

Should HPV vaccination be mandatory?

Should we force drug therapy because patients might get the disease based on future behavior?

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The news that Merck & Co. had developed a new quadrivalent vaccine (Gardasil) that was effective in targeting strains of human papillomavirus (HPV) that account for about 70% of today's cervical cancers prompted many state legislators to run to the microphone and push for mandatory vaccination of our 9-year-old daughters. Indeed, the governor of Texas unilaterally mandated the vaccine for school-age girls.* Yet, were they acting in the public's best interests or pushing an agenda?

As clinicians, we know that a person is likely to either be infected or exposed to more than one subtype of the sexually transmitted form of the HPV virus. The Gardasil vaccine however, suppresses only a few specific HPV types. (This is also the case with Cervarix, a bivalent vaccine that GlaxoSmithKline is seeking regulatory approval for.) Hence, those subtypes not suppressed will obtain an evolutionary advantage. They will become more prevalent and dominant, though the vaccine will have no effect on them.

Additionally, according to the data presented to the FDA (and which I have reviewed), it is clear that:¹

- 1) there is no evidence that Merck's vaccine works after 5 years.

* At press time, efforts were underway to overturn the governor's executive order.

- 2) two-thirds of those who had received the vaccine suffered from moderate to severe pain at the site of injection.
- 3) we do not know whether this vaccine will cause autoimmune and neurological problems, ie seizures, in the long term.
- 4) the risk for pelvic inflammatory disease, appendicitis, and gastroenteritis is at least doubled.
- 5) the vaccine has not been adequately tested in girls under age 16. (While the efficacy of the vaccine was assessed in 4 placebo-controlled phase II and III clinical studies, which evaluated women between the ages of 16 and 26 only, those under age 16 were excluded.)

Also disturbing: The researchers' choice of placebo. The placebo was not necessarily an innocuous vehicle such as normal saline, but one containing aluminum that is well known for its neurotoxicity. This would suggest that the actual and potential toxicity of the vaccine is probably higher than we think.

Is it ethical?

Mandatory vaccination also raises ethical issues. Under current proposals, we are talking about forcing people to un-

FAST TRACK

Unlike vaccination against mumps, measles, and rubella, we can't hope to nearly eradicate the disease

FAST TRACK**Vaccination costs \$360 a child and we don't know if booster shots will be needed**

dergo mandatory drug therapy (vaccination), when they have no disease, under the presumption that they might get a disease based on future behavior. This is medically unethical.

One might argue that we do have, as public policy, mandatory vaccinations for some infectious disorders such as mumps, measles, and rubella. This is true, in part under the idea of herd immunity, that is, if 97% to 98% of a population is immunized against a disease, the disease may be nearly eradicated. That argument, however, doesn't hold in this case, as the HPV vaccine is an incomplete vaccine. Also, let's not forget that men, who are not being asked to receive the vaccine, make up half of those infected with HPV. Thus, herd immunity will not develop.

Cost is a consideration

Let's not overlook the financial implications of mandatory vaccination. The vaccine costs \$120 a dose and must be administered three times, for a total cost of \$360 a child. Now multiply this times every school age child in the country; this translates into billions of dollars. Add to that the fact that the vaccine may not be effective in the long term. So will booster shots at \$120 be required?

All of this does not negate that the HPV vaccine does have value. We should, however, approach the idea of mandatory vaccination with caution.

Disclosure

No potential conflict of interest relevant to this article was reported.

The opinions and assertions contained herein are the private views of the author and not to be construed as official, or as reflecting the views of the National Institute of Diabetes, Digestive and Kidney Diseases, or the National Institutes of Health.

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1. Product approval information—licensing action, Gardasil. US Food and Drug Administration Web site. Available at: fda.gov/cber/label/hpvmr060806.htm. Accessed on March 8, 2007.

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