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Lying Down for Vaccinations

In this era of increased hesitancy about immunization, it's important for us to be as educated as possible about the vaccines we're giving—including their true possible adverse effects—and to be willing to share that information with our patients and their families.

There's been a lot of press lately about adverse effects associated with the four-valent human papillomavirus vaccine (HPV4, Gardasil). Some of these reports are accurate, but many are not. Practitioners are better prepared to talk to families about this and other vaccines if they are well informed themselves.

To date, more than 20 million doses of HPV4 vaccine have been administered. Between June 30, 2006, and August 31, 2008, a total of 10,346 adverse events following receipt of HPV4 vaccine were reported to the Vaccine Adverse Events Reporting System (VAERS). The number sounds high, but if you do the math, this is much less than 1% and the vast majority are nonserious events.

There have been 27 reported deaths from a variety of causes including acute myocarditis, influenza B, pulmonary embolism, drug overdose, and diabetic ketoacidosis. To date, no clustering by age group, onset interval, dose number, or clinical conditions has been noted that preceded or caused death.

Dizziness and syncopal events associated with HPV4 immunization are among the events that practitioners should be aware of. The fact that fainting is associated with a medical event is not surprising because most vasovagal events follow some type of trigger, such as the sight of blood or some other type of emotionally stressful event.

Fainting events are most often noted in adolescents and young adults. One study that looked at a medical student population found that 3% of men and 3.5% of women had experienced a vasovagal event in the past. It would not be surprising then that fainting following vaccination occurs, particularly among adolescents and young adults.

There is no clear evidence that fainting is more common following HPV4 vaccine than any other vaccine.

Indeed, an increase in syncope reported to VAERS between 2005 and 2007 coincided with the licensure and recommendation of other vaccines often given during adolescence, including meningococcal conjugate vaccine (MCV4) and the adolescent/adult version of the tetanus/diphtheria/acellular pertussis vaccine (Tdap), in addition to the HPV4 vaccine.

Although HPV4 vaccine was the most frequently reported vaccine associated with syncope when only one vaccine was given (52%), that is likely due to the fact that three doses of this vaccine are given (as opposed to one each for MCV4 and Tdap), as well as to the increased publicity and media attention surrounding HPV4 vaccine.

A subsequent active surveillance evaluation done by the Centers for Disease Control and Prevention using the Vaccine Safety Datalink (VSD) derived from managed care data for 3% of the U.S. population did not detect a "safety signal" for syncope among 377,960 administered doses of HPV4 vaccine.

How should practitioners use this information? Ask your patients *before* immunization or blood draw if they have ever fainted. If they have, ask if they experienced a particular prodrome. Individuals who have had syncopal episodes usually have an excellent idea of what prodromal symptoms to expect. Most can articulate the warning signs pretty well, describing visual disturbances, buzzing in the ears, lightheadedness, sweating, and nausea.

Importantly, one can prevent virtually 100% of these episodes by having patients lie down and elevate their legs while they receive the injection.

Emergency departments have learned these lessons well and routinely advise against letting parents stand while watching their children being sutured, or letting patients stand for venipunctures.

Even for patients who have never had a syncopal event, having them sit or lie down in your office for 15 minutes after receiving the vaccine is recommended.

The CDC's Advisory Committee on Immunization Practices in 2006 recommended that all recipients of all vaccines be observed for 15 minutes after vaccination (MMWR 2006;55[RR15]:1-48), although HPV4 vaccine is the only one to also contain the 15-minute wait recommendation in its package label, per the Food and Drug Administration.

Ask your patients *before* immunization or blood draw if they have ever fainted. If they have, ask if they experienced a particular prodrome.

The timing recommendation comes from analysis of 41 syncope reports following immunization during January 2005-July 2007 where secondary injuries occurred. The time from vaccination to syncope onset was less than 5 minutes in 49% and less than 15 minutes in 80% of the reports.

The 15-minute waiting period is intended to prevent serious injury associated with falling due to the vasovagal event, which has been linked to at least one documented death.

The CDC is now beginning a survey of providers to assess their attitudes about and adherence to this recommendation.

The bottom line: HPV4 appears safe and effective. Fainting can occur with any vaccine, but be particularly alert to this in the teenage population. It can be averted in those who are known to be prone to vasovagal events by having the patient lie down for blood draws and shots. It is expected that most injuries can be avoided with the use of a waiting period following vaccine receipt. ■

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