



Poverty, Wealth, and Access to Pandemic Influenza Vaccines

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On June 11, 2009, Margaret Chan, director general of the World Health Organization (WHO), declared that the status of the influenza A (H1N1) pandemic had reached phase 6 — active transmission

on a global scale. Until now, the case fatality rate of this influenza has been quite low, but history teaches us that the situation could take a turn for the worse during the next wave of the pandemic. If a 1918-like pandemic were to occur today, tens of millions of people could die, the vast majority of them in the world's poorest countries.

Fortunately, the prospects for developing an effective vaccine to prevent infection with the current H1N1 virus are excellent, and the world's pharmaceutical companies are working diligently at this task. In contemplating equal access to such a vaccine, it is important to consider three key issues: manufacturing capacity, cost, and delivery.

Only a few countries in the world have plants for manufacturing influenza vaccine, and three companies — GlaxoSmithKline, Sanofi-Aventis, and Novartis — account for most of the world's manufacturing capacity. The number of doses of vaccine against H1N1 influenza that could be produced with the existing capacity is very large, but the sobering truth is that even if production were switched over completely from seasonal influenza vaccine to pandemic influenza vaccine, there would not be nearly enough for everyone in the world. The size of the gap in potential supply depends greatly on the dose that is required, and it may be possible to reduce the necessary

dose by as much as 75% with the use of an adjuvant. The challenging problem is that much, if not most, of the manufacturing capacity is already spoken for through purchasing contracts held by many of the world's wealthy countries.

The second issue is cost. Despite the enormous technological investment required to create a vaccine, the traditional cost of seasonal influenza vaccines even in wealthy countries is quite low. For the pandemic H1N1 influenza vaccine, the major manufacturers have indicated a willingness to offer tiered pricing, with affordable prices for poor countries. Going even further, Sanofi-Aventis has committed to donating 100 million doses of its vaccine to a stockpile for poor countries, and GlaxoSmithKline has committed to donating 50 million doses. Nevertheless, financial commitments from wealthy

Principles to Guide Global Allocation of Pandemic Vaccine.*

1. The global community should take steps to protect all populations, including those without resources to protect themselves.
2. Vaccination should be considered in the context of comprehensive pandemic preparedness and response efforts in all nations.
3. Developed countries and vaccine manufacturers should urgently agree upon a mechanism to ensure access to vaccine by developing countries.
4. Influenza vaccine manufacturers should identify strategies such as tiered pricing and donations to make pandemic vaccine more accessible to developing nations.
5. Pandemic vaccines allocated to developing nations should become available in the same time frame as vaccines for developed nations.
6. The global community should obtain data to help establish a consensus on the safety and efficacy of adjuvants, and efforts should be made to ensure the fullest use of this and other dose-sparing strategies.
7. All countries obtaining pandemic vaccine should ensure that mechanisms are in place to provide the vaccine to their populations, to ensure that this scarce resource is not wasted, and donors should be prepared to provide resources and technical assistance to help countries bolster these mechanisms.
8. The World Health Organization is uniquely positioned to lead the global response to a pandemic virus and should support governments and industry in their efforts to implement these principles.

* From the Pneumonia and Flu Web site of the Bill and Melinda Gates Foundation (www.gatesfoundation.org/topics/Pages/pneumonia-flu.aspx).

countries will be needed to help poorer countries purchase vaccines — cost should not be a barrier to access.

Finally, the scope of access to vaccines will in part be determined by the infrastructure required to deliver them to all citizens in mass campaigns. Ironically, poor countries may have an advantage on this front, since many have recent experience with mass campaigns involving vaccines against polio, measles, and hepatitis B; delivery may therefore be less of a challenge for them, provided that the vaccines reach them in a timely fashion. By contrast, in many wealthier countries, such campaigns have not been undertaken for some time. Getting the vaccine to large numbers of young adults, in particular, may be a formidable task for which preparations must surely be made as soon as possible.

Our limited capacity for pro-

ducing potentially lifesaving vaccines presents a pressing moral challenge. I believe wholeheartedly that all lives have equal value (this is the basic principle motivating the Bill and Melinda Gates Foundation, where I work), and I believe that every stakeholder has a responsibility to ensure that the pandemic does not take a 1918-like toll on the world. We have therefore worked with partner stakeholders to develop a proposed set of principles to guide the global allocation of pandemic vaccine (see box).

Rich countries have a responsibility to stand in line and receive their vaccine allotments alongside poor countries, even if they have paid for their vaccine before others could do so. It would be inexcusable to force poor countries to wait until the rich have been served under their existing contracts with vaccine manufacturers. Moreover, rich coun-

tries must also consider how they can provide contributions to offset the cost of vaccines for countries that cannot afford to pay for them. Countries that are home to influenza-vaccine manufacturing plants have a special responsibility to avoid nationalizing those facilities in an effort to reserve their output for their own citizens before others. And all countries must prepare now for the rapid delivery of the vaccines as soon as they become available.

Manufacturers have a responsibility to apply their full capabilities to creating the greatest possible quantity of vaccine doses. Despite contractual obligations to supply many wealthy countries with their vaccines, manufacturers must resist the temptation to commit all their capacity to those who can pay the most. This is not a time to adhere to the “first come, first served” model of business, since we may be facing a health crisis of global proportions in which all people and countries are equally at risk. To ensure fairness, full adherence to a tiered pricing scheme in which the cost to the purchaser is proportionate to its ability to pay is essential. The generous donations made by Sanofi-Aventis and GlaxoSmith-Kline set an example that all manufacturers should emulate. In return for their responsible actions, it would be reasonable for manufacturers to be indemnified against liability from potential adverse reactions to their vaccines.

Regulatory agencies have an important responsibility in this impending crisis because they stand between the manufacturers of pandemic influenza vaccines and the people who will benefit from them. It is critically important that regulators apply their

usual rigorous standards in improving the new vaccines — but also that they do so in a timely fashion. A special task facing them is the rapid review and consideration of the safety and efficacy of adjuvants, whose use could greatly reduce the required dose of vaccine and thereby expand the number of doses that could be manufactured.

The WHO has provided strong

leadership as the world has contemplated the prospect of an influenza pandemic. We are counting on the organization to guide us, wisely and fairly, through the complex challenges that lie ahead.

The prospect of a worsening global influenza pandemic is real and will not go away anytime soon. I cannot imagine standing by and watching if, at the time of crisis, the rich live and the poor

die. It will take collective commitment and action by all of us to prevent this from happening.

Dr. Yamada reports holding equity in GlaxoSmithKline. No other potential conflict of interest relevant to this article was reported.

From the Global Health Program, Bill and Melinda Gates Foundation, Seattle.

This article (10.1056/NEJMp0906972) was published on August 12, 2009, at NEJM.org.

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Systemwide Cost Control — The Missing Link in Health Care Reform

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Successful health care reform requires effective control of health care spending — without it, rising costs will continue to strain federal and state budgets, businesses, and families, jeopardizing gains in insurance coverage. The reform legislation now before Congress, however, cannot be relied on to control spending.

The Obama administration and others have emphasized the cost-saving potential of prevention, comparative-effectiveness research, disease management, and health information technology. But there is little evidence that these worthwhile measures would produce meaningful cost control over the next decade.¹ The Congressional Budget Office (CBO) has consequently forecast scant savings from these sources, fueling debate about the affordability of reform² and raising concerns among fiscally conservative Blue Dog Democrats, without whom health care legislation cannot pass.

In response, the administration has touted a proposal establishing an Independent Medicare Advisory Council (IMAC). The

council would, along with the President, have broad authority to change Medicare rules in order to reduce program spending. Yet the scope of the savings that may be achieved through IMAC is impossible to know. And any savings would be limited to Medicare — a modest part of national health care spending.

Other cost-control proposals are more tangible. The Obama administration and Congress have proposed significant cuts in projected federal spending on Medicare over the next decade that largely involve reduced payments to hospitals and private Medicare Advantage plans. These savings, though, would be partially offset — at least in the House legislation — by the cost of canceling scheduled cuts in physician payments.

Moreover, there is a sharp distinction between restraining government spending on medical care and restraining systemwide spending. Slowing the growth of federal Medicare expenditures would not guarantee spending restraint outside Medicare. Indeed, to some

extent, medical providers could respond to reduced Medicare income by shifting costs to private payers.

Nor would creating a new public insurance program guarantee that national health care spending will be restrained. With lower administrative costs and greater purchasing power, such a plan could provide less expensive coverage than that offered by private insurers. This, in turn, could lead private plans to find ways to reduce premiums to stay competitive, potentially generating substantial savings.³ But the public-plan proposal has been steadily weakened during the reform debate. Senate Finance Committee leaders have indicated that they intend to pass a bill with no public plan. And the strongest proposed public-plan model, in the House bill, would, according to the CBO, enroll only 10 million persons — about 3% of the population — in 2019. With such limited enrollment, such a plan would not make much of a dent in national health care spending.

The missing link in reform