

The value of vaccines

Our ability to control infectious diseases is continuously being eroded by antimicrobial resistance, the decline in industrial antibiotic development and increasing development timelines from discovery to market. There has never been a better time to rediscover the value of vaccination.

As a preventative strategy in the fight against infectious diseases, vaccination is considered to be the most cost-effective medical intervention. Indeed, in many developed countries, measles, mumps, rubella, hepatitis B, *Haemophilus influenzae* type b, tetanus, pertussis and diphtheria have been controlled or nearly eliminated as chief causes of morbidity and mortality by the use of vaccines. Yet, despite their role in delivering many of the successes that have been achieved in infectious disease control, there seems to be relatively little enthusiasm for vaccine development among those who have the capability for vaccine development and production.

There are a number of contributing factors to this lack of enthusiasm, most of which are linked to economics. The simple truth is that the direct economic value that is associated with vaccines is negligible compared with that of pharmaceutical drugs. Globally, potential vaccine sales are approximately US\$6 billion per year. Although the vaccines sector is out-performing the rest of the industry in terms of revenue growth, it still represents less than 2% of the worldwide pharmaceutical market. Because of the low return for their investment, high regulatory costs, uncertain market conditions and exposure to legal liability, most pharmaceutical manufacturers do not consider the development and production of vaccines as an attractive business opportunity. For example, over the past 30 years, the number of companies that distribute vaccines in the United States has decreased from 30 to 5, a situation that has directly contributed to serious shortages of influenza, tetanus–diphtheria, measles–mumps–rubella, pneumococcal, meningococcal and other vaccines. Not surprisingly, there is even less incentive for the vaccine industry to develop new vaccines against diseases that are largely limited to the developing world.

Governments do have a number of well-documented and under-used tools at their disposal to make vaccines more attractive to industry. These options include: tax breaks or subsidies to reduce research and development expenses; extending patent protection for intellectual property that is related to vaccines of public health importance; working with industry and others to find ways to reduce the costs of meeting regulatory requirements; and allowing tiered pricing whereby vaccines can be sold at

higher prices in developed countries and lower prices in under-developed countries. It should also be possible to decrease liability risks (by measures such as the Vaccine Injury Compensation Program in the United States) and protect manufacturers from lawsuits that are related to the unanticipated adverse effects of a properly manufactured, safe and effective vaccine. Ultimately, however, an economic solution is required. There have been numerous demonstrations of the cost-effectiveness of immunization. Attributing the true economic value to vaccines — both real and intangible — will create a self-sustaining system to ensure the development and adequate supply of vaccines to those that need them most.

But how can governments be mobilized into action? If the ever-increasing threat of a public health calamity does not provide the necessary incentive, the promise of success might do the trick. An example that illustrates the effectiveness of a global approach to vaccination is the campaign for the eradication of poliomyelitis. Launched in 1985 for South America, it was taken up by the World Assembly, which in 1988 committed to the global eradication of poliovirus by the year 2000. Progress towards eradication of the virus has been fast. In 1988, 125 countries in 5 continents reported endemic poliovirus but by 2003 only 6 polio-endemic countries were reported and, officially, only 4 remain: India, Pakistan, Afghanistan and Nigeria. So, although the 2000 deadline passed with the incidence of disease stalled at around 2,000 cases per year, and there have been setbacks, including a recent outbreak in Nigeria, the initiative is an unequivocal example of how a globally coordinated effort can, within a short period of time, reduce the incidence of an infectious disease by more than 99.9%. The elimination of the disease from the remaining endemic regions is now achievable, leaving the welcome problem of whether, and how long, vaccination should be continued against a disease that no longer exists.

In their efforts to control infectious diseases, governments and non-governmental organizations need look no further than the poliomyelitis eradication campaign, both for their inspiration and justification in taking that first important step — placing vaccination back where it belongs, at the top of the global public health agenda.

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