Gardasil nine: Is the number enough??

Sir,

Gardasil (Merck and Co.), also known as Gardasil or Silgar, the quadrivalent human papillomavirus (HPV) recombinant vaccine for HPV types 6, 11, 16, and 18, approved by the USA Food and Drug Administration (FDA) on June 08, 2006 for girls, and women ages 9–26 years, and for boys ages 9–26 years, with the goal of eradicating HPV-related gynecologic, penile, colorectal, and head and neck cancers. The Gardasil vaccine has also been approved in 120 other countries. A second vaccine Cervarix (GlaxoSmithKline) with strong immunogenicity to HPV types 16 and 18, approved by the USA FDA on October 16, 2009 for girls 9–25-year-old. On December 10, 2014 the USA FDA approved 9-valent HPV recombinant vaccine Gardasil 9 (Merck Sharp and Dohme Corp., a subsidiary of Merck and Co.) for the prevention of certain diseases caused by nine types of HPV. Covering nine HPV types, five more than Gardasil, Gardasil 9 has the potential to prevent approximately 90% of cervical, vulvar, vaginal, and colorectal cancers. Gardasil 9 is a vaccine approved for use in females ages 9–26 years, and males ages 9–15 years, for the prevention of cervical, vulvar, vaginal, and colorectal cancers caused by HPV types 16, 18, 31, 33, 45, 52 and 58, and for the prevention of genital warts caused by HPV types 6 or 11. Gardasil 9 adds protection against five additional HPV types 31, 33, 45, 52 and 58, which cause approximately 20% of cervical cancers and are not covered by previously FDA-approved HPV vaccines. Thus, the approval of Gardasil 9 provides broader protection against HPV-related cancers.

FDA approval of Gardasil 9 is based upon a randomized, controlled clinical study conducted in the USA and internationally in approximately, 14,000 females ages 16–26 years who tested negative for vaccine HPV types at the start of the study. Study participants received either Gardasil or Gardasil 9. Gardasil 9 was determined to be 97% effective in preventing cervical, vulvar, and vaginal cancers caused by the five additional HPV types (31, 33, 45, 52, and 58). In addition, Gardasil 9 was as effective as Gardasil for the prevention of diseases caused by the four shared HPV types (6, 11, 16, and 18) based on similar antibody responses in participants in clinical studies.

Due to the low incidence of colorectal cancer caused by the five additional HPV types, the prevention of colorectal cancer is based on Gardasil’s demonstrated effectiveness of 78% and additional data on antibodies in males and females who received Gardasil 9. The effectiveness of Gardasil 9 in females, and males ages 9-15 years was determined in studies that measured antibody responses to the vaccine in approximately 1200 males and 2800 females in this age group. Their antibody responses were similar to those in females 16-26 years of age. Based on these results, the vaccine is expected to have similar effectiveness when used in this younger age group, Gardasil 9 is administered as three separate intramuscular injections at 0, 2, and 6 months. For all of the indications for use approved by the FDA, Gardasil 9’s full potential for benefit is obtained by those who are vaccinated prior to becoming infected with the HPV strains covered by the vaccine.

The safety of Gardasil 9 was evaluated in approximately 13,000 males and females. The most common reported adverse reactions were an injection site pain, swelling, redness, and headaches.

Dose and prescribing information of Gardasil 9.

Patient product information of Gardasil 9.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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