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Column

Don't rush your vaccines

The ethical debate about a vaccine for a sexually transmitted disease has been premature, says Apoorva Mandavilli; we don't even know how well it works.

Apoorva Mandavilli

Here's a good lesson: before you start pushing for a controversial vaccine to be made compulsory, best wait for the research — and I mean all the research — to come up with results.

For more than a year, we've been hearing that there is a vaccine that is 100% safe and effective in protecting young girls and women from the deadly viruses that cause cervical cancer.

Merck's Gardasil, a vaccine against human papilloma virus (HPV), has been hailed as perhaps the biggest boon for women since the contraceptive pill. Across the world, including many American states, politicians and activists have proposed laws to make Gardasil mandatory for girls in their early teens or younger. Australia has already started a national programme of free vaccines for young girls.

All that sounds a bit premature — and rightly so. As we find out more about this vaccine, including new studies in last week's New England Journal of Medicine[1,2], it's clear we simply don't know enough about it to be giving it to young girls en masse.

It's not that I think vaccinating young girls will encourage them to become promiscuous, as some conservative groups have argued. And I'm not going to question Merck's motives in pushing this vaccine because, well, what else do we expect pharmaceutical companies to do with their products?

I'm also not contesting that the vaccine is great at what it sets out to do: in trials, it was nearly 100% effective at preventing infection with the two strains of HPV (16 and 18), which cause about 70% of cervical cancers. It also seems to protect from two other strains that cause genital warts.

But that's not all we need to know.

Good for the young?

For example, because the initial trials tested the vaccine in women aged 16-26 over five years, we don't know for sure that the vaccine is effective in girls younger than 16, nor whether its effect — and safety — will last longer than five years (see 'Controversy over cervical cancer vaccine spurs safety surveillance ').

Another important piece of fine print: the vaccine is most effective before women are sexually active.

When scientists tested the vaccine in more than 18,000 women in two further trials, most of whom were already sexually active, the vaccine's effectiveness fell to less than 20% — a modest protection at best[1,2].

That's at least partly because some of those women were already infected with the virus strains that the vaccine is designed against. It might also be because the vaccine, by blocking four strains, allows other strains to flourish — which could negate the vaccine's benefit.

When we don't know the answers to so many questions, why are we in such a rush to make the jabs mandatory?

Good for the rich

Let's leave aside for the moment that only a fraction of cervical cancer cases in the world occur in countries where the debate is ongoing (that is developed nations), thanks in part to Pap smears, which can detect pre-cancerous conditions before they develop into full-blown cervical cancer. More than 80% of cervical cancer cases — expected to increase to 90% by 2020 — are in developing countries, which can't afford the pricey jab or the pap smear.

At the moment, the vaccine costs US$360 for the three required doses. Having governments provide the vaccine for free to millions of women and girls would add up to an enormous amount. That money might be better spent providing Pap smears to the women who can't afford them or at least diverted to more urgent health needs.

In the meantime, I do think the vaccine should be given — but with caution and perhaps only in girls and women who we know are not yet infected with two deadliest strains. Merck and GlaxoSmithKline, which also has a HPV vaccine in the works, are working on adding more of 20 known strains to their vaccines. Merck is also tracking Gardasil's long-term effects in the 40,000 women who have received it.

To be fair, the latest studies have only tracked three years of data, and after a longer follow up the vaccine might well prove to be worth all the hype. Then again, it might not. But until we have enough information to decide, let's admit we just don't know.

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References

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2. The FUTURE II Study Group. N. Engl. J. Med., 356 . 1928 - 1943 (2007).