Institute of Medicine report details for monitoring safety of childhood immunization schedule

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A review of the available evidence underscores the safety of the federal childhood immunization schedule, according to a report released today by the Institute of Medicine. University of Michigan population ecologist Pejman Rohani served on the 13-person committee that wrote the report.

Roughly 90 percent of American children receive most childhood vaccines advised by the federal immunization schedule by the time they enter kindergarten, the committee noted. However, some parents choose to spread out their children's immunizations over a different time frame than recommended by the schedule, and a small fraction object to having their children immunized at all.

Their concerns arise in part from the number of doses that children receive. The schedule entails 24 immunizations by age 2, given in amounts ranging from one to five injections during a pediatric visit.

"We reviewed the available data and concur with studies that have repeatedly shown the health benefits associated with the recommended schedule, including fewer illnesses, deaths and hospital stays," said Rohani, a professor of ecology and evolutionary biology, a professor of complex systems and a professor of epidemiology at the School of Public Health.

"Every new vaccine is tested for safety and evaluated in the context of the entire schedule before it is added. And the systems designed to detect possible harmful effects of immunization have worked well at discovering occasional problems with individual vaccines."

Until newer and bigger data collection systems can be harnessed, the Vaccine Safety Datalink (VSD) is the best available tool for exploring questions about the immunization schedule should the need arise, the committee concluded. This database contains information on the immunization histories of more than 9 million people covered by nine participating managed care organizations.

Researchers can identify individuals who were vaccinated according to alternative schedules as well as any diagnoses, medical procedures and outcomes they have experienced. VSD also contains data on race, age, gender and other factors that help researchers do better comparisons and account for factors that might affect participants' health. Already a research team has tapped VSD to explore patterns among children in the Kaiser Permanente Colorado system who are defined as under-vaccinated.

However, VSD tracks people from only eight states and looks at a smaller percentage of low-income and minority people than is in the U.S. population as a whole. Moreover, VSD's usefulness depends on the continuing involvement of participating health plans. The U.S. Department of Health and Human Services and its partners should maintain their commitment to funding VSD and consider bringing in additional health plan members to enhance the data and make it more representative of the full U.S. population, the report states.

Some critics of immunization policies have called for studies comparing health outcomes among vaccinated and unvaccinated children and for research to determine if subgroups exist that are predisposed to

experiencing harmful health effects from the vaccines.

Although randomized controlled trials are the gold standard for clinical research, such a trial cannot be safely and efficiently performed to compare health outcomes among vaccinated and unvaccinated or differently immunized children, the committee concluded. Among other reasons, children placed in the study group that does not receive vaccines in a timely fashion would be exposed to greater risk for contracting illnesses. Many parents who refuse immunization may object to their children being randomly assigned to the group that gets vaccines.

Some people have suggested comparing vaccinated children with children in "naturally occurring" populations of unimmunized individuals, such as certain religious communities. With less than 1 percent of the American population refusing all immunizations, however, it would be very difficult to recruit enough willing unvaccinated participants, the committee concluded.

It can take tens of thousands of study participants to discover uncommon health problems. Moreover, these populations tend to be much less diverse ethnically, racially, socioeconomically and genetically than the general population. Because such factors can influence health, it would be difficult to determine if differences between the study groups are the result of vaccines or these other factors, the committee concluded.

"The costs of conducting this kind of study, or a randomized controlled trial, likely would be prohibitive," Rohani said.

Newer data collection and surveillance systems offer great potential to monitor rare adverse events that may be associated with the childhood immunization schedule, the committee said. When fully implemented, the Sentinel Initiative program being developed by the U.S. Food and Drug Administration to monitor the safety of approved drugs and other

medical products will complement existing passive vaccine surveillance systems, the report says. FDA's new Post-License Rapid Immunization Safety Monitoring Program is amassing a large amount of health data, offering the potential to analyze vaccine exposures and adverse events with a greater degree of statistical power.

More information: The report, "The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies," was sponsored by the U.S. Department of Health and Human Services.

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