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IAP Q & A on Vaccines & Vaccinology



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CHAPTER 24

Varicella Vaccines

Tanu Singhal

Q1. What is the epidemiology of varicella in India relevant to vaccination?

Ans. Varicella is caused by the very highly contagious varicella-zoster virus (VZV), which has a worldwide distribution. Varicella spreads through inhalation of droplet nuclei and less commonly through contact with contaminated surfaces/lesions of the infected. It is highly communicable with secondary attack rates of >90% in the susceptible in household exposure and 15% in community exposure. The disease is usually benign in most children but can be severe in neonates, pregnant women, adults, and the immunocompromised. Absenteeism from schools and work places is another societal consequence.

The epidemiology of varicella largely depends on the climate and vaccination status of the population. Before the advent of immunization, the annual incidence was equal to the birth cohort. In temperate climates, most people were infected in early childhood and disease in adolescents and adults was rare. However, in tropical countries the age of natural infection is shifted upward. The exact reason is not known but may be due to reduced longevity of the virus in the vesicular fluid and surfaces due to higher temperatures and humidity.

Varicella is a common childhood illness in India. One study published from Kerala in 1978 reported the incidence as 74/100,000 population in 1973, 197.5/100,000 population in 1974, and 224.9/100,000 in 1975. Venkitaraman reported the incidence in medical staff and students between 1977 and 1982 as 720/100,000 population (0.72%), with the highest incidence in young adults aged 17–24 years. As a comparison, the incidence reported from the United States in the prevaccine era was 1,600 cases/100,000 inhabitants. Data from Asia Pacific about varicella rates in the absence of a universal vaccination program ranges from 100/100,000 in China (2007) to 2,530/100,000 in Taiwan (2000). There is no recent data available from India about incidence of varicella in the community. There is scanty data on mortality, complications, and hospitalizations in India. One study from Kolkata reported a mortality rate of 6% in 300 hospitalized cases of varicella.

A cross-sectional multicentric study on seroprevalence of varicella was performed in four major cities of India: Kolkata (formerly Calcutta)

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(outpatients), Mumbai (outpatients), Lucknow (walk-in patients to a diagnostic laboratory, orphanage, and factory workers), and Bengaluru (outpatients and walk-in patients to a diagnostic laboratory). A total of 1,609 volunteers from birth to 40 years of age were included in the study. The overall seroprevalence of anti-VZV antibodies was 68%. The age-related seroprevalence rate of anti-VZV antibodies was 29% in the age group of 1–5 years, 51% in 5–10 years, 72% in 11–15 years, 80% in 16–20 years, 88% in 21–30 years and 91% in 31–40 years. In another study done before the vaccine was available in India (1995–96), seroprevalence was 96.6% in the urban population versus 69.9% in the rural population. In a study in 5,000 nurses at the tertiary care hospital in Mumbai between 2014 and 2017, 28% were seronegative. Most of these nurses were from Kerala and in the age group of 21–30 years.

To summarize, there is limited recent data on the incidence and consequences of the disease in India. Seroprevalence data, however, indicates that a significant proportion of adolescents and adults are susceptible to the virus.

Q2. What is the risk of herpes zoster after natural varicella?

Ans. Varicella remains latent in the dorsal root ganglion to reactivate later in life. These reactivations may be subclinical or clinical as herpes zoster. The incidence of herpes zoster rises with advancing age. The lifetime risk of reactivation of herpes zoster is around 30%. Around 15% of all cases of herpes zoster present in children.

Q3. When was varicella vaccine first available in India? What is the uptake?

Ans. In India, varicella vaccine is available for immunization in the private sector since 1999. There are two studies reporting the uptake of the vaccine in the private sector; one reports this as 2.8% in children below 5 years in Chandigarh in 2004–2005 (doses not mentioned). Paradoxically, in another study interviewing educated mothers in the top socioeconomic sections of the society, coverage rates of 96.6% were reported and cost and access to the vaccine were not considered as barriers to vaccine uptake.

Q4. Which are the varicella vaccines available?

Ans. Monovalent varicella vaccines available in India currently are as under:

- *Variped (MSD)*: 1350 PFU/0.5 mL dose
- *Varilrix (GSK)*: $10^{3.3}$ PFU/dose
- *Biovac-V (Mf. China, Mkt-Wockhardt)*: 2,500 PFU
- *Varivax (Mf. China, Mkt-VHB Life Sciences)*: At least 2,000 PFU
- *Nexipox (Mf. China, Mkt-NovoMedi Sciences)*: 2,000 PFU
- *Zuvicella (Mkt Zuventus healthcare)*: At least 2,000 PFU

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- Other varicella containing vaccines include the MMRV vaccine (Measles, Mumps, Rubella with Varicella) and the Herpes Zoster vaccines.

Q5. What is the composition of the varicella vaccine?

Ans. All current vaccines are derived from the vOka strain. The Oka strain undergoes 11 passages in human embryonic lung cells, 12 passages in guinea pig embryo cells and 1 passage in WI 38 cells. This is common to all available varicella vaccines. Individual manufacturers subject this bulk substrate to further passages before producing the final vaccine product. *It needs to be emphasized that the number of passages has no relationship to the efficacy of the vaccine.* The World Health Organization (WHO) has not offered any guidelines regarding the choice of stabilizer.

Q6. How should the varicella vaccine be stored?

Ans. The vaccine is available in a lyophilized form and should be stored between 2 and 8°C in the refrigerator and has a shelf-life of approximately 2 years when stored appropriately. The diluent should be stored at 2-8°C or at room temperature; it should not be frozen. The vaccine should be reconstituted using the diluent provided and used preferably within 30 minutes of reconstitution.

Q7. What is the method for administration of varicella vaccine?

Ans. It is to be administered subcutaneously. It can be co-administered safely with all other vaccines. If given with measles, mumps, and rubella (MMR), then it should be administered either on the same day or 4 weeks apart. It can be given at any time interval with other killed or live vaccines. Salicylates should be avoided within 6 weeks of the vaccine owing to the risk of Reye's syndrome. The vaccine should not be given within 9–12 months of administration of intravenous immunoglobulin (IVIG).

Q8. What if varicella vaccine is administered intramuscularly?

Ans. Inadvertent intramuscularly (IM) administration has not been found to be associated with decreased seroconversion. Hence, it need not be repeated.

Q9. What is the immunogenicity of the vaccine?

Ans. The glycoprotein enzyme-linked immunosorbent assay (gp-ELISA) was the first test used to assess the immunogenicity of the vaccine. A gp-ELISA cut-off of 5 units/mL was seen to correlate better with protection against clinical disease as compared to seroconversion and this level was achieved in 86% of children following a single dose. Subsequent studies used fluorescent antibody to membrane antigen (FAMA) titers of >1:4 after 16 weeks of vaccination as a correlate of protection. FAMA antibody titers correlate better with protection against varicella as compared to ELISA and

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indirect fluorescent antibody (IFA) assays. It is postulated that the initial burst of antibodies that is measured by ELISA/IFA is inadequate to instill a T-cell memory response. By FAMA, a lower percentage of children (76%) achieve the protective cutoff following receipt of single dose of the vaccine as compared to the ELISA studies. Follow-up studies indicate persistence of antibodies for 7–10 years and even 20 years following vaccination. Since immunity to varicella is also cell-mediated, T-lymphocyte proliferation responses have been studied and found to be present in 87–90% of children for up to 5 years postvaccination.

The immunogenicity improves with a second dose of the vaccine in all respects, after one dose of varicella vaccine, 85-89% of children achieve protective antibody levels, and after two doses, >99% achieve this level.

The immunogenicity is similar whether the second dose is given 3 months or 4–6 years after the first dose **(Table 1)**.

The immunogenicity of the vaccine is lower in adolescents and adults and studies have demonstrated seroconversion rates of 72–94% following a single dose of the vaccine and 94-99% after two doses of the vaccine administered 4–8 weeks apart. Some studies indicate that 25–31% of adults lose their detectable antibodies by FAMA at multiple intervals (1–11 years) following vaccination.

Q10. What is the effectiveness of the varicella vaccine?

Ans. The pooled one-dose vaccine effectiveness (VE) was 81% (95% CI: 78–84%) against all varicella and 98% (95% CI: 97–99%) against moderate/severe varicella with no significant association between VE and vaccine type or study design ($P > 0.1$). For one dose, median VE for prevention of severe disease was 100% (mean = 99.4%).

Table 1: Immune response among children aged 12 months–12 years at 6 weeks postvaccination, by vaccine type and vaccination schedule—United States, 1988–2002 (MSD vaccine).

Immune response	*6 weeks after dose 1*		*6 weeks after dose 2 (after 3 months)*		*6 weeks after dose 2 (at 4–5 years)*	
	Varicella	*MMRV*	*Varicella*	*MMRV*	*Varicella*	*MMRV*
VZV IgG gp-ELISA > 5 units/mL	85.7	91.2	99.6	99.2	99.4	98.9
GMT VZV IgG gp-ELISA units/mL	12.5	13	142.6	588	212.4	317
Mean SI	28.6		36.9		58.6	

(GMT: geometric mean titers; gp-ELISA: glycoprotein enzyme-linked immunosorbent assay; IgG: immunoglobulin G; MMRV: measles-mumps-rubella and varicella; VZV: varicella zoster virus)

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Vaccine effectiveness for prevention of polymerase chain reaction (PCR)-confirmed varicella was 98% after two doses, compared with 86% for one dose ($P < 0.001$).

Q11. What is breakthrough varicella (BV)?

Ans. Varicella which occurs in children vaccinated >6 weeks after vaccination is called breakthrough varicella. It is generally milder and may present with just short-lasting maculopapular rashes and may not progress to the vesicular stage. BV has lesser fever, lesser number of lesions and a shorter duration of illness. However, it is infective, can result in transmission to susceptible contacts, and rarely result in severe complications and death.

Q12. Which are the risk factors for breakthrough varicella (BV)?

Ans.

- Vaccination below 12 months of age
- Not observing 28 days interval with MMR
- Immunocompromised child

Q13. Why is breakthrough varicella milder compared to varicella occurring in unimmunized persons?

Ans. In some individuals, one dose of the vaccine results in a suboptimal immune response resulting in the generation of an insufficient number of virus specific memory T-cells. While priming has occurred, the immunological response has been less than optimum resulting in suboptimal immunity and the resulting modified disease.

Q14. What is the effect of varicella vaccine on breakthrough varicella?

Ans. The risk of breakthrough varicella following one dose of the vaccine varies from 15 to 20%. Increased risk of primary vaccine failure is seen with lower age at first vaccine (12 months), lower titer vaccine, time since use of other live vaccines (within 4 weeks), receipt of oral or inhaled corticosteroids, and history of eczema or asthma.

In a 14-year prospective cohort study of the long-term effectiveness of varicella vaccine, it was noted that the highest incidence of breakthrough varicella was in the 1st year postvaccination (26.6/1,000 PY), but remained high in the first 6 years after vaccination (17.4/1,000 PY in the 6th year).

This tends to suggest that most of the vaccine failure is primary and not secondary. However, where the natural wild virus circulates, periodic boosting of immunity may lead to reduction in secondary vaccine failures.

Q15. What is the impact of varicella vaccination on herpes zoster?

Ans. The interplay between varicella vaccination and herpes zoster is complex. While both the vOka and wild virus establish latency, the capability of the vOka to reactivate is lesser than that of the wild virus. Studies also

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indicate lower incidence of herpes zoster in both immunocompromised and immunocompetent individuals vaccinated previously as against those who had natural varicella infection.

In immunocompromised children with leukemia, vaccination reduced the incidence of herpes zoster by 67%.

In the 14-year prospective cohort study of the long-term effectiveness of varicella vaccine, a 40% reduction in incidence of herpes zoster was noted.

But at a population level, matters are different. Universal vaccination is likely to reduce circulation of wild varicella virus and reduced exogenous boosting of older individuals with increased tendency for shingles.

Following the introduction of universal varicella vaccination in the United States of America, herpes zoster incidence has continued to increase in a generally steady manner among the younger adult age strata (i.e., aged 35 through 50–55 years), without any clear accelerations or decelerations during the study interval (1996–2016). However, among the older age strata (i.e., aged ≥50–55 years), a deceleration has been noted since 2006.

Q16. What are the adverse effects of varicella vaccination?

Ans. The vaccine is generally well tolerated and the side effects reported are mild and transient. Approximately, 6% of recipients develop vaccine-associated rash either generalized or localized or both, 1 month after vaccination. This is similar to varicella rash but less extensive. Other adverse events associated with varicella vaccine include fever (10–14%), and injection-site reactions (in up to 20%). The overall incidence of adverse effects following vaccination is 2–4/10,000 doses.

Case-control studies did not find any significantly increased risk of exacerbation or induction of diseases such as systemic lupus erythematosus, Guillain-Barré syndrome, multiple sclerosis, neuritis, thrombocytopenia, or vasculitis. One of the most comprehensive systematic studies reports 30 neurological adverse effect cases out of 16,683 adverse events reported. In none of these, however, was the vaccine strain found in the cerebrospinal fluid of subjects. Extensive rashes with pneumonia or neurologic symptoms have been reported in immunocompromised children who have been inadvertently administered the vaccine but these cases are but a handful. The excellent safety of the varicella vaccine is attributed to the fact that it is highly attenuated and does not revert to virulence and remains susceptible to the usual antiviral drugs. One study on use of two doses of varicella vaccine in children with acute lymphoblastic leukemia, given the vaccine after the intense chemotherapy was over, showed rash appearing in almost 40% of children with the first dose but not with the second dose.

Q17. What are the contraindications to varicella vaccination?

Ans.

- History of hypersensitivity to one or more components of the vaccine (including neomycin and gelatin) and previous varicella vaccine.

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- Immunodeficiency:
  - Any cell-mediated or combined immunodeficiency. It may be given in severe B-cell immunodeficiency such as agammaglobulinemia but is unlikely to be effective. Here, the monthly intravenous immunoglobulin therapy provides some passive protection. It can, however, be given in less severe B-cell immunodeficiencies such as immunoglobulin A (IgA) and immunoglobulin G (IgG) subclass deficiency and also in complement and phagocyte immunodeficiency.
  - Human immunodeficiency virus (HIV) infected children/adults with a CD4 count of ≤15% or clinical symptoms of HIV disease.
  - Persons receiving high-dose systemic immunosuppressive therapy, including persons on oral steroids ≥2 mg/kg of body weight (if <10 kg weight) or a total of ≥20 mg/day of prednisone or equivalent for persons who weigh ≥10 kg, when administered for ≥2 weeks. It may be given 1 month after cessation of steroid therapy.
  - Patients with cancer on chemotherapy and following solid organ transplant/hematopoietic stem cell transplant (HSCT). For cancer survivors varicella vaccine may be given 3–6 months after cessation of all chemotherapy. It may be given 24 months after HSCT if the patient is not on immunosuppressive drugs, does not have graft versus host disease, and the antivaricella IgG is negative.
  - Persons who have a family history of congenital or hereditary immunodeficiency in first-degree relatives (e.g., parents and siblings) unless the immune competence of the potential vaccine recipient has been clinically substantiated or verified by a laboratory.
  - The vaccine can be given safely to family contacts of immunodeficient hosts including those with HSCT. However, if the vaccinee develops a vaccine-induced rash then contact with the immunodeficient patient should be avoided.
- Pregnant women or women planning to become pregnant. Pregnancy should be avoided for a minimum 1 month and preferably 3 months following the vaccine. Registry data, however, indicates no increased risk of congenital birth defects following accidental vaccination in pregnancy or in women who become pregnant within a month after vaccination. Hence, medical termination of pregnancy (MTP) is not indicated in this setting.
- The safety of varicella vaccination in breastfeeding mothers has not been adequately studied.
- The efficacy and adverse event profile has not been studied in infants below the age of 9–12 months. However, there is need for studies of varicella vaccination in infants born to seronegative mothers and especially if there are due for solid organ transplants (liver transplant in infants with metabolic liver disease or extrahepatic biliary atresia).

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Q18. What are the ACVIP recommendations for the use of varicella vaccines?

Ans. Advisory Committee on Vaccines and Immunization Practices (ACVIP) 2018 recommends offering the vaccine to all healthy children with no prior history of varicella with special emphasis in all children belonging to certain high-risk groups as enumerated below:

- Children with humoral immunodeficiencies
- Children with HIV infection but with CD4 counts 15% and above the age-related cutoff
- Leukemia but in remission and off chemotherapy for at least 3–6 months
- Children on long-term salicylates. Salicylates should be avoided for at least 6 weeks after vaccination.
- Children likely to be on long-term steroid therapy. The vaccine may be given at any time if the children are on low-dose steroids/alternate day steroids but only 4 weeks after stopping steroids if the patients have received high-dose steroids (>2 mg/kg) for 14 days or more.
- In household contacts of immunocompromised children
- Adolescents who have not had varicella in past and are known to be varicella IgG negative, especially if they are leaving home for studies in a residential school/college.
- Children with chronic lung/heart disease
- Seronegative adolescents and adults if they are inmates of or working in the institutional setup, e.g., school teachers, daycare center workers, military personnel, and healthcare professionals.

Q19. What is the IAP schedule for vaccine administration?

Ans. The Indian Academy of Pediatrics (IAP) recommends administration of the first dose at 15–18 months and the second dose is recommended preferably 3 months after the first dose or at 4–6 years.

For catch-up vaccination in children aged 12 months to 12 years, two doses should be given 12 weeks apart; the minimum interval should be 4 weeks. For catch-up vaccination in children 13 years and above, two doses should be given 4–12 weeks apart. Here, the interval between the two doses can be short to ensure early protection.

Q20. What is the optimum timing for the second dose?

Ans. The timing of the second dose has been debated. Vaccine failure following varicella is more due to primary rather than secondary vaccine failure. Most cases of breakthrough varicella occur early after vaccination. Hence, shifting the second dose to the 2nd year of life should reduce the risk of breakthrough varicella further without compromising the safety and efficacy of the vaccine A modeling study estimates that shortening the interval between two doses could reduce twofold the cumulative number of cases of breakthrough varicella. The second dose should be administered 12 weeks after the first dose; the minimum acceptable interval is 4 weeks.

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Q21. What is the protocol for administration of varicella vaccine in children with acute lymphatic leukemia (ALL), with no evidence of immunity?

Ans. Since varicella is a devastating illness in the immunocompromised especially acute lymphatic leukemia (ALL), exclusive recommendations exist for administration in ALL.

In children between 12 months and 17 years of age with a negative history of varicella in whom leukemia is in remission for at least 12 months, the peripheral blood lymphocyte count ≥ 700 cells/mm^3 and the platelet count is ≥100,000/mm^3, two doses of varicella vaccine may be administered. Maintenance chemotherapy should be withheld for 7 days before and after at least the first dose.

Q22. If a child had a very mild chickenpox, will it provide adequate immunity? Is vaccine necessary?

Ans. Any varicella illness, whether mild or severe will confer immunity and hence vaccination is not necessary following the illness. However, if the diagnosis is in doubt, it is preferable to administer the vaccine, as vaccine administered to an immune child will not result in any increased adverse effects.

Q23. Can varicella vaccine be administered to a 10-month-old infant for postexposure prophylaxis?

Ans. No. Varicella vaccine is not licensed for use below the age of 1 year. Even if inadvertently administered before 1 year of age, it should be counted as an invalid dose.

Q24. Is postvaccination serology necessary following varicella vaccination?

Ans. Postvaccination serological testing is not recommended for anyone, including the high-risk groups.

Q25. How useful is varicella vaccination in postexposure prophylaxis?

Ans. Among children, protective efficacy was reported as ≥90% when vaccination occurred within 3 days of exposure.

Protective efficacy in preventing any type of disease was 62.3% [confidence interval (CI) 95%: 47.8–74.9)] and 79.4% (CI 95%: 66.4–88.9) in preventing moderate and severe disease, up to 5 days after exposure.

Vaccination still recommended for those with no other evidence of immunity even after 5 days of exposure because it will help provide protection against future exposures. Thus, vaccination >5 days postexposure is recommended to help protect against subsequent exposures and limit VZV transmission during an outbreak.

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Q26. What is the public health impact with varicella vaccination?

Ans. There are basically three approaches for varicella vaccination: universal vaccination with one or two doses, selective immunization of high-risk individuals, and finally immunization of patients who can pay for the vaccine. The WHO recommends that countries can consider introducing the varicella vaccine in the public program if they consider varicella a significant health problem and are able to maintain sustained coverage rates of >80%.

Universal vaccination has been implemented in some high-income countries including USA (two doses at 12 months and 4–6 years), Germany (two doses in the second year), Greece, Latvia, and some provinces of Italy and Spain. In the Asia Pacific, universal vaccination is practiced in Australia (two doses), New Zealand (two doses), Japan (two doses), South Korea (one dose), Taiwan (one dose), and Hong Kong (two doses). In the USA, in the prevaccination era there were about 4 million cases (about 1,600 cases per 100,000 inhabitants), 11,000–13,000 cases of hospitalization and 100–150 deaths per year in the early 1990s. With the introduction of vaccination in 1995, the number of cases decreased by 79% in the 2000–2010 period compared to the prevaccination era and, since the introduction of a second vaccine dose, by 93% in 2012. In the same year, hospital admissions and deaths from varicella decreased by 90%. No impact on the incidence of herpes zoster in adults was noted. Closer home, in Asia Pacific, rise in incidence of varicella following implementation of the universal vaccination program in Australia, South Korea, and Taiwan probably due to better reporting rather than true increase.

In some countries including areas of Spain and Italy, varicella vaccination has been recommended for high-risk patients.

In the rest of the countries including India, varicella vaccine is administered outside the national immunization program to children and patients who can afford the vaccine. Since only a small proportion of the population undergoes vaccination, it is not possible to study the public health impact of the program. At the author's institute since implementation of a varicella vaccination program for seronegative nurses in 2014, a significant decline in incidence of varicella in nurses was observed.

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