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Two Studies and a Commentary Reinforce the Safety of the 9-Valent Human Papillomavirus Vaccine

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Since 2014, the 9-valent human papillomavirus (HPV) vaccine has been approved for females and males ages 9 to 26 years. Despite this, some families are concerned about the safety of this cancer-preventing vaccine. To address these concerns, two independent vaccine safety studies are being published this week that underscore the safety of HPV vaccination. The first study, by Shimabukoro et al (10.1542/peds.2019-1791), reviewed the National Vaccine Adverse Event Reporting System (VAERS) from 2014 to 2017 to determine the frequency of serious reported events. During the study period, 7,244 reports about HPV vaccination were received, of which 97.4% were defined as non-serious, including syncope, headache, dizziness, and soreness or redness in the injection site. These reports were similar for males and females. The two most common reasons for reporting a result were syncope, a previously known as safety concern, and giving an incorrect dose. The authors also note two reports of death, but autopsy information and/or death certificates did not establish any link suggestive of causality. The authors conclude that the safety profile seen was no different than what had been reported in pre-licensure trials and resembled quite closely the same post-marketing safety data of the 4-valent vaccine that preceded the 9-valent version.

Independently, Donahue et al (10.1542/peds.2019-1808) looked at real-time safety surveillance for the first two years after the 9-valent vaccine became licensed using the Vaccine Safety Datalink, which surveys practices for vaccine safety events. The authors looked at data collected at six Vaccine Datalink sites for a series of pre-specified adverse events ranging from anaphylaxis to venous thromboembolism. Observed events were compared to those expected from prior pre-licensure data and if the rate of observed events were higher than expected, medical records were reviewed to better understand what had transpired. The authors found 4 unexpected increases during 105 weeks of surveillance (2015-2017), representing over 838,991 doses of vaccine: appendicitis in males after the third dose, pancreatitis in older teens and young adults, and allergic reactions in both younger and older teen females after the second dose. Record review

and temporal analysis did not confirm that these events were causally related to the vaccine. Thus again, no new or unexpected safety concerns were noted.

So why are these two studies of importance since we knew the vaccine had a strong safety profile leading to licensure? We asked Dr. Cody Meissner, specialist in pediatric infectious diseases to weigh in with an accompanying commentary (10.1542/peds.2019-2345). He takes us on a historical journey reminding us of how the HPV vaccine came into being, the significant role it plays in reducing cervical and other cancer incidence, and that these two studies with the large number of vaccinations administered showing no major safety concerns (i.e. 28 million in the Shimabukuro et al. study and >830,000 in the Donahue et al study) should put to rest any concerns about this vaccine other than to make sure every teen receives it, ideally before they become sexually active to insure highest efficacy. Give both these studies and commentary your best shot, and don't hesitate to share what you learn with teens or their parents who may still be hesitant to agree to the vaccine. It is yet another great story of how vaccines are one of the most effective and safest contributions to public health and wellbeing of the past two centuries.

- HPV Vaccine Delivery Practices by Primary Care Physicians
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