

## Human papillomavirus (HPV) vaccines: facts versus fiction

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Recently I was asked to review a paper for a reputable peer review journal which, for the large part, was devoted to criticizing the recent action of the Japanese government and Health authorities in their decision to stop actively recommending the HPV vaccine.

Throughout the article the authors, blamed the "theatrical hysteria" of the "alleged victims" and Japanese media which gave presumably the impression that the adverse events reported following HPV vaccine injection were causal while the authors claimed (on the basis of their opinion on this subject rather than any objective evidence), that the adverse events were purely coincidental and any allegation to the contrary was simply a product of overly emotional "anti-vaccine" groups.

Contrary to the author's claim, what we can glean from the medical literature is that the pattern of adverse events reported worldwide (including Japan) following HPV vaccination is remarkably similar. Namely, the most common symptoms point to a dysfunction of the autonomic nervous system rather than psychosomatic disorder as so conveniently parroted. These symptoms are: orthostatic intolerance/POTS, severe non-migraine-like headaches, excessive chronic fatigue, excessive sleeping cognitive dysfunction, gastrointestinal discomfort, widespread neuropathic pain, muscular weakness and paresthesias/allodynia. The newly published study by Martínez-Lavín et al. [1] in *Clinical Rheumatology* record such symptoms occurring in 45 individuals in 13 different countries. Moreover, these same group of symptoms pointing to dysautonomia in relation to HPV vaccination have been separately reported by Kinoshita et al. (40 cases) [2], a Danish group led by Dr Louise Brinth of Frederiksberg Hospital, in the *Journal Vaccine* (35 cases) [3], and *Danish Medical Journal* (53 cases) [4] and several other groups documenting isolated cases [5, 6].

Correlation of course does not equal causation. That is trumpeted over and over again by the vaccine manufacturer and various health and regulatory authorities. However, at what point does it become irresponsible to dismiss the correlation, particularly when it is increasingly medically documented worldwide?

In addition, we further have to deal with the inconvenient fact that the long term benefits of HPV vaccination have not been proven to date, a fact that the authors of the manuscript do acknowledge. There is indeed no evidence as of yet that the HPV vaccines prevented a single cervical cancer death and the duration of the protective effect of more than 10 years has not been proven either. On the other hand, worldwide, reports of serious adverse events continue to escalate. If HPV vaccination programme were to cease worldwide, there would be no cervical cancer crisis because HPV vaccines are neither better nor safer than already existing methods for treating and preventing cervical cancer. Unlike these vaccines, Pap smear and electrosurgical excision procedure which is used to remove pre-cancerous lesions, do not carry the risk of disabling autoimmune and neurological diseases.

In short, here are the two main points concerning the overall impact of HPV vaccines:

1) There is ZERO evidence that the HPV vaccines can actually prevent cervical cancer. Instead, what the clinical trials have shown is that HPV vaccines can prevent some of the pre-cancerous lesions associated with HPV-16 and HPV-18 infection, a large fraction of which are known to spontaneously resolve *regardless* of the vaccination status [7-9]. Indeed, the optimistic *assumptions* that HPV vaccination (even *if* proven effective against cervical cancer as claimed), will result in 70% reduction of cervical cancers as often claimed by vaccine manufacturers, is entirely based on exaggerated and invalid extrapolations derived from HPV vaccine efficacy against largely self-resolving precancerous lesions [8, 10, 11]. In this regard, German experts Gerhardus and Razum [11] have noted the following:

*“...unwarranted confidence in the new [HPV] vaccines led to the impression that there was no need to actually evaluate their effectiveness”*

*“the flawed estimate of the protective efficacy by the German Vaccination Committee influenced the decision to reimburse HPV vaccination in Germany, and probably led many physicians to recommend the vaccination under false assumptions”*

*“...decisions at the health policy level as well as the individual level might be misled”*

2) Even *if* proven effective against actual cervical cancer cases, HPV vaccines are unlikely to have any impact in further reducing the cervical cancer burden beyond what has already been accomplished with existing regular Pap test screening programs. These, unlike HPV vaccines have a proven success in cutting down cervical cancer mortality rates in developed countries by over 70% [12, 13]. In particular, due to implementation of regular screening programs the death rates from cervical cancer disease currently range from 1-2 per 100,000 cases in developed countries including U.S. and Western Europe [14]. The incidence of disease cases are 5-10 per 100,000 cases [14]. HPV vaccines cannot further reduce this rate. For example, with the cervical cancer screening that is already in place in the United States, 8.0 in 100,000 women develop the disease every year [15]. Estimates of the impact of HPV vaccination in the absence of screening, based on modeling *assumptions* that efficacy will last a lifetime and that all women will be vaccinated, predict that 9.5 in 100,000 women will develop cervical cancer annually with Cervarix, as will 14 in 100,000 with Gardasil [15]. Combining screening with vaccination is not expected to significantly lower the number of women getting cervical cancer every year. Commenting on these results, the authors (Harper and Williams) [15] have noted that:

*“This may not be information that influences increased uptake of vaccination, but physicians’ goals are not to sell vaccine product”*

Although countries with the heaviest cervical cancer burden could in theory benefit from HPV vaccination (providing long-term clinical benefits were actually demonstrated), Pap screens would still be needed as they are indispensable for successful management of cervical cancers. Notably, a paper from India by Gupta et al. [16] indicates that indeed screening and not HPV vaccination is the solution for reducing the cervical cancer burden in the third world. In a further

comment on the rationale for introducing mass vaccination with HPV vaccines in India, Gupta et al. [17] have stated that,

*“That India has been unable to mount an effective cervical screening program is a monumental public health failure – but not an excuse to mass vaccinate millions of women without adequate proof of effectiveness.”*

*“The fact that cervical cancer rates have declined over the past several decades and continue to decline has been extensively documented in several population-based Indian cancer registries and there is no reason to believe that this decline will suddenly halt, despite the wishful thoughts of vaccine advocates.*

*As testimony, for the very first time, cervical cancer incidence and mortality have fallen behind that of breast cancer for the whole of India. It is also a matter of well documented fact that this decline has occurred without systematic screening or mass vaccination. One can only imagine a situation where vaccination had been introduced several decades ago and the decline conveniently attributed to this intervention.”*

*“Cervical carcinogenesis (as indeed most cancers’ origins) is a complex multifactorial process involving several host and environmental factors – HPV is but one part of the jigsaw. Failure to appreciate this fact (or its deliberate obfuscation) lies at the heart of vaccine advocates’ inability to accept that dynamics other than HPV vaccination can consistently reduce the incidence of this disease.*

*“We remain of the considered opinion that health policy planners in India would be well advised to carefully assimilate independent opinion on this subject that is not influenced by vaccine manufacturers, who stand to gain enormously from implementation of this intervention in vast populations.”*

In summary, vaccination programmes are context-dependent. Deaths from cervical cancers in countries with regular Pap screening programmes are rare (1-2 cases per 100,000 per year). Such countries do not need a vaccine that has not yet demonstrated its long-term clinical benefit. The decision to vaccinate with HPV vaccine is a personal decision, not one that must be made for public health. HPV is not a lethal disease in 95% of the infections; and the other 5% are detectable and treatable in the precancerous stage [18].

All of the above are not anti-vaccine statements, but rather common sense reasoning. There is no rationale for exposing young healthy individuals to a risk from a vaccine that can bring them no long-term benefit.

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