Content regarding studies that received federal funding is solely the responsibility of the publishers and does not necessarily represent the official views of the National Institutes of Health.

Some of the photos shown in this annual report were obtained prior to the COVID-19 pandemic and, therefore, may not show current clinical masking standards or social distancing practices.
Welcome message from our Chief Research Officer

Amit Acharya, PhD
Chief Research Officer and System Vice President
Advocate Aurora Health

It is often said that translating research from bench to bedside takes about 17 years. As the coronavirus pandemic has illustrated, that time frame is simply too slow to help those in need. Fortunately, the speed of COVID-19 vaccine development proved that a 17-year gap is not always necessary when scientific minds are nurtured and empowered in an effective organization.

Since beginning my journey as chief research officer and system vice president for Advocate Aurora Health at the beginning of 2021, it has become my goal that when we at Advocate Aurora Research Institute look back on 2020, we see not only loss but also hope. That we can reflect on the scientific achievements of the past year and draw inspiration. And that our strong organizational culture will channel that inspiration into results for our patients and the communities that we have the privilege to serve.

Last year clearly demonstrated how much research can positively impact patient care and community health, particularly at scale. As part of one of the largest not-for-profit health systems in the country, with 26 hospitals, 75,000 team members, 10,000 physicians, 22,000 nurses and 3 million unique patients, our Research Institute has the potential to improve literally millions of lives.

The pandemic has rightfully elevated the role of research and the importance of scientific discovery. But, as we all look forward to a post-pandemic future, the Research Institute is above all committed to ensuring that work does not simply stop at the bench or end with a scientific publication, but is instead translated into improved health outcomes for our patients. That is at the heart of our organization’s strategic plan, and it is our promise to you – to advance care through research.

Sincerely,
Year in review

The year 2020 will foremost and forever be associated with the coronavirus pandemic. COVID-19 challenged our research efforts, just as it did our health system and every health care network around the world.

But even before COVID-19 entered our lexicon, 2020 was shaping up to be a momentous year for Advocate Aurora Research Institute. We had engaged with a health care consulting firm to develop our strategic plan, leveraging our organization’s existing strengths and preparing for new opportunities and successes in the future. We also began the search for a chief research officer to execute that strategic plan and launch a new era as a research enterprise.

Mid-year brought even greater recognition of the value of research in our organization when research continued to be highlighted in various communication channels and was identified as an integral component of Advocate Aurora Health’s 2020 Core Priorities.

The year drew to a close with two more significant developments: First was the naming of our first chief research officer – Amit Acharya, PhD. Second was the creation of an integration charter to begin the process of completely merging all research resources and functions of our two legacy research institutes – Advocate Research Institute and Aurora Research Institute – into a single legal entity – Advocate Aurora Research Institute, LLC – with centralized leadership, unified operations and a single brand.

Throughout it all, of course, the pandemic remained a constant – always with us, challenging us, taking from us, but also providing opportunity. Our response as a Research Institute to COVID-19 has, likewise, become a consistent point of pride. Despite, or perhaps because of, the pandemic, the Research Institute has achieved greater integration, improved its tools and processes, and strengthened teamwork between individuals working closely across regions and service lines. In a year when terms like “clinical trial” and “emergency use authorization” became almost universally recognized, research participants and team members seized the moment, doubling down on our mission of helping people live well through access to research and innovative therapies.

This annual report aims to share the stories of our research accomplishments and activities that best highlight that commitment to our patients and communities.

Denise Angst, PhD, RN
Vice President, Academic Research and Strategic Partnerships

Nina Garlie, PhD
Vice President, Clinical Trials

Kurt Waldhuetter
Vice President, Research Services
Led by Director Michelle Maternowski, Advocate Aurora’s Research Subject Protection Program (RSPP) is charged with the oversight of human and animal subject research conducted throughout the health system, safeguarding the rights, welfare and dignity of the human and animal subjects who participate in research. RSPP’s responsibilities include managing the Institutional Review Board, which reviews human subject research, and its Institutional Animal Care and Use Committee.

**Research Institute Overview**

### Clinical focus areas
- Cardiovascular
- Oncology
- Neuroscience
- Pediatrics
- Other specialties, including a new COVID-19 focus in 2020

### Types of research
- Clinical trials and patient-centered outcomes research
- Preclinical research (basic and laboratory research)
- Other research activities (registries, quality improvement projects and more)

### Research centers, programs and laboratories
- Advocate Center for Pediatric Research
- Aurora Medical Education Research
- Biorepository and Specimen Resource Center
- Center for Urban Population Health
- Discovery Laboratory (multiple sites)
- Ed Howe Center for Health Care Transformation
- Endocrine Research Laboratory
- James R. & Helen D. Russell Center for Research and Innovation
- Leona Loebler Memorial Cancer Research Laboratory
- National Cancer Institute Community Oncology Research Program (NCORP)
- Neuroanatomy Laboratory
- Advocate Center for Pediatric Research
- Aurora Medical Education Research
- Biorepository and Specimen Resource Center
- Center for Urban Population Health
- Discovery Laboratory (multiple sites)
- Ed Howe Center for Health Care Transformation
- Endocrine Research Laboratory
- James R. & Helen D. Russell Center for Research and Innovation
- Leona Loebler Memorial Cancer Research Laboratory
- National Cancer Institute Community Oncology Research Program (NCORP)
- Neuroanatomy Laboratory

### Infrastructure
- Council for Quality Assurance and Improvement in Research
- Research Analytics
- Research Development and Business Services
- Research Education
- Research Innovation
- Scientific Writing and Research Communications
- Sponsored Programs Office

### Health system partnerships
- Advocate Charitable Foundation and Aurora Health Care Foundation
- Compliance
- Finance
- Graduate Medical Education
- Health Informatics and Technology
- Human Resources
- Legal
- Pharmacy
- Brand, Consumer Experience & Public Affairs
- Research Subject Protection Program

### Board of Directors
- The Advocate Aurora Research Institute board of directors consists of Advocate Aurora Health leaders who serve in an advisory capacity, helping to shape the Research Institute’s future.

- **Amit Acharya, PhD**
  Chief Research Officer
- **Jeffrey Bahr, MD**
  Chief Medical Group Officer
- **Vincent Bufalino, MD**
  Chief Medical Group Officer
- **Rachelle (Shelly) Hart**
  Senior Vice President, General Counsel
- **Nan Nelson**
  Senior Vice President, Finance Operations
- **Dennis Potts (Chair)**
  Executive Vice President, Operations WI Region
- **Ajay Sahajpal, MD**
  Medical Director, Abdominal Transplant Program

*Led by Director Michelle Maternowski, Advocate Aurora’s Research Subject Protection Program (RSPP) is charged with the oversight of human and animal subject research conducted throughout the health system, safeguarding the rights, welfare and dignity of the human and animal subjects who participate in research. RSPP’s responsibilities include managing the Institutional Review Board, which reviews human subject research, and its Institutional Animal Care and Use Committee.*
2020 Data Summary

1,164 Total Research Projects*†‡

3,948 Consented Research Participants*

508 Clinical Trials*†

497 Patient-Centered Outcomes Research*†

53 Preclinical Studies*†‡

* Projects include clinical trials, patient-centered outcomes research, preclinical studies and other research activities
† Projects open at any point in 2020
‡ Duplicate projects across sites excluded

* Biorepository consents excluded

* Clinical trials open at any point in 2020
† Duplicate trials across sites excluded

* Patient-centered outcomes research projects open at any point in 2020
† Duplicate projects across sites excluded

* Preclinical studies open at any point in 2020
† Preclinical biorepository studies included
‡ Duplicate studies across sites excluded
2020 Data Summary

552 Scientific Articles*

* Advocate Aurora Health-authored, peer-reviewed journal articles

552
Cardiovascular (142) 26%
Pediatric (82) 15%
Specialty (216) 39%
Neuroscience (55) 10%
Oncology (57) 10%

$9.5M External Grants Awarded**†

* Continuing support included
† Grant-funded clinical trial awards excluded

$33.9M Research Funding Sources

External Contracts and Grants ($12,624,022) 37%
Institutional Investment ($117,384,179) 51%
Philanthropic Support ($3,550,295) 10%
Other ($298,772) <1%

$92K Internal Grants Awarded*

* Continuing support included

$92K
Specialty ($48,850) 42%
Pediatric ($48,143) 52%
Cardiovascular ($219,689) 2%
Neuroscience ($484,852) 5%
Oncology ($4,429,912) 47%
Patient-Centered Outcomes Research

With a large and diverse population of 3 million patients, Advocate Aurora Health is committed to advancing population health and other patient-centered outcomes research (PCOR) to benefit our patients and our communities.

Advocate Aurora Research Institute’s PCOR team focuses on improving health outcomes by developing evidence-based interventions in real-world settings to large patient populations with diverse demographic and clinical characteristics.

With expertise in epidemiology, biostatistics, implementation science, and evaluation and health services research, our PCOR researchers study a wide range of disease areas, such as cardiovascular disease, maternal and child health, COVID-19, behavioral health, neurology, and oncology. Interventions developed or evaluated include medications, devices, procedures, diagnostic tests, health information technology, behavioral therapies and more. The team collaborates with Research Analytics and has extensive experience in managing electronic health records using observational, retrospective study designs as well as collecting patient outcome data prospectively using both observational and interventional study designs.

During the past year, interim director Rasha Khatib, PhD, MHS, and the PCOR team have led and supported many studies across our large and diverse system and partnered with other top health systems, academic institutions and pharmaceutical companies to advance national research initiatives and develop and implement evidence-based practice in a real-world setting. As a result, the findings can be generalized to other U.S. health care systems and have been disseminated in major scientific conferences and peer-reviewed journals.

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The following annual report pages feature several innovative PCOR projects designed to improve health outcomes for patients with COVID-19 infection and the health care providers who care for them (pages 17 and 18), people of color with high blood pressure (page 23), newborn infants at risk for infection (page 36), mothers in need of prenatal care (page 38), and adults with Down syndrome (page 40).

Research Institute PCOR team members also direct and support the James R. and Helen D. Russell Center for Research and Innovation Summer Research Internship Program (see page 8), which pairs second-year medical students with Advocate Aurora Health investigators.

Led by Veronica Fitzpatrick, DrPH, PCOR manager and summer research internship program director, the program is a long-standing and successful collaboration with Rosalind Franklin University of Medicine and Science, Chicago Medical School in North Chicago, Illinois. The students gain clinical research knowledge and experience from mentors who are experts in their fields, and, in return, clinicians receive student support on their research projects.

Despite numerous challenges created by the COVID-19 pandemic, the PCOR team expanded the 2020 program and established new processes based on the need for virtual-only interactions, e-learning and remote work.

Additionally, the PCOR team provides research training and mentoring for new investigators and trainees from Advocate Aurora graduate medical education programs, including monthly research education sessions and quarterly REDCap data management workshops in partnership with Research Analytics. Education is offered for every phase of investigator-initiated research, from the initial study design to final dissemination of research findings through presentations and publications.
Ed Howe Center for Health Care Transformation

Ed Howe Center for Health Care Transformation, launched in 2018, supports projects focused on transforming health care delivery, improving outcomes related to quality and cost of care, and advancing the health and well-being initiatives that affect patients and populations.

Former Aurora Health Care CEO G. Edwin Howe's vision was to find faster and better ways to improve patient outcomes by transforming health care delivery through innovative research and practice. Upon retiring, he established the Howe Fund for Innovation through the Aurora Health Care Foundation with the help of donors, family, friends and colleagues.

Michelle Simpson, PhD, RN, director of the Howe Center, and her team have led and supported numerous research projects, some of which received external funding, were published in nationally recognized journals, and were presented at regional and national conferences.

In 2020, the Howe Center’s research focused primarily on geriatrics, behavioral health and rare diseases. (Read more about the Howe Center’s research on page 39.)

James R. and Helen D. Russell Center for Research and Innovation

The James R. and Helen D. Russell Center for Research and Innovation was established in 2012 with support from an endowment created by the estate of the late James and Helen Russell. The purpose of the Russell Center’s research is to enhance the quality of care and improve health outcomes for individuals and the community.

Led by Director Katie Wozniak, the Russell Center provides coordination and regulatory support for important programs that provide critical support to clinical investigators, including the:

- Small Research Project Grants Program, which provides seed funding for innovative, investigator-initiated research projects;
- Embedded Physician-Scholar Program, which gives protected research time to selected physician investigators; and
- Summer Research Internship Program, which pairs Rosalind Franklin University of Medicine and Science medical students with Advocate Aurora Health investigators, providing researchers with extra help and affording students an invaluable research experience.

The generosity of the Russell family (James, Helen and daughter, Jean) also has enabled the creation of important programs that provide critical support to clinical investigators, including the:

- Small Research Project Grants Program, which provides seed funding for innovative, investigator-initiated research projects;
- Embedded Physician-Scholar Program, which gives protected research time to selected physician investigators; and
- Summer Research Internship Program, which pairs Rosalind Franklin University of Medicine and Science medical students with Advocate Aurora Health investigators, providing researchers with extra help and affording students an invaluable research experience.

(Read more about the program on page 7.)
Technological infrastructure

Research Institute completes OnCore clinical trial management system implementation in Illinois

Advocate Aurora Research Institute went live in October 2020 with its OnCore clinical trial management system (CTMS) for Illinois team members. The journey to transition Illinois studies from Merge CTMS to OnCore was more than a year long and affected large swaths of the Research Institute in both Illinois and Wisconsin.

The effort was managed by the Core Team, a multidisciplinary group of staff experts from across clinical trial service lines and business services. The Core Team was led by the OnCore administrator, who is part of the Research Systems Administration team. Core Team leaders said the implementation was the largest integrated project between team members in Illinois and Wisconsin since the Research Institute began the merger process in 2018.

Research team members have already witnessed numerous benefits:

- Clinical research coordinators have seen a reduction of duplicative data entry using subject and protocol interfaces with Epic, the electronic health record system used at Advocate Aurora Health.
- The Research Institute has recognized OnCore as a single source of truth for managing the study portfolio.
- All service lines have adapted a standardized intake process for entering clinical trials into OnCore.
- Through system automation and streamlined workflows, there is increased communication between study teams and Research Business Services.

The Research Institute in 2018 signed a five-year, $1.8 million contract with Forte Research Systems, now Advarra Technology Solutions, to transition to OnCore. The Core Team implemented the CTMS in Wisconsin in 2019. The Core Team is exploring additional ways to utilize OnCore for the management of other types of research studies, including investigator-initiated studies, studies that don’t have funding and studies that don’t involve consenting patients.

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Research Analytics

Advocate Aurora Research Institute’s in-house Research Analytics department provides the data and server-based application support to advance innovative research.

Within the department, the Research Data Analytics team leverages the electronic health record (EHR) to align investigators’ research questions with the appropriate data available, performs feasibility analyses and builds reproducible datasets. Research Data Analytics programmers and analysts have decades of experience working with physician investigators, managing health data and developing data pipelines. These team members collectively have two dozen certifications across different data models within the EHR. Data delivered by Research Data Analytics have informed improvements in practice, been included in countless publications and produced new algorithms.

The Research Systems Administration team ensures that the server-based applications used by the Research Institute have clear and defined workflows for all users, are consistently used by all users and meet the ongoing needs of the Institute. These applications include the OnCore clinical trial management system, REDCap and Epic.
Discovery Laboratory

The Discovery Laboratory at Aurora Sinai Medical Center in Milwaukee is a modern research facility where experts in oncology and neuroscience research work on the development and evaluation of new and effective treatments. It features:

- An open floor plan, where researchers collaborate more easily and naturally, sharing information and resources;
- Specialized containment rooms, where researchers can safely process and grow cells, work with viruses, and test how cancer stem cells respond to novel oncolytic viral treatment and drug treatments; and
- A fully equipped vivarium for research using mouse models.

Biorepository program

Biorepository and Specimen Resource Center

The Biorepository and Specimen Resource Center (BSRC) collects, processes, stores and distributes biospecimens from consenting research participants at Advocate Aurora Health. These valuable samples are shared with researchers, academic institutions and pharmaceutical companies throughout the country to advance innovative research to improve patient outcomes.

By linking the whole blood, plasma and serum samples to the electronic health record, BSRC ensures that relevant de-identified clinical data are associated with every sample. In addition, BSRC collects tumor and other tissue samples by working closely with the surgery and pathology teams.

BSRC has developed Institutional Review Board-approved protocols that allow for efficient and compliant collection of biospecimens.

Leona Loeber Memorial Cancer Research Laboratory

The Leona Loeber Memorial Cancer Research Laboratory provides assistance with specimen preparation, processing and shipping for clinical trials, specifically COVID-19 studies in 2020. In addition, the Loeber Laboratory has served as a beta site for evaluation of new lab instruments. The lab technology also offers the opportunity to provide tissue microarray creation, which spares limited patient tissue samples for additional testing and conserves resources and time.

The laboratory was established in 2006 thanks to a generous gift from the Loeber family in memory of their late mother to increase access to innovative research opportunities.
Sponsored Programs Office

The Sponsored Programs Office (SPO) serves as the central office responsible for managing all external and internal sponsored research funding at Advocate Aurora Health. SPO is involved in the entire life cycle of the grant process. The pre-award team assists researchers in all aspects of the proposal submission process to ensure adherence to institutional and sponsor guidelines, regulations, policies, and procedures. The post-award team oversees the financial management of all research awards while complying with all federal, state and local guidelines. SPO negotiates all non-industry-sponsored contracts and oversees federal auditing.

Research Business Services

By managing the business aspects of research, including budgeting, contracting, billing and coverage analysis, Research Business Services allows Advocate Aurora Health investigators to focus on what's most important—world-class medical research that benefits Advocate Aurora patients.

Research Innovation

The Research Innovation team sits at the crossroads of scientific discovery and clinical practice. It oversees strategic alliances with academia and industry, leveraging research growth through the Biorepository and Specimen Resource Center, clinical trials and investigator-initiated research. The team also collaborates with Advocate Aurora Enterprises and Advocate Aurora Health’s Strategy & Innovation and Business Development teams in developing and evaluating innovative technologies to help people live well.

CQAIR (Council for Quality Assurance and Improvement in Research)

The Council for Quality Assurance and Improvement in Research oversees Advocate Aurora Research Institute’s quality management plan, which ensures high-quality, compliant research is conducted throughout the health system. Chaired by Nina Garlie, PhD, the council includes a broad representation of the Research Institute, as well as members from the Research Subject Protection Program and Research Compliance.

Research Education

The Research Education team provides centralized onboarding, preparation for research certification and professional development programs to team members across Advocate Aurora Research Institute. Partnering with Research Institute leadership, Quality, Compliance, the Institutional Review Board, clinicians and other stakeholders, education initiatives are implemented to ensure regulatory compliance and enhance high-quality research conduct and performance.

Scientific Writing and Research Communications

Working to raise the visibility of Advocate Aurora Research Institute, Scientific Writing and Research Communications highlights preclinical, clinical and investigator-initiated research by producing digital and print marketing materials, managing the Research Institute’s websites, and liaising with Advocate Aurora Health’s Brand, Consumer Experience & Public Affairs team. The Scientific Writing and Research Communications team also manages production of the Journal of Patient-Centered Research and Reviews (see page 12).
Journal of Patient-Centered Research and Reviews

Advocate Aurora Research Institute’s Journal of Patient-Centered Research and Reviews (JPCRR) celebrated its seventh year of publication by unveiling a modernized website design that fittingly displays the extensive and impactful scientific findings its readers have come to expect.

A peer-reviewed medical journal published quarterly, JPCRR is devoted to disseminating scholarly works that aim to advance patient-centered care delivery, health outcomes and patient experiences.

To date, readers in more than 200 countries have generated 200,000 article downloads and another 100,000 PubMed retrievals. With nearly half of the journal’s readership hailing from outside the United States, JPCRR truly is global in reach.

“As JPCRR’s popularity continues to steadily grow, our journal has evolved into a favored destination for works featuring patient-reported outcomes, patient-centered care practices and studies involving patient-partner researchers,” said Editor-in-Chief Dennis Baumgardner, MD.

Visit aah.org/jpcrr to access all current and archived content, submit a manuscript for peer review or sign up to receive quarterly email notifications of new issues. Also, follow @JPCRR on Twitter.

Aurora Medical Education Research

More than 300 Advocate Aurora Health clinicians and professionals serve as voluntary faculty on the clinical adjunct professor track at the University of Wisconsin School of Medicine and Public Health, teaching students, residents and fellows. The Aurora Medical Education/Aurora Founded in 2001 by Aurora Health Care, now part of Advocate Aurora Health, University of Wisconsin School of Medicine and Public Health and University of Wisconsin-Milwaukee, the Center for Urban Population Health (CUPH) offers a unique opportunity to combine multidisciplinary expertise on urban health from health care and academic institutions. After nineteen years, those founding institutions remain committed to improving the health and well-being of urban populations in Wisconsin and Illinois.

UW Medical Group Research Core is responsible for supporting research and scholarly activity in areas such as geriatrics, health care quality, maternal and child health, medical education, specific diseases, and women’s health. Dennis Baumgardner, MD, oversees these activities.

Center for Urban Population Health

Founded in 2001 by Aurora Health Care, now part of Advocate Aurora Health, University of Wisconsin School of Medicine and Public Health and University of Wisconsin-Milwaukee, the Center for Urban Population Health (CUPH) offers a unique opportunity to combine multidisciplinary expertise on urban health from health care and academic institutions. After nineteen years, those founding institutions remain committed to improving the health and well-being of urban populations in Wisconsin and Illinois.

JPCRR is indexed in PubMed Central, Directory of Open Access Journals, Google Scholar and Web of Science’s Emerging Sources Citation Index.

Read on page 41 about one CUPH investigator’s research into a care model for justice-involved individuals in Milwaukee County.
Prior to the COVID-19 pandemic, Advocate Aurora Research Institute did not have a program dedicated to infectious disease research. But in the spring of 2020, while clinical research leaders were busy halting clinical trials for patient and staff safety, they were simultaneously exploring and launching numerous COVID-19 treatment trials and research projects to improve the health of our patients and communities.

By the end of the year, Research Institute team members were well-versed at opening COVID-19 clinical trials and safely enrolling participants and had reviewed dozens of COVID-19-focused research proposals.

In the following pages, we share how the Research Institute navigated the early days of the pandemic and detail several COVID-19 clinical trials and investigator-initiated research projects conducted at Advocate Aurora Health.

Pandemic pivot

How the Research Institute took on COVID-19

By March of 2020, nearly every aspect of the world’s various health systems were shaken by the coronavirus outbreak – which had just been deemed a worldwide pandemic by the World Health Organization – and forced to quickly alter course, including Advocate Aurora Research Institute.

The pandemic was unlike anything nearly anyone alive had ever seen, which meant that, when it came to managing research activities across a vast network of clinics and hospitals spanning two states, the Research Institute had no handbook to follow. But thanks to the quick thinking and tireless work of its leaders and team members, the Research Institute was able to rapidly launch an incident command model that streamlined decision-making processes, enhanced efficiencies, and, most importantly, kept research participants and team members safe.

Through the incident command model, the Research Institute: developed a mandate for the ramp-down of research activities and a frequently-asked-questions website to inform research participants and team members of timely changes; successfully rolled out numerous COVID-19 clinical trials and investigator-initiated studies; guided countless team members through a conversion to remote work; aided both the Research Institute and the larger health system through team member redeployment; and reevaluated and improved the Research Institute’s internal study intake and start-up processes.

By the end of 2020, the Research Institute had again demonstrated its enormous value within Advocate Aurora Health.

One of our team’s most impressive accomplishments was launching our program for treating patients with convalescent plasma, or plasma donated by a COVID-19 survivor.

Katie Wozniak
Research Director
Laura Wrona, MSN, director of cardiovascular research, led the Clinical Trials Problem-Solving priority area: “As the pandemic reached our communities, the health and safety of our clinical trial participants and team members, of course, remained our priority. In an effort to minimize the risk of contracting or spreading COVID-19 through research interactions and preserve personal protective equipment for clinical care, the Research Institute, in partnership with the Institutional Review Board, mandated a ramp-down strategy for most on-site, in-person research activities, beginning in March.

“In mid-May, consistent with Advocate Aurora Health’s reactivation of its clinical sites, the Research Institute began slowly and gradually reactivating research activities while maintaining certain restrictions. Throughout the year, research leaders continued to closely monitor COVID-19 infection rates in our communities and adjust accordingly.”

Katie Wozniak, director of oncology, neuroscience and specialty research, led the COVID-19 Trials and Compassionate Use priority area: “At first, we were reaching out to industry partners, asking to be part of COVID-19 trials. But after a few weeks, companies began coming to us, one after another. We had opportunities for four or five trials per week. Suddenly, we had to build an infectious disease inpatient clinical trial program that never existed, including hiring additional team members. And many of the infectious disease physicians had never enrolled participants in clinical trials before, even though they were experts in their fields, so we had a huge effort bringing everyone up to speed with training.

“We relied on our expert clinicians to help us determine which trials to join. Did the trial look clinically appropriate? Was it relevant to the patients they were seeing? With COVID-19, the treatment path of each patient morphed quickly, so there was constant reevaluation by the clinicians of what investigational drugs might potentially benefit a trial participant.

“By the summer, our team members were experts in conducting these clinical trials. I knew I could give them any COVID-19 trial and they could handle it, even though they had no knowledge of infectious disease clinical trials a year ago. What’s more, I think many of these same physicians will remain interested in clinical research beyond the COVID-19 pandemic.

“One of our team’s most impressive accomplishments was launching our program for treating patients with convalescent plasma, or plasma donated by a COVID-19 survivor. Our research regulatory team worked urgently behind the scenes with the system’s clinical effectiveness team, transfusion team, blood banks and physicians. At first it was difficult to even obtain the plasma. There just weren’t enough COVID-19 survivors donating. But the entire Advocate Aurora Health organization pulled together and eventually joined the Mayo Clinic’s expanded access program, into which we enrolled approximately 750 patients who were treated with convalescent plasma and followed for study. The U.S. Food and Drug Administration granted an emergency use authorization for treatment of COVID-19 patients using convalescent plasma in the fall as a result of the trial.”

Rasha Khatib, PhD, MHS, interim director of patient-centered outcomes research (PCOR), helped lead the COVID-19 Investigator-initiated Research and Academic Research Partnerships priority area: “When the pandemic began, our team turned our focus to PCOR projects related to COVID-19. We sought out collaborative efforts with both new and established academic partners and worked with the Sponsored Programs Office on COVID-19 grants and calls for proposals. We ultimately launched four successful COVID-19-related investigator-initiated research projects.”

Cheryl Lefaiver, PhD, RN, director of the Advocate Center for Pediatric Research, led the COVID-19 Research Authorization and Protocol Review (RAPR) priority area: “Early in the pandemic, investigators were starting to bring forward ideas for COVID-19-related research, and the Research Institute realized that a central standard intake and review process across Illinois and Wisconsin for these proposals would be necessary. Within a month, the COVID-19 RAPR process was developed and put into practice by a core group of research leaders and team members. The central process included an online intake submission form, routing to a standard email, assessment of protocol completeness and assignment for committee review. Study proposals were assigned according to study type for review by panels composed of experts in research design, analytics and clinical infectious disease. The COVID-19 RAPR panels initially met once or twice per week and now convene as needed. Between March 2020 and March 2021, 86 COVID-related research proposals were reviewed, 55 were authorized, 19 were withdrawn, and 12 were declined because of feasibility, resources or safety concerns. The implementation of the COVID-19 RAPR process has led to a reimagining of the authorization and review process for all research proposals submitted to the Research Institute.”

>1,000 total patients treated with convalescent plasma
Clinical research highlights

Research Institute joins the fight against COVID-19

Advocate Aurora Health joined its first randomized clinical trial designed to combat COVID-19 in April 2020.

The phase 2 study aimed to determine the activity and safety of a low-dose oral course of the drug selinexor, manufactured by Karyopharm Therapeutics. Researchers evaluated whether selinexor could treat the infection and reduce intensive care unit admission by suppressing the inflammatory response and “viral load,” which refers to the number of viral particles being carried by an infected person and shed into the environment. By suppressing a patient’s viral load, clinicians may be able to reduce the likelihood that the virus is spread to people and surfaces around the patient.

The study also gauged whether selinexor was able to hasten time to clinical improvement, shorten hospital stay, and reduce morbidity and mortality for patients with severe cases of COVID-19 compared to the standard of care.

Researchers evaluated whether selinexor was able to hasten time to clinical improvement, shorten hospital stay, and reduce morbidity and mortality ...

Studying a drug shown to target and stop coronavirus

Advocate Christ Medical Center in Oak Lawn, Illinois, became the first site in the state, and one of the few U.S. sites selected, to join a new clinical trial evaluating investigational antiviral treatment molnupiravir in hospitalized adult patients with a laboratory-confirmed severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) infection.

“Molnupiravir has been shown to inhibit SARS-CoV-2 virus in preclinical studies, and if clinical research confirms its safety and effectiveness, it will be the first oral antiviral therapy available to directly target and stop the virus,” said Adam Treitman, MD, infectious disease specialist and site principal investigator.

The phase 2 trial, END-COVID, aims to determine the dosage that achieves maximum effectiveness with the fewest number of side effects. Study participants are randomized into one of four enrollment sections where they’ll receive either placebo or 200 mg, 400 mg or 800 mg molnupiravir pills taken twice daily for five days. Participants have a two-to-one chance of receiving molnupiravir vs. placebo.

Advocate Aurora Research Institute investigators plan to enroll about 10 participants. Patients who have had symptoms longer than one week or require mechanical ventilation or intensive care are not eligible for the trial.

END-COVID is sponsored by Ridgeback Biotherapeutics, LP.
Clinical research highlights

Advocate Christ studies combination therapy

Advocate Aurora Research Institute enrolled two participants at Advocate Christ Medical Center in Oak Lawn, Illinois, in a clinical trial to evaluate two drugs in combination that were also being independently studied to treat COVID-19. Critical care and emergency medicine physician Kenneth Dodd, MD, served as site principal investigator for the study.

The trial, sponsored in the U.S. by Genentech, Inc., was designed to compare remdesivir plus tocilizumab to remdesivir plus placebo in hospitalized patients with severe COVID-19 pneumonia.

Tocilizumab is a biologic medication approved by the U.S. Food and Drug Administration (FDA) to treat severe or life-threatening cytokine release syndrome (CRS), a form of severe toxicity induced by CAR T-cell therapy used to treat different cancers. Many treating clinicians and researchers have reported that CRS caused from cancer treatment is quite reminiscent of the “cytokine storm” endured by some patients with COVID-19.

Remdesivir given independently eventually earned FDA approval for treatment of COVID-19 in adults and older children for the treatment of COVID-19 requiring hospitalization. It was the first COVID-19 treatment to receive FDA approval.

COVID-19 trial comes to Aurora BayCare

Aurora BayCare Medical Center in Green Bay, Wisconsin, began enrolling participants in December 2020 for a study of a treatment for COVID-19 pneumonia. Aurora BayCare was one of 40 sites in the country participating in the study. Pulmonologist and critical care specialist Raul Mendoza-Ayala, MD, served as site principal investigator for the study.

The clinical trial, sponsored by CalciMedica, Inc., was designed to evaluate the intravenous drug Auxora as a potential therapy for patients with severe COVID-19 pneumonia.

Auxora is what’s called a calcium release-activated calcium channel inhibitor. This group of inhibitors is known to block the production and release of pro-inflammatory cytokines from immune cells and has the potential to interrupt the so-called “cytokine storm” that leads to acute lung injury and acute respiratory distress syndrome in patients with COVID-19.

Studying severe COVID-19

Advocate Aurora Research Institute enrolled 12 participants at Aurora St. Luke’s Medical Center in Milwaukee in a clinical trial studying an investigational drug to treat severely ill patients with COVID-19.

The study, sponsored by Incyte Corporation, compared two different doses of the drug ruxolitinib to placebo in participants with COVID-19-associated acute respiratory distress syndrome (ARDS) who were on a ventilator.

At the time the trial opened, studies showed that about 14% of patients with COVID-19 developed severe disease requiring hospitalization and oxygen support and 5% required admission to an intensive care unit. For patients with COVID-19 who develop ARDS, prior studies showed the disease had a 50% to 80% mortality rate, despite any treatment that a mechanical ventilator might provide, creating the need for alternative treatments.

Critical care specialist Charles Ojielo, MD, served as site principal investigator for Aurora St. Luke’s.
Pulling together to mount a COVID-19 antibody defense

More than 16K team members partner with researchers to uncover evidence about COVID-19 immunity

Advocate Aurora Health researchers and 16,233 team members partnered in a two-part study designed to determine if antibodies from SARS-CoV-2 – the virus that causes COVID-19 – provide a defense against future recurrences, how high antibody levels must be to fight reinfection and how long protection lasts.

Part one examined the prevalence of SARS-CoV-2 immunoglobulin G (IgG) antibodies, believed to be reliable indicators of past COVID-19 infection, in team members working in a range of health care roles with different exposure risks at hospitals and sites of care that span a multitude of urban, suburban and rural Midwest regions. Part two assesses COVID-19 reinfection rates at three and six months after the initial test.

Results from part one, published in the journal Public Health Reports, showed that the lowest SARS-CoV-2 IgG positivity rate was among individuals older than 65. Conversely, those younger than 45 had the highest antibody prevalence, which may have been impacted by exposure, as more than 75% of clinical team members working in COVID-19 units were under 45.

Researchers also found no difference in the number of COVID-19 infections between team members who worked from home and had no patient or hospital exposure and those who provided clinical care to patients without COVID-19.

"Finding no difference between clinical and non-clinical groups indicates Advocate Aurora COVID-19 prevention measures were effective in preventing the spread of SARS-CoV-2," said Jon Richards, MD, PhD, hematologist, oncologist and study principal investigator. "This evidence is critical to keeping our patients and team members safe; it strengthens our commitment to the Advocate Aurora Safe Care promise and may help guide preventive measures that other health care systems can utilize."

Advocate Aurora Research Institute patient-centered outcomes researchers Veronica Fitzpatrick, DrPH, manager, and Anne Rivelli, MPH, senior coordinator, serve as coinvestigators. Advocate Aurora Health funded the study.

"The BSRC advantage"

To help with testing and validation of new diagnostics and therapeutics for COVID-19, Advocate Aurora Research Institute’s Biorepository and Specimen Resource Center (BSRC) began collecting positive and negative COVID-19 blood specimens from consented patients in May 2020. The specimens are retrieved from surplus blood that’s been discarded after routine testing.

BSRC collects multiple specimens from each patient at various timepoints throughout their hospital stay to enable a longitudinal assessment of the virus. Additionally, BSRC divides the specimens into smaller aliquots to increase opportunities for future laboratory analyses.

As of March 2021, BSRC had collected samples from 156 patients who had tested positive and 423 patients who exhibited symptoms but tested negative for COVID-19.
Building a **U.S. data repository** to improve COVID-19 outcomes

Researchers join national collaborative to enable new discoveries through the analysis of millions of cases

Advocate Aurora Research Institute joined the National COVID Cohort Collaborative (N3C), a National Institutes of Health (NIH) initiative of the National Center for Advancing Translational Sciences (NCATS). N3C’s objective is to build the NCATS N3C Data Enclave – a singular U.S. resource of COVID-19 clinical data for the analysis and identification of potential treatments, long-term outcomes, and factors contributing to risk or providing protection from COVID-19 infection.

To do this, N3C created a new repository model to overcome the significant obstacles inherent in combining, sharing and analyzing millions of COVID-19 cases gathered from many different sources across the country. Real-world data must first be harmonized, so N3C uses a common data model to organize it into a uniform structure.

N3C is using NCATS’s secure and private cloud infrastructure to house and share the enclave and to ensure robust data analytics capabilities and data protections. NIH administrators maintain strict control, including determinations of user access, permissions and restrictions.

Advocate Aurora Health is one of more than 70 health care institutions participating in N3C. The Research Institute’s Patient-Centered Outcomes Research and Research Analytics teams are leading this project for the organization.

The Research Institute, as part of the **Institute for Translational Medicine (ITM)**, is among the NCATS-supported Clinical and Translational Science Awards Programs that are permitted to contribute and access COVID-19 data for approved research.

**Did you know?** Researchers are working on more than 200 N3C-approved COVID-19 research projects and counting.

**COVID-19 and beyond**

In 2020, Advocate Aurora Research Institute investigators launched numerous studies with the ultimate goal of improving the health outcomes of nontraditional COVID-19 patients, such as patients who also have cancer, pediatric patients and pregnant women. These research activities included clinical trials, registry studies and investigator-initiated research.

Advocate Aurora, the University of Chicago, Rush University, Loyola University Chicago, NorthShore University HealthSystem, and Illinois Institute of Technology share an NIH Clinical and Translational Science grant, whose funds support data provision to the N3C Data Enclave. NIH funding facilitated the Research Institute’s data infrastructure development, which made possible data harmonization and sharing with N3C’s common data model.

If successful, the N3C Data Enclave may become the national data repository prototype for the future study of other diseases, conditions or public health crises.

This project is supported by the National Center for Advancing Translational Sciences of the NIH through grant number UL1TR002389 that funds the ITM.
Cardiovascular research

With the help of cardiovascular clinical trial participants, as well as Advocate Aurora Research Institute’s patient-centered outcomes research in the field, we’re advancing therapies for conditions ranging from heart failure and arrhythmias to valvular disease and hypertension.

Continue reading to learn about a few of our 2020 research highlights and successes, including the story of how participation in a cardiovascular clinical trial helped one patient get her life back, as well as clinical trials studying investigational devices for arterial blockages and tricuspid valve repair and a patient-centered outcomes research project studying innovative approaches to overcome cardiovascular health disparities.

An optimized heart

How participating in a clinical trial helped one patient get back her life while paving the way for future patients just like her

Gloria Keyes is a walking, talking advertisement for the Impulse Dynamics, Inc., Optimizer® Smart System.

“I think the Optimizer is an awesome tool for people with a weak heart muscle, people with congestive heart failure,” said the 64-year-old Milwaukee native. “I’ve had friends with the same condition who are already gone, because all they had was a defibrillator, not the Optimizer.”

She’ll tell anyone with congestive heart failure (CHF) who is willing to listen that they should get the device.

And now they can. Thanks in part to her participation in the initial Optimizer clinical trial at Aurora St. Luke’s Medical Center in Milwaukee, the U.S. Food and Drug Administration in March 2019 approved the device for the treatment of heart failure.

Advocate Aurora Research Institute enrolled 18 participants in the Optimizer study under site principal investigator and electrophysiologist Imran Niazi, MD. And, in December 2020, Dr. Niazi implanted the health system’s first commercial Optimizer device.

It was a good feeling knowing I was one of the people who helped get it approved.

Gloria Keyes
Research Participant
An eager participant

Congestive heart failure is an incurable disease in which the heart does not pump blood throughout the body as well as it should, causing shortness of breath, dizziness, fainting and even death. More than 450,000 new cases are diagnosed in the U.S. each year, adding to the more than 2.8 million people already living with the condition.

Keyes had suffered from CHF since 2000. After eventually winding up in the hospital following a stroke in 2006, she was referred to Dr. Niazi.

“He told me I needed some help, that I was really sick,” Keyes said.

When initial treatment didn’t resolve the issue and her symptoms returned, Dr. Niazi and Rebecca Stebnitz, RN, research nurse coordinator, approached Keyes about participating in a clinical trial for an investigational treatment for CHF. It was Keyes’s first time learning about clinical research, but she didn’t hesitate.

“I was ready to sign up,” she said. “I just wanted to feel better. I was still young.”

Strengthening the heart muscle

The clinical trial was designed to evaluate whether the Optimizer system was safe and effective in treating the symptoms of CHF.

“Not all congestive heart failure is a result of an arrhythmia, for which cardiac resynchronization therapy using a pacemaker or defibrillator would be appropriate,” Dr. Niazi said. “For these patients, medications can sometimes lessen symptoms by making it easier for the heart to pump or supplying more oxygen to the heart. But there remained an unmet need for patients who remained symptomatic despite therapy with medication.”

Optimizer was developed to improve heart strength by stimulating the heart muscle with an electrical signal, called cardiac contractility modulation (CCM) treatment.

“Whereas a pacemaker or defibrillator modulates the rhythm of the heart, CCM works by modulating the strength of the heart,” said senior clinical trial coordinator Phyllis Runningen, BSN, who worked with Keyes during part of her study follow-up.

The device is about the size of a deck of playing cards and is surgically implanted through a small incision in the upper chest. Insulated wires, or leads, connect the device to the patient’s heart, recording electrical signals generated by the heart and delivering the CCM treatment.

“The way I explain it is my heart beats first on its own,” Keyes said. “Then the Optimizer sends an electrical shock, and this time my heart pumps harder.”

After receiving the device as part of the clinical trial in 2006, Keyes began to immediately feel better, her life going “back to normal.” Her last study follow-up was in 2019 when Runningen told her that the device had been approved for use outside of clinical trials.

“I thought that was fantastic,” said Keyes, who, with her husband, Billy, has six kids and 12 grandkids. “So many people need to enjoy life like I have. It was a good feeling knowing I was one of the people who helped get it approved.

“I thank God I’m here to see my youngest granddaughter. My son didn’t have any children yet at the time I began the clinical trial. I thank God for getting me here. And I thank the Optimizer for helping.”

Did you know?

Aurora St. Luke’s Medical Center was the first site in Wisconsin to implant the device when it was in the initial stages of research.

Did you know?

Aurora St. Luke’s Medical Center is now participating in a post-approval study evaluating the long-term safety and efficacy of the Optimizer® Smart System in a real-world setting.

Imran Niazi, center, was principal investigator for the Optimizer study.
Clinical research highlights

Reducing stroke risk is next step in TAVR research

Aurora St. Luke’s Medical Center in Milwaukee is the first site in Wisconsin to participate in a post-market clinical trial evaluating the ability of Boston Scientific Corporation’s Sentinel® Cerebral Protection System to reduce the risk of stroke for participants with aortic valve stenosis within 72 hours of undergoing a transcatheter aortic valve replacement (TAVR) procedure.

Although the TAVR devices and procedure have revolutionized heart valve replacements, researchers reported rates of major stroke between 3% and 7% for first-generation devices.

“As cardiologists have become more familiar with the devices and procedure, and as the devices themselves have improved, we have lowered but not entirely eliminated the risk of stroke during TAVR,” said interventional cardiologist Suhail Allaqaband, MD, site principal investigator for the study.

Clinicians have turned to cerebral embolic protection devices, such as the Sentinel system, to potentially further reduce the risk of post-TAVR neurological damage by capturing embolic material, such as pieces of calcium or plaque, during TAVR procedures and preventing blood vessel blockages that could lead to stroke.

Expanding research for less invasive heart valve treatments

Advocate Aurora Health joined the TRILUMINATE Pivotal Trial, which evaluates the TriClip™ Tricuspid Valve Repair System’s ability to treat severe tricuspid regurgitation by repairing the tricuspid valve without open heart surgery.

In patients with tricuspid regurgitation, the tricuspid valve’s three leaflets fail to close completely during each contraction of the heart’s right ventricle, which results in blood leaking into the right atrium.

The minimally invasive TriClip™ device is delivered to the heart through the femoral vein in the leg and works by clipping together a portion of the tricuspid valve’s leaflets to reduce the backflow of blood. The study is sponsored by Abbott, the manufacturer of the device.

Interventional cardiologist Suhail Allaqaband, MD, is site principal investigator for Aurora St. Luke’s Medical Center in Milwaukee, the first site in Wisconsin to join the study. Cardiologist Mark Goodwin, MD, is site principal investigator for Advocate Medical Group-Naperville in Illinois.

New treatment for major vessel blockage proves more effective

Interventional cardiologist and endovascular specialist Jaafar Golzar, MD, recently published substudy findings from the IMPERIAL clinical trial that the Eluvia stent, a drug-releasing device implanted in patients with long blockages inside the leg’s main artery, was both safe and effective in restoring and maintaining blood flow for one year. Dr. Golzar is Advocate Christ Medical Center’s principal investigator for the study and primary author of the publication in the Journal of Endovascular Therapy.

Arterial blockages in the leg can lead to pain, difficulty walking and eventual loss of the limb. Treatment for recurring blockages is a device, called a stent, that remains inside the blocked blood vessel after insertion and opening. Previous stents were designed to release a blockage-preventing drug for 30 days, but Eluvia releases medication for an entire year.

“Often, longer blockages require surgery, but these results are better than outcomes after bypass surgery and will likely expand treatment options for our patients,” Dr. Golzar said.

The international IMPERIAL trial, sponsored by Boston Scientific Corporation, follows participants for five years.
Clinical research highlights

Treating complex aortic aneurysms

Aurora St. Luke’s Medical Center in Milwaukee has joined a clinical trial evaluating an investigational stent-graft design for treating patients with two types of difficult-to-treat aneurysms. An aneurysm refers to the area of a blood vessel wall that is weak, enlarged and at risk for rupture.

“A thoracoabdominal aortic aneurysm (TAAA) is an aneurysm that begins in the upper portion of the aorta and ends in the abdominal aorta,” said vascular and interventional radiologist Mark Mewissen, MD, site principal investigator for the study. “A pararenal abdominal aortic aneurysm (PAAA) is one in which the aorta is enlarged along the entire length of the aneurysm, including the origins of the renal arteries of the kidney.”

Physicians have successfully treated some types of aneurysms by employing endovascular techniques using catheters to insert stent-grafts—a fabric tube with a metal mesh frame designed to support a weak spot in the artery. Those techniques, however, become more complicated when treating TAAA and PAAA, which require placement of stent-grafts in off-label configurations in places where blood vessels branch out into smaller blood vessels.

In this clinical trial, sponsored by W. L. Gore & Associates, Inc., researchers will assess whether the investigational GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device) is safe and effective in treating study participants with TAAA and PAAA.

Researchers expand studies of heart failure treatment

Two Advocate Aurora Research Institute research teams joined the PARAGLIDE-HF clinical trial to evaluate sacubitril/valsartan in patients with heart failure with preserved ejection fraction (EF). The teams previously contributed to the PIONEER-HF study, which evaluated the drug’s safety and effectiveness in patients with a different type of heart failure—reduced EF.

EF refers to the percentage of blood the heart’s main chamber is able to pump out to the body. Reduced EF is caused by a weakened pumping action, which reduces the percentage pumped out. Conversely, in heart failure with preserved EF (HFpEF), a normal percentage is pumped out. But because the heart muscle is stiffer and often thicker, the amount of blood able to enter the chamber is smaller.

“In PIONEER-HF demonstrated that sacubitril/valsartan decreased death and rehospitalization rate compared to standard treatment for stabilized hospitalized patients with reduced EF who had been admitted for a sudden and serious worsening of their symptoms, called an acute decompensated event,” said Leslie Brookfield, MD, cardiologist and site principal investigator at Advocate Lutheran General Hospital, Park Ridge, Illinois. “We hope sacubitril/valsartan is also effective for patients with HFpEF stabilized following an acute decompensated event. PARAGLIDE-HF can provide this data.”

Ali Valika, MD, leads the study at Advocate Good Samaritan Hospital in Downers Grove, Illinois. PARAGLIDE-HF is sponsored by Novartis Pharmaceuticals, manufacturer of study drug.

Did you know?

Heart failure affects approximately 6.2M adults in the U.S., according to the Centers for Disease Control and Prevention.
NIH funds $745K subaward to reduce a major U.S. health disparity

Researchers collaborate on a project to improve blood pressure control among people of color

Advocate Aurora Research Institute received a $745,000 five-year subaward from the National Institute on Minority Health and Health Disparities through a research collaboration with Brigham and Women’s Hospital. The project, “Reducing ethnic and racial disparities by improving undertreatment, control, and engagement in blood pressure management with health information technology,” or REDUCE-BP, evaluates new approaches to help providers and patients overcome health barriers common to people of color.

“Our organization is engaged in many efforts to eliminate health disparities across the many diverse communities we serve,” said Alvia Siddiqi, MD, Advocate Aurora Health vice president of Population Health in Illinois, Health Equity Council member and coinvestigator of the study. “Reducing disparities for our patients living with hypertension has become one of our most pressing initiatives.”

Almost half of all adults living in the U.S. are diagnosed with hypertension, and more than 75% of them won’t achieve healthy blood pressure control, according to the U.S. Centers for Disease Control and Prevention.

“While uncontrolled hypertension continues to be a significant health issue in our country, its prevalence is even higher among people of color, resulting in substantially greater rates of stroke, cardiovascular conditions and kidney disease in Black, Latino, Hispanic and Asian American populations,” said Marlon Everett, MD, Advocate Aurora Health interventional cardiologist and REDUCE-BP site principal investigator.

Epidemiologist Rasha Khatib, PhD, MHS, study coinvestigator and interim director of patient-centered outcomes research at the Research Institute, has extensively researched barriers to hypertension control in people of color. Dr. Khatib developed a conceptual framework with practical actions for overcoming these barriers.

Researchers will evaluate the effectiveness of REDUCE-BP e-tools compared with routine care to reduce high blood pressure in adult patients with a history of uncontrolled hypertension cared for at designated Chicagoland Advocate Medical Group clinics. The e-tools will include dashboard tools focused on identifying patients with poorly controlled hypertension by race and ethnicity, linked with information on social determinants. Additional tools at the point of care, designed using behavioral principles, will assist primary care providers with prescribing decisions based on hypertension treatment guidelines as well as providing integrated self-monitoring tools.

REDUCE-BP is a collaboration between investigators from Advocate Aurora, Brigham and Women’s Hospital, Harvard Medical School, Dartmouth and the University of California, San Francisco.

Research reported in this publication is supported by the National Institute on Minority Health and Health Disparities of the National Institutes of Health (NIH) under award number R01MD014874.

Did you know?

Uncontrolled hypertension increases risk of stroke and heart attack, and nearly half a million Americans die every year from hypertension-related causes.

Reducing disparities for our patients living with hypertension has become one of our most pressing initiatives.

Alvia Siddiqi, MD
VP, Population Health IL
 Patients with AFib benefit from hybrid treatment

JPCRR study shows hybrid ablation yields greater treatment success rate for patients with the dangerous heart condition

Nearly 83% of patients with persistent, or recurring, atrial fibrillation remained free of atrial fibrillation 12 months after receiving the “hybrid” ablation procedure, according to a retrospective research study led by cardiac surgeon David Kress, MD, and electrophysiologist Jasbir Sra, MD.

Atrial fibrillation, the most common irregular heart rhythm, affects about 2.7 million people in the U.S., according to the American Heart Association. Those living with the condition are at five times greater risk for stroke and twice as likely to undergo a heart-related hospitalization or death.

In a hybrid ablation, a cardiac surgeon collaborates with an electrophysiologist to perform a surgical ablation followed by a transcatheter ablation.

“Patients with persistent or long-standing paroxysmal atrial fibrillation are a challenging population to treat with ablation, and our results are noteworthy, given the lower rates of success reported by prior studies,” Dr. Kress said. “I believe the hybrid ablation approach has become an established superior treatment option for many patients suffering from a complex and highly dangerous condition.”

The study was published in the July 2020 issue of Advocate Aurora Research Institute’s Journal of Patient-Centered Research and Reviews.

Funds raised for heart research and new grant program

2020 Advocate Health Care First Look for Charity reception contributed more than $110K for Advocate Heart Institute adult, pediatric research

Chicago Auto Show’s 2020 First Look for Charity Advocate Health Care reception raised more than $110,000 to support research at Advocate Heart Institute and Advocate Children’s Heart Institute, part of Advocate Aurora Health, on Feb. 7 at McCormick Place, Chicago.

Award recipients of the newly developed Advocate Cardiovascular Health Small Grants Program, made possible through generous First Look for Charity donations and supported by Advocate Aurora Research Institute, were announced at the event. The grants program focuses on research that increases cardiovascular knowledge, transforms care and improves health outcomes.

Cardiac electrophysiologist Peter Brady, MD, and interventional cardiologist Neal Sawlani, MD, became the award’s first recipients. Dr. Brady’s study, “Frailty and mortality in patients eligible for cardiac resynchronization therapy,” seeks to determine the prevalence of frailty in those with heart failure who are eligible for cardiac resynchronization therapy and also explore how frailty is linked to important patient outcomes.

Dr. Sawlani’s study, “Quality of life after percutaneous mitral valve repair with MitraClip,” aims to systematically quantify the device’s impact on various measures of health-related quality of life and heart failure-associated symptoms and functionality, which are assessed before and after the procedure.

Hosted by Chicago Automobile Trade Association, First Look for Charity raised more than $2.8 million for 18 local nonprofit organizations, including Advocate Health Care.
Oncology research

With 206 open clinical trials in 2020, oncology is Advocate Aurora Health’s largest clinical research program.

In this section, we share the story of a Vietnam War veteran who bravely faced a familiar diagnosis with the help of his grandson’s optimism. Additionally, we highlight our participation in oncology clinical trials that search for potential treatments for glioblastoma, leukemia, colorectal cancer, lung cancer, breast cancer and other cancers that have metastasized to the brain.

Finally, we share an update on Team Phoenix – our fitness, research and cancer survivorship program – and detail our involvement in the National Cancer Institute (NCI) Community Oncology Research Program (NCORP), which brings clinical cancer trials to people in their own communities instead of only at major research institutions.

Caynen Norberg has taken to sitting on the couch next to his grandfather, Ray Harrison, and holding his hand. Some days, Caynen tells Ray that they’ll both be OK and that their cancer treatments aren’t that bad, then he rubs Ray’s now bald head for good luck.

“They’re Iron Man buddies,” said Karen Harrison, Ray’s wife and Caynen’s grandmother. “Caynen’s doctor told him he put an Iron Man badge on his chest.”

“Not on my chest, it’s in my chest,” said Caynen, proudly lifting his shirt to show off a chemotherapy port located near the center of his chest. Its placement matches the location of the device in Iron Man’s chest that gives the superhero his power.

Ray looked admirably at his grandson then raised his shirt too, revealing his own chemotherapy port located on his chest, right on top of the eagle, globe and anchor of a Marine Corps emblem tattoo.

It has been an unfathomably challenging pandemic for the family. After Karen and Ray discovered a lump on Caynen’s skull in August of 2020, the 7-year-old was diagnosed with Langerhans cell histiocytosis, a rare cancer that, for Caynen, affects his bones. Then, in January of 2021, Ray went in for a routine checkup and doctors found limited-stage small-cell lung cancer (LS-SCLC).

“I’d obviously prefer it be just me,” said Ray of having to face a cancer diagnosis.

But that, and admitting the closing of his esophagus from the radiation therapy is mildly annoying, is about as close to a complaint as you’ll hear from Ray or Karen, who are caregivers for Caynen.

“We’re putting it in God’s hands,” Karen said. “We have a lot of support through family and friends, and Caynen’s school even volunteered to make meals for us.”

A retired journeyman millwright who worked primarily in the printing industry, Ray had settled into his pandemic life like many others.

Iron men

A lung cancer clinical trial and the strength of his grandson, Caynen, offer hope following an all-too-familiar diagnosis for Marine Corps veteran Ray Harrison

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A retired journeyman millwright who worked primarily in the printing industry, Ray had settled into his pandemic life like many others.
Upon his cancer diagnosis, Ray was quickly approached about participating in a clinical trial by Karen Globke, RN, research coordinator for Advocate Aurora Research Institute, and Laura McGartland, MD, his treating oncologist at Aurora St. Luke’s Medical Center.

“What I was told was that it could not only help me but other patients too,” he said. “I said, ‘OK, fine. Let’s do it. What do I have to lose?’”

Neither Ray nor his wife had any familiarity with clinical trials, but that didn’t matter one bit for Ray, even after he was informed that, in a randomized study, he might not receive the study drug.

“I’ve been helping people all my life,” he said. “That’s not going to stop now. If someone will eventually get a benefit from this, if I can help someone else, I won.”

The study, sponsored by the National Cancer Institute and led by NRG Oncology and The Alliance for Clinical Trials in Oncology, evaluates whether doctors can lower the chance of LS-SCLC growing or spreading by adding an immunotherapy drug called atezolizumab to the standard treatment of chemotherapy and radiation therapy.

“Although the standard treatment has been shown to substantially reduce tumor size for patients like Ray, relapse occurs early and often, limiting long-term survival of the disease to just 25% of patients,” said hematologist and oncologist Shamsuddin Virani, MD, the Research Institute’s principal investigator for the study. “We need to do better than that for these patients, which is why researchers are studying promising combination treatments, such as chemoradiation plus immunotherapies.”

Previous studies have already demonstrated the efficacy of other immunotherapy drugs in patients with widespread or relapsed SCLC, and researchers have found evidence that atezolizumab effectively shrinks tumors in patients with a different type of lung cancer.

Someday soon, Ray hopes he and Karen can get back to traveling, or even just “doing things together outside of our four walls.”

But, for now, he and Caynen are continuing their treatments, drawing off each other’s strength and optimism.

“Our immune systems are down but not out,” Ray said. “We’re going to beat this.”

He and Karen spent their days in their Milwaukee home, guiding their grandson through virtual school, careful to avoid exposing his compromised immune system as the pandemic raged through the fall and winter.

“We’re not taking that chance,” Ray said.

Before his own diagnosis, Ray had zero symptoms or any clue he had cancer. Still, the lung cancer diagnosis wasn’t entirely a surprise. Ray is a Marine Corps veteran who was exposed to Agent Orange during his 13 months and 15 days serving in Vietnam. In fact, at just 70 years old, Ray isn’t even the first person he knows whose Agent Orange exposure has led to cancer.

“I’ve had several friends who have already passed away from it,” he said.

Agent Orange was a tactical herbicide used during the Vietnam War to clear vegetation for military operations. Today the chemical is considered a known carcinogen, and the U.S. Department of Veteran Affairs (VA) recognizes that Agent Orange exposure during military service is the probable cause of certain types of cancers, including lung cancers.

Ray said his doctors are certain of the role Agent Orange played in his diagnosis and that the VA has provided him with full disability benefits.

If someone will eventually get a benefit from this, if I can help someone else, I won.

Ray Harrison
Research Participant
Clinical research highlights

Investigational therapy for rare but fatal cancer offers hope

Advocate Aurora Research Institute has joined a clinical trial of a personalized, investigational treatment for patients with glioblastoma (GBM), an aggressive form of brain cancer.

“Average survival time for patients with GBM is only 15 months, and less than one third live beyond two years, so finding a treatment that significantly lengthens survival with a good quality of life is critically important,” said Nina Paleologos, MD, Advocate Aurora Health director of neurology and neuro-oncology in Illinois and study principal investigator at Advocate Lutheran General Hospital, Park Ridge.

The investigational treatment utilizes both pembrolizumab and HSPPC-96. Pembrolizumab blocks a receptor on the cancer cell so it can no longer protect itself from the patient’s immune system. HSPPC-96 is used to make a personalized cancer vaccine through exposure to the patient’s own tumor tissue. The vaccine delivers the tumor’s unique proteins to the patient’s immune system to stimulate a response against the tumor. Researchers hypothesize that once GBM receptors are blocked by pembrolizumab, the patient’s immune cells will become stimulated to attack GBM proteins made detectable by the vaccine.

Trial eligibility depends on many factors, including a screening prior to surgical removal of the tumor. As soon as GBM is suspected, interested patients should be screened at a participating trial site.

The National Cancer Institute sponsors the trial, “Radiation therapy plus temozolomide and pembrolizumab with and without HSPPC-96 in newly diagnosed glioblastoma.”

Can vitamin D help fight cancer?

Community cancer clinics in Illinois and Wisconsin, as part of Advocate Aurora Health’s National Cancer Institute (NCI) Community Oncology Research Program (NCORP), joined a clinical trial studying how well vitamin D3, given with the standard chemotherapy and immunotherapy drug bevacizumab, works in treating participants with previously untreated metastatic colorectal cancer, or cancer that starts in the colon or rectum that has spread to other parts of the body.

Researchers are interested in vitamin D3 as a potential alternative cancer treatment because of its wide availability, prior research that shows sufficient vitamin D3 levels are connected to lower colorectal cancer rates, and the toxicity of traditional anticancer drugs.

Adam Siegel, MD, is Advocate Aurora Research Institute’s Wisconsin principal investigator for the study, known as SOLARIS. Edward James, MD, Mebea Aklilu, MD, Syed Ahmed, MD, and Sandeep Chunduri, MD, are principal investigators for Illinois study sites.

Searching for genetically guided brain tumor treatments

Advocate Aurora Health joined a precision medicine clinical trial studying how well genetic testing can drive treatment for patients with cancer that has spread to the brain.

Researchers have found several genes that become altered or mutated when cancer metastasizes to the brain from elsewhere in the body. This clinical trial compares the use of several novel medications that target tumors with these specific genetic mutations. By genetically sequencing a clinical trial participant’s brain tumor, researchers may be able to provide more targeted and effective treatment for lung cancer, breast cancer and other cancers that have metastasized to the brain.

The clinical trial, known as A071701, is taking place at all 17 of Advocate Aurora’s National Cancer Institute Community Oncology Research Program (NCORP) sites in Wisconsin. Advocate Aurora Research Institute’s principal investigator for the study is Michael Thompson, MD, PhD, co-director of Advocate Aurora’s Oncology Precision Medicine Program.
Clinical research highlights

Institute invited by NCI to study presurgical care model

Advocate Aurora Research Institute was specifically selected by the National Cancer Institute (NCI) to participate in a clinical trial evaluating how well the OPTI-Surg presurgical screening and care model, or toolkit, improves patient function eight weeks following a surgical operation in older patients with cancer.

The toolkit involves screening elderly cancer patients for various types of vulnerabilities — such as those in cognition, nutrition, functional independence and social support — and then providing targeted resources, including printed reading materials and possibly referrals to other care providers, such as social workers and dieticians. By screening for and supplying resources to address the vulnerabilities associated with frailty, clinicians can potentially enhance recovery from surgery, reduce length of stay and decrease hospital costs.

Aaron Chevinsky, MD, is site principal investigator for Aurora St. Luke’s Medical Center in Milwaukee. Marc Mesleh, MD, is site principal investigator for Advocate Christ Medical Center in Oak Lawn, Illinois.

Institute contributes to trial that led to FDA approval of new treatment for common leukemia

By enrolling 15 participants at eight different cancer clinics, Advocate Aurora Research Institute contributed to the large, national clinical trial that led to the U.S. Food and Drug Administration’s approval of a new standard of care for patients with a common type of leukemia.

The study, known as E1912, found that the anticancer drug ibrutinib, when taken in pill form along with rituximab, an antibody therapy drug, was superior to the current standard treatment, a combination of chemotherapy drugs plus rituximab, in participants age 70 and younger with previously untreated chronic lymphocytic leukemia, one of the most common types of leukemia in adults.

The phase 3 clinical trial showed that the combination of ibrutinib and rituximab not only provided better leukemia control, but also prolonged life and had fewer side effects than the previously used chemotherapy.

Rubina Qamar, MD, served as the Research Institute’s principal investigator for the trial.

Team Phoenix goes virtual

Heading into its 10th season in the spring of 2020, Team Phoenix, Advocate Aurora Research Institute’s fitness and research program that trains cancer survivors to complete a sprint-distance triathlon, was set to expand beyond its original Milwaukee location and open a new program in the Racine-Kenosha area of Wisconsin. Of course, the global pandemic ultimately forced the program to postpone the 2020 season.

“Team Phoenix is about finding ways to overcome barriers in order to fit exercise into their daily routine, so we pivoted, modifying the in-person training program so that it could be provided virtually,” said Leslie J. Waltie, DPT, Advocate Aurora Health cancer rehabilitation specialist and Team Phoenix cofounder.

Deferred 2020 athletes and the more than 300 Team Phoenix alumnae were offered the opportunity to join the virtual training program and benefit from guided training sessions, live online group sessions, health and nutritional education, and social support from other cancer survivors.

“The online technology gave us the opportunity to engage additional athletes, and its success has us considering new options for future expansion,” said Ilka Hoffins, Team Phoenix program director.
Advocate Aurora Research Institute’s neuroscience portfolio includes the Alzheimer’s disease research program at the Advocate Memory Center in Park Ridge, Illinois, and the neuro-stroke research program, as part of Advocate Aurora Health’s cerebrovascular program. Neuro-stroke and neuro-endovascular clinical trials are offered at Advocate Lutheran General Hospital in Park Ridge, Illinois, Advocate Christ Medical Center in Oak Lawn, Illinois, and Aurora St. Luke’s Medical Center in Milwaukee.

Read on to learn about our leading-edge clinical trials evaluating potential stroke treatments, studies aimed at improving Alzheimer’s disease prevention and treatment, and neuro-oncology research conducted at the Neuroanatomy Laboratory at Aurora St. Luke’s Medical Center and the Discovery Laboratory at Aurora Sinai Medical Center, both in Milwaukee.

Research is transforming stroke care

Expanding the neuro-stroke research program to improve recovery and quality of life

Advocate Aurora Research Institute has expanded its neuro-stroke research program, with a goal to transform stroke care and improve health outcomes for our patients, the communities we serve and beyond.

Strokes, also referred to as brain attacks, are a leading cause of death, according to the National Institutes of Health. Someone in the U.S. suffers a stroke every 40 seconds, and a stroke-related death occurs every four minutes.

Although strokes occur more often in the older population, they can strike at any age. And more than one-third of stroke hospitalizations involve people younger than 65.

Strokes result from a lack of blood flow to the brain. Without blood supply, brain cells die, leading to permanent injury, disability and death. The most common type, ischemic stroke, is caused by a blockage in one of the blood vessels that supplies blood to the brain.

Advocate Aurora Health neurosurgeon Demetrius Lopes, MD, director of the cerebrovascular program and surgical director of the stroke network, and neurointerventionalist Thomas Wolfe, MD, medical director of the stroke network, lead neuro-stroke research at the Research Institute.

Dr. Lopes, Dr. Wolfe and the neuro-stroke research teams are actively engaged in a number of cutting-edge research trials designed to advance treatments for stroke and other cerebrovascular conditions so that patients facing these serious conditions may experience better recovery and quality of life.

“Research over the past 10 years has advanced and defined new standards for stroke treatment, and today’s clinical trials are refining and extending the boundaries of care we can provide,” Dr. Lopes said.
PROST is one of the clinical trials led by Dr. Lopes. It compares two stroke treatment devices – called thrombectomy devices – designed to remove blood clots that have blocked blood flow to the brain. Learn more about the PROST trial on page 32.

Thrombectomy devices comprise a very thin tube that’s visible by X-ray, which is inserted and threaded through the chain of blood vessels in the brain. Once the clot is reached, a compressed metal net is released from inside the tube, expanded so it surrounds the clot, then retracted along with the clot back into the tube, thereby removing the blockage and restoring blood flow. The thrombectomy device, along with the clot, is then withdrawn from the patient’s body.

Another clinical trial available at Advocate Aurora aims to help improve the care for people with acute ischemic stroke, caused by a blockage in one of the major arteries of the brain. Dr. Wolfe leads the TESLA study, which focuses on patients who have a moderate-to-large amount of pretreatment brain tissue death from blood loss, as seen on initial CT imaging of the brain. TESLA compares treatment with the current standard medical therapy versus treatment using thrombectomy devices in combination with standard therapy. Learn more about the TESLA trial on page 32.

"Neuro-stroke trials may provide our patients with investigational treatment options through research that otherwise wouldn’t be available to them," Dr. Wolfe said.

**Additional monitoring for safety and effectiveness**

Dr. Lopes and Dr. Wolfe are also site principal investigators for the ASSIST registry. ASSIST is an international study to evaluate health outcomes, quality of life and procedural success following use of Stryker thrombectomy devices that have already been approved by the U.S. Food and Drug Administration to treat people with acute ischemic stroke following blockage in a large blood vessel.

Registries, like ASSIST, help to further ensure the safety and effectiveness of approved medical devices. Continued monitoring in a larger number of people provides greater certainty that all possible negative – and positive – effects have been identified.

The ASSIST registry is sponsored by Stryker Neurovascular.

**Time is of the essence**

The National Institute of Neurological Disorders and Stroke advises treatment within three hours of the first onset of stroke symptoms for the best chances of recovery with minimal or no permanent injury.

The Research Institute offers neuro-stroke research at all three of Advocate Aurora’s comprehensive stroke centers located at Advocate Lutheran General Hospital in Park Ridge, Illinois, Advocate Christ Medical Center in Oak Lawn, Illinois, and Aurora St. Luke’s Medical Center in Milwaukee – making clinical trials available to Advocate Aurora patients closer to home, when time is of the essence.

"The goal is to screen patients who experience symptoms, such as a change in neurological status, as soon as possible, because time is critical and intervention is key to prevent disability and death," Dr. Lopes said.

**“Research over the past 10 years has advanced and defined new standards for stroke treatment, and today’s trials are refining and expanding the boundaries of care we can provide.”**

Demetrius Lopes, MD
Neurosurgeon
Approximately 6M people in the U.S. are affected by Alzheimer’s disease.

The current cost of care is estimated at $300B.

By 2050, the cost is expected to exceed $1T.

Did you know?

U.S. POINTER trial
U.S. POINTER is a clinical trial evaluating if a lifestyle program of healthy nutrition, physical exercise, and mental and social activities reduces cognitive decline in older adults who are at risk for dementia.

“Results of a similar study conducted in Finland (FINGER trial) showed that a combination of healthy behaviors protected cognitive function in at-risk older adults,” Dr. Gitelman said. “No medication tested to date has produced comparable results.”

Dr. Gitelman’s team is conducting U.S. POINTER in collaboration with Rush University Medical Center. Trial sponsors include the Alzheimer’s Association and the National Institute on Aging, in collaboration with Wake Forest University Health Sciences.

Clarity AD trial
Clarity AD, “A study to confirm safety and efficacy of lecanemab in participants with early Alzheimer’s disease,” is evaluating the investigational drug’s effectiveness in reducing amyloid in the brain and slowing cognitive decline. The accumulation of brain amyloid is associated with Alzheimer’s disease.

Enrollment is closed, but eligible participants who complete the 18-month treatment period may continue to receive lecanemab treatments in an open-label extension phase of the study.

Clarity AD is sponsored by Eisai Inc.

EMBARK trial
EMBARK, “A study to evaluate safety and tolerability of aducanumab in participants with Alzheimer’s disease who had previously participated in aducanumab studies,” is a phase 3 trial that also targets brain amyloid. Previous studies have suggested that aducanumab may slow the rate of cognitive decline.

The EMBARK clinical trial is sponsored by Biogen.

DIAN-TU trial
DIAN-TU, “A study of potential disease-modifying treatments in individuals at risk for or with a type of early onset Alzheimer’s disease caused by a genetic mutation,” aims to evaluate investigational treatments for their safety and effectiveness in people who may have a dominant genetic risk for the disease.

Participants enrolled in DIAN-TU are currently followed for changes in cognition over time and will have the opportunity in the future to join treatment trials.

DIAN-TU is sponsored by Washington University School of Medicine and supported by the National Institute on Aging, Alzheimer’s Association, DIAN-TU Pharma Consortium, GHR Foundation, an anonymous organization, industry partners (Eli Lilly, & Co., Roche/Genentech, Janssen, Eisai, Avid Radiopharmaceuticals, Cereveau Technologies, Signant Health, Cogstate) and private donors.

Art Therapy trial
This study examines whether joint participation in art therapy by a patient and their care partner will improve the patient’s and care partner’s perceptions of their relationship, the diagnosed individual’s self-esteem, and the care partner’s attitude toward persons with Alzheimer’s disease.

The study is supported through an award from the James R. and Helen D. Russell Center for Research and Innovation Small Research Project Grants Program.

Pursuing new discoveries for Alzheimer’s disease prevention and treatments

Advocate Aurora Research Institute supports a comprehensive program of Alzheimer’s disease research that is studying approaches for both prevention and treatment.

Alzheimer’s disease, a progressive condition that destroys memory and cognitive abilities, remains one of the top 10 causes of death, according to the U.S. Centers for Disease Control and Prevention. While medicine has made great gains in reducing death rates from heart disease and cancer, mortality rates continue to climb for Alzheimer’s.

Advocate Aurora Health behavioral neurologist Darren Gitelman, MD, senior medical director of Advocate Memory Center, leads clinical trials aimed at improving health outcomes for people with either sporadic or genetic forms of Alzheimer’s disease.

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Darren Gitelman, MD

Did you know?

• Approximately 6M people in the U.S. are affected by Alzheimer’s disease.
• The current cost of care is estimated at $300B.
• By 2050, the cost is expected to exceed $1T.
Improving clinical decisions in stroke treatment

Aurora St. Luke’s Medical Center in Milwaukee was the first site in Wisconsin to join a clinical trial comparing intra-arterial treatment (IAT) using mechanical thrombectomy to standard medical management in patients with acute ischemic stroke.

Neurosurgeon Demetrius Lopes, MD, director of Advocate Aurora Health’s cerebrovascular program and surgical director of the stroke network, is a leading investigator in a first-of-its-kind clinical trial comparing two medical devices for the treatment of occlusive stroke, a condition in which a blood vessel blockage stops vital blood supply to the brain.

The clinical trial, known as PROST, compares the pRESET thrombectomy device with the Solitaire revascularization device as treatment to remove a blockage-causing thrombus, or blood clot, and restore blood flow to the brain. Lack of blood flow results in brain tissue death, which can lead to significant disability and loss of life.

“During the last 5 to 10 years, care for people with occlusive stroke has advanced incredibly due to smaller and better devices,” said Dr. Lopes, who serves as the site principal investigator at Advocate Lutheran General Hospital and Advocate Christ Medical Center. “Research and technology have brought us to a point where we now have more than one approved device to compare side by side and determine if one produces better health outcomes for our patients.”

Nearly 800,000 people in the U.S. suffer from a stroke each year and almost 90% are caused by blood vessel blockages, according to the U.S. Centers for Disease Control and Prevention.

The PROST clinical trial is sponsored by phenox, manufacturer of the pRESET thrombectomy device.
Pediatric research

Under the leadership of Advocate Aurora Research Institute, researchers at the Advocate Center for Pediatric Research in Illinois and investigators in Wisconsin are making enormous strides in pediatric research.

In the pages ahead, we share some of our 2020 research highlights, including the story of a brave 10-year-old who eagerly joined a second study for childhood cancer survivors. We also detail our participation in pediatric clinical trials studying teen depression, an artificial heart valve for children, cystic fibrosis, infectious diseases and antibiotic stewardship. Finally, read about our preclinical researchers’ participation in a venture creation program for their first-of-its-kind rare disease screening tool for newborns.

Knowledge through research is power

A cancer survivor participates in a second clinical trial to help children like himself

Ten-year-old Jack Higgins beat cancer.

But the cancer treatment that saved his life often poses additional health challenges later in life. So Jack joined a second clinical trial aimed at helping child survivors like himself lead healthier lives.

Cancer treatment side effects that persist or arise months or sometimes years afterward are known as late effects. About 60% of childhood cancer survivors experience late effects, according to the Children’s Oncology Group (COG), which is the world’s largest research organization devoted to childhood and adolescent cancer research with more than 200 hospitals and institutions participating in its trials.

The late effects clinical trial Jack joined is evaluating how well an online, interactive, rewards-based program engages young survivors, aged 8 to 15 years, in physical activities and improves long-term health.

“Exercise positively impacts our physical and overall health, and that’s what this research study is all about,” said Rebecca McFall, MD, pediatric oncologist and principal investigator for the trial at Advocate Children’s Hospital in Illinois. “Although cancer treatments are administered as safely as possible, they can have serious side effects for the growing child, such as a loss of bone and muscle mass and altered coordination and strength. To help childhood cancer survivors return to baseline, we need to optimize other health factors.”

I think I went extra hard on myself because I know it was going for a good cause.

Jack Higgins
Research Participant
Pediatric research is critical to ensuring children have access to new medications, medical devices and therapies that are effective and safe for their developing bodies. And pediatric studies also ensure that childhood conditions are included in scientific discovery. Advocate Aurora researchers engage in clinical trials, outcomes studies and other research activities designed specifically for infants, children and adolescents.

We partner with the Institute for Advanced Clinical Trials for Children, known as I-ACT for Children, and the Pediatric Trials Network – two organizations committed to generating evidence for therapies and drug dosages that take into account every stage of childhood and the body’s unique physical needs during each new phase of growth and maturation.

Through our research activities and partnerships, we help to ensure that research findings will translate into appropriate product labeling and treatment guidelines that improve health outcomes for our youngest patients.
Clinical research highlights

Research transforms cystic fibrosis treatments

The Advocate Center for Pediatric Research has a long-standing program focused on advancing treatments for children and adults with cystic fibrosis, a genetic disease that can lead to organ failure and premature death.

“Research has made possible the discovery of new and better treatments that have increased survival and improved the health of our patients,” said Kimberly Watts, MD, a leading cystic fibrosis researcher at Advocate Children’s Hospital – Park Ridge in Illinois.

A new generation of treatments, called cystic fibrosis transmembrane conductance regulator (CFTR) modulators, are designed to correct for unique genetic mutations. One of the latest CFTR modulators, VX-445, is a triple combination therapy made from three modulators. VX-445 received approval from the U.S. Food and Drug Administration for use in people 12 years and older who have a specific type of mutation.

Arvey Stone, MD, director of the Advocate Adult Cystic Fibrosis Center, is leading a post-approval study evaluating VX-445’s long-term safety. Previous research demonstrated that VX-445 amplifies the benefits received from single and double-combination modulators.

The study is sponsored by Vertex Pharmaceuticals Incorporated, manufacturer of the therapy.

Improving treatment of congenital heart defects

Advocate Children’s Hospital researchers participated in the COMPASSION XT post-approval clinical trial of an artificial heart valve, SAPIEN XT, which was approved for use in children with congenital heart defects by the U.S. Food and Drug Administration in 2016. Clinicians evaluated the valve’s performance in a minimally invasive, catheter-based procedure by inserting the valve into the heart to control blood flow between a chamber of the heart and the pulmonary artery. Participants in the COMPASSION XT trial will be followed in the trial through 2025.

Post-approval trials, which further ensure safety and effectiveness in a larger group of people, are especially important with rare conditions like congenital heart defects. The COMPASSION XT study served as a precursor to the COMPASSION S3 trial, which received approval for the latest generation SAPIEN 3 valve in 2020.

While the SAPIEN XT valve is not currently available for this indication, SAPIEN 3 is commonly used to replace a valve or prosthesis that was previously implanted during surgical repair of a serious congenital heart defect. Instead of requiring complex and potentially risky open heart surgery, clinicians implant the SAPIEN 3 valve during the minimally invasive procedure, described above, through a small incision in the thigh to access a vein for valve implantation.

“Artificial valves wear out over time and require replacement, which could lead to multiple open heart surgeries over a patient’s lifetime,” said Alexander Javois, MD, pediatric interventional cardiologist and Advocate Aurora Research Institute’s principal investigator of the study.

Pediatric cardiologist Dhaval Patel, MD, serves as coinvestigator of the COMPASSION XT post-approval study. The study is sponsored by Edwards Lifesciences.

Combating teen depression during a pandemic

Mental health experts have raised concerns that teen depression rates may be climbing during the COVID-19 pandemic due to increased social isolation, stress, uncertainty and grief.

To help prevent teen depression, Advocate Aurora Health researchers are enrolling participants in the Path 2 Purpose clinical trial, which compares the effectiveness of two online interventions in teaching strategies for coping with negative thoughts, managing conflicts and planning for significant life changes. Participants are enrolled in either CATCH-IT (Competent Adulthood Transition with Cognitive-behavioral and Interpersonal Training), a series of self-directed computer-based modules, or TEAM5 (Teens Achieving Mastery over Stress), a more traditional online group therapy prevention model.

The study is open at four Advocate Children’s Hospital primary care pediatric clinics. Cathy Joyce, MD, PhD, adolescent medicine specialist, serves as study principal investigator. Coinvestigators include Cheryl Lefaiver, PhD, RN, and program manager Ashley McHugh, LCSW.

The research is a collaboration between UI Health, part of the University of Illinois at Chicago; Katherine Shaw Bethea Hospital, Dixon, Illinois; University of Louisville, Kentucky; and Advocate Aurora. The study is funded through a $7 million Patient-Centered Outcomes Research Institute (PCORI) grant.

Research reported in this article was funded through a PCORI Award (IHS-2017C3-9333). The statements in this article are solely the responsibility of the publishers and do not necessarily represent the views of PCORI, its Board of Governors or Methodology Committee.

Did you know? Depression affects 13% of U.S. adolescents, yet only 40% of that group receive treatment.
Casting a wider net for rare diseases in infants

Research Institute team engages with startup accelerator on first-of-its-kind rare disease infant screen

On average, it takes seven years for people with rare diseases to receive the correct diagnosis, and the lack of early detection can dramatically limit treatment options. To help rectify this, Advocate Aurora Research Institute scientists, clinicians and the commercialization team engaged with venture creation specialists at gALPHA Milwaukee about INFAGENE™, a first-of-its-kind rare disease infant screen they are developing to enable detection soon after birth.

Sheldon Garrison, PhD, research scientist and project lead, Angela Navarrete-Opazo, MD, PhD, senior research associate, and Shivam Bharti, research business innovation manager, engaged gener8tor, one of the top startup accelerators in the U.S., and completed its four-week gALPHA Milwaukee entrepreneurial program to facilitate product development and speed up availability.

Currently, all babies receive a newborn screening test within the first few days of life, but state screening varies widely. For example, Illinois currently screens for 65 conditions and Wisconsin monitors for 48 – yet there are an estimated 7,000 rare conditions. INFAGENE is intended to screen infants for hundreds of medically actionable rare diseases that are life-threatening or life-shortening, so treatments can begin as early as possible.

The team has benefited from Advocate Aurora Health clinical advisors Jennifer Thomas, MD, Jillene Kogan, MD, PhD, and Laura MacFarlane, certified genetic counselor.

Improving newborn antibiotic practices

Journal publishes study of safer antibiotic strategies for NICU

Although antibiotics can be lifesaving, unnecessary usage risks harmful side effects and increases in antibiotic-resistant bacteria that can cause life-threatening infections.

Advocate Children’s Hospital neonatologists Preetha Prazad, MD, and Jeffrey George, DO, published a study in the Journal of Neonatal-Perinatal Medicine that reduced unnecessary antibiotic use in the neonatal intensive care unit (NICU).

Care for newly admitted infants often included routine antibiotics to prevent a serious bacterial infection known as early onset sepsis, or EOS. However, a 10-year decline in NICU EOS cases led Dr. Prazad, Dr. George and Vrinda Arora, MD, to study this practice.

They assembled a team of physicians, nurses and pharmacists who reviewed the scientific evidence and decided on two strategies: 1) new guidelines to reduce the amount and duration of preventive antibiotics, and 2) use of a validated tool that determines an infant’s EOS risk.

A comparison of the data before and after antibiotic stewardship strategies were implemented showed a nearly 30% decline in the antibiotic usage rate for EOS prevention – and EOS infections continued to be correctly identified and safely treated using the new guidelines and tool.

Dr. Arora, primary author, completed the project and manuscript during her Advocate Children’s Hospital neonatal-perinatal medicine fellowship.

Searching for better diagnostic testing

The James R. and Helen D. Russell Center for Research and Innovation Small Research Grants Program awarded funding to Ronda Oram, MD, Advocate Children’s Hospital pediatric infectious disease specialist, for her study, “Clostridium difficile in pediatric oncologic patients: Defining predictive markers for clinical infection.”

Clostridium difficile, or C. diff, bacteria can cause potentially severe and fatal infections for at-risk patients, such as children with cancer. Currently available laboratory tests cannot differentiate between active infections (requiring treatment) and common C. diff presence (no treatment).

The collaborative project, with University of Chicago Medicine Comer Children’s Hospital as part of the Chicagoland Children’s Health Alliance, is the first study to perform C. diff whole genome sequencing from stool, assess antibody response and evaluate testing that accurately identifies C. diff infections.
Specialty research

Our specialty research encompasses behavioral health, endocrinology, gastroenterology, geriatrics, mental health, population health, primary care, women’s health and more.

This section details a care-changing publication on colon cancer testing from two of our gastroenterology researchers; grants from the Robert Wood Johnson Foundation for research aimed at reducing barriers to prenatal care and from the John D. and Catherine T. MacArthur Foundation for implementation of a research-based care model for formerly incarcerated patients; and patient-centered outcomes research into opioid use disorder treatment and the prevalence of co-occurring conditions affecting adults with Down syndrome. Additionally, learn about the recent work of the researchers in our Endocrine Research Laboratory at Aurora St. Luke’s Medical Center in Milwaukee.

Study questions effectiveness of widely used colon cancer screening method

Advocate Aurora Health investigators find 40% of patients with a positive multitarget stool DNA test for colon cancer had no precancerous lesions at colonoscopy

A commonly used at-home colon cancer screening method yields a high rate of positive results in patients who do not have cancer or precancerous lesions, according to a team of Advocate Aurora Health researchers that published a study in the journal Gastrointestinal Endoscopy.

Multitarget stool DNA (MT-sDNA) tests allow patients to take an at-home stool sample and send it to a lab for an analysis that detects colon cancer and precancerous lesions, called advanced adenomas. Patients with a positive test result must undergo colonoscopy to diagnose cancer or remove precancerous lesions to prevent cancer.

For the retrospective study, the researchers found that 75% of patients with a positive MT-sDNA test result did not have an advanced adenoma or cancer upon colonoscopy, and 40% of the patients with a positive MT-sDNA test had no adenomas of any size.

“Our study originated from observations in treating Advocate Aurora patients,” said Nimish Vakil, MD, gastroenterologist and lead author of the study. “Over the last few years, we have had patients referred to us for colonoscopy after a positive stool DNA test obtained for colon cancer screening. We were struck by the number of colonoscopies that showed no colon cancer or only a small adenoma in patients with a positive stool test.”

In the study, “Multitarget stool DNA testing for the prevention of colon cancer: Outcomes in a large integrated healthcare system,” the researchers also found that 27% of patients with a positive MT-sDNA test result failed to undergo colonoscopy, the required next step in this screening strategy.
“Ours is an effectiveness study, performed under routine clinical conditions, as opposed to a randomized, controlled efficacy study,” Dr. Vakil said. “Although randomized, controlled clinical trials are important, life outside of such conditions is messy and tends to reveal the true value or limitations of a given therapy or test.”

For the full story, visit bit.ly/3jXBGiV.

…”over one quarter of patients did not complete follow-up colonoscopy after the positive MT-sDNA test result.”

Kristin Ciezki, PhD
Lead investigator and coauthor

Advocate Aurora Research Institute epidemiologist Veronica Fitzpatrick, DrPH, MPH, manager of patient-centered outcomes research (PCOR), received a grant award of $399,995 from the Robert Wood Johnson Foundation (RWJF) to conduct her research titled, “Cost conversations in routine prenatal care,” or CONTINUE, for short.

The CONTINUE study builds on Dr. Fitzpatrick’s previous research, also funded by RWJF, that led to the development of a tool to help obstetric health care providers initiate and facilitate cost-of-care conversations with pregnant woman of low-income status, a population more likely to lack adequate prenatal care.

“Findings from our phase 1 study suggested women in low-income populations have reduced prenatal care adherence rates because of their inability to anticipate and plan for incidental costs, such as time off work, childcare, parking and transportation,” Dr. Fitzpatrick said. “Participants reported significant stress about their financial circumstances and reported these costs as common barriers to following their doctor’s orders.”

Prenatal care that’s initiated early on and continues throughout the pregnancy is an important factor in improving maternal and infant health outcomes, according to the U.S. Centers for Disease Control and Prevention. Delayed or non-existent care and education during pregnancy brings a risk of undetected complications that may lead to serious maternal health conditions and even death.

In 2014, based on the published results of a clinical trial, the U.S. Food and Drug Administration approved MT-sDNA tests as a colon cancer screening option. Few large studies have evaluated the performance of MT-sDNA tests in routine clinical practice.

“It is alarming that over one quarter of patients did not complete follow-up colonoscopy after the positive MT-sDNA test result,” said Kristin Ciezki, PhD, a lead investigator and coauthor of the study from Advocate Aurora Research Institute. “Colon cancer screening is done to detect cancer at the earliest possible stage when treatments are most effective and to prevent cancer by removing precancerous lesions during colonoscopy. If patients with a positive MT-sDNA result do not have colonoscopy, they are at increased risk of having undiagnosed, untreated cancer. If they have a precancerous lesion, it can be removed during colonoscopy and cancer will never develop. Without the crucial follow-up step of colonoscopy, there is no diagnosis and no cancer prevention.”

In 2014, based on the published results of a clinical trial, the U.S. Food and Drug Administration approved MT-sDNA tests as a colon cancer screening option. Few large studies have evaluated the performance of MT-sDNA tests in routine clinical practice.
An app to support opioid recovery
Howe Center investigators launch pilot study of first-of-its-kind mobile application for performance-based opioid use disorder treatment

In partnership with the University of Chicago and University of California – Berkeley, Advocate Aurora Research Institute scientists launched a new pilot study believed to be the first randomized evaluation of a mobile application for performance-based opioid use disorder treatment.

"Providing reinforcers for abstinence from drugs has consistently been shown to reduce drug use and increase treatment duration,” said Mindy Waite, PhD, research scientist for Advocate Aurora Behavioral Health Services within the Research Institute’s Ed Howe Center for Health Care Transformation and the study’s principal investigator. “The biggest obstacle has always been logistics – how can clinics most efficiently manage tracking and delivery of these reinforcers, train staff, and measure behavior?”

The app, developed by DynamiCare Health, addresses this issue by providing a ready-to-use solution that patients can easily access on their mobile devices. Through the app, participants can submit videos of themselves taking their opioid-related medication or at-home saliva drug tests, which are then verified as negative or positive by remote staff. The app also measures attendance at substance use treatment sessions. After a behavior is verified, the app will automatically deliver reinforcers to patients via a smart debit card that supports recovery.

"The delay between monitoring of the target behavior and the delivery of reinforcers has been shown in prior studies to significantly detract from the treatment effect,” Dr. Waite said. “Our technology allows patients to receive reinforcers almost immediately after performing the desired behavior – a first in this type of opioid use treatment.”

The study monitors 30 participants as they navigate the different components of the study app.

"Substance use disorder research is a priority area within the Howe Center, and this study highlights our commitment by testing new treatment applications for opioid use disorder,” said Michelle Simpson, PhD, RN, director of the Howe Center.

The study is designed to evaluate the effects of the reinforcers as well as the effects of the monitoring process itself on substance abuse.

Additionally, Dr. Waite and her team will compare two versions of the program to evaluate whether it is more effective to directly reinforce the desired outcome – drug abstinence – or to reinforce behaviors that are meant to lead to drug abstinence. In one version, participants will only receive reinforcers for opioid-negative saliva tests; in a second version, participants will only receive reinforcers for taking medications and attending substance use treatment appointments; in a third version, participants will receive reinforcers for performing all of those behaviors.

Finally, by randomly varying the size and timing of the reinforcers offered to participants, the researchers seek to determine, with additional studies, how to best structure a behavioral reinforcement program for maximum effectiveness over time.

The study is funded through a grant from the Abdul Latif Jameel Poverty Action Lab (J-PAL). Co-principal investigators for the study include Rebecca Dizon-Ross, PhD, of the University of Chicago, and Ariel Zucker, PhD, of the University of California – Berkeley.
With medical advances helping adults with Down syndrome to live longer, knowledge of commonly co-occurring conditions is critical to a healthy life.

Researchers from Advocate Aurora Research Institute and the University of Chicago are conducting research to help fill a current gap in medical knowledge about the chronic conditions and progressive diseases commonly affecting adults with Down syndrome.

People with Down syndrome develop health conditions differently than those without Down syndrome. For example, people with Down syndrome are at a greater risk for developing hypothyroidism, type 1 diabetes and Alzheimer’s disease but at a lower risk for atherosclerotic disease, hypertension and many solid tumors. Therefore, standard disease prevention and screening practices may need to be altered. Unfortunately, data is limited on the prevalence of many conditions that co-occur more commonly in people with Down syndrome.

The research project, one of the largest in the U.S. to date, utilized 28 years of electronic health record data. Researchers used standardized diagnosis codes to determine the presence or absence of Down syndrome and more than 40 conditions of interest within the categories of cancer, heart disease, mental health, infections, neurology, endocrine, gastrointestinal, orthopedic and miscellaneous.

Analyses of the data revealed that prevalence of almost all of the conditions studied differed significantly between people with and without Down syndrome.

The researchers are preparing an in-depth, four-article series for submission to the Journal of Patient-Centered Research and Reviews that details their findings and analyses.

Prevalence of almost all of the conditions studied differed significantly between people with and without Down syndrome.

Endocrine Research Laboratory

Researchers at the Endocrine Research Laboratory at Aurora St. Luke’s Medical Center, Milwaukee, were involved in many basic, translational and clinical research projects in 2020. Ashley Gehrand, senior research technologist, Jonathan Phillips, senior research technologist, and endocrinologist Hershel Raff, PhD, coauthored three publications that showcase some of their work:

- “Cortisol, adrenal, and the pituitary-gonadal axis in neonatal rats: Effect of maternal separation and hypoxia,” published in Endocrinology;
- “Serum soluble urokinase plasminogen activator receptor (suPAR) in adolescents: Interaction of chronic pain and obesity,” published in PAIN Reports; and
- “Prospective evaluation of late-night salivary cortisol and cortisone by EIA and LC-MS/MS in suspected Cushing’s syndrome,” published in the Journal of the Endocrine Society.

This work was funded in part by a National Institutes of Health award (#3UL1TR002389-03S1).
Milwaukee County, by way of the Milwaukee Community Justice Council, presented a John D. and Catherine T. MacArthur Foundation Safety and Justice Challenge (SJC) subaward totaling $50,000 to Advocate Aurora Health for an initiative led by Sarah Reimer, MD, a clinician investigator for Advocate Aurora Research Institute and the Center for Urban Population Health, and by Jacob Bidwell, MD, vice president of medical education and associate dean for the Advocate Aurora Health/Eastern Academic Campus of the University of Wisconsin School of Medicine and Public Health.

Dr. Reimer’s recent research, conducted in a population of Milwaukee County residents who have been incarcerated, demonstrated the underlying need for a culturally competent care model by revealing that Advocate Aurora cares for 80,000 recently justice-involved individuals in Milwaukee County. The subaward will allow Advocate Aurora to implement such a care model by hiring six community health workers in two phases and launching the “Transitions Clinic model” within three Milwaukee community health clinics: Aurora Sinai Family Care Center and the Progressive Community Health Centers on West Lisbon Avenue and West Kilbourn Avenue.

“Mass incarceration in the United States has caused incarceration to become an unfortunate expected life stage in some communities,” Dr. Reimer said.

Wisconsin incarcerates black males at nearly twice the national average, and Milwaukee has the one of the most heavily incarcerated ZIP codes in the entire country, according to national statistics.

“We know the difference that can be made by investing in programs that address the underlying conditions that put too many Wisconsin residents in a no-win situation once they enter the system – or put them at a disadvantage even before they’ve committed an offense at all,” Milwaukee County Executive David Crowley said. “The funds available to help reverse outcomes for Milwaukee County residents are the kinds of investments needed to reverse this trend.”

Pending available funding, Dr. Reimer’s research team would like to study the impact of justice involvement on certain diseases that are more common in justice-involved populations.

To read the full story, visit bit.ly/2TR6V8t.

Dr. Reimer was also selected to participate in a prestigious national data-sharing mentoring program called Data Across Sectors for Health. She received coaching and technical training in integrating the data necessary to determine eligibility for the local Transitions Clinic program and to measure cross-sector impacts during the first year of its implementation.

Did you know?

... the Transitions Clinic model decreases probation and parole violations and results in 25 fewer days in jail on average for patients.

Sarah Reimer, MD
Clinician Investigator
Together, we’re
advancing care through research

Philanthropic support of research at Advocate Aurora Health allows us to participate and conduct important and novel research that ultimately contributes to better patient care, enhanced safety and improved health outcomes.

Every dollar you donate goes toward research that will benefit people in our communities and beyond. Whether exploring new technologies in the lab or advancing best practices at the bedside, your gift will be dedicated to medical discovery and innovation.

If you wish to donate to research, please contact Advocate Charitable Foundation or Aurora Health Care Foundation at 877-460-8730 or donate online to Advocate Aurora Research Institute at advocategiving.org/aahresearch.

Our annual report would not be complete without recognizing the generosity of our benefactors.

Many research opportunities made possible through philanthropic contributions have resulted in improved health and quality of life, reduced hospitalizations, and decreased health care costs.

This past year alone, charitable gifts significantly contributed to grant programs for innovative patient-centered outcomes research and sponsorship of on-site programs and resources that support our clinician-investigators and help provide the key personnel and infrastructure necessary to conduct research at the bedside, across our communities and in the laboratory.

We are grateful for the partnership of our many generous donors. Together, we’re advancing care through research.
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