Alternatives to traditional ventilators could be possible with a 3-D printer and a few simple tools

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Several collaborative projects are underway at VCU to automate and create potential improvements to existing ventilators so health systems across the country and around the world can recreate the innovative designs. Credit: Trevor Beck Frost

Like doctors across the country, Benjamin Nicholson, M.D., knows the surge is coming.

The emergency department doctor has seen the predictions for the spread of COVID-19 and knows a finite supply of ventilators exists across the country to support the growing number of patients experiencing respiratory symptoms of the novel coronavirus.

Nicholson, who is also a clinical instructor at Virginia Commonwealth University's School of Medicine, had an idea: What if he could take a manual resuscitator, the bag valve mask used by first responders and seen on every medical TV show, and automate it? And what if he could make the plans available to other health systems or providers, anyone with access to a few tools and a 3-D printer?

The device needed to be simple and able to be assembled rapidly. "And it needs to be something that someone with my level of technical background could put together," Nicholson said.

Three weeks ago, he contacted Charles Cartin, Ph.D., an associate professor of mechanical and nuclear engineering and director of makerspaces in VCU's College of Engineering, and Adam Hamel, the technician for the Mechanical and Nuclear Engineering Innovation Lab, with that idea. Soon, respiratory care specialists, coders, engineers, graphic designers, nurses, business administrators, faculty and students from across VCU's campuses were at the ready to design and promote a product they hope will save lives in Virginia and across the country.

It's one of many projects set in motion since the COVID-19 crisis began that utilizes the interdisciplinary research and innovation infrastructure already in place at VCU—and in service of the community that relies on VCU Health.

"A box of parts and a step-by-step process to put them together'

In severe cases of the virus, it infects and inflames the lungs, filling them with fluid and debris. A ventilator, in essence, mechanically replaces the role lungs would play, bringing oxygen into a body and removing carbon dioxide.

To make Nicholson's idea a reality, Cartin and Hamel needed to design the physical elements (paddles, levers, etc.) of a simple device that would fit around a manual resuscitator.

"We approached it in the same way that we educate engineering students," Cartin said. "They need a set of materials and clear instructions. It's kind of like it was when you were in high school shop class. We give you a box of parts and a step-by-step process to put them together."

Peter Pidcoe, Ph.D., D.P.T., a professor and assistant chair in the Department of Physical Therapy in VCU's College of Health Professions, wrote the software that tells the device what to do.

This automated version of a hand-pumped bag valve mask, frequently used by EMS teams, could be an alternative for health systems in need of additional ventilator capacity. Credit: Trevor Beck Frost

One challenge, among others, was the element of precision. First responders and other health care providers must pump bag valve masks by hand, so the amount of air a patient receives depends on the strength and frequency of the squeeze. Patients experiencing the lung distress caused by COVID-19 need something more accurate and precise, which the automated device can do. The team is excited by early tests of their device.

"It's incredibly accurate," said Nicholson, who graduated from VCU's

School of Medicine in 2015. "Our testing … showed the machine's consistency; we were at 1 to 2 milliliters of volume difference from breath to breath."

One challenge they didn't have: Making it all happen across multiple disciplines in record time.

"It's this network of people at VCU I get excited about," said Pidcoe, director of the Engineering and Biomechanics Lab. "I sent out emails to five people saying, "I have this idea; I need help." Within an hour, I got 12 responses from people I didn't even email saying, "How can we help and what do you need?'"

The device to support the bag valve mask is expected to cost around $500 to assemble. Some parts can be bought at a local hardware store; others can be 3-D printed. Assembly requires an Allen wrench, a screwdriver, a pair of wire cutters, a hacksaw and glue.

"It's like a mini-vent," Pidcoe said. "It doesn't have all the bells and whistles that a ventilator has, but it is certainly appropriate for maintaining and managing someone."

The team is in contact with a manufacturer in western Virginia that is interested in producing and selling them at cost. And the team hopes others will follow suit.

Rapidly responding to medical needs

The device is one of two ventilator projects in the works by teams of researchers at VCU. Pidcoe is also working on a separate design for a splitter that would modify a regular ventilator so that the pump could sustain up to four patients.

"We've created a culture of collaboration at VCU that allows people to start projects like these at a grassroots level," said Henry J. Donahue, Ph.D., the Alice T. and William H. Goodwin Jr. Professor and Distinguished Chair of the Department of Biomedical Engineering and a member of the operations committee at the C. Kenneth and Dianne Wright Center for Clinical and Translational Research, which supports clinical trials and medical research at VCU.

The department's presence, as well as that of the Institute for Engineering and Medicine, which Donahue co-directs, within the College of Engineering and School of Medicine lends itself to interdisciplinary projects, he added.

These devices designed by VCU researchers attach to a common ventilator to serve as a ventilator splitter, which allows the ventilator to provide airflow for up to four patients. This device, if FDA-approved, would allow health systems across the U.S. where there is a significant need for ventilators to regulate oxygen flow for multiple patients at once. Credit: Peter Pidcoe

The ventilator devices are only part of the VCU community's rapid response to medical and patient needs in light of the pandemic. Researchers began clinical trials for an experimental treatment drug in March. Time magazine recently featured a VCU graduate student for his quick work in 3-D printing face shields for medical workers. And last month the VCU Health clinical microbiology laboratory independently developed a COVID-19 test.

From engineering, Nicholson's project found its way to Brent Fagg at VCU's Innovation Gateway. Fagg helped patent Nicholson's device, although they intend to make the schematics free to download for all.

"The patent and copyright allow us to give other people permission to use it, even if it's for free," Fagg said. "But downloading and assembling it isn't practical for some hospitals right now, so we're also looking at manufacturing partners to rapidly scale production."

That's where the VCU School of the Arts comes in.

Matt Woolman, the school's interim associate dean for research, innovation and graduate studies, will draft and design assembly guidelines and manuals for the manufacturers and users seeking to make the device. Woolman recruited a colleague in the Center for the Creative Economy, Garreth Blackwell, Ph.D., to develop a website, and together they are creating naming options in their capacity as usability experts and user-experience designers.

"Engineers are great at coming up with a solution and engineering an outcome that solves a problem, and where we come in is helping engineers humanize the product," said Woolman, who is also executive director of VCU's Center for the Creative Economy. "In this particular project, we'll help others manufacture the parts, assemble the product and use it safely and efficiently."

VCU's Wright Center is contributing expertise and guidance through the complex Food and Drug Administration process. The College of Health Professions is opening up its training areas for equipment testing. Virginia's Health Innovation Consortium provided crucial early funding. And VCU's da Vinci Center for Innovation is leading a team tackling the issue of supply chain: How to make sure the simple supplies that this device needs won't run out.

"In this case, with all hardware, medical device components and 3-D-printed parts in hand, one should have a functioning ventilator within hours," Cartin said.

Preparing for the surge

FDA approval on Nicholson's device is still pending, and he's quick to note that none of these devices replaces a regular ventilator. However, he wants health systems and providers to be prepared for a worst-case scenario that he hopes won't come to fruition.

The collaborative experience has been inspiring for Nicholson, who returned to VCU last year after his residency in Boston.

"It's been frankly pretty amazing to actually see this all work," he said.

Provided by Virginia Commonwealth University

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