Disease control is defined as a reduction of disease incidence, prevalence, morbidity, or mortality to a locally acceptable level achieved through deliberate efforts.[3] Ongoing disease surveillance and program intervention efforts are usually required to document and maintain that level of control.

Disease elimination is a more specific degree of disease control defined as the reduction to zero of the incidence or occurrence of a specific disease within a defined geographic area as a result of deliberate programmatic efforts. As with *disease control*, maintaining *disease elimination* in a defined geographic area requires ongoing public health efforts.

Disease eradication has been defined as the reduction to zero of the worldwide incidence or occurrence of a specific disease as a result of deliberate programmatic efforts. To date, only two infectious diseases, smallpox (1977)[4] and rinderpest (2011),[5] have been eradicated successfully, both through strategic use of vaccines.

However, vaccines may not always be required for successful disease eradication. For example, global campaigns against two specific parasitic diseases, onchocerciasis ("river blindness") and dracunculiasis ("guinea worm") have been making steady progress in reducing the burdens of those diseases. This progress has been achieved using community health education combined with administration of the antiparasitic drug ivermectin for onchocerciasis and with provision of safe drinking water for dracunculiasis. Finally, eradication of some specific noninfectious diseases

3. This and the subsequent definitions are from Centers for Disease Control and Prevention, "Global Disease Elimination and Eradication as Public Health Strategies," *Morbidity and Mortality Weekly Report* 48 (1999): Supplement 1 (24).

4. *Extinction* is a disease-control term that has been used to describe a situation in which a specific microbe no longer exists in nature or in laboratories; however, no infectious agent has yet achieved that status. Smallpox (variola) virus stocks remain in two known locations: high-security laboratories in Russia and in the United States. A decision to destroy the last stocks of that virus has been postponed on several occasions, most recently in 2011. See K. Senior, "Smallpox: Should We Destroy the Last Viral Stocks?" *Lancet/Infection* 10 (2010): 588.

5. Rinderpest is a severe and untreatable disease of cattle caused by a virus closely related to both human measles and canine distemper viruses. Global eradication of rinderpest was certified in 2011.

such as severe deficiencies of dietary vitamin A and iodine that are major causes of blindness and mental retardation, respectively, is also theoretically possible.

Characteristics of Diseases Suitable for Control by Vaccine and Immunization

Some characteristics of specific diseases that lend themselves to control by vaccines or by immunization are indicated in box 1. Not fitting one or a few of the "ideal" characteristics does not automatically rule out a specific disease for possble control through immunzation, but each missing characteristic would complicate control efforts in one or more ways. Parenthetically, measles is a disease that has all the listed characteristics. The failure to successfully control measles on a worldwide basis to date—despite the availability for nearly 50 years of an inexpensive and highly efficacious vaccine with few adverse effects—is testimony to the complexity of the vaccine-based disease-control process.

Box 1. Characteristics of Diseases and Microbes Most Amenable to Control through Immunization Programs

- *Disease is well-known by public*, so that many people are aware of its existence and importance.
- *Disease occurs "commonly,"* so that it contributes significantly to society's disease burden.
- *Disease is recognizable by health workers*, (e.g., causes rash), so that the consequences of the disease can be linked to a specific type of microbe and disease outbreaks can be recognized.
- *Disease's short-term or long-term effects* on individuals can sometimes be severe or permanent, so that the public (e.g., parents, health workers, and policymakers) support preventing its future occurrence.
- *Disease is difficult to control* at a population level without the use of immunization programs.
- *Disease's incubation period* (time between the exposure to the microbe and development of disease symptoms) is not too short, so that vaccine can still provide at least partial protection if given after exposure (e.g., measles vaccine given early in the 10–14 day incubation period or rabies vaccine given soon after animal bite exposure).
- *Microbe has no nonhuman reservoir* from which it can be reintroduced into the human population after adequate control has been achieved.
- *Genetic mutations that result in biochemical changes to the microbe's outer coat occur very slowly, if at all, so that the vaccine's ability to prevent infection and disease is well maintained over time.*
- *Infection with the microbe does not result in mild (subclinical) disease or in a prolonged "carrier state,"* so that there are no infected people who could easily spread the disease to susceptible contacts because they themselves do not feel ill or appear ill.

The Ideal Vaccine

Consideration of an "ideal" vaccine's characteristics can help provide some perspective on the shortcomings and challenges of current vaccines (see box 2). For example, many—most—current vaccines require more than a single dose for a complete regimen and then require booster doses at various intervals. Vaccines that are freeze dried or that otherwise do not require strict refrigeration greatly simplify the design and requirements of national immunization programs. Similarly, vaccines (such as oral polio vaccine or oral typhoid vaccine) that do not require injections have a great theoretical advantage over vaccines requiring needles and syringes for administration.

Box 2. Characteristics of an "Ideal" Vaccine

- *It is highly immunogenic,* so that a single vaccine dose provides a complete immunization regimen.
- *The recommended vaccine regimen is highly efficacious* in preventing disease in individual vaccine recipients,
    - Including recipients with weakened immune systems from HIV infection, severe malnutrition, malignancies, or congenital immunodeficiency.
- *It has a long duration* of immunity, so that frequent booster doses are not needed.
- *It limits spread of infection,* because it prevents vaccine recipients from spreading infection to other people.
- *It is heat stable*, so that refrigeration ("cold chain") is not required during shipping and storage.
- *Injection is not required* for administration, e.g., a nasal spray of vaccine can be used.
- *It can safely be administered simultaneously with other vaccines*, either as a part of a specific combination vaccine (e.g., measles-mumps-rubella) or as separate individual vaccines.
- *Adverse effects in vaccine recipients are few*, nonsevere, and temporary; in particular,
    - The microbe used to prepare the vaccine does not cause disease in recipients who have immune systems weakened by HIV infection, severe malnutrition, malignancies, or congenital immunodeficiency.
    - The microbe used to prepare the vaccine never reverts to "wild type" or otherwise mutates to cause disease in vaccinated people or in their close contacts.
- *It is technically simple to manufacture*, so that it can be produced in less sophisticated settings.
- *It is inexpensive to manufacture*, distribute, and administer, so that it is affordable by the maximum number of people.

Current Vaccines in Public Health Settings

A large number of vaccines are now in widespread use around the world (see box 3), with additional vaccines expected to become available within the next few years.

Selection of Target Populations for Specific Vaccines

Programmatic decisions about recommending vaccine administration to certain group(s) are often more complex than they may appear and are generally made by global or national expert committees on the basis of risk management concepts that include balancing information on the severity and likelihood of the disease, the vaccine's efficacy in preventing occurrence or transmission of the disease, and the likelihood and severity of vaccine side effects (see table 1).

Box 3. Some Specific Vaccines Now in Widespread Global Use

Cholera	Pertussis (whooping cough)
Diphtheria	Pneumococcal
Haemophilus influenzae Type B	Polio (oral and injectible vaccines)
Hepatitis B	Rabies
Human papilloma virus	Rotavirus
Influenza A	Rubella
Influenza B	Tuberculosis (BCG)
Japanese B encephalitis	Typhoid
Measles	Varicella (chicken pox)
Mumps	Yellow Fever

Table 1. Examples of Concepts Used to Select Vaccine Target Populations

Target Population	Examples of Vaccines and Target Groups
All persons beginning at certain age	Polio vaccine at 2, 4, and 6 months; zoster (shingles) vaccine for those over 50 years
Persons at high risk of severe outcome	Measles vaccine to malnourished children in refugee camps
Persons at higher risk of becoming infected	Tetanus toxoid to pregnant women; influenza vaccine to health workers
Persons likely to expose others at high risk	Pertussis vaccine to grandparents of infants
Persons recently exposed	Rabies vaccine after high-risk animal bites

Who among the Target Populations Actually Receives the Recommended Vaccines?

Even vaccines with high efficacy and few adverse effects are unlikely to reach all who could theoretically benefit from them. Most of the challenges that restrict access of children and others to needed vaccines stem from the concept of equity. These include: (1) vaccine affordability; (2) lack of patient or parental awareness of vaccine availability; (3) immunization program effectiveness in reaching target populations, especially those who are in minority populations or who live in remote areas; (4) resistance to vaccination within the target population(s); and (5) production shortages of recommended vaccines.

Herd Immunity

Herd immunity is a public health concept describing the protection from a specific disease that exists in a population due to the preexisting immunity of many people in the population, either from being immunized or from having had the natural infection. The greater the number of people in a given population who are not susceptible to a specific disease because of prior infection or immunization, the less chance there is that an infected (and contagious) person coming in from outside that population will encounter and be able to infect a disease-susceptible person inside the population. And even if a susceptible individual within that population becomes infected (and contagious), the high rate of preexisting immunity would mean that the newly infected population member would also have a lesser chance of encountering and infecting yet another susceptible person within that population.

Strategies such as mandatory school immunizations laws and regulations that require proof of specific vaccinations or serologic proof of prior disease are intended to raise—and maintain—levels of herd immunity to those diseases with the potential for rapid spread (e.g., measles, mumps, and rubella) in student populations. One ironic consequence of herd immunity is that individuals who choose to opt out of vaccination against one or more diseases—or whose parents opt out on their behalf—are still protected from those diseases by the herd immunity that exists as a result of the immunizations of most individuals around them.

The Process and Lessons of Global Smallpox Eradication

The global smallpox eradication effort initially involved mass immunization of entire national or subnational populations as well as enhanced surveillance efforts to identify persons infected with the disease. As numbers of reported smallpox cases began to decrease, surveillance was enhanced still further, and a "ring vaccination" process of concentrating vaccination activities in the populations immediately surrounding each identified smallpox-infected individual was used to complete the eradication.[6] Once smallpox was certified as eradicated in 1977 and routine smallpox vaccination was stopped in most nonmilitary populations around the world, the economic benefits of the global smallpox eradication program began to be realized, and the global toll of adverse effects from smallpox vaccination was reduced sharply.

Changes in Vaccine Recommendations

Information that becomes available only after particular immunization programs have been in place for some time can lead to changes in program recommendations, if the new information changes the risk-benefit balance for at least some population groups. A classic example of this shift in risk-benefit balance is the Guillain-Barré syndrome that was ultimately linked to influenza vaccine during and after the 1976 swine influenza vaccine campaign. The risk of that severe neurological adverse effect was eventually found to be about 1 per 100,000 vaccine recipients. Although

6. Vaccination against smallpox involves administration of vaccinia virus, a relatively benign distant relative of the *variola* virus that causes smallpox. For a history of the Global Smallpox Eradication Program, see D. A. Henderson, *Smallpox: The Death of a Disease* (Amherst, NY: Prometheus Books, 2009).

occurrence of the syndrome was considered an important adverse effect of vaccines, it had not been observed previously, and it clearly would not have been possible to identify Guillain-Barré syndrome as a vaccine-related adverse effect in the kind of small influenza vaccine field trials that were traditionally done before the mass vaccination campaign of each influenza season in those days. The Guillain-Barré syndrome episode helped emphasize the importance of reporting and investigating suspected vaccine-related adverse effects.

The following provide more recent examples of postmarketing changes in vaccine recommendations:

- New data on a slightly higher risk of febrile seizures in young children receiving the quadrivalent measles-mumps- rubella-varicella (MMRV) vaccine led to a recommendation to use a separate dose of varicella vaccine in young children with a personal or family history of seizures.
- A vaccine against 13 strains of the pneumococcus bacterium that causes severe pneumonia and other pneumococcal disease has recently become available, replacing an earlier version of that vaccine that protected against only 7 of those 13 strains. New data indicating that severe pneumococcal infections were continuing to occur among those who had received the older 7-strain vaccine but not the newer 13-strain vaccine have led to a strengthened recommendation for a booster dose of the newer vaccine to protect against the additional six microbial strains not protected against in those who had received only the older vaccine.
- A recent study on the safety and efficacy among 50–59-year-olds of the herpes zoster vaccine given to prevent *shingles* among older people has led to a new recommendation that the lower age limit for the vaccine should be reduced from 60 to 50 years of age.
- Yellow fever vaccine has long been considered a very safe and efficacious vaccine. However, a recent report described a number of unexplained deaths among reproductive-age women who had recently received yellow fever vaccine. Although recommendations for that vaccine have not yet changed, these newer data have led to a recommendation for enhanced surveillance and for collection of additional data.

The Roles and Challenges of Mandatory School Immunization Policies

School immunization laws requiring smallpox vaccination were considered an important factor in the reduction of smallpox incidence in the United States in the 1920s and 1930s and in its virtual disappearance in the 1940s. Similarly, the enforcement of school immunization laws in the late 1970s and early 1980s was felt to be an important factor leading to the elimination of measles in the United States. In each case, the reinforcement of herd immunity through higher vaccine coverage played an important role, and, in each case, the enforcement of school immunization laws brought legal challenges. As vaccine coverage expands, these complex discussions of school-based or community-based mandatory vaccine provision may take place in other countries as well.

The Paradox of Successful Immunization Programs

As a specific vaccine-preventable disease becomes less common under the pressure of a successful immunization program and as the disease burden from that disease falls, public awareness of the disease and public interest tend to fall as well. A major challenge then becomes how to maintain public interest and public resources (that translate into high vaccine coverage) as the disease continues to become less common. The current measles situation in Europe, where cases continue to occur in many European countries with suboptimal vaccine coverage, is an illustration of that challenge.

The Benefits and Challenges of Combination Vaccines and Vaccine Combinations

Because of a nearly universal goal of keeping the number of vaccine injections to a minimum, an effort is often made to combine new vaccines with existing vaccines—or existing vaccine combinations—in a single injection. Although this goal makes a lot of sense, each new such combination of vaccines given at the same time, regardless of whether they are combined in the same injection, requires a separate set of efficacy and safety studies to ensure that the individual vaccines in the new combination maintain their ability to induce immunity in recipients and that mixing those particular vaccine components does not change the spectrum or severity of adverse effects.

Vaccine Efficacy and Vaccine Failures

Vaccine efficacy is a numerical concept describing the reduction in disease occurrence among vaccinated individuals in a population compared to the disease occurrence rate among the unvaccinated individuals in the population.

The term *vaccine failure* refers to situations in which vaccine recipients become infected with the microbe that the vaccine was intended to protect against. Even vaccines with known high efficacy (e.g., measles vaccine with greater than 95 percent vaccine efficacy) will fail to immunize a small proportion of individual recipients. However, sometimes data may suggest that vaccine failure is occurring more frequently than expected. Vaccine failure can be a concern in several kinds of situations:

- A manufacturing problem, in which an error in vaccine production leads to a vaccine batch that was not capable of inducing immunity.
- A "cold chain" problem, in which failure to refrigerate vials of vaccine properly leads to a large group of individuals receiving vaccine doses that have lost their ability to induce immunity in recipients.
- A vaccine "pseudo-failure," in which misunderstanding of the basic concepts of vaccine efficacy can lead to a concern that vaccine failure is occurring when, in fact, it is not. As an example of the latter situation, consider the concerns expressed when a measles epidemic was reported in a middle school with 1,000 students.[7] The overall attack rate of measles among all students at the school was reported as 8 percent, i.e., 80 measles cases among 1,000 students. Half (40) of those ill students had not previously had measles vaccine while the other half of measles infections occurred among children who had received measles vaccine. The school nurse and principal were concerned that the measles vaccine was not working, since so many measles-vaccinated students were becoming ill with measles. The measles data from that school are shown in table 2.

7. For convenience, rounded numbers are used in this hypothetical example.

Table 2. Measles Infections and Measles Attack Rates among Vaccinated and Nonvaccinated Students during a Hypothetical Middle School Measles Outbreak

Students' Measles Vaccine Status before Outbreak	Students in Category	Number Infected with Measles	Measles Attack Rate (%)
Vaccinated	920	40	4.3
Nonvaccinated	80	40	50.0
Total students	1,000	80	8.0

Note: The attack rate is the rate (%) of disease in the exposed population or subpopulation.

Although, as shown in the table, half the students with measles had indeed received measles vaccine, the true measure of the vaccine's value becomes much clearer when the vaccine efficacy is calculated correctly, as in the formulas shown below, by comparing the difference between the 50 percent attack rate (AR) of measles infection among unvaccinated students to the 4.3 percent attack rate among vaccinated students:

$$\text{Vaccine efficacy} = \frac{\text{AR (\%) among unvaccinated children} - \text{AR (\%) among vaccinated children}}{\text{AR (\%) among unvaccinated children}}$$

$$\text{Vaccine efficacy} = \frac{(50.0 - 4.3)}{50.0} = \frac{45.7}{50.0} = 91.4\%$$

Thus, the group of students in that school that had received measles vaccine had an overall measles attack rate that was 91.4 percent lower than the attack rate among the group of students who had not received measles vaccine.

Mass Vaccination Programs

Mass vaccination programs are useful for rapidly increasing population immunity in several circumstances, e.g., for optimizing the benefits of a newly introduced vaccine, for containing disease outbreaks, and for preventing disease in humanitarian emergencies. In particular, those natural disasters, civil conflicts, or other humanitarian emergencies that lead to displacement of large populations can create unusual and high-risk exposure circumstances. For example, children who have been displaced in these situations and may be living in crowded refugee camps can be at particular risk from measles because of a confluence of circumstances: (1) disrupted routine immunization programs, leading to lower predisplacement rates of measles immunization; (2) moderate-to-severe malnutrition, leading to more severe disease and high mortality from measles; and (3) crowding, leading to transmission of higher doses of airborne measles virus that results in more severe clinical disease.[8]

8. M.A. Connolly, "Communicable Disease Control in Humanitarian Emergencies," in *Control of Communicable Diseases Manual*, 19th ed., ed. David Heymann (Washington, D.C.: American Public Health Association, 2008), A57–66.

Other Populations or Subpopulations Needing Special Attention from Immunization Programs

Some groups of children or others may warrant special attention from immunization programs because of their unusual exposure circumstances, because of their greater risks of severe disease outcome in case of infection, or, for those with weakened immune systems, because they may require additional doses to be completely immunized.

For example, a recent outbreak of hepatitis A in Minnesota was traced to a newly adopted child from a developing country. Results of the investigation emphasized that parents or other family members of children to be adopted from developing countries should receive hepatitis A vaccine before the adoption because they may be at greater risk of exposure from the new adoptee.[9]

Another recent recommendation is that older people who are grandparents or are otherwise likely to be in contact with infants or very young children should receive booster doses of the current pertussis (whooping cough) vaccine, both because of the severity of pertussis among infants and because the current acellular pertussis vaccine has many fewer adverse effects than the vaccine used in earlier years.

Other groups needing special attention include those whose immune systems may be less responsive to vaccines, e.g., premature infants and children or others with HIV infections, sickle cell disease, or other immune deficiencies.

Misunderstandings about Possible Benefits of Vaccines

Sometimes an overly simplistic approach to vaccine concepts can lead to an overly optimistic sense of a vaccine's possible benefit. For example, an editorial in a major U.S. newspaper soon after the September 2011 release of the results of the field trials of the RTS/S malaria vaccine implied that the vaccine's limited success put the world a step closer to malaria eradication. In fact, even a highly successful RTS/S vaccine that would protect a large proportion of individual vaccine recipients would be unlikely to have a major impact on overall malaria transmission in a population living in a malaria-endemic area.

One More Specific Disease Challenge to Consider

The world now has theoretical access to a highly effective vaccine for preventing infection with human papilloma virus (HPV), a sexually transmitted infection that is the major cause of cervical cancer in later life. A challenge for the global community will be to see if policy discussions about expanded use of this vaccine can avoid the kinds of unscientific debates about use of this vaccine recently experienced in the United States. The oft-heard assertion that providing protection against a sexually transmitted disease—and in this case a fatal malignant disease—leads to more premarital sex has been repeatedly demonstrated to be untrue.

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9. K. Sweet, W. Sutherland, K. Ehresmann, and R. Lynfield, "Hepatitis A Infection in Recent International Adoptees and Their Contacts in Minnesota," *Pediatrics* 128 (2011), http://pediatrics.aappublications.org/content/128/2/e333.full.html.

Discussion and Recommendations for Nontechnical Policymakers

Deciding who should receive which vaccines and working to ensure access is a complex and detail-oriented enterprise. This issue will become even more challenging as additional vaccines are added to the disease-control armamentarium.

Learn the Programmatic and Policy Lessons

Although the eradication of other vaccine-preventable diseases may be feasible, especially measles and polio, efforts for most vaccine-preventable diseases for the immediate future should focus on enhanced disease control, while the lessons of the eradication of smallpox and rinderpest and the control of other diseases are being carefully studied and incorporated into vaccine-based disease-control programs.

Keep Risk and Benefit Information Up to Date

Accurate and timely collection of postmarketing information on adverse effects of vaccines and on the changing epidemiology of vaccine-preventable diseases is critical to the accurate balancing of vaccine risks and benefits. Although surveillance does not have the same cachet as research into a new vaccine against "important disease "X," policymakers and immunization program funders should ensure that necessary surveillance activities are carried out within these programs.

Equity in Immunization Programs

Policymakers should be aware that some of the current burden of vaccine-preventable disease — both globally and within most countries—is a result of inequities of resource allocation, including unaffordable vaccines and unequal program access, among others. In addition, those policymakers should also be aware that, in the event that a vaccine-related injury is documented, vaccine recipients or their families in most countries do not have the same compensation benefits available that Americans do.

The Roles of Transparency, Trust, and Listening

Awareness among the public about the severity and importance of specific vaccine-preventable diseases needs to be improved, even as—or perhaps especially as—their burden begins to decrease. In addition, individuals in populations targeted for immunization programs need to better understand the benefits and risks of vaccines to individuals and the herd immunity benefits to populations. Immunization program communications with community leaders and individual citizens in that regard need to allow for the raising of concerns and for responses to those concerns.

Additional Sources of Information

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1800 K Street, NW | Washington, DC 20006
Tel: (202) 887-0200 | Fax: (202) 775-3199
E-mail: books@csis.org | Web: www.csis.org