ISSN-0971-8400

YOJANA

SPECIAL ISSUE

Azadi Ka Amrit Mahotsav

OCTOBER 2021 A DEVELOPMENT MONTHLY ₹ 30

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Combating Covid-19

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It was on 11 March 2020 that WHO declared Covid-19 a pandemic after watching the growth of the disease from when the organisation declared it a 'Public health emergency of international concern' on 30 January 2020. The Covid-19 pandemic caused by SARS-CoV-2 was unprecedented on many counts, testing and stretching the health care preparedness globally. Every country struggled to put into place, a rapid response action plan to fight the crisis, and developed models suited to their specific economic, healthcare, and scientific preparedness.

For India, the challenges were manifold, given our population, the population-dense areas, diversity, and the state of our healthcare systems. Nowhere else in the world did the government have to deal with such complexity and scale during the pandemic. In each area-testing, tracing, isolation, public health measures such as wearing masks and distancing, medical care, vaccine development, its procurement and delivery—the challenges encountered were immense, complex, and constantly changing.

The scientific community in India responded to the crisis with such a sense of urgency and responsibility that has never been seen before. Soon after the WHO declared Covid-19 a pandemic, the first inter-ministerial committee chaired by Dr V K Paul, Member of NITI Aayog, and Prof K VijayRaghavan, Principal Scientific Adviser to the Government of India met on 21 and 24 March 2020, to review India's preparedness to the crisis.

Major decisions regarding creating a web portal, contact tracing app, handbook, and laboratory manual for training of RT-PCR testing were taken, and these were quickly put into place. Regulators and regulatory departments were asked to fast-track approvals, set up harmonised protocols for clinical trials, standardise specifications at warp speed for Personnel Protection Equipment (PPE), and put into place an IT support for Covid-19 management as an immediate priority.

Preventive measures such as the mask advisory 'Face Covers for Curbing the Spread of SARS-CoV-2 Coronavirus: Manual on Homemade Protective Cover for Face and Mouth' issued on 30 March 2020, by the Government of India, were amongst the earliest in the world, ahead of the advisory on mask usage issued by the World Health Organization (WHO) or Centre for Disease Control (CDC), USA.

The Prime Minister's Office constituted the Vaccine Task Force (VTF)

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for focused research and development of Corona vaccine and other science and technology issues on April 14 2020. A series of regular meetings with experts and vaccine companies to discuss and debate key aspects of vaccine development and other S&T matters were held. The VTF was monitored directly by the Prime Minister of India and his office, as were other empowered committees.

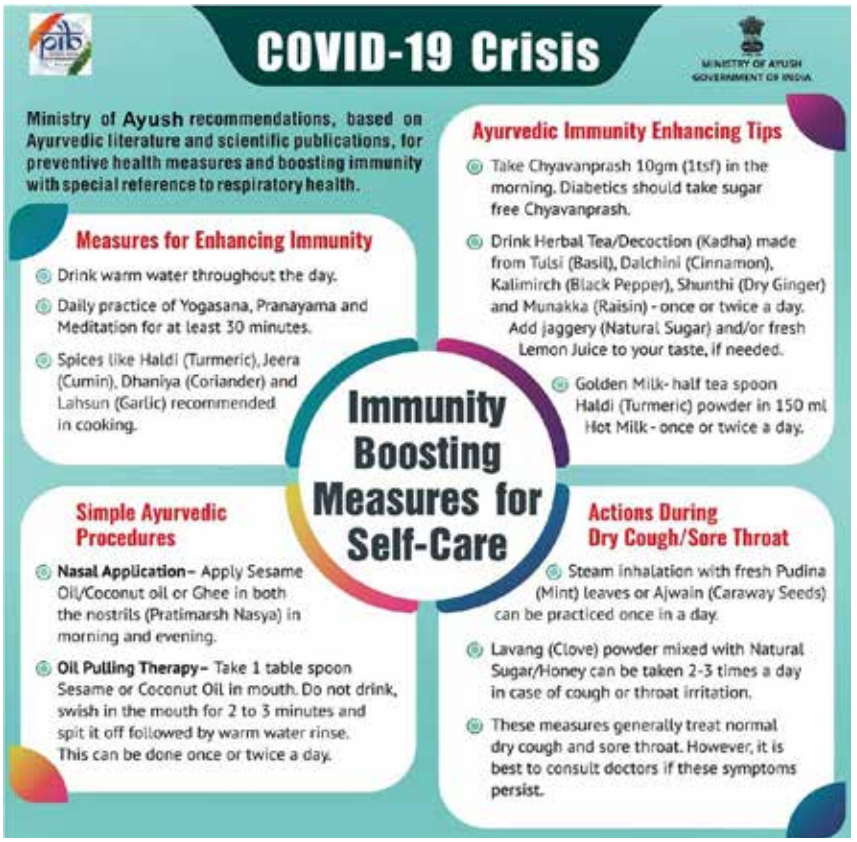
The Vaccine Task Force strategised the urgent and critical action plan for India's Scientific R&D response to Covid-19 pandemic, shouldered on six major pillars:

- Vaccine Development
- Personnel Protection Equipment (PPE) and Ventilators
- Testing, Tracking, and Diagnostics
- Therapeutics and drugs
- Surveillance: Seroprevalence and genome sequencing
- Regulation and regulatory support

Vaccine Development

As early as in the second meeting of The VTF, held on 20 April, 2020, presentations by Bharat Biotech, Serum Institute of India Pvt Ltd, Zydus Cadila, Biological E, and Mynvax were arranged and the industry was assured that all support- regulatory, technical, and financial would be fast-tracked and provided.

A cohesive and coherent coming together of government-academia-industry led to one of the most successful stories of Indian science, the development, and production of vaccines for Covid-19 in record time. The first week of January 2021 saw the Emergency Use Authorization (EUA) accorded to two Indian vaccines: Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike glycoprotein, ChAdOx1 (Covishield) from the Serum Institute of India Private Limited, and the whole virion inactivated vaccine BBV152 (Covaxin) from Bharat Biotech International Limited. Covaxin was developed in collaboration with the



Indian Council of Medical Research (ICMR). These vaccines being available in record time, nine months from the declaration of the pandemic, is a testimony to the capacity of the Indian vaccine industry to respond rapidly, underlying India's reputation as a global player in vaccine development and manufacturing. This was reinforced with the third vaccine from India- the SARS-CoV-2 DNA vaccine candidate (ZyCoV-D), from Zydus Cadila being granted Emergency Use Authorization in August 2021.

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India also saw the emergence of smaller companies and startups developing Virus Like Particle (VLP) vaccine candidate and Mynvax/IISc Bangalore thermo-stable Receptor Binding Domain (RBD) of Spike protein of SARS-CoV-2 based vaccine candidate.

Today, about 50% of India has been vaccinated for the first dose, a total of 63.07 crore persons, 8.2% of the total world population, which is unparalleled and awe-inspiring, to say the least. The momentum of vaccination has picked up, crossing 1 crore (10 million) on 27 August 2021.

Personnel Protection Equipment (PPE) and Ventilators

India also moved rapidly from an acute shortage of masks and PPEs to becoming an exporter of quality PPEs, much due to the efforts of the Defence Research and Development Organisation (DRDO), and the South India Textile Research Association (SITRA), Ministry of Textiles.

"The Ventilator Project"—now a well-documented story of how a world-class ventilator was designed and built by a startup incubated at IIT Kanpur—is a validation of the coming of age of India's startup ecosystem. Many other companies too have manufactured ventilators and other equipment. Notable is the role played by the AMTZ (the Andhra Pradesh Medtech Zone), Vishakhapatnam.

Testing, Tracking, and Diagnostics

Testing, tracking, and diagnostics are the essential tools for Covid-19 management, containment, and availability of testing at will. The effective deployment of this strategy allows travel and livelihood to return to what is believed as normalcy. Scaling of testing requires both easy sample collection protocols and affordable test diagnostics. Diagnostic kit development saw various sectors, research institutions, validation, certification, and manufacturing industry working together for creating a milieu of these kits.

CSIR-IGIB (Council of Scientific and Industrial Research- Institute of Genomics and Integrative Biology), Delhi developed FELU-DA, FnCas9 Editor Linked Uniform Detection Assay and partnered with TATA Health to create the TATA MD CHECK, CRISPR Feluda Cas9 based integrated system for collection, testing, reporting, and tracing. The data is being managed in a centralised cloud from where it can directly be sent to ICMR database.

The single gene PCR diagnostic test developed by IIT Delhi has been approved and validated by ICMR. It is low cost, scalable, works with very basic models of the PCR machines, and is now available in the market as "Corosure".

Dry Swab Collection-Direct RT-PCR Diagnostic protocol has been developed by CSIR's Centre for Cellular and Molecular Biology (CCMB), Hyderabad. It has been approved and validated by ICMR and is being deployed for sero-surveillance.

Therapeutics and Drugs

Four categories of drug development, namely, repurposing, new chemicals, phyto-pharmaceuticals, and drugs from traditional medicinal knowledge, those pioneered by the Ministry of Ayush, were prioritised. The Central Drugs Standard Control Organisation (CDSCO) approved five drugs in June 2020 to help treat patients with severe COVID-19; antivirals Remdesivir and Favipiravir; steroid dexamethasone; and immune-suppressant monoclonal antibodies-Tocilizumab and Itolizumab. Ayurvedic products were also made readily available.

Every country should prepare not only to tackle the present crisis, but for future crisis as well. India's capacity in drug design needs support and long term investment, especially in view of the supply chain of Active Pharmaceutical Ingredients (APIs) being affected severely during lockdown, with a single node as the major procurement source. All drug candidates, including Ayurvedic ones, need robust clinical trials to provide scientific evidence for the efficacy that has been appreciated during the pandemic.

Surveillance: Seroprevalence and Genome Sequencing

The VTF recognised the importance of serosurvey very early into the pandemic and recommended the drawing out of a national plan for serosurvey. Subsequently, serosurveys were conducted at Kolar, Karnataka, and Delhi region, providing evidence for the spread of the disease and possible solutions.

In September 2020, a phylo-genetic cluster called the B.1.1.7 (now called the alpha variant) in the UK was detected, resulting in a large number of cases and the alarming second wave of the UK. This lineage quickly accumulated about 23 mutations across 5 genes, of which 17 are of relevance and are non-synonymous variants, and two are important variants, responsible for increased infectivity as well as increased

virulence. Increased transmission in the population can be prevented very early by surveillance on large scale. The UK had been sequencing the SARS-CoV-2 extensively and was able to detect the variant quickly. The need for a common platform for harmonised protocols for virus surveillance, genome sequencing, and characterisation was reiterated by the VTF, and following this, the Indian SARS-CoV-2 Genomic Consortium (INSACOG) was established. INSACOG conducts on a large-scale an epidemiological surveillance of circulating strains of SARS-CoV-2 in the country.

Regulation and Regulatory Support

The most rapid response from the government was the Gazette Notification on 18 May, 2020, allowing the industry to stockpile vaccines after approval of Phase I of the clinical trials, as this was an enabling and trust-inducing notification by the government.

Fast track clearances were facilitated, with a recognition that regulatory processes needed an overhaul and evolution into a permanently efficient system. The onslaught of the pandemic also revealed the gaps in our preparedness. India was unprepared for participation in global trials due to a lack of identified clinical trial sites. Robust networks for clinical-trials research with harmonised CT protocols for both industry and academia are foundational to vaccine development. The pandemic saw underpowered clinical trials being carried out in India with few such trials aiming to look for definitive answers, these should be lessons learned and more pragmatic research cohorts designed in the future.

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The VTF recommended that Government must support and partner with the industry in vaccine development Phase 3 clinical trials and set up testing and certification labs like Central Drugs Laboratory (CDL), Kasauli, in other parts of India. This has now been done.

It was also evident that to rapidly bring a product to market at a good scale, the procurement system needs to be favourable for indigenously developed products, as most Indian kits have to deal with procurement specs which are largely inclined towards established standards.

Internationally easy-to-use tests are now emerging in the market, therefore, India should seize this opportunity, and apply for international certification and clearance for global markets.

There are many efforts not recounted here, suffice to say that while the pandemic saw desperately low times, it also saw Indian science and scientists rise to collaborate, and synergise with industry, and deliver on all accounts.

The success of Indian vaccine development during the Covid-19 pandemic will go down in history as a self-reliant India that came together with an unprecedented political will, governance, and partnership of academia and industry, to develop and deploy the vaccine, making it available to the Indian population in record time, with equity and equal access. The Indian science community has a lot to be proud of, viz vaccines, PPEs, ventilators, diagnostic kits, etc., however, much more needs to be accomplished. Our country has the attention of the governance and political leadership of the country, therefore, now is the time to show the world that Indian science has the potential to be a major participant in global science leadership. ❑