

# 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.

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. □

#### FAST TRACK

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

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

## IS IT ETHICAL?

Mandatory vaccination also raises ethical issues. Under current proposals, we are talking about forcing people to undergo 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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**Revista presei medicale  
românești și internaționale**

### Exercise on par with drugs for aiding depression

AMY NORTON

NEW YORK (Reuters Health) – Regular exercise may work as well as medication in improving symptoms of major depression, researchers have found.

In a study of 202 depressed adults, investigators found that those who went through group-based exercise therapy did as well as those treated with an antidepressant drug. A third

group that performed home-based exercise also improved, though to a lesser degree. Importantly, the researchers found, all three groups did better than a fourth group given a placebo – an inactive pill identical to the antidepressant. While past studies have suggested that exercise can ease depression symptoms, a criticism has

been that the research failed to compare exercise with a placebo. This leaves a question as to whether the therapy, per se, was responsible for the benefit.

The new findings bolster evidence that exercise does have a real effect on depression, according to the researchers.

Doctors may not start widely prescribing exercise as a depression

treatment just yet. But for patients who are motivated to try exercise, it could be a reasonable option, the study authors say.

"If exercise were a drug, I'm not sure that it would receive FDA approval at this time," noted study author Dr. James A. Blumenthal, a professor of medical psychology at Duke University Medical Center in Durham, North Carolina.

"But," he told Reuters Health, "there is certainly growing evidence that exercise may be a viable alternative to medication, at least among those patients who are receptive to exercise as a potential treatment for their depression."

The study, published in the journal *Psychosomatic Medicine*, included 202 men and women age 40 and older who were diagnosed with major depression. They were randomly assign-

ned to one of four groups: one that worked out in a supervised, group setting three times per week; one that exercised at home; one that took the antidepressant sertraline (Zoloft); and one that took placebo pills.

After 16 weeks, the patients completed standard measures of depression symptoms.

By the end of the study, Blumenthal's team found, 47 percent of patients on the antidepressant no longer met the criteria for major depression. The same was true of 45 percent of those in the supervised exercise group.

In the home-based exercise group, 40 percent had their symptoms go into remission. That compared with 31 percent of the placebo group.

There are several theories on why exercise might improve depression. For example, physical activity seems to affect some key nervous system

chemicals – norepinephrine and serotonin – that are targets of antidepressant drugs, as well as brain neurotrophins, which help protect nerve cells from injury and transmit signals in brain regions related to mood.

Exercise may also boost people's feelings of self-efficacy and promote positive thinking. Some experts speculate that group exercise, with its social aspect, may have added benefits.

Though the home exercise group in this study did better than the placebo group, it's not clear whether it's as good as supervised classes, according to Blumenthal. "Home exercise may be more convenient," he noted, "but patients not push themselves as hard on their own."

He added that supervised exercise may also be safer for some people, such as those with heart disease.

Source: *Psychosomatic Medicine*, September 2007.

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