

# Could It Happen Here? Vaccine Risk Controversies And The Specter Of Derailment

A successful immunization system depends mostly on people's willingness to have themselves and their children vaccinated.

by James Colgrove and Ronald Bayer

**ABSTRACT:** Controversy over vaccine safety has achieved high visibility over the past decade. At the same time, however, levels of coverage for routinely recommended childhood vaccines in the United States are at their highest ever. We examine this apparent paradox. We consider the ways in which concerns over vaccine safety have emerged and diffused through the popular media, legislative hearings, and Internet-based activism. As a case study, we review the controversy over the alleged connection between autism and the measles-mumps-rubella (MMR) vaccine and consider why it had a dramatic effect on the vaccine's acceptance in Great Britain but virtually none in the United States.

PUBLIC HEALTH EXPERTS OFTEN WARN that the system of routine childhood immunization in the United States rests on a tenuous foundation of public support. The very success of widespread immunization, these analyses often stress, diminishes the threat of illness that leads to support for use of vaccines and causes attention to focus disproportionately on the risks of vaccination rather than its benefits. A confluence of trends in recent years has heightened fears that public support may erode. The schedule of vaccines routinely recommended for children and adolescents has expanded during a time of societal preoccupation with environmental and iatrogenic risks, while the Internet has accelerated the dissemination of rumors and unfounded theories. In this atmosphere, allegations of vaccine-related harm have proliferated, resulting in an onslaught of negative media attention and congressional scrutiny during the past decade.

Looming large over current events is the memory of a dramatic vaccine-safety controversy that shook the United Kingdom in the 1970s. After a widely publicized report in *Archives of Diseases of Childhood* suggested a connection between the whole-cell pertussis vaccine and neurological damage in children, acceptance of the vaccine plummeted in Great Britain from some 80 percent coverage in 1974 to

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James Colgrove (jc988@columbia.edu) is an associate research scientist, and Ronald Bayer, a professor, at Columbia University's Mailman School of Public Health in New York City. Bayer served as a member of the Institute of Medicine's immunization safety review panel from 2001 to 2004.

30 percent in 1978.<sup>1</sup> Widespread resurgences of pertussis followed on the heels of this drop. Similar sequences of events occurred in several other countries, although the United States never experienced the steep declines seen abroad.<sup>2</sup>

The debates over the safety of the vaccine continued for two decades, prompting numerous studies and the eventual adoption of a safer acellular vaccine. Since that time, the specter of a massive public turn against one, some, or all vaccines—the derailment of the country’s highly successful efforts—has haunted immunization programs in the United States. Could it happen again? Could it happen here?

Current data from the National Immunization Survey provide at least some reassurance. Levels of immunization for children ages 19–35 months stand at their highest ever.<sup>3</sup> These data present an apparent paradox: Even as the controversies about vaccine safety have grown in volume and intensity in the past several years, so have rates of child immunization steadily risen. Between 1999 and 2003, when concern about the connection between autism and the measles-mumps-rubella (MMR) vaccine was the subject of repeated congressional hearings, investigations by the Institute of Medicine (IOM), and reports in the media, the percentage of children ages 19–35 months who had received one or more doses of the vaccine increased, from 91.5 percent to 93 percent.

This paper examines the atmosphere of contention that has prevailed during the past decade and the ways it has—and has not—affected immunization in the United States and Great Britain. We consider why the controversy over MMR had a dramatic effect in Great Britain but virtually none in the United States, and we suggest lessons for policymakers.

## **Vaccination In A Risk Society**

In addition to the decline in vaccine-preventable diseases, which has lessened the perceived need for immunization, concern about risks in the United States has been heightened by the expansion of the schedule of recommended vaccines for children. Between 1990 and 2000, vaccines against four diseases, entailing ten to twelve injections, were added to the schedule.<sup>4</sup> The fear that children were becoming “pediatric pincushions” struck an especially resonant chord during those years, when the ubiquity of risk in modern industrial society was a central concern of U.S. politics, law, and popular culture.<sup>5</sup> In areas as diverse as nuclear power plants, silicone breast implants, and genetically modified foods, the assessment, quantification, regulation, and communication of risk pervaded civic discourse at the turn of the twenty-first century.<sup>6</sup> This climate was a fertile one for allegations that vaccines are causally connected to sudden infant death syndrome (SIDS), asthma, multiple sclerosis, and immune system dysfunction.<sup>7</sup>

Health officials in particular have been concerned that mistrust of vaccines could lead to greater numbers of parents attempting to claim exemptions from legal requirements to have their children vaccinated before attending school. Even small numbers of unvaccinated children can lead to outbreaks of infectious dis-

ease.<sup>8</sup> Amid these concerns, immunization proponents have been forced into a defensive posture with respect to risk. They have drawn explicitly on analyses that emerged in other domains, especially the regulation of environmental hazards, to engage with the public perceptions of vaccines.<sup>9</sup> In an early sign of the seriousness with which health professionals viewed the threat to public trust that theories of vaccine-related harm might create, the IOM in 1996 and 2000 held several workshops on risk communication and vaccines.<sup>10</sup> Informing the official responses to vaccine risk perceptions has been psychological literature that identifies heuristics and biases in people's assessment of risk, such as a preference for errors of omission over errors of commission.<sup>11</sup> According to these models, several features of vaccine-induced injuries serve to magnify concern about them: They primarily affect children; they are human-made rather than naturally occurring; and they are involuntary, because of school-entry mandates.<sup>12</sup>

■ **Role of the Internet.** The spread of dissenting views of vaccination has been facilitated by the Internet, where dozens of Web sites challenge the safety and efficacy of vaccination.<sup>13</sup> Parents seeking to inform themselves by searching online, in addition to encountering official sources such as the U.S. Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP), are likely to find sites that cast vaccines in a negative light, showing dramatic vignettes and photos of children allegedly harmed by vaccines. "I just typed in the word 'vaccines' and everything that popped up was anti-vaccine material," one mother told *Consumer Reports* in 2001.<sup>14</sup>

■ **Congressional input.** Perhaps the most high-profile example of concern in the United States over vaccine safety was a series of hearings by the House Committee on Government Reform at which immunization proponents were often cast in an adversarial role against parent activists and a small number of scientists who dissented from the orthodox view of vaccines. It was the potent support of a congressional committee chair that most alarmed those who believed that the structure of childhood immunization was vulnerable to assault. The committee held seven hearings in 1999 and 2000, prompting the CDC to ask the IOM to convene a special committee to review immunization safety. Between 2001 and 2004 the IOM published eight reports on the hypothesized connections between vaccines and various disorders. Of these hypotheses, one of the most contentious has been the alleged connection between the MMR vaccine and the apparent rise in autism among children. The controversy's origins and diffusion on each side of the Atlantic provide a cautionary tale about the unpredictable effects of risk concerns on the beliefs and behavior of the public and health professionals.

## The Rise And Fall Of A Risk Hypothesis

■ **A "red flag" event.** On 28 February 1998, the British medical journal *Lancet* published an account of an investigation of the link between chronic gastrointestinal disease and severe developmental regression in children. The research team at

London's Royal Free Hospital was careful to note in its report that although in "most cases, onset of symptoms was after measles, mumps and rubella immunization," they had not proved a causal link.<sup>15</sup> But this cautious wording was belied by the press conference the hospital called to publicize the findings. At the event, lead investigator Andrew Wakefield claimed that it would be safer for parents to opt for individual vaccinations against measles, mumps, and rubella instead of the combined shot (a position his coinvestigators did not publicly endorse). Presiding over the event, the dean of the medical school associated with the hospital warned against alarmist reports that might undermine confidence in the MMR vaccine.<sup>16</sup>

The *Lancet* article was not the first red flag raised about the MMR vaccine. Concerns over MMR and autism had surfaced in earlier media reports of litigation by parents who believed that the vaccine had precipitated autism in their previously healthy infants. More than a year before the *Lancet* article, the London daily *Independent* had reported on an eight-year-old boy whose mother blamed the MMR vaccine for her son's autism.<sup>17</sup> (The boy was part of the Wakefield study that resulted in the *Lancet* publication.) Vaccination rates for MMR had already fallen by about 2 percent as a result of these fears. But the *Lancet* article and the attendant publicity dramatically ramped up the level of scrutiny and kicked off a saga that would extend over six years, as public health officials struggled to regain the confidence of worried parents.

■ **Impact on parents and clinicians.** Soon after the *Lancet* report, the U.K. Department of Health issued an "urgent communication" warning parents not to reject MMR vaccinations, and an array of respected health organizations publicly supported the warning.<sup>18</sup> But despite such urgings, the controversy was clearly affecting parents' willingness to immunize their children. Citing a survey showing that in 20 percent of doctors' offices, five or more parents had refrained from accepting the MMR vaccine, the London daily *Guardian* commented that parents were "voting with their feet."<sup>19</sup> Nor was the impact only on parents. A survey of health professionals in Wales revealed that 13 percent of general practitioners (GPs), 27 percent of practice nurses, and 7 percent of health visitors (visiting nurses) believed that there was a "very likely or possible association between MMR and autism."<sup>20</sup>

■ **Impact on immunization rates.** Between 1998 and 2004, despite repeated efforts at reassurance by the U.K. medical establishment, MMR immunization declined steadily in Britain. And while the drop-off was never as drastic as the precipitous fall for pertussis vaccine in the 1970s, health officials were haunted by the specter of the earlier event and the consequences for childhood disease. An editorial in the *British Medical Journal* drew the comparison: "The media excitement and public concern after a *Lancet* report linking MMR with autism kindles a sense of déjà vu. It is highly reminiscent of similar scares over pertussis in the 1970s which resulted in much suffering and many deaths...both in Britain and internationally."<sup>21</sup>

Even as the press reported the results of two new studies that rejected the link between MMR and autism in mid-1999, the erosion of support for what the *Inde-*

pendent called the “battered” vaccination program was clear.<sup>22</sup> In response, the government launched a £3 million advertising campaign directed at parents and health professionals.<sup>23</sup> It was against this backdrop that arguments for offering an alternative to the “single jab”—giving parents the option of separate vaccinations against measles, mumps, and rubella—began to gain political currency. Prime Minister Tony Blair’s refusal to answer queries about whether his son had received the combined MMR vaccination only added fuel to the fire. Liam Fox, the Conservative Party’s shadow health secretary and a former GP, asserted that it was necessary to consider an alternative to the preferred course “to get inoculation rates up.”<sup>24</sup> Health officials opposed such suggestions as dangerous and a “capitulation to media pressure.”<sup>25</sup>

By early 2002, 25 percent of parents believed that the “weight of scientific evidence suggests a link between MMR and autism,” and another 39 percent thought that “there was equal evidence on both sides.”<sup>26</sup> By 2003, MMR immunization rates had fallen to 80 percent in the United Kingdom and to 62 percent in some parts of London.<sup>27</sup> Nothing seemed able to slow the gradual but relentless decline.

■ **A change in public opinion.** And then a series of events changed the course. In November 2003, Simon Murch, one of Wakefield’s collaborators on the *Lancet* report, publicly denounced assertions of a link between MMR and autism. In a widely reported letter to the *Lancet*, Murch declared that there was “unequivocal evidence that MMR is not a risk factor for autism.”<sup>28</sup> Early in 2004, Wakefield was accused of having misled the *Lancet* editor by concealing the fact that his research had been funded in part by the legal team seeking redress for parents who believed that their children had been injured by the MMR vaccine.<sup>29</sup> And in March 2004, ten of the original collaborators on Wakefield’s study formally retracted their support for the autism hypothesis.<sup>30</sup> Wakefield, who had been put forth as a heroic defender of truth against convention, was increasingly isolated. At the same time, media attention shifted to the increase in measles cases. “These boys were disabled by measles... They are the real victims of Britain’s MMR scare,” ran a typical headline.<sup>31</sup>

Each of these events contributed to a shift in parental attitudes. So too did the turnaround in the perspective of health professionals: Less than 3 percent now believed that there was a link between MMR and autism, and 97 percent of GPs felt “confident” about explaining the benefits of MMR to parents. A survey of parents found that 88 percent planned to have their children immunized with MMR, and 82 percent said that they thought the vaccination safe.<sup>32</sup> These changes were reflected in the apparent end to the annual decline in immunization rates.

Throughout the six-year controversy, public health officials and other advocates of childhood immunization repeatedly gave voice to fears that the skepticism and distrust would affect broader vaccination efforts. It is thus noteworthy that even as MMR vaccination rates declined to levels far below what public health officials deemed minimally necessary, the uptake for pertussis vaccination in the United Kingdom barely budged, remaining at 90 percent.<sup>33</sup>

## Atlantic Transfer?

When he decided to break publicly with Andrew Wakefield in 2003, Simon Murch gave as one of his reasons that he “got fed up at the data we had generated in our labs being presented at these revivalist meetings in the United States.”<sup>34</sup> While Murch was correct in his assessment of the extent to which U.S. activists had seized upon the 1998 *Lancet* report, the MMR-autism debate attained remarkably little traction on the U.S. side of the Atlantic.

■ **Congress and the IOM.** Most important in the shape of the U.S. debate on MMR were hearings in the spring of 2000 before the House Committee on Government Reform. The committee chair and leading congressional critic of vaccines was Rep. Dan Burton (R-IN). Burton’s granddaughter was hospitalized after receiving a hepatitis B vaccine, and his grandson has autism, which Burton believed was the result of the MMR shot the child received. Following the hearing, both Burton and Rep. Henry Waxman (D-CA), the ranking minority member, called on Donna Shalala, secretary of health and human services (HHS), to bring together a panel of experts to resolve the scientific issues. The IOM, which had published earlier studies of vaccine safety, was asked to convene another panel on immunization safety.

In the period leading up to the IOM’s first meeting in March 2001, there was considerable media attention to the MMR controversy, but nothing approaching the intensity of coverage in Britain. A segment on the CBS *60 Minutes* news program, which aired 12 November 2000, noted that “while most doctors say there is no proof [of a link between MMR and autism], more and more parents seem to think there is.” Nevertheless, the overall tone of the program was reassuring about the vaccine’s safety. And whether or not parental anxiety was growing, there was no impact on the uptake of MMR vaccination: U.S. rates remained virtually unchanged at close to 92 percent.<sup>35</sup>

When the IOM committee issued its report, it was a clear rebuff to those who had claimed that apparently increasing rates of autism could be attributed to the MMR vaccine. “The evidence,” the committee wrote, “favors rejection of a causal relationship at the population level between MMR vaccine and autism spectrum disorders.”<sup>36</sup> Three years later the IOM committee once again rejected the putative causal relationship between vaccines and autism in light of extensive new epidemiological evidence.<sup>37</sup> Although a small group of activists and their political allies refused to accept the IOM reports and the overwhelming weight of scientific opinion, the controversy over MMR and autism has, for now, all but come to an end in the United States. Neither that theory nor any of the other risk hypotheses that have circulated in recent years have led to the derailment that immunization proponents fear.

■ **A residue of feeling.** Even though uptake rates have remained high, theories of vaccine-related harm have clearly affected public perceptions. From 1998 to 1999, calls to the CDC’s National Immunization Information Hotline from parents concerned about adverse events increased 200 percent.<sup>38</sup> More than two-thirds of phy-

sicians in the spring of 2000 reported a “substantial increase” in the number of parents expressing concerns in the previous year—the year during which the Burton hearings began, the controversy over the vaccine preservative thimerosal became public, and the recently introduced rotavirus vaccine was pulled from the market because of a rare, potentially fatal side effect.<sup>39</sup> In a widely cited study published in 2000, about a quarter of parents believed that children received more shots than were good for them and that too many vaccinations could weaken a child’s immune system.<sup>40</sup> Four years later, in spite of sustained efforts by public health advocates and pediatricians to counter such fears, another survey found that about the same proportion of parents in an ethnically diverse inner-city community held such beliefs.<sup>41</sup>

### Why Didn’t It Happen Here?

Many of the factors that fueled the crisis in Britain would seem to be equally potent catalysts in the United States: mistrust of the pronouncements of scientific experts and government agencies; concerns about environmental risks; and the resonance of a media-produced narrative in which a lone scientist crusaded against a supposedly corrupt establishment. But there are several differences between the two countries that helped account for the contrasting outcomes.

■ **Legal infrastructure.** Perhaps the most notable difference is the legal infrastructure around immunization: Although immunization is voluntary in the United Kingdom, it is compulsory in the United States through a network of state-level laws for children entering school and licensed day care facilities. There is empirical evidence that requirements for vaccination prior to school attendance are effective at raising coverage rates among school-age youth.<sup>42</sup> But these laws do not fully explain the high rates among children under age three. Moreover, some evidence suggests that laws covering day care may be less effective than those targeting school-age children.<sup>43</sup>

■ **More fertile U.K. ground.** Another reason for the difference may be that previous scandals in Britain involving health risks provided a more fertile ground for discontent to spread. The MMR vaccine had been at the center of controversy in the early 1990s, when cases of meningitis were linked to the mumps component of the shot.<sup>44</sup> (The British MMR vaccine used a strain of mumps virus different from the one used in the United States.) Further, the credibility of the British government had already taken a blow because of what was seen as its poor handling of the crisis over risks of mad cow disease.<sup>45</sup>

■ **Differences among clinicians.** Another possible factor is differences in the practices of those on the immunization front lines. Most “jabs” in Britain are given by GPs, while the majority of U.S. children receive theirs from pediatricians; U.S. children seen by private-sector pediatricians have higher rates of vaccination than British children seen by GPs.<sup>46</sup>

Also, the British medical community was divided over the alleged risks of MMR, while clinicians responsible for vaccination in the United States remained more unified in their support for the shot.<sup>47</sup> Nevertheless, it remains a matter of

speculation whether U.S. pediatricians were more confident and emphatic in reassuring parents than U.K. clinicians were. Some surveys have suggested that U.S. pediatricians and other clinicians spend little time discussing vaccine risks with parents and that they often do not do so at all.<sup>48</sup>

■ **Differences in media coverage.** A fourth possible reason for the contrasting outcomes in the two countries may lie in differences in media coverage. In the United States, unsubstantiated press reports have been responsible for the spread of erroneous information about vaccines in the past.<sup>49</sup> But in the case of MMR, the coverage in the United Kingdom appears to have been far more inflammatory. A systematic analysis of the British newspaper and television stories characterized the response to the autism theory as a “feeding frenzy” that presented the story as if there were equal evidence for and against the theory; this coverage had an autocatalytic effect, with declines in vaccine acceptance fueling more articles, which in turn spurred greater declines.<sup>50</sup> Like differences in provider practices, this explanation is conjectural; further analysis of MMR press coverage in this country is needed.

### **From Vaccine Controversy To Strength**

Ultimately, the differences in the contours of the MMR controversy on each side of the Atlantic remain something of a conundrum, with none of the factors discussed above providing an adequate explanation. Nevertheless, the events in both countries reinforce several principles that have become axiomatic in recent years about how to maintain the strength of vaccination efforts.

■ **Vaccine education for parents.** Given the way in which safety controversies can rapidly and unexpectedly balloon, clinicians must be constantly alert to the potentially devastating impact of vaccine controversies and prepared to discuss vaccine safety concerns with parents. Research in the United States has shown that providers' practices are the most important determinant of the immunization status of children seen by private pediatricians, and their willingness to address concerns and provide reassurances are crucial in persuading reluctant parents to accept vaccination.<sup>51</sup> Promotional efforts specifically addressing parental concerns are an important component of this effort. For example, in 2000 the Children's Hospital of Philadelphia launched a center for vaccine education to produce materials for both parents and providers, which included videos and a Web site.<sup>52</sup>

■ **Safety monitoring.** To provide a solid evidence base to which clinicians and the public can turn, independent advisory bodies are needed, such as the review panel convened by the IOM. Members of that panel were all carefully screened to avoid conflict of interest.<sup>53</sup> Ongoing safety monitoring systems are clearly needed as well, although there is disagreement about what form these should take, as illustrated in a recent exchange in the *American Journal of Public Health*. A team of vaccine experts at the Johns Hopkins University called for the establishment of a permanent independent review panel, modeled on the National Transportation Safety Board, that would coordinate postlicensure vaccine safety functions now spread among

several federal agencies.<sup>54</sup> But in a skeptical response, CDC officials countered that such a change would be “of unproven efficacy, redundant, and costly.”<sup>55</sup> In late February 2005, the CDC announced that it was separating its program for promoting vaccines from its program for monitoring vaccine safety.<sup>56</sup> The move—a response to persistent political pressure from critics—signaled the importance the agency attached to avoiding even the appearance of a conflict of interest. Whatever regulatory or administrative form that safety monitoring takes, the system must be transparent and open to public participation to avoid the appearance of stonewalling. A study in Britain of parental attitudes toward vaccination found that many parents, especially those against vaccinations, considered doctors too likely to “toe the party line” with respect to vaccine safety.<sup>57</sup>

**T**HE SUCCESSFUL MAINTENANCE of the U.S. immunization system ultimately will depend on interrelated structural factors: a stable and adequate supply, payment mechanisms for increasingly costly new vaccines, effective delivery systems, and promotional efforts to reinforce the need for vaccination.<sup>58</sup> But it will depend most of all on people’s continued willingness to receive existing and newly developed vaccines for themselves and their children.

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#### NOTES

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