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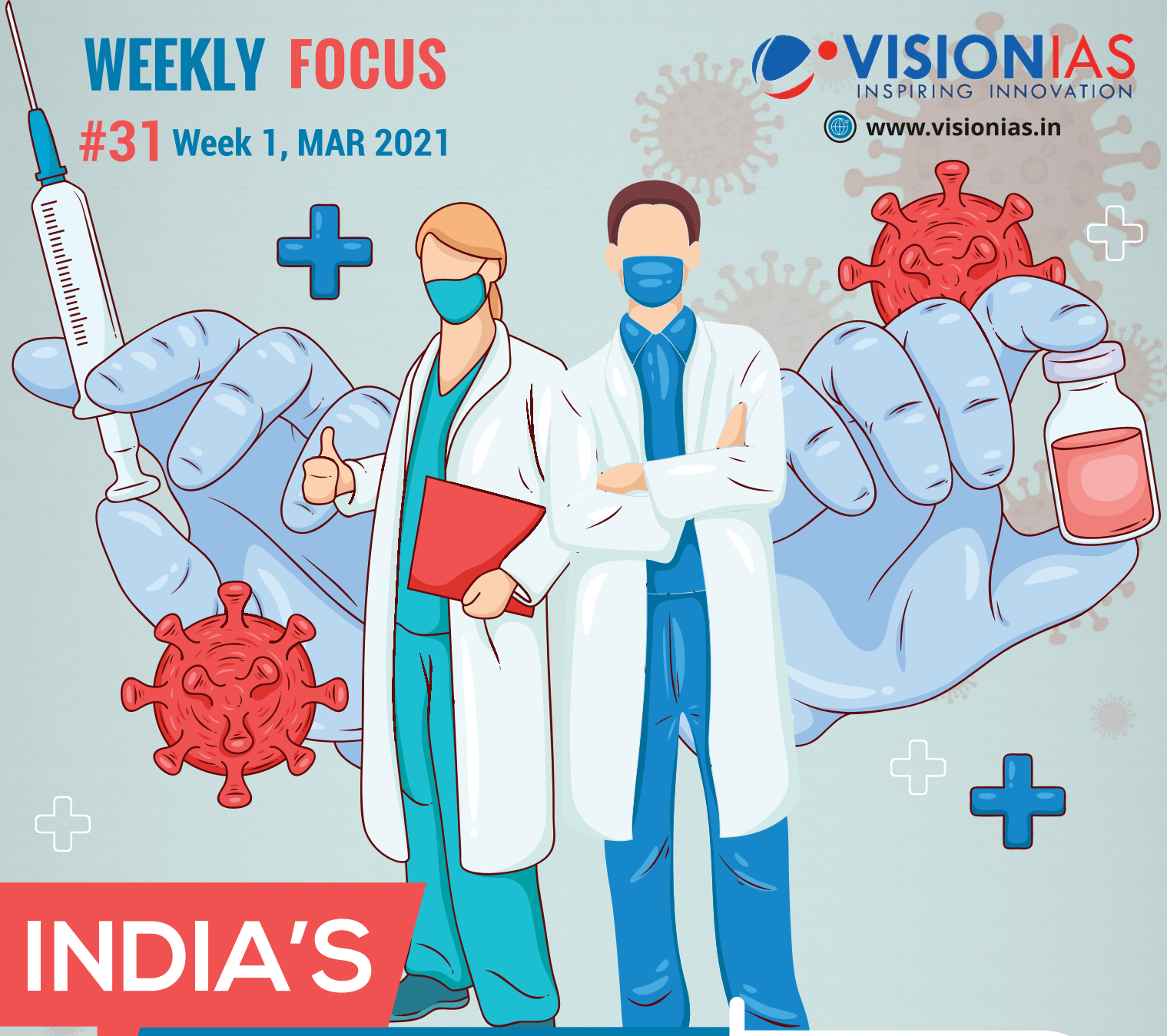


INDIA'S VACCINATION DRIVES

STRATEGY, OBSTACLES & OPPORTUNITIES

Introduction

Vaccination is one of the most successful public health interventions in contemporary human history. It has enabled eradication of multiple diseases and brought many others to the brink of elimination. Currently, global rollout of COVID-19 vaccines has begun under the COVAX Facility.

Almost a year after India reported its first case, on 16th January, the country launched the world's largest vaccine drive and has administered the COVID-19 vaccine to more than 80 lakh people in just one month. Being the largest producer of vaccines in the world, India has the experience, ability and credentials to meet its goal of vaccinating 250 million people by July 2021. At the same time, India is also using vaccine diplomacy as a tool of its foreign policy. However, one of the major challenges in India is the vaccine rollout—a massive exercise that it will have to execute using a health sector delivery system that is in dire need of an upgrade.

2 vaccines in circulation

COVAXIN Indigenously produced	**Developer** Bharat Biotech **Manufacturer** Indian Council of Medical
COVI -SHIELD	**Developer** Oxford-AstraZeneca **Manufacturer** Serum Institute of Pune

In this context, it is vital to learn about India's past experience with regard to Vaccinations, What enables India to be the global leader in vaccine production, What are the challenges related to development and distributions of vaccines in India, What are the learnings and opportunities for India in future and What steps can India take to overcome these challenges and realise the prevalent opportunities? In this edition, we will provide answers to these questions.

What has been India's past experience with regard to Vaccinations?

The story of vaccines in India is centuries old, and it has carved major landmarks of its own before and after Independence.

A glance at vaccine development over the centuries

- Vintage technique 'variolation' was practiced in India around 1000 AD to treat Smallpox.
- **1798** Edward Jenner discovered & developed Smallpox Vaccine.
- 1802 : Smallpox vaccine was administered in India
- 1904-07 : Many vaccine research institutes were set up.
- **1918** Spanish Flu Pandenic killed 25-50 mn people worldwide.
- 1948 : India's first BCG vaccination drive was launched.
- **1952** Nearly 60000 cases of Polio documented in USA.
- 1978 : National Immunisation program launched in India.
- **1980** Smallpox became first infectious disease eradicated by vaccination.
- 1985 : Universal immunisation program launched in India.
- 1995 : Pulse Polio immunisation program launched in India.
- **2000s** Measles & Rubella no longer epidemic in USA.
- 2014 : Mission Indradhanush was launched in India.

As a result of this vast experience, over the years, India has emerged as the world's leading manufacturer of vaccines. Today, **India accounts for 60 % of global vaccine production,** contributing 40 to 70% of the WHO demand for Diphtheria, Tetanus and Pertussis (DPT) and Bacillus Calmette-Guérin (BCG vaccines), and 90% of the WHO demand for the measles vaccine

What enables India to be the global leader in vaccine development?

Factors that have played an important role in cementing India's position as the leading manufacturer of vaccines include:

- **Robust pharma industry:** The Indian pharma industry today is the **third largest market globally** in terms of volume and 14th largest by value and is expected to **grow at CAGR of 15 to 20% annually** as per reports by McKinsey and others.
  - Additionally, India's pharmaceutical industry is best known for **producing generic drugs,** which are identical to brand-name drugs but less expensive because they're made after the patent on the branded version has expired.
- **Presence at global level:** A number of Indian firms are key players in the global vaccine industry:

Regulatory framework in India

- Setting up of vaccine manufacturing units and grant of permission of clinical trials and final licensing and marketing authorization for vaccines in India is provided by the **Central Drug Standards Control Organization (CDSCO),** which is a National Regulatory Authority (NRA) in the country.
- The regulatory control over quality of drugs in the country is exercised through the **Drug and Cosmetics Act, 1940.** The schedule Y of this Act regulates clinical and pre- clinical testing of the products. As per the Act, vaccines and other biological products are considered to be a 'new drug' and thus are governed by rules and regulations applicable to a new drug.
- The vaccine manufacturing and procedures for clinical trials have become systematic in India in recent years. In 2006, the **Indian Council of Medical Research (ICMR),** New Delhi, India released a new set of **guidelines for conduct of research on human subjects.**
  - There is a section on vaccine research and clinical trials in these guidelines and all the vaccine related trials now need to be registered in clinical trial registry and to be done in accordance with these guidelines.

- The Pune-based Serum Institute of India (SII) is the world's largest vaccine maker and makes 1.5 billion vaccine doses every year that are being used in around 170 countries across the globe for their immunisation programmes.
- Ahmedabad-based Zydus group was the first to develop and indigenously manufacture the vaccine to combat Swine Flu during the outbreak in 2010.

- **Relatively low cost of manufacturing:** The cost of producing drugs, including vaccines, in India is relatively low because of cheaper labour and the nation's large-scale manufacturing facilities. For instance, a rotavirus vaccine by Indian pharma giant Bharat Biotech, costs almost one-fifteenth as much as rotavirus vaccines developed outside of India.
- **Large pool of scientists and skilled professionals:** Over 2,25,000 pharmacy students graduate from India every year. The workforce includes highly-skilled medical practitioners and specialists who bring significant expertise and actively contribute to clinical research. This is boosted by highly-skilled people working in the field of clinical research across the industry and academia.
- **Affordable clinical trials:** India is advantageously positioned for the conduct of clinical trials for several reasons like large and diverse genetic pool of a treatment-naive population, and the emergence of chronic diseases like cancer, diabetes, cardio-vascular system (CVS) and central nervous system (CNS) disorders driving the demand for newer therapies.
- **Quality Vaccines:** Several vaccine products from Indian vaccine manufacturers have received WHO prequalification.
  - The World Health Organization has a standard mechanism for assessing the quality of vaccines and that of manufacturing units and provides prequalification to vaccines for procurement for United Nation supply.

What are the challenges related to development and distribution of vaccines in India?

Vaccine Development

- **Lack of funding:** A major challenge in vaccine production in India is sub-optimal investment by public sector for vaccine research. The vaccine manufacturing units set in India are still producing some of the traditional vaccines and there appears to be a need for more funding and research on newer antigens.
- **Dearth of 'knowledge-base' in immunology:** The number of trained people in vaccinology and immunology in India is less than what country of India's size requires.
- **Inadequate experience in life cycle immunisation:** India has seen a relatively successful national immunisation programme, especially with its Polio drive. However, these initiatives were meant specifically for children and pregnant women, and therefore a life-cycle immunization programme will require a proper structure and larger-scale operations.
- **Legal challenges to conduct of Clinical Trials:** India's clinical trials industry faced serious legal challenges and disruption of all clinical trials activity due to 2011 litigation, challenging the regulatory framework and patient safety guidelines. The result was the implementation of a restrictive three tier clinical trial application process, which considerably delayed approval timelines making India less competitive in comparison with other emerging markets for the conduct of clinical trials.
- **Issues related to Intellectual Property Rights (IPR):** Voluntary licences granted by vaccine developers to Indian manufacturers prevent the latter from transferring the technology to other Indian companies or from exporting to countries not covered by COVAX. India's public health experts fear that it would be difficult for Indian vaccine manufacturers to scale-up vaccine production and supply to the levels required by India, quickly.
  - Recently, Countries such as Australia, Brazil, Japan, UK and the US have refused to support a proposal that was put forth by India and South Africa to waive off IPR on drugs and pharmaceuticals needed to prevent, diagnose and treat COVID-19.

Vaccine Distribution

- **Lack of cold storage facilities:** In order to conduct an efficient and effective vaccination drive for COVID-19, the country would require at least 10 times the number of facilities operating currently—i.e., almost 800,000 cold chain units. Not only will this require increasing the number of facilities in highly populated districts to reach more people, but also setting up cold chain units at smaller towns and villages that are now emerging as COVID-19 hotspots.
  - An associated challenge is the unavailability of reliable electricity supply at several primary health centres (PHCs) in remote and rural areas.
- **Accessibility:** A significant percentage of the population of India lives in remote areas like forests, mountainous regions, islands, etc. Getting vaccines to people living in these regions is a daunting task.

- **Vaccine misinformation and hesitancy:** Given India's troubled past with regard to vaccination, a sizeable population has strong hesitancy to vaccination, where certain sections of the society are reluctant or may refuse to vaccinate due to falsehoods, conspiracy theories and wild rumours about the efficacy and side-effects of COVID-19 vaccines.
  - For instance, Muslims in Uttar Pradesh were opposed to oral poliovirus vaccine as they felt it may lead to 'infertility'.
- **Questions over Vaccine efficacy: India granted emergency use authorisation** to two COVID-19 vaccines. As for Covaxin, Phase 3 trials are still underway and no data is available regarding its efficacy. Vaccine experts are questioning the government's decision to approve the vaccines in the absence of adequate efficacy of data.

Steps taken in India to deal with the challenges

- **Co-WIN App:** The government has put in place the CO-WIN digital platform (formerly called eVIN or Electronic Vaccine Intelligence Network, which was developed in 2015 to monitor immunisation among children). Individuals will be able to enrol on the platform which will confirm the date and time for the vaccine.
  - Once successfully administered, the app will also issue certificates. The platform will provide a host of information to the authorities starting from the availability of vaccine stocks to the temperatures in the cold chain.
- **Supporting clinical research while balancing patient safety:** In 2014, India re-established new guidelines and protocols for patient consent, patient reimbursement, and adverse events, and issued a directive that clinical trials could only be carried out at accredited centers. More checks and balances have been put in place for certification of sites, ethics committees, and limiting the number of concurrent trials by a principal investigator.
- **Funding for Vaccine research:** Finance Minister announced Rs 900 crore funding as a part of the Atmanirbhar Bharat package under COVID Suraksha Mission for research and development of COVID-19 vaccine research in the country.
- **Digital Infrastructure:** India plans to re-purpose a digital platform used in the Universal Immunisation Programme **for inventory management and last-mile delivery** of COVID-19 vaccines to track movement of COVID-19 vaccine stocks. This will help trace those who are to receive the shots and ensure last-mile vaccine delivery.

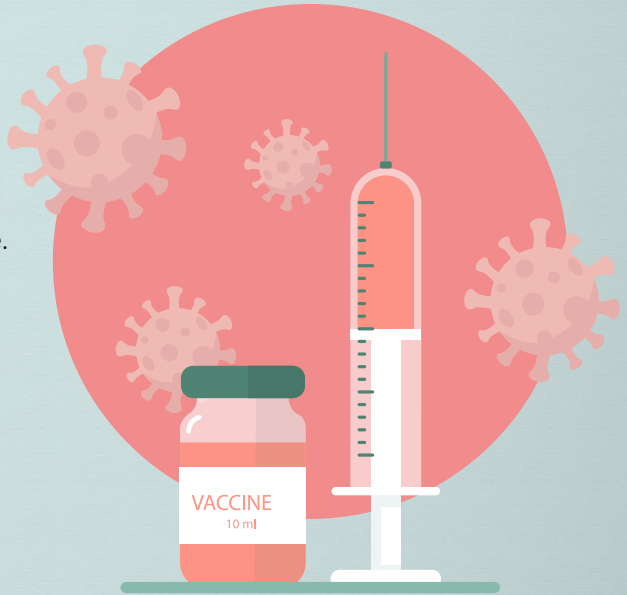
International Initiatives

- **Ensuring vaccine accessibility:** Global Alliance for Vaccines and Immunizations (GAVI) was created in 2000 to improve access to new and underused vaccines for children living in world's poor countries. At the same time, Developing Countries Vaccine Manufacturing Network (DCVMN) was formed with the objective to provide consistent and sustainable supply of quality vaccines at an affordable price to developing countries.
- **Recently, for the accelerated development, production and equitable global access:** Access to COVID-19 Tools (ACT) Accelerator was created as a collaborative platform by WHO, European nations, the Bill and Melinda Gates Foundation, and the Wellcome Trust.
  - **COVAX** is one of three pillars of the ACT Accelerator. It is Coordinated by GAVI, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO, and will act as a platform to support the research, development and manufacturing of a wide range of COVID-19 vaccine candidates, and negotiate their pricing. All participating countries, regardless of income levels, will have equal access to these vaccines once they are developed.
  - **Encouraging Funding:** European Union (EU) hosted a pledging event, called the Coronavirus Global Response Initiative, where world leaders, celebrities and philanthropists pledged some 7.4 billion euros for research into COVID-19 vaccines, treatment and testing.

What are the opportunities for India in the future?

The outbreak of the pandemic, efforts taken at national and global level to ameliorate it and India's vaccine development potential, have collectively created tremendous growth opportunities for India's Pharmaceutical Sector and Vaccine development sector.

- **Developing ancillary Industries:** With adequate incentive and assurance from the government the entire ancillary industry to make vials, syringes, packaging, boxes, cold storage, transportation etc can witness a big surge.
  - **For instance,** India is the biggest exporter of syringes in the world, with a capability of producing over 1 billion syringes for vaccination on a yearly basis.
- **Utilizing the Supply Chain created for vaccination drives:** A large network of refrigerated storage and transport created for the pandemic could have wider uses. For instance, an efficient cold chain would help permanently raise farmers' access to markets, reduce wastage and control food inflation.



- **Capitalizing on the infrastructural and human resource capacity created during the Pandemic:** The current pandemic provides an opportunity to upgrade our existing health resource potential through efforts such as proper use of the newly constituted Health and Wellness Centres as well as Primary healthcare Centres (PHCs) and a comprehensive network of Accredited Social Health Activists (ASHAs) and anganwadi workers. Utilisation of this infrastructure can aid with reaching the priority population in the distant regions of the country.
- **Harnessing Pharma Sector's potential:** The COVID-19 crisis has galvanized the Indian scientific community to collaborate like never before in finding interdisciplinary solutions to give the country an edge in this high-stakes battle against a deadly virus. The Economic Survey has mentioned that Indian pharmaceutical sector needs to rise to the opportunity presented by the pandemic and move up the value chain from generics to Novel Chemical Entities (NCEs).
- **Maintaining focus on preventive care:** The awareness generated about preventive healthcare during the COVID-19 crisis, both among healthcare professionals and individuals, has made it possible to integrate wellness and the idea of immunity into our healthcare system. This can indirectly boost nutrition levels and promote healthy living patterns.
- **Improving detection and care for patients of Non-communicable diseases(NCDs):**The strategy for COVID-19 vaccination can be dovetailed into a comprehensive screening programme for people aged 50 and over for major NCDs like diabetes, cardiovascular disease (CVD) and even common cancers. This will reveal the undetected cases of hypertension and diabetes and may help in reducing NCD mortalities by one-third in line with Sustainable Development Goal 3.4.

Case Study: Polio Eradication in India

India completed 5 years as a "polio-free nation" in January 2016. The Global Polio Eradication Initiative (GPEI) considered India to be the most difficult region of the world to eliminate wild polio virus (WPV) transmission and then maintain that status for 5 years. India's triumph over polio is replete with lessons to be learned.

Challenges faced by India:

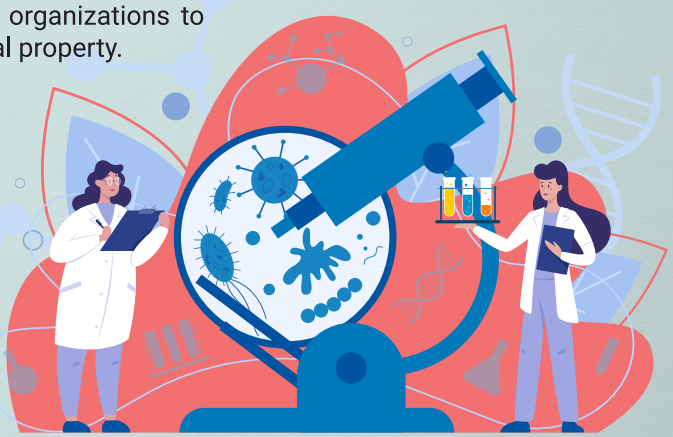
- With high population density, poor civic infrastructure, poor sanitation, an almost non-existent public health system, rampant malnutrition and diarrhea, difficult-to-reach locales, high population mobility, and extremely high force of WPV transmission in few states, **the interruption of WPV transmission was extremely difficult and demanding.**
- Eradication efforts were plagued by **low coverage and poor monitoring of routine immunization** and supplementary immunization activities.
- **Community fatigue and extremely low efficacy** of trivalent oral polio vaccine (OPV).
- **Resistance to immunization drives** owing to negative rumors about the safety of OPV.

Lessons Learned:

- **Government ownership** of the initiative at all levels of governance, absolute accountability, meticulous microplanning, and real-time monitoring and review of the ongoing program.
- **A sound, multipronged communication strategy** was employed to galvanize the entire population to achieve public ownership.
- **Certain innovative strategies** such as "transit vaccination," in which OPV was administered to mobile and transitory populations, were introduced. Also, an "underserved strategy" was introduced in high-risk endemic areas to reach marginalized sections of the society.
- **Novel yet simple measures** such as finger marking, inclusion of female staff in the vaccinators team, "bindi marking" to denote number of under 5 children in the household, newborn tracking, and mapping missed children greatly facilitated OPV delivery.
- **Building partnerships with the private sector,** along with **involvement of socio-religious leaders and celebrities,** to tackle social resistance against a mass public health campaign.

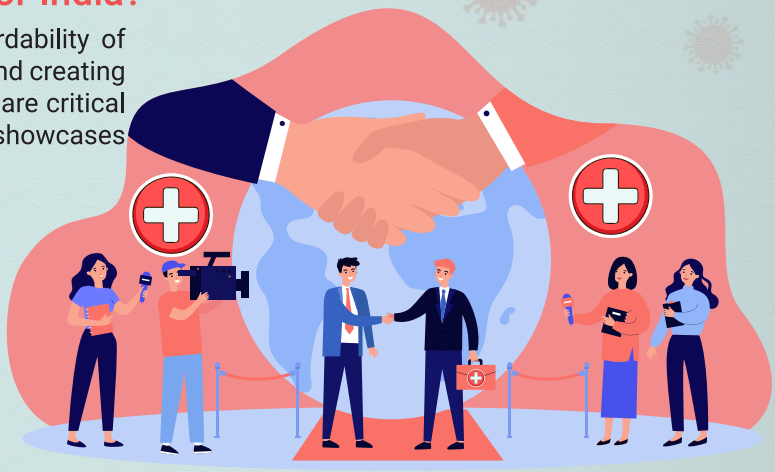
What steps can India take to overcome challenges and realise opportunities?

- **Increase R&D expenditure:** Fiscal incentives, such as the tax credits and enhanced tax deductions, are key to this strategy as they allow research-oriented organizations to effectively leverage their R&D prowess for creating valuable intellectual property.
- **Enhancing public confidence:** It's vitally important for the government to have a well thought out communication strategy to fortify public confidence and reduce vaccine reticence in the population. **Learnings from our past experience in Polio Vaccinations can play a critical role** here.
  - There is a need for **imaginative social and behavioural research** that takes on board the scientific uncertainties and helps to build trust in the health service system and the community. This **requires a climate of transparency and data sharing** about the regulatory processes and authorisation **that allows for public scrutiny and a healthy debate.**



- **Human Resource Development:** Following the newly amended labour laws, India can create large-scale fixed term employment amongst educated rural youth with basic digital training to undertake the registration and vaccination drive Also, large numbers of nursing students, auxiliary nursing midwife trainees, and retired Army and defence services personnel in every village can also be mobilised for the vaccination drive.
- **Compulsory licencing (CL):** Ongoing novel coronavirus pandemic certainly qualifies as a national emergency under section 92 of the Patents Act. CL can thus be a powerful public health tool to work around concerns over an insufficient supply of important pharmaceutical products.
- **Stockpile vaccines against certain diseases with potential to cause outbreaks:** The National Vaccine policy has recommended that the quantity needed for a stockpile should be assessed together with the National Disaster Management Agency (NDMA), and the manufacturers of these vaccines should communicate the decision ahead of time for planning production, and adequate cold chain equipment earmarked for storage.
- **Preventing Vaccine Fraud:** Vaccine traceability is a must considering the long history of counterfeiting in the pharmaceutical supply chain and the unprecedented demand for Covid vaccinations. Blockchain and IoT technology can be leveraged to track every dose and verify that counterfeits aren't being delivered to vulnerable populations.
- **Strengthening of ancillary industries:** Micro, small and medium enterprises (MSMEs) have significant presence within the ancillary industries. Several short-term and long-term efforts that are required include-
  - Short-term focus should be on providing financial relief to MSME ancillaries, robust disaster management framework, greater transparency, cross-industry collaboration to proactively identify supply risks.
  - Long-term goals for the ancillary industry should include reducing reliance on imports to manage supply disruptions and this will require the government to identify strategic active pharmaceutical ingredient (APIs) for indigenous manufacturing.

Medical Diplomacy: How beneficial is it for India?



- India is deeply committed to ensuring access and affordability of medicines and believes that access to medical products and creating an enabling legal and trade environment for public health are critical to achieving the SDG Agenda. Various initiatives that showcases India's medical diplomacy are:
  - India has organized a series of World Conferences on "Access to Medical Products" over the last 2 years.
  - Promotion of Ayurveda and Yoga around the world.
  - Providing low-cost solutions to the HIV-AIDS pandemic.
- But the COVID-19 pandemic has brought about a new dimension in India's role as a global health provider, and its health diplomacy. Days after it began vaccinating its own population against the coronavirus, India has begun dispatching millions of doses of its indigenously manufactured vaccines to its South Asian neighbours and key partner countries. (India calls it Vaccine Maitri (Vaccine Friendship)). Apart from this, India has also taken various other steps:
  - Supplied vital medicines as a gift to over 40 countries and ensured commercial exports of them to another 60 countries, including those in the US and Europe.
  - Facilitating the transfer of skill and knowledge to medical professionals through the capacity building modality of South South Cooperation.
  - Humanitarian assistance to several countries in Africa, Uganda, Zambia, Niger etc.
  - SAARC Initiatives including COVID-19 emergency fund, online training of health professionals, COVID information exchange platform(COINEX) among others.
  - Massive evacuation exercises conducted for stranded Indian and Foreign nationals.
  - Outreach initatives: Engaging with the world through the G-20 and bilateral interactions in virtual conversations with over 100 countries to enhance the global pandemic response.
- Vaccine diplomacy is beneficial for India in the following ways:
  - Countering Vaccine nationalism: India's gesture of sharing its vaccine supplies with other countries stands in sharp contrast to several rich countries that are cornering, even hoarding vaccine supplies. Although a handful of rich countries account for just 16 percent of the world's population, they have cornered 60 percent of the vaccines bought globally.
  - It will add to India's credibility as a reliable vaccine producer.
  - Commercial supply of the vaccines will benefit Indian pharmaceutical businesses now and in the long run.
  - To polish India's global image and earn goodwill, especially in South Asia.

- It will serve as a **powerful soft power tool to counter China's considerable influence** in South Asia, Africa and elsewhere.

- **Criticisms:** While there is much euphoria in India over the global role the country is playing in fighting the pandemic, experts are debating whether India should be exporting the vaccine when its domestic needs are high. Could surging exports of Covaxin and Covishield result in diminishing vaccine doses being available for domestic use? Analysts are also warning that the positive impact of such goodwill gestures is transient as gratitude does not last long in relations between countries.

India's vaccine diplomacy is unlikely by itself to change its relations with its neighbors overnight. But it is a step in the right direction and could contribute in perceiving India as a gentler giant.

As India seeks to cement a new frontline position in tune with its size and importance, healthcare has emerged as a clear sector where such leadership can be shown because in its neighbourhood demand for good, low-cost healthcare is ever prevalent, and set to grow as climate change concerns heighten.

Conclusion

The evolution of vaccination efforts in India is a long journey. Though preventive efforts from diseases were practiced in India, the reluctance, opposition and slow acceptance of vaccination have been the characteristic of vaccination history. Apart from limited acceptance, operational challenges kept the vaccine coverage inequitable in the country. Despite all this, India is embarking on a monumental mission, not just in terms of vaccinating its own population, but also vaccinating a large part of the world, thanks to its position as the world's leading vaccine producer. Thus, the demand of the hour is to evaluate stakes and hurdles after analysing the lessons from the past events and realise the opportunities that the present situation offers.

TOPIC AT A GLANCE

INDIA'S VACCINATION DRIVES

India accounts for 60 % of global vaccine production, contributing 40-70% of the WHO's demand for DPT and BCG vaccines, and 90% of the measles vaccine

India's Past Experience in Vaccinations

Year	Developments
1000 AD	The vintage technique known as 'variolation' was practiced to treat small pox
1802	Smallpox vaccine was administered in India for the first time
1904-07	Many vaccine research institutes were set up
1948	Independent India's first BCG vaccination drive
1978	National Immunization programme
1985	Universal Immunization Programme
1995	Pulse Polio immunisation programme
2104	Mission Indradhanush(MI)

Enabling Factors for India to be the World Leader in Vaccines

- Robust pharma industry: 3rd largest market in terms of volume and 14th largest by value globally.
- Presence at global level with key players like Serum Institute of India.
- Relatively low cost of manufacturing because of cheaper labour and large-scale manufacturing facilities.
- Large pool of scientists and skilled professionals
- Affordable clinical trials due to presence of diverse genetic pool of a treatment-naive population.
- Production of Quality Vaccines

Challenges in Vaccine Development and Distribution

Development	Distribution
Lack of funding	Lack of cold storage facilities
Dearth of 'knowledge-base' in immunology	Accessibility
Inadequate experience in life cycle immunisation	Vaccine Misinformation
Legal challenges to conduct of Clinical Trials	Vaccine Hesitancy
Issues related to Intellectual Property Rights	Questions over Vaccine efficacy

Opportunities Arising out of Vaccination Drives

- Developing ancillary Industries such as vials, syringes, packaging, boxes, cold storage, transportation etc.
- Utilizing the Supply Chain created for vaccination drives in other areas such as agriculture and food processing.
- Capitalizing on the infrastructural and human resource capacity
- Harnessing Pharma Sector's potential
- Focussing on preventive care to integrate wellness and the idea of immunity into our healthcare system.
- Improving detection and care for patients of Non-communicable diseases(NCDs) using COVID 19 screening strategy.

Ways to deal with Challenges and Realize Opportunities

- Increase R&D expenditure through fiscal incentives, such as the tax credits.
- Enhancing public confidence through communication strategies, transparency and data sharing.
- Human Resource Development
- Compulsory licencing (CL) to deal with concerns over an insufficient supply of important pharmaceutical products.
- Stockpile vaccines against certain diseases with potential to cause outbreaks
- Preventing Vaccine Fraud by leveraging technologies like blockchain and IoT.
- Strengthening MSME industries that have huge presence in ancillary industries.