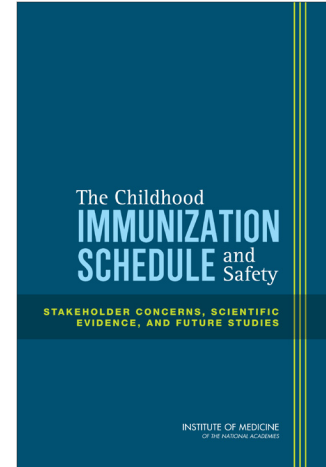


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The Childhood Immunization Schedule and Safety

Stakeholder Concerns, Scientific Evidence, and Future Studies



Vaccines are among the most effective and safe public health interventions to prevent serious disease and death. Because of the success of vaccines, most Americans have no firsthand experience with such devastating illnesses as polio or diphtheria. Widespread immunizations have resulted in a decline in vaccine-preventable diseases.

Health care providers who vaccinate young children follow a schedule prepared by the U.S. Advisory Committee on Immunization Practices (ACIP). The current recommended U.S. childhood immunization schedule is timed to protect children from 14 pathogens by inoculating them at the time in their lives when they are most vulnerable to disease. Under the current schedule, which applies to children younger than 6, children may receive as many as 24 immunizations by their second birthday and may receive up to five injections during a single doctor's visit. Technological advances have reduced the number of antigens—that is, inactivated or dead viruses and bacteria, or altered bacterial toxins that cause disease and infection—in vaccines. New vaccines undergo rigorous testing prior to approval by the Food and Drug Administration (FDA). However, like all medicines and medical interventions, vaccines carry some risk.

Some parents' attitudes toward the childhood immunization schedule have shifted, driven largely by concerns about potential side effects from vaccines. In light of this, the Department of Health and Human Services (HHS) asked the Institute of Medicine (IOM) to identify research approaches, methodologies, and study designs that could address questions about the safety of the current childhood immunization schedule. The IOM committee's report, *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies*, summarizes its findings.

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The Current Schedule

Newly approved vaccines are tested within the context of the existing ACIP-recommended schedule and are reviewed by clinical researchers who weigh the new vaccine's benefits against its possible risks. Before the ACIP recommends adding a new vaccine to the immunization schedule, it reviews comprehensive data about that vaccine's safety and efficacy in clinical trials, injuries and deaths caused by the disease the vaccine is designed to combat, and the feasibility of adding the new vaccine into the existing schedule, among other factors.

Every year, the Centers for Disease Control and Prevention (CDC) issues guidance on immunization use and schedules for children (birth to age 6), adolescents (ages 7 through 18), and adults, based on these ACIP recommendations.

Stakeholder Concerns

In the course of its work, the IOM committee solicited feedback from a diverse group of stakeholders, including researchers; advocacy groups; federal agencies and advisory committees; the general public, including parents; the health care system and providers; international organizations; the media; nongovernmental organizations; philanthropic organizations; and vaccine-related industries, distributors, and private investors.

More than 90 percent of children entering kindergarten have been immunized with most recommended vaccines in accordance with the ACIP-recommended schedule, according to an analysis of U.S. data. Still, parents, providers, and public health officials agree that there has been insufficient communication between providers and parents about vaccine safety concerns.

A number of concerned parents say the schedule is too "crowded" and have requested flexibility, such as delaying one or more immunizations or having fewer shots per visit. Some parents have rejected the vaccines outright, arguing that the potential harm of their child suffering a side effect from the vaccine outweighs the well-documented

benefits of immunizations preventing serious disease. Other parents delay or decline immunizations due to worries that family history, the child's premature birth, or an underlying medical condition may make them more vulnerable to complications. Some simply distrust the federal government's decisions about the safety and benefits of childhood immunizations.

While parents generally worry about children's health and well-being, and their concerns about immunization safety can be viewed in that context, delaying or declining vaccination has led to outbreaks of such vaccine-preventable diseases as measles and whooping cough that may jeopardize public health, particularly for people who are under-immunized or who were never immunized. States with policies that make it easy to exempt children from immunizations were associated with a 90 percent higher incidence of whooping cough in 2011.

No Evidence of Safety Concerns

Upon reviewing stakeholder concerns and scientific literature regarding the entire childhood immunization schedule, the IOM committee finds no evidence that the schedule is unsafe. The committee's review did not reveal an evidence base suggesting that the U.S. childhood immunization schedule is linked to autoimmune diseases, asthma, hypersensitivity, seizures, child developmental disorders, learning or developmental disorders, or attention deficit or disruptive disorders.

Existing mechanisms to detect safety signals—including three major surveillance systems of FDA-approved products maintained by the CDC and a supplemental vaccine safety monitoring initiative by the FDA—provide further confidence that the current childhood immunization schedule is safe.

Despite the reassuring available evidence, the committee calls for continued study of the immunization schedule using existing data systems.

Answering research questions of the most importance to stakeholders could be done through

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a variety of methods. The committee does not endorse conducting a new randomized controlled clinical trial that would compare the health outcomes of unvaccinated children with their fully immunized peers. Although this is the strongest study design type, ethical concerns prohibit this study, as unvaccinated individuals and communities intentionally would be left vulnerable to morbidity and mortality. While stakeholder concerns should be one, but not the only, element that drives continued searches for scientific evidence, the committee writes that these concerns alone, absent epidemiological or biological plausibility of potential safety problems, do not warrant further study.

A new observational study, a complex undertaking that also would require a considerable investment, would be less likely than a randomized controlled clinical trial to conclusively reveal differences in health outcomes between children who are fully immunized and unimmunized children. Fewer than 1 percent of Americans refuse all immunizations. Enrolling sufficient numbers of unvaccinated children and matching them with vaccinated children of the same age, gender, ethnicity, and geographic location—a necessary step to rule out chance findings—would be prohibitively difficult and time-consuming.

The IOM committee finds analysis using existing databases to be the most feasible approach to studying the safety of the childhood immunization schedule. It concludes that the Vaccine Safety Datalink (VSD), a collaborative effort between the CDC and nine managed care organizations

that monitors potentially rare and serious side effects after vaccines are marketed, is the best available system for studying the U.S. immunization schedule. VSD data represent more than 9 million children and adults—roughly 3 percent of the U.S. population—and include medical details, such as the diagnoses and procedures associated with outpatient, inpatient, and urgent care visits. For this reason, the committee concludes that the VSD is currently the best available system for studying the childhood immunization schedule.

The committee notes one potential limitation of the VSD: children who are immunized with alternative vaccination schedules may differ in meaningful ways from children who adhere to the schedule, and these differences could make it difficult to tease out health differences that are attributable to the immunization schedule. In order to bridge such data gaps, the VSD system could be modified to enable new analyses of important questions, participants could be asked additional questions, and medical records could be reviewed. The federal government also should continue to build on this component of its robust vaccine safety net by enhancing the quality of VSD's demographic information and including more diversity in its study populations.

Conclusion

Since the late 1970s, IOM committees have conducted more than 60 studies of vaccine safety, attesting to society's sustained interest in safely



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vaccinating populations from preventable disease. This committee's report is unique in that it is the first to attempt to examine the entire childhood immunization schedule as it exists today.

In this most comprehensive examination of the immunization schedule to date, the IOM committee uncovered no evidence of major safety concerns associated with adherence to the childhood immunization schedule, which should help to reassure a diverse group of stakeholders. Indeed, rather than exposing children to harm, following the complete childhood immunization schedule is strongly associated with reducing vaccine-preventable diseases.

As scientific advances continue and new vaccines are developed, the childhood immunization schedule may grow even more complex. Looking to the future, the IOM supports HHS's efforts to ensure that stakeholders are more fully involved in addressing benefits and concerns regarding the safety of the childhood immunization schedule. 

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