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CENTERING ON CORONAVIRUS

THE VENTILATOR SHORTAGE

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Centering on Coronavirus: The Ventilator Shortage

As COVID-19 cases exceed 1.5 million globally, medical supplies used to treat patients around the world are rapidly being depleted. This reality is forcing some medical professionals in particularly hard-hit areas to decide who gets access to potentially life-saving supplies and treatment, and who doesn't.

The most fraught choice of all may be who gets a ventilator, a device critical for patients who are experiencing the worst respiratory symptoms of the novel coronavirus.

In this issue brief, The New Center discusses the importance of ventilators in the fight against coronavirus, what is causing their current shortage, and how governments and the private sector are responding to ensure as many people as possible have access to these life-saving devices.

What are Ventilators?

A ventilator is a medical device that delivers oxygen to a patient's lungs to support the necessary functions of other organs. Depending on the severity of a patient's case, a ventilator can be used to either assist patients who have difficulty breathing or completely take over breathing functions for a patient unable to breathe on their own.

Ventilators fall within two broad categories: invasive and non-invasive. Invasive ventilation, or "tracheal intubation," involves placing a tube in a patient's trachea. Non-invasive ventilation, on the other hand, can be set up either through a tight-fitting mask placed over the patient's mouth or a hood that completely covers a patient's head, with no mask required.

How are Ventilators Relevant in the Fight Against Coronavirus?

A novel coronavirus (COVID-19) disease first identified in Wuhan, China in December 2019 is now known to be caused by a severe acute respiratory syndrome coronavirus (SARS-CoV-2). Individuals who have been infected with this strain of coronavirus suffer from a variety of symptoms ranging from fever, dry cough, and loss of smell to more advanced complications such as pneumonia.

For patients whose coronavirus disease leads to a severe respiratory infection, mechanical ventilation serves as one of the last lines of defense to keep organ functions stable and lung damage minimal while the body fights the virus, as there is currently no widespread approved treatment or vaccine.

What is the Current State of the Ventilator Shortage?

Estimates as to the amount of mechanical ventilators available in the United States to help treat COVID-19 patients fall within the range of about 60,000 to 200,000 ventilators depending on different studies conducted. For example, a March 2020 report from the New England Journal of Medicine estimates that there are between 60,000 and 160,000 ventilators available, "depending on whether those that have only partial functionality are included." And a February 2020 report from the Johns Hopkins University Center for Health Security estimates that alongside 62,000 full-featured ventilators, there are 98,000 additional non full-featured ventilators that can provide basic functions and 16,600 ventilators in the CDC Strategic National Stockpile that could be deployed in 24-36 hours. To put this shortfall in perspective, a 2005 Department of Health and Human Services Pandemic Influenza Plan suggested the U.S. would need over 700,000 ventilators if faced with a respiratory infection outbreak on par with the 1918 Spanish flu.

Even if the United States had a big enough national stockpile of ventilators, particularly hard-hit regions of the country could still face shortages if the ventilators couldn't be moved to where they were needed fast enough.

Why Do We Have a Ventilator Shortage?

Under normal circumstances, about 50,000 ventilators are produced each year globally. This is reflective of the normal demand from hospital systems, which have to factor in the cost of the ventilators (between $25,000 to $50,000 per unit) and the trained staff required to operate them when placing orders with manufacturers.

Today, these limited resources designed for a non-pandemic health environment are increasingly strained, and not just because of unit shortages. In one of his daily coronavirus briefings to the general public, New York State Governor Andrew Cuomo said that "COVID-19 patients stay on ventilators for 11 to 21 days, longer than patients with other respiratory ailments," which means that "the machines can't be turned over to others as quickly."

WHAT ABOUT THE STRATEGIC NATIONAL STOCKPILE?

The Strategic National Stockpile (SNS), created in 2003 by President George Bush as a successor to the National Pharmaceutical Stockpile created by President Bill Clinton, serves as a multi-location repository for essential pharmaceutical and medical supplies that can be deployed in the event of a national emergency. In a television interview on March 15, 2020, Dr. Anthony Fauci revealed that the Stockpile contained 12,700 ventilators—which increased to 16,600 as the threat of coronavirus grew in the United States.

Beyond the primary issue that the ventilator supply in the stockpile is not enough to meet the demand from states and hospital systems, there is a concern that many of the ventilators are either outdated or don't work. Ventilators are complex pieces of machinery with specialized parts that require regular maintenance, and some have been sitting in storage for a decade. The State of California, for example, announced that 170 of the ventilators it received from the SNS were "broken," and New York Presbyterian Hospital claimed that 220 ventilators it received "needed repair."

Efforts to Ramp Up Ventilator Availability

In an effort to meet a growing demand for ventilators and other essential products, the government and private sector have taken several steps in the hopes to quickly increase supply.

FDA ISSUES REGULATORY FLEXIBILITY

On March 2, 2020, the FDA and CDC issued a joint statement saying that certain respirators approved by the National Institute for Occupational Safety and Health (NIOSH) which had previously only been designated for use in industrial settings could now be used in health care settings as well.

It is important to note that these devices are not meant to assist patients with breathing, but rather are respiratory protective devices intended to be worn by medical personnel to filter out airborne particles.

In a follow up to the March 2 declaration, on March 27, 2020 the FDA issued an Emergency Use Authorization (EUA) allowing certain ventilators, modified anesthesia gas machines, positive pressure breathing devices, ventilator tubing connectors, and ventilator accessories that meet FDA standards to be used in health care settings. Another EUA issued on the same day allows for imported non-NIOSH-approved respirators that meet specific standards to also be used in health care settings.

PRESIDENT TRUMP EVOKES THE NATIONAL DEFENSE PRODUCTION ACT

The Defense Production Act was enacted in 1950 in response to the Korean War as a mechanism for the federal government to ensure an adequate supply of essential materials and supplies.

On March 27, 2020, President Trump invoked the Defense Production Act in order to "require General Motors to accept, perform, and prioritize Federal contracts for ventilators." In a press release, GM and its production partner Ventec Life Systems estimated that they would eventually be able to manufacture 10,000 critical care ventilators per month, but did not provide specifics on how many could be delivered in April or when they would be able to arrive at full-capacity production.

On April 2, 2020, President Trump invoked the Defense Production Act for a second time (relating to the COVID-19 outbreak) in order to facilitate General Electric Company, Hill-Rom Holdings Inc., Medtronic Public Limited Company, ResMd Inc., Royal Philips N.V., and Vyaire Medical Inc. receiving materials for ventilator production from suppliers.

This call and response is not limited to companies in the United States; when household appliance company Dyson received an order from the U.K. government to produce 10,000 ventilators, it decided to design its own new ventilator in 10 days (dubbed CoVent) which it claims can be produced "quickly, efficiently, and at volume."

Efforts to Ramp Up Ventilator Availability

In some cases, industry has responded with new and often simpler ventilator designs, even without a direct government mandate.

- In Italy, a group of engineers designed 3D-printed adapters that can turn a snorkeling mask into an emergency ventilator.
- Prisma Health designed the VESper, a connective device that allows four patients to use one ventilator at the same time.
- A team of engineers at the Massachusetts Institute of Technology known as MIT E-Vent is designing a ventilator that can be built for $100, with all designs to be published online.

Persisting Obstacles and Challenges

One of the biggest challenges that governments and industry will have to overcome in the race to manufacture more ventilators is the breaks in global supply chains due to the spread of COVID-19. Writing for IndustryWeek, Supply Chain Advisor Paul Ericksen notes that "ventilators require 156 purchased parts, many of them sourced across 14 different foreign countries." The complexity of manufacturing a ventilator is therefore exacerbated by closures of land borders, airports, and seaports in an effort to mitigate the spread of the virus.

Even if ventilators are manufactured quickly, medical professionals will still grapple with shortages of drugs involved in the ventilation process, as well as trained staff to operate the machines. According to data from the American Society of Health-System Pharmacists, in March 2020 there were shortages reported for five drugs used to support patients on ventilators. These drugs, like vecuronium and hydromorphone, make the ventilation process less stressful for patients and medical staff by sedating and, when necessary, paralyzing patients while they are being intubated.

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ABOUT CENTERING ON CORONAVIRUS

Centering on Coronavirus is a new policy series from The New Center that provides insights and analyses of how coronavirus is progressing, how it is impacting our health system, economy and workers, and the extraordinary human, policy, and technological resources that are being mobilized to fight it.

ABOUT THE NEW CENTER

American politics is broken, with the far left and far right making it increasingly impossible to govern. This will not change until a vibrant center emerges with an agenda that appeals to the vast majority of the American people. This is the mission of The New Center, which aims to establish the ideas and the community to create a powerful political center in today's America.

THE NEW CENTER

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