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Medical Technology during COVID 19 in India: A Commentary

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The COVID 19 pandemic is still evolving in India and how it will unfold is anybody's guess at the moment. Among various other matters, the COVID 19 pandemic also contributed to an Infodemic. As an offshoot, medical devices and *in-vitro* diagnostics which was generally not as much a matter of concern to the common man in India as drugs and vaccines became a topic of discussion and scrutiny. While this commentary captures some part of the story, it cannot claim to be comprehensive nor complete and has a risk of being outdated as the pandemic unfolds and more and more interventions are introduced.

The unprecedented challenge that COVID 19 posed was met with an unparalleled collective response in the country. Research and academic institutions, industry across domains and segments, healthcare institutions, policymakers, regulators, associations of persons and individuals, all and sundry started ideating on how best to beat COVID 19. In the initial phase, it was anything but natural that confusion, duplication of efforts and trivialization of the problem-solution prevailed but it did ultimately help in accelerating the pace of the solution-finding process.

At the outset, it was not clear what medical product (device, equipment, testing kit etc) is needed, when and in what quantities. Fortunately, the churning of various thoughts and ideas quickly pointed to the fact that whatever solution is proposed must be available now and here in large numbers. The focus shifted quickly to making available solutions that would work or reasonably work (meaning be effective) to mitigate the COVID 19 pandemic in the required quantities.

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In the absence of a drug or a vaccine, it was quite evident that prevention is the key. To prevent transmission of the virus in the community, public campaigns such as "Break the Chain" campaign proposed by the Kerala Health Department led the way for highlighting the utility of hand sanitization, followed by the use of face masks. People at large immediately took to the habit of washing hands with soap or use hand sanitizers, depending upon affordability and availability. For a country where the use of hand sanitizers is still not common, the advisory that washing with soap is as effective as alcohol-based sanitizer came as a relief. The sudden surge of the requirement of hand sanitizers prompted various chemistry labs and institutions to prepare locally made sanitizers, and invariably most of them adopted the WHO guidelines in this regard. Large scale manufacturing also was initiated by existing industry and new entrants were driven by an altruistic and commercial motive. While the availability of Isopropyl Alcohol, a key ingredient in the preparation of hand sanitizer was ensured through government intervention, the bottleneck turned out to be the bottle itself! The availability of each raw material and consumable in a medical product, however small or inexpensive came to light.

Screening for fever using non-contact infrared thermometers, both hand-held portable devices for individual testing and Artificial Intelligence-based facial recognition systems for mass screening became a new order of things in offices, airports etc. leading to an unserviceable demand for these products. As most of the electronic manufacturers of these devices in India were essentially assembling the products with components sourced from other countries including China, the need for either keeping a large stock of outsourced components handy or having multiple sources became a lesson learnt the hard way.

Medical ventilators came under the spotlight of media and policymakers and remains a subject of interest though with a

lesser degree of concern. Reports projecting huge gap between availability (supply projection of 10,000) and need (demand projection of 1,00,000 numbers) of ventilators in India created much scare and it almost became the top priority of everyone to find ways and means of finding a solution for it. For the first time, everyone in the country wanted to know who makes ventilators in India. When it came as a revelation that only a few companies manufactured Ventilators in India (domestic manufacturers include Skanray Technologies in Mysore, AgVa Healthcare in Noida, AB Industries of Vadodara, Air Liquid Medical Systems of Chennai, AVI Healthcare at Mumbai, Life Line Biz at Ahmedabad and Thane-based Medion Healthcare), the question was who else could make ventilators in India. Strategies for sharing available ventilators was also proposed and several similar looking designs of ventilator sharing circuits and kits consisting of 3D printed flow diverting valves became quite popular in the open. Most of these designs may not have progressed beyond the design or prototyping stage and not much is reported whether such a ventilator sharing strategy was deployed in patients.

Online training sessions and videos on how to intubate a patient or use a ventilator was quite educative and helped prepare clinicians from other disciplines to be ready for critical care if there was a need. In the COVID 19 crisis, from college students to start-ups to MSMEs to large corporates took to ventilators like fish to water!

The functional requirements, the performance standards, the specifications, the reliability etc. were not the considerations initially. The enthusiasm was towards making a contrivance that would supply oxygen to the lungs and hopefully keep the patient alive. The design considerations were predominantly to make use of easily available or sourceable components and the choice often fell on automobile components for which the Indian automobile and ancillary industry had ready stocks. The design for manufacture also placed a higher emphasis on 3D printing as compared to machining or moulding processes, wherever possible. Many start-ups and tech enthusiasts explored open source ventilator designs from universities such as MIT or industry such as Medtronic. The Indian ventilators market in 2018 was estimated at 9250 units, valued at Rs. 487 crores by Medical Buyer, a trade journal. According to the journal, 79 per cent share by value and a 63.8 per cent share by units of the Indian market was met by imports.

The ventilator development mission saw several tie-ups and public announcements that received much attention, which in some cases were driven by philanthropic interests. One of such high profile tie-up was of India's leading automobile company Mahindra and Mahindra with Skanray Technologies to produce 30,000 ventilators in six weeks. Maruti Suzuki announced its partnering with Noida-based AgVa Healthcare to produce 10,000 ventilators a month. Public sector Bharat Heavy Electricals Limited offered support to AgVa Healthcare with electronic chips for the ventilators. IIT Kanpur and a start-up Nocca Robotics signed an agreement with defence public sector company Bharat Dynamics Ltd for manufacturing ventilators on a not-for-profit basis for India initially with a target price of about Rs. 1.5 lakh per unit. Brakes India, a venture of TVS Group, announced that it started manufacturing a low-cost automated respiratory assist device - Sundaram Ventago – with medical institutions and Indian Institute of Technology Madras (IIT-M) and with guidance from MIT, Boston. Another public sector enterprise Bharat Electronic Ltd proposed to manufacture with 5,000 units initially and work on indigenisation of key components alongside Defence Research and Development Organisation (DRDO). Bharat Dynamics Limited (BDL) announced a tie-up with a private start-up in Pune to develop a prototype of the ventilator to be subjected to testing and certification. Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) tied up with Wipro 3D, Bengaluru, for an emergency breathing assist system. Indian public sector companies like BHEL and Central Electronics Ltd expressed interest in entering into strategic partnerships with partners having approved Critical Care Ventilator suitable for COVID19.

To give impetus to production, the Indian government extended help with sourcing components and easing bottlenecks. India's drugs regulator CDSCO allowed companies to make ventilators without a manufacturing license. The public sector company HLL Lifecare Ltd was entrusted with procurement tasks for ventilators. The most recent news regarding the ventilator is the announcement that three Indian companies (Alpha Design Technologies Pvt Ltd, Bharat Forge Ltd and Medha Servo Drives Pvt Ltd) are among the 13 International manufacturers selected from countries like Australia, Brazil, Canada, Mexico, Egypt, UAE, Turkey, and Malaysia to manufacture VITAL (Ventilator Intervention Technology Accessible Locally), which was developed by engineers at NASA's Jet Propulsion Laboratory (JPL) in just 37 days. The high-pressure ventilator was designed to use one-seventh the parts of a traditional ventilator, relying on parts already available in supply chains.

Just as the thought of lack of ventilator created a scare, the thought of overfilled ICUs also created a scare and prompted action on how to create temporary ICUs. Designs and prototypes of make-shift structures to scientifically designed ICUs meeting containment strategies evolved. Most of these structures would be easily deployable, would work with solar power and assembled in the DIY way. Designs of Isolation pods for transporting patients or for hospital use came to the fore but as of now, it has not been necessary to go into mass production. Similarly, the need for safety during sample collection from patients and creating a barrier between the patient and medical worker led to several design ideas for sample collection kiosks or booths and patient examination kiosks. The demand for these is likely to grow in large numbers as the testing requirement grows. Mobile units with this functionality have also been introduced recently.

Personnel protective equipment (PPE) shot to prominence due to an apparent acute shortage initially, potentially caused by misinformation, panic buying and stockpiling. PPE includes gloves, medical masks, goggles or a face shield, gowns, coveralls, headgear and foot cover. Sourcing the critical raw material (melt-blown non-woven fabric) for PPE that is breathable and resistant to fluid and viral contamination, posed difficulty as did shortage of heat sealing machines. The shortage of testing facility and certification created entry barriers to new entrepreneurs. The ramping up of production by domestic manufacturers of PPE (Preventive Wear Manufacturers' Association of India) and a surfeit of new entrants to the production of PPE coupled with guidelines on the rational use of PPE in healthcare and community settings has resulted in the availability of PPEs to a great extent. Responding to the need for improving the comfort levels of those stuffed in the PPEs, several startups and innovators have been designing albeit little success in introducing more comfortable and ventilated PPEs.

The availability, reliability and affordability of diagnostic kits for detection of SARS CoV 2 virus continued to make headlines. Indigenous development of diagnostic kits using RT-PCR platform showed some success. Pune-based molecular diagnostics company Mylab Discovery Solutions Pvt Ltd claimed the honour of being the first 'made in India' test kits for COVID-19. Named as Mylab PathoDetect COVID-19 Qualitative PCR kit, the company has started the commercial sale of the kit after obtaining approvals from Indian Council for Medical Research (ICMR) and Central

Drugs Standard Control Organisation (CDSCO). As on 30 May 2020, the ICMR website lists 86 RT-PCR kits that have been evaluated by ICMR validation centres and found to be satisfactory. However, only about 5 of these are indigenous kits. Other notable initiatives in diagnostic kits include LAMP-based test kit being developed and initially validated by SCTIMST, Trivandrum. National Institute of Virology in Pune, an ICMR institute, successfully developed the first indigenous ELISA (enzyme-linked immunosorbent assay) test kit for the antibody detection of the novel coronavirus. Pharmaceutical company Zydus Cadila will undertake the mass-scale production of these kits.

An interesting issue related to COVID 19 testing was the shortage of RNA extraction kits which was necessary for undertaking any RT-PCR or LAMP based testing. Indigenous efforts to develop these RNA extraction/isolation kits saw success in SCTIMST, wherein a magnetic nanoparticle-based kit was realised and transferred to Agappe Diagnostics Ltd. More interesting was the acute shortage of sample collection swabs (nasopharyngeal swabs) and associated Viral Transport Media (VTM). SCTIMST was able to develop both of these and transferred the know-how to domestic manufacturers.

As awareness about disinfection and hygiene increased, a good number of start-ups and MSMEs came up with disinfection equipment and cabins. Most, if not all, use UV-C light and have developed metallic chambers that can be used to disinfect personal small objects or for disinfecting disposables such as masks and gowns before discarding them. These appear to make good business opportunity at the moment.

The COVID 19 scare and lockdown in the country gave an unprecedented push to Telemedicine efforts that were long-languishing for want of takers. Start-ups like Practo, Portea and Lybate, which facilitate remote medical check-ups, along with many regional telemedicine solution providers, are witnessing a heyday as Indians started reaching out to doctors online. The demand for telemedicine hardware, digital stethoscope, remote patient monitoring systems and the like has increased many folds. While many tracing and tracking tools were initially proposed by start-ups, the Aarogya Setu mobile application, an open-source Indian COVID-19 contact tracing, syndromic mapping and self-assessment digital service developed by the National Informatics Centre under the Ministry of Electronics and Information Technology (MeitY) became the 'App of choice'. New technologies like Artificial Intelligence (AI), Internet of Things (IoT), Big Data and Machine Learning to fight COVID 19 remained predominantly in the realm of interest of start-ups.

Several government funding agencies including Department of Science and Technology (through Technology Development Board, SERB and NSTEDB), Department of Biotechnology and BIRAC have called for proposals for evaluating innovations and technologies that will be relevant and ready to deploy for COVID 19 pandemic. These are in evaluation or funding stage and hopefully, new technologies from Indian start-ups and Innovators will start hitting the market soon.

The key lesson learnt in combating COVID 19 is stating the obvious- that the country needs to be self-reliant to the extent possible for its medical devices and diagnostic needs. Domestic manufacturing of this equipment must focus on self-reliance in raw materials, components and manufacturing equipment. Adequate testing and evaluation facilities and appropriate regulatory oversight must be in place. Research and Development organizations must develop know-how that can be manufactured at scale quickly by industry. Liberal funding support must be extended to innovative ideas that can be quickly scaled up and reach the market.