

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,^[1] 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.^[2,3]

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.^[4–6]

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.^[7] 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.^[8] 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.^[8]

Patient product information of Gardasil 9.^[9]

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

**Puneet Kumar Bagri, Saurabh Samdariya,
Puneet Pareek, Vrinda Pareek¹**

Departments of Radiation Oncology and ¹Psychiatry,
All India Institute of Medical Sciences, Jodhpur, Rajasthan, India

Correspondence to: Dr. Puneet Kumar Bagri,
Department of Radiation Oncology, Room No. 206, Resident Hostel,
All India Institute of Medical Sciences Residential Complex,
Basni Phase II, Jodhpur - 342 005, Rajasthan, India.
E-mail: drpuneetkb@yahoo.com

REFERENCES

1. FDA Approves Expanded Uses for Gardasil to Include Preventing Certain Vulvar and Vaginal Cancers. U.S. Food and Drug Administration (FDA); September 12, 2008. Available from: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/208/ucm116945.htm>. [Last retrieved on 2009 Nov 11]. [Press release].
2. The Ethics of Vaccination. Springer Publishing Company. Available from: <http://www.credoreference.com.wcezproxy.westminster>.

- edu/entry/suppbopeth/the_ethics_of_vaccination. [Last retrieved on 2013 Oct 03].
3. Haupt RM, Sings HL. The efficacy and safety of the quadrivalent human papillomavirus 6/11/16/18 vaccine gardasil. *J Adolesc Health* 2011;49:467-75.
 4. FDA Approves Cervarix, GlaxoSmithKline's Cervical Cancer Vaccine. GlaxoSmithKline; 16 October, 2009. Available from: http://www.gsk.com/media/pressreleases/2009/2009_pressrelease_10112.htm. [Last retrieved on 2009 Oct 30]. [Press release].
 5. Approval Letter Cervarix. U.S. Food and Drug Administration (FDA). October 16, 2009. Available from: <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm186959.htm>. [Last retrieved on 2009 Nov 13].
 6. Einstein MH, Baron M, Levin MJ, Chatterjee A, Edwards RP, Zepp F, *et al*. Comparison of the immunogenicity and safety of Cervarix and Gardasil human papillomavirus (HPV) cervical cancer vaccines in healthy women aged 18-45 years. *Hum Vaccin* 2009;5:705-19.
 7. FDA Approves Gardasil 9 for Prevention of Certain Cancers Caused by Five Additional Types of HPV. 10 December, 2014. Available from: <http://www.esmo.org/Oncology-News/FDA-Approves-Gardasil-9-for-Prevention-of-Certain-Cancers-Caused-by-Five-Additional-Types-of-HPV> [Last retrieved on 2015 Feb 28]. [Press release].
 8. Available from: http://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf. [Last accessed on 2015 Jul 11].
 9. Available from: http://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_ppi.pdf. [Last accessed on 2015 Jul 11].

This is an open access article distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as the author is credited and the new creations are licensed under the identical terms.

Access this article online

Quick Response Code:



Website:

www.cci-j-online.org

DOI:

10.4103/2278-0513.164718

Cite this article as: Bagri PK, Samdariya S, Pareek P, Pareek V. Gardasil nine: Is the number enough??. *Clin Cancer Investig J* 2015;4:687-8.