THE NEW OLD COLLEGE TRY

Academia takes COVID-19 to school

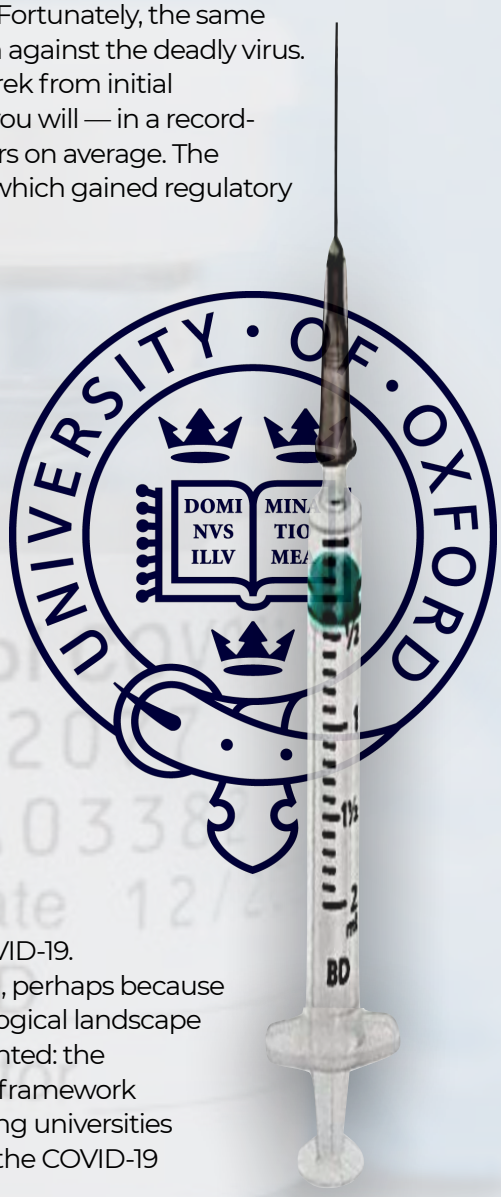
Jeffrey G. Harris, MBA & Richard A. Skinner, PhD

The COVID-19 crisis is, by almost any measure, unprecedented. Fortunately, the same goes for the ongoing effort to inoculate the world's population against the deadly virus. Vaccines with efficacy rates exceeding 90 percent made the trek from initial development to regulatory approval — *from alarm to arm*, if you will — in a record-setting 10 months. Typically, the process takes far longer — 10 to 15 years on average. The previous record-holder for speed to market was the mumps vaccine, which gained regulatory approval in 1967 — after four years of development.

"This is shattering that record," said Otto Yang, MD, an infectious disease specialist at UCLA Health. "This is really an amazing achievement." Penny Heaton, MD, chief executive officer of the Bill & Melinda Gates Medical Research Institute, offered a similar assessment in the journal *The Lancet*. "What's happened so far," she said, "has been nothing short of amazing."

What accounts for the rapid launch of medical science's counterattack on COVID-19?

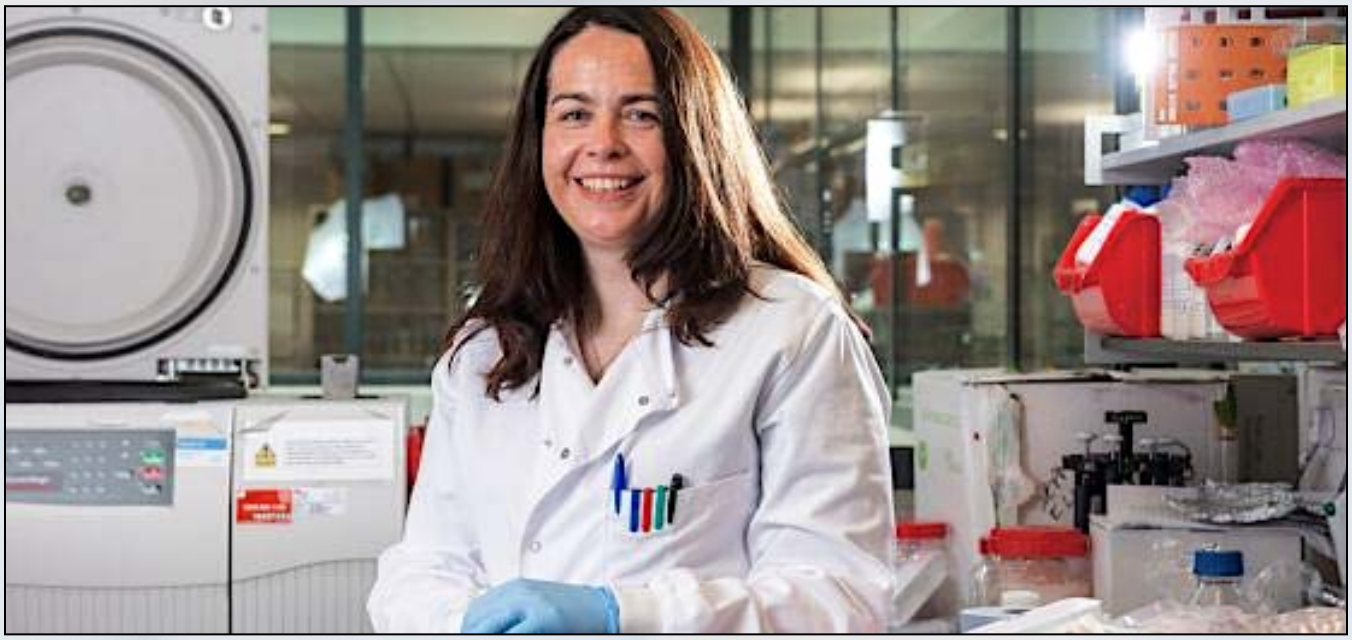
Was it the sheer scope and severity of the threat presented by the novel coronavirus, SARS-CoV-2? Was it the research community's longstanding familiarity with other members of the coronavirus "family," such as severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), and the common cold? Was it the willingness of the public and private sectors to pour billions of dollars into the search for a vaccine? Was it the altruism and cooperation shown by scores of leading researchers, including the scientists who, early on, mapped the virus's genetic sequence and then shared their findings, no strings attached, to colleagues around the world?



The answer, of course, is *yes*. All of the foregoing factors contributed to the historically speedy rollout of vaccines targeting COVID-19.

There's another key factor, however, that tends to get less attention, perhaps because it has become something of a constant in an ever-evolving epidemiological landscape — a force so pervasive and so predictable that it is all but taken for granted: the wholehearted, trailblazing involvement of academia. Building upon a framework that dates to the 1950s and the war on polio, many of the world's leading universities played critical roles in the development, evolution, and distribution of the COVID-19 vaccines.

Indeed, but for the work done by campus-based laboratories and academic medical centers, COVID-19 inoculations would likely still be months, if not years, away.



University of Oxford

"I love science and working on vaccines," says researcher Teresa Lambe, an associate professor at the University of Oxford, "and I am lucky that this means I get to do something constructive in this pandemic."

'Oxford vaccine' makes a name for itself

One of the most potent weapons in the global battle against COVID-19 is a vaccine with an obvious academic pedigree: ChAdOx1, widely known as the "Oxford vaccine."

More than 100 researchers at the University of Oxford — or, more specifically, the Oxford Vaccine Group and the university's 25-year-old Jenner Institute — threw themselves into perfecting the vaccine, made from a weakened version of a common cold virus.

"The search for a vaccine took over my life. I've never worked harder," Oxford Associate Professor Teresa Lambe, PhD, principal investigator at the Jennings Institute, recounted in an essay in the journal *Nature*. "We started our quest as soon as the genetic information for SARS-CoV-2 was published in January, when the virus was still largely confined to China. My brother was there at the time, so, over-protective big sister that I am, I was paying extra attention to what was going on."

By mid-February, after working nights and weekends, Lambe's team had developed a vaccine that produced an antibody response in a small preclinical trial.

"We were well prepared to act quickly," she wrote. "The lab had been working on vaccines for other pathogens, including a type of coronavirus that causes MERS. We already had viral vector, a modified cold virus that could safely and reliably deliver pieces of coronavirus to host cells, thereby triggering a response from the immune system.

"People ask why and how we moved so fast, but this is what we do. We develop and test vaccines."

Oxford's contribution to the fight against COVID-19 promises to be a global game-changer, thanks to its relative simplicity, its affordability, and its hardiness. The dual-dose vaccine can be stored for up to six months with normal refrigeration. In comparison, the more fragile messenger RNA vaccine developed by Pfizer and BioNTech must be kept below minus 94 degrees Fahrenheit.

The United Kingdom pre-ordered 100 million doses of the Oxford vaccine, and, by mid-November, some 4 million were ready to be shipped, pending regulatory approval. Meanwhile, Oxford's manufacturing partner, the European pharmaceutical company AstraZeneca, made arrangements to supply at least 3 billion doses on a not-for-profit basis, at least for the duration of the pandemic.

Distribution began in late December when the vaccine received emergency-use authorization from the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA).

'This is a great day for British science and a great day for universities everywhere," said Louise Richardson, PhD, vice-chancellor at Oxford. "Above all, it is a great day for the many people whose lives will be saved by this vaccine. We are greatly indebted to those who have designed, developed, manufactured, and evaluated ChAdOx1."

'Universities are often where it starts'

While the Oxford vaccine might be the quintessential poster child for academic vaccinology, it is by no means the only COVID-19 vaccine birthed in a university lab.

On March 4, 2020, a full week before the World Health Organization declared the novel coronavirus a pandemic, *Inside Higher Ed* reported that work on a vaccine was already underway at a number of U.S. institutions, including Baylor College of Medicine, Colorado State University, the University of Texas at Austin, and Washington University in St. Louis. Some universities were working alone, often building on earlier vaccine research. Others were collaborating with drug manufacturers.

"The diversity of vaccine candidates and other innovations is really exciting," said Barry Bloom. PhD, an immunology professor at Harvard University's T.H. Chan School of Public Health. "Everyone has a shot of making a contribution, and universities are often where it starts."

One of the first legitimate vaccine candidates emerged from the University of Pittsburgh, where the legendary virologist Jonas Salk, MD, had developed the polio vaccine nearly seven decades earlier. Delivered through a dime-size skin patch, the PittCoVacc — short for Pittsburgh Coronavirus Vaccine — produced enough antibodies in mice to neutralize the SARS-CoV-2 virus.

When a paper on the vaccine appeared April 2 in *EBioMedicine*, a publication of *The Lancet*, the university touted it as the first peer-reviewed study of a potential COVID-19 vaccine.

"Our ability to rapidly develop this vaccine was a result of scientists with expertise in diverse areas of research working together with a common goal,"

University of Pittsburgh

One of the first COVID-19 vaccine candidates emerged from the University of Pittsburgh. Dubbed PittCoVacc — short for Pittsburgh Coronavirus Vaccine — the vaccine is delivered, bottom, through a dime-size skin patch.

said co-senior author Louis Falo, MD, PhD, chair of dermatology at Pittsburgh's School of Medicine and the University of Pittsburgh Medical Center.

At Stanford University, researchers repurposed a lab that had been dedicated to developing vaccines for HIV, Ebola, and influenza. Their newfound focus: a vaccine containing nanoparticles studded with the same proteins that make up the distinctive spikes found on SARS-CoV-2. The nanoparticle spikes can trigger an immune response in the human body — even though the virus itself isn't present.

"Our goal is to make a single-shot vaccine that does not require a cold-chain for storage or transport," said Peter S. Kim, PhD, the Virginia and D. K. Ludwig Professor of Biochemistry at Stanford. "If we're successful at doing it well, it should be cheap, too. The target population for our vaccine is low- and middle-income countries."

Meanwhile, researchers at the University of Georgia were developing multiple vaccine candidates, including an engineered version of parainfluenza virus 5 — the culprit behind the canine affliction kennel cough — that showed promise in promoting an immune response.

"We have an opportunity now to use our technology to help people," said Biao He, PhD, the Fred C. Davison Distinguished University Chair in Veterinary Medicine. "At the University of Georgia, we have the people and we have the facilities, so we have been able to quickly mobilize resources to develop this vaccine."

As of January 2021, a database maintained by the World Health Organization contained 172 vaccine candidates. Of those, at least 64 — or more than one-third — had direct ties to universities or campus-based research institutes.

In addition to the schools previously cited, the list of U.S. developers included Ohio State University, Thomas Jefferson University, the Icahn School of Medicine at Mount Sinai, the University of Miami, and the University of Virginia.

The international representation was even greater, owing to the likes of Ege University in Turkey, Griffith University in Australia, Osaka University in Japan, Shiraz University in Iran, Tampere University in Finland, Tel Aviv University in Israel, the University of Sao Paulo in Brazil, and the University of Manitoba in Canada.

Schools help administer 'final exams'

Even bigger than the number of universities developing vaccines was the number of academic medical centers taking part in pivotal late-stage clinical trials, which are, by definition, massive undertakings. More than 40,000 volunteers at 152 sites worldwide, for example, took part in the Phase III trial of Pfizer and BioNTech's BNT-162. The final round of testing of Moderna's mRNA-1273 involved more than 30,000 participants at close to 100 locations across the United States.

"This is going to be a big American opportunity for people to come on board as our partners, to take part in what is a historic effort to bring to an end what has been the worst pandemic our world has seen in over 100 years," said Francis Collins, MD, PhD, director of the National Institutes of Health (NIH).

That the vaccines in question were targeting such a profound threat complicated the evaluation process, especially the recruitment of participants. As *The Washington Post* noted in a story about the launch of Moderna's Phase III trial in July, researchers couldn't conduct information sessions about the trial with groups, as they might under normal circumstances, or let people gather in a communal waiting room after vaccination.

The added complexity of protocols associated with the randomized, double-blind testing of COVID-19 vaccines made the participation of major research universities all but essential. Simply put, they knew what they were doing, and they had the facilities and equipment necessary to get the job done properly. What's more, they had the visibility and credibility to persuade large numbers of people to become, in effect, walking, talking test labs.

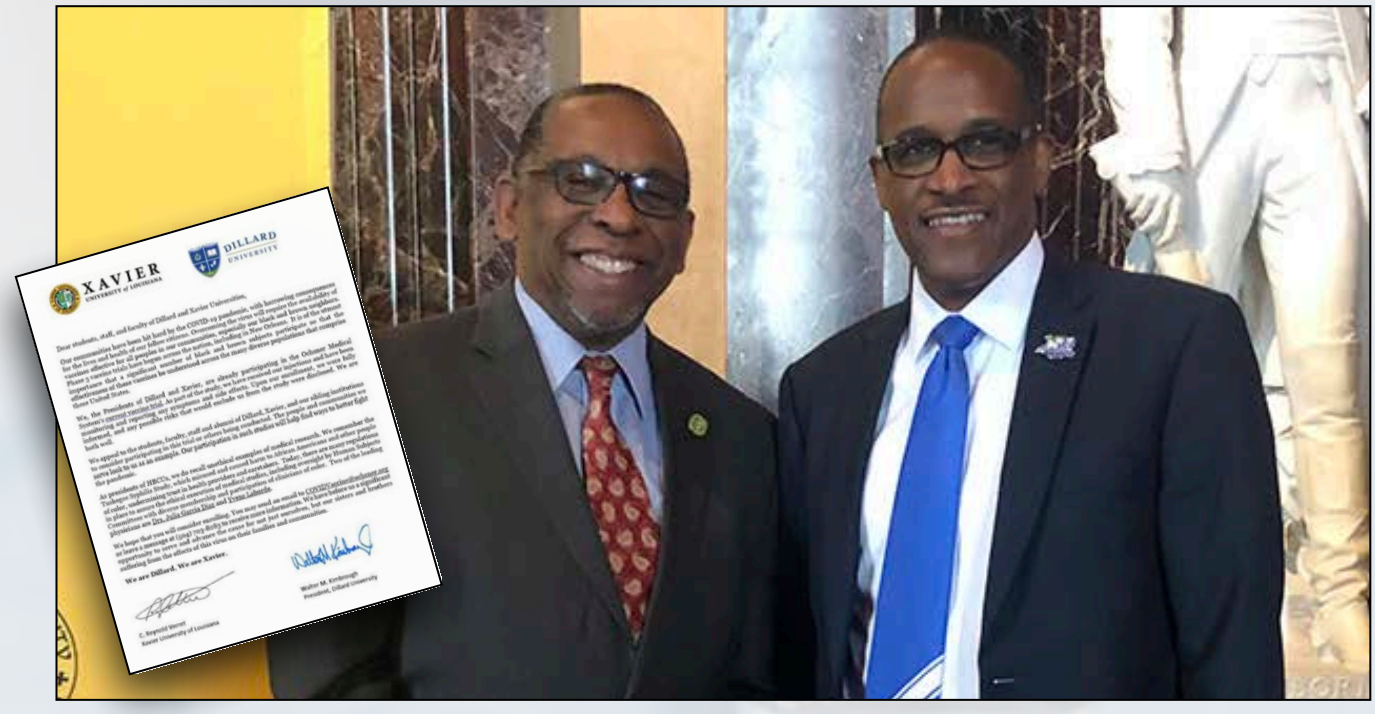
In August, for example, the University of California Davis announced that it was seeking participants for a late-stage trial evaluating the efficacy of the Pfizer/BioNTech vaccine. The public response was overwhelming, said Allison Brashear, MD, MBA, dean of the UC Davis School of Medicine. Within a week, some 3,500 people had volunteered to be screened for 200 available spots in the study.

"Before all of this," Brashear said, referring to the pandemic, "I don't think we would have had that kind of community engagement. It was a wonderful outpouring from the community, and it was a great example of how the community intersects with academic medicine — to really be 'all in' on trying to find a vaccine, a treatment."

Academia's capacity for high-volume recruitment proved particularly valuable with the Phase III trial of JNJ-78436735, a single-dose COVID-19 vaccine candidate developed by Johnson & Johnson's Janssen Pharmaceuticals. Janssen set out to secure 60,000 test subjects — twice the number of volunteers sought for the trials of the Pfizer/BioNTech and Moderna vaccines.

Janssen contracted with a number of high-profile institutions to recruit up to 2,000 subjects apiece. Janssen's Phase III partners included Rutgers University, Tulane University, the University of California San Diego, the University of Kentucky, and the University of Chicago.

"We are looking for individuals from all walks of life to participate in this study," said trial leader Habibul Ahsan, MD, director of the Institute for Precision and Population Health at UChicago Medicine. "This includes healthy adults, but also individuals with comorbidities, all genders, older adults, and people of all races. We want to be sure that the community our hospital serves is well represented in this trial."



Urban Faith

C. Reynold Verret, president of Xavier University of Louisiana, left, and Walter M. Kimbrough, president of Dillard University, signed up to participate in a Phase III clinical trial and encouraged others to follow suit.

Academic medicine leads by example

Capturing a true cross-section of society, however, is easier said than done. Many Black Americans, of course, harbor a deep distrust of the nation's public health system and its vaccine-development programs.

Their suspicion can be traced to the infamous "Tuskegee Study," in which doctors affiliated with the U.S. Public Health Service withheld treatment from Black men with syphilis so they could track the infectious disease's progression. During the study, which began in the 1930s and continued for decades, at least 128 male patients died from syphilis or its complications, 40 spouses contracted the infection, and 19 children acquired congenital syphilis.

Historically, Blacks make up just 5 percent of participants in U.S. clinical trials, even though they constitute 13 percent of the nation's general population. Hispanics are similarly underrepresented.

Inasmuch as COVID-19 has taken a disproportionate toll on people of color, such individuals must be fully represented in the clinical trials of vaccines targeting the virus.

To encourage participation among minorities, the presidents of two historically Black colleges in New Orleans, Walter M. Kimbrough of Dillard University and C. Reynold Verret of Xavier University of Louisiana, signed up for late-stage clinical trials and urged students to do likewise.

In a joint statement, Kimbrough and Verret acknowledged that "unethical examples of medical research" had "misused and caused harm to African Americans and other people of color, undermining trust in health providers and caretakers." However, the campus leaders urged people of color to look beyond those injustices in the interest of overcoming COVID-19 and the "harrowing consequences" it has wrought for minority communities.

"Overcoming the virus will require the availability of vaccines effective for all peoples in our communities, especially our black and brown neighbors," they wrote. "Phase III vaccine trials have begun across the nation, including in New Orleans. It is of the utmost importance that a significant number of black and brown subjects participate so that the effectiveness of these vaccines be understood across the many diverse populations that comprise these United States."

CNN

Rutgers University

In an effort to allay concerns about the safety of the newly authorized COVID-19 vaccines, some of academic medicine's most prominent figures rolled up their sleeves. Valerie Montgomery Rice, MD, president and dean of the Morehouse School of Medicine, left, got her initial dose on CNN. Robert L. Johnson, MD, dean of Rutgers University's New Jersey School of Medicine, also invited the media to chronicle his inoculation.

Drive-throughs, arenas, and 'The Big House'

Once regulators cleared the way for vaccines to be administered, higher education was again front and center — this time as part of the distribution process.

Across the United States, scores of academic medical centers scrambled to set up vaccination clinics. One of the first to open was at Rutgers University's New Jersey Medical School (NJMS). On December 15, ust four days after the Pfizer/BioNTech vaccine secured emergency-use authorization from the U.S. Food and Drug Administration, NJSM began inoculating frontline health workers.

"This vaccination is one of the most important steps we can take to protect us from the devastations of COVID-19," NJSM Dean Robert L. Johnson, MD, said after rolling up his sleeve.. "At this historic time, Rutgers New Jersey Medical School and University Hospital are united to fight the spread of this virus. I'm confident that by working together, we can significantly reduce the spread of COVID-19 in our communities."

As during the vaccines' clinical trials, some of academic medicine's most prominent Black leaders stepped up to address the concerns of minority communities.

On December 18, for example, Valerie Montgomery Rice, MD, president and dean of the Morehouse School of Medicine, sought to underscore the vaccines' safety by getting her initial dose on CNN — during a live segment with Sanjay Gupta, MD, the network's chief medical correspondent.

"There are Black scientists in the room where decisions are being made. There are Black scientists who are (involved) in the development of the vaccine," Rice told CNN. "We are in the rooms where it's happening, so we clearly are not going to go against ourselves."

Soon, drive-through clinics were popping up throughout the United States, courtesy of institutions such as Oregon Health and Science University, Texas A&M University, the University of Arizona, the University of Arkansas, the University of Mississippi, University of Texas, the University of South Carolina, and the University of Utah.

Other schools, such as Ohio State University, Southern Illinois University, and the University of New Mexico, also took a novel approach: Eager to inoculate as many people as possible as quickly as possible, they transformed their basketball arenas into temporary vaccination clinics.

The granddaddy of all vaccination clinics may have been at the University of Michigan, which administered shots in its 108,000-seat football stadium, "The Big House" — the largest venue in all of college football.

BioNTech

Although the first successful COVID-19 vaccine candidates reached the market in record time, their rollout to vulnerable populations was plagued by logistical missteps. Saying he was "incredibly frustrated," Ashish Jha, MD, dean of Brown University's School of Public Health, took to Twitter to call for greater federal involvement.

"We, as a state, have a big mountain to climb with regard to the number of people who need to be vaccinated, so it is fitting that the University of Michigan has opened up The Big House for this effort," said infectious disease specialist Preeti Malani, MD, the university's chief health officer. "Every healthcare worker we can vaccinate gets us closer to offering vaccines to all. Michigan Stadium helps us increase that capacity to vaccinate."

Although the first batches of successful COVID-19 vaccine candidates reached the market in record time, their rollout to vulnerable populations was plagued by logistical missteps.

One of the first experts to sound an alarm was Ashish Jha, MD, dean of Brown University's School of Public Health. Saying he was "incredibly frustrated," Jha took to Twitter to criticize the White House for failing to provide the states and local hospitals with what he viewed as adequate support.

"The worst part is no real planning on what happens when vaccines arrive in states," Jha wrote. "No plan, no money, just hope that states will figure this out." Jha noted that as recently as December, federal officials projected that 20 million Americans would get their initial shots by the end of the year. According to the Centers for Disease Control and Prevention, however, just 2.8 million people were inoculated by December 31 — even though Pfizer and Moderna, the developers of the first two vaccines to receive FDA authorization, had by then shipped more than 14 million doses.

"Ultimately," Jha told *The News York Times*, "the buck seems to stop with no one."

'We're racing a virus … and we aim to win'

The week before taking office as the United States' 46th president, Joe Biden declared the initial vaccine rollout "a dismal failure" and outlined a five-point plan to inoculate 100 million Americans in his administration's first 100 days.

The president-elect said he was prepared to enlist the aid of low-income community health centers and pharmacies around the country and, if necessary, mobilize the Federal Emergency Management Agency and the National Guard.

"This will be one of the most challenging operational efforts we've ever undertaken as a nation," Biden said. "We'll have to move heaven and earth to get more people vaccinated, to create more places for them to get vaccinated, to mobilize more medical teams to get shots in peoples' arms."

Anthony Fauci, MD, director of the National Institute of Allergy and Infectious Diseases, said Biden's goal is "absolutely a doable thing." The incoming head of the Centers for Disease Control and Prevention, Rochelle Walensky, MD, MPH, a professor of infectious diseases at Harvard Medical School, was also optimistic.

"We have looked carefully and we are confident that we have enough vaccines for the 100 million doses over the next 100 days," Walensky told CBS News. "That's what the president-elect has promised. It will be a hefty lift, but we have it in us to do that."

Ultimately, of course, the feasibility of Biden's plan won't be known until spring. One thing, however, is abundantly clear now: That the president can focus on *distributing* vaccines rather than *developing* vaccines is a testament to the potency of university research and the capacity of academic medicine and public health to meet existential challenges.

In short, thank goodness for higher education's higher mission.

So, back to the question at hand: What accounts for the rapid launch of medical science's counterattack on COVID-19?

Oxford University tackles the question in an animated video titled *How To Make a Vaccine in Record Time*.

"It's still complex work and the science takes as long as it needs to take," the video's narrator intones over the rousing finale of Gioachino Rossini's William Tell Overture. "But by throwing all our resources at the problem and running stages of development in parallel, we've made it as fast as it could possibly be. And we're not on our own; we're one of dozens of such trials — as well as treatments, public health interventions, the works.

"We're not in a race against other researchers. We're racing a virus, and however long that takes, we aim to win." ■

About Harris Search Associates

Harris Search Associates is a leading global higher education executive search firm. Established in 1997 by Jeffrey G. Harris, the firm focuses on the recruitment of senior leaders to support the growth of universities, research parks, national laboratories, hospitals, and academic healthcare enterprises. Based in Dublin, Ohio, a suburb of Columbus, Harris Search Associates maintains regional offices in Dallas and San Francisco. The firm is a shareholder member of IIC Partners, one of the world's largest executive search organizations, with 44 offices in 33 countries.

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Jeffrey G. Harris is founder and managing partner of Harris Search Associates. He is an active member of CUPA-HR, the American Council on Education (ACE), the American College of Healthcare Executives (ACHE), and the Executive Search Roundtable, a group dedicated to the development of best practices in higher education talent recruitment. Mr. Harris holds a bachelor's degree from Ithaca College and an MBA from the University of Dayton.

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