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The information presented in this annual report is intended for general information and educational purposes. It is not intended to replace the advice of your own physician. Contact your physician if you believe you have a health problem.

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.

On the cover:

(right) Michela Primavera, clinical research coordinator, walks with a young patient at Advocate Children’s Hospital in Park Ridge, Illinois; (left) Christian Donahoe, senior research coordinator, transports a research participant at Aurora St. Luke’s Medical Center in Milwaukee, Wisconsin.
At Advocate Aurora Research Institute, our research is transforming patient care, our achievements are garnering national attention, and our collective efforts are strengthening Advocate Aurora Health and the communities we serve.

As we continue the work of integrating our two research institutes – Advocate Research Institute and Aurora Research Institute – we look back on the advancements we achieved in 2019 with pride and a renewed commitment to our shared mission of helping people live well through innovative research.

Employing more than 280 team members, the research institute provides infrastructure and oversight for research that spans numerous clinical focus areas and sites of care across Illinois and Wisconsin. In 2019, our team members supported more than 1,200 unique clinical trials, outcomes research projects and preclinical studies throughout Advocate Aurora.

With our research activities embedded within the greater Advocate Aurora system, we are uniquely positioned to use our size and diverse population to attract cutting-edge clinical trials of novel drugs and devices for our patients, improve our care practices through outcomes research, and use preclinical research to identify potential targets or risk factors that can inform future therapies. We are actively engaged in many partnerships with industry and academia to translate findings from the bench to the bedside and to the many communities we serve.

Our research participants are our inspiration. Often for no personal benefit, they willingly participate in research studies, offering hope to future patients in need of new treatments and creating the valuable evidence needed to transform and improve care.

This annual report aims to share some of those participants’ stories, as well as highlights of the research breakthroughs and innovative studies conducted by our research teams across the organization.

On behalf of Advocate Aurora’s entire research team and our board of directors, thank you for reading.

Sincerely,

Denise Angst, PhD, RN
Vice President, Patient-Centered Research

Nina Garlie, PhD
Interim Vice President, Patient-Centered Research

Kurt Waldhuetter
Vice President, Research Development & Business Services
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.

Chair:
Dennis Potts
Executive Vice President, Operations WI Region

Members:
Jeffrey Bahr, MD
Chief Aurora Medical Group Officer

Vincent Bufalino, MD
Chief Advocate Medical Group Officer

Rachelle (Shelly) Hart
Senior Vice President, General Counsel

Michael Lappin
Chief Administrative Officer

Nan Nelson
Senior Vice President, Finance Operations

Ajay Sahajpal, MD
Medical Director, Abdominal Transplant Program

Research Institute Overview

Types of research
• Clinical research (patient-centered clinical trials and outcomes research)
• Preclinical research (basic and laboratory research)
• Other research activities (registry, quality improvement and more)

Clinical focus areas
• Cardiovascular
• Oncology
• Neuroscience
• Pediatrics
• Other specialties

Research centers, programs and laboratories
• Advocate Center for Pediatric Research
• Aurora Neuroscience Innovation Institute
• Aurora UW Medical Group Research Core
• 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 Loeber Memorial Cancer Research Laboratory
• National Cancer Institute Community Oncology Research Program (NCORP)
• Neuroanatomy Laboratory
• Translational Oncology Research: Quest for Understanding & Exploration (TORQUE)

Infrastructure
• Council for Quality Assurance and Improvement in Research*
• Research Analytics
• Research Communications and Publications
• Research Development and Business Services
• Research Education
• Research Innovation
• Sponsored Programs Office

Health system partnerships
• Advocate Charitable Foundation and Aurora Health Care Foundation
• Compliance
• Finance
• Health Informatics and Technology
• Human Resources
• Legal
• Pharmacy
• Public Affairs and Marketing
• Research Subject Protection Program (RSPP)**

Did you know?

Journal of Patient-Centered Research and Reviews is a peer-reviewed medical journal produced by the Research Institute. See Page 6 for more information.

* 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 RSPP and Research Compliance.

** 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.
Welcome and overview

Biorepository and Specimen Resource Center

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 (EHR), 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 surgery and pathology teams.

BSRC has developed institutional review board (IRB)-approved protocols that allow for efficient and compliant collection of biospecimens.

Leona Loeber Memorial Cancer Research Laboratory

A core research facility for Advocate Aurora Health researchers, the Leona Loeber Memorial Cancer Research Laboratory provides an array of services to support IRB-approved protocols, including histology, processing of fresh human tissue, paraffin/frozen block tissue sectioning, and assistance with specimen preparation, processing and shipping.

In addition, Loeber Laboratory supports collaborations with multiple academic and industry partners, serving as a beta site for evaluation of new lab instruments and providing tissue microarray creation, a technology that 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.

Powered by ORBIT and Research Analytics

BSRC utilizes a robotic system tied to the EHR called ORBIT, or Open-access Robotic Biorepository and Informatics Technology, to identify and obtain eligible biospecimens for specific research studies. ORBIT is managed and supported by Advocate Aurora Research Institute’s in-house Research Analytics team, which also analyzes research studies for feasibility and identifies and assembles data from numerous sources.
James R. and Helen D. Russell Center for Research and Innovation

An endowment to support research at Advocate Lutheran General Hospital, created by an estate gift from the late James and Helen Russell, made it possible to establish the James R. and Helen D. Russell Center for Research and Innovation in 2012.

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 clinical trials and comprehensive resources for investigator-initiated, patient-centered outcomes research that ranges from study design and statistical support through medical writing.

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

• 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 students with Illinois-based Advocate Aurora investigators, providing researchers with extra help and affording students an invaluable research experience.

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 improve patient outcomes by transforming health care delivery. Upon retiring, he established the Howe Fund for Innovation through Aurora Health Care Foundation with the help of donors, family, friends and colleagues.

Since the Howe center’s launch, Director Michelle Simpson, PhD, RN, and her team have 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 2019, the Howe center also launched the Ed Howe Center for Health Care Transformation Seed Grant Program and hired additional research staff, including its first visiting scholar and behavioral health research scientist. Team members collaborated on research projects with several local and national health care providers, such as Ovation Jewish Home Care Center and Spire Health. The Howe center’s 2019 research was supported in part by Hearst Foundation and Bader Philanthropies Inc.
Welcome and overview

Research Institute completes Wisconsin OnCore clinical trial management system implementation, begins work in Illinois

As 2019 came to a close, Advocate Aurora Research Institute was wrapping up implementation of its new OnCore clinical trials management system (CTMS) in Wisconsin and accelerating implementation in Illinois, with a July 2020 completion goal.

The Research Institute in 2018 signed a five-year, $1.8 million contract with Forte Research Systems to transition to OnCore.

At the end of 2019, nearly 300 protocols and more than 3,200 subjects had been migrated into OnCore.

The benefits:
• Clinical research coordinators have already seen a reduction of duplicative data entry using subject and protocol interfaces with Epic, the electronic health record system used at Advocate Aurora.
• 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 clinical trials.
• Through system automation and streamlined workflows, there is increased communication between study teams and Research Business Services.
• Utilization of the financials console has led to transparent and reliable revenue recognition and financial planning.

“A successful implementation of OnCore would not have been possible without the tireless efforts of the core team, a multidisciplinary group of staff experts from across clinical trial service lines and business services,” said Manager of Research Analytics Andy Marek, who is overseeing the OnCore transition.

Scholarly journal earns place in prestigious National Institutes of Health search index

Journal of Patient-Centered Research and Reviews (JPCRR) has been accepted into PubMed Central, one of the U.S. National Library of Medicine’s premier indexes of biomedical and health research literature. JPCRR articles from 2017 to the present are now available on PubMed.gov, which provides users access to the PubMed Central index.

“Acceptance to PubMed Central validates our journal as a rigorous, editorially diverse and critically impactful scientific publication,” said Editor-in-Chief Dennis Baumgardner, MD.

Published since 2014 by Aurora Health Care, now part of Advocate Aurora Health, JPCRR is a peer-reviewed medical journal focused on disseminating scholarly works that lead to improvements in patient outcomes and care delivery.

Accessed by readers in 192 countries to date, JPCRR has published articles by authors from across the United States, as well as from Canada, Europe, Africa and Asia. The journal’s editorial board includes a broad range of clinical specialists representing many renowned health providers throughout the United States and the United Kingdom.

Technological infrastructure

Journal of Patient-Centered Research and Reviews

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JPCRR article downloads in 2019

>40K

20% download increase from 2018
2019 Data Summary

$36.8M
Research Funding Sources

$6M
External Grants Awarded*†

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

$84K
Internal Grants Awarded*

* Continuing support included
2019 Data Summary

505
Scientific Articles*

3,202
Consented Research Participants*

1,259
Total Research†

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

† Projects include clinical trials, clinical outcomes research, preclinical studies and other research activity
2019 Data Summary

621
Clinical Trials*

Oncology (279) 45%
Cardiovascular (130) 21%
Specialty Research (49) 8%
Neuroscience (29) 5%

Pediatric (134) 22%

* Duplicate trials across sites excluded

51
Preclinical Studies*

Oncology (9) 18%
Neuroscience (12) 24%
Cardiovascular (7) 14%
Specialty Research (18) 35%
Pediatric (5) 10%

* Preclinical biorepository studies included

411
Clinical Outcomes Research Projects*

Oncology (56) 14%
Cardiovascular (118) 29%
Neuroscience (29) 7%
Specialty Research (154) 37%
Pediatric (54) 13%

* Duplicate projects across sites excluded
Thanks to 978 newly consented cardiovascular clinical trial participants, as well as Advocate Aurora Research Institute’s preclinical and patient-centered outcomes research in the field, we’re advancing therapies for conditions ranging from heart failure and arrhythmias to structural and coronary heart disease.

In the following pages, we share a handful of our 2019 research highlights and successes: the story of how a transcatheter aortic valve replacement (TAVR) restored a Wisconsin man’s quality of life; clinical trials of investigational devices for heart failure and nonvalvular atrial fibrillation and a study of diagnostic evaluation strategies for coronary artery disease; and investigator-initiated research examining clinical and treatment patterns in patients during the first year after a heart attack and developing machine learning software to analyze electrocardiograms.
The last TAVR frontier

How an Advocate Aurora Health patient’s participation in research opened the door for a final group of patients in need of valve replacements

As an avid bike-rider, Greg Szymanski, 73, of Mukwonago, Wisconsin, knew what it felt like to have his heart racing a bit. But what he was feeling in the early summer of 2019 was not that.

“This was not normal,” he said.

After meeting with his primary care doctor, who noticed a heart murmur, Szymanski was referred to cardiovascular disease specialist Bijoy Khandheria, MD, based at Aurora St. Luke’s Medical Center in Milwaukee, who confirmed a diagnosis of aortic stenosis.

The aortic valve is positioned between the aorta and the left ventricle of the heart and prevents blood from moving backward into the heart. Szymanski would need a new one.

“A healthy aortic valve is about 4 centimeters squared,” Dr. Khandheria said. “Due to calcification that can come with age, Greg’s was less than 1 centimeter squared. That’s aortic stenosis.”

Today, most patients with aortic stenosis are treated with the revolutionary, minimally invasive transcatheter aortic valve replacement (TAVR) procedure. Aurora St. Luke’s is a leader in TAVR research and began performing TAVR procedures in 2011, as part of clinical trials conducted through what was then Aurora Research Institute. The TAVR team at Aurora St. Luke’s has now performed more than 2,100 procedures.

At the time of Szymanski’s heart problems, however, open heart surgery was still the standard of care for low-risk patients such as himself.

Fortunately, Dr. Khandheria was able to enroll Szymanski in Medtronic’s Evolut Low Risk Trial, which was evaluating the TAVR procedure specifically for low-risk patients. Aurora St. Luke’s was the only site in the state participating in the study.

“It was amazing,” Szymanski said. “After the surgery happened, I came into recovery and immediately felt much better. And there was absolutely no pain from the procedure.”

In August 2019, shortly after Szymanski’s procedure, the U.S. Food and Drug Administration approved the TAVR procedure for treatment of low-risk patients based on results of the Evolut Low Risk Trial.

“Low-risk patients were the final group approved for the TAVR procedure,” said Tanvir Bajwa, MD, interventional cardiologist and site principal investigator for Aurora St. Luke’s. Dr. Bajwa performed Szymanski’s TAVR.

“These patients represent a large portion of the severe aortic stenosis patient population.”

By September 2019, Szymanski’s heart was pumping hard once again – but for a healthier reason.

“I’m back on my bike,” he said.

“There was absolutely no pain from the procedure.

Greg Szymanski
Research Participant
Cardiovascular research

Clinical research roundup

Research Institute supports heart failure trial at nine sites

Advocate Aurora Research Institute is supporting the GUIDE HF clinical trial to evaluate the CardioMEMS HF device at nine locations across Illinois and Wisconsin.

The implanted CardioMEMS HF device reads pressure inside of the pulmonary artery, a large blood vessel that carries blood from the heart to the lung. Higher pressures indicate an increase of fluid, which may signify worsening heart failure. The device has been shown to alert physicians before the patient experiences symptoms.

Advocate Aurora Health contributed to the 2014 U.S. Food and Drug Administration approval of the device. This latest trial, sponsored by Abbott, manufacturer of the device, will study the effectiveness of the device in an expanded population.

Maria Rosa Costanzo, MD, is the principal investigator for Illinois. Nasir Sulemanjee, MD, is the site principal investigator for Aurora St. Luke’s Medical Center in Milwaukee.

Advocate Aurora Health enrolled 93 participants as of the end of 2019 in the PRECISE clinical trial, which studies the comparative effectiveness of diagnostic evaluation strategies for stable coronary artery disease performed in outpatient settings, including primary care and cardiology practices.

Cardiologist Victor Marinescu, MD, is the site principal investigator for Advocate Medical Group, Naperville, and Advocate Medical Group, Elmhurst. Sorin Danciu, MD, is the site principal investigator for Advocate Illinois Masonic Medical Center and Advocate Medical Group, Chicago-Cardiology. M. Fuad Jan, MD, is the site principal investigator for Aurora St. Luke’s Medical Center in Milwaukee. Dr. Marinescu and his research staff were recognized in October 2019 by the study’s sponsor, Heart Flow Inc., for becoming the top-enrolling site in the U.S.

Studying a new device for nonvalvular atrial fibrillation

Advocate Aurora Research Institute enrolled 46 participants in the Amplatzer Amulet LAA Occluder trial that recently closed enrollment after 2,079 participants volunteered worldwide.

Abbott Medical Devices sponsored the trial that compares its investigational Amulet device with Boston Scientific’s Watchman device, which is already approved, in people with nonvalvular atrial fibrillation. Though not approved by the U.S. Food and Drug Administration, Amulet has been commercially available in Europe for more than six years. With help from researchers at Aurora St. Luke’s Medical Center, Milwaukee, the Watchman device has been approved for use in the United States since 2015.

Both Amulet and Watchman were designed to close a pocket that forms in the left atrium of the heart. Closure of the pocket, called a left atrial appendage, prevents blood clots from developing and escaping, which can lead to stroke or embolism.

Advocate Aurora Health researchers recruited participants at Advocate Christ Medical Center in Oak Lawn, Illinois, Advocate Medical Group in Naperville, Illinois, and Aurora St. Luke’s. When the study closed, the Naperville site ranked 14th in enrollment out of 114 sites.
Researchers study patients in clinical settings to improve heart health

Advocate Aurora Research Institute researchers are conducting a large retrospective study of more than 23,000 patients across Advocate Aurora Health sites in Illinois to better understand how to improve health outcomes following an acute heart attack, called a myocardial infarction (MI). Interventional cardiologist, Neal Sawlani, MD, serves as principal investigator of the study.

Having an MI predisposes people to an increased risk for other major adverse cardiovascular events (MACE) and loss of life. Previous studies have shown statins – cholesterol-lowering medications – may protect against MACE in patients who have had an MI.

Researchers are evaluating statin treatment and patient use patterns, cholesterol changes, and MACE in patients during the first 12 months post-MI to uncover real-world clinical evidence. Knowledge gained from this study may enhance understanding of current preventive treatments and improve future health outcomes and quality of life.

The study is conducted in collaboration with Amgen, a biotechnology company.

Research Institute names first Colton Scholar

Data scientist to develop software using machine learning to analyze electrocardiograms

Through a generous $1 million donation to Aurora Health Care Foundation, Advocate Aurora Research Institute’s first Colton Scholar in Cardiology Research has begun developing software that aims to predict serious cardiac events based on electrical activity of the heart. The software will focus on patients with hypertrophic cardiomyopathy, a potentially life-threatening condition that may disrupt the heart’s normal pumping rhythm.

The Research Institute selected Christopher Beal as its first Colton Scholar in June 2019. The Colton Scholar in Cardiology Research in Honor of A. Jamil Tajik, MD, fund was created with the intention of providing a researcher the opportunity to advance understanding of cardiovascular disease under the mentorship of A. Jamil Tajik, MD, president emeritus of Aurora Cardiovascular Services and an internationally known cardiovascular disease expert.

“The software will use machine learning methods to recognize patterns in electrocardiograms,” Beal said. “The software will be designed specifically to aid the work of cardiologists, providing another tool to help them better identify high-risk patients and quickly determine the right course of treatment.”

M. Fuad Jan, MD, is also advising Beal on the project.
Oncology is Advocate Aurora Health’s largest research specialty. In 2019, 653 newly consented research participants helped Advocate Aurora Research Institute contribute to clinical trials evaluating new cancer therapies.

In this section, we share highlights from studies of acute myeloid leukemia, breast cancer, chronic lymphocytic leukemia, multiple myeloma and non-muscle invasive bladder cancer. Additionally, one research participant recalls her cancer research journey, and we share an update on Team Phoenix, a fitness, research and cancer survivorship program.

Finally, the National Cancer Institute (NCI) awarded Advocate Aurora with the largest grant in the health system’s history to expand its participation in the NCI Community Oncology Research Program (NCORP).
Research restores hope
A journey back to health inspires the future

“People tend to ask one another, ‘What has been your longest relationship?’ When I share that it’s with my oncologist, it often surprises them,” said Grishma Shah, research participant. “I consider it a blessing.”

Shah was just 16 years old when a desmoid tumor was discovered and she first met Pamela Kaiser, MD, oncologist and hematologist at Advocate Aurora Health. While Shah received treatments for the tumor, including chemotherapy, radiation, surgery and postoperative rehabilitation therapies, school was put on hold. Despite missing out on her junior year of high school, determination and doubling up on courses brought Shah back on track and she graduated with her class.

During Shah’s freshman year of college, the tumor returned, forcing yet another break from school to undergo an amputation. After some time, Shah was able to resume her studies once she regained her health.

But at the age of 20, Shah suffered a third occurrence. This time, surgery was no longer an option and she began intravenous chemotherapy treatment for the second time.

An opportunity to participate in a clinical trial evaluating an investigational cancer drug became available six years following Shah’s initial diagnosis. “My family and I discussed what the possibilities might be and there was a feeling of hope,” Shah said. “We were very hopeful, and we decided to participate.”

Participation in the trial continued for 10 years with study visits every two to three months. Shah continued taking the oral chemotherapy drug for a total of 16 years. Dr. Kaiser, Shah’s oncologist, also served as an investigator of the trial for Advocate Lutheran General Hospital.

“Research offers patients novel therapies that may not be available as part of standard health care, which is especially important in rare diseases,” Dr. Kaiser said. “Clinical trials help to discover new treatments that increase patient survival and quality of life. They allow patients more options to treat their disease.”

Today, Shah adds cancer survivor to the list of identities that help describe her personal journey, along with artist and doctoral student.

“Research restores hope in the lives of patients and their families. I constantly think about how the way we live our lives impacts our future generation and how researchers have impacted my life,” Shah said. “Now I want to do something to push that envelope forward and be a better human being because someone was a better human being for me.”

“I constantly think about how the way we live our lives impacts our future generation and how researchers have impacted my life.”

Grishma Shah
Research Participant
Clinical research roundup

Studying molecular therapy for common leukemia

Aurora St. Luke’s Medical Center in Milwaukee is the first site in Wisconsin participating in an international clinical trial studying the use of a specific anticancer molecular therapy for patients with a common type of leukemia, acute myeloid leukemia (AML).

Chemotherapy is the main treatment for AML, which starts in the bone marrow but often moves quickly into a person’s blood. Sponsored by Hoffmann-La Roche and managed locally by Advocate Aurora Research Institute, the MIRROS study compares the effectiveness of the investigational molecular therapy drug idasanutlin combined with the chemotherapy drug cytarabine to cytarabine with a placebo.

“Previous studies of idasanutlin have shown promising results for the treatment of solid tumors,” said hematologist and oncologist Sherjeel Sana, MD, site principal investigator for the clinical trial. “This trial will examine its ability to help fight leukemias, which affect the blood.”

Building on care-changing research

In late 2019, Advocate Aurora Research Institute opened, through the National Cancer Institute (NCI) Community Oncology Program (NCORP), two new clinical trials studying potential therapies to treat patients with chronic lymphocytic leukemia (CLL), the most common leukemia in adults.

Advocate Aurora researchers had previously contributed to two studies, whose findings immediately established the combination of anticancer drug ibrutinib and antibody drug rituximab as the new standard of care for some patients with CLL.

There is hope, however, that a new antibody drug, obinutuzumab, may outperform rituximab. The two trials – Alliance for Clinical Trials in Oncology’s A041702 and ECOG-ACRIN Cancer Research Group’s EA9161 – opened in late 2019 and will evaluate the combination of ibrutinib and obinutuzumab with and without the chemotherapy drug venetoclax.

The Research Institute is enrolling participants at all 17 of its NCORP cancer clinics in Wisconsin. Oncologists Sherjeel Sana, MD, and Shamsuddin Virani, MD, are the studies’ principal investigators.

Offering access to novel blood cancer trial

Advocate Lutheran General Hospital is the only center in Illinois and one of just three U.S. sites participating in a clinical trial evaluating the investigational treatment AMG 420 for multiple myeloma that has not responded to previous treatment or has returned after remission. Multiple myeloma, an incurable cancer of the white blood cell, accounts for 20% of all blood cancers.

Tulio Rodriguez, MD, hematologist, oncologist and bone marrow transplant specialist, serves as site principal investigator for the trial designed to assess the safety, tolerability and anti-myeloma activity of two AMG 420 dose levels.

Research participants receive daily study drug infusions during a 28-day cycle that is repeated following two weeks of rest for as long as they receive clinical benefit, depending on side effects and tolerability. Study follow-up continues for up to a total of five years.

Amgen, manufacturer of AMG 420, sponsors the clinical trial with an expected study completion in February 2025.
More cancer clinical trials, closer to home

A six-year, $10.2 million award – largest in the health system’s history – from National Cancer Institute increases access to studies at 30 local cancer clinics

Advocate Aurora Health continues to play a leading role in bringing innovative clinical trials to patients with cancer across Illinois and Wisconsin with a recent $10,173,928, six-year grant from the National Cancer Institute (NCI).

NCI named Aurora Health Care, part of Advocate Aurora Health, an NCI Community Oncology Research Program (NCORP) site (National Institutes of Health award number 2UG1CA190140-06).

The recognition builds on Aurora’s initial five-year NCORP funding award and has allowed Advocate Aurora to expand access to NCI clinical trials at 30 local cancer clinics throughout Illinois and Wisconsin.

“NCORP is a critical, federally funded program that allows our health system to bring cancer clinical trials to people in their own communities instead of restricting them to major research institutions,” said Thomas Saphner, MD, Wisconsin co-principal investigator for the NCORP grant, along with Michael Thompson, MD, PhD. “We’re proud to have been selected to continue this important work as a partner of the National Cancer Institute.”

Larger network

In 2019, Advocate Aurora Research Institute transitioned Illinois cancer clinics into its NCORP network.

Thirteen cancer clinics across northeastern Illinois joined the network, accompanying the 17 existing cancer clinics across eastern Wisconsin. The Illinois sites include a children’s hospital with two campuses, which enable the system’s merged NCORP network to participate in pediatric clinical trials.

Although new to NCORP, the Illinois clinics have participated in hundreds of NCI adult clinical trials and Children’s Oncology Group pediatric cancer trials.

“This marks the first major joint research initiative for Advocate Aurora Health,” said Sigrun Hallmeyer, MD, the Illinois principal investigator for the NCORP grant.

Building on success

The health system completed its initial NCORP funding cycle in July 2019, receiving more than $4.6 million from NCI since 2014.

“Over the past five years, participation in NCORP has allowed our researchers to connect patients to a wide variety of clinical trials, including those for brain, breast, lung and prostate cancers, as well as for leukemia, lymphoma and myeloma,” Dr. Thompson said.

During the initial five-year grant, the health system’s NCORP network opened 78 new NCI trials that enrolled more than 1,200 participants. The program was recognized several times by NCI, Alliance for Clinical Trials in Oncology and NRG Oncology as a top-enrolling NCORP site.
Patient-centered outcomes research

A data-driven approach to bladder cancer guidelines

Through a collaboration between University of Wisconsin Carbone Cancer Center and Advocate Aurora Health, researchers have developed a data set of more than 1,200 patients to improve guidelines for non-muscle invasive bladder cancer (NMIBC), the fourth most common cancer in men.

Led by Advocate Aurora Research Institute Senior Research Scientist Kourosh Ravvaz, MD, PhD, the team published its latest findings evaluating the newest NMIBC recurrence risk in Journal of Urology, the highest-ranked urology journal in North America.

“We found that the new guidelines from the American Urological Association/Society of Urologic Oncology provide a similar predictive performance to previous NMIBC risk models,” Dr. Ravvaz said. “However, we discovered that age may significantly impact a patient’s probability of experiencing cancer recurrence or progression and should possibly be factored into the guidelines.”

The team leveraged Advocate Aurora’s vast patient population, working with Research Analytics and the system’s cancer registry, to guide analysis of the de-identified patient information.

The study – “American Urological Association non-muscle invasive bladder cancer risk model validation: Should patient age be added to the risk model?” – was supported by a 2018 Advocate Aurora Health Oncology Research Award.

Contributing to national breast cancer consortium research

Advocate Aurora Health, through its collaboration with University of Illinois at Chicago (UIC) and Metro Chicago Breast Cancer Registry (MCBCR), participates in the Breast Cancer Surveillance Consortium (BCSC), a national registry network.

BCSC research aims to improve breast cancer detection, reduce screening-related harm and increase survival rates. In 2019, Nila Alsheik, MD, diagnostic radiologist at Advocate Lutheran General Hospital, with support from Advocate Aurora Research Institute, coauthored research findings from two BCSC-funded studies.

New breast cancer risk predictor

A study of magnetic resonance imaging (MRI) revealed that breast parenchymal enhancement (BPE), which occurs when injected dye highlights elevated hormone concentrations in the breast, may be a new predictor of increased risk for invasive breast cancer. Results of the study, published in Journal of Clinical Oncology, demonstrated that women with mild, moderate or marked levels of BPE are at increased cancer risk compared to women with minimal BPE. The authors suggest that BPE could be a factor included in breast cancer risk models among women undergoing MRI.

Optimal recall rates for digital screening mammography

Mammography screening can be inaccurate, leading to false positive results and unnecessary biopsy testing. Experts differ on what should be the optimal rate of recall, or the percentage of patients who undergo screening and are called back for additional testing.

Dr. Alsheik and researchers at UIC and MCBCR are studying how cancer detection varies by recall rate. They have taken a novel approach by analyzing the volume of increased biopsy testing that is necessitated by higher recall rates. The authors presented preliminary findings at the Society for Epidemiologic Research 2019 Meeting and are preparing a manuscript for submission to a scientific journal.

Did you know?

Breast cancer is the second most common cancer among U.S. women, according to Centers for Disease Control.
Finding potential treatment against drug-resistant breast cancer

Discovery Laboratory scientist publishes previously unreported study findings in an international medical journal

Discovery Laboratory scientist Jun Yin, PhD, led a study, recently published in Cancer Letters, which found that a known anticancer drug also demonstrated effectiveness in treating a common type of breast cancer that is often resistant to traditional treatment.

The project focused on human epidermal growth factor receptor 2 (HER2)-positive breast cancer cells. Traditional first-line treatment for this type of breast cancer involves the drug trastuzumab.

"Trastuzumab has been shown to improve survival of patients with HER2-positive breast cancer, however, nearly a quarter of patients treated with trastuzumab demonstrate resistance to the drug and experience cancer recurrence within 10 years," Dr. Yin said.

In the study, Dr. Yin and her research team proved that AZD1775, a potent anticancer agent that has been studied as a treatment for a range of cancer types, specifically and effectively targets trastuzumab-resistant cancer cells, both inhibiting their growth and killing them.

Furthermore, the researchers discovered that AZD1775 targets cancer stem-like cells (CSCs), which are thought to be responsible for tumor recurrence and resistance to treatment. The researchers found that AZD1775 blocks CSC formation by suppressing the gene MUC1, which had not been previously reported in HER2-positive breast cancer.

The study was conducted in part with a tumor cell line created from tissue donated by Advocate Aurora Health patients to the Biorepository and Specimen Resource Center.

In 2019, Team Phoenix also launched a five-year research project, building a biorepository to help study the connection between exercise and cancer-related biomarkers that may predict cancer treatment outcomes. The research project is overseen by Amy Beres, PhD, the Research Institute’s director of oncology research, and Jun Yin, PhD, research scientist.

Supporters

Advocate Aurora Research Institute’s Team Phoenix, a 14-week fitness and research program, redefined cancer survivorship for a record 56 women who completed a sprint-distance triathlon in July 2019 at Ottawa Lake State Park in Dousman, Wisconsin.

In its ninth year, Team Phoenix was led by a team of multidisciplinary clinicians, triathlon coaches and volunteers who encourage and assist cancer survivors to regain endurance, strength, flexibility, and overall health and wellness after cancer treatment by training for a sprint-distance triathlon. The program is led by cofounders Judy Tjoe, MD, breast cancer surgeon, and Leslie Waltke, DPT, cancer rehabilitation specialist for Aurora Physical Therapy, as well as Michael Mulane, MD, medical oncologist.

In 2019, Team Phoenix also launched a five-year research project, building a biorepository to help study the connection between exercise and cancer-related biomarkers that may predict cancer treatment outcomes. The research project is overseen by Amy Beres, PhD, the Research Institute’s director of oncology research, and Jun Yin, PhD, research scientist.

The 2019 Team Phoenix season was made possible by community support from Carroll University, Pettit National Ice Center, Race Day Events, Wheel and Sprocket, and Xperience Fitness, and generous donations to Aurora Health Care Foundation from Hoopla Foundation, National Association of the Remodeling Industry (NARI) Milwaukee, Nev’s Ink, PepsiCo, Ruud Family Foundation, The Chocolate Factory, Vince Lombardi Cancer Foundation and many individual donors.
Advocate Aurora Research Institute’s neuroscience portfolio includes the neuro-oncology research of Neuroanatomy Laboratory at Aurora St. Luke’s Medical Center and the Discovery Laboratory at Aurora Sinai Medical Center, both in Milwaukee, as well as the work of Advocate Memory Center in Park Ridge, Illinois.

In 2019, with the help of 232 newly consented patients, the Research Institute supported clinical trials studying potential treatments for conditions such as chronic rhinitis, relapsing multiple sclerosis and stroke. Read on to learn about two of our clinical trials evaluating therapies for Alzheimer’s disease and chronic migraine in patients with rebound headaches.

Finally, a research participant shares her inspiration for joining an Alzheimer’s disease trial.
Committed to research and finding a cure

One woman follows in her mother’s footsteps so her sons may walk a different path

Janice McPeak chose to participate in an Alzheimer’s disease clinical trial hoping to prevent her sons from becoming her family’s third generation to face a diagnosis that has no cure.

“Like any disease or condition that comes along, there’s research until there’s a cure. And, the cure comes out of the research,” McPeak said. “My children could be involved in the same struggle. Maybe my participation is going to help the doctors and researchers figure it out down the road.”

Having witnessed the last 15 years of her mother’s life with Alzheimer’s, McPeak had been preparing for the possibility that this could happen to her and understands the challenges ahead.

Shortly after receiving her own diagnosis, McPeak learned about a clinical trial evaluating the effectiveness of an investigational drug, tilavonemab, in slowing the gradual decline of memory, thinking and behavior that occurs with Alzheimer’s disease.

With both her sons and mother in mind, she consented to participate in the research study.

“My mother showed me what it was to be involved in experimental drugs, experimental processes to fight Alzheimer’s, and she fought pretty hard in that realm,” McPeak said. “So, I’m willing to do that also.”

Previous research has shown that abnormal proteins, tau and amyloid, increase in the brains of people living with Alzheimer’s disease. McPeak is participating in a study at Advocate Memory Center in Park Ridge, Illinois, that will determine if the antibody tilavonemab, designed to block tau buildup, slows damage to the brain.

“The growing number of individuals affected by Alzheimer’s disease – approximately 40 million people worldwide – has made discovery of preventive therapies and treatments a global health priority,” said Darren Gitelman, MD, behavioral neurologist, senior medical director of Advocate Memory Center and site principal investigator for the study. “We are so thankful for the dedication to research of study participants like Ms. McPeak, who will one day help lead us to a cure.”

Participants in the tilavonemab study are randomized to one of four treatment groups. One group receives placebo and each of the remaining three groups receives a different amount of study drug. All treatments are administered by infusion once every four weeks over a two-year period.

The international clinical trial, “A study to evaluate the efficacy and safety of ABBV-8E12 in subjects with early Alzheimer’s disease,” is sponsored by AbbVie, manufacturer of the drug. Data collection will continue until anticipated study completion in 2021.

“Like any disease or condition that comes along, there’s research until there’s a cure.”

Janice McPeak
Research Participant
Clinical research roundup

Researchers help advance potential Alzheimer’s treatment

Drug manufacturer Biogen surprised the medical and pharmaceutical communities in October 2019 by reevaluating its drug aducanumab after additional data suggested the drug may successfully fight plaque buildup in the brain that characterizes Alzheimer’s disease, as well as slow the rate of patients’ cognitive and functional decline. The strongest results were seen in study participants who receive the highest dose of the drug for the longest period of time. Biogen announced it will apply for drug approval by the U.S. Food and Drug Administration in 2020.

This surprise news came after Biogen initially halted two studies in March 2019 after preliminary analyses suggested the trials would not meet effectiveness goals.

Nearly 3,300 participants enrolled in two Phase 3 studies of aducanumab – including 10 at Advocate Memory Center in Park Ridge, Illinois, under the guidance of behavioral neurologist Darren Gitelman, MD.

“Of course, the announcement is very exciting in that it has potential to be the first disease-modifying drug ever approved for Alzheimer’s,” Dr. Gitelman said. “Other drugs commonly used today treat only the disease’s symptoms, but do not change the rate of decline.”

The positive study results also validate the predominant theory of how Alzheimer’s begins and progresses: the amyloid hypothesis, which holds that the accumulation of a protein called beta-amyloid, is an important early step in the process that leads to Alzheimer’s disease, according to Dr. Gitelman.

Biogen has launched a new aducanumab trial that is enrolling patients who participated in one of the previous studies of the drug. Participants in this new trial, called Embark, will all receive the highest doses of the study drug. The Advocate Memory Center will be a site for this new trial.

“... it has potential to be the first disease-modifying drug ever approved for Alzheimer’s.”

Darren Gitelman, MD
Behavioral Neurologist

Aurora BayCare joins study of rebound headaches caused by chronic migraine medication overuse

Aurora BayCare Medical Center in Green Bay, Wisconsin, is the first site in the state participating in an international clinical trial studying an investigational product’s effectiveness in preventing chronic migraine in participants with rebound headaches.

In a vicious cycle, chronic migraine sufferers may get rebound headaches from long-term use of migraine medication, medically known as medication overuse headache. The disorder affects 1% to 2% of the population worldwide.

The trial will compare the product erenumab to placebo for participants with chronic migraine who are diagnosed with medication overuse headache because of preventive treatment failure.

“Medication overuse headache can paradoxically contribute to increased pain severity and frequency,” said neurologist Aaron Bubolz, DO, site principal investigator for the study. “Patients often take more pain medication to overcome medication overuse headache, which can result in a worsening of already painful headaches.”
Researcher wins award for first case series of novel neurosurgical approach

Alejandro Monroy-Sosa, MD, research scientist at the Neuroanatomy Laboratory, was awarded the Sergio Gómez Llata Andrade of Neuroanatomy Award at the 25th Annual Mexican Society of Neurological Surgeons Congress, July 3 to 5, 2019, in Nuevo Vallarta, Mexico.

Dr. Monroy-Sosa received the award for his study titled “Transsulcal parafascicular corridor in brain tumors assistance with navigation and tractography: case series and surgical proposal.”

Neuroanatomy Laboratory researchers presented five additional studies at the July 2019 conference.

In the Neuroanatomy Laboratory at Aurora St. Luke’s Medical Center in Milwaukee, research fellows and clinicians work together to develop and refine complex neurosurgical techniques using the latest technology that can be translated to the operating room.

A joint effort between the Advocate Aurora Research Institute and Aurora Neuroscience Innovation Institute, the Neuroanatomy Laboratory is filled with more than $4 million in surgical and imaging equipment that replicates a neurosurgery operating suite to enable simulation of surgical procedures on cadaver specimens for training and research purposes.

Discovery Laboratory

The Discovery Laboratory at Aurora Sinai Medical Center in Milwaukee is a modern research facility where experts in cardiology, oncology and neuroscience work with advanced equipment to search for 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 diseased cells respond to different drugs or treatments; and

• Multiple specialties coming together, with heart and cancer researchers treating the damaging effects chemotherapies can have on the heart and neurosurgeons working with cancer researchers on treatments for brain tumors.
Primarily through Advocate Center for Pediatric Research, our researchers are making enormous strides in pediatric research. Advocate Children’s Hospital’s two locations at Oak Lawn and Park Ridge, Illinois, are network sites for Advanced Clinical Trials (I-ACT) for Children. The I-ACT designation provides access to pediatric clinical trials, best practices, quality improvement strategies, and research education and training.

In this section, see how our 430 newly consented pediatric clinical trial participants in 2019, as well as our preclinical and patient-centered outcomes researchers, contributed to the study of investigational therapies to treat adolescent depression, chronic lung disease, eosinophilic esophagitis, severe pediatric brain injury and more. Additionally, read the story of a brave pediatric research participant.
One family’s commitment to preventing childhood disease

Physicians enroll their son into clinical trial evaluating a pediatric vaccine

Controversial media and internet posts have caused some new parents to question vaccinating their newborns. But, first-time parents and physicians Emily Dudek, DO, and Minyong Yu, DO, have observed the value of vaccines firsthand.

Drs. Dudek and Yu’s medical training also helped them decide to allow their 2-month-old son, William, to participate in a clinical trial evaluating the safety and effectiveness of a pediatric vaccine designed to protect against pneumococcal bacteria, a germ responsible for serious and sometimes life-threatening infections.

“I’ve seen how respiratory illnesses, such as pneumococcal pneumonia, have devastated my patients,” Dr. Yu said. “Seeing how devastating these illnesses can be and how vaccines can prevent or reduce the risk of contracting pneumococcal pneumonia – that’s so important, so vital.”

Pneumococcal pneumonia is responsible for about 150,000 hospitalizations each year and nearly 4,000 people die from pneumococcal meningitis and bacteremia, according to the Centers for Disease Control and Prevention.

Children with certain conditions and those younger than 2 years old are at greatest risk of serious illness. The investigational vaccine is being evaluated for its potential to reduce the risk of seven types of pneumococcal infection.

Advocate Children’s Hospital-Park Ridge is the only clinical trial site in Illinois.

“We’re very excited to be a part of this study because the investigational vaccine has the potential to reduce disease and death for thousands of children now and as they grow into adulthood,” said Jeanne Lovett, MD, pediatrician and site principal investigator for the study.

Drs. Dudek and Yu recognize that research is necessary to establish the safety and effectiveness of investigational drugs and vaccines before they become standard of care. “Being physicians, we definitely appreciate and have benefitted from medical research,” Dr. Yu said. Dr. Dudek, who served as a pediatric research technician prior to medical school, added,

When I think about my son’s participation in the vaccine study, I feel a lot of pride because our son may be helping future patients.

Minyong Yu, DO
Parent of Research Participant
Clinical research roundup

Exploring treatment for adolescents with debilitating disease

Eosinophilic esophagitis, also known as EoE, causes significant and chronic symptoms in children and adults, such as difficulty swallowing, vomiting and abdominal pain. The negative impact on quality of life and the ability to obtain adequate nutrition may be severe.

First reported in the scientific literature in 1993, EoE is a relatively new disease with no known cure. Since then, the number of children and adults affected has been increasing.

Thirumazhisai Gunasekaran, MD, pediatric gastroenterologist at Advocate Children’s Hospital-Park Ridge, serves as site principal investigator of a clinical trial evaluating the safety and efficacy of an investigational treatment dupilumab in reducing symptoms of EoE in adolescents and adults. Dupilumab blocks proteins in the body believed to contribute to diseases, like EoE, that cause allergic inflammatory responses.

The global clinical trial, sponsored by Regeneron Pharmaceuticals, will enroll 425 participants with EoE who are 12 years of age and older.

Protecting premature infants

Aurora Sinai Medical Center in Milwaukee is the first site in Wisconsin and the fifth in the world to participate in an early phase clinical trial studying the investigational drug SHP607 to prevent chronic lung disease in extremely premature infants.

Premature infants miss out on important proteins and growth factors and are thus at a much greater risk of developing complications such as chronic lung disease, which can often result in long-term neurocognitive disabilities or eventual death.

Chronic lung disease is among the most common conditions affecting preterm infants, however, no single therapy has demonstrated a significant impact on the incidence or severity of the condition. The study drug has the potential to be a preventive therapy for these babies.

Neonatologist Jeffrey Garland, MD, director of Aurora Sinai’s Level III neonatal intensive care unit, is the site principal investigator for the study, sponsored by biotechnology company Shire.

Improving pediatric cancer survivor health

Physical activity has previously been shown to provide health benefits to childhood cancer survivors, many of whom are at greater risk for chronic health conditions, such as cardiovascular disease. Yet, exercise sometimes proves challenging because of prolonged inactivity during illness and treatment that leads to sedentary lifestyle changes and cancer therapy-related side effects, including loss of muscle mass and coordination and balance difficulties.

Advocate Children’s Hospital researchers are studying an online, interactive, rewards-based physical activity program to evaluate how well it engages children and adolescents and improves long-term health. Rebecca McFall, MD, pediatric oncologist, serves as site principal investigator.

Research participants receive educational handouts, a wearable activity tracker and access to one of two six-month online programs: 1) limited feedback, and 2) socially interactive and reward based. Changes in cardiometabolic and inflammation markers, fatigue, quality of life and school attendance are monitored and compared between program groups.

The clinical trial, sponsored by Children’s Oncology Group and National Cancer Institute, is expected to continue through 2022.

Most cancers diagnosed in children differ from those in adults, and pediatric treatments are essential, according to National Cancer Institute.
Pediatric research

Studying depression prevention in teens

Through a collaboration with the University of Illinois at Chicago (UIC), Advocate Children’s Hospital pediatric researchers are participating in a randomized clinical trial designed to evaluate a new online teen depression prevention program, Project CATCH-IT.

The Patient-Centered Outcomes Research Institute awarded Benjamin Van Voorhees, MD, of UIC, a $7 million grant to conduct the trial. Advocate Children's Hospital investigators Cathy Joyce, MD, PhD, and Cheryl Lefaiver, PhD, RN, are contributing their research expertise to the project, which aims to enroll more than 500 at-risk teens.

Project CATCH-IT involves a series of self-directed modules: 14 for adolescents and five for their parents. The trial compares Project CATCH-IT outcomes to those receiving intervention via a more traditional group therapy depression prevention model.

Preclinical research

Seeking an alternative treatment for a type of severe perinatal brain injury in newborn infants

Michelle Davis Ramos, MD, a neonatal-perinatal medicine fellow in the neonatal intensive care unit at Advocate Children’s Hospital Park Ridge, Illinois, received more than $21,000 from the Russell Center for Research and Innovation Small Research Projects Grants Program for her preclinical research study exploring treatment for hypoxic-ischemic encephalopathy (HIE), a serious condition in newborns caused by lack of oxygen or blood flow to the brain that may result in brain dysfunction and death.

“There is currently only one proven therapy for HIE – hypothermia, which cools the whole body, including the brain, to reduce HIE severity,” Dr. Davis Ramos said. “Unfortunately, it’s only 40% effective in decreasing death and major neurodevelopmental disabilities.”

Previous research has shown that a chemical compound named IRL 1620 may help to protect the brain and prevent injury. The objective of Dr. Davis Ramos’s study is to evaluate whether IRL 1620 can reduce the severity of HIE in a laboratory setting.

Dr. Davis Ramos is conducting the study in collaboration with Midwestern University in Downers Grove, Illinois.

Family conferences for PICU patients

Rani Ganesan, MD, physician specialist in pediatric palliative and intensive care, has received a two-year subaward of more than $52,000 through her collaboration with Lurie Children’s Hospital of Chicago for a research project that will test and further develop criteria that identify pediatric intensive care unit (PICU) patients who would benefit from “family care conferences.”

Having children in the PICU is difficult on families. Family care conferences may improve communication between health care providers and families of patients, making the ordeal less stressful. Results of this feasibility study will be used in future research designed to improve and tailor PICU communication for these vulnerable patients and families.

The subaward is funded by National Palliative Care Research Center.
Our specialty research encompasses behavioral health, endocrinology, gastroenterology, geriatrics, mental health, population health, primary care, women’s health and more. Team members in these fields consented 909 new research participants in 2019.

In the pages ahead, read how research participants and clinicians helped advance studies designed to improve care for depression, diagnostic imaging, Down syndrome, gastroesophageal reflux disease and nutrition. Also, read about a teenager’s experience participating in an asthma trial and meeting an Olympian who never let asthma slow her down.

We also detail the research advances of the Ed Howe Center for Health Care Transformation, the Endocrine Research Laboratory, Aurora UW Medical Group and the Center for Urban Population Health.
An Olympic inspiration

A young patient helps improve asthma care and meets an Olympic champion who never let asthma slow her down

“He was really, really tense. He wasn’t eating. His stomach was hurting,” said Ruthia Humphrey, recalling a night seven years ago when her son, Tyler Scott, woke up feeling ill. “Then he started vomiting, and I said, ‘OK, I better take him in.’”

The emergency room doctor quickly identified the problem: Tyler, who was 5 years old at the time, was having an asthma attack. He was admitted to the hospital and treated with a course of inhalers.

Once his condition stabilized, Tyler met with his primary physician, Lisa Sullivan Vedder, MD, a family medicine practitioner at Aurora Sinai Medical Center in Milwaukee. Dr. Sullivan Vedder was the site principal investigator for a clinical trial studying asthma in black patients, such as Tyler. The clinical trial had the potential to both improve Tyler’s condition and advance research in the field.

“Black patients have long been underrepresented in asthma research,” Dr. Sullivan Vedder said, “despite the fact that black patients suffer disproportionately higher rates of asthma attacks and asthma-related hospitalization and death.”

Tyler and Humphrey were apprehensive at first. Neither of them knew much about clinical trials nor medical research.

“But I trust her,” Humphrey said of Dr. Sullivan Vedder.

So, Tyler, despite being a nervous 5-year-old, joined the study. The clinical trial, “Best African American response to asthma drugs (BARD),” studied different ways to treat participants whose asthma was not well controlled on a low dose of inhaled corticosteroid, which is used to treat airway inflammation. The study compared increasing the dose of the inhaled corticosteroid to increasing the dose of the inhaled corticosteroid plus adding a long-acting bronchodilator, which is used to help open airways. The study was funded by the National Heart, Lung, and Blood Institute, part of the National Institutes of Health.

Tyler met regularly with Dr. Sullivan Vedder and her research team to monitor how the treatment was working.

“I had to breathe into a machine and pretend to blow out the birthday cake candles,” Tyler said.

Seven years later, Tyler is a healthy, football-playing 12-year-old. His asthma still slows him down at times, but he’s learned it can’t stop him, thanks to a little inspiration from an Olympian.

In October 2019, Jackie Joyner Kersee, a three-time gold-medal-winning track and field athlete, visited Aurora Sinai, where Tyler, Humphrey and local track and field athletes listened to her speak about her lifelong struggle with asthma.

“It was cool to see her in person,” Tyler said.

In late 2019, researchers published results from the BARD study in the New England Journal of Medicine. The researchers found that adolescent and adult participants responded differently to the asthma treatments than children, and that children may respond equally well to two different treatment options.

“The results suggest that black children with poorly controlled asthma may respond equally well to several treatment options, as opposed to black adolescents and adults who showed a better response to the addition of a long-acting bronchodilator,” Dr. Sullivan Vedder said. “This allows physicians and families to work together to make more informed decisions about best treatment options when caring for black children with asthma.”
Clinical research roundup

Using big data to advance Down syndrome research

Advocate Aurora Health collaborates with the Institute for Translational Medicine (ITM) – a network funded by the National Institutes of Health (NIH) to accelerate health research. The ITM received a $500,000 NIH award to participate as one of 25 U.S. research sites selected for the INCLUDE project. Advocate Aurora and University of Chicago share the ITM project award.

INCLUDE uses big data analytics to identify co-occurring conditions among individuals with Down syndrome, while investigating factors for common diseases in all people, such as Alzheimer’s, autism and diabetes.

“We hope to ultimately identify new treatments and improve quality of life for individuals with and without Down syndrome,” said Brian Chicoine, MD, lead researcher and medical director of Advocate Medical Group’s Adult Down Syndrome Center, one of the largest centers in the U.S.

Supported by Advocate Aurora Research Institute, researchers will study more than 175 million global, de-identified electronic health records to uncover new information and apply findings to advance health.

(This project is supported by the National Center for Advancing Translational Sciences of the NIH through Grant Numbers UL1TR002389, KL2TR002387, and TL1TR00238 that fund ITM.)

Comprehensive nutrition program improves health

Advocate Aurora Health collaborated with Abbott to evaluate a 90-day comprehensive home health nutrition quality improvement program for participants recovering from illness, injury or recent hospitalization. Nutrition is essential for healing, yet one third of home health patients in the United States are at risk for malnutrition.

Study findings, published in Journal of Parenteral and Enteral Nutrition, demonstrated that, after program completion, risk of rehospitalization for participants initially at moderate-to-high risk for malnutrition was reduced by 24% in the first 30 days of the program, almost 23% percent through 60 days and 18% after 90 days. Health care cost avoidance due to decreased readmissions translated to more than $2.3 million or $1,500 per patient.

Results from the Phase 1 research collaboration found that a nutrition program for hospitalized participants at risk for malnutrition shortened hospital stays and decreased 30-day readmission rates – a potential health care cost savings of more than $4.8 million or $3,858 per patient.

Both studies, supported by Advocate Aurora Research Institute, demonstrate how research transformed care delivery, improved patient health and increased health care cost savings.

On the forefront of Down syndrome research

Advocate Aurora Health’s Adult Down Syndrome Center is one of 11 U.S. research sites to join the first Down Syndrome-Clinical Trials Network study, “Longitudinal investigation for enhancing Down syndrome research (LIFE-DSR).”

Designed to collect data on changes in cognition, behavior, function and health over time, LIFE-DSR’s goal is to enhance understanding of conditions for which adults with Down syndrome are at high risk, particularly Alzheimer’s disease. Blood samples are also collected to help in future development of an Alzheimer’s diagnostic blood test.

Researchers hope knowledge gained from LIFE-DSR may lead to preventive and therapeutic treatments. Brian Chicoine, MD, cofounder and medical director of the Adult Down Syndrome Center, is site principal investigator.

Down Syndrome-Clinical Trials Network is directed by LuMind IDSC Foundation and sponsored by Alana Foundation, AC Immune and Lundbeck. Advocate Aurora received a LuMind IDSC research grant of more than $300,000 to participate as the first clinical trial site in Illinois.
Breathing easier

Howe center researchers study exercise to address breathing restrictions in older adults

"Movement is medicine" has become a common refrain in the health care community.

In older adults, however, difficulty breathing can make movement nearly impossible, which increases their risk for numerous comorbidities.

Bader Philanthropies, Inc. awarded the Ed Howe Center for Health Care Transformation and Ovation Communities a two-year, $75,000 grant to study the effectiveness of a first-of-its-kind exercise intervention for older adults with restrictive lung function, called Breathing Room, designed to open the thoracic cage, increase strength of the respiratory muscles and teach an optimized breathing technique. The study, titled “Achieving better lung health,” is led by Christine Kovach, PhD, visiting scholar at the Howe center and director of research at Ovation Communities, Michelle Simpson, PhD, RN, director of the Howe center, and Murad Taani, PhD, assistant professor at University of Wisconsin-Milwaukee.

“Addressing the problems uncovered in our research – what are called ‘restrictive ventilatory patterns,’ or RVP – has the potential to improve strength, decrease or delay functional decline, and prevent pneumonia,” Dr. Kovach said. “In practical terms, we want a resident at a senior living center to have the strength to continue going out and walking to his or her favorite local lunch spot.”

In 2018, Drs. Kovach and Taani conducted a study at Ovation Communities among residents at three senior living centers in southeastern Wisconsin. They found that 51% of the residents had moderate or severe RVP, which contributes to two prevalent problems in older adults: the development of pneumonia and other lower respiratory infections and declining endurance for physical activity.

“Our project found that people with RVP were more likely to have lower muscle strength, a stooped posture, difficulty breathing and dementia,” Dr. Kovach said.

People who had RVP were less likely to still be walking independently, with or without an assistive device, such as a cane or walker.

“The problem of RVP is not on the radar screen of people working in geriatrics or with those conducting research on problems like pneumonia and declining physical functioning,” Dr. Simpson said. “We have the opportunity to bring national attention to this problem and to begin providing evidence regarding a possible solution to the problem.”

Endocrine Research Laboratory

Led by endocrinologist Hershel Raff, PhD, researchers at the Endocrine Research Laboratory at Aurora St. Luke’s Medical Center, Milwaukee, published three manuscripts in 2019.

Journal Endocrinology published the research team’s study titled “A long-acting neutralizing monoclonal ACTH antibody blocks corticosterone and adrenal gene responses in neonatal rats,” coauthored by Ashley Gehrand, Jonathan Phillips and Dr. Raff.

The Journal of the Endocrine Society published the team’s study titled “Bedtime salivary cortisol and cortisone by LC-MS/MS in healthy adult subjects: evaluation of sampling time,” coauthored by Phillips and Dr. Raff.

The journal Physiological Reports published the team’s study titled “The effects of flutamide on the neonatal rat hypothalamic-pituitary-adrenal and gonadal axes in response to hypoxia,” coauthored by Phillips, Gehrand and Dr. Raff.

Aurora Metro Summer Research Interns Maya Guenther and Minhal Gardezi were also coauthors on the manuscript.
A supplemental therapy for GERD

Advocate Aurora Research Institute is supporting an international clinical trial studying a drug for gastroesophageal reflux disease, or GERD.

GERD causes stomach acid and other contents of the stomach to back up into the esophagus and sometimes even into the throat and mouth. Proton pump inhibitors currently are the standard treatment.

“Up to 40% of GERD patients still experience symptoms while taking proton pump inhibitors, and many have been waiting a long time for a new treatment option,” said Nimish Vakil, MD, gastroenterologist and site principal investigator for Aurora Medical Center in Summit, Wisconsin.

Sponsored by Ironwood Pharmaceuticals Inc., the clinical trial, “Trial of IW-3718 for 8 weeks in patients with persistent gastroesophageal reflux disease (GERD) receiving proton pump inhibitors,” will allow patients to remain on their proton pump inhibitors while evaluating the drug IW-3718, which is designed to bind to bile acids in the stomach and prevent them from entering the esophagus.

Did you know? 60 million adults suffer from GERD worldwide.

New software may reduce expensive diagnostic imaging

A study published in PLOS ONE and led by radiologist and nuclear medicine specialist Sarah Reimer, MD, found that software designed to help doctors make better decisions could decrease the use of certain medical scans by about 6%, possibly reducing health care costs and allowing more efficient care for patients, who wouldn’t receive high-cost testing.

The study came on the heels of a new mandate from the Centers for Medicare & Medicaid Services requiring use of a clinical decision support tool to evaluate the appropriateness of high-cost imaging. Dr. Reimer’s study evaluated the effects of American College of Radiology’s ACR Select tool at Wisconsin-based Advocate Aurora Health sites, which had already implemented the tool.

The study, developed and conducted over three years, was supported by Arnold Ventures through a $542,000 grant award. Dr. Reimer worked in collaboration with health economics researchers from Massachusetts Institute of Technology and the Abdul Latif Jameel Poverty Action Lab North America.

An app to help with depression

Advocate Aurora Health and Takeda-Lundbeck collaborated to develop a mobile app, named Pathway, to help people with depression record, monitor and share symptoms, medications and therapy with their primary care providers.

A pilot study led by Advocate Aurora’s Illinois Behavioral Health Medical Director David Kemp, MD, with support from Advocate Aurora Research Institute, tested Pathway’s feasibility and effectiveness in 40 research participants with major depressive disorder in a primary care clinical setting who were randomized to receive standard medical care or standard medical care plus Pathway.

Study findings demonstrated improvements in symptoms, depression severity and quality of life for both groups. Additionally, patient-provider engagement scores were favorable and participants using Pathway scored higher on surveys measuring the ability to self-manage their depression.

The research collaboration is now focusing efforts to create a Pathway Platform, powered by Fora Health, a Ctrl Group product, with app enhancements and education about its functions and features. Next steps also include development of an interface between Pathway and the electronic health record and a future study to further evaluate Pathway’s effectiveness.
Advocate Aurora Research Institute

33 | Specialty research

Aurora UW Medical Group

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 AUWMG 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.

Family-centered cesarean

One strategy to improve the birthing experience among those undergoing cesarean delivery is a family-centered approach, which mimics aspects of a vaginal delivery by providing for immediate skin-to-skin contact and the ability for the mother to see the birth through a clear drape.

Women having planned cesarean sections at term were randomized to traditional or family-centered cesarean. Marie Forgie, DO, and colleagues found no differences in baseline characteristics or maternal or neonatal outcomes between groups. However, skin-to-skin contact was established on average 11 minutes earlier among those randomized to the family-centered approach. Moreover, patients tended to be more satisfied with the family-centered approach.

Did you know?

This method results in earlier skin-to-skin contact, which has been associated with earlier breastfeeding initiation.

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) offered a unique opportunity to combine multidisciplinary expertise on urban health from health care and academic institutions. Seventeen years later, those founding institutions remain committed to improving the health and well-being of urban populations.

Improving neighborhood life expectancy

Advocate Aurora Health recently announced its plan to help lessen economic, racial and environmental disparities in Illinois and Wisconsin through a five-year, $50 million initiative.

The project will begin in 2020 and focus on low-income communities with lower life expectancies. The project’s partners will work with leaders of small and diverse business development and affordable housing initiatives, community health centers, and food centers.

CUPH researchers Kayla Heslin and David Frazer created a baseline study of the life expectancy at birth for the zip codes served by Advocate Aurora, which will allow the health system to prioritize specific neighborhoods for investment and track health improvement over time.

$50M pledged by Advocate Aurora Health over five years to help lessen economic, racial and environmental disparities
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 region 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 Aurora Health Foundations at 877-460-8730 or donate online to Advocate Research Institute at donate.advocategiving.org/research and Aurora Research Institute at give.aurora.org/research.

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

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.

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

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