Editorial

Ventilator Politics—The Big Picture

Deepak Agrawal[1]

[1]Department of Neurosurgery, All India Institute of Medical Sciences, New Delhi, India

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Neurosurgeons have been crying themselves hoarse over the dire need of ventilators for neurotrauma patients across India for the last few decades. It took COVID-19 to suddenly make ventilators a hot topic of discussion not only in the medical fraternity but also in the policy-making bodies of India. This "sudden" scarcity of ventilators has led everyone—from filmmakers to car makers—to jump into the fray to announce plans for developing ventilators, ostensibly to help the health care system. The real reason, however, is to do with the profit margins ventilators command in the market. It is another matter that barring a couple of companies, no new company in the world has been able to come up with a production-ready ventilator. The reasons are not hard to find. A ventilator is a mission-critical device which allows no room for error and has complex technology, software algorithms, and fail-safe systems working in tandem to ensure not 99.9%, but 100% uptime.

Low-cost manufacturers of ventilators like AgVa Healthcare have disrupted the health care market, like what Google did in the information technology space. Being a co-inventor of the AgVa ventilator, I have the unique insight of the manufacturing cost and technologies which go into the making of a state-of-the-art intensive care unit (ICU) ventilator. It has taken us close to 4 years to develop AgVa ventilator from the ground-up, innovating, and indigenizing key technologies to make it both affordable and best-in-class. This has also resulted in filing of eight patents over the same duration.

Some of the innovations incorporated in the AgVa ventilator (model AV-AD-Covid) include use of active solenoid-controlled *disposable* inspiratory and expiratory valves which have been especially designed to have fast opening and closing times, ensuring excellent inspiratory and expiratory pause, even at respiratory rates of 60/min. The use of disposable valves also ensures that there is zero risk of viral contamination inside the ventilator. As consistent 100% FiO_2 is an important consideration, we designed a special blender utilizing a 2 × 2 valve with software-based artificial intelligence which ensures homogenous mixture, while at the same time conserving use of oxygen at an extremely economical price point. Use of a built-in reducer valve ensures that the ventilator can be connected out-of-the-box to a high-pressure source (central pipeline/oxygen cylinder) or to a low-pressure source like an oxygen concentrator!

One of the biggest discerning points of AgVa ventilator is the use of an Android (Google Inc. In collaboration with the Open Handset Alliance) tablet with an app as the graphical user interface. This was a conscious decision to ensure higher reliability and safety of the ventilator. As the tablet has its own microprocessor, sensors, and battery, even if the ventilator completely fails, the tablet will continue to sound (and show) alarms, so that corrective action can be taken immediately. This unique feature is not available in any other ventilator in the world.

With the COVID-19 crisis staring us in the face and projected requirement of 1 to 10 lakhs ventilators in India, the government knew that it had a massive task at hand. With almost all countries being in the midst of COVID-19, no one was ready to supply ventilators at any price point. Also, there were hardly any domestic player in the ventilator market. It was then in March 2020 that urgent steps were taken to address the situation. CDSCO (Central Drugs Standard Control Organisation), which is the Indian equivalent of FDA (U.S. Food and Drug Administration), released an order exempting ventilators from any regulatory requirements and/or certifications. The government also decided to purchase more than 50,000 ventilators urgently and essential specifications were drafted by an expert committee constituted for this purpose. AgVa checked all the boxes and bagged an order for 10,000 ventilators. It could have asked for more but was confident of producing 10,000 ventilators within the stipulated period and therefore did not over commit. Amongst the other vendors who got orders were BEL–Skanray–DRDO combined which got an order for 30,000 ventilators and AMTZ (under license from AgVa itself) for 14,000 ventilators. As of writing this editorial (May 7, 2010), no vendor except AgVa is in a position to supply even a single ventilator. AgVa remains on track having already produced 4,000 ventilators with another 6,000 planned within the next few weeks.

What is interesting that the AgVa ventilator costing less than 1.5 lakh Indian Rupees (INR) competed for the same specifications for which other companies quoted models costing between 8 and 22 lakh INR! This shows the disruptive power of AgVa in this domain and this naturally has led to extreme anxiety amongst ventilator vendors worldwide who are using shadow politics to discredit players like AgVa.

Address for correspondence
Deepak Agrawal, MBBS, MS, MCh, Department of Neurosurgery, All India Institute of Medical Sciences, Ansari Nagar, New Delhi 110029, Delhi, India (e-mail: drdeepak@gmail.com).

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At a larger level, this vendor–doctor nexus has taken a toll on India's health care system, with doctors, under the influence of vendors, wanting more and more features in medical equipment like ventilators, most of which they will never use. This has resulted in specifications being tailored for extremely expensive equipment even in government hospitals (including All India Institute of Medical Sciences, New Delhi, India) resulting in overall lack of medical equipment at all levels. It is amusing to see the clause of FDA/CE requirement in specification after specification, despite government orders to the contrary. When the COVID-19 crisis reaches its peak, India would not be in a position to afford CE/FDA-certified ventilators costing 22 lakhs/piece instead of home-grown versions like the AgVa costing one-tenth of the price. Unfortunately, the harsh reality is that doctors are ready to treat patients on Ambu bag (the most primitive form of ventilation) but when it comes to purchasing equipment, they want the best (most expensive) at the cost of the common man!

The moot question is whether I would use an uncertified home-grown ventilator like AgVa on myself or my family members? The answer is a resounding "yes." I use and manage ventilators in my daily practice and say that undoubtably the AgVa ventilator is equal to, if not better than, the best ICU ventilator in the market currently. It is also for this reason that Neurotrauma Society of India (the apex body of neurotrauma in India) endorsed AgVa ventilator for use on patients. One can only hope that India sees the potential in Indian products which will help in decreasing the dependence on imports besides decreasing overall costs significantly.

Conflict of Interest
None declared.