The NEW ENGLAND JOURNAL of MEDICINE

Perspective

JANUARY 13, 2011

The Age-Old Struggle against the Antivaccinationists

Gregory A. Poland, M.D., and Robert M. Jacobson, M.D.

Since the introduction of the first vaccine, there has been opposition to vaccination. In the 19th century, despite clear evidence of benefit, routine inoculation with cowpox to protect people against smallpox was hindered by a burgeoning antivaccination movement. The result was ongoing smallpox outbreaks and needless deaths. In 1910, Sir William Osler publicly expressed his frustration with the irrationality of the antivaccinationists by offering to take 10 vaccinated and 10 unvaccinated people with him into the next severe smallpox epidemic, to care for the latter when they inevitably succumbed to the disease, and ultimately to arrange for the funerals of those among them who would die (see the Medical Notes section of the Dec. 22, 1910, issue of the *Journal*). A century later, smallpox has been eradicated through vaccination, but we are still contending with antivaccinationists.

Since the 18th century, fear and mistrust have arisen every time a new vaccine has been introduced. Antivaccine thinking receded in importance between the 1940s and the early 1980s because of three trends: a boom in vaccine science, discovery, and manufacture; public awareness of widespread outbreaks of infectious diseases (measles, mumps, rubella, pertussis, polio, and others) and the desire to protect children from these highly prevalent ills; and a baby boom, accompanied by increasing levels of education and wealth. These events led to public acceptance of vaccines and their use, which resulted in significant decreases in disease outbreaks, illnesses, and deaths. This golden age was relatively short-lived, however. With fewer highly visible outbreaks of infectious disease threatening the public, more vaccines being developed and added to the vaccine schedule, and the media permitting widespread dissemination of poor science and anecdotal claims of harm from vaccines, antivaccine thinking began flourishing once again in the 1970s.[1]

Little has changed since that time, although now the antivaccinationists' media of choice are typically television and the Internet, including its social media outlets, which are used to sway public opinion and distract attention from scientific evidence. A 1982 television program on diphtheria–pertussis–tetanus (DPT) vaccination entitled "DPT: Vaccine Roulette" led to a national debate on the use of the vaccine, focused on a litany of unproven claims against it. Many countries dropped their programs of universal DPT vaccination in the face of public protests after a period in which pertussis had been well controlled through vaccination[2] —

The Cow Pock — or — the Wonderful Effects of the New Inoculation.

J. Gillray, 1802. Courtesy of the National Library of Medicine.

the public had become complacent about the risks of the disease and focused on adverse events purportedly associated with vaccination. Countries that dropped routine pertussis vaccination in the 1970s and 1980s then suffered 10 to 100 times the pertussis incidence of countries that maintained high immunization rates; ultimately, the countries that had eliminated their pertussis vaccination programs reinstated them.[2] In the United States, vaccine manufacturers faced an onslaught of lawsuits, which led the majority of them to cease vaccine production. These losses prompted the development of new programs, such as the Vaccine Injury Compensation Program (VICP), in an attempt to keep manufacturers in the U.S. market.

The 1998 publication of an article, recently retracted by the *Lancet*, by Wakefield et al.[3] created a worldwide controversy over the measles–mumps–rubella (MMR) vaccine by claiming that it played a causative role in autism. This claim led to decreased use of MMR vaccine in Britain, Ireland, the United States, and other countries. Ireland, in particular, experienced measles outbreaks in which there were more than 300 cases, 100 hospitalizations, and 3 deaths.[4]

Today, the spectrum of antivaccinationists ranges from people who are simply ignorant about science (or "innumerate" — unable to understand and incorporate concepts of risk and probability into science-grounded decision making) to a radical fringe element who use deliberate mistruths, intimidation, falsified data, and threats of violence in efforts to prevent the use of vaccines and to silence critics. Antivaccinationists tend toward complete mistrust of government and manufacturers, conspiratorial thinking, denialism, low cognitive complexity in thinking patterns, reasoning flaws, and a habit of substituting emotional anecdotes for data.[5] Their efforts have had disruptive and costly effects, including damage to individual and community well-being from outbreaks of previously controlled diseases, withdrawal of vaccine manufacturers from the market, compromising of national security (in the case of anthrax and smallpox vaccines), and lost productivity.[2]

The H1N1 influenza pandemic of 2009 and 2010 revealed a strong public fear of vaccination, stoked by antivaccinationists. In the United States, 70 million doses of vaccine were wasted, although there was no evidence of harm from vaccination. Meanwhile, even though more than a dozen studies have demonstrated an absence of harm from MMR vaccination, Wakefield and his supporters continue to steer the public away from the vaccine. As a result, a generation of parents and their children have grown up afraid of vaccines, and the resulting outbreaks of measles and mumps have damaged and destroyed young lives. The reemergence of other previously controlled diseases has led to hospitalizations, missed days of school and work, medical complications, societal disruptions, and deaths. The worst pertussis outbreaks in the past 50 years are now occurring in California, where 10 deaths have already been reported among infants and young children.

In the face of such a legacy, what can we do to hasten the funeral of antivaccination campaigns? First, we must continue to fund and publish high-quality studies to investigate concerns about vaccine safety. Second, we must maintain, if not improve, monitoring programs, such as the Vaccine Adverse Events Reporting System (VAERS) and the Clinical Immunization Safety Assessment Network, to ensure coverage of real but rare adverse events that may be related to vaccination, and we should expand the VAERS to make compensation available to anyone, regardless of age, who is legitimately injured by a vaccine. Third, we must teach health care professionals, parents, and patients

how to counter antivaccinationists' false and injurious claims. The scientific method must inform evidence-based decision making and a numerate society if good public policy decisions are to be made and the public health held safe. Syncretism between the scientific method and unorthodox medicine can be dangerous.

Fourth, we must enhance public education and public persuasion. Patients and parents are seeking to balance risks and benefits. This process must start with increasing scientific literacy at all levels of education. In addition, public–private partnerships of scientists and physicians could be developed to make accurate vaccine information accessible to the public in multiple languages, on a range of reading levels, and through various media. We must counter misinformation where it is transmitted and consider using legal remedies when appropriate.

The diseases that we now seek to prevent with vaccination pose far less risk to antivaccinationists than smallpox did through the early 1900s. Unfortunately, this means that they can continue to disseminate false science without much personal risk, while putting children, the elderly, and the frail in harm's way. We can propose no Oslerian challenge to demonstrate our point but have instead a story of science and contrasting worldviews: on the one hand, a long history of stunning triumphs, such as the eradication of smallpox and control of many epidemic diseases that had previously maimed and killed millions of people; on the other hand, the reality that none of the antivaccinationists' claims of widespread injury from vaccines have withstood the tests of time and science. We believe that antivaccinationists have done significant harm to the public health. Ultimately, society must recognize that science is not a democracy in which the side with the most votes or the loudest voices gets to decide what is right.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Mayo Clinic Vaccine Research Group (G.A.P., R.M.J.), the Department of Medicine (G.A.P.), and the Department of Pediatric and Adolescent Medicine (G.A.P., R.M.J.), Mayo Clinic, Rochester, MN.

1. Wolfe RM, Sharp LK. Anti-vaccinationists past and present. BMJ 2002;325:430-2.
2. Gangarosa EJ, Galazka AM, Wolfe CR, et al. Impact of anti-vaccine movements on pertussis control: the untold story. Lancet 1998;351:356-61.
3. Wakefield AJ, Murch SH, Anthony A, et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. Lancet 1998;351:637-41. [Retraction, Lancet 2010;375:445.]
4. McBrien J, Murphy J, Gill D, Cronin M, O'Donovan C, Cafferkey MT. Measles outbreak in Dublin, 2000. Pediatr Infect Dis J 2003;22:580-4.
5. Jacobson RM, Targonski PV, Poland GA. A taxonomy of reasoning flaws in the anti-vaccine movement. Vaccine 2007;25:3146-52.

ACOs and the Enforcement of Fraud, Abuse, and Antitrust Laws

Robert F. Leibenluft, J.D.

Hospitals and physicians are eagerly awaiting regulations for accountable care organizations (ACOs), which many observers view as the best hope provided by the Patient Protection and Affordable Care Act (ACA) for needed delivery system reform. Starting in 2012, health care providers in ACOs that furnish efficient, high-quality care to Medicare patients will share in Medicare's savings. Providers are concerned, however, that in creating ACOs they risk violating fraud, abuse, and antitrust laws.[1] To address these fears, the Department of Health and Human Services (DHHS), the Federal Trade Commission, and the Department of Justice, under the direction of the White House, are collaborating to provide waivers, safety zones, and guidance to providers.

An ACO, as defined by the ACA, is an organization of health care providers that agrees to be accountable for the quality, cost, and overall care of Medicare patients for whom they provide the bulk of primary care services.[2] ACOs must have defined processes for promoting evidence-based medicine, reporting data with which to evaluate the quality and cost of care, and coordinating care. ACOs that meet specified quality standards will receive a share of the savings if Medicare's cost for the care of their assigned patients is below a certain benchmark. ACOs, along with bundled payments and other payment innovations, are intended to transform the health care delivery system both by replacing fee-for-service payments, which tend to increase utilization, and by boosting collaboration among providers so as to reduce costs and improve quality.

However, providers organizing ACOs may fear violating fraud-