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### **Vaccination against cervical cancer.**

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Human papillomavirus-associated cervical cancer is a worldwide problem and vaccines against certain virus types are under development. Here, Pamela Greenwell and Sanjiv Rughooputh take a brief look at the current position.

# Vaccination against cervical cancer

**Human papillomavirus (HPV)-associated cervical cancer affects almost half a million sexually active females each year worldwide. Recently, however, clinical trials of two HPV vaccines have demonstrated successful results.**

The Gardasil vaccine (Merck) targets HPV types 16 and 18, which are associated with cervical cancer, and also HPV types 6 and 11, which are associated with genital warts. In the trial, 552 women aged 16–23 were recruited from Brazil, Europe and USA, and the study was carried out by the Ludwig Institute for Cancer Research in Brazil. A total of 277 women were randomly assigned to be given the vaccine and received injections on the first day of the study, and then again after two and six months. The participants were followed up for 36 months with regular gynaecological examinations.

Among the women who received a placebo, 36 contracted HPV or developed one of the diseases associated with the virus. Of these 36 women, three developed genital warts and three developed precancerous cervical lesions. Among the women who received the vaccine, four contracted HPV but none developed any of the diseases associated with the virus.

Although HPV antibody levels fell at the end of the study period among women who received the experimental vaccine, antibody

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levels were higher in this group than in women naturally infected with HPV. According to the researchers, the vaccine was 89% effective in preventing infection with the four HPV types, and 100% effective in preventing the diseases associated with these types.

Elsewhere, GlaxoSmithKline has reported that its new vaccine Cervarix shows the potential to prevent more than 70% of cervical cancers in phase 2 clinical trials. As with the Gardasil vaccine, Cervarix targets HPV types 16 and 18.

Interestingly, participants in the two trials were young (16–23 years) and some studies have shown that most HPV-infected women in this age group will not show any evidence of infection for six to 12 months after exposure and that 80% clear the infection after 18 months. However, both companies have now moved to phase 3 clinical trials and have recruited around 20,000 participants each. GlaxoSmithKline plans to file for regulatory approval for Cervarix in Europe in 2006, while Merck plans to apply for US Food and Drug Administration (FDA) approval in late 2005.

Both companies would like to make these vaccines available to children as young as 10, before they become sexually active. However, it may prove difficult to convince parents of the need to vaccinate their children against a potential sexually transmitted disease at this age. There is a school of thought to suggest that the vaccine should be given to babies, thus circumventing discussions of age

of first sexual activity, but some cultures may view HPV vaccination as unethical and rule it out completely.

Although these two vaccines target HPV types 16 and 18, which account for more than 80% of cervical cancer-associated infection, there are other high-grade HPVs, such as types 31, 33 and 39, not covered by the vaccines. Hence, these two vaccines, if used, would not give protection against all high-grade HPV types.

Furthermore, the economic cost would make it impossible for developing countries to adopt these vaccines in the short-term, but the cost could be outweighed by the cost of treating patients affected with cervical cancer. Even if the vaccine is successful and there are developments of new vaccines to cover all HPV types, it should be remembered that the vaccine will be of little use to those already infected and that screening, diagnosis and treatment will be required for decades to come.

Clearly, although these vaccines will contribute to the fight against cervical cancer, they are not the entire solution to the problem. ■

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