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## Clinical cancer chemoprevention: From the hepatitis B virus (HBV) vaccine to the human papillomavirus (HPV) vaccine

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#### A R T I C L E I N F O

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#### ABSTRACT

Approximately 2 million new cancer cases are attributed to infectious agents each year worldwide. Vaccines for the hepatitis B virus (HBV), a risk factor of hepatocellular cancer, and human papillomavirus (HPV), a risk factor of cervical cancer, are considered major successes in clinical chemoprevention of cancer. In Taiwan, the first evidence of cancer prevention through vaccinations was provided by HBV vaccination data in infants. The Taiwanese HBV vaccination program has since become a model immunization schedule for newborns worldwide. Persistent infection with high-risk HPV is generally accepted as prerequisite for cervical cancer diagnosis; however, cervical cancer is a rare complication of HPV infections. This is due to the fact that such infections tend to be transient. The safety and efficacy of both available HPV quadrivalent vaccine and bivalent vaccine are not in doubt at the present time. Until a human cytomegalovirus (CMV) vaccine becomes available, simple hygienic practices, such as hand washing, can prevent CMV infection both before and during pregnancy. Each country should establish her official guidelines regarding which vaccines should be used to treat various conditions, the target population (i.e., universal or limited to a selected population), and the immunization schedules. After a vaccine is recommended, decisions regarding reimbursement by the public health care fund are evaluated. The guidelines become part of the immunization schedule, which is updated annually and published in the official bulletin. In conclusion, both HBV and HPV vaccines are considered major successes in the chemoprevention of cancer.

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#### Introduction

Vaccines for the hepatitis B virus (HBV), a risk factor of hepatocellular cancer, and human papillomavirus (HPV), a risk factor of cervical cancer, are considered major successes in clinical chemoprevention of cancer. In Taiwan, the first evidence of cancer prevention through vaccinations was provided by HBV vaccination data in infants. The Taiwanese HBV vaccination program has since become a model immunization schedule for newborns worldwide. The safety and efficacy of both two available HPV vaccines (quadrivalent vaccine and bivalent vaccine) are not in doubt at the present time. This review is to summarize the current conception of immunization and vaccination for general obstetricians and gynecologists, and women health care personnel.

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#### **Case review**

Worldwide, approximately 2 million new cancer cases are attributed to infectious agents each year [1]. Protection against infectious disease through prior asymptomatic infection is based on the concept of variolation (inoculation with smallpox). In 1796, upon recognizing that dairymaids infected with cowpox were immune to smallpox, English physician Edward Jenner deliberately infected 8-year-old James Phipps with cowpox. After repeating the experiment on other children, including his own son, Doctor Jenner concluded that vaccination provided immunity to smallpox without the risks associated with variolation. Results of the first successful smallpox vaccination were published in 1798. New vaccination policies should include considerations of safety, efficacy, and cost-effectiveness. Guidelines for immunization should consider the ages of subjects, the number of doses, as well as dosing intervals, precautions, and contraindications of vaccines [2].

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Vaccines for the hepatitis B virus (HBV), a risk factor of hepatocellular cancer (HCC), and human papillomavirus (HPV), a risk factor of cervical cancer, are considered major successes in clinical chemoprevention of cancer. The first randomized blind controlled trial of hepatitis B immunoglobulin (HBIG) and hepatitis B vaccine in Taipei was reported in 1983. In that study, the infants of mothers carrying the e-antigen-positive hepatitis B surface antigen (HBsAg) were given HBIG immediately after birth, followed by one of three vaccination schedules. No difference in efficacy was observed between the three schedules, and the combined efficacy was 94% [3]. A total of 38 healthy infants received two 20 µg doses of the vaccine through the intramuscular route with a 1-month interval between doses. All developed antibodies to HBsAg (anti-HBs) following the third dose at the age of 7 months. Furthermore, anti-HBs were maintained at high levels after vaccinating infants who initially possessed passive antibodies [4]. In another study conducted in 1983, a total of 100 healthy children received two doses of HBV vaccine (10 µg, 20 µg, or 40 µg) at 1-month intervals, 90% of the children still presented antibodies 12 months after vaccination [5].

Hepatitis B is a common infection worldwide, and the severity of the infection is related to the age of the affected individual. The development of the hepatitis B vaccine is considered a major achievement of modern medicine. Current hepatitis B vaccines are extremely safe and provide an efficacy rate < 90%. Nonetheless, more than 2 billion individuals worldwide present serological evidence of hepatitis B infection. Of these, 400 million are chronic carriers, and between 0.5 and 1.2 million die annually from cirrhosis and HCC [6].

By 2004, 18,779 people under the age of 30 years (including neonates) had been administered the universal hepatitis B vaccination in Taiwan. The seropositive rate for HBsAg was found to be 1.2% in these individuals. These results demonstrate that the universal HBV vaccination program provided protection for up to 20 years [7]. In a systematic review of hepatitis B immunization in infants born to HBsAg-positive mothers, the results of 29 randomized clinical trials (five of which are considered high-quality) that compared vaccination to placebo/no intervention showed that vaccinations reduced the occurrence of hepatitis B [relative risk (RR) 0.28, 95% confidence interval (CI)] 0.20 to 0.40, four trials. In studies that compared the efficacy of different vaccines, the administration of vaccines and HBIG succeeded in reducing the occurrence of hepatitis B (RR 0.54, 95% CI) 0.41 to 0.73, 10 trials [8]. Additionally, chronic HBV infection (HBsAg-positive) rates in the general population < 20 years of age dropped considerably from 10-17% before the mass HBV vaccination program to 0.7-1.7% after the program. The incidence of HCC among Taiwanese children 6-14 years old also fell from 0.52-0.54 to 0.13-0.20 per 100,000 (RR = 0.25 - 0.36) [9]. Thus, in Taiwan, the first evidence of cancer prevention through vaccinations was provided by HBV vaccination data in infants. The Taiwanese HBV vaccination program has since become a model immunization schedule for newborns worldwide. The concept of a cancer preventive vaccine can be extended to other infectious agents and their related cancers [10].

For reference, the immunization schedule for routine vaccinations in the U.S. is summarized below [11].

#### Vaccination of all children aged 0–18 years

Vaccinate all newborns with monovalent vaccine before discharge from hospital. Give the second dose at 1-2 months and the final dose at 6-18 months. After the first dose administered at birth, the series may be completed using two doses of single-antigen vaccine or as many as three doses of Comvax

[Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) & Hepatitis B Vaccine (Recombinant)] (ages 2 months, 4 months, 12-15 months) or Pediarix [Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine Combined] (ages 2 months, 4 months, 6 months). For cases in which the mother is HBsAgpositive, the newborn is to be administered HBIG and the first dose within 12 hours of birth. The series should be complete by the age of 6 months or, if using Comvax, by the age of 12–15 months. For cases in which the HBsAg status of the mother is unknown, the newborn should also be administered HBIG and the first dose of vaccine within 12 hours of birth. The same protocol should be followed for cases of low birth weight (<2000 g). For cases of low birth weight and an infant weighing  $\geq 2000$  g, whose mother is subsequently found to be HBsAg-positive, the infant is to be administered HBIG as soon as possible/immediately (no later than 7 days following birth), followed by the hepatitis B immunization schedule for infants born to HBsAg-positive mothers.

#### Catch-up vaccination

No vaccination series is to be restarted, regardless of how much time has elapsed since the previous dose. Three-dose series can be started at any age with the minimum interval between doses as follows: 4 weeks between the first and second doses, 8 weeks between the second and third doses, and at least 16 weeks between the first and third doses.

Special note:

Monovalent vaccine brands are interchangeable. For patients aged 0–19 years, administer 0.5 mL of either Engerix-B or Recombivax HB.

An alternate dosing schedule for unvaccinated adolescents aged 11–15 years is as follows: two doses Recombivax HB 1.0 mL (adult formulation) spaced 4–6 months apart. (Engerix-B is not licensed for a two-dose schedule.)

#### Preterm infants

Preterm infants weighing < 2000 g and born to HBsAg-negative mothers should have their first vaccine dose delayed until 1 month after birth or at the time of hospital discharge. Preterm infants weighing < 2000 g and born to HBsAg-positive mothers should receive both HBIG (0.5 mL) and single-antigen hepatitis B vaccine  $\leq$ 12 hours after birth, administered at various injection sites. The initial dose of vaccine (birth dose) should not be counted as part of the vaccine series, and three additional doses of the vaccine (for a total of four doses) should be administered beginning when the infant reaches 1 month of age. For cases in which the mother's HBsAg status cannot be determined, preterm infants weighing < 2000 g should receive both HBIG (0.5 mL) and single-antigen hepatitis B vaccine within 12 hours of birth. The birth dose should not be counted as part of the vaccine series, and three additional doses of vaccine (for a total of four doses) should be administered according to the schedule determined by the HBsAg status of the mother.

#### HPV vaccine

It has been estimated that in 2012, there were as many as 300 million HPV infections without detectable abnormalities, 10 million high-grade precancerous lesions [12], and 490 thousand cases of cervical cancer [13]. Cervical cancer is the third most commonly diagnosed form of cancer and the fourth leading cause of cancer-related death among females worldwide. Furthermore, cervical cancer accounted for 9% (529,800) of new cancer cases and 8%

(275,100) of total cancer deaths among females in 2008 [14]. Persistent infection with high-risk HPV is generally accepted as prerequisite for cervical cancer diagnosis; however, cervical cancer is a rare complication of HPV infections. This is due to the fact that such infections tend to be transient and do not give rise to cervical lesions. It takes an average of 12–15 years before a persistent HPV infection progresses through consecutive premalignant stages (i.e., squamous intraepithelial lesions) and becomes an overt cervical carcinoma.

HPV and cytomegalovirus (CMV) are ubiquitous, and HPV and CMV infection are very common. Quadrivalent HPV vaccine (Gardasil, dosing interval 0 months, 2 months, and 6 months) and Bivalent L1 virus-like particles vaccine (Cervarix, dosing interval 0 months, 1 month, and 6 months) are widely available. Gardasil provides effective protection against genital warts and vulvar/ vaginal neoplasia associated with the vaccine Types (6, 11, 16, and 18). In other trials, Gardasil protected mid-adult women from incidental infection of cervical intraepithelial neoplasia (CIN) caused by the vaccine types and protected men against incidental infection, genital warts, and anal intraepithelial neoplasia associated with vaccine types. Cervarix has been shown to protect against vaccine-targeted anal infections in women [15]. The safety and efficacy of these two vaccines are not in doubt. For example, in a combined analysis of four randomized clinical trials (20,583 female patients aged 16-26 years), the primary endpoint was the development of Grade 2 and Grade 3 CIN and adenocarcinoma in situ (AIS). Among women who tested negative for HPV 16 and HPV 18 infection during the vaccination regimen (n = 17,129, per protocol), vaccine efficacy was 99% for the primary endpoint 93–100 (95% CI) [16]. Moreover, HPV vaccines have shown considerable promise as key components in cervical cancer prevention. Unfortunately, the high cost of HPV vaccines is a barrier to further implementation. Despite moral, religious, political, economic, and socio-cultural controversies, the mandatory HPV vaccination of all middle school girls can be justified on scientific and public health grounds. The development of vaccines targeting oncogenic types of HPV has eliminated approximately 70% of all forms of invasive cervical cancer in women. It is clear that targeted educational initiatives must be continued to inform healthcare professionals, the media, patients, and parents about these issues [17].

In the USA, the recommended age for HPV vaccination of females is 11-12 years and vaccines can be administered to girls as young as 9 years. Catch-up vaccinations are recommended for females aged 13-26 years who have not been previously vaccinated [18]. In Taiwan, the age-specific seroprevalence of HPV 16 and HPV 18 increases among young adults > 18 years; therefore, the optimal age for universal HPV vaccination is  $\leq$  15 years [19]. To encourage adherence to national immunization guidelines, educational initiatives should be directed toward pediatricians and family physicians. These initiatives should target the modifiable predictors of intention to vaccinate, such as HPV knowledge and attitudes toward vaccination. Furthermore, women up to 45 years of age have been shown to exhibit strong immune responses to the bivalent HPV vaccine, which could be expected to reduce the risk of HPV reinfection and address the second peak of HPV related malignancy that occurs later in life, generally after 45 years of age. Early data from randomized trials testing the quadrivalent HPV vaccine in women older than 25 years also suggest that the vaccine has high efficacy comparable to younger women [20]. However, when the vaccine is administered to women up to 45 years of age, the prescribing physician bears the responsibility of off-label use, which brings with it the possibility of unanticipated risks. Physicians should therefore be prepared for possible malpractice suits.

Additionally, significant cross-protection of the Adjuvant System 04-adjuvanted HPV 16/HPV 18 vaccine against incidental

and persistent infection has been observed, notably against HPV 45, the third most prevalent type of HPV associated with cervical cancer [21]. This protection against HPV 45 could provide an additional protection against invasive cervical cancer and may also have a significant impact on endocervical adenocarcinoma, a condition that is not effectively prevented by screening and is becoming increasingly prevalent among young women. Results from PATRICIA (PApilloma TRIal against Cancer In young Adults) have demonstrated the cross-protective efficacy of the HPV 16/HPV 18 vaccine against four oncogenic HPVs: HPV 33, HPV 31, HPV 45, and HPV 51 [22]. In Taiwan, the third most prevalent type of HPV associated with cervical cancer is HPV 58, followed by HPV 33 and HPV 52 [23]. These results are on par with those obtained throughout eastern Asia [24]. It will be interesting to see whether the HPV vaccine has cross-protection against other types of HPV. In a follow-up study of 17,622 generally HPV-naive women aged 16-26 years, the vaccine for HPV 6/HPV 11/HPV 16/HPV 18 was shown to reduce the risk of CIN 2-3/AIS associated with nonvaccine types of HPV, which are responsible for approximately 20% of cervical cancer cases [25]. In Phase 3 efficacy studies of sexually active women aged 16-26 years, vaccination reduced the rate of HPV 31/HPV 33/HPV 45/HPV 52/HPV 58 infection and also the rate of CIN 1–3 or AIS [26]. Therefore, these next most common HPV carcinogenic types should be considered for the development of second-generation HPV prophylactic vaccines.

Many countries have implemented vaccination programs for adolescent females and given the indication for use of the vaccine in males. Both sexes are affected by HPV; therefore, the vaccination of males against the disease should also be adopted [27]. Despite the fact that, only limited conclusions can currently be drawn about the cost-effectiveness of HPV vaccination for males, the vaccination regime appears more cost-effective when all HPV-related diseases, and/or lower vaccine prices are considered [28].

An even greater proportion of other HPV-related cancers (i.e., noncervical cancers) are caused by HPV 16 and HPV 18 (HPV types that are targeted by currently available vaccines). For example, current data indicate that HPV infection is associated with 90–93% of anal cancers, 12-63% of oropharyngeal cancers, 36-40% of penile cancers, 40–64% of vaginal cancers, and 40–51% of vulvar cancers [29]. Therefore, current HPV vaccines show considerable promise in reducing the burden of both cervical and noncervical cancers associated with HPV [30]. Moreover, multivalent vaccines against additional oncogenic HPV strains are currently under development. Future evaluations should consider the costeffectiveness of next generation nonavalent vaccines designed to protect against up to 90% of all cases of cervical cancer. Furthermore, the effects of vaccination on cervical screening programs are likely to be country-specific, depending on the catch-up age range, coverage of vaccinations, and the age at which screening begins. Thus, future evaluations should also focus on the effects of disparities in screening and vaccination uptake, the potential effects of vaccination on screening participation rates, and the effects of imperfect compliance with screening recommendations [31].

#### Immunization

Until a human CMV vaccine becomes available, simple hygienic practices, such as hand washing, can prevent CMV infection both before and during pregnancy. Preventative behaviors such as hand washing, not sharing drinking glasses or eating utensils with young children, and not kissing young children on the mouth, appear to be effective in general [32]. There appears to be a consensus that inactivated viral vaccines, bacterial vaccines, and toxoids are safe during pregnancy. Pregnant women are further encouraged to be vaccinated for influenza. Women who are breastfeeding are eligible for immunization; however, live and/or live-attenuated virus vaccines are contraindicated during pregnancy due to a high theoretical risk to the fetus. Moreover, many vaccines require improvement, because they only cover a portion of the many pathogenic serotypes that cause disease (rotaviruses, HPV, or Streptococcus pneumoniae). Developing preventive vaccines against chronic diseases such as AIDS and hepatitis C will require additional time. In the future, new methods of vaccine delivery (i.e., other than injection) are likely to be used (e.g., mucosal administration) and new vectors or adjuvants will be added to vaccines to stimulate specific responses. Novel vaccines can also be obtained using virallike particles (VLPs) of HPV, conjugate polysaccharides (e.g., Neisseria meningitidis, S. pneumoniae), and the reassortment of segmented genomes (e.g., rotavirus, influenza) [33]. A permanent advisory committee (Comité technique des vaccinations) in France, has already established official guidelines regarding which vaccines should be used to treat various conditions, the target population (i.e., universal or limited to a selected population), and the immunization schedules. After a vaccine is recommended, the Transparency Commission for Transmissible Diseases of the Superior Public Health Authority (Haute Autorité de Santé) and the economic committee on drugs, usually make decisions regarding reimbursement by the public health care fund. These guidelines become part of the immunization schedule, which is updated annually and published in the Official Bulletin of the Minister of Health and in the Bulletin épidémiologique hebdomadaire [34].

In conclusion, both HBV and HPV vaccines are considered major successes in the chemoprevention of cancer.

#### **Conflicts of interest**

The author has no conflicts of interest relevant to this article.

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