Overloaded Immunisation Basket

The HPV Vaccine Tale

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The decision to add more vaccines to the public immunisation programme, with HPV leading the list, is short sighted and blinkered.

In the last decade or so, vaccines have been developed against the Human Papilloma Virus (HPV), a sexually transmitted infection linked to cervical cancer. This vaccine is part of public immunisation programmes in a number of developed countries as part of comprehensive preventive and treatment services. It is administered to pre-adolescent girls, i.e. before they are expected to be sexually active.

The HPV vaccine might seem to be a no-brainer for India, where more than 132,000 women develop cervical cancer every year, and over 73,000 die from the disease that accounts for more than a quarter of all cancer deaths in women in the country.

However, the Indian government's plans to introduce the HPV vaccine in India's universal immunisation programme (UIP) have not been well received (http://www.deccanherald.com/content/496411/3-vaccines-added-immunisation-programme.html. Diverse activists have protested the plan, posing many questions, such as: How effective is the vaccine? Is it safe? Is it worth the price? Is a vaccine the best public health choice to reduce cervical cancer in India?

Such questions must, understandably be asked and answered satisfactorily before any vaccine is introduced into the programme, and the HPV vaccine is no exception. Unfortunately, the government is silent on such questions. It seems hell bent on ignoring the need for comprehensive health care, instead directing resources to more and more expensive vaccines of dubious safety and efficacy.

There are many reasons to question the government's plan to introduce the HPV vaccine in the UIP.

First, HPV infection does not necessarily lead to cancer. Some 90 per cent of HPV infections clear up routinely. For persistent HPV infection to progress to cervical dysplasia and cervical cancer, additional risk factors must be present, such as early sexual activity, HIV infection, long-

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term use of hormonal contraceptives, greater number of sexual partners, and greater number of pregnancies. These factors affect women's overall health and must be addressed as well independent of the vaccine issue.

Second, the HPV vaccine is not 100 per cent effective. It only protects against the HPV subtypes that cause 70 per cent of cervical cancer. Further, it is not known how long any immunity will last and whether booster doses will be necessary every few years.

Third, the vaccine's safety has not been studied in India where it would be given to more than 27 million children every year, and in conditions where reporting and follow-up of adverse events is grossly inadequate. The vaccines by Merck and GlaxoSmithKline were approved hastily in India, with studies on a few hundred women and girls. At least seven deaths were reported in the two large trials of Merck and GSK vaccines in Gujarat and Andhra Pradesh. These trials were shut down following evidence of gross ethical violations. The Parliamentary Committee report found adverse events were under-reported and investigations were shoddy at best. Introducing new vaccines without ensuring that adverse events will be monitored and followed up is a recipe for disaster.

Fourth, the vaccine is expensive. The 'discounted' rate is Rs 700. This is a hefty price considering that the cost of the entire bundle of vaccines for India's universal immunisation programme was just Rs 100 until recently.

Fifth, the vaccine will not do away with the need for functioning health services. Sexuality education is critical for reduction of sexually transmitted disease including HPV infection. Screening programmes using inexpensive techniques would prevent many if not most of the 132,000 cases of cervical cancer that occur each year. Accessible and affordable health care can prevent many of the 72,000 deaths from cervical cancer each year. Many lives would be saved if the immunisation programme reached more children --- at present fewer than half of all Indian children get the essential vaccines, and at the right time. These are comprehensive programmes requiring investment in infrastructure, human resources, equipment and supplies and they serve multiple health needs. These are being neglected in favour of a single-minded focus on vaccines.

The HPV vaccine is only the latest in a slew of vaccines being rushed into the immunisation programme. The pentavalent vaccine is being introduced in more states despite increasing reports of deaths following vaccination. Vaccines for rubella, pneumococcus, Japanese encephalitis and an injectable polio vaccine will be added soon. Bharat Biotech's rotavirus vaccine was fast-tracked through clinical trials and is being introduced even though it is admittedly of only 'modest efficacy' and there are many questions about its safety. The

'discounted' price of one course of the rotavirus vaccine is Rs 300 ($5). The UIP budget is expected to go from Rs 1,000 crore to more than Rs 3,500 crore annually.

The decision to spend public money on a vaccine-centric model, rather than strengthen comprehensive health services, clearly serves the interests of industry.