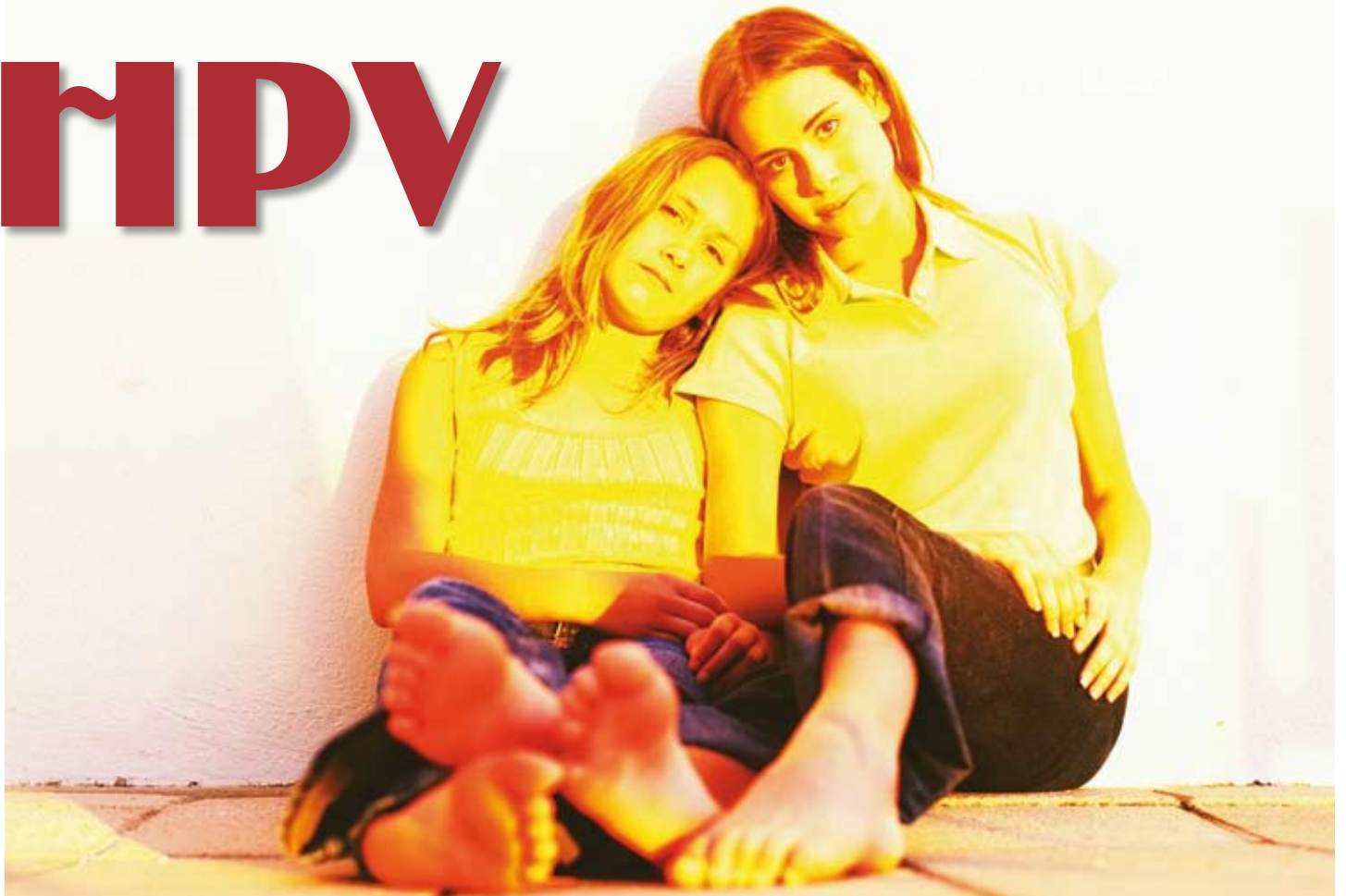


HPV



– Cervical Cancer Vaccine

By Suzanne Nelson

The stupidity of Western medicine's 'one size fits all' medical policy becomes self-evident when we consider the fact that infants and children will be targeted with this untested and unproven vaccine to prevent a sexually-transmitted disease.

How many vaccines is too many?

In October the Joint Committee on Vaccination and Immunisation is set to determine whether pre-adolescent girls in the U.K. will receive a vaccine for a sexually transmitted disease at primary school.

The vaccine, Gardasil, marketed by Sanofi Pasteur MSD, was approved for use in women by British authorities in July, and by the end of the year GlaxoSmithKline's version, Cervarix, is likely to be available. Both target human papillomavirus (HPV), a virus transmitted exclusively by sexual contact that in rare cases leads to cervical cancer.

Paralleling a similar debate in the United States, much of the controversy about putting the vaccine on the childhood schedule has been about whether doing so will give youngsters a false sense of safety and lure them into promiscuous sex.

Yet in the process of engaging that discussion, we're not talking about whether giving the vaccine to pre-adolescent girls makes sense in terms of their overall health, the long-term safety of the vaccine or whether it should be given in school – all subjects much more controversial than news coverage would have you believe.

HPV is not a virus a kid catches by sitting next to someone at school. It is not spread by sharing juice boxes or trading germs

on the bus. That makes this vaccine completely different from the 10 others on the U.K.'s childhood vaccination schedule.

This vaccine aims to protect people from a virus that is basically only transmitted when a person engages in what amounts to optional behaviour. HPV is not a public health threat in the same way, say, polio or measles are. And that gives governments much less of a compelling interest to mandate that children be vaccinated for it.

Let's put aside for the purposes of discussion the bizarrely controversial notion that parents should be able to decide what enters their children's body via injection, especially when that shot carries the risk of harm or death.

HPV does not lurk in the air, in swimming pools or on playground equipment. That makes the vaccine's public health credentials dubious at best.

Yes, 3,000 women in the U.K. contract cervical cancer every year, and a third of them die. But just having HPV doesn't mean you're going to get cancer. The U.S. Food and Drug Administration said as much in its press release announcing the approval of Gardasil: "For most women, the body's own defense system will clear the virus and infected women do not develop related health problems."

Estimates of the number of people with HPV vary wildly, but perhaps up to 80% of women in the United States, for example, are infected with HPV at one time or another before they are 50. Yet given that high incidence, the number of women who develop cervical cancer in the U.S. is pretty low, about 10,000 cases each year. Pap smears usually catch abnormal cells before cancer has

Clinical trial investigators dismissed most of the 102 serious adverse events including 17 deaths that occurred in the clinical trials as unrelated to the study.

in the U.K. die of cervical cancer every year, and there is thus an urgent public-health need to vaccinate every adolescent girl – without mentioning that many if not most of those women did not have regular screenings – is somewhat disingenuous.

But even if the vaccine proves to be successful at reducing overall HPV infection, and the reduced number of HPV infections lead to a correlating decline in cervical cancer cases – both are still huge assumptions at this point, as the vaccine hasn't been studied nearly long enough to determine that – some parents still may not want to give it to their daughters.

For starters, it could cause harm. All vaccines carry the risk of injury or death. During trials, 9 individuals developed arthritis after receiving the vaccine versus 3 for the placebo, out of approximately 21,000 individuals in that trial. Nine kids with arthritis after receiving the vaccine might not seem like a big deal in the grand scheme of things. After all, arthritis is better than cancer, right? That depends.

Given the fact that cervical cancer is relatively rare, highly preventable and most often successfully treated early on, maybe the risk of arthritis – a painful and often debilitating disease – isn't a worthwhile trade-off.

And maybe we won't know the true incidence of harmful effects until the vaccine is given to millions, rather than thousands, of children and young adults.

Moreover, the whole concept of a placebo was turned on its head during the trials, preventing any valid comparison between those who were given a placebo and those who received the vaccine.

In order to learn the truth about an unknown, honest science dictates that we have to compare it to a known. When most people think about a vaccine placebo, they are probably thinking about saline. But that's not what was used during these trials.

The 'placebo' in this case was an aluminium-containing shot. The vaccine itself also contains aluminium.

Aluminium hydroxide is what's known as an adjuvant – it stimulates immune response. Studies in both animals and humans have found that aluminium adjuvants can cause death of brain cells. Similar studies have also shown that aluminium adjuvants in vaccines can cross the blood-brain barrier, as well as cause injection-site inflammation leading to chronic joint and muscle pain and fatigue.

Aluminium adjuvants have never been subjected to clinical trials for safety. Read that again: Although the metal has been used in vaccines for decades, it has never been rigorously studied for long-term safety.

If this vaccine turns out to have safety issues are we even going to know? Or will it remain on the childhood vaccinations schedule long after many girls suffer serious side-effects or worse?

progressed, when women are treated with extraordinarily high rates of success.

The greatest risk factor for cervical cancer is not being screened or being screened at intervals greater than 5 years.

That's not to say that it's not painful or tragic for thousands of women, but it's nonetheless relatively rare. There's a reason that just about every prediction about a reduction in cervical cancer due to the HPV vaccine is reported as a worldwide statistic. The numbers in the U.K. are just not that high as a percentage of the population. The same is true in the U.S., where cervical cancer is listed as a rare disease by the National Institutes of Health.

Most women who develop invasive cervical cancer have not had regular pap smears. So to say that because 1,000 women

So perhaps the 1 case of lupus and 2 cases of arthritis out of 9,701 participants who received the 'placebo' were not just statistical anomalies. Maybe it was the aluminium. Perhaps that would also explain the 1 case of juvenile arthritis, 2 cases of rheumatoid arthritis, 5 cases of arthritis and 1 case of reactive arthritis in 11,813 Gardasil recipients. We'll never know. (Some of the trial participants did, in fact, receive straight saline but there's no way to tell from the data released which cases are which.)

More importantly, a reactive placebo artificially decreases the appearance of danger of an experimental vaccine in a clinical trial because the drug company only has to prove that adverse events weren't statistically significant in the vaccine group versus the placebo group. So using aluminium-containing placebos falsely inflates the adverse-event data of the 'placebo' group, making the vaccine look relatively safe by comparison.

Gardasil contains 225 mcg of aluminium. Neither Merck nor the U.S. FDA would answer my questions as to how much aluminium was used in the placebo. (Sanofi Pasteur MSD is marketing the vaccine in Europe and is a joint venture of French company Sanofi Pasteur and U.S. pharmaceutical company Merck.)

Clinical trial investigators dismissed most of the 102 serious adverse events including 17 deaths that occurred in the clinical trials as unrelated to the study. But given the reactivity profile of aluminium, can we really say that for sure?

Nearly 90% of all Gardasil recipients and 85% of those who received the 'placebo' reported one or more adverse events within 15 days of vaccination. Pain and swelling at the site of injection affected approximately 83% of Gardasil recipients and 73% of those who received the aluminium placebo. About 60% of those who received either the vaccine or the placebo had systemic adverse events including headache, fever, nausea, dizziness, vomiting, diarrhoea and myalgia. Those who received the vaccine reported even more serious adverse events such as gastroenteritis, appendicitis, pelvic inflammatory disease, asthma, bronchospasm and arthritis.

In a never before done study, scientists recently found a link between aluminium in vaccines and symptoms associated with Parkinson's, amyotrophic lateral sclerosis (ALS, or Lou Gehrig's disease) and Alzheimer's.

"This is suspicious," neuroscientist Chris Shaw told the *Georgia Straight*, Canada's largest urban weekly. "Either this [link] is known by industry and it was never made public, or industry was never made to do these studies by Health Canada. I'm not sure which is scarier."

Shaw said there could be 10,000 studies showing aluminium hydroxide is safe to be injected, but that he hasn't been able to find one study that looked beyond the first few weeks of injection. The reason this is significant, according to Shaw, is that neurological damage can take years to manifest.

"There is absolutely no evidence that the vaccine prevents anything when administered at this young age... Vaccinating these children against HPV with a vaccine that is of unknown duration of efficacy will only postpone their exposure to an age which they are less likely [to] clear the infection on their own and be subject to more severe disease."

**– Dr Clayton Young
(obstetrician gynaecologist)**

Indeed, this is what we see time and again in vaccine studies. Either the placebo itself contains aluminium, which doesn't allow us to learn much about the reactivity profile of the experimental vaccine, or the participants are only monitored for safety issues for a small frame of time, or as in the case of Gardasil, both.

What Shaw and his colleagues found was neuron death. That's no small thing, as it's implicated in hundreds of medical conditions. If someone has a controlled, long-term study that shows aluminium hydroxide is safe, he said, please "put it on the table. That's how you do science."

Participants in the Gardasil studies were monitored for, at most, 4 years and many for a considerably shorter time frame. The largest trial is scheduled to be ended early and the people who were given a placebo now will be given the vaccine, meaning it's no longer possible to study long-term differences in health between those who received the vaccine and those who received the placebo.

In terms of long-term safety, one sentence in the FDA's insert is particularly revealing. "Gardasil has not been evaluated for the potential to cause carcinogenicity or genotoxicity," according to the insert. Yes, carcinogenicity means the ability to cause cancer. It's also not known whether the vaccine can cause chromosomal damage. We don't know because researchers didn't look. The trials were not set up to examine that question.

The vaccine is approved for use in girls as young as 9. The rationale for doing so is that the vaccine is only effective prior to exposure to HPV and actually leads to increased risk of precursors to cervical cancer in those previously infected, so it's best to catch girls as early as possible. Yet only 100 9-year-olds received Gardasil in trials, adding to the unknowns about administering a vaccine on still developing bodies. Those children have only been followed for 18 months.

If this vaccine turns out to have safety issues are we even going to know? Or will it remain on the childhood vaccinations schedule long after many girls suffer serious side effects or worse?

Even more terrifying is the idea – being put forth by some HPV vaccine proponents – of giving the vaccine to toddlers so as to weaken the possible connection between a vaccine for a

sexually transmitted disease and 'promiscuous' behaviour by youngsters.

Dr Anne Szarewski, a consultant for Cancer Research UK who worked on the vaccine trials, told *The Telegraph* that giving the shot to young children was a good idea, provided that its efficacy could be proved to last into adulthood.

"There is an argument to giving it to toddlers, because you get away from any links between sexual activity and the whole ethical question that it poses," Szarewski said.

Even entertaining the idea of giving the vaccine to 2- and 4-year-olds is ludicrous at this stage given that the trials have thus far lasted well short of a decade, and we have no idea how a toddler's immune system would cope.

We do know generally that vaccines stimulate qualitatively inferior immunity than natural exposure, and for this reason most vaccines are "boosted" periodically during childhood or adolescence. Naturally acquired immunity lasts much longer, perhaps even a lifetime. The vast, vast majority of people who contract HPV pass the virus without symptoms.

Even if we're talking about vaccinating 9- to 12-year-olds, we still have no reason to believe at this point that the duration of immunity would last that long or until their first sexual encounter.

Dr Clayton Young, a board-certified obstetrician gynaecologist in Texas, outlined his objections this way: "Vaccinating these children against HPV with a vaccine that is of unknown duration of efficacy will only postpone their exposure to an age at which they are less likely [to] clear the infection on their own and be subject to more severe disease.

"The study of the vaccine in children and adolescents is limited to only measuring the development of antibodies to the HPV subtypes in the vaccine," Young continued. "There is absolutely no evidence that the vaccine prevents anything when administered at this young age. Merck expects you to extrapolate their adult data to the immune response in children. If they were really interested in vaccine efficacy in children, should it not be studied properly in children?"

Sanofi Pasteur and Merck have an enormous amount at stake in the universal administration of the shots. A place on the childhood vaccination schedule means a steady and exponentially larger revenue stream. Financial analysts predict Gardasil could be Merck's most important pipeline contributor to top-line growth, with peak sales of at least \$2 billion – revenue Merck badly needs after the Vioxx scandals. That revenue figure assumes that Gardasil will be required for school admittance.

"It's a stockholder's dream," said Barbara Loe Fisher, president of the NVIC, a U.S. non-profit organisation that promotes the right to informed consent on vaccine decisions. Fisher sat on the F.D.A.'s committee that reviews vaccines in 2001, when the vaccine underwent early reviews.

Fisher went on to explain that Merck did not reveal in public documents exactly how many 9- to 15-year-old girls were in the clinical trials and how many of them had serious adverse events after being injected with Gardasil or the aluminium-containing placebo. "For example, if there were fewer than 1,000 little girls actually injected with three doses of Gardasil, it is important to

know how many had serious adverse events and how long they were followed for chronic health problems, such as juvenile arthritis.

"This has nothing to do with kids and whether they are going to have sex," Fisher added. "It has to do with whether they are going to be set up for chronic inflammatory disease" from yet another vaccine being added to the litany of those they already receive. "I would want more data on long-term effects of autoimmunity on certain genotypes," she said in an interview, "and whether this vaccine is going to harm far more girls than it is going to protect."

Dr Jacqueline Laing, a specialist in medical ethics at London Metropolitan University, was equally as critical: "Diseases associated with promiscuity will never be eradicated by universal state vaccination," she told *The Telegraph*. "The interests of the vaccine manufacturers should not take precedence over the rights and safety of children." ■

Suzanne Nelson is a freelance journalist and writer living in New Orleans. She spent five years covering the U.S. Congress for Roll Call Newspaper in Washington, D.C., and now focuses on subjects pertaining to health. She also maintains a health blog at: honesthuman.com

