

## Human Papillomavirus, *Gardasil* and Vaccination Programmes

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When the news broke early in 2007 that a new vaccine (*Gardasil*) was available that would protect young girls from the effects of the human papillomavirus (HPV), the CCBI issued a press report outlining our objections to the way in which this vaccine was being promoted. In the US, some states had urged mandatory vaccination for girls from Grade 6 onwards. The main reason given was that HPV has been shown to be one of the causes of cervical cancer in women.

More recently, in Canada the provincial governments of Nova Scotia, Newfoundland and Ontario have advocated and made provisions for the administration of this vaccination through schools for the same age groups (in Ontario from Grade 8), although it is made clear that parents have the right to opt out. There are, however, several ethical questions to be raised about this vaccine and its use.

### Our primary message is that sexual intercourse is for marriage

The CCBI objects to a mandatory or mass approach to such vaccination. If there are no other ways to prevent children (and in Grade 6, we are talking about children) and adults from contracting a specific disease, then vaccination is clearly a good action. If, on the other hand, a disease is preventable by some other means, surely it makes sense to employ those means? This virus is contracted as a result of sexual intercourse. If young (or older) people are not sexually active, they will not contract it. Prevention of the virus, therefore, is possible by means other than vaccination.

Catholic teaching recognizes and has long taught that the gift of sexual intercourse belongs to the covenanted relationship of marriage. This teaching is perennial, in terms of being faithful to the Lord's commands. It is important that young people should be educated about sexuality and sex, as well as learning about HPV, and all other sexually transmitted diseases. They should be made aware of everything that is possibly involved in so-called "casual" or "recreational" sexual activity. It is not a sport, but an activity that demands thought and care.

Yes, some people will say this is idealistic, and that young people are going to go ahead and "have" sex, regardless of the consequences. According to that view, society should protect them as far as possible from every possible transmission of

disease. With all the stress currently placed on autonomy, it is surprising that such a view would be easily accepted. Wouldn't a wiser course of action be to encourage children to become mature, to develop as individuals, to think about their future careers, to learn how to "be" with members of the opposite sex, without expectations that they will necessarily be sexually active? Of course it is known that some young people in these grades *are* sexually active, but I doubt that parents actually agree that that's a good thing, and that, as long as they are protected against any consequences of their actions, they should go right ahead.

### Educate for responsible sexual behaviour

The awareness we have today of all the potential dangers involved in premature sexual activity should be leading parents not only to educate their children about sex, but also to teach them to say "no" at these young ages and stages. Young people are not as knowledgeable as they (or we) think they are. Anyone who is involved in a sexual relationship should be old enough to accept responsibility for what is going on, and to know all the possible consequences of sexual activity, including the possibility of pregnancy. Responsibility for one's actions in turn belies the need for mandatory vaccination, and leaves the responsibility where it should be – with the individual concerned, or, in the case of underage children, with the parent who perhaps sees that the child needs to be protected, almost against himself/herself.

If a parent knows that an older daughter is sexually active, it would perhaps make sense to talk to her about vaccination, to try to prevent the consequences, should the girl contract this particular virus. But the parent has the primary obligation of telling her daughter that she is putting herself at risk physically, emotionally and psychologically through her premature sexual activity, and that she should stop. Part of our current problem in society is that we do not stress looking at long-term consequences of our actions. Satisfaction of "needs" and "desires" seems to trump the consideration of looking at possible long-term results. It is difficult to do that, and young people need help and guidance to do so; yet it has to be developed at some point. Why not at these times?

### Appearance of condoning early sexual activity

In our press release, we said that a socially condoned, mass approach to vaccination gives a message that early sexual intercourse is allowed, as long as one is "protected". This societal message also implies that young people are not capable of making decisions for themselves: in other words, society is really saying they are too young to make good decisions. If this

is the case, then these young people most definitely should NOT be contemplating sexual intercourse!

There is a need for consistency here. If young people need to be protected from the consequences of their own behaviour, would it not make more sense to encourage them to examine that behaviour, and to try to understand some of the consequences? Instead, society is rushing to protect, without rushing to explain. Yet society does not have a problem saying that under age drinking is potentially dangerous – why do we not do the same about underage sexual activity? ALL behaviour has consequences. Sex may be seen in a different light, but it, too, is behaviour for which people are personally responsible. Let's deal with that, instead of calling for this vaccination without further reflection!

### More long-term testing needed

There are some scientific challenges to the efficacy of the vaccine itself. As a society, we may disagree about moral values concerning sexual behaviour. When it comes to factual matters, it is important to look at the claims of all groups including those who insist that the clinical trials performed in testing *Gardasil* for HPV did *not* prove that it is safe to give to young girls.

One group charges that the developer of the vaccines was allowed by the FDA to use a potentially reactive aluminum-containing placebo as a control, rather than a non-reactive saline solution placebo.<sup>1</sup> Apparently, a reactive placebo can artificially increase the appearance of safety of an experimental drug or vaccine in a clinical trial. Animal and human studies have shown that aluminum can cause nerve cell death, and that vaccine aluminum adjuvants can allow aluminum to enter the brain, as well as cause chronic joint and muscle pain and fatigue.

According to this group, the developer of the vaccine did not reveal how many nine-to-fifteen-year-old girls were in the clinical trials. How many of them received hepatitis B vaccine and *Gardasil* simultaneously was not stated, nor how many of them had serious adverse effects. The group argues that there is too little long-term safety and efficacy data to recommend *Gardasil* for universal use. Nobody at the manufacturer, the Centers for Disease Control nor at the FDA knows if these injections into all preteen girls will make some of them more likely to develop arthritis, or other inflammatory, autoimmune, and brain disorders as teenagers and adults. The group argues that it is far too early to give all young girls three doses of a vaccine that has not been shown to be safe or effective for that age group.

### Gardasil protection questionable

Many dispute the figures depicting HPV as the leading cause of cervical cancer in any case.<sup>2</sup> Some statistics show that HPV is the cause in only one per cent of these cancers. Merck itself warns that *Gardasil* does not protect against all cervical

cancers, and that those vaccinated must still be screened.<sup>3</sup> These factors do not eliminate the gravity of this disease, but, if accurate, they show that a rush to mass vaccination against HPV is, to say the least, scientifically disproportionate.

### Costs and allocation of resources

Cost may be a significant factor here. Girls must have a three-dose treatment, and the cost is estimated at \$380.00 per person. When we think of the sums that are needed for better palliative care and mental health, for example, both areas grossly underfunded in Canada, and yet both of which are essential for human well being, we may well ask why states and provinces are willing to spend huge sums of money for mass vaccinations for a disease that IS preventable?

### Conclusion

When all these points are taken together, it appears that the provision of this vaccine is not without serious ethical and physical concerns. If there is a rush to implement general screening programmes for girls from Grade 6 or Grade 8 onwards, without further reflection on these concerns, then something is sadly “out of kilter” in how young girls and women are valued in society today.

<sup>1</sup> National Vaccine Information Center, “Merck’s Gardasil Vaccine Not Proven Safe for Little Girls,” June 27, 2006

<sup>2</sup> Cf. *Cancer Monthly*, April 18, 2007. “How effective is Gardasil in decreasing the incidence of cervical cancer? 100%? 50%? No one really knows because this question has not yet been answered. As of today, the Gardasil vaccine has never been proven to decrease the actual incidence of cervical cancer. In the studies that led to the vaccine’s approval, the incidence of cervical cancer was not measured. Instead CIN (cervical intraepithelial neoplasia) 2/3 and AIS (adenocarcinoma in situ) were used as the surrogate markers for prevention of cervical cancer because according to the vaccine’s insert “CIN 2/3 and AIS are the immediate and necessary precursors of squamous cell carcinoma and adenocarcinoma of the cervix, respectively.” While this is true it is also true that CIN 2/3 and AIS usually do not lead to cancer. For example, according to published data, CIN2 only leads to invasive carcinoma 5% of the time and CIN3 only leads to invasive carcinoma 12% of the time.

<sup>3</sup> Merck’s website on Gardasil, its effects and side effects: [www.gardasil.com](http://www.gardasil.com)

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