



An Objective Overview of Covid19 Vaccine Situation in India

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ABSTRACT

Entire world was eagerly waiting for the vaccine against SARS-CoV2 ever since Covid19 pandemic started. India is the second largest populous nation and is among the very few nations who has developed a vaccine against SARS-CoV2. India is also a major vaccine producing hub supplying large quantum of vaccines to the rest of the world. Efficacy, advantages and comparison between various covid vaccine has been largely discussed by the scientific community. However, there are various other factors affecting the vaccine situation in a nation, may it be the plan, strategy, its implementation, local context, health infrastructure etc. While there are many news and views related to covid-19 vaccine, one need to look beyond & into so many other aspects related to the factors affecting this situation. Through discussion of some of these key factors, we tried to draw an overall picture of the Covid19 vaccine situation in India. Keeping in line with our objective, we keep the focus of our discussion on vaccine development & manufacturing issues, diplomatic decisions on vaccine & the reasons behind the same, international factors etc. We have purposefully restricted our discussion to these factors and did not go in details of the national level policy and its implementation details in this article.

Key words: Covid19, Vaccination, India, Overview

During the year 2020, the novel coronavirus spread across the world.¹ India being the 2nd most populous nation was at very high risk of transmission. The absence of herd immunity among population, created a situation with dichotomous option for the population. One of the options is to develop natural immunity through successful recovery from natural infection of SARS-CoV2, but it also involves high risk of mortality particularly in people with old age and/or with other comorbid conditions.² The other option is to develop acquired immune response against the virus through vaccination. Although, the second option of vaccinating people is undoubtedly the best, the problem early in the pandemic was that effective vaccine was not immediately available. Any successful vaccine development was likely to take at least around 1-2 years, during which there is risk of pan-

demical transmission reaching its peak, if effective control measures are not applied with strict enforcement.

Fortunately, we got the news of successful vaccine development, within very short time which give some signs of relief. The first vaccine was available in less than a year's time at the ground level.³ Covid19 vaccination serves multiple purposes but most importantly, it protects against the consequences and complications of Covid.⁴ Even if the vaccine may not protect fully against the occurrence of covid19, it surely prevents deaths due to covid19.⁵ Vaccination helps one's immune system to recognize and clear the virus more quickly and quite early in the illness, often without any obvious clinical symptoms. The faster the vaccine recipients clear the infection; less

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likely it is that the recipient spread the infection to others. Thus, the vaccine offers the protection from illness and facilitates early recovery from covid19, and helps in controlling the spread of pandemic by reducing the risk of transmission as well.⁶⁻⁸ It also reduces the health cost for the covid19 health care management, and indirectly helps in survival of the economy with a revival boost in the time of pandemic crisis.

There are various vaccines against covid19, and there may be certain limitations with all the vaccines. However, in pandemic times, what is more important is to get earliest protection with whatever vaccine that is available or offered.⁹ So, instead of focusing on various vaccines, we have tried to focus on various other issues directly affecting covid19 vaccination in India. While, vaccination seems to be the best and most effective way to end the pandemic, the following are some of the factor's worth noting from covid19 vaccination situation in India.

VACCINE DESIGN & DEVELOPMENT

Although the developed nations like US and UK, are way ahead in terms of research and new vaccine development, India is not far behind. Technically highly skilled and brilliantly academic scientists from India, have contributed in development of an indigenous vaccine "Covaxin".¹⁰ This shows India's excellence in the field of vaccine design & development. This also helps in reducing India's dependence on other developed nations for vaccine.

VACCINE MANUFACTURING

India is an important and globally recognized hub for vaccine manufacturing. Indian vaccine industry has established a strong hold over the entire chain of vaccine research & development right from basic science to bulk manufacturing of vaccine. Indian vaccines are known for world-class manufacturing at an affordable rate with high quality. India is said to be the vaccine production hub for the world, producing about 60% of the world's vaccines.¹¹ India is also the biggest supplier of vaccine to the UN agencies, supplying between 60-80% of the vaccines that they buy each year to supply these vaccines to many developing countries. Considering this existing situation, India definitely has an upper edge while considering the vaccination against covid19.

VACCINE FORMULA - TECHNOLOGY TRANSFER

Indian Council of Medical Research (ICMR) and National Institute of Virology (NIV) have developed the first indigenous vaccine against covid. However, once developed, the vaccine technology is shared with only one private sector manufacturer (Bharat Biotech) as part of contract. This means that the vaccine formulation for Covaxin was not shared with more production units with licensure. Involving more companies for vaccine production could have avoided the

vaccine shortage scenario and might have helped in preventing plentiful deaths & millions of lives affected with covid19 infections. After a lot of criticism on this, in May 2021, government invited all manufacturers with BSL3 (Bio Safety Level 3) to join hands in manufacturing Covaxin.¹² Although a bit late, but this wise and correct decision made the additional doses of vaccine available for the eagerly waiting citizens of India as well as other nations.

VACCINE PRODUCTION CAPACITY – GOVERNMENT SECTOR

There are different categories of vaccine production units in India.¹³ There are three Government manufacturing units which used to contribute in vaccine production in the past. These are Central Research Institute, Kasauli; BCG Vaccine Laboratory, Guindy; and Pasteur Institute of India, Conoor. The license for these 3 vaccine production units had been cancelled in 2008 as they were not following the good manufacturing practices laid down in the Drugs and Cosmetic Rules, 1945. These are government manufacturing units and efforts to revive them to improve India's functional capacity seems to be insufficient.

VACCINE PRODUCTION CAPACITY – PSU & PRIVATE SECTOR

There are four units with public sector undertaking and more than a few as private sector manufacturing units. However, there are only 2 units which are part of Covid19 vaccine production during the early part of 2021. This clearly shows lack of preparedness and underutilization of existing vaccine production capacity. This is more so true, when we are aware, for more than a year now, that effective vaccine is the only safest way out of this pandemic. In spite of knowing this fact, probably we have not done enough on this front. Although, partnership in vaccine production requires licensing and many other formalities, still the efforts seem to be insufficient. In a quite belated move, on April 16, 2021, the government announced a plan to include three PSUs (namely Haffkine Biopharmaceutical Corporation Ltd, Mumbai, Indian Immunological Limited, Hyderabad & Bharat Immunological and Biologicals Limited, Bulandshahar) in the vaccine-making process. If more production units would have been revived and made part of covid19 vaccine production in a timely manner during 2020, then the situation would have been much different.

SELF-LESS ALTRUISTIC INDIA

Developed nations like USA, UK have reserved all vaccines for domestic consumption & complete vaccination of their own citizen is their first priority. European Union (EU) countries are sharing their vaccine but that too within themselves. On the other hand, the Low- & Middle-Income Countries (LMICs) are experiencing a great crisis as they are unable to

manufacture vaccine on their own and they are completely dependent on other nations for their vaccine requirement. India is in an extremely crucial position in the middle of both these extreme situations, maintaining and managing equilibrium. Historically, India has been the country with the biggest heart. Whether its sending military personnel for UN peace keeping mission or lifting its ban on exports of medicines to other countries when they need it (e.g., Hydroxy Chloroquine to USA), India has always stood first in charity for others, and this has paid off very well. When India needed Oxygen, medicines & many other resources to combat the pandemic situation, the world stood hand in hand with us. Even the issue of raw material supply to India which was required for vaccine production, got resolved in a very short time, positively in India's favor.

VACCINE APARTHEID

Looking at the global covid19 vaccine scenario, developed nations, who are the key manufacturers of covid vaccine, have manufactured large amount of vaccine for themselves, stocked vaccines and refuse to release the vaccine to the third world countries in dire need. They even refuse to export supplies of intermediate products and raw materials required to produce vaccines in other countries. While these countries heading towards normalcy & mask-free status again, the rest of the world is still experiencing the Covid nightmare. India has strongly recommended waiver for an intellectual property right for the Covid vaccine in the World Trade Organisation.¹⁴ This is required to ramp up the manufacturing of the vaccine. Those who are against this waiver argue that no company would invest for vaccine development in future pandemic, if trend of such waiver starts now onwards. The developed nations insist on exclusive licenses and considers technology transfer as the only option for speeding up the production. Fortunately, it is this technology transfer with which Serum Institute of India (SII) is able to manufacture and supply large doses of Covishield vaccine. However, technology transfer would also mean reliance or dependence on limited production units and it will still involve royalty, which adversely affects the cost-restricting measures.

VACCINE MAITRI PROGRAMME & VACCINE DIPLOMACY

India started sharing its initial lot of vaccines under the "Vaccine Maitri" initiative almost at the same time when domestic covid19 vaccination programme starts.¹¹ India shared a large chunk of its vaccine with multiple other countries, mostly those in the developing and underdeveloped world. Under this Vaccine-Maitri initiative, India exported millions of doses of COVID-19 vaccines to almost 95 countries worldwide.¹⁵ This also include supplies under the COVAX - the global alliance to distribute vaccines to poor countries. While its own citizens were still not

completely vaccinated, some might consider that such donations or transfer of vaccine to other countries was a big mistake, an immature act without proper consideration of the need or urgency of covid19 vaccination in India. However, the reality is different.

The shelf life of Covishield vaccine is about 6-9 months or so. Serum Institute of India is not a public company but a private sector unit & so its CEO, more so on a humanitarian ground, took a calculated financial risk to produce large chunk of vaccine while the trials were still ongoing.¹⁶ The expiry date of these vials manufactured before the approval was approaching very close. Moreover, any vaccine rollout program takes some time to pick up the speed, and so these vials were less likely to be immediately used by the government of India for its covid vaccination drive. On the other hand, the HCW and the FLW in many developing & third world countries were eagerly waiting for a vaccine as a support to their war against covid. Whether it is due to diplomatic relationships, due to empathetic attitude of Indian Government or due to international pressure on India, as some might say, India took a quick decision to support other nations in their war against covid by supplying available vaccine. These few million doses won't make a big difference in terms of percentage vaccinated in India, but makes a great impact on other countries of the world. By sharing the covid vaccine, India extended an invaluable help to multiple other countries, which soon reflected back as help when India required support during the 2nd wave of pandemic.

VACCINE SCARE & SKEPTICISM

While the approval to 'Covaxin' was looked upon as a great achievement by Indian scientists and was looked upon as a firm step towards "Aatma-Nirbhar Bharat" On the other hand scientifically unqualified people including politicians called it as "Chest-thumping vaccine nationalism".¹⁷ Although, it may be looked upon just as an effort to take political mileage but it has also undermined India's scientific achievement. This was further fueled by some elite and influential but unqualified opinion-makers, who flooded the various social media platforms with messages that raise doubts and convey that the vaccine is unsafe. This had created a scare against the vaccination in India and seem to be responsible for the slow to start vaccination campaign in India.

OVERCONFIDENT INDIA: CELEBRATING TOO EARLY!!

As compared to other developed nations from the western world, India passed through the first wave of pandemic in a much better way than expected. It was still not clear that whether it was due to early-complete lockdown, or due to partial protection through herd immunity or just because of unreliable data sources but this partial upper edge, resulted in-

to a good amount of complacency. One may call it an act of complete ignorance, but, overconfident India, at one stage, almost declared its victory in the war against covid19.¹⁸ In this euphoria, we failed to recognize the severity of the second and third wave occurring in the western countries. However, due to the continued unrestricted travel and movement from the different countries, as well as internal complacency and gathering for social, political, or religious reasons created the most conducive environment for the surge of the covid cases and the import of the new variants from abroad.¹⁹ The wide spread increase has also stimulated the growth of additional mutants, a natural behaviour among the virus. Not anticipating the impending crisis situation & celebrating the partial advantage as victory, we have probably invited a much bigger problem back to our courtyard.

PRESENT SCENARIO

India has successfully vaccinated most of its population with the first dose and quite a major chunk of its population with two doses. Recently, it has also started additional precautionary dose for the HCWs & elderly aged 60 plus. Effect of vaccination was obvious during the peaks which were recorded after the introduction of covid vaccination. Multiprong efforts by the health department & government authorities to improve vaccination coverage has paid off in terms of morbidity and mortality. The increased production of vaccines by more manufacturing units has contributed significantly in controlling the pandemic situation in India. There are certain things which we have done very well and there are instances from which we have to learn, all in all, we have learned some very good lessons from the pandemic situation and its control through effective vaccination. Any future pandemic will surely be dealt with, in a much more efficient way, if we focus on learning from this Covid19 pandemic.

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