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ALLINA HEALTH RESEARCH

COVID-19 Response

Research to combat a
once-in-a-century pandemic



JANUARY 2021

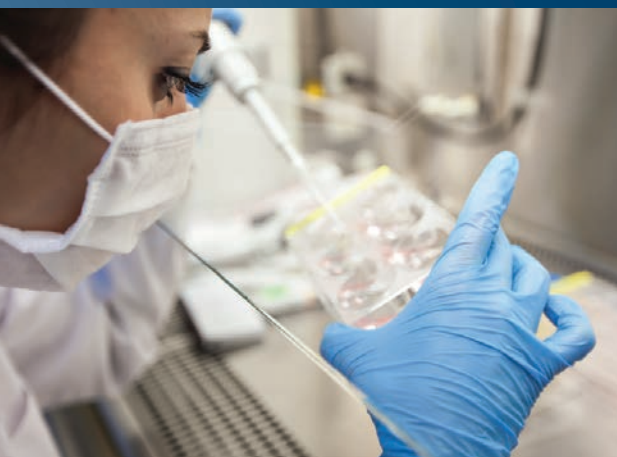
At first, we watched from afar.

In the early weeks of 2020 and in countries across the globe—from China to Europe—a novel coronavirus was spreading swiftly and taking thousands upon thousands of lives in overwhelmed hospitals. The images from Wuhan and later from Italy and other European countries seemed so distant.

On January 21, the Centers for Disease Control (CDC) confirmed the first case in the United States in Washington state. On February 11, the World Health Organization gave the coronavirus a name—COVID-19. On February 26, the first case of community spread was documented in California. On March 1, New York announced its first case. And on March 13, a national emergency was declared as the total of cases surpassed 2,100 with 50 deaths due to the virus. The pandemic quickly upended life as we knew it in the United States.

As of Dec. 31, 2020, more than 341,000 Americans and 5,323 Minnesotans have died from COVID-19.

The COVID-19 response from Allina Health combined clinical expertise with a commitment to the community. This report outlines the breadth and depth of Allina Health Research in response to this once-in-a-century worldwide pandemic.



ALLINA HEALTH RESEARCH VISION

To be a recognized leader in innovative clinical research that advances health care, improves patient lives and promotes population health in the communities we serve.



Dear friends, colleagues, donors and patients,

Allina Health's commitment to clinical research has remained steadfast during the unprecedented challenges of 2020.

The Allina Health Research team was well-positioned to meet the rapidly evolving COVID-19 research needs in support of our employees and the communities we serve. Through our partnerships with other organizations and the robust research infrastructure built over many years, we quickly pivoted to a research team focused on understanding COVID-19 treatments, protocols and safety, while safely continuing our many other areas of research.

During this challenging time, our city was also faced with the killing of George Floyd in May 2020. This horrific event made us pause to reflect on how our research must focus on health disparities in our communities.

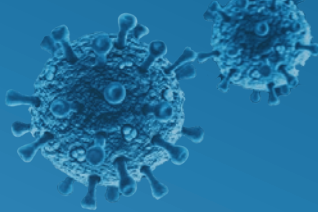
At Allina Health, our research has a responsibility to address the inequities in our community. We see the alarming statistics on how the COVID-19 pandemic has disproportionately affected Black, Indigenous and People of Color. As a nation and as a health care system, we are committed to addressing these inequities. We do not have time to waste.

We remain committed to innovative research to address the pandemic—and to continuing our research across clinical disciplines to advance health outcomes, improve patient lives and promote population health in the communities we serve.

On behalf of the Allina Health Research team, I invite you to learn more about our COVID-19 research in this report and online at allinahealth.org.

A handwritten signature in black ink, appearing to read 'Vani Nilakantan', with a long horizontal line extending to the right.

Vani Nilakantan, PhD
Vice President of Research



COVID-19 key dates

Nov 17, 2019

A mysterious illness emerges in Wuhan, China

Jan 11, 2020

China reports first death from the virus

Jan 21, 2020

Centers for Disease Control and Prevention (CDC) confirms first case in U.S. in Washington state

Dec 31, 2019

China's Wuhan Municipal Health Commission reports 27 cases of a viral pneumonia

Feb 21, 2020

CDC warns U.S. citizens that a pandemic is likely

Feb 26, 2020

First case of community spread is documented in California

Mar 1, 2020

New York announces its first case

Mar 10, 2020

U.S. surpasses 1,000 confirmed cases

Mar 11, 2020

The World Health Organization (WHO) characterizes the COVID-19 outbreak as a pandemic; U.S. introduces restrictions for travelers arriving from Europe

Mar 13, 2020

President Trump declares a national emergency; U.S. reaches 50 deaths

Mar 19, 2020

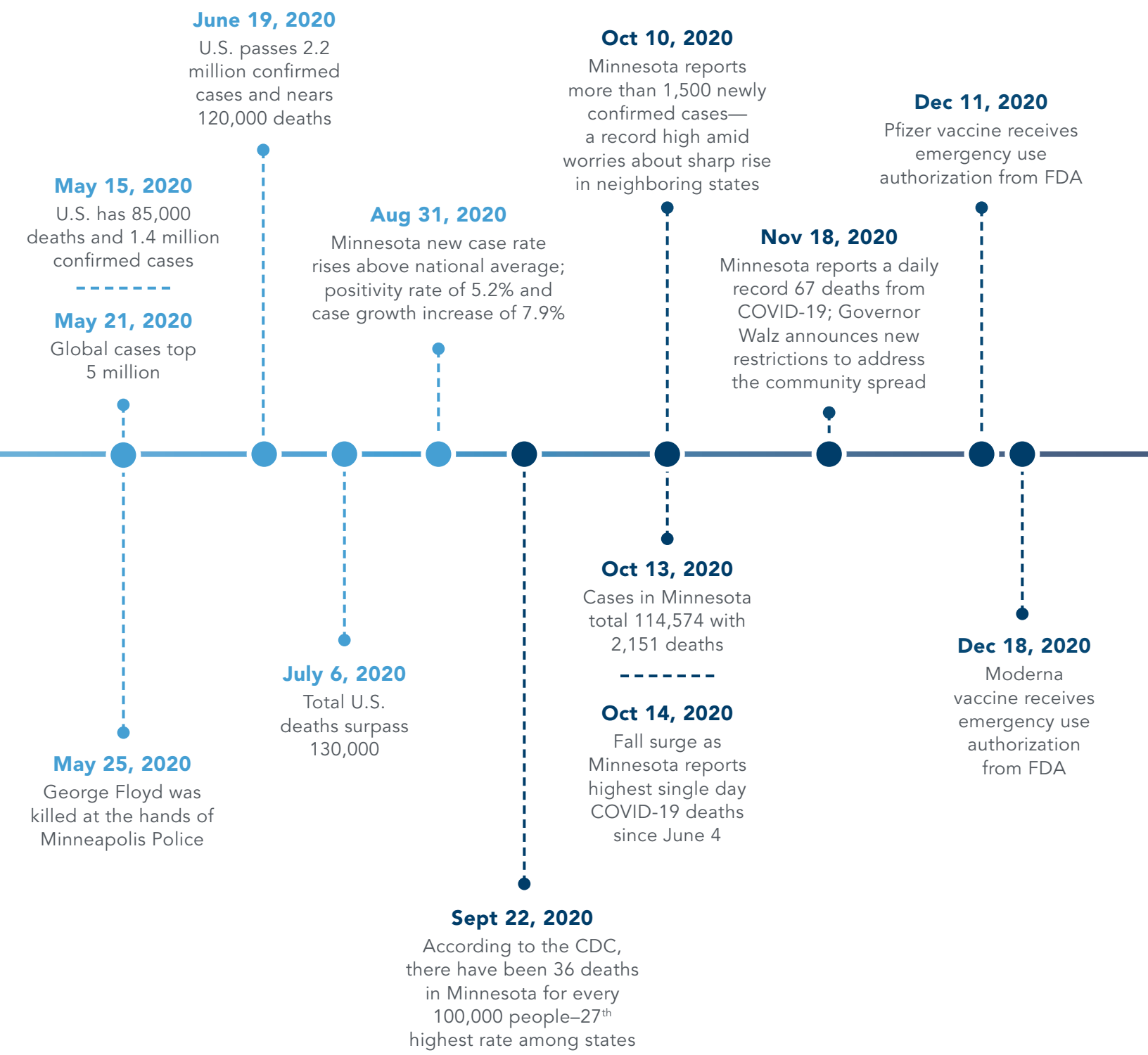
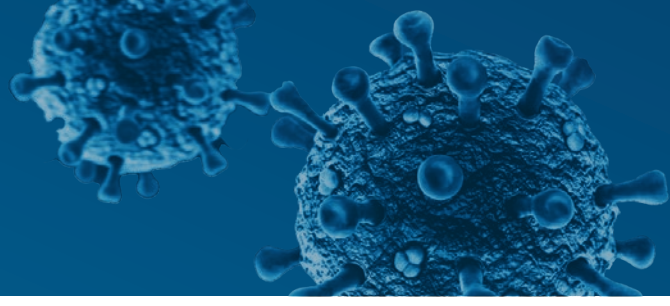
U.S. surpasses 10,000 confirmed cases

Apr 1, 2020

U.S. surpasses 200,000 confirmed cases and records more than 1,000 deaths in a single day for the first time

Apr 30, 2020

Federal social distancing guidelines lapse



Allina Health Research Team Response

In March 2020, the Allina Health Research team quickly adapted to the rapidly evolving needs to support COVID-19 trials and studies. The pace and needs were unprecedented.

Identifying and evaluating research opportunities

A multi-disciplinary **Government Funding Task Force** was established in April to support researchers and caregivers across Allina Health. This group focused on funding opportunities through grants, the CARES Act, FEMA and other sources. This 15-member task force included representatives from Accounting, Treasury, Research, Compliance, Strategy and Business Development, Government Relations and other departments.

In addition, a **COVID-19 Funding Committee** was formed to evaluate other grant opportunities from industry sponsors, the federal government, the Minnesota Department of Health and other sources.

Research guidance during COVID-19

When the pandemic began in Minnesota and shelter-in-place orders were set to slow the spread, Allina Health implemented a five-year telehealth visit plan in a mere two weeks. "Everyone stepped up in different capabilities," said Gayle Kusch, MSA, director of the Human Resource Protection Program, Research Compliance, and Outside Interests and Conflict Management.

For the Research team, this included an evaluation of all research studies currently underway at Allina Health. "We had an emergency Institutional Review Board meeting to review COVID-19 studies and determine which research could continue during the shelter-in-place orders," said Kusch. "We came up with COVID-19 research guidance, paused some studies to conserve personal protective equipment and determined which studies could safely continue."

Kusch and her team also worked with the Allina Health Telehealth team to plan for virtual visits for participants in research studies through Vidyo—a HIPAA-compliant, user-friendly videoconferencing tool.

"Whenever possible, research investigators and team members are using remote capabilities for research activities," said Kusch. "We remain vigilant and prepared to ramp down research activities as necessitated by a COVID-19 resurgence."

BY THE NUMBERS

27+

research studies

1 in 4

COVID-19 patients in Minnesota cared for at Allina Health hospitals

1 goal

improving care and safety for COVID-19 patients and health care workers

Commitment to addressing health disparities and inequities

How does Allina Health address racial and social equity in research?



Mary Radomski, PhD

The civil unrest following the death of George Floyd—a horrific event in the community served by Allina Health—brought a greater sense of urgency and a mandate to address racial disparities for the care of COVID-19 patients and for equity in clinical research.

“These racial inequities have catalyzed our thinking about what we need to do to advance social justice and health equity going forward,” said Mary Radomski, PhD, Courage Kenny Rehabilitation Institute’s research director. “We are evaluating all strategies for recruiting participants to research studies and we need to ensure that the research we conduct has relevance for all communities we serve.”

Radomski notes that the death of George Floyd serves as a pivotal point in addressing inequities and disparities in care and research. “It’s a real touchstone for self-reflection on so many levels,” she said. “We need to ensure that we are being deliberate in creating community partnerships so that when we do recruit for research studies, we are reaching out to diverse populations. Sufficient inclusion and equity won’t happen magically on its own. It’s really on all of us to figure out how we address this thoughtfully and intentionally.”

According to the CDC, cases of COVID-19 are 2.6 times higher in Blacks than whites nationally and deaths are 2.1 times higher.



For our organization, the interlocking crises of a global pandemic, economic inequality and systemic racism have led us to an inflection point in how we seek to understand our role as a health care provider — to facilitate change for those we are privileged to employ and serve across Minnesota and the region.

We are committed to eliminating racial disparities and inequities in care for all. We acknowledge this is a long-term journey and as an institution we have much to learn.”



Penny Wheeler, MD, CEO, Allina Health in a letter to the Minnesota House Select Committee on Racial Justice

Clinical Research Informatics & Analytics (CRIA)

Support for COVID-19 studies, projects and registries

In addition to providing clinical data and technology tools to Allina Health researchers, the CRIA team supports global, national, state and local COVID-19 registries. In 2020, the CRIA team contributed to more than 25 research studies and projects related to the COVID-19 pandemic.

The CRIA team participates in a research network called PCORnet, the National Patient-Centered Clinical Research Network. PCORnet includes 251 health care systems and academic medical centers throughout the United States. As part of the Greater Plains Collaborative (GPC), one of the 12 networks within the PCORnet research network, CRIA maintains a technical infrastructure for data collection that includes a datamart with specific COVID-19 data for research and disease surveillance.

Allina Health's CRIA team has one of the highest records for sustained data quality and responsiveness to data requests within the PCORnet network, according to Cass Rodgers, site project manager for GPC/PCORnet at Allina Health. Because of CRIA's performance in the PCORnet network, the CDC selected Allina Health Research as one of 43 sites to participate in the CDC-sponsored COVID-19 Electronic Health Data Initiative, a national registry to help decision makers track trends and capture insights on patients infected with COVID-19. CRIA also participates in three other registries:

- Society for Critical Care (SCCM) VIRUS COVID-19 Registry, a global registry of COVID-19 positive patients admitted to a hospital; 24 countries and 287 sites participate in this registry
- State of Minnesota COVID Electronic Health Record Consortium registry, which tracks symptomatic and non-symptomatic groups and comorbidities
- Allina-wide registry of COVID-19 patients.

The CRIA team provides weekly updates for these global, national, state and local COVID-19 registries. "Researchers will use this data to understand the characteristics COVID-19 patients share and to gain insights from this data to help fight the pandemic," said Narayana Mazumder, infrastructure architect and lead data analyst for CRIA.

CRIA's work exemplifies the value of good data and the importance of delivering summary COVID-19 information accurately and quickly for research and public health surveillance to help fight the pandemic.

How many hospitalized patients included

Hospital Admissions

43885

ICU Admissions

8215

Median Age

63

25th-75th %ile: 50-75 years
N: 40229

WORLD LOCATIONS

US LOCATIONS



Viral Infection and Respiratory Illness Universal Study (VIRUS) COVID-19 Dashboard: The CRIA team participates in the Society for Critical Care (SCCM) VIRUS COVID-19 Registry, a global registry of COVID-19 positive patients admitted to a hospital. Allina Health is one of 287 sites worldwide to contribute to the registry.

COVID-19 Research Studies

The following summaries represent a fraction of the research studies approved, in process or completed at Allina Health during the COVID-19 pandemic.

ENSEMBLE COVID-19 vaccine trial begins at Allina Health



Allina Health is the only clinical trial site in Minnesota to participate in Janssen Pharmaceutical's COVID-19 vaccine study. Janssen Pharmaceutical, part of Johnson & Johnson,

developed the investigational vaccine that is now in phase 3 of its clinical trial.

"This is one of the most important trials we have conducted at Allina Health," said Vani Nilikantan, PhD.

Worldwide, the goal is to have 40,000 participants in the clinical trial. The vaccine is a single-dose and can be kept at refrigerator temperature for a month after taking it out of a freezer, making usage in remote areas much easier. It also requires only one dose.

Using a disabled common cold virus, scientists developed the vaccine based on the virus's genetic instructions for building the spike protein. Once injected, the spike protein is synthesized in the body to create an immune response to the virus that causes COVID-19.



As a group, these phase 3 COVID-19 vaccine trials are the most important medical studies of this century."

Frank Rhame, MD
Infectious Diseases physician,
Allina Health



FACTS & FIGURES FROM THE ENSEMBLE TRIAL

phase 3 trial

40,000
study participants
worldwide



200
study sites across
the globe

1 of 4
vaccines in U.S.
phase 3 trials

“The issue is way more complex than just does the vaccine work or not,” said Frank Rhame, MD, infectious diseases physician, Abbott Northwestern Hospital, and principal investigator for the Allina Health ENSEMBLE trial. “Because we care most about whether it works in people who have severe disease or moderately severe disease because they’re the ones who really suffer.”

Allina Health’s announcement of its participation in the ENSEMBLE vaccine trial received significant media attention in the Minneapolis-St. Paul region and nationally, including NBC’s Today Show.

Allina Health enrollment in the ENSEMBLE study is in the top quarter of all U.S. sites. One of the study participants, Darrell Martin, was inspired to volunteer in memory of his 98-year-old mother who died from COVID-19 in October 2020. “She was a loving and giving person and I think she would have appreciated the opportunity to do something,” said Martin.



The tsunami of COVID-19 has challenged every health care organization at multiple fronts leading to a realignment of priorities. Many non-academic centers rightly diverted resources towards clinical care. Allina Health was able to rise to the occasion to put the needs of our patients first while also contributing to much needed clinical research in our fight to understand this new disease. This was possible with an extremely talented and well-organized Research team with unwavering support from senior leadership.

The successful launch of the ENSEMBLE study exemplified the coordinated efforts from dedicated stakeholders coming together and breaking down silos to achieve a larger purpose. Allina Health’s efficient research infrastructure makes it easy for any researcher to bring ideas to fruition. I am honored to be part of such a talented group.”

Venkat K. Iyer, MD, MBA
medical director, Medical
Specialties, Allina Health



single-dose vaccine



Allina Health is the
only ENSEMBLE
clinical trial site
in Minnesota



ONE COMPLICATED QUESTION

Does it work to prevent moderate
or severe cases of COVID-19?

COVID-19 RESEARCH STUDIES

Preserving personal protective equipment (PPE)

Use of Half-Face Reusable Respirator in the Clinical Care Environment: Health Care Worker Perceptions



In the early days of the pandemic, health care systems throughout the country suffered from a shortage of essential PPE for health care workers. Allina Health researchers applied for and received an Emergency Fund Grant from the Minnesota Department of Health to purchase more than 15,000 pre-assembled elastomeric respirators and other supplies for health care workers at Abbott Northwestern and United hospitals.

Health care workers in designated COVID-19 units were fit tested and trained to use the elastomeric respirator for use in the clinical setting, including nurses, laboratory technicians, dietary staff and other patient-facing roles. "In the grant application, we felt that it was important to include a research component," said Catherine St. Hill, DVM, PhD, principal research scientist, Care Delivery Research. "This grant and research allowed us to purchase the necessary respirators and supplies and also better understand first line workers' needs so they can have the best experience using them."

One benefit of the respirator is the ability to reuse this PPE for an extended period of time, allowing for expansion of the patient population with whom staff can wear the N95 level of protection, increasing the safety to staff, reducing costs related to training, and preserving N95 respirators for use in unique situations in which they are most appropriate.

"What I'm most proud of is how Allina Health values

the protection and safety of its employees," said Ruth Bryant, PhD, MS, RN, CWOCN, director of Nursing Research.

PRIORITY:

Pregnancy Coronavirus Outcomes Registry

A joint initiative between researchers from the University of California, San Francisco and the University of California, Los Angeles, the PRIORITY nationwide study is collecting data on pregnant and recently pregnant women under investigation for or recently diagnosed with COVID-19. Allina Health ob-gyn physicians and providers have referred patients to PRIORITY for screening to participate in the study.

The goal of the study is to better understand how pregnant and postpartum women are affected by COVID-19 including what their symptoms are, how long they last, and how COVID-19 may impact their pregnancy and their newborn. Information gained from the study will help researchers understand the impact of COVID-19 on the health and well-being of pregnant women and their newborns.

Society of Critical Care Medicine (SCCM) COVID-19 Registry

In April 2020, SCCM launched its COVID-19 registry with national and international contributors. Named VIRUS (Viral Infection and Respiratory illness Universal Study), Allina Health hospitals are participating in the SCCM's prospective, cross-sectional, observational study and registry for patients diagnosed with COVID-19. The registry will end in April 2021 with de-identified data collected for group analysis.

"Allina's contributions to this registry were made possible by a dedicated multidisciplinary team and Abbott Northwestern Hospital Foundation funding support. It will allow intensivists, hospitalists and physicians focused on medical education to

establish future external research collaborations and to develop exciting new ways of care delivery for our patients,” said Catherine St. Hill, DVM, PhD, principal investigator for Allina’s SCCM initiative and principal research scientist.

Intensivists and hospitalist leaders at Abbott Northwestern Hospital will conduct research based on patient data on chronic medical conditions, demographics, epidemiology data, symptoms data, pre-medications, processes of care, microbiology data, labs, imaging, intensive care unit (ICU) meds, syndromes, hospital length of stay (LOS), cardiac echo data and outcomes including ICU and hospital discharge status.

By participating in the registry, Allina Health researchers are assisting with the creation of a real-time SCCM COVID-19 registry of ICU and hospital care patterns, which allows for evaluation of COVID-19 practices.

Mother Baby implications



For pregnant women, a COVID-19 diagnosis presents a new set of health care challenges and questions. The Allina-wide registry of COVID-19 positive patients collects a wide range of data that is accessible to all investigators at Allina. The registry includes data on pregnant patients with COVID-19 so that Allina can conduct its own research on how to best care for mothers and babies. “Allina Health providers are staying on top of national and international research on COVID-19 and pregnant women,” said Abbey Sidebottom, MPH, PhD, principal research scientist. “They are taking the latest research into account as they plan for any needs on how to modify patient care for mothers and babies.”

Data acquisition for both registries is supported by generous funds from Abbott Northwestern Hospital Foundation.

HERO Research Program: Preventing COVID-19 infections in health care workers

Allina Health is one of 35 clinical trial sites for the HERO study to understand the impact of COVID-19 on health care workers—and to evaluate whether hydroxychloroquine (HCO) can be used effectively to prevent COVID-19 infections in health care workers.

The focus on prevention is critical given the vital role of health care workers on the front lines of treating patients with the novel coronavirus. The HERO Research Program out of Duke University includes two parts—a national registry and a clinical trial. The registry has enrolled 1,358 health care workers including 29 at Allina Health. The second part of the program is a randomized clinical trial to determine if hydroxychloroquine is effective in preventing and decreasing the rate of COVID-19 infection in this population. The study will also explore the potential for the drug to prevent health care workers from unintentionally spreading the virus to others.

Ang2 Protocol:

A randomized clinical trial in patients hospitalized with pneumonia and presumed or confirmed COVID-19

Allina Health participated in a clinical trial with Eli Lilly to determine the safety and efficacy of an inpatient IV medication to limit the severity of the disease. The trial evaluated an investigational selective monoclonal antibody to test its effectiveness to inhibit the effects of Angiotensin 2, which is known to be elevated in patients suffering Acute Respiratory Distress Syndrome from COVID-19. The goal of the study was to investigate the drug’s anti-inflammatory activity.

Patients were enrolled in the trial at Abbott Northwestern, Mercy and United hospitals to determine the medication’s effectiveness. With leadership from Ayesha Rashid, MBBS, United Hospital infectious diseases specialist, Frank Rhame, MD, served as the principal investigator for the trial.

COVID-19 RESEARCH STUDIES

Expanded Access Programs

Convalescent Plasma

Allina Health participated in a program to provide expanded access to convalescent plasma to hospitalized COVID-19 positive patients and was the highest enrolling site. Initially coordinated by Mayo Clinic, 247 Allina Health patients received convalescent plasma before the Food and Drug Administration issued an emergency use authorization (EUA) for investigational convalescent plasma for the treatment of COVID-19 on Aug. 23, 2020. The FDA concluded that convalescent plasma may be effective in treating COVID-19 and that the known and potential benefits of the product outweigh the known and potential risks.

Remdesivir

On Aug. 23, 2020, the Food and Drug Administration also expanded access to Remdesivir for hospitalized adult and pediatric patients with suspected or laboratory-confirmed COVID-19 through an EUA. A total of 617 Allina Health patients received Remdesivir before the EUA based on the FDA's review. Two separate randomized trials conducted by the National Institute of Allergy and Infectious Diseases evaluated how long it took for patients to recover from COVID-19 after being treated with Remdesivir.

Most effective tools against the virus until the population is vaccinated:

Practice social distancing.

Wash your hands.

Wear a mask.

The importance of philanthropy to Allina Health Research

TOGETHER, WE MAKE IT POSSIBLE

Philanthropy enables Allina Health to conduct groundbreaking COVID-19 research, recruit and retain brilliant scientists and continue to make exciting advances in patient care.

To learn more about supporting research at Allina Health, contact:

Stephen Bariteau
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