

## ► **Concerns dim vaccines' luster**

*Despite the benefits of inoculations against life-threatening diseases, some parents and pediatricians worry about dangerous side effects.*

BY JULIE L. McDOWELL

Before Cindy\* was admitted to the hospital in 1999 to give birth to her daughter, she made it clear to the doctors and nurses that she did not want her child to receive any vaccines. "The doctors kind of frowned upon us," she remembers, "but I stood fast and explained that we were refusing all vaccines."

One of the first vaccines Cindy's baby would have received would have been for the rotavirus (a virus that causes a severe diarrheal illness), which many infants were given within the first 24 hours after birth. A few weeks after Cindy brought her new baby home from the hospital, the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics recommended suspending the rotavirus vaccine because of evidence linking it with bowel obstruction among infants during the first two weeks after it was administered.

"I was angry and disappointed," recalls Cindy. "I knew there had been injuries and deaths associated with it before I gave birth, yet the nurses at the hospital tried to play it down and make my husband and I feel guilty for not giving it to our daughter."

### **Setting the stage**

Vaccines are a compulsory, rather than optional, rite of passage for most young children. Indeed, all public and many private schools prohibit children from entering their doors without being fully inoculated unless they obtain an exemption, which is usually only granted by the state for religious reasons. Currently, the immunization

\* Name changed at subject's request.

schedule in the United States calls for children to receive up to 15 shots of 5 vaccines by five months of age and 5 additional shots of 7 more vaccines by the age of two, according to a report issued this year by the Institute of Medicine (IOM), a division



of the National Academy of Sciences. These shots protect against 11 diseases, including diphtheria, tetanus, pertussis (whooping cough), polio, measles, mumps, rubella, and hepatitis B.

There is no question that vaccines have been effective in wiping out deadly diseases. According to the CDC, the incidence of measles has decreased by 99% since the vaccine was introduced in 1963. Smallpox, which threatened 60% of the world's population in 1967, was eradicated by 1979 thanks to vaccines, according to the World Health Organization (WHO). But beginning in the mid-1970s, the safety of vaccines was questioned after an increase in the

number of lawsuits alleging neurological injury as a result of receiving the diphtheria, pertussis, and tetanus (DPT) vaccine. In 1986, Congress passed the National Childhood Vaccine Injury Act, which required doctors to alert parents to all the benefits and risks of the vaccine and file adverse event reports in the case of severe side effects.

### **Avoiding shots**

In 1998, concern once again surfaced when Andrew Wakefield, a British researcher, published a study in *The Lancet* (1998, 351, 637–641) pointing to some childhood vaccines, including the measles, mumps, and rubella (MMR) vaccine, as a possible cause of autism. Even though critics in the medical and scientific fields denounced Wakefield's findings as based on anecdotal evidence from parents rather than rigorous scientific examination, many parents claim that their children began showing signs of autism soon after receiving the MMR and other routine childhood vaccines.

At least two scenarios are outlined by researchers at the Autism Research Institute (a nonprofit organization founded in 1967 by parents and professionals to fund medical research on this disorder) that link vaccines to autism. In the first one, the sheer number of vaccines overwhelms the underdeveloped immune systems in babies, which can lead to neurological damage. Critics point out that this could make the MMR—which is three vaccines in a single shot—potentially dangerous to infants.

The second scenario involves thimerosal, once used widely as a vaccine preservative (although not in the MMR vaccine) and which is composed of almost 50% mercury, a known neurotoxin. In 1999, a policy paper issued by the American Academy of Pediatrics stated that certain vaccines, such as DtaP (a later version of



DPT) and pneumococcal vaccine, contain levels of mercury that could be dangerous to infants. Depending on what vaccines are administered, a six-month-old infant could have up to 187 µg of mercury introduced into his system. Even though this amount is considered a low-level exposure, it exceeds federal safety standards and guidelines for mercury exposure set forth by the Environmental Protection Agency, the Agency for Toxic Substances and Disease Registry, and the FDA, especially for infants (*JAMA* 1999, 282, 1763–1765).

Months before the rotavirus vaccine was banned, a then-pregnant Cindy and her husband had decided that their child would not be immunized. Cindy has severe allergies to some medications—a reaction to codeine once confined her to bed for five days, and a dose of Demerol had previously caused her throat to swell. Twelve years earlier, Cindy fell seriously ill after receiving a tetanus shot.

Barbara Loe Fisher, co-founder and president of the National Vaccine Information Center, a nonprofit educational organization advocating reformation of the mass-vaccination system, agrees with Cindy. “One of the biggest problems with the current vaccination system is that it’s based on a one-size-fits-all approach,” says Fisher, whose oldest son has multiple learning disabilities and attention deficit disorder that she believes might be linked to a severe reaction to his fourth DPT shot in 1980. “There hasn’t been enough research into genetic and other biomarkers that would better predict those who would be at risk to have an adverse reaction to a vaccine.”

### Evidence to the contrary

Despite these concerns, an independent committee of the IOM stated in February 2002 that there was inconclusive evidence to link vaccines with immune-related disorders. It also said that there was no reason for federal health officials to change the current immunization schedule. Many international and federal medical institutions, including the CDC, WHO, NIH, and the Institute for Vaccine Safety (IVS) at the Johns Hopkins School of Public Health, agreed and stated that there is no conclusive evidence that any vaccine causes autism. But the poten-

tial link prompted the House Committee on Government Reform to investigate the MMR–autism association in 1999. Its findings, however, agreed with those of the CDC and the IOM.

“The overall conclusion is that the evidence clearly does not support the hypotheses,” says IVS director Neal Halsey, who testified before the House Committee in 1999. Halsey also conducted an independent review of Wakefield’s study with other experts at the American Academy of Pediatrics. “Dr. Wakefield put together a chain of hypothetical scenarios that would need to take place for MMR to be predisposed to autism, and none of them held up under intense review of all the scientific data.”

But regardless of their attitudes toward vaccine safety, most researchers believe that thimerosal has no place in vaccines. “As of April 2002, thimerosal as a preservative is no longer used in the routine vaccines that are given to children less than one year of age,” says Halsey. “But to the best of my knowledge, there has not been a statement that thimerosal should be removed from all vaccines, because there are some vaccines administered to adults where thimerosal would be difficult and unnecessary to remove.”

However, the question remains, could thimerosal have damaged children who

received routine vaccinations? “The question has not been answered,” states Halsey. “There are long-term studies that are being done now that will take a couple of years to try to determine whether or not there were any risks of any problems from the thimerosal. The concern is whether it could cause some learning disabilities because of the mercury component.”

Halsey emphasizes to parents that the risks from the diseases that vaccines protect against, especially measles, mumps, and rubella, are “a thousandfold greater” than the risks from the vaccines. “The evidence demonstrates that the MMR is a very safe vaccine and that it is the best way to protect children against measles, mumps, and rubella,” says Halsey. “I have no reservation in strongly endorsing the vaccine for all healthy children. I gave that vaccine to my two children, and I would do it again today.”

### Further reading

Centers for Disease Control and Prevention’s National Immunization Program; [www.cdc.gov/nip](http://www.cdc.gov/nip).  
Institute for Vaccine Safety; [www.vaccinesafety.edu](http://www.vaccinesafety.edu).  
National Vaccine Information Center; [www.909shot.com](http://www.909shot.com).

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## Experts warn of smallpox vaccine’s dangerous side effects

This past June, the U.S. government’s Advisory Committee on Immunization Practices recommended smallpox vaccination for 15,000 health care and law enforcement workers likely to be “first responders” to a biological attack. Currently, this vaccine is restricted to scientists who work with smallpox and related viruses in a laboratory (only 11,000 people have received the vaccine since 1983, according to the CDC).

The recommendation came after the CDC asked the panel to determine if more Americans should get the smallpox vaccine following the anthrax attacks during the fall of 2001. So far, doctors and scientists have decried mass smallpox vaccination because the vaccine’s dangers seem to outweigh its benefits, especially if a known threat is not present. Side effects can range from minor discomfort to death. Fever, sore arms, and swollen lymph nodes can occur in up to 50% of recipients.

Because the virus is live, pregnant women, children under one year of age, and patients who have weakened immune systems due to AIDS, cancer, or other conditions are especially at risk for adverse side effects. If given this vaccine, people with eczema or skin disorders such as atopic dermatitis may develop eczema vaccinatum, a life-threatening rash. Experts say that the smallpox vaccine can cause encephalitis (which can lead to brain damage) in about 1 in 100,000 recipients and death in about 1 in 1 million recipients.