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New report shows that HPV vaccine trials can be significantly shortened

Lyon, France, 25 August 2014 - A new report from a Working Group convened by the International Agency for Research on Cancer (IARC), the specialized cancer agency of the World Health Organization, and the United States National Cancer Institute (NCI) shows how the evaluation and licensing of prophylactic human papillomavirus (HPV) vaccines could be significantly accelerated.

Experts with wide-ranging expertise in HPV vaccines reviewed the scientific evidence to determine under what circumstances vaccine efficacy can be established at an earlier stage of the infection, rather than the clinical onset of disease in the cervix.

The experts also looked at whether immunobridging trials could be sufficient for licensure under specific circumstances.

The report, entitled Primary End-points for Prophylactic HPV Vaccine Trials**,** provides a series of technical recommendations for clinical efficacy trials.

“Being able to evaluate vaccine efficacy at an earlier stage can lead to faster approval and implementation, providing major public health benefits,” says IARC Director Dr Christopher Wild.

Currently, there is considerable interest in conducting additional clinical trials of prophylactic HPV vaccines. “These recommendations could help reduce the cost and duration of clinical studies and facilitate research in important areas, such as reducing the number of doses of the current vaccine, or evaluating new vaccines similar to those already licensed,” stresses Dr Rolando Herrero, Head of the Prevention and Implementation Group at IARC and organizer of the HPV Working Group.

HPV infection and cancer

Virtually all cases of cervical cancer are attributable to HPV infection. Cervical cancer is the fourth most common cancer in women, and the seventh most common overall, with an estimated 528 000 new cases worldwide in 2012[1].

At least 13 HPV types are recognized as being able to cause cervical cancer. HPV 16 and HPV 18 are the most oncogenic and account for about 50–60% and 10–20% of cervical cancers, respectively.

HPV types 16 and 18 are also associated with cancers at a variety of other sites, including the vulva, vagina, penis, anus, and oropharynx[2]. HPV 16 accounts for 80–90% of such non-cervical cancers, and HPV 18 accounts for some additional cases.

Whereas in developing countries HPV-associated cancers are dominated by cervical cancer, in at least some industrialized countries HPV-positive cancers are divided more evenly among the different sites where HPV infection is widely accepted as potentially leading to malignant disease.

The report, which can be downloaded free of charge from http://www.iarc.fr/en/publications/pdfs-online/wrk/wrk7/, provides a useful tool for researchers, clinicians, and all those involved in the production of vaccines.

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References
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(2) IARC Working Group on the Evaluation of Carcinogenic Risks to Humans (2009). *A Review of Human Carcinogens. Part B: Biological Agents*. Lyon, France: IARC. (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 100B). Chapter 6, Human papillomaviruses, pp. 255–313. Available from: http://monographs.iarc.fr/ENG/Monographs/vol100B/mono100B-11.pdf

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The International Agency for Research on Cancer (IARC) is part of the World Health Organization. Its mission is to coordinate and conduct research on the causes of human cancer, the mechanisms of carcinogenesis, and to develop scientific strategies for cancer control. The Agency is involved in both epidemiological and laboratory research and disseminates scientific information through publications, meetings, courses, and fellowships. If you wish your name to be removed from our press release e-mailing list, please write to com@iarc.fr.