Public Health Policy and Vaccine-Preventable Disease: The Case for Immunization

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Abstract

Vaccines have been tremendously successful as a public health policy tool. As far back as 1905, compulsory vaccine regimens have been recognized by the Supreme Court as a legitimate expression of the government’s responsibility to provide for the common welfare (see Jacobson v Massachusetts), largely in response to the demonstrated potential of vaccines to stem the spread of disease (Parmet & Goodman, 2005). As a result, vaccine programs are now mandated in all fifty states and the District of Columbia. Some diseases, such as smallpox, have been wholly eradicated; while with others, such as measles and rubella, the incidence of disease has been vastly decreased (Dowdle & Cochi, 2011). Based on these successes, the payoff to society for vaccination programs would seem to be clear; vaccines dramatically improve public health outcomes. This doesn’t mean that there is no risk associated with modern vaccination efforts, however. Some vaccine candidates have been shown to be insufficiently effective, or to have harmful side effects (see Kimmel, 2002; Horien & Grose, 2012). It is such reservations about vaccine safety that help to explain the small but growing trend among some parents to refrain from having their children immunized (Smith et al., 2004). The role of government has been to successfully manage this risk in a way that provides widespread public health benefits. It is our position that both the demonstrated and potential benefits of well-regulated vaccine programs far outweigh the potential health risks posed to the general public.

1 How Vaccines Work

Vaccines are effective to the extent that they help boost the body’s natural immune system. When a pathogen enters the body, the body is able to recognize part of the infectious agent, and produce antibody proteins that mold themselves to the pathogen (Baxter, 2007). The body’s immune system, much like the nervous system, can “remember” these experiences. For example, if the body encounters an antigen from a virus or a bacterium, an immune response is triggered after a few days, rises rapidly, and then gradually disappears. Once the body encounters the same antigen again, a different, more intense response is then triggered: the period between encountering the antigen and the immune response is shorter, and the response tends to be far greater. This is due to the influence of naïve leukocytes, which after confronting an antigen for the first time, multiply and differentiate into memory cells able to recognize the specific pathogen. Vaccines harness this process to “train” the body to respond to pathogens, effectively defending the body from harmful infectious material.

Of real benefit is the fact that vaccines are effective at offering protection of this sort to a community even when only a portion of it is immunized. Called herd immunity, this concept recognizes that using vaccines to minimize infections among some members of the community reduces the likelihood of broader outbreaks of disease. In this way, individuals who would otherwise be
susceptible to infection (those who choose not to be vaccinated, infants, the immuno-compromised, etc.) are offered some degree of protection (Garnett, 2005; May, 2003).

2 State Mandates
The herd immunity effect serves as the main rationale for state vaccination mandates. Public schools (and in many states, daycare centers as well) serve as the intervention point for state immunization efforts. Although requirements differ from state to state, most require children to be vaccinated against mumps, measles, rubella, diphtheria, pertussis, tetanus, and polio (CDC, 2011a). All states allow medical exemptions from vaccination, however, with most also allowing exemptions for religious reasons (Mississippi and West Virginia are the only exceptions), and many (nineteen) for philosophical reasons. Notably, the process of obtaining nonmedical exemptions is not particularly onerous, often requiring less effort than simply complying with state immunization requirements (Rota et al., 2001). Not surprisingly, the granting of such exemptions is on the rise (Omer et al., 2006).

3 The Impact of Vaccine Programs
The effect of the rising number of exemptions in the states illustrates the positive impact vaccines have had on public health (and the negative impact of exempting too many persons from state vaccine requirements). A 2006 study in the Journal of the American Medical Association indicated that the mean exemption rate of those aged 18 and younger grew from 0.99 percent in 1991 to 2.54 percent in 2004 (Omer et al., 2006). This trend is troubling from a public health perspective, since those granted exemptions have been found to be more susceptible to disease. For example, exempted individuals are 22 times more likely to have contracted measles, and 5.9 times more likely to have contracted pertussis, than children who received their immunizations (Feiken et al., 2000). In addition, the number of exemptions has been found to correlate with the incidence of measles and pertussis in nonexempt children (Ibid.). This latter finding underscores how granting exemptions can diminish the positive effects of herd immunity within a given population.

More directly, vaccines are estimated to save the lives of a tremendous number of children worldwide in a given year. Andre (2003) puts the number at approximately three million children yearly, with an additional two million who could be saved if not for vaccine shortages. In the U.S. context, the story is similar. During the twentieth century, over 675,000 American children died of just measles and diphtheria (Malone & Hinman, 2007). By way of contrast, in the year 2000, only 81 American children died of measles, and just four of diphtheria. This represents an improvement of over 99%. Vaccination programs are largely responsible for the observed changes (Ibid.). Similarly positive results have been found for other vaccines as well, including those for rubella, mumps, tetanus, polio, and smallpox (CDC, 1999a).

4 The Risks Associated with Vaccine Use
It should be noted that there is inherent risk with any vaccine, whether of the killed or live attenuated variety. This ranges from minor side effects, such as low-grade fevers, or bruising and soreness at the site of injection, to more serious complications (Fiore et al., 2009; Kimmel, 2002). An example of the latter involves the commonly-mandated measles, mumps, and rubella (MMR) vaccine. Per one million doses, there tends to be one associated case of encephalitis, 0 to 0.7 cases of subacute sclerosing panencephalitis, two cases of pneumonia, 0.5 to 33 cases of thrombocytopenia, 0.3 cases of orchitis, and five cases (none fatal) of anaphylaxis (Kimmel, 2002). Nevertheless, receiving the MMR vaccine is still considered much safer compared to not receiving the vaccine (Ibid.).

Other complications stem from contaminated lots of vaccines, or from live attenuated vaccines reverting to their virulent form and actually causing the disease rather than preventing it. One of the more well-known examples of such problems occurred in 1942, when contaminated human serum, used as a stabilizer in the yellow fever vaccine, resulted in approximately 28,000 cases of hepatitis B (Ward, 2000). Similarly, in 1955, incomplete inactivation of the killed polio virus vaccine caused 204 cases of paralytic polio (Ibid.). These examples constitute serious breaches of vaccine safety. Yet, far more people have been protected from yellow fever and polio through vaccination than suffered from complications due to contaminated or inactivated vaccines. In other cases, however, a vaccine’s side-effects can be so serious as to outweigh the benefits of immunization. A recent and well-known example of this is the Rotashield® vaccine, which was designed to protect individuals from rotavirus infection. Around the time the vaccine was introduced in 1998,
rotavirus infection accounted for 20-40 deaths annually in the United States, and approximately 50,000 hospitalizations for severe dehydration and diarrhea (CDC, 1999b). Though it was shown to be safe and efficacious in pre-licensure clinical trials, post-licensure studies in 1999 identified a serious intestinal disorder as a side-effect linked to the vaccine (Ibid.). In response, the manufacturer pulled the vaccine from the market.

5 Organizing Against Vaccine Programs
These examples of vaccine-associated risks are often the basis for organized anti-vaccine groups and organizations, which argue that vaccination programs are dangerous to public health. Typically, groups such as K.N.O.W. Vaccines, the Coalition for Safe Minds, and the U.S. National Vaccine Information Center, either oppose universal vaccination outright, argue that parents should have the right to choose whether their children are vaccinated, or take issue with particular adjuvants administered with vaccines (Shetty, 2010). While some advocacy groups make greater use of scientific methodology than others to promote their cause, anti-vaccine groups are generally known to make skillful use of electronic media and the internet to spread their message (Kata, 2012; Zimmerman et al., 2005). In this way, they are able to negatively influence the perception of people who would not otherwise be opposed to vaccination programs (Kata, 2012; Larson et al., 2011; Poland & Jacobson, 2001). The result is documented lower rates of vaccination, and thus higher numbers of reported cases of disease (Grant, 2010; Gangerosa et al., 1998; Poland & Jacobson, 2001). This was the case with measles in both the U.S. (Grant, 2010) and the U.K. (Owens, 2002), as it was with pertussis over a range of countries studied (Gangerosa et al., 1998).

6 Government Regulation of Vaccine Safety
The federal government plays the key role in ensuring the risks associated with vaccines and vaccination programs are kept within acceptable limits. The U.S. Department of Health and Human Services, particularly through its Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC), regulates vaccine research and development, assesses the safety of vaccines, and licenses vaccines for utilization in vaccine programs (Johnson et al., 2000).

Prior to licensing by the FDA, vaccine candidates are thoroughly investigated in the laboratory, first with animal model systems, and later in human clinical trials to confirm their safety and effectiveness (CDC, 2011b). As complicated and thorough as this process is designed to be, it can typically take up to ten years or more for a vaccine to be granted a license. Over the course of this process, the FDA evaluates results from clinical trials, inspects the vaccine production facilities, and assesses production techniques to ensure public safety. Only when the FDA is satisfied with the vaccine’s safety and manufacturing protocols is it approved for use by the general public (Ibid.).

The FDA established in 1997 a Fast Track program to accelerate the development and review of drugs and vaccines that are aimed at treating serious or life-threatening diseases, and that show the possibility of addressing unmet medical needs (Reichert et al., 2008). An unmet need is commonly defined as providing a treatment where none currently exists or offering a therapy which might possibly be superior to existing therapies. If there are existing therapies, a Fast Track candidate must demonstrate relative improvement, including superior efficacy, decreased side-effects, or decreased toxicity, among others (www.fda.gov). Once a vaccine candidate has received a Fast Track classification, early and frequent communication occurs between the company and FDA throughout the vaccine development and review process. Throughout, the FDA takes special care that the reduced time needed for development and approval does not jeopardize the safety and efficacy of the vaccine (Reichert et al., 2008). Moreover, the increased communication ensures that issues are solved in a prompt manner, often resulting in faster approval of the vaccine and therefore earlier access to individuals in need. (www.fda.gov).

In addition to the safeguards in place for laboratory testing and licensure, the FDA and CDC established in 1990 a surveillance system to screen for adverse medical events after vaccination, known as the Vaccine Adverse Event Reporting System (VAERS). Under this system, any individual can file a VAERS report, but vaccination providers must report any adverse events that follow vaccination, as well as lot numbers of vaccines dispensed (Malone & Hinman; CDC, 2011b). As such, VAERS provides a way for data to be collected and analyzed regarding the side-effects related to vaccines currently in use. Though helpful, the utility of VAERS is limited, since it is difficult to ascertain whether the vaccine in question was...
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7 Discussion and Conclusion

Vaccines have been tremendously helpful in limiting, and in some cases fully eradicating, virulent disease. The payoff in terms of human lives saved has been extraordinary. In fact, immunization programs have been so effective, that people living today in developed countries do not often have first or second-hand experience of the impact that diseases now suppressed by vaccination programs once had on society. This makes it easier for those with concerns over vaccine safety to consider refraining from immunization altogether. Given the ease with which people can travel today, and the influx of visitors to developed countries from, say, polio or measles-endemic regions, this has troubling implications for the potential of herd immunity to protect vulnerable human populations. Although it is of course important to fully embrace precautions for vaccine safety of the sort mentioned in this chapter, the general efficacy of vaccines and the potential for positive public health outcomes should not themselves be minimized without cause. Smallpox has already been eradicated worldwide, while significant regional reductions have occurred with other disease threats; for example, measles and rubella in the Americas (Dowdle & Cochi, 2011). Moreover, other diseases have been identified to have eradication potential, including polio, dracunculiasis, lymphatic filariasis, and mumps (Ibid.). There is a great deal of disease-related human suffering to yet be alleviated, and modern vaccine science offers the best potential for positive outcomes in this regard.

Challenges to progress in eradicating disease still remain, of course. Many diseases are not currently the focus of large-scale eradication efforts, including “neglected diseases” such as hookworm, ascariasis, and dengue fever. Efforts to fight such neglected diseases are often afforded less funding relative to more prominent disease threats (Molyneux, 2004). Similarly, there is sometimes insufficient profit motive for private-sectorsources to take on the immense task of undergoing FDA approval for vaccines to treat diseases found primarily in developing countries (Robertson et al., 2012). Resource questions of this sort permeate the vaccine policy environment. Yet, with success comes opportunities for advancement in the application of vaccine science. One thing that’s certain is that vaccination efforts will remain a prime public health policy tool as governments endeavor to manage outbreaks of virulent disease.

References


