Like the rest of the world, much of DCRI’s focus for the latter part of the year centered on SARS-CoV-2, the virus that causes COVID-19. The virus spread quickly and required immediate answers to reduce infections and save lives. Through a combination of new collaborations and existing partnerships, the DCRI addressed a pressing research challenge: how to rapidly respond to a pandemic.

Protecting the Front Line

In early April, as the world watched COVID-19 infection rates soar, leadership at the Patient-Centered Outcomes Research Institute (PCORI) identified opportunities to support COVID-19 research through PCORnet®, The National Patient-Centered Clinical Research Network. They turned to a trusted partner on past projects: the DCRI, which both leads the PCORnet Coordinating Center and also has significant experience leveraging PCORnet to conduct research.

In a matter of days, DCRI Executive Director Adrian Hernandez, MD, MHS, assembled a team that pulled from all corners of the DCRI, and in a matter of weeks, the team launched the two-pronged Healthcare Worker Exposure Response & Outcomes (HERO) research program to help support a vital population: health care workers.

The foundation of the HERO program is a registry open to individuals from across the nation who work in any facet of health care. The registry, which is led by DCRI epidemiologist Emily O’Brien, PhD, invited doctors, nurses, first responders, respiratory therapists, custodial staff, cafeteria workers, and nursing home staff to participate. Participants in the registry respond to surveys about their COVID-19 risks, concerns, and symptoms, enabling researchers to collect information in real time about how the pandemic is affecting essential frontline workers. The registry also provides a pool of potential participants for other trials and studies related to COVID-19 or examining other questions pertinent to the health care worker population.

“Rapid start-up of this critical COVID-19 research program required fast action and collaboration of everyone across the DCRI.”

Tyrus Rorick

“By relying on longstanding relationships with PCORnet and its sites and health systems across the nation, we were able to develop and launch the project in record time in response to an urgent need,” said DCRI Pragmatic Health Systems Research program manager Lauren Cohen, MA, who is overseeing the operations of the HERO project.
Participants in the registry also are given the opportunity to participate in clinical trials. The first trial, HERO-HCQ, is led by DCRI infectious disease expert Susanna Naggie, MD, and is testing whether hydroxychloroquine can prevent COVID-19 infections in health care workers. Other projects and trials leveraging the HERO platform are in development.

“Rapid start-up of this critical COVID-19 research program required fast action and collaboration of everyone across the DCRI,” said Tyrus Rorick, DCRI’s head of research operations. “The HERO team relied on every functional group, from Grants and Proposals Services to Technology and Data Solutions to Biostatistics. We tested our resilience and resolve in leveraging our talent base and sharing resources—and it worked!”

**Shaping New Guidance**

In a landscape in which new information emerges daily, experts from across the DCRI have been engaged in critical decisions at both the local and federal levels. Naggie, who in addition to being a DCRI faculty member serves as the Duke University School of Medicine’s Vice Dean for Clinical Research, was invited by Anthony Fauci, MD, the nation’s leading infectious disease expert, to join a panel charged with shaping national COVID-19 guidelines.

Other data that helped to rapidly shape federal COVID-19 guidance came from the DCRI Pharmacometrics Center in partnership with the Pediatric Trials Network (PTN), for which the DCRI acts as the coordinating center. The research network is made up of experts focused on finding safe and effective doses of frequently prescribed medicines for pediatric populations.

DCRI investigators leveraged this expertise to examine pediatric doses of two potential COVID-19 treatments: hydroxychloroquine and remdesivir. Pharmacokinetic modeling for hydroxychloroquine revealed that the recommended adult and pediatric dosage of the drug was way below the level needed for a potential antiviral effect. These findings were cited in the U.S. Food and Drug Administration (FDA)’s decision to revoke the emergency use authorization it had issued for hydroxychloroquine. In addition, the PTN will study potential treatments used in pediatric COVID-19 cases to confirm their modeling data with data taken from patient care.

“The DCRI is also helping to answer questions locally. DCRI pediatricians Danny Benjamin, MD, PhD, MPH, and Kanecia Zimmerman, MD, MPH, recruited colleagues from across the Duke University School of Medicine and at the University of North Carolina at Chapel Hill to form the ABC Science Collaborative. Funded by the National Institutes of Health (NIH), the collaborative is partnering with public schools across North Carolina to collect, synthesize, and interpret the latest COVID-19 data to help school leaders make data-driven decisions.

“By relying on longstanding relationships with PCORnet® and its sites and health systems across the nation, we were able to develop and launch the project in record time in response to an urgent need.”

Lauren Cohen, MA
Beyond conducting COVID-19 research, DCRI faculty are also practicing physicians, and many of them provide care for patients with COVID-19. Because some cases are associated with cardiovascular complications, DCRI and Duke cardiologists worked together to create a care pathway for patients who have COVID-19 and are experiencing these complications.

“When we equip schools with the information they need, they will be able to decide on procedures that keep students and their families safer and healthier.”

Kanecia Zimmerman, MD, MPH

The framework, which was published in May in the American Heart Journal, outlined guidelines in order to streamline care, evenly distribute resources, and limit risk. The work, which was shared with other health systems to serve as a model, was led by DCRI cardiology fellow Rahul Loungani, MD, under the mentorship of DCRI cardiologist and Duke Heart Center Director Manesh Patel, MD.

Launching a Nationwide Network

In addition to overseeing the creation of the COVID-19 care pathway, Patel has been involved in another effort that is targeted toward helping people across the country manage their COVID-19 symptoms.

The Pandemic Response Network offers a Community Health Watch program, which operates SMS text reminders and phone calls, as well as an online platform, to support people in monitoring their symptoms and caring for themselves at home.

The network is the brainchild of the Duke Institute for Health Innovation, but since its inception in April, many other Duke entities and external partners have signed on to help the effort, including Patel’s Duke Heart Center Clinical Research Unit. To date, over 7,000 people in 48 states have signed up for symptom monitoring. The DCRI is also providing digital services and other support to the project.

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Replicating Rapid Research

Although the pandemic will one day no longer be a threat, Hernandez doesn’t see any end in sight for rapid-cycle research. Traditionally, clinical trials have been criticized for their lengthy timelines—but the DCRI has proven it can launch quality research in a fraction of the time it would typically take to plan and implement a study.

“Our ability to rapidly plan and launch studies correlates directly with our ability to quickly find the answers that patients need for improved quality of life and better outcomes.”

Adrian Hernandez, MD, MHS

“I’m proud of our teams, who really took our mission to improve health to heart and worked day and night to ensure successful launches for our COVID-19 research,” Hernandez said. “But regardless of whether there’s a pandemic, we need to replicate this rapid response for other urgent health problems. Our ability to rapidly plan and launch studies correlates directly with our ability to quickly find the answers that patients need for improved quality of life and better outcomes.”