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.

Randall Lambrecht, PhD
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System Vice President, Advocate Aurora Health

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The annual report is presented by the office of the president of Advocate Aurora Health Research Institute, which oversees research conducted throughout Advocate Aurora Health.

On the cover:
(top left) Judy Tjoe talks with a patient. (top right) Andrew Van Bergen reunites with his patient, Tanner (right), and his sister, Madeline. (middle) Sigrun Hallmeyer talks with a patient. (bottom) Research scientists and technologists experiment in Discovery Laboratory.
In 2018, Advocate Health Care and Aurora Health Care merged to create one of the largest nonprofit health systems in the United States — Advocate Aurora Health. Integration of these two contiguous health systems will result in more research opportunities to further improve patient outcomes and transform the lives of individuals and populations.

Our two research institutes, Advocate Research Institute and Aurora Research Institute, are working to integrate into a single Advocate Aurora Health Research Institute. With this inaugural annual report, our goal is to share research highlights from last year in which both entities worked toward transforming care.

Our stories showcase how knowledgeable scientists and passionate clinicians with research questions transform discoveries into health care innovations. The newly integrated health system brings our researchers nearly twice the depth of electronic health record data to mine, greater diversity in biospecimens to study, and more opportunities for academic, government and industry sponsor collaborations. This will allow us to accelerate discovery, ultimately leading to quicker delivery of new options for our patients, improved treatments and reductions in health care costs overall.

We gain inspiration from our research subjects, who willingly participate in studies, often with little benefit for themselves. We dedicate this report to the thousands of patients we are partnering with to advance health and medicine for future generations.

On behalf of the research institute and its board of directors, I am pleased to provide this highlight of our 2018 outcomes.

Helping people live well through innovative research,

Randall Lambrecht, PhD
President, Advocate Aurora Health Research Institute
System Vice President, Advocate Aurora Health
## Board of Directors

The Advocate Aurora Health Research Institute board of directors consists of Advocate Aurora Health leaders and serves in an advisory capacity, helping to shape the institute’s future.

**President:**
Randall Lambrecht, PhD

**Chair:**
Dennis Potts

**Members:**
Jeffrey Bahr, MD  
Vincent Bufalino, MD  
Rachelle (Shelly) Hart, JD  
Michael Lappin, JD  
Nan Nelson  
Ajay Sahajpal, MD

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## Research Institute leadership

### Executive Team

- **Randall Lambrecht, PhD**  
  President, Advocate Aurora Health Research Institute  
  System Vice President, Advocate Aurora Health

- **Denise Angst, PhD, RN**  
  Vice President, Research

- **Kelly Piacsek, PhD**  
  Vice President, Research

- **Kurt Waldhuetter**  
  Vice President, Research Development and Business Services

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### Advocate Research Institute

#### Directors

- **Christopher Blair**  
  South Central Region and Patient-Centered Outcomes Research

- **Wendy Landow**  
  Research Operations

- **Cheryl Lefaiver, PhD, RN**  
  Advocate Center for Pediatric Research

- **Katie Wozniak**  
  Oncology, Neuroscience and Specialty Research;  
  Russell Center for Research and Innovation;  
  and Leona Loeb Memorial Cancer Research Laboratory

- **Laura Wrona, MSN**  
  Cardiovascular Research

#### Managers

- **Rasha Alkhatib, PhD**  
  Patient-Centered Outcomes Research

- **Carlos Corado**  
  Neuroscience and Specialty Research

- **Veronica Fitzpatrick, DrPH**  
  Patient-Centered Outcomes Research

- **Jillian Lux**  
  Cardiovascular Research

- **Sandy Maki**  
  Pediatric Research

- **Dana Villines**  
  Patient-Centered Outcomes Research

#### Leads

- **Darilyn Greenhow, RN**  
  Quality Assurance Program

- **Jan Lewis**  
  Research Billing

#### Aurora Research Institute

#### Directors

- **Amy Beres, PhD**  
  Oncology Research

- **Nina Garlie, PhD**  
  Neuroscience and Specialty Research

- **Michelle Simpson, PhD, RN**  
  Ed Howe Center for Health Care Transformation

#### Chief Scientific Strategist

Amin Kassam, MD

#### Medical Research Directors

- **Dennis Baumgardner, MD**  
  Aurora UW Medical Group and Editor-in-Chief, Journal of Patient-Centered Research and Reviews (JPCR)

- **Michael Thompson, MD, PhD**  
  Early-Phase Cancer Clinical Trials,  
  National Cancer Institute Community Oncology Research Program  
  Co-Principal Investigator and Oncology Precision Medicine Co-Director

- **Judy Tjoe, MD**  
  Breast Cancer (Translational Oncology Research: Quest for Understanding & Exploration, TORQUE)

#### Managers

- **Julie Basquin**  
  Financial Planning

- **Shivam Bharti**  
  Research Business Innovation

- **Karen Cheek, RN**  
  Oncology Clinical Trials

- **Wendy Dunaj, RN**  
  Cardiovascular Clinical Trials

- **Katie Klein**  
  Research Publications

- **David Krum**  
  Translational Research

- **Rajeev Kumar, PhD**  
  Translational Research

- **Andy Marek**  
  Research Analytics

- **Karen Michel**  
  Translational Research

- **Annette Paul**  
  Aurora BayCare Medical Center Research

- **Natalie Polinski**  
  Biorepository Program

- **Katie Richter**  
  Clinical Trial Business Services

- **Carol Tutino, BSN**  
  Neuroscience and Specialty Clinical Trials

- **Mindy Waite, PhD**  
  Research Grants and Projects

#### Supervisors

- **Carla Fuentes**  
  Oncology Clinical Trials

- **Jennifer Mathieu**  
  Oncology Clinical Trials
In 2018, Advocate Aurora Health Research Institute supported more than 1,350 unique clinical trials and outcomes research projects, preclinical studies, and other research activity throughout Advocate Aurora Health. Employing more than 270 team members, the research institute provides infrastructure and oversight of different types of research that span clinical focus areas and sites.

The research institute, a not-for-profit, limited liability company of the integrated health system, was a $35.7 million operation in 2018. Under the leadership of Randall Lambrecht, PhD, the research institute is focused on discovering new findings and transforming those discoveries into innovative care for individuals and populations.

Types of research
- Clinical research (patient-centered clinical trials and outcomes research)
- Preclinical research (basic, 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
- Neuroanatomy Laboratory
- Translational Oncology Research: Quest for Understanding & Exploration (TORQUE)

Infrastructure
- Research Institute
  - Patient-Centered Clinical Research
  - Preclinical Scientific Discovery
  - Quality Assurance and Education
  - Research Communications and Publications
  - Research Development and Business Services
  - Research Innovation
  - Sponsored Programs Office
- Health System
  - Compliance
  - Finance
  - Legal
  - Pharmacy
  - Human Resources
  - Information Technology
  - Research Subject Protection Program

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.
Clinical trials management systems, single electronic health record make doing research easier

Aurora Research Institute in 2018 signed a five-year, $1.8 million contract with Forte Research Systems to transition to its OnCore clinical trials management system (CTMS).

The OnCore system will provide the institute with a comprehensive tool for managing research studies and their participants. Insights gained from the new CTMS will allow the institute to connect more patients with more targeted clinical trials and ensure quality, compliant and sustainable practices.

“The investment will lead to tangible improvements in clinical research processes and patient care,” said Kurt Waldhuetter, vice president of research development and business services.

Efficiency, capacity

A best-in-class clinical trials management system became necessary as the institute’s research portfolio continued to grow in size and complexity, according to the project’s point person, Katie Rowe, research management systems analyst on the Research Analytics team. Of the institute’s more than 680 research projects in Wisconsin, more than 300 are clinical trials. Research coordinators are performing data entry in multiple systems, most of which is duplicative in nature, Rowe said.

The transition will require a 12- to 15-month system rollout, which will be completed by the end of 2019.

Integration, expansion

In Illinois, Advocate Research Institute utilizes IBM Clinical Trial Management System for Sites to manage its portfolio of more than 300 clinical trials.

As integration of Advocate Aurora Health Research Institute continues, work will begin to move the Illinois trials to OnCore, allowing seamless management of Wisconsin and Illinois clinical trials in a single system. That work will commence in 2020 and will include an extended rollout.

That rollout will keep pace with the EPIC implementation in Illinois to bring Advocate Health Care sites onto the same electronic health record system as Aurora Health Care. This work started in 2018 and will continue until Advocate Aurora Health uses one electronic health record.

The investment will lead to tangible improvements in clinical research processes and patient care.

Kurt Waldhuetter
Vice President of Research Development and Business Services
Welcome and Overview

Journal reaches milestone with more than 100,000 article downloads since 2014 launch

Published quarterly by Aurora Health Care through Aurora Research Institute, Journal of Patient-Centered Research and Reviews is dedicated to improving patient outcomes and care experiences by sharing open access scholarly works by authors from around the world. In 2018, JPCRR completed its fifth year of publishing transformative, peer-reviewed medical science.

All articles published in JPCRR are available online. By the end of 2018, these articles had been downloaded more than 100,000 times by readers in 180 countries. Readership has increased every year since the journal’s launch and is split evenly between U.S. and international readers.

“Just as the journal’s readership has grown, so has the scope of authors submitting works,” Editor-in-Chief Dennis Baumgardner, MD, said. “This diversity of contributors reflects JPCRR’s impact as a truly global medical journal.”

JPCRR was founded with generous support from the Robyn Temkin Memorial Fund and receives continuing support from individual sponsors through donations to Aurora Health Care Foundation. To make a gift to research, visit give.aurora.org.

Visit aurora.org/jpcrr to browse content, submit a manuscript or sign up to receive email notifications. The editorial office can be reached at JPCRR@aurora.org. Follow the journal on Twitter @JPCRR.

Photo: Joe Grundle (left), who serves as managing editor, discusses an upcoming issue of the journal with Dennis Baumgardner.
Aurora Research Institute launched in 2018 the Ed Howe Center for Health Care Transformation and named Michelle Simpson, PhD, RN, as its inaugural director.

The Howe center 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.

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 Russell center research is to enhance the quality of care and improve health outcomes for individuals and the community.

Led by Director Katie Wozniak, Russell center provides coordination and regulatory support for clinical trials and resources from study design and statistical support through medical writing for investigator-initiated, patient-centered outcomes research.

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

- Small Research Project Grants Program, which provides seed funding for innovative, investigator-initiated research projects (check out Page 52)
- Embedded Physician-Scholar Program, which gives protected research time to selected physician investigators (check out Page 61)
- Summer Research Internship Program, which pairs Rosalind Franklin University of Medicine and Science students with Advocate investigators, providing researchers with extra help and affording students an invaluable research experience (check out Page 8)

Dr. Simpson is an experienced clinician and well-funded researcher who most recently served as a senior research scientist focused on older adult care, acute and chronic cognitive impairment, transitions of care, and post-acute rehospitalization.

Dr. Simpson’s first order of business was to establish the Ed Howe Center for Health Care Transformation Seed Grant Program to support research projects that fit the center’s research mission and to help investigators gather sufficient preliminary data that will enable them to publish and create highly competitive research proposals for future extramural support.

Michelle Simpson (standing) and Christine Kovach (right), describe the measurement of muscle strength for an upcoming study to a couple at Ovation Communities.

Veronica Fitzpatrick (left) and Yangyang Liu discuss patient-centered outcomes research at Russell Center for Research and Innovation.
Cultivating future researchers, health care leaders

Russell center pairs medical students, physician researchers

Advocate Research Institute’s James R. & Helen D. Russell Center for Research and Innovation in 2018 matched seven second-year medical students from Rosalind Franklin University of Medicine and Science with investigators who served as mentors as part of the Summer Research Internship Program.

Research interns worked with investigators on adult and pediatric research projects at Advocate Lutheran General Hospital and Advocate Children’s Hospital-Park Ridge. In addition to gaining clinical research experience, the interns received weekly educational research sessions coordinated by the institute. Interns were also invited to attend hospital-based resident lectures and department-specific conferences, grand rounds and journal clubs.

At the end of summer, research interns presented their projects through oral and scientific poster presentations at Advocate Lutheran General Hospital and Rosalind Franklin University.

Aurora Research Institute ‘graduates’ largest group of summer interns

Aurora Research Institute launched its Summer Student Internship Program in 2011 to provide promising future researchers hands-on experiences that will give them an edge as they pursue health care careers. The institute has since collaborated with two long-standing Aurora Health Care research internship programs — Aurora Metro Medical Staff Summer Research Fellowship Program and Aurora BayCare Medical Center Research Internship Program.

When combined, the three programs supported 34 students in 2018, the most since the institute launched its program eight years ago with two students.

Clinical, laboratory-based and professional opportunities were available. Each intern was paired with one or more mentors. Together, mentors and interns researched different health care topics or worked on different projects throughout the summer, culminating with each intern presenting a capstone project to the institute and guests at a symposium designed to prepare participants for future scientific and professional presentations.

Touring the institute

Advocate Aurora Health Research Institute welcomes students to tour facilities and shadow researchers.

Through NEWaukee’s Make It in Milwaukee program, which provides college students with a free trip to the city to learn about Advocate Aurora Health’s career opportunities, participants toured the institute’s Discovery Laboratory. Additionally, the institute participated in Discovery World’s Inside the Human Body summer camp, inviting campers on a tour of the Neuroanatomy Laboratory.

Donors to Aurora Health Care Foundation make the Aurora Metro Medical Staff Summer Research Fellowship Program possible and partially support cardiovascular initiatives through the Aurora Research Institute Summer Student Internship Program.
Biorepository and Specimen Resource Center

Powered by ORBIT (Open-Access Robotic Biorepository and Informatics Technology)

Biorepository and Specimen Resource Center collects, processes, stores and distributes biospecimens from consenting research participants throughout Aurora Health Care. This allows researchers, academic institutions and pharmaceutical companies throughout the country to advance innovative research to improve patient outcomes.

Supported by the institute’s Research Analytics team, the ORBIT system identifies eligible blood products (whole blood, plasma and serum), and these biospecimens are then linked to the electronic health record so 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

Supported by a generous gift by the Loeber family made in memory of their late mother

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

In addition, the lab supports collaborations with multiple academic and industry partners, serving as a beta site for evaluation of new laboratory 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.
2018 data summary

Research funding sources

$35.7M
Advocate Aurora Health Research Institute expenditures

$9.7M
Advocate Research Institute expenditures

$25.9M
Aurora Research Institute expenditures

More than
71K
inventory of whole blood, plasma and serum samples

554
tissue collections in 2018

500
samples stored and shipped

165
coordinator sample processing requests fulfilled, supporting 15 projects

Cardiovascular
342
62%

Oncology
165
29%

Neuroscience
49
9%

Institutional Investment
19,864,417
56%

External Contracts and Grants
12,139,009
34%

Philanthropic Support
3,394,158
10%

Other
275,827
1%

Institutional Investment
3,652,957
38%

External Contracts and Grants
4,859,288
50%

Philanthropic Support
1,216,414
13%

Other
2,076
<1%

Institutional Investment
16,211,460
62%

External Contracts and Grants
7,279,721
28%

Philanthropic Support
2,177,444
8%

Other
273,751
1%

Welcome and Overview
External grants awarded

$2.8M
Advocate Aurora Health Research Institute external grants awarded*

*Excludes Advocate Research Institute grant-funded clinical trial awards

$207K
Advocate Research Institute external grants awarded*

$2.6M
Aurora Research Institute external grants awarded*

Internal grants awarded

$411K
Advocate Aurora Health Research Institute internal grants awarded

$137K
Advocate Research Institute internal grants awarded

$273K
Aurora Research Institute internal grants awarded

Oncology
(Cardiovascular)
(Pediatric)
(Stem Cell and Regenerative Medicine)
(Translational Science)
Research participants

2,964
Advocate Aurora Health Research Institute total newly consented research participants*

765
Advocate Research Institute total newly consented research participants

2,199
Aurora Research Institute total newly consented research participants

Scientific articles

460
Advocate Aurora Health-authored, peer-reviewed journal articles

286
Advocate Health Care-authored, peer-reviewed journal articles

174
Aurora Health Care-authored, peer-reviewed journal articles

*Excludes biorepository consents
Total research

1,358
Advocate Aurora Health Research Institute unique* research projects**

*Duplicate projects excluded

**Projects include clinical trials and outcomes research, preclinical studies, and other research activity

Preclinical studies

58
Advocate Aurora Health Research Institute preclinical studies

9
Advocate Research Institute preclinical studies

49
Aurora Research Institute preclinical studies

710
Advocate Research Institute research projects

687
Aurora Research Institute research projects
2018 Annual Report

Welcome and Overview

Clinical trials

645
Advocate Aurora Health Research Institute unique* clinical trials

331
Advocate Research Institute clinical trials

349
Aurora Research Institute clinical trials

Clinical outcomes research projects

577
Advocate Aurora Health Research Institute unique* clinical outcomes research projects

336
Advocate Research Institute clinical outcomes research projects

241
Aurora Research Institute clinical outcomes research projects

*Duplicate clinical trials excluded

*Duplicate projects excluded
Cardiovascular research
Advocate Aurora Health Research Institute supports 352 clinical, preclinical and other cardiovascular research studies throughout Advocate Aurora Health in Illinois and Wisconsin.

With the help of 779 newly consented research participants, we advanced cardiovascular research focused on heart failure, structural and coronary heart disease, and abnormal heart rhythms in 2018. Because of the willingness of research participants to sign up for these experimental new treatments or procedures, new medical breakthroughs are made every day. And from this research, clinical trial sponsors — often device and pharmaceutical companies — obtain Food and Drug Administration (FDA) approval to make these treatments and procedures broadly available.

Learn about one of our research participants on Page 17. She participated in a clinical trial studying a drug to treat chronic heart failure, contributing to findings published in New England Journal of Medicine.

At the bench, our preclinical laboratory scientists are studying ways to measure electrical signals in heart cells to advance research of abnormal heart rhythms. Instead of using living heart tissue, which is difficult to obtain, these scientists are using an innovative method to grow beating heart cells in a dish to support their research.

Cardiovascular research requires significant resources. In 2018, Advocate Aurora cardiovascular researchers were awarded $518,080 through grants from external sources and institute programs that are supported by the generosity of donors to Aurora Health Care Foundation.

Advocate Aurora’s cardiovascular researchers have shared their expertise with the world through the scholarly activity of scientific publication, with 145 peer-reviewed articles in 2018. These studies are conducted by dedicated clinicians and scientists seeking to translate research findings into improved practices and cardiovascular health outcomes for our patients.
Mother of two and grandmother of seven, Jacqueline Castellano of Elmhurst, Illinois, will always remember how she spent Mother’s Day 2016 — hospitalized because of acute heart failure.

The then 71-year-old had suddenly felt exhausted and weak, her breathing becoming severely labored and her blood pressure dropping to a dangerously low level.

She didn’t yet know her condition would allow her to contribute to a clinical trial studying a new treatment for chronic heart failure.

I needed a walker and was so out of breath, I couldn’t walk very far. I was very depressed. I wanted my normal life back.

Jacqueline Castellano
Research Participant

Willing to be a pioneer

Research participant contributes to clinical trial studying heart failure drug after an acute decompensated heart failure event

Acute heart failure

Heart failure occurs when the heart is unable to pump blood throughout the body as well as it should. When the pumping ability becomes suddenly weakened, it is referred to as acute heart failure.

Patients hospitalized after an acute heart failure episode receive treatments to help their heart regain sufficient pumping ability, often called hemodynamic stability. While hospitalized, Castellano met Debbie Heidenreich, BSN, senior research nurse.
coordinator at Advocate Research Institute, who provided information about the PIONEER-HF clinical trial, sponsored by Novartis.

Through the PIONEER-HF clinical trial, researchers sought to evaluate the safety and effectiveness of sacubitril-valsartan, a combination drug sold as Entresto, in participants who reached hemodynamic stabilization following acute heart failure hospitalization.

Although her condition had stabilized, Castellano initially remained fatigued, weak and unable to perform ordinary physical activities.

“I needed a walker and was so out of breath, I couldn’t walk very far,” she said. “I was very depressed. I wanted my normal life back.”

Castellano elected to participate in the study and was randomly assigned to receive either Entresto or standard drug treatment. Neither Castellano nor the clinical research team knew which drug was assigned, consistent with routine clinical trial protocol.

After discharge home, she returned for follow-up visits with Heidenreich and Ali Valika, MD, cardiologist at Advocate Medical Group, Elmhurst, and principal site investigator of the PIONEER HF study. Castellano’s health slowly improved.

Clinical trial results

The Pioneer-HF trial was open for enrollment at 129 U.S. sites, including three Advocate Health Care locations, where 14 participants were enrolled.

Trial findings, published in New England Journal of Medicine and presented at the American Heart Association’s 2018 Scientific Sessions, revealed that, compared to participants taking standard treatment, research participants hospitalized for heart failure who took Entresto had lower levels of a heart failure biomarker, a result associated with better outcomes and quality of life.

“This is a major win for the one million heart failure patients hospitalized each year,” said

Did you know?

More than six million people in the United States live with heart failure.

Maria Rosa Costanzo, MD, medical director of heart failure research at Advocate Heart Institute and one of the trial’s site principal investigators at Advocate Medical Group, Naperville, Illinois.

Leslie Ann Brookfield, MD, also served as site principal investigator for Advocate Lutheran General Hospital, Park Ridge, Illinois.

Heart-healthy living

As for Castellano, the vibrant 75-year-old now walks, drives and lives independently. During basketball and hockey seasons, she can often be found in the bleachers at her grandchildren’s games, cheering them on. Castellano adheres to a heart-healthy diet, watches her fluid intake, maintains a consistent weight and sees Dr. Valika for regular follow-up visits.

Through it all, she continues to feel gratitude for Heidenreich, Dr. Valika and the entire study experience.

“I cannot stress enough the support and kindness and caring that they gave me,” she said of the research team. “Debbie was so patient with me, so helpful. I could call her anytime, and she would call to check on me. They’re all angels, and I appreciate everything they’ve done.”

Did you know?

More than six million people in the United States live with heart failure.
When migraine symptoms turned into something much worse, a now-FDA approved device saved a woman's life

Jessica Thompson, then 29, was getting ready for bed when she started having migraine symptoms. Going to bed with a migraine was nothing unusual for her. She thought she could sleep it off and asked her husband to wake her in the morning so she wouldn’t be late for breakfast with friends.

One January night in 2014, Jessica Thompson, then 29, was getting ready for bed when she started having migraine symptoms. Going to bed with a migraine was nothing unusual for her. She thought she could sleep it off and asked her husband to wake her in the morning so she wouldn’t be late for breakfast with friends.

“I went to bed thinking I had a migraine, but the next morning I didn’t wake up,” Thompson said. “At first my husband thought I was joking, but then he called 911.”

Thompson, from Bristol, Wisconsin, was rushed to a nearby hospital, where tests revealed she’d suffered a stroke.

“They found a hole in my heart, and told me there was little they could do,” Thompson said.

Undeterred, Thompson’s sister began researching her condition and found a clinical trial taking place at Aurora St. Luke’s Medical Center in Milwaukee. The study was evaluating the GORE CARDIOFORM Septal Occluder, an umbrella-like device that is permanently implanted in the heart to close a patent foramen ovale (PFO), a hole in the heart that didn’t close properly after birth.

Thompson was soon put in touch with Deborah Waller, BSN, research nurse coordinator, who managed the clinical trial for Aurora Research Institute. After Thompson had enrolled in the trial, but shortly before her surgery to receive the implant, she suffered another attack that blocked blood flow to her brain. Subsequent tests revealed she had a second hole in her heart.

“Fortunately, the septal occluder was able to cover both holes,” said Tanvir Bajwa, MD, the cardiologist who performed the surgery and site principal investigator. “The device was implanted through a catheter, which allowed for minimal recovery time.”

Since her February 2014 surgery, Thompson, now 34, hasn’t had any more strokes or migraines.

Based on the results of research participants like Thompson, the device received Food and Drug Administration approval in April 2018 for the closure of PFO to reduce the risk of recurrent stroke in certain patients. (GORE CARDIOFORM Septal Occluder was not designed for the treatment of migraines.)

Thompson has some memory loss from her stroke, but that night when she asked her husband to wake her up the next morning remains crystal clear.

“Every day since,” she said, “he wakes me up in the morning.”

I went to bed thinking I had a migraine, but the next morning I didn’t wake up.

Jessica Thompson (back right) is pictured with her husband, Mike (back left), and her children (front, left to right) Colten, Peyton and Jacob.

Wake-up call

Jessica Thompson (back right) is pictured with her husband, Mike (back left), and her children (front, left to right) Colten, Peyton and Jacob.

Did you know?
According to American Heart and Stroke Association, 25 percent of the general population has a hole in the heart that didn’t close properly after birth.
Clinical trials roundup

Not your conventional pacemaker

Aurora St. Luke’s Medical Center, Milwaukee, and Aurora Health Center-Lake Geneva are the only sites in Wisconsin to participate in an international heart failure clinical trial studying a new leadless pacemaker.

The WiSE CRT System, pictured, is an implantable cardiac pacing system that delivers pacing energy to the left ventricle of the heart without using a pacing lead. Instead, the system paces the heart via a tiny wireless electrode, the size of a grain of rice, implanted directly in the heart’s left ventricle.

The study will evaluate WiSE-CRT in patients with heart failure who failed to respond to or could not receive conventional cardiac resynchronization therapy.

Electrophysiologist Imran Niazi, MD, is the site principal investigator for the study, known as SOLVE CRT, which is sponsored by EBR Systems Inc.

Preventing rehospitalization for heart failure

Advocate Aurora Health researchers are examining the effectiveness of the CardioMEMS HF System in an expanded population. Having contributed to Food and Drug Administration approval for New York Heart Association Class III heart failure, researchers will study whether the CardioMEMS device can reduce heart failure hospitalization and improve survival and quality of life for people living with Class II and IV heart failure through the trial known as GUIDE-HF.

The CardioMEMS HF System from Abbott supports heart failure management by measuring pulmonary artery pressure from within the body.

Seven Advocate Health Care locations are participating, along with Aurora St. Luke's Medical Center, Milwaukee. Cardiologist Maria Rosa Costanzo, MD, is the principal investigator for the Advocate sites. Cardiovascular disease specialist Nasir Sulamanjee, MD, is the site principal investigator for Aurora St. Luke's.

Hypertension care without medications

Aurora St. Luke’s Medical Center, Milwaukee, is the only site in Wisconsin to offer a clinical trial to evaluate a device for patients with high blood pressure or hypertension.

The study will assess use of the investigational Symplicity Spyral renal denervation system, pictured, in participants with hypertension without use of antihypertensive medications. Renal denervation is a minimally invasive procedure that can regulate the nerves leading to and from the kidneys with the intent of lowering blood pressure.

Interventional cardiologist Suhail Alaqaband, MD, is the site principal investigator for the trial, “SPYRAL HTN-OFF MED Study,” sponsored by Medtronic Vascular.

Nicole Baecker escorts a clinical trials participant at Aurora St. Luke’s Medical Center.
Sullivan Cardiac Research Award funds research evaluating antiplatelet medication absorption

Patients with coronary artery disease often require stents to open narrowed or blocked arteries. To prevent serious and sometimes fatal stent-related complications, patients take antiplatelet medications like ticagrelor. With the help of a $30,000 Sullivan Cardiac Research Award for Residents and Fellows, cardiovascular disease fellow Thomas Wilson, MD, is examining whether ticagrelor is absorbed faster when chewed rather than swallowed whole.

The award is available thanks to a $1 million donation in 2014 by Tim Sullivan, who was a member of Aurora Health Care’s board of directors, and his wife Vivian Sullivan to support the research of Tanvir Bajwa, MD.

Researchers seek to improve care for apparent heart attack

Researchers are conducting a study to advance patient care and reduce unnecessary use of health care resources for patients evaluated in the emergency department for apparent heart attack.

Analysis of the data may lead to tools that help physicians select the best diagnostic test for specific symptoms and suspected diagnoses.

Choosing the most appropriate test is critical to ensuring an accurate diagnosis, which leads to prescribing the best treatment and decreasing the need for repeat testing or additional hospital visits.

Physicians may use single photon emission computed tomography myocardial perfusion imaging, exercise treadmill testing and echocardiography for patients with known or suspected cardiovascular disease.

Dana Villines, manager of patient-centered outcomes research for Advocate Aurora Health Research Institute, is leading a retrospective study of 12,130 patients evaluating use of these tests for patients admitted to the emergency department with probable type I myocardial infarction, or heart attack.

The goal of the study is to quantify which of these tests lead to the most accurate diagnosis and treatment plan based on the need for repeat testing and subsequent emergency department visits.

The research manuscript has been accepted for publication in a peer-reviewed scientific journal, with an expected release of study results in late 2019.

Astellas Pharma Global Development Inc. provided funding support.
Scientists publish study demonstrating new way to record action potentials, which may advance research in cardiac electrophysiology

Discovery Laboratory researchers developed a new, noninvasive approach to measuring long-term electrical activity in heart cells. The researchers published the study in the journal Stem Cell Reports.

“Our model will be valuable not only for studying heart cell development, but also for drug screening and disease modeling,” said Research Scientist Rosy Joshi-Mukherjee, PhD, who was the senior author on the article.

To study action potentials, the electrical signals that trigger contraction of heart cells, the research team used multielectrode array (MEA) technology, which has been used for other types of electrical recordings in cells, but has not been harnessed for action potential measurements.

The researchers used the MEA system to gain access to the inside of the cells and measure action potentials without any detrimental effects on the cells. This approach allows for measurements over the course of several days, enabling researchers to study heart cell biology and electrophysiology.

This new approach also allowed the researchers to simultaneously obtain high-resolution measurements from multiple cardiac cell networks, which is an improvement over other methods that only measure action potentials in one cell at a time, after which the cell dies.

Human cardiac cell samples can be difficult to obtain, so the researchers used induced pluripotent stem cell (iPSC) technology to generate beating heart cells in a dish. iPSC technology allows for the reprogramming of patient cells into an unlimited cell source for heart cell production.

The study, “A multiwell cardiac µGMEA platform for action potential recordings from human iPSC-derived cardiomyocyte constructs,” was funded by an Aurora Research Institute Cardiovascular Surgery Research Award supported by generous donors to Aurora Health Care Foundation.
EXTERNAL FUNDING

Influenza vaccine to effectively stop cardiothoracic events and decompensated heart failure
Investigator: Nasir Sulemanjee, MD
National Heart, Lung, and Blood Institute subaward from Brigham and Women’s Hospital
$150,000 (continuing support)

Predictive optimal anticlotting treatment for segmented patient populations
Investigator: Kourosh Ravvaz, MD, PhD
National Institutes of Health subaward from Harvard University
$120,035 (continuing support)

Using systems science methods to study cardiac risk in the Somali community
Investigator: Ahmed Dalmar, MD
National Institutes of Health subaward from HealthPartners Institute for Education and Research
$20,860 (continuing support)

Biomarkers to identify patients at risk for heart failure after cardiac surgery
Investigator: Farhan Rizvi, PhD
David V. Uihlein Foundation
$15,000
$10,000

Aortic wall stress in bicuspid aortic valves: Correlation with surgical outcomes
Investigator: Renuka Jain, MD
$45,800 (Cardiovascular Surgery Research Award)

Molecular dissection and signature of human atrial and ventricular fibroblasts
Investigator: Farhan Rizvi, PhD
$39,700 (Cardiovascular Surgery Research Award)

Implications of aorta calcification by routine CT scan and its implications on stroke after continuous flow ventricular assist devices
Investigator: Vinay Thohan, MD
$12,000 (Cardiovascular Surgery Research Award)

Chewed versus integral pill of ticagrelor in all patients undergoing primary percutaneous coronary intervention – a platelet reactivity and patient outcomes study
Investigator: Thomas Wilson, MD
$30,000 (Sullivan Cardiac Research Award for Residents and Fellows)

Impact of simultaneous exercise testing and measures of central hemodynamics on the clinical outcomes of patients supported with CF-LVADs
Investigators: Abdur Rahman Ahmad, MD; Owais Malick, MD
$24,050 (Sullivan Cardiac Research Award for Residents and Fellows)

Multiwell hiPSC-Cardiac μGMEA model for cancer drug induced cardiotoxicity
Investigator: Rosy Joshi-Mukherjee, PhD
$25,000 (Cardio-Oncology Research Award)

AXL expression and sAXL levels in patients with heart disease
Investigator: Nasir, Sulemanjee, MD
$5,014 (Research Seed Grant Program)

Various projects
Investigators: Abdulwahab Hritani, MD; Zuber Ali, MD; Moheen Khan, MD; Daniel Ortiz, MD; Vimalkumar Patel, MD; Bilal Omery, MD; Amir Chaudhari, DO; Daniel Harland, MD; Matthew McDiarmid, DO; Aditi Wani, MD; Robert Richmond, DO; Payal Sharma, MD
Total: $20,621 (Aurora Cardiovascular Services Research Support Fund)

INTERNAL FUNDING

$202K awarded to Aurora Health Care researchers by Aurora Research Institute

Cardiovascular research grants

Aurora Health Care

$316K awarded by external sources

Aurora Research Institute internal awards are possible due to the generosity of donors to Aurora Health Care Foundation.
Advocate Health Care 2016–2018

Aurora Health Care 2016–2018

Cardiovascular volumes

Source: Heartbase Cardiac Registry database

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Cardiovascular research projects

Cardiovascular research participants

Cardiovascular scientific articles

2016 Annual Report | 24
Oncology research
Making a difference in the fight against cancer, Advocate Aurora Health Research Institute supports 385 clinical, preclinical and other oncology research studies throughout Advocate Aurora Health — the most of any clinical focus area.

In 2018, we advanced research focused on breast cancer, leukemia, ovarian cancer and more with the help of 894 newly consented research participants. This research — often sponsored by National Cancer Institute (NCI) National Clinical Trials Network Groups or pharmaceutical companies — has changed our understanding of many cancers leading to more effective treatments.

Learn about one of our research participants on Page 27. She participated in a clinical trial studying a drug that was found to better control leukemia, prolong life and cause fewer side effects. The results immediately changed care for some patients with leukemia.

With its designation as one of 34 NCI Community Oncology Research Program (NCORP) sites in the country, Aurora Health Care provides access to cancer clinical trials close to home in Wisconsin. Advocate Health Care’s cancer clinics will integrate its active clinical trials program with Aurora NCORP as part of the systems’ 2018 merger, increasing access to cancer clinical trials in Illinois.

Through our translational breast cancer research program, TORQUE, our preclinical laboratory scientists are searching for genetic biomarkers to predict resistance to cancer treatment. Too often, cancer therapies initially work, but over time the cancer stops responding to the treatment. Knowing which patients may develop a resistance would guide treatment selection.

Advocate Aurora oncology researchers in 2018 were awarded $1,454,281 through grants from external sources and institute programs that are supported by the generosity of donors to Aurora Health Care Foundation.

Translating research findings into the latest oncology advances, Advocate Aurora’s oncology researchers have shared their expertise with the world through scientific publication, with 53 peer-reviewed articles in 2018.

Wendy Walters (left) and Michael Thompson meet with an oncology clinical trial participant.
How an experimental anticancer therapy changed the life of one leukemia patient and what it means for others

Choosing to participate in a clinical trial “takes a little soul-searching,” said Rosalie Henschel, who was diagnosed with chronic lymphocytic leukemia (CLL) in 2012 at the age of 63.

Research participants aren’t guaranteed any benefit to themselves. The goal of most clinical trials is to prove a drug or device is effective and, possibly, the new standard of care for future patients. In a randomized controlled trial, participants are randomly assigned the experimental treatment or the current standard or a placebo.

“What if this drug I receive is not the good one?” Henschel asked, referring to the experimental drug. “But I knew it would help somebody down the line. That’s what kept me going. It made me feel like it was important to do.”

In Henschel’s case, she did receive the experimental drug treatment, ibrutinib-based anticancer therapy studied as part of a phase 3 clinical trial known as ECOG-ACRIN E1912 (National Institutes of Health award number 5UG1CA190140). The findings from the first analysis immediately established ibrutinib-based therapy as a new standard of care for patients who are diagnosed with CLL before turning age 71.

Henschel, now 70, was one of 15 Aurora Health Care participants to volunteer for the trial supported by Aurora Research Institute.

Cancer journey

An elementary school librarian aid for 25 years in Elkhart Lake, Wisconsin, Henschel and her family were blindsided by her CLL diagnosis. Henschel is a grandmother to nine and a mother of three, whom she raised on an Elkhart Lake dairy farm with her husband, Gary.

CLL is the most common type of leukemia in adults, according to American Cancer Society. It typically occurs during or after middle age and rarely occurs...
in individuals younger than 40. The cancer is termed “chronic” because it develops very slowly, beginning in certain white blood cells called lymphocytes in the bone marrow and spreading into the blood.

“Even though most patients with CLL don’t show symptoms at the time of diagnosis, and may go several years before starting treatment, the diagnosis can still be very difficult for families, as they must plan and wait for the inevitability of cancer treatment,” said Henschel’s hematologist and oncologist, Cheruppolil Santhosh-Kumar, MD.

Following her diagnosis, Henschel’s leukemia progressed for more than two years before she and Dr. Kumar decided to begin treatment. She met the lengthy list of inclusion criteria for the trial and, after some discussion with her family, ultimately decided to enroll in the study.

“She had developed increased pain, night sweats and progressive lymphadenopathy, a disease that causes swelling of the lymph nodes,” said Mary Theodoroff, BSN, senior research coordinator. “After only one cycle of treatment, many of her enlarged lymph nodes had completely resolved and several others significantly decreased in size. Her other symptoms also improved soon after treatment began with ibrutinib.”

Henschel received treatment as part of the study for 27 months, until March of 2017. It ultimately took some time for her blood work to show that the cancer was disappearing and that the study treatment was working, but, sure enough, she is now in remission.

Did you know?
Chronic lymphocytic leukemia is the most common type of leukemia in adults.

New standard of care
Just as it did for Henschel, the ibrutinib-based therapy proved so successful for other participants that ECOG-ACRIN Cancer Research Group’s Data and Safety Monitoring Board overseeing the trial recommended that the study results be released immediately given their significance to public health. Researchers presented the data as a late-breaking abstract at the American Society of Hematology annual meeting in December 2018.

Sponsored by National Cancer Institute, the trial found that the combination of ibrutinib, taken in pill form, plus rituximab, a type of antibody therapy, was superior to the current standard treatment, a combination of other chemotherapy drugs with rituximab, for research participants age 70 and younger newly diagnosed with CLL. The trial showed that the combination of ibrutinib and rituximab not only provided better leukemia control, but also prolonged life and had fewer side effects.

“Based on the findings from the analysis of the E1912 trial,” said Aurora Health Care oncologist Rubina Qamar, MD, the institute’s principal investigator for the trial, “ibrutinib-based therapy becomes a new standard of care for the initial treatment of CLL in patients age 70 and younger.”
Aurora NCORP receives increased fifth-year funding, applies for six-year grant renewal

As one of 34 National Cancer Institute (NCI) Community Oncology Research Program (NCORP) community sites nationwide, Aurora Health Care provides access to cancer clinical trials locally.

Conducting clinical trials in a range of communities small and large means that a more diverse patient population can participate in clinical trials in “real-world” health care settings. This expanded access to clinical trials, in turn, generates more broadly applicable evidence that contributes to improved patient outcomes and a reduction in cancer disparities.

Thomas Saphner, MD, and Michael Thompson, MD, PhD, serve as principal investigators for Aurora NCORP.

In 2018, for the fifth year in a row, NCI increased the annual grant allotment to Aurora NCORP, supported by Advocate Aurora Health Research Institute, bringing the total for the five-year grant to $4,601,617, more than half of a million dollars beyond the projected amount.

NCI designated Aurora as an NCORP site in 2014 with a grant award of $3.8 million over five years (National Institutes of Health award number 5UG1CA190140). The five-year NCORP grant cycle ends in 2019.

In year four of its grant, Aurora NCORP was once again recognized by Alliance for Clinical Trials in Oncology as a top 50 enrolling site. The program enrolled 339 research participants in the fourth grant year compared to 249 in the third grant year.

In year five of its grant, Aurora NCORP added a new cancer clinic, the Vince Lombardi Cancer Clinic at Aurora St. Luke’s South Shore in Cudahy, Wisconsin.

Twelve Advocate Health Care oncology sites will be integrated with Aurora NCORP, following Aurora Health Care’s 2018 merger with Advocate Health Care into Advocate Aurora Health.

Aurora NCORP’s application for a renewed six-year NCORP grant took into account the merger, requesting additional funds to support the clinical trials at Advocate clinics, including pediatrics trials at Advocate Children’s Hospital’s two locations.

Increased grant allotment

Did you know?
Advocate Aurora Health serves approximately 16,500 newly diagnosed adult and pediatric cancer patients annually throughout Wisconsin and Illinois.

Access to cancer clinical trials close to home

More than 50 NCORP clinical trials open to accrual
New cancer therapy receives FDA approval with help of Advocate Aurora Health researchers

Advocate Aurora Health Research Institute contributed to the recent Food and Drug Administration approval of a new treatment approach for several cancers that affect women through participation in a national clinical trial.

The NRG Oncology GOG-0218 trial studied the use of the tumor-starving drug bevacizumab on its own after the combination of chemotherapies carboplatin and paclitaxel with bevacizumab as an upfront treatment for women with advanced stage III or IV ovarian, fallopian tube or primary peritoneal cancer following initial surgery to remove the cancer.

“Bevacizumab is a protein designed in a lab to block the blood supply that feeds a tumor, which can stop it from growing and spreading,” said hematologist and oncologist Timothy Lestingi, MD, who served as site principal investigator for Advocate Lutheran General Hospital, Park Ridge, Illinois. “Adding this drug after combining it with chemotherapy may allow people to live longer without cancer growing or spreading.”

Researchers found that the median length of progression-free survival was 18.2 months for women treated with bevacizumab alone, compared to 12.8 months for women treated with bevacizumab and chemotherapy but with no single-agent bevacizumab following initial treatment.

“FDA approval of this combination chemotherapy treatment allows for its availability to a vastly greater number of patients,” said gynecological oncologist Elizabeth Dickson Michelson, MD, who was the Aurora Health Care principal investigator for the trial. “This is exciting news for gynecological oncologists, as new cancer therapies such as this can improve the lives of women with ovarian cancer.”

Aurora enrolled 24 participants and Advocate enrolled 14. Nationally, the trial enrolled 1,873 women at 632 sites.

The study was conducted by Gynecologic Oncology Group, now part of NRG Oncology, and was sponsored by the Cancer Therapy Evaluation Program, part of the National Cancer Institute under its Cooperative Research and Development agreement with Genentech, maker of bevacizumab (National Institutes of Health award number U10CA027469).

Adding this drug after combining it with chemotherapy may allow people to live longer without cancer growing or spreading.

Timothy Lestingi, MD
Hematologist and Oncologist

38 participants enrolled in this study by Advocate Aurora Health
Largest study ever done of breast cancer treatment changes care for patients at intermediate risk

Results from an international breast cancer study, supported by Advocate Aurora Health Research Institute investigators, found that most women with node-negative breast cancer can safely skip chemotherapy when guided by a diagnostic test.

Aurora Health Care oncologist Thomas Saphner, MD, co-authored the New England Journal of Medicine article reporting the results of the “Trial Assigning Individualized Options for Treatment (Rx),” or TAILORx, in June 2018. TAILORx was available in Wisconsin at all Aurora Cancer Care clinics. In Illinois, the site principal investigators were hematologist and oncologist Sigrun Hallmeyer, MD, at Advocate Lutheran General Hospital, Park Ridge, hematologist Rami Haddad, MD, at Advocate Christ Medical Center in Oak Lawn, and Deepti Singh, MD, at Advocate Illinois Masonic Medical Center in Chicago.

“At the TAILORx study results are revolutionary and will immediately help inform treatment decisions for many women with breast cancer recurrence,” Dr. Saphner said.

Researchers enrolled 10,273 women from across the U.S., Australia, Canada, Ireland, New Zealand and Peru. Advocate Aurora Health enrolled a total of 99 participants.

When patients enrolled in the trial, their tumors were analyzed using a molecular test that assessed 21 genes known to be associated with breast cancer recurrence. The test assigned a risk score for recurrence, on a scale of 0-100. Based on evidence from earlier trials, participants with low risk scores (0-10) received only hormone therapy, and those with high risk scores (26 and above) received hormone therapy and chemotherapy.

Women in the trial who had a score in the intermediate range (11-25) were randomly assigned to either group.

At nine years of follow-up, the two treatment groups had similar rates of invasive disease-free survival.

“In the past, doctors were uncertain what treatment to recommend to women with intermediate risk of recurrence,” Dr. Hallmeyer said. “The TAILORx findings show no benefit to chemotherapy for most of the women with this type of breast cancer.”

The trial was for women with hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative, axillary lymph node-negative breast cancer, which accounts for about half of all breast cancers.

The research also found that the chemotherapy may be beneficial for women 50 years old or younger with risk scores between 16 and 25.

The trial, which opened in 2006, was designed and led by the ECOG-ACRIN Cancer Research Group. It was sponsored by the National Cancer Institute, part of the National Institutes of Health (National Institutes of Health award numbers U10CA021115/U10CA180820).
Coping strategies for breast cancer survivors

Having worked in cancer care for more than two decades, Katharine Szubski, BSN, research nurse coordinator, knows that breast cancer survivors continue to face new challenges long after cancer treatments are over.

One persistent side effect is cognitive dysfunction, which refers to any impairment in mental thought and reasoning, such as lack in judgement, memory, language ability or concentration. Regardless of impairment severity, survivors have reported feelings of shame, depression, poor physical functioning and loss of quality of life.

Concerned that too little is being done to help survivors manage this condition, a team, including Szubski, Peggy Kupres, BSN, and Heather Jernstad, BSN, investigated interventions to help them.

The team created a coping strategy handout and education session. With help from Sigrun Hallmeyer, MD, director of Advocate Lutheran General Hospital Oncology Service Line and Cancer Survivorship Center, the team designed a research study to determine if the intervention will positively impact a survivor’s quality of life.

Enrollment of 100 survivors with cognitive function is planned. Participants will be randomly assigned to either the intervention or control group and will complete a validated cognitive function survey upon enrollment and at four, eight and 16 weeks. The intervention group will receive the coping strategy handout and education prior to survey completion.

The study team includes oncology nurse navigators and research nurse coordinators at six Illinois hospitals.

Breast cancer screening

Led by Nila Alsheik, MD, a diagnostic radiologist at Advocate Lutheran General Hospital, Park Ridge, Illinois, researchers compared breast cancer screening technologies and found women and doctors may need to go beyond mammography to get a better picture of breast cancer risk.

Mammography uses low-dose X-rays to deliver 2-D images of the breast. Unfortunately, 2-D images may obscure cancerous tissue that become hidden by pockets of dense breast tissue.

TOMOSYNTHESIS imaging, however, creates 3-D impressions via low-dose X-rays and image-building software, which offer greater tissue transparency.

Dr. Alsheik’s findings, published in Academic Radiology, showed 3-D imaging had better cancer detection rates, fewer false positives and greater imaging efficiency because fewer women required repeat scans.

The study results were particularly relevant due to the volume and diversity of data analyzed: 325,729 mammograms from 247,431 women screened at 39 facilities. Big data analysis indicates results are not specific to a unique population and will be similar for women throughout the United States.

Funding support was received by Hologic Inc., manufacturer of breast imaging products and equipment.
Team Phoenix completes record-setting eighth season; gives cancer survivors new direction

Fifty-one female cancer survivors began the Team Phoenix triathlon training program in April 2018. And all 51 completed a sprint-distance triathlon 14 weeks later during the Tri-ing for Children’s Triathlon at Ottawa Lake State Park in Dousman, Wisconsin. This was the first time in the program’s eight-year history that every athlete who signed up for the training program also completed the program and crossed the finish line.

Judy Tjoe, MD, breast cancer surgeon, founded Team Phoenix along with Leslie Waltke, DPT, cancer rehabilitation specialist for Aurora Physical Therapy, with the purpose of teaching the joys of lifelong fitness and improving quality of life and overall health and wellness after cancer treatment by training for a sprint-distance triathlon. Today the program is also led by Michael Mullane, MD, medical oncologist and hematologist and director of the Hereditary Cancer Prevention and Management Center at Aurora St. Luke’s Medical Center, Milwaukee.

TORQUE researchers are unlocking new ways of diagnosing, treating and surviving breast cancer through access to national clinical trials, vast data available in the electronic medical record and collaboration with Biorepository and Specimen Resource Center for breast cancer tissue samples.

Research component
Team Phoenix seeks to better understand the effects of group-led, goal-oriented exercise and psychological well-being after cancer treatment.

In a collaboration with Marquette University, Drs. Tjoe and Waltke recently explored the physiological, psychological and motivational aspects of team triathlon training for cancer survivors. The study earned the 2018 Western Journal of Nursing Research/Midwest Nursing Research Society Best Faculty Paper Award.

For a highlight of TORQUE’s preclinical research, see Page 34.
Vince Lombardi Cancer Foundation gift funds research into a gene signature to predict resistance to breast cancer treatment

In nearly 20 percent of all breast cancers, patients have a gene that produces too many copies of a protein, which may cause cancer cell growth.

First-line treatment for this cancer, human epidermal growth factor receptor 2 (HER2)-positive breast cancer, typically involves an anti-HER2 monoclonal antibody, such as trastuzumab, which is a formulated protein that binds to the HER2 proteins to slow or stop cancer growth.

Anti-HER2 treatment with trastuzumab has been shown to improve survival of patients with HER2-positive breast cancer. Yet nearly a quarter of patients with early stage HER2-positive breast cancer treated with trastuzumab experience recurrence within 10 years.

Finding a gene signature

Sharing her findings at the 2018 San Antonio Breast Cancer Symposium (SABCS), Research Scientist Jun Yin, PhD, has identified a biomarker, found by analyzing a patient’s tumor tissue, that could predict whether that patient may experience initial resistance to trastuzumab or develop a resistance.

“This gene signature could assist clinicians in diagnosing patients with trastuzumab-resistant HER2-positive breast cancer, selecting treatments for those patients with a more accurate risk evaluation and offering alternatives such as immunotherapy,” Dr. Yin said.

Dr. Yin first presented these research findings at the 2018 Aurora Scientific Day at which her poster won first place. Research Technologist Andrea Sand, intern Mitchell Piacsek, Director of Patient-Centered Oncology Research Amy Beres, PhD, and breast oncology surgeon Judy Tjoe, MD, coauthored the study.

Dr. Yin also shared findings at SABCS from her study “HER2 overexpression in ductal carcinoma in situ: A biomarker for risk stratification and therapeutic implication.” Research Coordinator Brittany Last, Senior Biostatistician Maharaj Singh, PhD, and Dr. Tjoe coauthored the study.

Donations to cancer research

This research was made possible in part because of a generous $150,000 gift from Vince Lombardi Cancer Foundation to Aurora Research Institute. To conduct biomarker research, $100,000 of the gift was directed to Translational Oncology Research: Quest for Understanding & Exploration.

For her research, Dr. Yin used tissue donated by Aurora Health Care patients to the institute’s Biorepository and Specimen Resource Center.

With support from the foundation and the biorepository, Dr. Yin also collaborated with institutions such as MD Anderson Cancer Center in Houston on other biomarker-related studies, which were published in Cancer Cell and International Journal of Cancer.
Advocate Health Care

$73K awarded by external sources

EXTERNAL FUNDING

Risk-based breast cancer screening and surveillance in community settings
Investigator: Firas Dabbous, PhD
National Institutes of Health/National Cancer Institute subaward from University of California-Davis
$43,714

Comparative effectiveness of breast cancer, screening, diagnosis and management in community practice
Investigator: Firas Dabbous, PhD
Patient-Centered Outcomes Research Institute subaward from University of California-Davis
$23,467

Advancing translational science in Metropolitan Chicago
Investigator: John Park, MD
National Institutes of Health/National Center for Advancing Translational Sciences subaward from University of Chicago
$5,960

Oncology research grants

Aurora Health Care

$1.3M awarded by external sources

EXTERNAL FUNDING

National Cancer Institute Community Oncology Research Program
Investigators: Thomas Saphner, MD, Michael Thompson, MD, PhD
National Institutes of Health/National Cancer Institute
$1,188,290 (continuing support)

Team Phoenix and biomarker discovery program
Investigator: Judy Tjoe, MD
Vince Lombardi Cancer Foundation
$140,000

NRG Oncology trials support
Investigator: Rubina Qamar, MD
National Institutes of Health subaward from NRG Oncology
$16,000

Comparative effectiveness of breast cancer, screening, diagnosis and management in community practice
Investigator: Firas Dabbous, PhD
Patient-Centered Outcomes Research Institute subaward from University of California-Davis
$23,467

Advancing translational science in Metropolitan Chicago
Investigator: John Park, MD
National Institutes of Health/National Center for Advancing Translational Sciences subaward from University of Chicago
$5,960

INTERNAL FUNDING

Empirical validation of the AUA/SUO risk-stratification approach for predicting the prognosis of nonmuscle invasive bladder cancer with a multi-center population
Investigator: Kourosh Ravvaz, MD, PhD
$25,000 (Oncology Research Award)

Signature-guided biomarker discovery and therapy for trastuzumab-resistant HER2/ERBB2-positive breast cancer
Investigator: Jun Yin, PhD
$6,000 (Research Seed Grant Program)

Patient-derived lung cancer, primary cell line
Investigator: Paul Mintz, PhD
$5,850 (Research Seed Grant Program)

Aurora Research Institute internal awards are possible due to the generosity of donors to Aurora Health Care Foundation.

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.
## Oncology Research

### Advocate Aurora Health

#### 2016–2018

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*Estimated; complete data not available at time of publication

CNS, central nervous system
Neuroscience research
Research requires a lot of effort by a lot of people. It takes dedicated clinicians and scientists, sponsors and donors, administrators and support staff, and courageous patients willing to volunteer.

With the help of 103 newly consented research participants, Advocate Aurora Health Research Institute advanced 93 clinical, preclinical and other neuroscience research studies throughout Advocate Aurora Health. The studies focused on memory loss, stroke, brain cancer, surgical approaches and more in 2018.

Using the data from our research participants, new medical breakthroughs are made every day. Clinical trial sponsors and researchers transform their findings into care through Food and Drug Administration approval, scientific publication, and presentation at national and international meetings to make these treatments and procedures broadly available.

These ideas can originate in unlikely places. Learn about how a high school student inspired one of our neurosurgeons on Page 39. Her contribution led to a clinical trial studying the use of aromatherapy during brain surgeries that are performed while the patient is awake.

In Discovery Laboratory, our preclinical laboratory scientists, in collaboration with Aurora Neuroscience Innovation Institute physicians, are studying ways to fight brain cancer with a virus. The goal is to program the virus to target cancer cells and ignore healthy cells, reducing recurrence and improving survival rates.

Advocate Aurora’s neuroscience researchers have shared their expertise with the world through scientific publication, with 47 peer-reviewed articles in 2018. These articles share research findings that advance neuroscience innovations and transform care.

Our research wouldn’t be possible without investment by the health care system, donors and external funding sources. In 2018, Advocate Aurora neuroscience researchers were awarded $112,368 in grants from external sources and institute programs that are supported by the generosity of donors to Aurora Health Care Foundation.
California teenager’s suggestion to study aromatherapy during awake brain surgeries passes smell test

When Kailah Cathey, 16, from Los Angeles, has free time, she often reaches for a book. But what she pulls off her shelf isn’t typically young adult or popular fiction. She reads medical books and dreams of becoming a cardiovascular pediatric surgeon.

“I take pieces of different studies and try to combine them,” she said.

With aromatherapy being an area of particular interest to her, Cathey wondered how its effects might benefit other therapies and medical procedures.

And because of kitchen-table conversation, she’ll now play a role in answering that question, as neurosurgeon Richard Rovin, MD, incorporated Cathey’s ideas and research into a clinical trial studying the effects of lavender aromatherapy during awake craniotomies, which is a form of brain surgery.

**Kitchen-table conversation**

One day in 2016, Cathey was sharing her aromatherapy research with her parents. She was 14 at the time. Her brother had invited a friend, who happened to be Dr. Rovin’s son, over for dinner. After hearing about Cathey’s research idea, he relayed it to his father.

Before long, Dr. Rovin flew out to California to meet with Cathey and discuss her ideas on aromatherapy.

“... after talking with Kailah, it clicked for us: Why not use aromatherapy during the surgery?“

Richard Rovin, MD
Neurosurgeon

Sniffing out surgical innovations
Incorporating Cathey’s ideas, Dr. Rovin and his team at Aurora Research Institute and Aurora Neuroscience Innovation Institute (ANII) launched the clinical trial “Feasibility of Aromatherapy in an Awake Craniotomy Environment.”

Awake craniotomy is increasingly used in brain surgery since it grants surgeons the ability to remove deep-lying tumors and blood clots and provides access to areas of the brain that are difficult or impossible to reach through traditional methods. ANII neurosurgeons use ultra-precise navigation technology and high-definition imaging equipment to make the technique possible.

Most patients tolerate awake craniotomies well, however, some studies found that roughly 30 percent of patients experience moderate to severe pain and anxiety, 50 percent report moderate fear, and 11 percent report severe fear.

Enter aromatherapy.

“We were looking for alternative methods to mitigate pain, anxiety and fear,” Dr. Rovin said. “Lavender aromatherapy has proved to work in a preoperative setting. But after talking with Kailah, it clicked for us: Why not use aromatherapy during the surgery?”

Patients in the study were offered lavender aromatherapy via a nasal inhaler every 30 minutes in addition to the typical local anesthetic and mild intravenous sedative.

Dr. Rovin and his team will evaluate aromatherapy’s ability to reduce patient anxiety and improve satisfaction with pain control medications.

The trial was sponsored by Aurora Health Care and funded through the Aurora Research Institute Research Seed Grant Program. The trial enrolled 40 patients at Aurora St. Luke’s Medical Center in Milwaukee and was completed in 2018.

Did you know?
There are about two dozen clinical trials around the world studying the use of lavender aromatherapy for different conditions and medical procedures, including the trial at Aurora St. Luke’s Medical Center.

Visiting Aurora St. Luke’s
Cathey and her mother, Jacquelyn, visited Aurora St. Luke’s in July 2018 as guests of Dr. Rovin. The Catheys watched from an observation room as Dr. Rovin performed an awake craniotomy using aromatherapy.

“I can’t put into words the experience I had there with my daughter,” Jacquelyn Cathey said. “Everyone was amazing. I was amazed to see the surgery and how the aromatherapy worked during the awake brain surgery.”

The trip was the first time Kailah Cathey had left her home state of California, but if she gets her wish, it won’t be the last. Howard University, Columbia University and Princeton University are on her short list of schools at which she’d like to study medicine.

And if all goes according to plan, she’ll have an impressive accomplishment to include on her college application: Dr. Rovin said Cathey will be listed as author on any research publications that may come out of the aromatherapy study.

“When I found out, I cried,” Jacquelyn Cathey said. “For an established physician to take notice of her and implement her research is awesome. I’m so proud of her.”

[Image: Richard Rovin (center) performs neurosurgery at Aurora St. Luke’s Medical Center in Milwaukee.]

[Image: Richard Rovin (left) explains the awake craniotomy procedure to Kailah Cathey during her visit.]
Clinical trial tests immunotherapy drug for early Alzheimer’s disease

Advocate Memory Center researchers are studying a new immunotherapy drug for treatment of early Alzheimer’s disease as part of an international early phase clinical trial.

According to U.S. Centers for Disease Control and Prevention, 5.7 million people currently live with Alzheimer’s disease, and the number continues to rise each year. The fifth leading cause of death in individuals 65 years and older, Alzheimer’s disease gradually and persistently destroys memory, thinking and behavior. Currently, no cure or prevention therapies are approved by the Food and Drug Administration for this disease.

Darren Gitelman, MD, behavioral neurologist and senior medical director of Advocate Memory Center, serves as the Advocate Lutheran General Hospital principal investigator for the clinical trial, “A Study to Evaluate the Efficacy and Safety of ABBV-8E12 in Subjects with Early Alzheimer’s Disease.”

Developed by AbbVie, the trial sponsor, ABBV-8E12 is designed to target an abnormal protein, tau, that builds up in brain cells, and forms the “tangles” seen as part of the pathology of Alzheimer’s disease. The trial will determine if early delivery of the drug can prevent the accumulation of tau and halt further brain damage.

“The accumulation of tau is closely linked to both the cognitive deficits and spreading of the pathology of Alzheimer’s disease throughout the brain,” Dr. Gitelman said. “We are excited to be taking part in the trial because it represents a different approach to treating Alzheimer’s disease. We hope that by reducing tau the drug will limit disease progression.”

Overall planned enrollment at study sites throughout the world is 400 patients with mild cognitive impairment or mild Alzheimer’s disease, who have been randomized to one of four treatment groups. Participants in three of the groups receive ABBV-8E12, but at a unique dose depending on the group. Participants in the fourth group, the control group, receive a placebo drug.

Participants receive the study drug or placebo by infusion every four weeks during the two-year trial period. Researchers are evaluating safety and drug effectiveness throughout the study based on adverse events and dementia symptom severity.

Participants will be followed until 2021. Data analysis will follow.
Researchers validate Stroke Network of Wisconsin scale

Aurora Health Care researchers developed a new large vessel occlusion screening scale, called the Stroke Network of Wisconsin scale, to predict stroke caused by a blockage in one of the major arteries in the brain.

Acute ischemic stroke accounts for 87 percent of all strokes and occurs when blood flow through a brain artery is blocked by a clot. A large vessel occlusion is an ischemic stroke that results from a blockage in one of the major arteries of the brain and may lead to death if not treated quickly.

To identify a large vessel occlusion using the scale, one of three signs must be present: S) speaking difficulty, N) neglect (inability to use one side of the body), or O) ocular deviation (eye deviation to one side).

The researchers, led by Aurora Neuroscience Innovation Institute vascular neurologist Kessarin Panichpisal, MD, published their findings in Journal of Vascular and Interventional Neurology, validating the scale as a tool to identify large vessel occlusion. The study received support from Advocate Aurora Health Research Institute Senior Biostatistician Maharaj Singh, PhD, and Research Associate Reji Babygirija. It was designed to compare the Stroke Network of Wisconsin scale to the most widely and commonly used stroke scale.

The study was first presented at Aurora Scientific Day 2018 and then at the 2018 Annual American Academy of Neurology meeting.

Hospital joins stroke trial as only site in Wisconsin

Aurora St. Luke’s Medical Center, Milwaukee, is the only site in Wisconsin participating in an early phase clinical trial studying the safety of n-butylphthalide (NBP) softgel capsules for the treatment of mild to moderate acute ischemic stroke in adults.

Previous studies have found NBP, developed from celery seed extract, may improve stroke symptoms and the ability to perform personal care activities following an acute ischemic stroke.

Neurologist Rehan Sajjad, MD, is the site principal investigator for the study, “NBP in Adult Patients With Acute Ischemic Stroke (AIS),” which is sponsored by CSPC-NBP Pharmaceutical Co. Ltd.

The trial will enroll 400 participants for 30 days of treatment and 60 days of follow-up assessments.
Researchers receive internal grants to study a virus as a treatment for glioblastoma

Glioblastoma is a deadly form of brain cancer for which the standard treatment — surgery followed by chemotherapy and radiation — is not particularly effective. Within six months, most tumors grow back from the remaining glioblastoma stem cells that then resist and survive additional treatment. Drugs have proved incapable of eliminating those stem cells. But some viruses may be able to do just that. Research Scientist Parvez Akhtar, PhD, and his team are studying whether a particular virus, which targets stem cells in the developing brain, can be made to enter and destroy glioblastoma stem cells. The researchers then hope to modify the virus to ensure it doesn’t attack healthy brain cells. If it works, the reprogrammed virus could supplement existing cancer therapy, reducing recurrence and improving survival rates.

To carry out his research, Dr. Akhtar won an Aurora Research Institute 2018 Oncology Research Award for his study, “Evaluating axl-mediated virus entry and productive infection in glioblastoma stem cells as oncolytic viral therapy.” With the $24,900 grant, the researchers are studying brain tumor tissue collected by the institute’s Biorepository and Specimen Resource Center.

The institute also awarded Dr. Akhtar with $4,514 to study a potential biomarker for patients with glioblastoma. “There are currently no biomarkers to diagnose, predict and monitor response to treatment, or to provide a prognosis for patients with glioblastoma,” said Dr. Akhtar, who conducts his research in the biosafety level two virology laboratory within Discovery Laboratory. “As biomarkers can also identify treatment targets for a disease, the search for biomarkers is important.”

The award was part of the institute’s Research Seed Grant Program, launched in 2017 to help investigators create competitive research proposals for publication and external funding.
Six studies provide greater understanding of the anatomy of the brain, approaches to brain surgery

Researchers with the Neuroanatomy Laboratory shared findings for a modified approach to brain surgery that accesses a new route and five other studies at the North American Skull Base Society’s 29th Annual Meeting.

“This was an exciting opportunity for my colleagues and me to represent the institute and share during podium sessions some of the exciting research we are doing in the Neuroanatomy Laboratory,” said Srikant Chakravarthi, MD, post-doctoral research fellow.

Showcasing the efforts of the institute’s Neuroanatomy Laboratory team of research fellows and clinicians, Dr. Chakravarthi presented two studies — one providing an anatomic guide to micro-brain surgery and another exploring the use of an innovative surgical platform for the treatment of meningioma brain tumors located at the base of the skull.

Research Fellow Laila Perez de San Roman-Mena, MD, described the modified neurosurgical approach and provided greater understanding of the anatomy of the brain.

Another research fellow, Alejandro Monroy-Sosa, MD, shared additional anatomy findings and three keys to managing brain cancer surgery.
EXTERNAL FUNDING

Genetic variation, stress and functional outcomes after stroke rehabilitation
Investigator: Terrence Li, MD
National Institutes of Health/National Institute of Nursing Research subaward from Rosalind Franklin University of Medicine and Science
$22,464

Atrial cardiopathy and antithrombotic drugs in prevention after cryptogenic stroke
Investigator: Rehan Sajjad, MD
National Institute of Neurological Disorders and Stroke subaward from Columbia University
$60,490

INTERNAL FUNDING

Evaluating AXL-mediated virus entry and productive infection in glioblastoma stem cell as oncolytic viral therapy
Investigator: Parvez Akhtar, PhD
$24,900 (Oncology Research Award)

Is soluble AXL a biomarker for glioblastoma: pilot study
Investigator: Parvez Akhtar, PhD
$4,514 (Research Seed Grant Program)

Aurora Research Institute internal awards are possible due to the generosity of donors to Aurora Health Care Foundation.
### Neuroscience Volumes

#### Advocate Health Care

**2016–2018**

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(For cancers of the brain and central nervous system, see table on Page 36.)

#### Aurora Health Care

**2016–2018**

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(For cancers of the brain and central nervous system, see table on Page 36.)

### Neuroscience Research Projects

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### Newly Consented Neuroscience Research Participants

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### Neuroscience Scientific Articles

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Only about 30 percent of medications used in children have been tested in children, and the percentage is even less for infants.

Primarily through Advocate Aurora Health Research Institute’s Advocate Center for Pediatric Research, researchers are studying treatments and therapies designed for young participants. With the help of 356 newly consented pediatric research participants, we advanced 226 clinical, preclinical and other pediatric research studies throughout Advocate Aurora Health in 2018.

The studies focused on pediatric cardiology, telehealth for complex cases and more.

One such clinical trial provided a treatment choice for a mother worried about her child. While drugs approved for blood clot prevention in adults are numerous, the options available to children are limited. Advocate Children’s Hospital’s involvement in a pediatric clinical trial permitted a new option for her son she wouldn’t have had anywhere else in Illinois. Read their story on Page 49.

Because of Advocate Children’s Hospital’s commitment to research and clinical trial readiness, the Institute for Advanced Clinical Trials for Children, known as I-ACT for Children, selected the hospital’s two locations at Oak Lawn and Park Ridge, Illinois, as network sites. The I-ACT designation provides access to pediatric clinical trials, best practices, quality improvement strategies, and research education and training.

At the preclinical level, through strong collaborations with outside partners, our researchers are exploring ways to help newborns who experience a lack of oxygen at birth and have published their findings.

Our pediatric researchers have shared their expertise with the world through scientific publication, with 52 peer-reviewed articles in 2018. These articles share research findings that advance pediatric innovations and transform care.

This research isn’t possible without the investment by the health care system, donors and external funding sources. In 2018, our pediatric researchers were awarded $154,091 through grants from external sources and institute programs that are supported by the generosity of donors to Advocate Charitable Foundation.
After her toddler son’s open heart surgery to repair a birth defect, Angela Smit had a decision to make that would affect the next year of his life.

Although the Fontan surgical procedure successfully restored proper heart circulation and blood flow, the new changes put Tanner Smit at increased risk for developing blood clots during the next 12 months.

The Food and Drug Administration has approved five medications to prevent blood clot formation in adults, but none are approved for children. However, warfarin has been used over the years.

Unfortunately, a potential side effect of warfarin is uncontrolled bleeding. While on the medication, adults and children must control their diet because certain foods affect the body’s blood-clotting abilities, and drug levels can vary greatly requiring frequent blood draws for monitoring.

“He was 2 1/2, so, of course, that’s the time kids are running around and being crazy, and it just made me very nervous about him being on Coumadin (warfarin’s trade name),” said Smit, a nurse who is familiar with the medication’s many side effects. “We get so many patients that come in while they’re on blood thinners, and they’re bleeding like...”
crazy. I was just terrified that something like that would happen to him.”

But because of Advocate Children’s Hospital’s involvement in the UNIVERSE pediatric clinical trial, Smit had another option for her son she wouldn’t have had anywhere else in Illinois.

Approved for adults

After Tanner’s surgery, Andrew Van Bergen, MD, pediatric cardiologist and Director of Pediatric Cardiac Critical Care and the Cardiac Neurodevelopmental Program for Advocate Children’s Hospital, informed Smit about the UNIVERSE trial.

Research trial participants are randomized to receive either a daily baby aspirin or an oral anticoagulant, a medication to prevent blood clot formation that’s approved for use in adults, but not yet in children. The study objective is to evaluate the oral anticoagulant’s safety and effectiveness when administered to children in the first year following the Fontan surgical procedure. Researchers plan to enroll about 110 children 2 to 8 years old.

Unlike warfarin, the oral anticoagulant doesn’t require a special diet because it prevents blood clotting in a different way. As a result, this investigational drug also requires much fewer blood draws for drug level monitoring.

Advocate Children’s Hospital is the only site in Illinois participating in the international clinical trial, sponsored by Janssen Research and Development LLC, investigational drug manufacturer.

“At Advocate Children’s Heart Institute, we know our commitment to research provides our young patients and families the unique opportunity to receive novel medications, medical devices and nonconventional therapies that wouldn’t otherwise be available to them,” said Dr. Van Bergen, site principal investigator for the trial.

One of ten

While carefully weighing available treatment options, Smit once again drew from her nursing experience and decided to enroll Tanner in the UNIVERSE trial.

“I know all about the blood draws and diet changes you have to make [with warfarin],” Smit said. “I knew it would be more difficult with a toddler on Coumadin (warfarin) and trying to control his diet. So, it was definitely a drug that I was kind of nervous about him being on.”

Tanner, one of the first 10 research participants (part A), received the investigational drug before the trial transition (part B) to random assignment of the study medication or baby aspirin. Now at 4 years of age, Tanner doesn’t remember his 13-month study experience, but Smit reflected on what it meant to her as a parent.

“I just really wanted to do something different because I was more worried about him being on Coumadin than I was about the surgery itself,” Smit said. “That’s terrifying when you’re talking about a toddler who can’t tell you things like an adult can.

“And, the fact that Tanner can be somebody who can change the lives of children...so, if it can save another kid from getting poked all the time, it’s well worth it to me.”

The UNIVERSE trial is ongoing. The Smits’ experience should not be used to predict outcomes of this trial.

Did you know?

Researchers plan to enroll 110 children at 62 sites worldwide.

Angela (left) and Tanner Smit
Researchers conduct study to find safe and effective anticlotting treatment for children

Advocate Children's Hospital-Oak Lawn, Illinois, is participating in an international clinical trial to investigate the safety and effectiveness of edoxaban, an anticlotting medication, for use in children with blood clots in the vein, known as venous thromboembolism (VTE).

Although these blood clots in children are rare, they are occurring more frequently in seriously ill children due to advanced medical therapies that increase risk for blood clots, such as catheters placed inside the vein to administer medications, fluids and nutrition.

Blood clots that break free from the vein wall may end up in the lungs, blocking the blood supply and causing death.

Standard treatment for children is an anticlotting medication. Currently, one medication used in children, warfarin, requires a strict diet and frequent blood drawing to monitor medication levels and prevent episodes of uncontrolled bleeding.

Another anticlotting medication must be administered by injection or catheters placed inside the vein.

The study medication, however, does not require a special diet or extra blood draws and is available as a liquid or pill that may be swallowed.

"Scientific inquiry into pediatric VTE treatment is a high priority due to the rising incidence of this rare, but potentially life-threatening condition," said Marie-Ellen Sarvida, MD, pediatric hematologist and oncologist and site principal investigator. "Finding safe and effective alternative treatment options that have been tested and approved for use in children is critical."

Researchers plan to enroll 274 children younger than 18. Edoxaban will be compared to standard treatments for breaking up the clots, preventing clots and incidence of major bleeding episodes.

Daiichi Sankyo Inc., developer of edoxaban, sponsored the study, "Hokusai Study in Pediatric Patients with Confirmed Venous Thromboembolism (VTE)."
Researchers study use of virtual reality to teach physicians about congenital heart defects

Varsha Gharpure, MD, pediatric critical care intensivist at Advocate Children’s Hospital-Park Ridge, Illinois, is studying the use of a virtual reality (VR) educational model to teach physicians-in-training about congenital heart defects.

The Stanford Virtual Heart was created by Stanford University and Lighthaus Inc. to improve understanding through direct visualization of complex and spatially challenging heart defects and corrective surgical procedures.

Developed with the same VR technology used in video games, the Stanford Virtual Heart enables users to rotate, open and dissect eight congenital heart defects, and observe how blood flows through the heart and blood vessels.

While VR offers 3-D simulation, it may also pose technological challenges to inexperienced learners, and, in some cases, cause simulation sickness.

Dr. Gharpure designed a research study to determine if VR is effective, well-tolerated and appealing to learners, as measured through knowledge tests and participant surveys.

Research participants comprised 117 Advocate Children’s Hospital physicians, physicians-in-training and nurses. Each participant was randomly assigned to a 30-minute education session taught through either an instructor-led VR realm with 3-D images or a traditional classroom presentation with projected 2-D images.

Preliminary results revealed the Stanford Virtual Heart experience was as effective as the traditional teaching method. Participants reported VR to be a highly enjoyable, engaging and preferred learning option.

“Virtual reality is changing the landscape of traditional medical education,” Dr. Gharpure said. “Leading academic institutions and medical schools have already begun to adopt virtual reality teaching methods. Now, Advocate Children’s Hospital is also incorporating virtual reality in our training of congenital heart disease.”

The Stanford Virtual Heart was produced by David Axelrod, MD, Stanford Medicine, and David Sarno, Lighthaus Inc., with support from Oculus Inc. and Betty Irene Moore Children’s Heart Center at Stanford. The Stanford Division of Pediatric Cardiology provided software and Oculus Rift immersive VR systems for this study.

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More than just fun and games

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Pediatric Critical Care Intensivist

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Use of home-based telehealth device reduces hospital days and health care costs for children with complex medical conditions

Frequent health care appointments required by children with complex medical conditions are challenging for families to manage in terms of logistics and cost. Many have needs that make transportation to appointments difficult, such as continuous medical device support. As a result, comprehensive physical examinations must often be replaced by telephone calls from caregivers to the health care provider. But advances in telehealth technology are now enabling physicians to examine patients remotely.

Pediatric researchers at Advocate Children’s Hospital-Oak Lawn, Illinois, and Advocate Research Institute set out to determine if telehealth technology could positively impact these children and their families.

Twenty-four patients from the hospital’s pediatric complex care program enrolled in the study, and researchers followed them for four months. Caregivers in the intervention group used the telehealth device from their homes to capture and transmit ear, throat and skin images; heart and lung sounds; and heart rate and temperature readings to clinicians during a real-time, interactive, audiovisual examination.

Those assigned to the control group called the office when health concerns arose as they normally would. When examinations were necessary to address these concerns, caregivers of control group participants scheduled standard in-person visits.

Study findings, recently published in Telemedicine and e-Health, demonstrated telehealth technology could increase health care access for these children and their families. Results also showed lower rates of hospitalization and health care costs for participants whose caregivers had access to the telehealth device.

“The results of this pilot study are quite encouraging and serve as the foundation for future models of care,” said Kathleen Webster, MD, medical director of pediatric telemedicine at Advocate Children’s Hospital and author of the manuscript. “Plans are already underway for new projects that leverage telehealth technology to improve quality of services and access to care for all children with special health care needs.”

In addition to Dr. Webster, Advocate authors included Elise Gentile, APN, Denise Angst, PhD, RN, and Cheryl Lefaiver, PhD, RN.

The TytoCare Telehealth Solution, including a home device and full stack online platform, used in the study was provided by TytoCare.
Newborns may be deprived of oxygen during childbirth. This oxygen deprivation, known as asphyxia, leads to oxidative stress, which may cause irreversible tissue and organ injury, such as heart damage, because newborns lack natural antioxidant buildup.

Preclinical researchers at Advocate Children’s Hospital-Park Ridge, Illinois, and Rosalind Franklin University of Medicine and Science sought to determine whether an antioxidant drug, yGlu-Cys, would protect newborn cells. In their first of two laboratory research studies, Ramesh Vazzalwar, MD, and Gospodin Stefanov, MD, PhD, Advocate neonatologists and neonatal-perinatal medicine fellowship program directors, and Darryl Peterson, PhD, professor of physiology and biophysics at Rosalind Franklin University, confirmed that yGlu-Cys protected heart muscle cells from oxidative stress-induced cell death.

Their findings, published in the American Journal of Therapeutics, open the possibility of a future antioxidant treatment for the prevention of oxidative stress heart injury in newborns.

“The success of this study shows the importance of preclinical research collaborations between clinical and academic partners,” Dr. Vazzalwar said. “Advocate has enjoyed a long-standing and productive relationship with Rosalind Franklin University, and we’re excited by the prospects of our combined research.”

Drs. Vazzalwar, Stefanov and Peterson have also completed experiments in a follow-up study that evaluated yGlu-Cys. The researchers are analyzing the data from those experiments and planning future studies with this drug.

Both preclinical research projects were supported by the James R. and Helen D. Russell Center for Research and Innovation Small Research Grants Program. Funding for the Russell Center Small Research Grants Program is possible due to the generosity of James, Helen and Jean Russell.

Dr. Peterson and Rosalind Franklin University were awarded a patent for use of the study drug in treatment of stroke.
EXTERNAL FUNDING

TrialNet TN01 — natural history study of the development of type 1 diabetes
Investigator: Kanika Ghia, MD
University of Chicago
$49,227 (continuing support)

Institute for Advanced Clinical Trials for Children Inc.
Investigator: Cheryl Lefaiver, PhD, RN
Food and Drug Administration
$15,000

The Thirty Million Words Initiative, newborn implementation trial
Investigator: Frank Belmonte, DO
Einhorn Family Charitable Trust subaward from University of Chicago
$11,284

Wolff-Parkinson-White Syndrome in children
Investigator: David Gamboa, MD
Rock the Heart Foundation subaward from University of Utah
$1,000

INTERNAL FUNDING

Combined effects of common neonatal medications, morphine and caffeine, on the postnatal rat pop brain expression of endothelin receptors and mitochondrial functional markers
Investigator: Sweatha Kasala, MD
$25,000 (Russell Center Small Research Grant)

Immersive virtual reality for learning congenital heart diseases: Novel and cool — but is it effective?
Investigator: Varsha Gharpure, MD
$23,913 (Russell Center Small Research Grant)

Effect of urinary tract infection on neonatal levels of acute kidney injury urine biomarkers
Investigator: Jessica Chiang, MD
$18,888 (Russell Center Small Research Grant)

Central venous catheter placement confirmation via saline flush on ultrasound
Investigator: Shefali Aggarwal, MD
$9,779 (Russell Center Small Research Grant)

Advocate Research Institute internal awards are provided through the James R. and Helen D. Russell Center for Research and Innovation. Funding for the Russell Center Small Research Grants Program is possible due to the generosity of James, Helen and Jean Russell.
### Advocate Aurora Health

#### 2018

**Pediatric volumes**

<table>
<thead>
<tr>
<th>Patients</th>
<th>Advocate</th>
<th>Aurora</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deliveries</td>
<td>19,280</td>
<td>12,621</td>
<td>31,901</td>
</tr>
<tr>
<td>Inpatient Admissions and Observations</td>
<td>21,576</td>
<td>14,771</td>
<td>36,347</td>
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<tr>
<td>Outpatient Visits</td>
<td>241,652</td>
<td>39,307</td>
<td>280,959</td>
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<tr>
<td>Emergency Room Visits</td>
<td>116,225</td>
<td>46,440</td>
<td>162,665</td>
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<tr>
<td>NICU Admissions</td>
<td>1,919</td>
<td>1,420</td>
<td>3,339</td>
</tr>
<tr>
<td>PICU Admissions</td>
<td>2,550</td>
<td>-</td>
<td>2,550</td>
</tr>
<tr>
<td>Transports</td>
<td>3,734</td>
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<td>3,734</td>
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**Source:** EPIC, Strata, Surginet

<table>
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<tr>
<th>Surgeries</th>
<th>Advocate</th>
<th>Aurora</th>
<th>TOTAL</th>
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<tbody>
<tr>
<td>Cardiac</td>
<td>430</td>
<td>63</td>
<td>493</td>
</tr>
<tr>
<td>Dental</td>
<td>320</td>
<td>135</td>
<td>455</td>
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<tr>
<td>Pediatric General</td>
<td>1,714</td>
<td>284</td>
<td>1,998</td>
</tr>
<tr>
<td>Ear, Nose and Throat</td>
<td>3,448</td>
<td>1,958</td>
<td>5,406</td>
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<tr>
<td>Neurosurgery</td>
<td>273</td>
<td>7</td>
<td>280</td>
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<tr>
<td>Ophthalmology</td>
<td>369</td>
<td>205</td>
<td>574</td>
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<tr>
<td>Orthopedics</td>
<td>1,230</td>
<td>826</td>
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<tr>
<td>Plastic</td>
<td>494</td>
<td>36</td>
<td>530</td>
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<tr>
<td>Trauma</td>
<td>33</td>
<td>0</td>
<td>33</td>
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<tr>
<td>Urology</td>
<td>667</td>
<td>108</td>
<td>775</td>
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</table>

**Source:** EPIC, Strata, Surginet

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Advocate</th>
<th>Aurora</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastroenterology</td>
<td>1,438</td>
<td>107</td>
<td>1,545</td>
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<tr>
<td>Pulmonology</td>
<td>36</td>
<td>2</td>
<td>38</td>
</tr>
</tbody>
</table>

**Source:** EPIC, Strata, Surginet

*Includes pediatric beds across the Advocate Aurora system, including Advocate NorthShore/ANPP Pediatric Partnership beds
Research at Advocate Aurora Health is not confined to cardiovascular, oncology, neuroscience or pediatrics. Investigators from the following specialties and more engage in research:

- Behavioral Health
- Endocrinology
- Gastroenterology
- Geriatrics
- Primary Care
- Women’s Health

With the help of 832 newly consented research participants, Advocate Aurora Health Research Institute advanced 302 clinical, preclinical and other research studies across a variety of specialties throughout the health system in 2018. The studies focused on gastroesophageal reflux disease, Group B streptococcus in pregnancy, functional decline in older adults, depression, post-traumatic stress disorder and more.

Through clinical research, our researchers are studying whether a digital technology — a mobile health application designed to improve patient-provider engagement — improves outcomes for participants with major depressive disorder.

At the preclinical level, endocrinology researchers are studying the body’s hormonal response to stress and applying their findings to a condition in which the stress of birth deprives the body of necessary oxygen. These researchers published two manuscripts related to this work.

Representing different specialties, Advocate Aurora’s researchers have shared their expertise with the world through scientific publication, with a total of 163 peer-reviewed articles in 2018. These articles share research findings that advance innovations and transform care for individuals affected by a variety of conditions.

Investment by the health care system, donors and external funding sources allow our researchers to advance care. In 2018, Advocate Aurora specialty researchers were awarded $1,009,316 through grants from external sources and institute programs that are supported by the generosity of donors to Advocate Aurora Health Foundations.
Clinical trial available in Wisconsin only at Aurora Medical Center in Summit examines nonsurgical outpatient procedure for the treatment of gastroesophageal reflux disease

Aurora Medical Center in Summit, Wisconsin, was the first site in the nation to enroll and randomize a participant in a multicenter clinical trial studying a nonsurgical outpatient procedure for the treatment of gastroesophageal reflux disease, or GERD.

Researchers are evaluating the safety and efficacy of Aluvra, an injectable bulking agent for the treatment of GERD. Aurora Medical Center in Summit is one of eight sites in the United States. Affecting nearly 65 million people in the U.S., GERD occurs when regulation of the sphincter, the opening between the esophagus and stomach, is weak and allows stomach acid into the esophagus. This causes heartburn, or a burning pain in the chest.

Current treatments include lifestyle modifications, over-the-counter or prescription medications, and surgical approaches.

“The treatment is nonsurgical and performed as an outpatient procedure with very few postoperative side effects,” said Nimish Vakil, MD, gastroenterologist and site principal investigator.

Aluvra is administered during an outpatient procedure called an endoscopy to bulk up the tissue, allowing it to close and stop stomach acid from backing up into the esophagus.

“Auvra may significantly reduce GERD symptoms, allow patients to reduce or eliminate the use of medications (proton pump inhibitors), and avoid surgery,” said Nimish Vakil, MD, gastroenterologist and site principal investigator.

Sponsored by Aluvra manufacturer Impleo Medical Inc., the study “Novel Endoluminal Clinical TreAtment of Reflux (NECTAR)” will enroll up to 100 participants, who will be randomized to either receive Aluvra or a saline placebo and followed for a year.

Kristin Ciezki enrolls a participant in a clinical research trial.
the mothers to their babies, causing pneumonia, sepsis and meningitis.

Centers for Disease Control and Prevention (CDC) guidelines require GBS screening before childbirth and antibiotics administered during labor if a woman has GBS bacteria growth. However, the use of antibiotics may increase incidence of resistance, diarrhea, Clostridium difficile and fungal infections in the mother, and may cause a disturbance to the balance of bacteria in the gut, infections and allergic risk in the newborn.

This clinical trial will determine if once daily ingestion of a probiotic from 28 weeks pregnant until labor reduces the number of women with GBS bacteria growth, thus reducing the number of women who must receive antibiotics during child birth.

Participants will be randomized to either receive the probiotic or a placebo.

“This study will test a low-cost, safe, innovative approach to prevent GBS bacterial growth in pregnant women while adhering to CDC guidelines,” said Nina Garlie, PhD, director of patient-centered specialty research.

Marquette’s principal investigator is Lisa Hanson, PhD, professor and director of the Marquette University Nurse-Midwifery Program. Hanson worked as a certified nurse-midwife at Aurora Sinai Medical Center for 29 years.

Did you know?
One in three women carry GBS bacteria vaginally.

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.
The desire to make a difference motivated Amy Stewart, MD, of Advocate Lutheran General Hospital, Park Ridge, Illinois, to become a critical care surgeon. It also inspired her to conduct research on post-traumatic stress disorder (PTSD).

PTSD, characterized by unrelenting mental and emotional stress, can occur in patients requiring complex care in the intensive care unit (ICU).

Searching for a way to help her patients, Dr. Stewart designed a pilot study to determine factors associated with PTSD in patients admitted to the ICU and evaluate if journaling thoughts and feelings may reduce symptoms.

Although her study is ongoing, preliminary results revealed more than half of the 100 research participants tested positive for PTSD. Factors linked to PTSD included greater numbers of injuries, medical procedures, ICU memories and length of hospitalization/ICU stay.

Dr. Stewart has expanded her study to the surgical, medical, pediatric and neonatal ICUs at Advocate Lutheran General. Future results will provide data on journaling's effects.

Protected time to conduct the study is possible because of the Embedded Physician-Scholar Program, and the Small Research Grants Program awarded funding for the study. Both programs are provided by the James R. and Helen D. Russell Center for Research and Innovation through a philanthropic gift from the Russell family (James, Helen and their daughter, Jean).

Study funding was also received through an Advocate Lutheran General Health Partners Endowment grant.

Managing depression with technology

Advocate Health Care, in collaboration with pharmaceutical partners Takeda-Lundbeck, has developed a user-friendly mobile application (app) (pictured) to help people with depression easily record and share details about their symptoms, medications and therapy with clinicians.

To evaluate Advocate Pathway App’s feasibility and effectiveness, David Kemp, MD, medical director of behavioral health at Advocate, is leading the study, “Patient Management of Depression Through Technology: A Study of Digitally Enabled Engagement.”

“This study, supported by our patient-centered outcomes research team, represents how successful partnerships with clinician-researchers and industry bring innovative technology to the patients we serve,” said Christopher Blair, director, Advocate Aurora Health Research Institute.

Forty research participants enrolled in the trial will be randomized to receive either standard medical care or standard medical care plus use of the app. They will be asked to complete surveys when they begin the study and after 18 weeks to examine patient engagement and changes in their treatment outcomes.

Researchers also will assess health resources used over time by telephone at the end of one year.
‘Hot-spotting’

In the United States, 5 percent of patients incur 50 percent of health care costs.

Health care providers may improve patient outcomes and decrease costs by employing an intervention called ‘hot-spotting.’ Refined in Milwaukee at Aurora St. Luke’s Medical Center Family Practice Center and Aurora Sinai Medical Center Family Care Center, Milwaukee, the method uses multidisciplinary teams to identify and provide help for patients with the greatest need for more in-depth care.

Glenda Sundberg, FNP, presented study findings that validated a pilot program for the method at the 2018 Aurora Scientific Day and the North American Primary Care Research Group. Hot-spotting teams meet three times a year to create comprehensive care plans that include home visits and increased communication. In 2018, hot-spotting teams met with 35 patients.

AUWMG plans to expand the program to a third Milwaukee program location at Aurora Health Center Midtown.

‘Hot-spotting’ benefits

There was a 46 percent decrease in hospital admissions among the ‘hot-spotting’ group, a 25 percent decrease in emergency room visits, cost savings of $87,000 and a 2.1:1 return on investment.

Acupuncture in the emergency department

Aurora West Allis Medical Center, Wisconsin, was the first hospital in the state to sponsor a pilot program offering acupuncture in the emergency department. A quality improvement study of the pilot revealed acupuncture reduced acute pain by almost 50 percent based on average pain scores before and after acupuncture (6.5 vs. 3.4).

The study, led by Integrative Medicine leaders Nancy Conway and John Burns, in collaboration with Center for Urban Population Health and AUWMG, suggests acupuncture could provide emergency department patients with acute pain an alternative to medications and possibly help reduce the prescription of opioids.
Funding allows expansion of transition-of-care model for older adults in rural health care settings to two additional hospitals and corresponding home care markets

**Grants, gift support Bundled HELP**

New grant funding from Bader Philanthropies and Hearst Foundations and a donation from Aurora Health Care Foundation in 2018 will allow Michelle Simpson, PhD, RN, director of patient-centered research for the Ed Howe Center for Health Care Transformation, to continue expansion of the Bundled Hospital Elder Life Program (HELP).

Bundled HELP combines the HELP model with her team’s adapted HELP at Home model, which is deployed by health care clinicians at each home visit.

“The transition-of-care program is designed to improve care for vulnerable older adults within and beyond the hospital with the intention of preventing functional and cognitive decline and avoidable rehospitalization,” Dr. Simpson said.

Using a previously awarded grant from Bader Philanthropies, Dr. Simpson and her team created a home care-to-hospital readmission risk measure. Two more grants from Bader Philanthropies supported the pilot study to implement and examine the impact of the Bundled HELP model of care at Aurora Medical Center in Burlington, Wisconsin, and Aurora Lakeland Medical Center in Elkhorn, Wisconsin.

The 2018 funding will allow Dr. Simpson and her team to replicate Bundled HELP and expand it to Aurora Medical Center in Manitowoc County in Two Rivers, Wisconsin, and Aurora Medical Center in Oshkosh, Wisconsin. Researchers plan to evaluate the impact of Bundled HELP on patient outcomes and identify an organizational infrastructure for sustaining the care model.

Since 2015, the project has raised $568,000 in grant funding and donations to study, replicate and expand the program within four hospital communities throughout Wisconsin.

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**Endocrine researchers publish results**

Led by endocrinologist Hershel Raff, PhD, researchers at the Endocrinology Research Laboratory at Aurora St. Luke’s Medical Center, Milwaukee, are primarily studying how the body’s hormone system responds to neonatal hypoxia, a condition in newborns in which the stress of birth deprives the body of necessary oxygen.

The journal Endocrinology published the team’s manuscript, “Programming of the adult HPA axis after neonatal separation and environmental stress in male and female rats.”

In American Journal of Physiology Regulatory, Integrative and Comparative Physiology, the team published the results of its study, “Effect of a melanocortin type 2 receptor (MC2R) antagonist on the corticosterone response to hypoxia and ACTH stimulation in the neonatal rat.”

Additionally, Dr. Raff and his team are developing a diagnostic test involving the measure of the hormone cortisol in a patient’s saliva that could help evaluate the body’s response to a variety of diseases and conditions.

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Ashley Gehrand (left) and Jonathan Phillips at ENDO 2018, the Endocrine Society’s annual meeting
Center for Urban Population Health

Founded in 2001 by Aurora Health Care, University of Wisconsin School of Medicine and Public Health, and University of Wisconsin-Milwaukee, Center for Urban Population Health (CUPH) offered a unique opportunity to join health care with the multidisciplinary expertise that existed within participating institutions. Seventeen years later, those founding institutions remain committed to addressing the health and well-being of urban populations.

Milwaukee Community Health Needs Assessment

Every three years, Milwaukee Health Care Partnership’s health system members — which includes Aurora Health Care — design the Community Health Needs Assessment for six southeastern Wisconsin counties. The assessment serves as the foundation from which hospitals and local health departments develop their respective community health improvement strategies. The assessment findings are also intended to inform a broader audience about the top health issues facing its communities.

The Milwaukee County assessment consists of three data sources:

• A community health survey of 1,312 Milwaukee County residents;
• Interviews of 80 individuals representing 40 key informants and four focus groups; and
• Health Compass Milwaukee, a compilation of publicly reported health data (see below).

CUPH helped develop and supported the Milwaukee County assessment reports.

The results of the analysis and collective reports found the top five health issues facing Milwaukee County include chronic disease, substance use, mental health, violence and access to health care. Key informants and survey respondents have, for several years, cited a number of indicators requiring urgent and persistent attention, including infant mortality, sexually transmitted infections and binge drinking.

Health Compass Milwaukee

Where one lives, learns, works and plays — known as the social determinants of health — are increasingly recognized as having a much greater impact than clinical care on an individual’s length and quality of life. As part of the Community Health Needs Assessment process, CUPH, in partnership with the Milwaukee Health Care Partnership, launched Health Compass Milwaukee to provide a deeper understanding of what is contributing to the health of Milwaukee.

This website (pictured) centralizes the most current health, social, economic and environmental indicators for Milwaukee County. It provides mapping, reporting and comparative analytic tools to support research and planning for health care, public health, academic, philanthropic and governmental sectors, as well as the broader community. CUPH staff manages the website and maintains many of the indicators. Visit HealthCompassMilwaukee.org.

30 projects conducted by Center for Urban Population Health

$2.4M in extramural funding

State 45%
Federal 33%
Local contracts 22%
EXTERNAL FUNDING

Assessing and modeling network-level of consequences of patient navigation
Investigator: Dana Villines
National Institutes of Health subaward from University of Illinois
$25,183

Medication focused outpatient care for underutilization of secondary prevention
Investigator: Christine Schumacher, PharmD
University of Iowa
$9,639 (continuing support)

INTERNAL FUNDING

The impact of cytochrome P450 abnormalities in patients with delirium. A pilot study
Investigator: David Ronin, MD
$25,000 (Russell Center Small Research Grant)

Evaluating the prevalence of post-traumatic stress disorder in the post-intensive care population and improving intensive care unit communication with ICU diaries
Investigator: Amy Stewart, MD
$21,000 (Russell Center Small Research Grant)

Diabetes prevention: Healthy moms healthy babies
Investigator: Carol Victor, APN
$3,839 (Russell Center Small Research Grant)

The impact of cytochrome P450 abnormalities in patients with delirium. A pilot study
Investigator: David Ronin, MD
$10,000 (Advocate Lutheran General Hospital Partners Endowment)

Advocate Research Institute internal awards are provided through the James R. and Helen D. Russell Center for Research and Innovation and Advocate Lutheran General Health Partners Endowment. Funding for the Russell Center Small Research Grants Program is possible due to the generosity of James, Helen and Jean Russell. Advocate Charitable Foundation uses income from the Advocate Lutheran General Health Partners Endowment Fund to make grants to research, develop or implement improved health care service delivery methods within areas served by Advocate Lutheran General Hospital and Advocate Children’s Hospital-Park Ridge.
INTERNAL FUNDING

To determine the long-term colectomy rates in Ulcerative Colitis patients since the implementation of anti-TNF agents as standard therapy
Investigator: Lilani Perera, MD
$5,000 (Research Seed Grant Program)

Aurora Research Institute internal awards are possible due to the generosity of donors to Aurora Health Care Foundation.
At Advocate Aurora Health, we call employees team members. Team members from across the health system play important roles in discovering new findings and transforming those discoveries into innovative care.

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.

The Council for Quality Assurance and Improvement in Research oversees Advocate Aurora Health 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 institute, as well as members from RSPP and Research Compliance. The council is responsible for maintaining a quality dashboard, developing a strategic annual quality monitoring plan, assessing key performance indicators and making recommendations to improve the quality of research. It reports its findings annually to the Advocate Aurora Health Safety and Health Outcomes Committee.

Research activities wouldn’t be possible without the support of other team members throughout the system who support necessary operations like finance, legal, human resources, information technologies and more.

But it is the core research team that embraces our guiding purpose to help people live well through innovative research. Our diverse team members are motivated by this purpose built on the values of excellence, compassion and respect.

Not only do our research team members pursue the common goal of advancing medicine to improve outcomes for patients and creating a better tomorrow just by coming to work every day, they give of themselves in so many other ways as well.

This commitment along with a collaborative culture makes all the difference in making healthy happen.
Aurora Research Institute honored 15 award recipients for their contributions to research at its ninth annual Research Recognition Event on Sept. 13, 2018, at Aurora St. Luke’s Medical Center in Milwaukee.

- Julie Schroeder, Research Hero Award
- Bijoy Khandheria, MD, Cardiovascular Research Award
- J. Scott Maul, MD, Oncology Research Award
- Kessarin Panichpisal, MD, Neuroscience Research Award
- Parvez Akhtar, PhD, Principal Investigator Award
- Pamela Rynes, BSN, Clinical Trials Research Award
- Gary Dennison and Christina Schreiter, BSN, Research Appreciation Award
- Andinet Alemu, MD, Maharaj Singh, PhD, Chris Blumberg, John Richards, PhD, Martin Oaks, PhD, and Michael Thompson, MD, PhD, Journal of Patient-Centered Research and Reviews Article of the Year Award
- Julie Basquin, Aurora Research Institute’s President’s Award

Aurora BayCare Medical Center, Green Bay, Wisconsin, hosted its 10th annual Fall Research and Medical Education Reception on Oct. 4, 2018. The event is dedicated to highlighting achievements in research and medical education.

- James Napier, MD, Medical Educator of the Year
- Neurology, Medical Education Department of the Year
- Tom Halloin, MD, Medical Education Lifetime Achievement Award
- Diane Mayland, MD, Medical Education Lifetime Achievement Award
- Nita Jensen, Most Valuable Person in Medical Education
- Ubaid Nawaz, MD, Principal Investigator of the Year
- Vinay Mehta, MD, Innovation Award
- Mitchell Voss, Principal Investigator in Clinical Research Award

(Left to right) Alex Albers, Vinay Mehta and Sara Beno-Chambers
Advocate Christ Medical Center Interdepartmental Research Day

Researchers shared findings with nearly 90 presentations at the annual Interdepartmental Research Day on May 10, 2018, at Advocate Christ Medical Center, Oak Lawn, Illinois.

- Clinical Poster Awardee:
  Amer Al Homssi, MD — Metastatic Gastrointestinal Stromal Tumor Disguising as Pancreatic Pseudocyst

- Original Research Oral Presentation Awardee:
  Arya Nikamal, DO — The Impact of a Dedicated Night Intensivist Program on Patient-Centered Outcomes in an Academic Medical Intensive Care Unit

- Clinical Vignette Oral Presentation Awardee:
  Hassan Mashbari, MD — Rare Case of Multilevel Femoropopliteal Aneurysmal Disease Involving Bilateral Lower Extremities.

Pediatric Research & Quality Improvement Symposium

For the fifth year, the Pediatric Research & Quality Improvement Symposium, held May 16, 2018, on the Oak Lawn campus, showcased scholarly activities conducted at Advocate Children’s Hospital.

- Best Overall Research Project:
  Nirbhay Parashar, MD — Comparison Between Non-invasive Neuromuscular Ventilator Assist and High Flow Nasal Cannula After Extubation In Pediatric Cardiac Patients

- Best Overall Quality Improvement Project:
  Vrinda Arora, MD — Antibiotic Stewardship in the NICU: When Less Is More

- Best Overall Interprofessional Team Project:
  Milada Gorelik — Standardized Process for Scheduling Appointments Facilitates a Safe and Quality Transition from Hospital to Home

- Best Overall Project Led by a Trainee:
  Sandy Thakadiyil, MD — Effect of Oxycodone Exposure on CNS Protein Expression in the Neonatal Rat Brain

- Best Overall Project by a Nurse:
  Kathie Kobler, PhD, APN — Health Care Professionals’ Awareness of a Child’s Impending Death

Aurora Scientific Day

Researchers presented research and quality projects at the 44th annual Scientific Day, held May 23, 2018, at Aurora Conference Center on the Aurora St. Luke’s Medical Center campus in Milwaukee.

- Rieselbach Distinguished Paper:
  Courtney Horvat, PharmD — Impact of a Passive, Prescriber Directed, Electronic Best Practice Alert on Antibiotic Prescribing Rates for Ambulatory Adult Patients With Acute Uncomplicated Bronchitis

- Rieselbach Distinguished Paper:
  Parvez Akhtar, PhD — Axl-Mediated Entry and Productive Infection in Glioblastoma Stem Cells

- 1st Place Oral Presentation:
  Judy Tjoe, MD — HER2 Overexpression in Ductal Carcinoma In Situ: A Biomarker for Risk Stratification and Therapeutic Implication

- 2nd Place Oral Presentation:
  Andrew Ackerman, PharmD — Evaluating Clinical Outcomes in Critically Ill Patients With Hypoalbuminemia Receiving Ceftriaxone

- 3rd Place Oral Presentation:
  Kelly Schneider, DPT — The Effects of a Preoperative Physical Therapy Visit on Patient Outcomes Following Total Knee Arthroplasty

- 1st Place Judged Poster:
  Jun Yin, PhD — Signature-Guided Biomarker Discovery and Therapy for Trastuzumab-Resistant HER2-Positive Breast Cancer

- 2nd Place Judged Poster:
  Elizabeth Mellott, DO — Cesarean Hysterectomy and Prophylactic Occlusive Balloon Catheters: Is It Worth the Risk?

- 3rd Place Judged Poster:
  Laura Reindl — Noninvasive Estimation of Optimal Positive End-Expiratory Pressure (PEEP) for Mechanically Ventilated Obese Patients

- Best in Show - General Poster:
  Sarah Ward, MD — Isolation of Cryptococcus-Like Yeast From Natural Environments
Advocate Aurora Health Research Institute and its team members participated in charitable acts and giving in 2018. In addition to facilitating and participating in larger programs such as Greater Gift and First Look for Charity, team members also collected holiday gifts for nearly 100 families, donated dozens of winter clothing items to numerous local nonprofits, and staffed booths and fielded teams at fundraising events such as the Head for a Cure Foundation 5K Run/Walk, Aurora Mindful Tri and Walk to End Alzheimer’s.

Philanthropy supports research, local communities

First Look for Charity supports cardiovascular research

More than $210,000 was raised at Chicago Auto Show’s 2018 First Look for Charity event to expand Advocate Health Care’s cardiovascular research program. Proceeds from the event, attended by nearly 700 generous benefactors, were used to grow and enrich cardiovascular research activities to benefit the many patients and communities served by Advocate Heart Institute and Advocate Children’s Heart Institute.

Institute celebrates research participants with Greater Gift

People who participate in research often receive no benefit for their contribution while their selfless act benefits the greater good in the form of new drugs, treatments and techniques that improve countless lives.

To celebrate this contribution, Aurora Research Institute in 2018 made a $30,000 donation on behalf of research participants to Greater Gift, which provides vaccines to children in need worldwide through Gavi, the Vaccine Alliance. New research participants receive a certificate acknowledging the institute’s heartfelt appreciation for furthering its mission to help people live well through innovative research.

Aurora Health Care is the only Greater Gift partner site in Wisconsin.

To make a gift to research, visit:
• advocate.giving.org (Illinois)
• give.aurora.org (Wisconsin)

[Photo, left: Sigrun Hallmeyer (left), children Hendrik, Hans and Hanna, and husband, Michael Milaniak]
[Photo, right: Andrew Van Bergen (right) and husband, Rafael Jimenez Rivera]

Julie Schroeder (front), the institute’s first Greater Gift recipient, with Kathy Behrens (back, left to right), Michelle Bennett, Tanvir Bajwa and Kelly Piacsek
We help people live well through innovative research.

Strategic imperatives:

- Leverage system resources
- Consumer first — Enhance patient outcomes
- Cultivate a culture of excellence
- Promote reputation and scholarship

Thank you

Team members from within the integrated research institute and throughout the merged health system provided information, images and approvals to tell the story of our research through this annual report. We thank all of the contributors. To the clinician researchers, research scientists and the teams that support them, we are proud to highlight your efforts to discover new findings and transform those discoveries into innovative care. To the collaborators, sponsors and donors, we couldn’t have advanced health without your partnership — thank you. Most importantly, to the thousands of research participants, thank you for making the future a better place.