Indian National Young Academy of Sciences (INYAS)

INYAS COVID-19 Vaccine Awareness Campaign

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COVID19, Vaccination and The Common Questions

Even though COVID 19 is now showing a declining graph in varying degrees globally, vaccination is the only step to eliminate the scare and volatility of this era. With various factors (such as expedited trials, political views and mixed opinion from experts as well as non-experts), people have a lot of apprehension for COVID19 vaccines. The scepticism is deterring the people from accepting vaccines and may actually lead to failure of the mass immunisation program, that the Government of India is rolling out. There have been several articles and documents which have been created to promote the vaccines and to provide clarification to the common misconceptions. We, INYAS - a national science academy of young scientists, have made some efforts to collate the important points in the form of top thirty questions and answers.

The questions are divided into following sections:

1. About corona virus and COVID-19
2. About vaccines: function, approval and production
3. Vaccination protocol - protection, side effects, and efficacy
4. Health, ethical and religious concerns
5. Post vaccination and future vaccines

About Corona Virus and COVID-19

1. What is corona virus and is it stronger than other viruses?

   Coronaviruses are a group of viruses characterized by RNA as the genetic material having an envelope encasing it. The word 'corona' means crown like and this comes from the presence of crown like structures on the surface of these viruses. COVID-19 or SARS-CoV-2 is one among the members of the coronavirus family.
   When it comes to virulence, it is not correct to categorize COVID-19 as stronger or not virulent as compared to all other viruses that exist. The mode of transmission through direct contact of the infected person or even at close proximities expedited the spread and lost many lives globally. There have been reports of possible airborne transmission as well which makes this virus easy to spread. In comparison to past pandemics, COVID 19 has tricky and complex mechanisms that have facilitated its rapid. Spectrum of effects from mild to severe ending in death has been observed along with long lasting health issues of varying degree after recovery. The decline in death rate could be due to the change in genetic makeup known as mutations, which help virus to better adapt to its host, making less virulent In this cycle of mutation and adaptation, new mutations might emerge that could be more virulent or more transmissible and thus might lead to cycles of more and less cases before 'herd immunity' is achieved. Since time taken to achieve herd immunity is not predictable, it is important the therapeutic measures are available to better manage the crisis.

2. What is herd immunity?
   Herd immunity is protection from a disease due the resistance developed in a large percentage of population towards infection.

About Vaccines: Function, Approval and Production

3. How do Vaccines work?

   Vaccines are the biological preparations and they work by helping the immune system to recognize, remember and destroy a pathogen. It trains the immune system to remember the pathogen as foreign and recognize it in any future infection through key immune effector (T & B cells). Along with destruction of a pathogen or pathogen infected cells by cytotoxic T cells or antibodies produced by B cells, the generated memory cells will assist in immunological memory to remember the pathogen for a long time and prevent re-infection. Thus, vaccine induces both immediate protections *via* antibody production as well as long term protective by evoking immunological memory.

4. What are the stages from development to approval of vaccine? What is the status of approval in India?

   Vaccines are developed through three phases – Phase 1 where testing for safety and dosage will be done. Phase 2 focuses on expanded safety trials and phase 3 for large scale efficacy tests. After the completion of three phases, vaccines will be authorized and granted licence by the drug regulation authorities based on stringent analysis and data on safety and efficacy trials. After the approval and obtaining clearance from the regulatory bodies, vaccines are introduced in any country. In India, at present 2 vaccines (Covishield and Covaxin) are in use under emergency use authorization after consent from volunteers. Both vaccines do not need intense cold chain requirements and hence included in mass immunization programme.

5. How many vaccines are approved and are at what stages?

   The details on leading vaccines which completed phase 3 is tabulated below

Vaccine	**Developer**	**Nature of action**
Covishield	Oxford-AstraZeneca (Producing by Serum Institute of India)	modified version of a chimpanzee adenovirus, known as ChAdOx1/AZD1222
Pfizer	Pfizer-BioNTech	mRNA (wrapped in lipid nanoparticles)
Moderna	Massachusetts-NIH	mRNA1273
Covaxin	Bharat Biotech, National Institute of virology and Indian Council for Medical Research (ICMR)	inactivated coronaviruses (by treating with chemical - beta-propiolactone)

Sputnik V (Gam-Covid-Vac)	Gamaleya Research Institute (Russian Ministry of Health)	Double stranded DNA inside adeno virus (Ad26 and Ad5)
Convidecia (Ad5-nCoV)	CanSino Biologics, China	Ad5 adeno virus based
BBIBP-CorV	Beijing Institute of Biological Products (Produced by Sinopharm, China)	inactivated coronavirus vaccine

Other Indian companies like Biological E, Cadila Healthcare and Genova are also in the advanced stage of vaccine development.

6. Which vaccine to choose and who will get the priority?

   In India, currently we only have two vaccines (Covishield and Covaxin) available for public use. Most of the vaccination centres have one or the other. We can either accept the one available, or wait for another turn. It will take more time before we have multiple options for general public. Even though currently price is not a concern, the vaccine type (like RNA or DNA) as well as its make (indigenous or foreign) will affect the price in future.

   In the priority list, government of India has selected around 30 crore people, called as "Prioritized Population Groups" for COVID-19 vaccination programme. They include about

   - 1 crore healthcare workers from both government and private sectors
   - Nearly 2 crore frontline workers such as security personnels and people involved in essential services
   - Approximately 27 crore Prioritized Age Group peoples (<50 yrs. old and with co-morbidities.

Vaccination protocol – Protection, side effects and efficacy

7. How vaccines will be given? What is the process?

   Vaccines will be deployed through public and private centres managed by trained staffs (like doctors, dentists, nurses and paramedics) with a maximum of 100 vaccinations per day. In order to get vaccinated, one has to register on COVID Vaccine Intelligence Network (Co-WIN) mobile app. Through the registered mobile number, the eligible beneficiaries will be informed regarding the vaccination centre, scheduled time and date. The vaccine recipient has to wait for 30 minutes before leaving the centre post-vaccination.

ID cards with Photo like (Aadhar Card/Driving License/Health Insurance Smart Card issued by the Ministry of Labour/Mahatma Gandhi National Rural, Employment Guarantee Act (MGNREGA), Job Card/Official identity cards issued to MPs/MLAs/MLCs/ PAN Card/Passbooks issued by Bank/Post Office/Passport/Pension Document/Service Identity Card (with photograph) issued to employees by Central/ State Govt./ PSUs/Public Limited Companies/Voter ID/Smart card issued by RGI under NPR) may be produced at the time of registration as well as vaccination.

8. What is a vaccine dry run?

   Dry run is a mock immunisation process of a vaccine candidate conducted across all states and Union territories (UT), to assess the operational feasibility of Co-WIN app, to understand the possible field related application problems (like storage, supply) and to plan the logistics for actual implementation. In the dry run, a test vaccines beneficiary includes mostly staffs of the designated vaccine centres as well as volunteered health care workers. During dry run, each designated vaccine centre is supposed to conduct each and every step of immunization protocol from registering test beneficiaries in CoWin database with their ID card, verification, mock vaccination and post-vaccine observation.

9. What is Co-WIN?

   Co-WIN is a mobile application which will be available from play stores. It is world's first, digital, end to end, vaccine distribution and management system. It includes beneficiary registration, authentication, document verification, session allocation, AEFI (Adverse Event Following Immunization) reporting and certificate generation. It is currently in the pre-product stage and operational feasibility analysis carried out during dry run. A Co-WIN portal is also being developed as part of National Digital Health Mission, which combines the data from various agencies like ICMR, Ministry of health and Ayushman Bharat.

10. If I fall in the category of priority list by any chance, how do I contact the appropriate vaccination authority?

    This will be managed through the mobile app 'Co-WIN', which will categorize your priority based on the relevant details.

11. Does India have the capacity to store the COVID vaccine at temperature of +2 to +8 degree Celsius and to transport them at required temperature?

    Yes. India runs one of the largest Immunization programmes in the world, catering to the vaccination needs of more than 26 million new borns and 29 million pregnant women. The programme mechanisms are being strengthened / geared up effectively to cater the country's large and diverse population. The storage and transport in normal refrigeration temperature (+2 to +8 degree Celsius) is not a limiting factor. Many more, Serum Institute of India had partnered with GAVI and Bill and Melinda Gates foundation for the efficient vaccine manufacture and distribution for low- and middle-income countries also.

12. What is the recommended dose and schedule? If multiple doses, are they same and what if only single dose is taken?

    As per the vaccination schedule, two doses are given 21 - 28 days apart (depending on the vaccine type). On getting due dose of COVID 19 vaccine; the beneficiary will receive SMS on their registered mobile number. After all doses of vaccine are administered, a QR code based certificate will also be sent to the registered mobile number of the beneficiary. In most vaccines, the same dose will be given twice. However, Sputnik- V vaccine has both doses as different vector viruses, so will be marked as dose 1 and 2. Covishield vaccine may also come out with first dose as half dose. However, the main antigen administered is the same.

    Single dose can only provide partial protection (60-80%) and might not last long enough. Hence for complete protection two doses must be taken at the recommended intervals. Incase if somebody forget or unable to take the second dose on the defined date, it can be taken at the nearest possible date and there is no need to repeat the first dose.

13. Do vaccination required for COVID 19 recovered patients? Can it be administered to an individual who has received plasma as treatment for COVID19?

    The immunity developed after a natural COVID-19 infection will depend on the severity of infection. Thus, for those who had mild infections, protection might not have been ensured. The donor plasma contains anti COVID-19 antibodies has been used for the treatment. Those who recovered naturally or through plasma treatment might not need vaccine at early phase. But plasma only provides temporary antibodies to aid the recovery process and does not provide immunological memory for long term prevention. Thus, both recovered categories with and without plasma treatment eventually should also undergo vaccination at later time point to ensure long term protection.

14. Is vaccine safe for pregnant lady, lactating mother and diabetic patients?

    Regarding pregnant ladies and lactating mothers, it's not advised yet to receive vaccinations as they have not been tested in such cases. Thus CDC (Centre for disease control and prevention) has advised against giving vaccine to these groups and UK authorities have also advised women not to get pregnant for two months after the shot. Since the vaccines available till now are not live vaccines, it should not cause any problem if given inadvertently.

    But in case of diabetic patients, it's safe and very much advised to ~~must~~ get vaccinated on priority as there has been an established risk factor for severe diseases like diabetes and COVID 19. Getting vaccinated is still a choice and completely voluntary, but definitely advisable.

15. Children of what age can be vaccinated? Is the dose same as adults or lesser dose to be given?

Till now trials have been done only for adults (above 18), while trials for children (above 12) have also initiated. Doses will be decided only after the trials done on younger children and infants. Thus, vaccination of children is subjected to successful trial results.

16. Can it be given to immunocompromised individuals?

    The mRNA vaccine and inactivated vaccines are safe. Covishield and Sputnik-V adenovirus vector vaccines are also safe as they are non-replicating viral vector vaccines. Live vaccines and replicating viral vector vaccines will have to be avoided.

17. Is it mandatory to take vaccines? If offered a choice, which one should, we take?

    In majority of countries, it will not be mandatory. Choice is yours. Currently there are only two options available and hence no choice at vaccination centres. It might be wise to think positive that at least one is being offered a vaccine ahead of others. But it must be ensured that the entire schedule of vaccination (*i.e.* two doses)

18. How many days after getting vaccine would develop protection and how long will it last?

    Best protection starts 10 days after the second dose. Efficacy is around 70-90% against all severity and 100% against hospitalization. Immediate aim is to prevent hospitalisation and mortality. Being a new technology, we exactly don't know regarding the safety span. This could be answered after following up the immunized people for long time.

19. Due to expedited trials, what compromises were made in case of COVID19 vaccines?

    Vaccine development is a long-term process involving three phases with many check points to ensure only safe and efficacious candidates with long lasting immunity are rolled out for public use. There are three major clinical trial phases (I, II and III) each having its own purpose and also differing from one another based on the fact that number of volunteers recruited vary from 10s to 100s to 1000s from phase I to III respectively and that phase I is meant to ensure safety, phase II for immunogenicity and phase 3 for efficacy. For most of the current vaccine candidates in the market reached phase 3, while on few cases interim results of phase 3 trial was made available and the approval was given based on the same (complete phase 3 trial data is expected to come in near future). As we are facing a pandemic and this pandemic has seen many deaths and sufferings, it is a public health emergency situation. Hence, some vaccines have been approved for emergency use based on available interim data while one of the vaccines have been approved for vaccination in informed clinical trial mode which means the vaccinated people will be a part of phase 3 trial and will be monitored in future.

20. What are the side effects expected and reported?

    The side effects reported by the trial population are mostly mild COVID like symptoms like some fever, myalgia, malaise and fatigue. Local injection site pain and induration are also reported. Reports of transverse myelitis and facial palsy have not been found

to be related to the vaccine. In case of Covishield, warmth, tenderness, redness, swelling or bruising at injection site along with flu-like symptoms have been reported in less than 1%. For Covaxin other than the above symptoms, stiffness of the arm, nausea, vomiting as well as allergic symptoms (difficulty in breathing, rashes, swelling of face, dizziness) has also been reported in less than 1%.

21. As virus keep on getting mutated there could be a need for another vaccine. So is it logical to wait?

    COVID-19 virus like any virus has also undergone many mutations. But the mutation rate is not akin to more frequently mutating ones like the Flu virus. Some of the mutations like the D614G or the more recent one like the UK strain have drawn attention and has sparked a new state of panic globally. Currently we lack in enough evidence or data to comment on the effect of these mutations on the efficacy of current vaccine candidates specially if a candidate vaccine is based on full spike protein or the whole virus as then alternate antigenic regions are available to retain the desired function of a vaccine. It is important to remember that we don't know whether these variants are also 'serotypes' *i.e.* antigenically distinct enough to evade host cell immune response distinctly as compared with other existing variants.

Health, ethical and religious concerns

22. As some vaccines are mRNA based, is there any possibility that the messages from vaccine gets incorporated into the human genome and alter our genetic structure?

    No. There is no such possibility as mRNA is localized in the cytoplasm while DNA is localized in the nucleus of the cell. mRNAs translate to produce polypeptides/ proteins that it codes for in the cytoplasm. Thus mRNA vaccine carries a message to the cell to produce the antigen of interest (e.g. spike protein or receptor binding domain etc) as a result of mRNA translation. In due course this antigen is processed inside the cell and it ultimately induces antibody production and generation of memory and effector T and B cells.

23. Do COVID vaccines linked to health issues like autism or impotency?

    Based on existing information, these reports are baseless. A paper linking MMR with autism was reported in 1985, while follow up survey involving millions of children have conclusively proven that there is no relationship. Till date there are no reports on effect of vaccines linked to impotency also.

24. Can any other vaccine help to protect against COVID-19?

    Although there have been studies in this line understanding the effect of tuberculosis vaccine – *i.e.* Bacille Calmette-Guérin (BCG towards COVID-19, but we do not have any conclusive data.

25. Being vegetarian or allergic to egg, will it affect the effect of vaccine in our body?

COVID -19 vaccine is like another vaccine available for common public and should not be called as vegetarian or non-vegetarian origin. Similarly, eggs are not used for production of vaccines and hence can be taken safely even if you are allergic to egg.

26. Are COVID-19 vaccines *HALAL?*

    COVID -19 Vaccine is like another vaccine available for common public and should not be called as *HALAL* or *HARAM*.

Post vaccinations and future of vaccines

27. Are there any preventive measures and precautions that one needs to follow at the vaccination centre?

    Its requested to take rest at the vaccination centre for at least half an hour post vaccination. Inform the nearest health authorities / ANM (Auxiliary Nurse Midwife) / ASHA (Accredited Social Health Activist) in case you feel any discomfort or uneasiness subsequently. Remember to continue key COVID behaviours like wearing of mask, maintaining hand sanitization, avoiding touching the face with unwashed hands, keeping physical distance etc.

28. Is there a need to wear mask even after getting vaccinated and why?

    Yes, as of now it's important to keep on continuing the COVID behaviours. One can stop wearing mask only when the majority of the population has either got the disease, received the vaccine or achieved herd immunity. It is important to understand that vaccination only ensures that the vaccinated individual does not get the 'disease'. Vaccination will not prevent infection. A vaccinated person may still get infected and transmit the virus although he/she does/does not suffer from the disease.

29. Can we expect newer and better COVID vaccines in near future?

    As of December 2020, more than 250 vaccines are under trial in different phases. A lot of research is underway to develop newer delivery methods also. Nasal spray vaccine is probably the most promising. A multi-dose nasal spray delivery device can be very convenient as it will produce local IgA antibodies to block the virus at entry itself. It will reduce nasal colonisation and thus prevent transmission of disease also. Unfortunately, since it will be a live vaccine, it will need maximum and most stringent trials and thus will take longest time to hit the market. Among the candidates, which one is better or more efficacious can only be ascertained after rigorous phase 3 clinical trials are completed and results compared and that will take its due course.

30. Who should not get this vaccine?
    Immunocompromised individuals as well as who has history of allergic reactions towards vaccines or its ingredients shouldn't be taking the vaccine.

Editors

Upasana Ray
Mudrika Khandelwal

Managing Editor

Veda Krishnan

Cover Design

Akshai Kumar A. S

Indian National Young Academy of Sciences (INYAS)

Indian National Science Academy, 2, Bahadur Shah Zafar Marg,
New Delhi-110 002, India

@INYAS_INSA

Contact us:
Email: inyas@insa.nic.in; inyasindia@gmail.com
Website: http://inyas.in/