CDC Report Stirs Controversy For Merck's Gardasil Vaccine

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A government report released Tuesday raises new questions about the safety of the cervical cancer vaccine Gardasil. The vaccine has been linked to 32 unconfirmed deaths and shows higher incidences of fainting and blood clots than other vaccines.

But while some physicians expressed concern over the findings, other doctors viewed the report as reassuring, showing that the vaccine was not associated with any more unusual and serious side effects as other vaccines.

The results of the report appeared along with an accompanying editorial discussing whether the potential benefit of the HPV vaccine is worth its potential risks in the Journal of the American Medical Association. The editorial, in particular, could give pause to many parents faced with the decision of whether or not to have their 11- and 12-year-old daughters vaccinated against the certain strains of the human papillomavirus, or HPV.

On Wednesday morning, ABC News Chief Medical Editor Dr. Timothy Johnson said that he, too, would encourage parents to learn more about the shot before getting their daughters vaccinated.

"I am very much in favor of childhood vaccines," Johnson told Chris Cuomo on Wednesday's "Good Morning America," adding that there is little doubt that the vaccine does have its benefits.

"We know it does what it says – it prevents HPV infections," he said.

But he added that when it comes to comparing the benefits of the HPV vaccine against its potential risks, he believes there simply is not enough evidence to recommend to all parents that they have their daughters vaccinated.

"I don't think we yet know the long term benefits or risks," Johnson said. "I'm taking a pass on this one and saying to parents, 'Study the issue, read the editorial... talk to your doctor.'"

Those who search for more information on the vaccine may also find stories from other parents who say the vaccine had ill effects on their daughters. One of these parents, Emily Tarsell, started her daughter Christina on Gardasil -- a vaccine that protects against four of the most common cancer-causing strains of the human papilloma virus (HPV) -- after her first visit to a gynecologist and at the doctor's recommendation.

Eighteen days after Christina received her final vaccine shot, she died.

"I know it was the Gardasil," Tarsell said, although the official cause of death was undetermined. "They were really recommending it, saying that there weren't any side effects, that it was safe. So I kind of went against my better instinct [and let her] get the shot."

Deaths like Christina's are one of several types of complications reported to the U.S. Vaccine Adverse Event Reporting System (VAERS) following Gardasil distribution in 2006. Some of these adverse events were serious, including blood clots and neurological disorders, and some were non-life threatening side effects from the vaccine, including fainting, nausea and fever.

Although experts agree that the accuracy of data from VAERS reports -- which can be made by anyone and are not verified or controlled for quality -- is questionable, they remain divided as to whether extreme adverse events, which are serious but rare, are cause enough to stop recommending and administering the Gardasil vaccine without further investigation.

"Although the number of serious adverse events is small and rare, they are real and cannot be overlooked or dismissed without disclosing the possibility to all other possible vaccine recipients," said Dr. Diane Harper, director of the Gynecologic Cancer Prevention Research Group at University of Missouri. "The rate of serious adverse events is greater than the incidence rate of cervical cancer."

As of June 1, 2009, the CDC reported that over 25 million doses of Gardasil, which is recommended for women between ages 9-26, have been distributed in the U.S. and there was an average of 53.9 VAERS reports per 100,000 vaccine doses. Of these, 40 percent occurred on the day of vaccination, and 6.2 percent were serious, including 32 reports of death.

In a statement yesterday from Merck, the pharmaceutical company that manufactures Gardasil, the company backed the vaccine's efficacy and said they encourage further research on its safety.

"We are pleased that the study published by JAMA [yesterday] further reinforces the safety profile of Gardasil," said Dr. Richard M. Haupt, head of the clinical program for Gardasil at Merck. "We welcome continued study and discussion about the safety of this important vaccine."

But some clinicians are not ready to accept wide use of the drug based on the available safety data.

Dr. Jacques Moritz, director of gynecology at St. Luke's-Roosevelt Hospital, said he would not offer the Gardasil vaccine to patients when good cervical cancer screening techniques and treatments exist. He has also chosen not to have his 11-year-old daughter get the HPV shot because of his concerns.

"I'm pro preventing cervical cancer and HPV," Moritz said. "I'm not pro that the physicians don't know the risks and side effects."

But clinicians on both sides of the vaccination debate agree that data provided by the VAERS report is limited because it lacks any baseline comparison for the adverse events reported. This makes it difficult to draw cause and effect relationships when a death, for example, occurs soon after administering the Gardasil vaccine.

In fact, the JAMA study authors showed that 90 percent of those with blood clots had typical risk factors for clots, outside of having received the vaccine -- using oral contraceptives, for example, or smoking.

"The problem is that there is a difference between an adverse reaction caused by the vaccine, as opposed to an adverse event reported in association with the vaccine," said Dr. Lauren Streicher, an obstetrician-gynecologist at Northwestern Medical School, who supports use of the vaccine. "Patients need to understand the true risk of the vaccine, as well as the risks of not getting the vaccine."

The overwhelming consensus regarding Gardasil use is that physicians who are not well versed in the risks of HPV and cervical cancer and the side effects of the vaccine cannot adequately counsel patients whether or not to be vaccinated.

Dr. Joseph Zanga, chief of pediatrics at the Columbus Regional Healthcare System in Columbus, Ga., pointed out that Gardasil does not prevent women from contracting HPV in every instance, that many people who are infected will spontaneously rid themselves of the virus, and that routine pap smears are still the best prevention against cervical cancer.

"Perhaps the most important, currently missing 'warning' is that the vaccine may not be forever," Zanga said. "We know that it protects for 5-7 years so that a girl getting the series at [age] 11-12 will enter the time of her most likely sexual debut unprotected but believing herself to be."

Dr. L. Stewart Massad, the Practice and Ethics Committees chair for the American Society for Colposcopy and Cervical Pathology, said his organization has educated thousands of clinicians about the risks of HPV and the Gardasil vaccine.

"We based our education [program] criteria on data from the CDC's risk assessment," he said. "Certainly there are differences of opinion when it comes to how adverse events are, you have to balance the risk for each patient."

Massad also noted that the ASCCP was unable to secure government or other non-profit funding for education outreach programs when the vaccine was first introduced and turned instead to private companies, including Merck, which manufactures Gardasil.

Harper said that the next step in determining the severity of the risks associated with the Gardasil vaccine would be for the CDC to investigate the reported adverse events and verify a causal relationship. But this may prove a difficult task, she said, because many of those events were reported by Merck and did not include sufficient information to perform an investigation.

Still, the report is unlikely to prevent most doctors from continuing to provide the vaccine to patients.

"There are 772 serious problems identified in 23 million doses of vaccine," said Dr. Kevin Ault, associate professor of Gynecology and Obstetrics at Emory University. "I usually tell my patients that these serious events are tragic, rare and likely unrelated to the vaccine."

ABC News' Tyeese Gaines-Reid contributed to this report.