Patient-Centered Research

ANNUAL REPORT 2015
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Aurora Research Institute unifies the innovative research efforts throughout Aurora Health Care, aiding the health system in its mission to help people live well by providing investigational options for patients.

**Best Brand**

Transforming over 14,000 square feet at Aurora Sinai Medical Center as part of a more than $5 million capital investment, the institute created a unique research environment known as Discovery Laboratory. Opened in October 2015, researchers are working on discoveries for cancer and cardiovascular diseases.

The neuroanatomical laboratory that opened in May 2015 at Aurora St. Luke’s Medical Center has served as a useful research resource and an educational tool for visiting students, drawing local media attention.

Advancing scientific breakthroughs, Aurora’s Journal of Patient-Centered Research and Reviews continues to expand its global reach with more than 11,500 article downloads in more than 100 countries in 2015 alone.

**Best Value**

Providing an environment of innovation, the institute participated in the studies necessary for APN Health LLC to receive Food and Drug Administration clearance for its Navik 3D heart imaging system.

Collaborations with industry and other research partners allow Aurora to bring neurosurgical innovations and the latest cancer therapies to patients.

**Best People**

Aurora has emerged as a national destination for research as evidenced by recruitment of leading scientists and clinicians focused on new breakthroughs and dedicated caregivers who give of their time and resources.

Counting them among our numbers – this work to help people live well would not be possible without the thousands of patients who participate in clinical trials or donate tissue and the donors who drive innovation with their generous gifts.

On behalf of Aurora Research Institute and its board of directors, I am pleased to provide this highlight of our 2015 outcomes. As always, I welcome your feedback.

Randall Lambrecht, PhD
Senior Vice President, Aurora Health Care/President, Aurora Research Institute
Randall Lambrecht, PhD, president of Aurora Research Institute, oversees all clinical research at Aurora Health Care, one of the largest integrated health care systems in the country.

Under Dr. Lambrecht’s leadership, hundreds of clinical trials and investigator-initiated research studies are being conducted across Aurora’s 15 hospitals and more than 150 clinics. He also facilitates the advancement of innovative health care technologies.

Dr. Lambrecht has spent nearly 30 years as a researcher and professor. He has secured numerous federal research grants to study molecular and cellular mechanisms of infectious disease, authored more than 60 publications, presented over 110 lectures/seminars and developed molecular-based diagnostic tests that were subsequently commercialized.

Dr. Lambrecht holds certification by the American Society of Clinical Pathologists and is a fellow for the Association of Schools of Allied Health Professions. He serves as a scientific reviewer for several journals and on numerous professional and community boards.
CONTRIBUTING TO AURORA’S WAY FORWARD

2016 AND BEYOND

BEST BRAND

• Aurora Research Institute completed its first year as a separate legal entity from Aurora Health Care.

• The institute unveiled its new Discovery Laboratory on the Aurora Sinai Medical Center campus. The state-of-the-art facility houses a number of research laboratories that support cellular, molecular, proteomic, imaging and stem cell research in cancer, cardiovascular and neurosciences.

• Journal of Patient-Centered-Research and Reviews experienced huge increases in readership and worldwide downloads allowing the editorial team to apply for elite indexing status after only two years.

• The Sponsored Programs Office in conjunction with the Investigator-Initiated Research Department tracked a number of major research grants and collaborations including Michael Michalkiewicz, PhD, and his National Institutes of Health award from Vanderbilt University for precision medicine.

• The Clinical Trials Department participated in major multicenter trials for devices – CoreValve, WATCHMAN and Evera MRI SureScan ICD System – that received Food and Drug Administration approval in 2015.

• During a site visit, National Institutes of Health auditors applauded Aurora NCORP (National Cancer Institute Community Research Oncology Program) for its first successful year of the grant under the direction of principal investigators Thomas Saphner, MD, and Michael Thompson, MD, PhD.

• A major study on the risk of testosterone therapy and heart disease helped change the course and recommendations of pending federal guidelines.

• Wisconsin Lt. Gov. Rebecca Kleefisch visited Aurora St. Luke’s Medical Center and toured research areas and neurosciences facilities.

BEST VALUE

• The Aurora Neuroscience Innovation Institute received a $1 million award to develop a neuro-oncology research program.

• A tribute to Sheikh Khalifa bin Hamad Al Thani was unveiled on a wall outside Center for Integrative Research on Cardiovascular Aging at Aurora St. Luke’s Medical Center, recognizing his $2 million gift.

• The Biorepository and Specimen Resource Center was awarded a grant to help establish itself as valuable resource for biomedical and clinical research.

• The institute received approval to make a significant investment with the purchase of a clinical trial management system, and opening of a grant management position to help support the growing number of sponsored research projects.

• A much needed review and internal audit of research was conducted to help shape policies and procedures. Policies developed or revised included conflict of interest, clinical trial billing and research misconduct.

BEST PEOPLE

• Through annual research recognition events at Aurora St. Luke’s and Aurora BayCare Medical Centers and at Aurora Scientific Day, outstanding researchers received recognition for their efforts.

• A total of 18 college students spent time conducting research during the summer either in research laboratories or supporting other research activities as part of the institute’s summer student research programs.

• Caregivers gave of themselves to support charitable events and organizations including Vince Lombardi Cancer Foundation, American Heart Association, Aurora Health Care Foundation and the students of Hawthorne Elementary School.

By working with internal and external parties, I help put into place the required study and other underlying agreements that enable collaborative studies to be conducted.

– Lee Banfi, MBA, CPA
Sponsored Programs Specialist, Sr.

I contribute to patient-centered research by helping investigators submit their research to the Institutional Review Board.

– Nooreen Wynn, MS, MS
Research Regulatory Specialist, Sr.

I contribute to patient-centered research on a daily basis by developing a rapport with patients leading to the screening, consenting and enrolling of patients in one of the several clinical trials I oversee.

– Jennifer Cooper, BSN
Research Nurse Coordinator, Sr.

Aurora Research Institute’s administrative assistant team works together to ensure communication among our multidisciplinary researchers is effective and efficient.

– Diane Gentilini
Administrative Assistant, Sr.
On display behind glass walls, Aurora Health Care researchers work from the molecular to cellular levels to gain a better understanding of genes and proteins and how they react to new and existing therapies.

In Aurora Research Institute’s Discovery Laboratory, the goal is to find innovative ways to improve patient outcomes for cancer, cardiovascular diseases and neurological disorders. More simply put, the goal is to discover cures.

To facilitate this research, the institute transformed over 14,000 square feet on the Aurora Sinai Medical Center campus as part of a more than $5 million capital investment. The innovative transformation includes a unique laboratory environment, small animal facility and offices.

Efficient, artistic

The space-saving layout of Discovery Laboratory features shared work stations and communal core equipment. This efficient design avoids duplication found in traditional pod-like laboratories and enhances communication among researchers.

The tissue processing and microscopy area is equipped for preparation, staining and analysis of slides. Typically this service is outsourced, which would add cost and time to research projects.

An enclosed area at biosafety level 2 allows for genetic manipulation using viruses and other microorganisms to develop new immunotherapies.

A refrigerated room allows for cold-temperature experiments. A separate room houses deep freeze cryogenic equipment for storage of tissues, cells and supplies at -20, -80 and -150 degrees.

Rounding out the laboratory are traditional human and animal cell and tissue preparation and culture spaces.

And don’t forget to look up. A barrel vault ceiling features an artistic DNA sequence design.

Learn more about how Aurora researchers are trying to cure heart disease (see story on page 14) and cancer (see story on page 37).
Labs within the lab

- Imaging Laboratory
- Experimental Optics Laboratory
- Microscopy/Histology Laboratory
- Cell Biology Laboratory
- Flow Cytometry Laboratory
- Virology Laboratory
- Protein and Molecular Laboratory

Areas of study and centers

- Neurosciences
  Aurora Neuroscience Innovation Institute (ANII)
- Breast and other cancers
  Translational Oncology Research: Quest for Understanding and Exploration (TORQUE)
- Cardiovascular diseases and aging
  Sheikh Khalifa bin Hamad Al Thani Center for Integrative Research on Cardiovascular Aging (CIRCA)
- Acute kidney injury
- Precision medicine

Grand opening celebrations

Oct. 27
Ribbon-cutting ceremony

Oct. 28
Open house

Recognized leaders

- Nina Garlie, PhD
- Vani Nilakantan, PhD
- Bob Stoltz, MBA, MT
- David Krum, MS

Featured scientists

- Santhi Konduri, PhD
- Sanjay Kansra, PhD
- Amber LaCrosse, PhD
- Scarlet Shi, PhD
- Larisa Emelyanova, PhD

“

Discovery Laboratory was possible because of the commitment of many bright and talented researchers, physicians and caregivers along with the hope and generosity of friends and donors.

Aurora Health Care, Aurora Sinai Medical Center and Aurora Health Care Foundation provided the administrative fortitude and support that allowed the unique laboratory environment to be created.

But, most importantly, discoveries can only be translated into innovative patient care with the courage and involvement of patients and their families.

- Randall Lambrecht, PhD

“

Bob Stoltz, MBA (top), David Krum, MS (middle), and Vani Nilakantan, PhD (bottom), lead tours through the Discovery Laboratory.
JPCRR year in review

2015 highlights

- Surpassed 16,000 article downloads
- Expanded reach to 115 countries
- Indexed in Directory of Open Access Journals, search engine Google Scholar
- Selected to publish scientific abstracts presented at Health Care Systems Research Network’s annual conference
- Applied to PubMed Central

Popularity of Aurora Health Care’s Journal of Patient-Centered Research and Reviews soared in its second year of publication.

The articles published quarterly by JPCRR reached more than 100 countries, forging a global footprint that spans the United States, Japan, Chile, Kenya, Germany, Australia and everywhere in between.

Moreover, article downloads from JPCRR online exceeded 11,500 in 2015, doubling the web traffic of the journal’s inaugural year.

Most read

Such rapid growth inspired the journal’s editorial board to create the JPCRR Article of the Year award.

At Aurora Research Institute’s Greater Milwaukee Clinical Research Recognition Event in September, author Leslie Waitke, DPT, became the first recipient of the award for her article on exercise rehabilitation in cancer patients, which has been downloaded 4,500 times to date.

Special issues

With the help of guest editors, JPCRR published two specialty theme issues.


JPCRR closed the year with an issue dedicated to the underrecognized field of integrative medicine. Guest edited by family physician Tiffany Mullen, DO, the issue shed light on the clinical roles of healthy diet, herbal supplements, acupuncture, tai chi and sleep patterns, among other holistic practices.

Sponsored by Robyn Temkin Memorial Fund, JPCRR is a multispecialty medical journal overseen by Editor-in-Chief Dennis Baumgardner, MD, managing editor Joe Grundle and production manager Julie Walters.
Recognizing our best people

Sixth Annual Greater Milwaukee Clinical Research Recognition Event
Held September 30 at Aurora St. Luke’s Medical Center, Aurora Research Institute recognized achievements in research by Aurora Health Care caregivers in the Greater Milwaukee area.

Focus on Innovation
- **Daniel O’Hair, MD**, shared the successes of Aurora’s Transcatheter Aortic Valve Replacement Program, which has grown from involvement in clinical trials to a destination for patients with aortic stenosis throughout the United States and abroad.
- **Richard Rovin, MD**, shared robotic optical imaging advances for the care of patients with neurological disorders that Aurora is leading.

Fall Research and Medical Education Reception
Held October 1 at Aurora BayCare Orthopedic and Sports Medicine Center, Aurora BayCare Medical Center recognized achievements in research and education by Aurora Health Care and BayCare Clinic caregivers in the Green Bay area.

Focus on Innovation
- **Danzhu Guo, MD, and Danqing Guo, MD**, shared their innovative way to treat carpal tunnel.

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2015 Greater Milwaukee Award Recipients

**Subject Hero Award**
Craig Hummer (see page 19)

**Clinical Trials Research Award**
Elizabeth Marriott, MD

**Investigator-Initiated Research Award**
Michael Michalkiewicz, PhD

**Senior Investigator Award**
Joseph Davies, MD

**New Investigator Award**
Ulugbek Negmadjanov, MD

**Research Champion Award**
Michael Mullane, MD

**Research Team Award**
Biorepository and Specimen Resource Center
(Natalie Polinsky, MS, Anne-Marie McAnely, Kujana Clayton, Brittany Last)

**Research Service Award**
Ashley Gehrand, MS
Whitney Jacobson, BSN
Robyn Shearer, MS

**JPCRR Article of the Year Award**
Leslie Waltke, DPT

2015 Green Bay Award Recipients

**Medical Educator of the Year Award**
Ashwani Bhatia, MD

**Medical Education Department of the Year Award**
Obstetrics and Gynecology

**Principal Investigator Award**
Brandon Scharer, DPM
Jason DeVries, DPM

**Innovation Award**
Danzhu Guo, MD
Danqing Guo, MD

**Lifetime Achievement Award**
Paul Summerside, MD

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**Paul Summerside, MD**, former chief medical officer at BayCare Clinic, retired at the end of 2015, closing the book on an 18-year career with the Green Bay-based health organization. Summerside, emergency medicine physician and research champion, most recently served as president of BayCare Joint Ventures, where he oversaw the organization’s external partnerships and related strategies.
Academic relations

Cultivating future researchers

Through different internship opportunities this past summer, 18 students gained valuable insights about research and, in turn, supported a variety of initiatives.

Mentors from Aurora Research Institute, Aurora UW Medical Group, Aurora Health Care Metro and Aurora BayCare Medical Center provided promising future researchers opportunities that will give them an edge as they pursue careers in medicine and other health care professions.

Aurora Research Institute
Summer Student Internship Program

Led by: Randall Lambrecht, PhD, and Vani Nilakantan, PhD

MAX ALBIERO
Year/University: senior/University of Wisconsin-Madison
Project: MGMT inhibition leads to CDK4/6 inhibition and enhances palbociclib’s activity in breast cancer
Mentors: George Bobustuc, MD, Santhi Konduri, PhD

DANIEL BAKER
Year/University: senior/University of Wisconsin-Madison
Project: Muriel and Jack Winter Family Research Institute and the Milwaukee Heart Project exhibit
Mentor: Kurt Waldheuter, MS

MEGAN HUBER
Year/University: junior/Oregon State University, Corvallis
Project: Epidemiology study of blastomycosis in eastern Wisconsin and laboratory study of chemically resistant soil fungi
Mentors: Dennis Baumgardner, MD, Jessica Kram, MPH

MELISSA KERLIN
Year/University: senior/University of Wisconsin-Madison
Project: Effect of teriflunomide on breast cancerigenesis
Mentors: Sanjay Kansra, PhD

COURTNEY POKRYWA*
Year/University: second-year medical resident/University of Wisconsin School of Medicine and Public Health
Project: Use of opioids in chronic, noncancer pain management
Mentors: Dennis Baumgardner, MD, Fabiana Kotovicz, MD, Jessica Kram, MPH

ALEX REDDY
Year/University: senior/University of Wisconsin-Milwaukee
Project: RAPID Withdrawal
Mentors: Andy Marek, Jon Cook

JUSTIN ROUNTREE
Year/University: senior/Carroll University, Waukesha, Wis.
Project: Implications of resting outpatient clinic heart rate among patients with left ventricular ejection fraction <35%
Mentor: Scarlet Shi, PhD

PAYDEN WHITE
Year/University: junior/University of Wisconsin-Madison
Project: Aurora’s Biorepository and Specimen Resource Center
Mentor: Natalie Polinske, MS, Anna-Marie McAnolly

Aurora Health Care Metro Medical Staff
Summer Research Fellowship Program

Led by: Neil Guenther, MD, and Hershel Raff, PhD

Supported by: physicians who donate to Aurora Health Care Foundation’s Medical Staff Endowment Fund

TANVIR BAJWA JR.
Year/University: senior/Loyola University, Chicago
Project: Studies on Ca2+ mobilization capacity in cardiac fibroblasts from failing hearts
Mentor: Gracious Ross, PhD

CATIE DOWNEY
Year/University: junior/Amherst College, Amherst, Mass.
Project: To elucidate mechanism(s) of progressive fibrosis through inhibition of programmed cell death in fibroblasts from human heart
Mentors: Arshad Jahangir, MD, and colleagues

MACIEJ GRACZ
Year/University: senior/Marquette University, Milwaukee
Project: Blocking of prostaglandin E2 receptor EP2 may be involved in modifying immune response
Mentor: John Richards, PhD

COLE LEONOVICH
Year/University: senior/University of Miami, Florida
Project: Epigenetic programming of the adult rat phenotype by neonatal hypoxia and hypothermia
Mentor: Hershel Raff, PhD

ELIZABETH STOECKL
Year/University: junior/University of Notre Dame, Indiana
Project: Ranolazine protects failing human cardiac fibroblasts against doreadone-induced mitochondrial dysfunction and oxidative stress
Mentors: Arshad Jahangir, MD, Larisa Emeljanova, PhD, and colleagues

MIKE WALLACE
Year/University: senior/College of Charleston, South Carolina
Project: Chemosensitization of malignant gliomas by a natural compound
Mentor: Chang-Hyuk Kwon, PhD

MEGAN WAPLES
Year/University: sophomore/Emory University, Atlanta
Project: Effects of intravenous immunoglobulin and its glycoforms on secretion of antibodies by plasma cells
Mentor: Martin Oaks, PhD

*Aurora UW Medical Group Department of Family Medicine Summer Student Research and Clinical Assistantship
Aurora BayCare Medical Center interns

Led by: Annette Paul, MAT

ALEX CHRISTENSEN
Year/University: junior/University of Wisconsin-La Crosse
Project: Various oncology database research studies
Mentor: Dhimant Patol, MD

MARK (MAC) GARDON
Year/University: postgraduate/Xavier University, Cincinnati
Project: Comparing abdominal, laparoscopic and vaginal hysterectomy techniques across the Aurora Health Care system to determine best practice goals
Mentor: Brian Dobbins, MD

ASHLEY HEESACKER
Year/University: postgraduate/University of Wisconsin-Milwaukee
Project: Procalcitonin sepsis
Mentor: Darren Heesacker, MD

Shadow opportunities

From summer campers to college students, Aurora Research Institute provides research training and educational opportunities to create a pipeline of future health care professionals.

Middle-schoolers attending a Discovery World summer camp viewed a neurosurgery and toured the anatomy lab and Regenerative Medicine Center during a field trip to Aurora St. Luke’s Medical Center on Aug. 5.

Local media outlet CBS 58 interviewed Nina Garlie, PhD, and some of the students for its newscast.

Students from Cardinal Stritch University toured the Regenerative Medicine Center and Sheikh Khalifa bin Hamad Al Thani Center for Integrative Research on Cardiovascular Aging (CIRCA) at Aurora St. Luke’s on Nov. 19.

The opportunity provided the students with real-world applications for the skills they are learning in school and how they can be translated into careers that involve a variety of laboratory techniques in the future.
Caregivers who care

In a variety of ways, Aurora Research Institute caregivers support organizations with missions to change lives for the better.

Aurora Health Care Foundation

Through Aurora Health Care Foundation’s 2015 Aurora Partnership Campaign, institute caregivers embraced the giving spirit, contributing more than $17,500 to a variety of public agencies, including about $11,350 to Aurora-specific funds. Available during October and November, the campaign provides a way for Aurora caregivers to support internal and external charitable funds.

We help the causes we believe in.
Because caring is what we do.

The institute’s ongoing partnership with Aurora’s foundation also benefitted the neonatal intensive care unit at Aurora Sinai Medical Center with a Tradition of Caring event sponsorship and raised awareness about the translational research being conducted in the newly opened Discovery Laboratory.

Adopt-a-student program

Participating in Aurora Sinai Medical Center’s Adopt-A-Student program, institute caregivers in December fulfilled holiday wishes of warm clothes, action figures, dolls and more for 16 students who attend Hawthorne Elementary School. In total, Aurora adopted 266 students in 2015, donating more than 2,000 gifts for economically disadvantaged students.

Taking strides to fight disease

Tackling cancer in Milwaukee and Green Bay, institute caregivers, family and friends raised $950 for the Vince Lombardi Cancer Foundation through its Lombardi Walks/Runs in June. A beneficiary of the Lombardi foundation, the institute also helped sponsor the Vince Lombardi Award of Excellence Dinner Ball in April.

Institute caregivers, family and friends raised $544 for the American Heart Association through its 2015 Milwaukee Heart and Stroke Walk/Fun Run on Sept. 20 at Veterans Park, Milwaukee. Fundraising activities included an inaugural basket raffle. Providing a community benefit, the institute organized a booth at the AHA event with people donning gloves to learn about anatomy with animal hearts and getting a printout of their heart rhythm with portable technology.
Cardiovascular research

79 cardiovascular clinical trials open to accrual and follow-up as of Dec. 31, 2015

- Electrophysiology (19) 24%
- Interventional/Medical (20) 25%
- Congestive Heart Failure (10) 13%
- Peripheral Vascular (15) 19%
- Pulmonary Hypertension (9) 11%
- Translational (2) 3%
- Surgery (4) 5%

589 total cardiovascular clinical trial enrollments in 2015

- Electrophysiology (179) 30%
- Interventional/Medical (132) 22%
- Congestive Heart Failure (88) 15%
- Peripheral Vascular (5) 1%
- Pulmonary Hypertension (5) 1%
- Surgery (24) 4%

>$600,000
in external grant funding awarded for investigator-initiated cardiovascular research studies

35%
of Aurora’s research is cardiovascular-related

55%
of Aurora’s cardiovascular research is investigator-initiated
Sheikh Khalifa bin Hamad Al Thani
Center for Integrative Research on Cardiovascular Aging

Led by medical research director Arshad Jahangir, MD, the Sheikh Khalifa bin Hamad Al Thani Center for Integrative Research on Cardiovascular Aging (CIRCA) is one of a few research centers in the world devoted entirely to study the effect of aging on the cardiovascular system.

With the support of a generous $2 million donation from His Highness in 2014, CIRCA’s mission is to conduct basic, translational and clinical research on the biology of aging, and to develop new ways to predict, diagnose and treat age-related cardiovascular dysfunction to preserve wellness and improve the quality of life of older people.

In the Discovery Laboratory at Aurora Sinai Medical Center and the cardiovascular research laboratory at Aurora St. Luke’s Medical Center, Dr. Jahangir and the CIRCA research team of scientists, associates and assistants are studying the molecular basis for the aging heart’s decreased ability to tolerate stress and increased susceptibility to injury and heart rhythm disorders.

CIRCA in the news

CBS 58: Is your heart older than your age?

TMJ4: Ask the Expert: What factors affect cardiovascular aging?

Publications/presentations

In 2015, the CIRCA team shared its research findings through manuscript publication in peer-reviewed journals and abstract presentation at national and international meetings, advancing the collective understanding of the aging heart.


National Institutes of Health

To receive grant funding from the National Institutes of Health (NIH), applications are reviewed by members of various scientific study sections. The NIH appoints “the most accomplished, broad-thinking and creative scientists and experts to serve as peer reviewers.”

Dr. Jahangir continued as a peer reviewer for the Myocardial Ischemia and Metabolism study section in 2015. The study section reviews applications for research of myocardial ischemia/reperfusion, coronary circulation and myocardial metabolism.

(Left) Research associate Kelsey Kraft works in the newly opened Discovery Laboratory on the Aurora Sinai Medical Center campus.

(Below) Senior research scientist Scarlett Shl, PhD, presents some of her cardiovascular research findings during the open house celebration of Discovery Laboratory.
Intramural funding

Through new and continued projects, CIRCA researchers were awarded $230,000 in intramural funding through the Cardiac and Cardiovascular Surgery research award programs.

Research scientist Larisa Emelyanova, PhD, hopes to determine why a drug that helps people with atrial fibrillation can be harmful in patients with heart failure and how this detrimental effect can be avoided by pretreatment with another drug.

The study is supported by a 2015 Cardiovascular Surgery Research Award.

Gracious Ross, PhD, is studying a targeted approach to reducing calcium loading in cardiac fibroblast cells obtained from patients undergoing open heart surgery. The goal of this research is to find a way to slow the progression of heart failure.

CIRCA launches new induced pluripotent stem cell program

Effective ways to prevent cardiovascular dysfunction are not available. Results of animal testing cannot always be translated to patient care as those methods do not completely reproduce the human condition. A lack of cardiac tissue from patients for research purposes is another barrier.

A new approach to studying the biology of cardiovascular disease involves reengineering, or inducing, cells from tissue donated by adult patients into pluripotent stem cells, which is an embryonic-like state. From these IPS cells, researchers can grow cardiac cells that contain genetic information, including the mutation that causes disease.

This “disease-in-a-dish” approach allows researchers to study cardiovascular disease biology and different therapies to correct abnormalities that cause cellular dysfunction.

Rosy Joshi-Mukherjee, PhD, a new CIRCA research scientist, has launched an innovative research program to define the underlying causes of abnormal heart function and test therapies in miniature beating hearts grown from IPS cells. Initially, Dr. Joshi-Mukherjee will focus on hypertrophic cardiomyopathy, a condition in which the heart muscle becomes abnormally thick and affects how the heart functions.

In patients with particular genetic abnormalities, this precision medicine initiative may help reduce progression of their heart condition and prevent development of the disease in affected family members.

(Above) Research associate Ulugbek Negmatjanov, MD, received the New Investigator Award at the annual Clinical Research Recognition Event. The award recognizes new researchers with less than two years of service at Aurora who show success with a research project and potential for growth in the research community.

Study highlight

(Above) Research associate Stacie Edwards uses a centrifuge while studying stem cells. (Below) Research scientist Rosy Joshi-Mukherjee, PhD, obtains stem cells from a freezer.
Funded projects

Institute gives nearly $500,000 in start-up boosts for cardiac-related studies

Researchers are like gardeners. Their hypothesis is the seed.

And Aurora Research Institute’s internal grant program is like a starter pot. Funding from the program gives researchers an initial boost that spurs future, larger projects with the goal of benefitting patients and the community.

In 2015, the institute awarded $498,239 through the Sullivan Cardiac Research Award for Residents and Fellows, Cardiac Research Award and Cardiovascular Surgery Research Award to 10 Aurora Health Care investigators to conduct cardiac-related research.

The awards are possible because of the generosity of donors to the Aurora Health Care Foundation. The Sullivan research award is possible thanks to the generosity of Tim Sullivan, a member of Aurora Health Care’s board of directors, and his wife Vivian Sullivan. They donated $1 million to support the cardiovascular research of interventional cardiologist Tanvir Bajwa, MD, via the fellowship program.

Complication prediction model

Transcatheter aortic valve replacement has emerged as a minimally invasive approach to treat heart valve disease. Aurora engaged in early clinical trials to test the approach using Medtronic Inc.’s CoreValve – the only health system in Wisconsin to do so – and was the first in the state to implant the prosthetic valve after it received Food and Drug Administration approval.

CoreValve has since gained FDA approval for use in patients who have previously received a tissue valve and are in need of a second one.

Despite its success, complications persist. In collaboration with Marquette University, Setu Trivedi, DO, is laying the groundwork for a predictive model based on anatomical variations to determine which patients will have the best outcomes with the procedure.

Dr. Trivedi received a nearly $30,000 grant from the Sullivan Cardiac Research Award for Residents and Fellows for this work. Tanvir Bajwa, MD, and Arshad Jahangir, MD, are serving as mentors to Dr. Trivedi.

(From left) Daniel O’Hala, MD, Tanvir Bajwa, MD, and Setu Trivedi, MD, collaborate during a transcatheter aortic valve replacement procedure at Aurora St. Luke’s Medical Center.

2015 INTRAMURAL AWARD RECIPIENTS

Sullivan Cardiac Research Award for Residents and Fellows

Up to $30,000 each

Setu Trivedi, DO
Evaluation and prediction of complications after transcatheter aortic valve replacement using computational methods

Imaad Razzaque, MD
Increased mortality in patients undergoing aortic valve replacement: Does undiagnosed cardiac amyloidosis play a role? A research-driven protocol to detect cardiac amyloidosis with technetium pyrophosphate imaging

Cardiac Research Awards

Up to $40,000 each

Larisa Emelyanova, PhD
A novel strategy to protect against droperidone-induced myocardial dysfunction in the failing heart (new)

Modulation of mitochondrial function as a novel approach to prevent myocardial injury in the diabetic heart (second-year continuation)

Ryan Cooley, MD
A novel pathophysiology-based approach to the management of postural orthostatic tachycardia syndrome

Ekhnson Holmuhamedov, PhD
Mitochondrial voltage-dependent anion channels in pathogenesis of alcoholic cardiomyopathy

Cardiovascular Surgery Research Awards

Up to $50,000 each

Vinay Thohan, MD
Implications of absolute and relative ratio of omega-3 and -6 in physiologic fat reservoirs and patterns of coronary heart disease in humans (new)

The association between novel clinical factors and gastrointestinal bleeding among patients supported with continuous flow left ventricular assist device therapy (second-year continuation)

Gracious Ross, PhD
Store-operated Ca2+ channels in ventricular fibroblasts as a potential target to prevent progression of heart failure (new)

A novel calcium entry mechanism in myofibroblast as a therapeutic target for prevention of cardiac fibrosis (second-year continuation)

Kourosh Ravvaz, MD, PhD
Predicting the quality of postoperative anticoagulation therapy following heart valve replacement surgery

Ulugbek Negmadjanov, MD
Cytokine-mediated fibroblast activation increases resistance toward cell death: mechanistic insights and therapeutic complications (second-year continuation)

Martin Oaks, PhD
Analysis of the Fc glycans of antibodies to HLA antigens in cardiac and renal transplant candidates (second-year continuation)
Intramural, extramural funding support

Since starting with Aurora Health Care as director of the Advanced Heart Failure Therapies program in 2013, Vinay Thohan, MD, has launched several investigator-initiated projects with funding—totaling nearly $150,000—from both internal and external sources.

A nearly $50,000 grant from a Cardiovascular Surgery Research Award will support collaborative efforts to understand how the ratio of omega-3 and -6 fatty acids in tissue and fat stores on the outer layer of the heart may contribute to coronary heart disease. This work could lead to greater understanding of coronary heart disease changes to dietary recommendations to prevent this disease.

Completing work started for a separate Cardiovascular Surgery Research Award received in 2014 with nearly $50,000 in additional funds, Dr. Thohan is working to identify clinical factors that may predict the development of gastrointestinal bleeding in patients with left ventricular assist devices (LVADs). The purpose of the study is to improve the selection criteria for patients and develop a better understanding of the risks for patients who receive an LVAD as lifesaving therapy.

A third project supported by the Greater Milwaukee Foundation with a nearly $50,000 grant is targeting how best to stratify the risk among patients with heart disease who undergo noncardiac surgery. This study may lead to a readily available risk-stratifying tool and interventions that lower risk so patients can undergo surgeries safely.

Senior research scientist Scarlet Shi, PhD, is collaborating on these projects.

Precision medicine and population health

People who receive a new heart valve are more susceptible to heart attack and stroke because of the increased risk of clot formation in the bloodstream after surgery. The anticoagulation medication warfarin is the only drug approved by the Food and Drug Administration to prevent strokes and heart attacks in patients with new heart valves. However, warfarin is challenging to prescribe as it works well for some people, but causes harm in others.

With $50,000 support from a Cardiovascular Surgery Research Award grant, senior research scientist Kourosh Ravvaz, MD, PhD, is leading an investigator-initiated precision medicine study to develop a model that will help physicians predict the quality of warfarin therapy in patients undergoing heart valve surgery.

To create and test the prediction model, Dr. Ravvaz and his research team are combining data from Aurora’s electronic health record system with genetic data from blood samples stored in the Biorepository and Specimen Resource Center.

Working with investigators at Harvard Medical School and University of Minnesota, Dr. Ravvaz is simultaneously trying to further efforts to personalize warfarin therapy while comparing the effectiveness of multiple protocols across different populations.

Through this collaboration, Dr. Ravvaz received $120,000 from Harvard’s National Institutes of Health grant to serve as principal investigator of this multiyear study at Aurora Health Care.
Physician leads nationwide trial on same-day discharge

Does implantation of an implantable cardioverter-defibrillator require an overnight stay or is it safe to go home the same day?

This is a question Indrajit Choudhuri, MD, wanted to answer so he partnered with Ranjit Suri, MD, of Heart Rhythm Associates of New York as national principal investigators and secured St. Jude Medical Inc. as the sponsor (SDD for ICD, clinicaltrials.gov identifier: NCT01993862).

Nearly 30 sites enrolled more than 260 subjects receiving an ICD for primary prevention against sudden cardiac death. Aurora St. Luke’s Medical Center was the only recruitment site in Wisconsin.

This trial was the first of its kind to clarify that there are no significant differences in complications with either discharge strategy, be it same or next day. Patients readily accepted being discharged on the same day as their procedure. The findings will be presented at the Heart Rhythm Society annual scientific session.

Data collection on patient outcomes continues. Phyllis Runningen, BSN, is serving as site coordinator.

Registry tracks outcomes of rejection monitoring test

Patients who receive a transplanted heart, or an allograft, require long-term monitoring for possible organ rejection. The current standard of care calls for invasive biopsies every month or every other month during the first year and biannually thereafter to monitor for organ rejection.

Principal investigator Nasir Sulemanjee, MD, is tracking short- and long-term outcomes for CareDx Inc.’s AlloMap test, a noninvasive option to avoid the risks and discomforts associated with the biopsy procedure (OAR, clinicaltrials.gov identifier: NCT01833195). Aurora St. Luke’s Medical Center is the only recruitment site in the state.

Subjects provide a blood sample at the same intervals as for the biopsy procedure. Gene expression of immune system cells are profiled using the AlloMap method, which has been cleared by the Food and Drug Administration.

This registry trial builds on a previous trial that found the AlloMap test to be comparable to biopsy. The goal is to enroll about 2,000 subjects and assess them for five years. Marilyn Miller, RN, is serving as site coordinator.

The goal is to enroll about 2,000 subjects and assess them for five years.

Clinical trial coordinator Marilyn Miller, RN, explains the registry trial that will track short- and long-term outcomes of the noninvasive AlloMap test to a potential subject during the informed consent process.
Trial tests whether investigational drug reduces adverse events

When a person’s heart is unable to contract normally, it can’t pump with enough force to circulate blood adequately. These patients with impaired left ventricular systolic function face possible complications or death when they undergo surgery to repair it.

Frank Downey, MD, is leading a clinical trial at Aurora St. Luke’s Medical Center, the only recruitment site in Wisconsin, to study the effectiveness of an investigational drug levosimendan (Tenax Therapeutics Inc.) in improving outcomes after subjects with left ventricular systolic dysfunction undergo cardiac surgery (LEVO-CTS, clinicaltrials.gov identifier: NCT02025621).

Researchers plan to enroll an estimated 760 patients at about 60 sites in the U.S. and Canada.

Jennifer Cooper, BSN, is serving as site coordinator.

Researchers study safety, effectiveness of bioprosthesis valve

Not all patients are eligible for minimally invasive transcatheter aortic valve replacement. Many patients still require open heart surgery to replace diseased aortic valves.

David Kress, MD, is leading a clinical trial to study Medtronic Inc.’s Model 400 aortic valve bioprosthesis at Aurora St. Luke’s Medical Center, the only recruiting site in Wisconsin (PERIGION, clinicaltrials.gov identifier: NCT02088554).

As part of the Phase III international clinical trial, Dr. Kress is studying the safety and effectiveness of the investigational valve in the treatment of subjects with moderate or greater aortic stenosis, which is narrowing of the valve, or regurgitation, in which blood flows in the reverse direction.

No more than 1,300 subjects will receive the valve at about 40 sites throughout the United States, Europe and Canada. Researchers will assess the subjects for five years after implant with regard to valve-related adverse events and death.

Jennifer Cooper, BSN, is serving as site coordinator.

FDA approvals

Aurora Research Institute was instrumental in bringing these innovations to market through participation in clinical trials.

CoreValve® Transcatheter Aortic Valve System (Medtronic)

Expanding the uses for CoreValve, the Food and Drug Administration in March 2015 approved the valve-in-valve indication for patients who previously had their aortic valve surgically replaced and need a replacement. CoreValve, implanted via a minimally invasive transcatheter approach, also is approved for patients who are not candidates for surgery. First in the state to implant the artificial aortic valve through a clinical trial, Aurora researchers Tanvir Bajwa, MD, and Daniel O’Hare, MD, continue to study additional uses at Aurora St. Luke’s Medical Center, the only recruiting site in Wisconsin for these trials. Michelle Bennett, RN, Kelly Magee, MSN, Dob Wallor, BSN, and Wendy Schmidt, RN, are part of the team that supports transcatheter aortic valve replacement trials.

Evera MRI (Medtronic)

Approved by the FDA in September 2015, the Evera MRI is the world’s first implantable cardioverter-defibrillator safe for use with magnetic resonance imaging. Atul Bhatia, MD, served as principal investigator at Aurora St. Luke’s, the only recruiting site in Wisconsin for the international trial. Anthony Chambers, BSN, served as site coordinator.

Praluent (Sanofi U.S.)

Stephen Welka, MD, is serving as principal investigator at Aurora Memorial Hospital of Burlington for a multicenter trial that resulted in FDA approval of Praluent (alirocumab) injection in July 2015. Praluent is the first cholesterol-lowering treatment approved in a new class of drugs known as PCSK9 inhibitors. Carol Feldhausen, BSN, serves as site coordinator.

WATCHMAN™ (Boston Scientific Corp.)

Providing the first-of-its-kind alternative to long-term warfarin therapy for stroke risk reduction in patients with nonvalvular atrial fibrillation, Boston Scientific Corp. in March 2015 received FDA approval for its WATCHMAN™ Left Atrial Appendage Closure Device. Jasbir Sra, MD, and Tanvir Bajwa, MD, serve as principal investigators at Aurora St. Luke’s for the two clinical trials. Anthony Chambers, BSN, serves as site coordinator.
Angel or hero? Institute recognizes subject for cardiovascular clinical trial participation

He wrote a story of his experience titled “Angels in Our Midst,” and he should count himself among their ranks.

When he was 55, Craig Hummer, 57, of Muskego suffered a major stroke caused by a hole between the top two chambers of his heart, otherwise known as a patent foramen ovale.

“Apparently I’ve had this condition since I was born,” Hummer said.

To correct it and reduce his chances of a future stroke, he decided with support from his wife Kimberly to pursue a clinical trial studying the safety and effectiveness of a septal occluder device produced by W. L. Gore & Associates (clinicaltrial.gov identifier: NCT00738894).

“He took a chance not only for himself, but for all of us to try something new, a new treatment that hadn’t been tested,” said Deb Waller, BSN, the research nurse coordinating the trial. “He didn’t know if he would benefit personally and he knew there were risks, but he jumped in.”

Implanted in February 2015 by Tanvir Bajwa, MD, principal investigator of this Phase III trial at Aurora St. Luke’s Medical Center, Hummer was one of the last subjects randomized to receive the device. Nationwide, researchers enrolled 664 subjects, testing the device plus stroke prevention drugs against the drugs alone for prevention of future strokes.

Hummer, who remains involved in the study for about four more years, said he is “back to 100 percent, which is rare for that severe of a stroke.”

For his willingness to participate in a clinical trial – or get his hands dirty as he put it – Aurora Research Institute in September recognized Hummer with the 2015 Subject Hero Award.

During his acceptance speech, Hummer thanked the caregivers at Aurora St. Luke’s from the “top” of his heart.

Craig’s Angels
Kimberly Hummer, wife
Paul (Layla) Weis, son (daughter-in-law)
Jessica Niebuhr, daughter
Kaila, Hadley, Hunter, grandchildren
Anthony Niebuhr, son-in-law
Alvin Kuhn, father-in-law
Mary Ann Kuhn, mother-in-law
Scott Kuhn, brother-in-law
Wade Hummer, brother
Roxanne Klejsmits, sister
Donna (Bryan) Nitzel, sister (brother-in-law)
Connie (Gary) Lehwalt, sister (brother-in-law)
Denise Widerski, sister
Mark Hummer, brother
Kathy Plues, sister
Eric Hummer, brother
Scott Stuckart, friend
Rory Mulholland, coworker
Maurice Parker, former (retired)
Matt Peters, coworker
New Berlin Emergency Medical Services paramedics
David Bokerman, MD, emergency medicine physician
Umang Shah, MD, neurologist
Intensive Care Unit doctors, nurses, nursing aides
Deb Waller, BSN, senior research nurse coordinator
Tanvir Bajwa, MD, interventional cardiologist

In the news
Milwaukee Journal Sentinel: A close friendship, a quick response, and a tragedy averted

Hummer’s experience should not be used to predict outcomes of the clinical trial. Data collection continues.

Craig Hummer and grandson Hunter at the Greater Milwaukee Clinical Research Recognition Event.
Food and Drug Administration clears advanced 3D cardiac mapping system developed at Aurora

Nearly nine years after realizing the need for simpler, cost-effective and innovative techniques, internationally recognized cardiac electrophysiologist Jasbir Sra, MD, received Food and Drug Administration clearance to market a new three-dimensional cardiac mapping system that could transform the treatment of heart rhythm abnormalities such as atrial fibrillation.

Incorporating APN Health LLC, Dr. Sra brought together scientists and engineers from all over the world to work over this unique concept over the last four years. The first product developed by an Aurora Health Care physician to receive FDA clearance, Navik 3D™ can be used to create 3D maps of the cardiac chamber of interest, pinpointing the exact locations of catheters and guiding them to specific points in the heart to treat arrhythmias. It is the first cardiac mapping system that does not require specialized equipment, using existing patient monitoring and fluoroscopic imaging systems in hospital labs.

“FDA clearance of Navik 3D represents a major milestone,” said Dr. Sra. “We are proud that we’ve been able to develop a cost-effective and simple technology that will allow physicians throughout the world to more easily, accurately and confidently complete their procedures.”

With backing from Aurora and support from Aurora Research Institute, the new technology builds on their commitment to innovation.

The first product developed by an Aurora Health Care physician to receive FDA clearance

“Aurora Health Care and the Aurora Research Institute are proud to support the work of Dr. Sra and his talented team in the development of this leading-edge technology that will ultimately better treat patients with heart irregularities,” said Randall Lambrecht, PhD, president of the institute. “Dr. Sra is a pioneer in his understanding of heart arrhythmias and we were thrilled to see the FDA clearance of Navik 3D.”

APN Health contracted with Aurora to conduct the necessary studies to obtain FDA clearance. The collaboration included approval by Aurora’s institutional review board to allow testing that helped develop the software. Going forward APN Health has contracted with Aurora to conduct patient studies for further improvement before the device sees widespread clinical use.

The technology is anchored by a growing portfolio of patented intellectual property.

“Our proprietary digital image processing techniques and algorithms provide us with a remarkable platform from which to provide even greater functionality for electrophysiologists,” Dr. Sra said.
Cardiovascular Research Advisory Committee
Suhail Allaqaband, MD
Khawaja Ammar, MD
Tarvish Bajwa, MD
Indrajit Choudhuri, MD
Anthony DeFranco, MD
Nina Garlie, PhD
Arshad Jahangir, MD
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Renuka Jain, MD

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(co-chair)
Anthony DeFranco, MD
Nina Garlie, PhD
Arshad Jahangir, MD
M. Fuad Jan, MD

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Nina Garlie, PhD
Arshad Jahangir, MD
M. Fuad Jan, MD

Cardiovascular volumes – systemwide

<table>
<thead>
<tr>
<th>Cardiovascular surgery</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary artery bypass graft (CABG), total</td>
<td>882</td>
<td>926</td>
<td>921</td>
</tr>
<tr>
<td>CABG on pump</td>
<td>691</td>
<td>768</td>
<td>792</td>
</tr>
<tr>
<td>CABG off pump</td>
<td>191</td>
<td>158</td>
<td>129</td>
</tr>
<tr>
<td>Valve procedures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aortic valve replacement</td>
<td>367</td>
<td>446</td>
<td>356</td>
</tr>
<tr>
<td>Mitral valve replacement</td>
<td>107</td>
<td>107</td>
<td>104</td>
</tr>
<tr>
<td>Other valve replacement</td>
<td>6</td>
<td>19</td>
<td>19</td>
</tr>
<tr>
<td>Aortic valve repair</td>
<td>5</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Mitral valve repair</td>
<td>76</td>
<td>61</td>
<td>69</td>
</tr>
<tr>
<td>Other valve repair</td>
<td>16</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>Cardiac ablation-open</td>
<td>100</td>
<td>95</td>
<td>122</td>
</tr>
</tbody>
</table>

| Interventional cardiology | | | |
| Heart catheterization, total | 9,449 | 9,394 | 8,194 |
| Cardiac catheterization | 7,266 | 7,049 | 6,057 |
| Angiogram without pressures | 2,183 | 2,345 | 2,137 |
| Coronary intervention | 2,590 | 2,568 | 2,376 |
| With stent | 2,448 | 2,441 | 2,228 |
| Drug-eluting stent only | 2,086 | 2,129 | 2,010 |
| Bare-metal stent only | 326 | 300 | 204 |
| Both | 36 | 12 | 14 |
| Percutaneous coronary intervention without stent | 142 | 127 | 148 |

| Myocardial biopsy | 434 | 343 | 357 |
| Patent foramen ovale/atrial septal defect closure, total | 135 | 135 | 98 |
| Open | 63 | 75 | 58 |
| Closed | 72 | 60 | 40 |
| Transcatheter aortic valve replacement (TAVR) | 112 | 201 | 272 |
| Transcatheter mitral valve replacement (TMVR) | 3 | 17 | 14 |
| Balloon valvuloplasty (percutaneous) | 37 | 40 | 34 |

| Heart failure and transplant | | | |
| Ventricular assist device | 28 | 44 | 50 |
| Heart transplant | 22 | 22 | 24 |

<table>
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<tr>
<th>Vascular medicine</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
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<tr>
<td>Peripheral vascular intervention</td>
<td>1,564</td>
<td>1,710</td>
<td>1,774</td>
</tr>
<tr>
<td>With stent</td>
<td>893</td>
<td>954</td>
<td>908</td>
</tr>
<tr>
<td>Without stent</td>
<td>671</td>
<td>756</td>
<td>866</td>
</tr>
<tr>
<td>Endarterectomy</td>
<td>452</td>
<td>504</td>
<td>486</td>
</tr>
<tr>
<td>Carotid endarterectomy</td>
<td>282</td>
<td>303</td>
<td>326</td>
</tr>
<tr>
<td>Other endarterectomy</td>
<td>170</td>
<td>201</td>
<td>160</td>
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<tr>
<td>Abdominal aortic aneurysm repair</td>
<td>153</td>
<td>172</td>
<td>194</td>
</tr>
<tr>
<td>Endovascular</td>
<td>120</td>
<td>132</td>
<td>166</td>
</tr>
<tr>
<td>Open</td>
<td>33</td>
<td>40</td>
<td>28</td>
</tr>
<tr>
<td>Thoracic aortic aneurysm repair</td>
<td>92</td>
<td>99</td>
<td>125</td>
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<tr>
<td>Endovascular</td>
<td>17</td>
<td>22</td>
<td>29</td>
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<tr>
<td>Open</td>
<td>75</td>
<td>77</td>
<td>96</td>
</tr>
<tr>
<td>Lower extremity bypass</td>
<td>157</td>
<td>175</td>
<td>109</td>
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<tr>
<td>Extracranial intervention</td>
<td>73</td>
<td>34</td>
<td>37</td>
</tr>
<tr>
<td>With stent</td>
<td>67</td>
<td>33</td>
<td>28</td>
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<tr>
<td>Carotid stent</td>
<td>63</td>
<td>28</td>
<td>24</td>
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<td>Other extracranial stent</td>
<td>4</td>
<td>5</td>
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<tr>
<td>Without stent</td>
<td>6</td>
<td>1</td>
<td>9</td>
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<tr>
<td>Intracranial intervention</td>
<td>13</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>With stent</td>
<td>7</td>
<td>5</td>
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<tr>
<td>Without stent</td>
<td>6</td>
<td>1</td>
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<tr>
<td>Atherectomy</td>
<td>0</td>
<td>0</td>
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<table>
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<tr>
<th>Electrophysiology</th>
<th>2013</th>
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<tr>
<td>EP study</td>
<td>1,113</td>
<td>1,130</td>
<td>951</td>
</tr>
<tr>
<td>Cardiac mapping</td>
<td>948</td>
<td>839</td>
<td>769</td>
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<tr>
<td>Cardioversion</td>
<td>1,052</td>
<td>1,175</td>
<td>1,161</td>
</tr>
<tr>
<td>Ablation – percutaneous</td>
<td>1,021</td>
<td>1,050</td>
<td>884</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>878</td>
<td>1,057</td>
<td>982</td>
</tr>
<tr>
<td>Single/dual chamber</td>
<td>777</td>
<td>964</td>
<td>896</td>
</tr>
<tr>
<td>Cardiac resynchronization therapy-pacemaker</td>
<td>101</td>
<td>93</td>
<td>86</td>
</tr>
<tr>
<td>Defibrillator</td>
<td>763</td>
<td>805</td>
<td>747</td>
</tr>
<tr>
<td>Single/dual chamber</td>
<td>424</td>
<td>579</td>
<td>536</td>
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<tr>
<td>Cardiac resynchronization therapy-defibrillator</td>
<td>339</td>
<td>226</td>
<td>211</td>
</tr>
<tr>
<td>Lead extraction</td>
<td>48</td>
<td>68</td>
<td>59</td>
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</table>
Cardiovascular publications

2015 Aurora-authored, peer-reviewed

Journal articles/Book chapters


Abstracts


Kazmi SS, Riaz A, Ahmad MN, Husain FA, Husain I, Yousaf H, Shah S, Ammar KA, Gupta A. A baseline Pd/Pa of 0.86 obviates the need for FFR measurement and adenosine infusion in intermediate coronary stenoses: a large tertiary care experience. J Am Coll Cardiol 2015;65(10S):A1738.


172 oncology clinical trials open to accrual and follow-up as of Dec. 31, 2015

348 total oncology clinical trial enrollments in 2015

$225,000 in external grant funding awarded for investigator-initiated oncology research studies

41% of Aurora’s research is oncology-related

17% of Aurora’s oncology research is investigator-initiated
Through her research program, medical director Judy Tjoe, MD, is dedicated to changing the face of breast cancer care and survivorship.

Translational Oncology Research: Quest for Understanding & Exploration (TORQUE) spans the spectrum from survivorship to clinical and lab-based research. Under the TORQUE umbrella, researchers study the effects of exercise after cancer treatment through Team Phoenix.

Employing a “bedside-to-bench” approach, TORQUE scientists leverage patient data in the electronic health record against tissue and blood samples in the Biorepository and Specimen Resource Center at Aurora St. Luke's Medical Center for longitudinal epidemiological and biomarker analyses.

Based at Aurora Sinai Medical Center, Dr. Tjoe collaborates internally with researchers in the Discovery Laboratory to study ways to trigger the patient's own immune system response to fight cancer. Externally, she works with biotechnology companies to better understand how cancer develops, discover biomarkers and develop new targeted drug therapies.

**Publications/presentations**

In 2015, Judy Tjoe, MD, shared her research findings through manuscript and abstract publication in peer-reviewed journals.

Notably, Dr. Tjoe et al. standardized best-practice care throughout Aurora Health Care by evaluating breast cancer diagnostic practices. The evaluation led to collaboration among surgeons and radiologists to make minimally invasive biopsy the diagnostic modality of choice systemwide. Her poster presentation on the study at the American College of Surgeons 2014 Clinical Congress was recognized as the Faculty Presentation of the Year by Aurora University of Wisconsin Medical Group. The findings were later published in the Journal of the American College of Surgeons and Dr. Tjoe was interviewed about the study for a MedicalResearch.com article.

**TORQUE in the news**

**TMJ 4:**
Ask the Expert: What to do after a cancer diagnosis

**CBS 58:**
Team Phoenix empowering women who have survived breast cancer

**Kenosha News:**
Cancer survivors train for triathlon

**Waukesha Freeman:**
Purple people leaders: Cancer survivors compete in triathlons to keep cancer at bay

**FOX 6/FOX 11:**
“One small step at a time,” Team Phoenix program that culminates in triathlon helping cancer patients heal

**Tom Smith and John Richards, PhD:**
Analyze breast cancer cells using flow cytometry in the newly opened Discovery Laboratory. Flow cytometry is a core feature of the new lab.
Effects of exercise posttreatment: Team Phoenix survivorship program

The Team Phoenix survivorship program helps motivate breast cancer survivors and improve their quality of life. Led by Judy Tjoe, MD, and cancer rehabilitation specialist Leslie Waltke, DPT, patients train under medical guidance for a triathlon, learning best practices for removing physical and psychological barriers for initiating and maintaining a regular exercise routine after cancer treatment.

Exercise physiologists and cardiologists are working collaboratively to study how exercise affects heart function after cardiotoxic breast cancer treatments as part of continuing efforts between TORQUE researchers and Marquette University.

Immunology and endocrinology researchers John Richards, PhD, and Herschel Raff, PhD, together with collaborators at Marquette are investigating ways to improve quality of life by reducing cancer-related fatigue in patients who have undergone treatment.

Studies conducted by TORQUE researchers are supported by generous donors. In 2015, Team Phoenix received $25,000 from Vince Lombardi Cancer Foundation.

Patient spotlight

Giving of yourself: Tissue donation advances research

Meaningful breast cancer research requires the focused energies of invested patients, clinicians, scientists and industry to create forward-moving scientific momentum.

This collaborative atmosphere includes TORQUE researchers and industry partner Stemcentrx Inc. using residual tissue donated by patients to study the molecular makeup of tumor cells in avatars, which improves understanding about how cancer develops, allows discovery of genetic biomarkers and spurs development of new targeted drug therapies.

Breast cancer survivor Ruby Stimmel, 71, of West Bend was willing to contribute her residual tissue after approached by certified clinical research coordinator Brittany Last.

"What good was it doing me?" Stimmel asked. "And if I could help someone and save them the grief that we went through? It was an easy decision."

Ruby’s story

Diagnosed during a regular check-up, Stimmel was put in touch with fellowship-trained breast oncology surgeon Judy Tjoe, MD.

"There was so much information," Stimmel said. "Dr. Tjoe spent two hours with us. She went over absolutely everything, even drawing diagrams."

Stimmel endured nine hours of surgery for a bilateral mastectomy, four rounds of chemotherapy and reconstructive surgery.

"Throughout all of it, I tried to remain focused and positive," Stimmel said. "I couldn’t have done it without my husband of 52 years (Dick). He did things for me. He was super."

Now Stimmel is cancer-free.

"I was told to go ahead and live my life," she said. "It’s made me appreciate what I have a little more and it’s made me thankful. I have six grandchildren I need to live for."

Quite the gem

A giving woman, Stimmel hopes to get back to her volunteerism, pushing wheelchairs at the local hospital and playing games with residents at a nearby assisted living facility.

Her tissue is a valuable gift as it may contain hidden clues — genetic biomarkers — that could lead researchers to predict which patients are susceptible to progression from noninvasive to invasive disease. This knowledge may result in less use of radiation, avoidance of potential side effects and prevention of unnecessary surgery to remove one or both breasts.

Without this knowledge, patients choose to avoid the risk of recurrence.

"Choosing a bilateral mastectomy ultimately was my decision," Stimmel said. "I didn’t want to take a chance of cancer coming back."

TORQUE researchers continue to search for these biomarkers and develop genetic tests through additional partnerships with Genentech Inc., Rock River Cancer Research Foundation, Celcuit LLC and others.
Early Phase Cancer Research Program

Led by medical research director Michael Thompson, MD, PhD, the Early Phase Cancer Research Program is gaining momentum at Aurora Health Care.

Ten early phase cancer clinical trials received initial Institutional Review Board approval in 2015, a testament to the program's mission to provide more early (Phase I and II) therapeutic clinical trials offering the latest options for patients with cancer.

Based on statistical power, Phase I trials evaluate safety and Phase II assess how well investigational treatments work before they can be tested against the current standard of care (Phase III trials).

In the four years prior to Dr. Thompson joining Aurora in 2013, two to three early phase cancer clinical trials, on average, received IRB approval a year. That number increased to 12 in 2013, 8 in 2014 and 10 in 2015.

A clinical trials advocate, Dr. Thompson was selected for the American Society of Clinical Oncology (ASCO) Best Practices in Cancer Clinical Trials Initiative. The process culminated with stakeholders collaborating on best practices in clinical research, with the goal of promoting practical solutions to meeting existing regulatory and administrative requirements on research. Dr. Thompson continues as a member of the ASCO Cancer Research Committee. He is also chair-elect for the ASCO Community Research Forum and chair-elect to the ASCO Cancer Education Committee as well as member of numerous other research and educational activities at the national level.

In the news

**MDigitalLife press release:**
Correcting and replacing new analysis of cancer-related tweets shows emergence of physician “supersusers”

**Mayo Clinic News Network press release:**
Leading experts prescribe how to make cancer drugs more affordable

**M Magazine:**
New cancer centers provide lifesaving treatments

**Milwaukee Journal Sentinel article:**
Overhyped stories on new cancer drugs do more harm than good

**Healthcare Professional Digital Opinion Leaders blog:**
Digital Opinion Leaders have twice the reach online, shows ASCO study

**Healthy Living article:**
Hashtags help organize online conversations about cancer care, research

Clinical trial spotlight

Genetic testing to guide chemotherapy

Testing the theory that therapy designed for each individual’s tumor will improve outcomes, Aurora Health Care in 2015 joined a multicenter Phase II clinical trial that uses genetic testing to guide chemotherapy prescription in patients who did not respond to treatment before surgery and have residual breast cancer after surgery.

Sponsored by Bryan Schneider, MD, of the Indiana University Melvin and Bren Simon Cancer Center, the goal of the trial is to compare two-year survival rates of subjects treated with neoadjuvant chemotherapy with and without the information genetic testing can provide (clinicaltrials.gov identifier: NCT02103385).

Researchers from about 25 study locations plan to enroll more than 130 subjects. Principal investigator Michael Thompson, MD, PhD, is leading the research at Aurora Health Care.

Subjects with residual breast cancer after surgery who are randomized to genetically directed therapy will receive one of 12 different types of chemotherapy based on their molecular biomarkers, indicators that may predict which treatment will best work against that particular person’s tumor.
Institute gives nearly $200,000 in start-up boosts for cancer-related research studies

Aurora Research Institute awarded $194,360 through the Aurora Cancer Care Research Award to seven Aurora Health Care investigators to conduct cancer-related research.

Funds for the program are available due to a generous $1.2 million gift from Vince Lombardi Cancer Foundation. Read about how the gift also is supporting the development of Aurora’s neuro-oncology research program on page 37.

Pictured at left, James Weese, MD, vice president of Aurora Cancer Care, receives a check for $2.2 million from Brent Norris on behalf of the Vince Lombardi Cancer Foundation. More than half the funds went to research.

2015 Aurora Cancer Care research award recipients
Up to $25,000 each

Sanjay Kansra, PhD*
Interrogating the primary and recurrent lesions of breast atypia for concordance/discordance in their core cancer signaling networks

Kourosh Ravvaz, MD, PhD
Predicting clinical validity of bladder cancer nomograms

Richard Rovin, MD
Isolation and characterization of cancer stem cells from metastatic brain tumors (read more on page 38)

Cheruppoli Santhosh-Kumar, MD
Outpatient family conferences in advanced cancer to improve communication

Amin Kassam, MD
Establishment of brain tumor stem cell bank (second-year continuation)

Santhi Kondu, PhD
Preclinical evaluation of disulfiram as combination therapy in breast cancer (second-year continuation)

Preclinical evaluation of disulfiram as combination therapy in pancreatic cancer (second-year continuation)

Dhimant Patel, MD
A Phase I/II study to determine the safety and efficacy of curcumin in patients with oral mucositis secondary to chemotherapy and/or radiation (second-year continuation)

* Due to staffing changes, this project is temporarily on hold. Funding will be used to resume the biomarker analysis in 2016.

Study highlight

Reducing suffering for patients with advanced cancer

With advanced cancer, open lines of communication among caregivers, the patient and family members can ease difficult end-of-life discussions.

Hematologist oncologist Cheruppoli Santhosh-Kumar, MD, is assessing the impact of outpatient family conferences on quality of life and satisfaction of patients with advanced cancer using $25,000 support from an Aurora Cancer Care Research Award grant.

The Vince Lombardi Cancer Clinic in Sheboygan is the pilot site for the study. Attending the family conferences are the oncologist, a nurse navigator, a social worker, an occupational therapist, the patient and loved ones. During the conferences, patients learn about different aspects of palliative care. The purpose is to improve patients’ understanding of prognosis and treatment expectations and assess effectiveness of communication between the care team and family and between the patient and family.

The goals are to reduce suffering for patients with advanced cancer and to offer a model for other institutions to follow in dealing with such sensitive topics. Dr. Santhosh-Kumar presented preliminary findings at the American Society of Clinical Oncology 2015 Palliative Care in Oncology Symposium in October. The abstract was published in the Journal of Clinical Oncology.

FAMILY CONFERENCES

Nurse Navigator  Oncologist  Patient & Loved Ones  Social Worker  Occupational Therapist

Improved Knowledge of Palliative Care Aspects
- Radiation Oncology
- Interventional Radiology
- Psychology
- Chaplain
- Dietician
- Pharmacy
- Pain Management
- Integrative Medicine
One and not quite done: Patient agrees to be followed for clinical trial

A new option for treating early stage breast cancer, available in Wisconsin only at Aurora BayCare Medical Center, provides select patients with one targeted dose of radiation during surgery rather than the traditional method of 33 doses over the course of more than six weeks.

As part of a national clinical trial, William Owens, MD, is leading the research at Aurora BayCare to treat select patients with intraoperative radiation therapy (IORT) and then follow the patients for complications and breast cancer recurrence (TARGET-US, clinicaltrials.gov identifier: NCT01570998).

“I thought ‘go for it.’ They might find a cure for this someday and we might have helped.”

Mary’s story
After finding a lump, Blashka underwent testing – mammography, ultrasound and, eventually, biopsy. Her diagnosis was breast cancer.

“Dr. Owens was excellent from day one,” Blashka said. “He writes everything down for you and charts it out.”

Because the cancer was diagnosed at an early stage and did not have aggressive characteristics, she was eligible for IORT. Dr. Owens informed Blashka that she could have lumpectomy rather than mastectomy to surgically treat her breast cancer, but traditionally the lumpectomy would then be followed by weeks of radiation. It was welcome news when she learned that because of the clinical trial at Aurora BayCare, she qualified to have the radiation performed as a single treatment during surgery.

“They said my eyes lit up right away,” Blashka said. “(IORT) was less invasive and you wouldn’t have to go back for radiation.”

With IORT, radiation delivery time is about 20 to 35 minutes during surgery.

With the support of her husband, Richard, three children, five grandchildren and other family and friends, Blashka is cancer-free.

“They were behind me 100 percent,” Blashka said. “My husband was with me the entire time.”

Other than the expected recovery from undergoing surgery, Blashka suffered none of the side effects from traditional radiation therapy to the breast, such as redness, discomfort and fatigue.

Trial details
University of California-San Francisco is sponsoring the trial with a goal to enroll 755 subjects at about 25 sites in the United States. Patients selected for breast-conserving surgery who are considered to have a low risk of recurrence may be eligible. It is estimated that 25 percent of new breast cancer patients at Aurora BayCare will qualify.

Sarah Peterson, RN, is serving as site coordinator for the clinical trial.

Blashka’s experience should not be used to predict outcomes of the clinical trial. Data collection continues.

Clinical trial for bladder cancer treatment tests chemotherapy prior to surgery

Patients with bladder cancer that is likely to recur and spread typically undergo surgery to remove the affected upper urinary tract. However, this surgery often affects kidney function, preventing patients from receiving chemotherapy after surgery.

Rubina Qamar, MD, is leading a clinical trial at sites throughout Aurora Health Care to test an investigational approach to aggressive urinary tract cancer of initiating chemotherapy prior to surgery (clinicaltrials.gov identifier: NCT02412670).

This National Cancer Institute Phase II trial is sponsored by Eastern Cooperative Oncology Group (ECOG)-American College of Radiology Imaging Network (ACRIN) Cancer Research Group.

Researchers are testing whether chemotherapy before surgery, when the kidneys are at peak performance, may be more effective in killing or stopping the growth or division of tumor cells. Blood, urine and tumor specimen from the about 60 patients to be enrolled will be evaluated for potential markers of chemotherapy response or resistance.
Results show combination therapy extends life in advanced prostate cancer; follow-up continues

Only a small percentage of prostate cancers spread, and for most patients with advanced prostate cancer there is no cure. Current treatments attempt to slow its spread, improving survival and quality of life.

Results from a clinical trial showed that an investigational combination therapy extended life by more than a year for men with metastatic prostate cancer. Published in The New England Journal of Medicine in 2015, the results of the CHAARTED trial compared chemotherapy plus androgen ablation therapy to androgen ablation therapy alone (clinicaltrials.gov identifier: NCT00309985).

Rubina Qamar, MD, serves as principal investigator at Aurora Health Care.

Produced in the testicles and adrenal glands, androgens can cause prostate cancer cells to grow. The current standard of care is androgen ablation therapy, a minimally invasive procedure that destroys abnormal cells. The purpose of this Phase III clinical trial was to determine if adding the chemotherapy drug docetaxel, which works in a different way to stop the growth of cancer cells, is more effective in improving survival.

This National Cancer Institute trial is sponsored by the Eastern Cooperative Oncology Group (ECOG)-American College of Radiology Imaging Network (ACRIN) Cancer Research Group. Nationwide, sites enrolled 790 subjects who will be followed for up to 10 years.

An investigational combination therapy extended life by more than a year for men with metastatic prostate cancer.

Aurora NCORP on track to double enrollments

In the first year of its five-year grant, Aurora NCORP increased enrollments in National Cancer Institute-sponsored clinical trials from 84 to 140.

In August 2014, NCI designated Aurora Health Care as one of 34 institutions in the country an NCI Community Oncology Research Program site. With the designation comes $3.9 million over five years to bring NCI-sponsored clinical trials directly to the community.

Led by principal investigators Thomas Saphner, MD, and Michael Thompson, MD, PhD, Aurora NCORP is on pace to reach 165 enrollments in year two of the grant, nearly doubling enrollment from the year before the grant was available.

New membership to the Wake Forest, University of Rochester Cancer Center and Alliance for Clinical Trials in Oncology research bases played a key role in increasing patient enrollment.

NCORP includes a range of cancer prevention, screening, control and treatment clinical trials. Currently, there are more than 50 NCI trials open to enrollment throughout Aurora.

An example of a cancer control study, which focuses on enhancing quality of life and cancer care, is URCC’s PSYCH (Evaluation of Psychoeducation for Cancer Patients Eligible for Clinical Trials, clinicaltrials.gov identifier: NCT02054715). Aurora researchers recruited subjects to determine how different educational interventions affect patient preparedness for clinical trial participation.

Aurora NCORP also features precision medicine, studies like the ALCHEMIST trials (clinicaltrials.gov identifiers: NCT02194738, NCT02193282, NCT02201992). Using a subject’s genetic information, researchers prescribe treatment targeted specifically to genetic abnormalities.

Neha Glant serves as the research program administrator in collaboration with oncology clinical trials manager Jan DeBartolo, MSN.
Wife’s legacy continues to live on as center’s focus transitions to cardio-oncology specialty

Karen Yontz Women’s Cardiac Awareness Center, located inside Aurora St. Luke’s Medical Center, has offered education about heart disease to women for 20 years. Ken Yontz made the initial gift that helped start the center in 1996 in honor of his late wife Karen. Going forward, its focus will shift to the rapidly evolving cardio-oncology specialty.

“This new focus will really fit well into the cause of Karen’s death,” Ken said. “She had Hodgkin’s in her 20s and had a significant amount of chemotherapy and radiation. She died from a heart attack at the age of 48. Her heart disease was all related to her cancer treatment.”

That all too common result is precisely the kind of tragedy the cardio-oncology specialty was created to prevent. The new program, dubbed Karen Yontz Center for Cardio Oncology at Aurora Health Care, will be one of the first of its kind to feature a unique collaboration between cardiology and cancer service lines, advancing an initiative that has gained traction over the past few years.

“We’re building a database that will monitor patients who are treated with potentially cardiotoxic chemotherapy,” said cardiologist Bijoy Khandheria, MD. “This will allow us to track any cardiac side effects resulting from the cancer treatment and modify treatment plans as appropriate.”

James Weese, MD, vice president of Aurora Cancer Care, said the center will use molecular studies to find those patients at greatest risk for developing cardiac toxicity so that their physicians can individually tailor drug dosing and cardiac monitoring when using drugs with the potential to cause heart disease.

“This could change how cancer patients are cared for in the future,” Dr. Weese said. “Especially women, as many of the drugs being studied are often used to treat breast cancer.”

Dr. Khandheria said some patients, depending on their risk, will require heart screenings before, during and after their cancer treatment to see what kind of effect chemotherapy is having on the heart.

Ken is excited about the impact the program is going to have.

“I’m just really encouraged,” Ken said. “The doctors who are involved are extremely impressive individuals and they are very engaged. There’s a real need for this.”

“Because of donors like Ken, we’re going to advance the field and not just compete in it,” Dr. Weese said. “This is setting a new standard.”

Launched of Karen Yontz Center for Cardio Oncology at Aurora Health Care will advance Aurora-based research of new and better ways to diagnose and treat patients susceptible to the cardiotoxic effects of certain chemotherapy drugs. Existing research includes:

- In August 2015, Aurora authors Bijoy Khandheria, MD, Rubina Gamar, MD, and Charles Bomzer, MD, along with several Italian collaborators, published a manuscript on the different imaging options used in cardio-oncology in Journal of Oncology. The paper identified the conventional and newer modalities available for detecting the earliest alterations of heart function, allowing timely treatment management.

- A meta-analysis led by senior research scientist Scarlet Shi, PhD, reviewed the incidence and risk factors of cardiotoxicity using the breast cancer chemotherapy drug trastuzumab. The findings were presented at Aurora Scientific Day 2015 and the abstract published in Journal of Patient-Centered Research and Reviews.

- A special issue on cardio-oncology published in summer 2014 has been JPCRR’s most popular issue to date. Guest edited by Drs. Bomzer and Khandheria, the issue includes the journal’s top four most downloaded articles – all featuring Aurora authors – through the end of 2015.
Clinical Trials Department supports #CHUCKSTRONG

Championing cancer research, the Clinical Trials Department in collaboration with the Vince Lombardi Cancer Foundation participated in the #CHUCKSTRONG social media campaign in May 2015. In honor of Indianapolis Colts coach Chuck Pagano, the campaign celebrates champions who exhibit strength, perseverance and compassion, and promotes support of cancer research. Pagano is a cancer survivor.

Oncology volumes (new cases) - systemwide

Source: Cancer Registry

<table>
<thead>
<tr>
<th>Primary site of disease</th>
<th>2013</th>
<th>2014</th>
<th>2015*</th>
</tr>
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<tbody>
<tr>
<td>Oral cavity</td>
<td>134</td>
<td>149</td>
<td>210</td>
</tr>
<tr>
<td>Lip</td>
<td>4</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Tongue</td>
<td>44</td>
<td>47</td>
<td>52</td>
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<tr>
<td>Oropharynx</td>
<td>9</td>
<td>7</td>
<td>40</td>
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<tr>
<td>Hypopharynx</td>
<td>5</td>
<td>10</td>
<td>67</td>
</tr>
<tr>
<td>Other</td>
<td>72</td>
<td>81</td>
<td>49</td>
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<tr>
<td>Digestive system</td>
<td>1,074</td>
<td>1,036</td>
<td>1,061</td>
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<tr>
<td>Esophagus</td>
<td>79</td>
<td>70</td>
<td>89</td>
</tr>
<tr>
<td>Stomach</td>
<td>81</td>
<td>75</td>
<td>78</td>
</tr>
<tr>
<td>Colon</td>
<td>322</td>
<td>319</td>
<td>420</td>
</tr>
<tr>
<td>Rectum</td>
<td>159</td>
<td>143</td>
<td>137</td>
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<tr>
<td>Anus/anal canal</td>
<td>21</td>
<td>27</td>
<td>27</td>
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<tr>
<td>Liver</td>
<td>97</td>
<td>78</td>
<td>90</td>
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<tr>
<td>Pancreas</td>
<td>205</td>
<td>191</td>
<td>175</td>
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<tr>
<td>Other</td>
<td>110</td>
<td>133</td>
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<tr>
<td>Respiratory system</td>
<td>883</td>
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<td>931</td>
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<tr>
<td>Nasal/sinus</td>
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<td>7</td>
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<tr>
<td>Larynx</td>
<td>47</td>
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<tr>
<td>Lung/bronchus</td>
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<td>855</td>
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<tr>
<td>Other</td>
<td>17</td>
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<tr>
<td>Blood and bone marrow</td>
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<td>497</td>
<td>541</td>
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<tr>
<td>Bone</td>
<td>7</td>
<td>11</td>
<td>10</td>
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<tr>
<td>Connect/soft tissue</td>
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<td>36</td>
<td>64</td>
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<tr>
<td>Skin</td>
<td>383</td>
<td>393</td>
<td>465</td>
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<tr>
<td>Breast</td>
<td>1,325</td>
<td>1,237</td>
<td>1,264</td>
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<table>
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<tr>
<th>Primary site of disease</th>
<th>2013</th>
<th>2014</th>
<th>2015*</th>
</tr>
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<tbody>
<tr>
<td>Female genital</td>
<td>451</td>
<td>528</td>
<td>563</td>
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<tr>
<td>Cervix uteri</td>
<td>46</td>
<td>55</td>
<td>67</td>
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<tr>
<td>Corpus uteri</td>
<td>240</td>
<td>272</td>
<td>291</td>
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<tr>
<td>Ovary</td>
<td>111</td>
<td>118</td>
<td>123</td>
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<tr>
<td>Vulva</td>
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<td>61</td>
<td>62</td>
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<tr>
<td>Other</td>
<td>15</td>
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<tr>
<td>Male genital</td>
<td>872</td>
<td>895</td>
<td>935</td>
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<tr>
<td>Prostate</td>
<td>838</td>
<td>851</td>
<td>874</td>
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<tr>
<td>Testis</td>
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<td>59</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
<td>8</td>
<td>2</td>
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<tr>
<td>Urinary system</td>
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<td>580</td>
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<tr>
<td>Bladder</td>
<td>376</td>
<td>317</td>
<td>368</td>
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<tr>
<td>Kidney/renal</td>
<td>202</td>
<td>241</td>
<td>243</td>
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<tr>
<td>Other</td>
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<td>22</td>
<td>14</td>
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<tr>
<td>Brain &amp; central nervous system</td>
<td>233</td>
<td>366</td>
<td>542</td>
</tr>
<tr>
<td>Brain (benign)</td>
<td>144</td>
<td>280</td>
<td>378</td>
</tr>
<tr>
<td>Brain (malignant)</td>
<td>74</td>
<td>73</td>
<td>124</td>
</tr>
<tr>
<td>Other</td>
<td>15</td>
<td>13</td>
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<tr>
<td>Endocrine</td>
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<td>225</td>
<td>257</td>
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<tr>
<td>Thyroid</td>
<td>130</td>
<td>153</td>
<td>161</td>
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<tr>
<td>Other</td>
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<td>96</td>
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<tr>
<td>Lymphatic system</td>
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<td>324</td>
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<tr>
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<td>80</td>
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<tr>
<td>Other/Ill-defined</td>
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<td>34</td>
<td>31</td>
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<tr>
<td>Total</td>
<td>7,136</td>
<td>7,305</td>
<td>7,913</td>
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*Estimated. Complete data not available at time of publication.
Journal articles/Book chapters


Neurosciences research

- 22 neurosciences clinical trials open to accrual and follow-up as of Dec. 31, 2015
- 164 total neurosciences clinical trial enrollments in 2015

- Neuro-Oncology (7) 32%
- Surgical (6) 27%
- Interventional Radiology (4) 18%
- Stroke (1) 5%
- Multiple Sclerosis (2) 9%
- Epilepsy (2) 9%

- Surgical (138) 84%
- Neuro-Oncology (12) 7%
- Interventional Radiology (10) 6%
- Stroke (1) 1%
- Multiple Sclerosis (3) 2%

~$1.7 million in external grant funding awarded for investigator-initiated neurosciences research studies

6% of Aurora's research is neurosciences-related

29% of Aurora's neurosciences research is investigator-initiated
Aurora Neuroscience Innovation Institute

Setting the standard for innovation and patient-centered neurological care

Eighteen months after joining Aurora Health Care to lead the system’s neurosciences service line, neurosurgeon Amin Kassam, MD, realized his vision of a state-of-the-art facility to treat and study complex brain procedures.

Opened in May 2015, his reality – Aurora Neuroscience Innovation Institute (ANII) – includes a multidisciplinary clinic, education suite, neuroanatomical laboratory and four neurosurgical operating suites featuring first-in-the-world technology (see story on page 36) at Aurora St. Luke’s Medical Center.

With more than $1.4 million in equipment granted or donated by a variety of medical device companies, the neuroanatomical laboratory is equipped with surgical stations and imaging tools that replicate a neurosurgery suite to enable mock surgical procedures on cadaver specimens for training and research purposes.

New imaging technology allows scientists to visualize intricate anatomy in the brain that has never been seen before and will lead to the discovery of safe approaches to access deep seated lesions in the brain without disrupting normal brain anatomy.

After refining them in the neuroanatomical lab, Aurora researchers and clinicians will translate advanced neurosurgical techniques to the operating room, making procedures more accurate, less invasive and safer for patients.

Research associates Sarika Walia, MD, and Srikant Chakravarthi, MD, support activities in the lab.

Publications/presentations

In 2015, the ANII team shared its research findings through manuscript publication in peer-reviewed journals and abstract presentation at national and international meetings.

Sharing their expert knowledge through textbook chapters, ANII team members literally wrote the book on endonasal endoscopic surgery of skull base tumors.

Nina Garlie, PhD, leads tours of the neuroanatomical laboratory during the grand opening of Aurora Neuroscience Innovation Institute at Aurora St. Luke’s Medical Center.

Sarika Walia, MD, and Srikant Chakravarthi, MD, train on state-of-the-art neurosurgical equipment in the neuroanatomical laboratory.
First in the world to use robotic optical microscope

In a breakthrough with the potential to improve outcomes and reduce the risks of complex brain surgeries, the neurosurgical team at Aurora St. Luke’s Medical Center on April 20, 2015, successfully completed a first-in-the-world procedure with newly Food and Drug Administration-cleared technology for planning and resection.

The operation utilized the entire suite of Synaptive Medical Neurosurgical Solutions: BrightMatter™ Guide, Plan, Vision and Servo. This system is comprised of four technologies: advanced optical visualization with efficient light delivery to the surgical field, automated positioning of the optical system at the command of the surgeon, visualization of interaction of surgical tools with medical images and three-dimensional tractography planning. As a result, the procedure was successfully performed with an awake anesthetic technique and minimal risk to the patient’s brain function.

Aurora Neuroscience Innovation Institute neuroradiologist Melanie Fukui, MD, and neurosurgeons Amin Kassam, MD, and Richard Rovin, MD, worked together to plan and perform the surgery.

Neurosurgeon Richard Rovin, MD, consults with neuroradiologist Melanie Fukui, MD. With neurosurgeon Amin Kassam, MD, they successfully completed a first-in-the-world procedure.

Neurosurgeon Richard Rovin, MD, performs an awake craniotomy using Synaptive Medical Neurosurgical Solutions at Aurora St. Luke’s Medical Center.

ANII in the news

CBS 58:
Understanding a brain aneurysm after the sudden loss of community advocate Marc Marotta

FOX 6:
Milwaukee neurosurgeon reaches out to White House after POTUS calls on VP Biden to cure cancer (see page 36)

Milwaukee Journal Sentinel:
NEWaukee’s “speaker crawl” draws hundreds to Milwaukee Public Museum

Milwaukee Journal Sentinel:
Powerful imaging system — and patient’s voice — help guide brain surgeon

Milwaukee Magazine:
Brain gain: How a world-renowned neurosurgeon is making medical history in Milwaukee

BizTimes:
Aurora performs world’s first neurosurgery using new technology (additional coverage)

BizTimes:
Aurora Neuroscience Innovation Institute unveiled (additional coverage)

Fond du Lac Reporter:
Cancer patient beating the odds
Researchers kick start neuro-oncology research program with funds from Vince Lombardi Cancer Foundation

With a generous $1 million grant from Vince Lombardi Cancer Foundation, vice president of Aurora Neurosciences Amin Kassam, MD, is leading the development of a neuro-oncology research program.

Stem cell bank

Access to human brain tumor samples is essential for a successful neuro-oncology research program to thrive since the stem cells derived from the samples will be used to test new cancer therapies in the lab.

With an initial Aurora Cancer Care Research Award in 2014 and continued funding in 2015 totaling $50,000, Dr. Kassam established a brain tumor stem cell bank. The research award program is generously supported by Vince Lombardi Cancer Foundation.

Using residual tissue from surgeries to remove brain tumors, researchers are collecting samples to grow and store stem cells. The project was initiated in an existing laboratory in the Regenerative Medicine Center at Aurora St. Luke’s Medical Center. The proximity of the lab to the operating rooms was advantageous to facilitate effective communication between the study team, operating room staff and pathology, and efficient transfer of the tumor tissue from the operating room to the lab.

Coordination and streamlining of the process required the collaboration of neurosciences research nurse coordinators, representatives of the Biorepository and Specimen Resource Center, researcher scientists and technologists, and the surgeons.

From 60 patients, researchers collected 76 samples of a variety of brain tumors. Using a novel culture method, the team had an above average success rate of 54%, with 68% for brain and spine tumors, or gliomas. Tissue collection is ongoing.

Animal models

After construction of Discovery Laboratory and the vivarium at Aurora Sinai Medical Center, the neuro-oncology researchers moved into the state-of-the-art facility, setting up shop and beginning the next phase of the research – characterization of the cells in animal models.

Led by senior research scientist Chang-Hyuk Kwon, PhD, and neurosurgeon Richard Rovin, MD, the goal of the laboratory research is to determine whether the cells are able to reinitiate tumor growth in mice, since this stem cell characteristic of self-renewal contributes to tumor recurrence in humans.

In 2016, researchers will use new methods of magnetic resonance imaging, ramen spectroscopy and optical coherence tomography to identify differences between healthy and unhealthy tissue at molecular and structural levels.

MRI uses strong magnetic fields to create detailed images of tissues by detecting protons in water molecules.
Neurosurgeon believes cancer cure is possible

“We, like you and President (Barack) Obama, believe we can cure cancer.”

In an open letter, neurosurgeon Richard Rovin, MD, invited Vice President Joe Biden to check out the clinical and basic science research being conducted at Aurora Health Care, particularly in Aurora Research Institute’s new Discovery Laboratory.

Dr. Rovin, recipient of a $25,000 Aurora Cancer Care Research Award, is studying two methods to isolate and characterize cancer stem cells from metastatic brain tumors. The research award program is generously supported by Vince Lombardi Cancer Foundation.

To study these cancer stem cells in the lab, they need to be separated from the rest of the cells in the tumor. There are several different methods to do this, but none have been used to grow cancer stem cells from metastatic brain tumors. The purpose of this research is to find a reliable and efficient way of growing cancer stem cells from metastatic brain tumors by comparing the two different methods.

Five patients with breast or non-small cell lung cancer who underwent brain surgery at Aurora St. Luke’s Medical Center have provided metastatic brain tumor tissue for the study. Enrollment continues with a goal of 25 subjects.

A collaborative effort, the Biorepository and Specimen Resource Center is assisting with collection and storing of the tissues.

This research is the first step toward the long-term goal of finding the molecular and genetic changes that take place in the stem cells of metastatic brain tumors. This knowledge will help explain how and why tumors spread to the brain. It will also help researchers find ways to prevent metastasis and to treat tumors once metastasis has happened.

OCT is a “light” ultrasound that measures tissue topography and structure. RS uses light to measure tissue chemistry, akin to chemical fingerprinting.

Researchers are using these highly specialized imaging technologies before and after the tumor is removed from the patient, before the tumor stem cells are injected into mice and after the tumor has regrown in the mouse.

The next phase of the program is to test new therapeutics on the tumor stem cells and in tumor-bearing mice, using the imaging modalities to detect tumor shrinkage or elimination. One method includes reengineering brain tumor stem cells and redeploying them using viral vectors, the most effective means of gene transfer.
When faced with a lemon-sized tumor in the right side of her brain, Heidi Zellmer of Cedarburg began a journey that would lead the wife and mother of three boys to enroll in a clinical trial testing an investigational combination of chemotherapy for glioblastoma multiforme, a fast-growing brain cancer.

One fall day a few months before her 50th birthday, Zellmer completed a five-mile hike along the bluffs of Devil’s Lake in south central Wisconsin. About a week later, she went to the emergency department at Aurora Medical Center in Grafton with stroke-like symptoms. It wasn’t a stroke though. A CAT scan revealed the tumor.

**One-two punch**

After being transported via ambulance to Aurora St. Luke’s Medical Center, Zellmer spent about a week in the neurointensive care unit undergoing tests before Amin Kassam, MD, performed the awake craniotomy to remove the tumor. George Bobustuc, MD, took over her cancer care that included six weeks of chemotherapy and radiation at Aurora Grafton.

Near the end of her treatment cycle, Dr. Bobustuc informed Zellmer about a clinical trial testing whether temozolomide chemotherapy is more effective with veliparib at improving overall survival in subjects with a particular genetic indications ([National Cancer Institute](https://clinicaltrials.gov); identifier: NCT02152982). Acting as a one-two punch, the chemotherapy damages the cancer cell and the veliparib, a PARP inhibitor, prevents the body from producing a protein that would repair the cell, thereby making it easier to kill.

As part of the research protocol, subjects are randomized to receive the chemotherapy and PARP inhibitor or the chemotherapy and placebo. Zellmer agreed to enroll in the trial, even though she couldn’t be sure she would receive the PARP inhibitor.

“If it could extend my life, why not?” Zellmer said.

**Surrounded by beauty**

The family’s vacation to Hawaii, originally planned for Christmas, transformed into Zellmer’s 50th birthday celebration in February. Though she didn’t want to feel ill from the therapy during the trip, she didn’t want it looming over her head either. She started the first round of the study treatment, an oral therapy, in Hawaii.

“It was still worth it,” Zellmer said. “Being in Hawaii, being outside surrounded by beauty, was very good for my well-being.”

Feeling ill the first two days, she checked in with research study coordinator Lynda Yanny, BSN, who told her how to “stay ahead” of the symptoms.

**Support and care**

A spiritual person, Zellmer has relied on her Christian faith, positivity and extensive support system to carry her through. Not only has her immediate family – husband John and sons Zachary, 22, Benjamin, 10, and Aaron, 8 – stepped up, her mother and sister in Washington, her brother in Alaska as well as friends and neighbors – “people we didn’t even know” – have pitched in.
And she couldn't say enough about her care team throughout Aurora Health Care. “I feel like I’m getting the best care I can get,” she said.

**Looking forward**

Zellmer takes one day at a time. She’s looking forward to seeing Zachary graduate college in Seattle this June. Study treatments wrap up then, though she will be followed for 10 years.

“I think medicine has changed a lot,” Zellmer said. “I’m thankful it is the decade we live in now and hope there are more studies to cure this.”

Walking a mile a day, Zellmer hopes to hike the bluffs of Devil’s Lake again this fall. She goes for an MRI every eight weeks to see if the tumor has grown back. Her scan in March was clear of tumors.

Zellmer is participating in a trial being conducted by Alliance for Clinical Trials in Oncology. Alliance is a member of the National Cancer Institute National Clinical Trials Network and serves as a research base for the NCI Community Research Oncology Program. Aurora St. Luke’s Medical Center is member of the Alliance NCTN network. Zellmer’s experience should not be used to predict outcomes of the clinical trial. Data collection continues.

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**Clinical trial spotlight**

Researchers track outcomes of new multiple sclerosis drug

Recurring attacks, or relapses, of neurological symptoms are common in multiple sclerosis. The drug dimethyl fumarate cuts down on the number of relapses.

James Napier, MD, is leading an observational clinical trial at Aurora BayCare Medical Center to track serious adverse events that lead to the discontinuation of dimethyl fumarate in patients with relapsing multiple sclerosis (ESTEEM, clinicaltrials.gov identifier: NCT02047097).

The drug dimethyl fumarate cuts down on the number of relapses.

Sponsored by the drug’s manufacturer Biogen Inc., the global study will follow about 5,000 subjects for five years. Researchers will track different serious adverse events, including infections, hepatic events, malignancies and renal events.

Jennifer Homa, MS, is serving as site coordinator.

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**Targeted treatment**

**Testing new precision cancer therapies**

Developing new strategies to treat the most frequent forms of brain cancer is the driving force behind the research of senior research scientist Santhi Konduri, PhD, and neuro-oncologist George Bobustuc, MD.

Patient-derived cancer cells are tested to identify different markers associated with glioblastoma multiforme and meningioma brain cancers. The long-term goal is to understand molecular changes that occur during tumor development and to use these molecular markers as therapeutic targets, individualizing treatment to the patient’s specific genetic make-up.

The ultimate goal is to design a safe, effective system allowing for use of a combination of drugs and therapies unique to each patient.

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**Neuro Research Committees**

**Neurosciences Research Committee**

George Bobustuc, MD  
Juanita Celis, MD  
Srikant Chakravarthi, MD  
Denise Coley  
Monica Cucciar

Deb Donohoe  
Amin Kassam, MD (co-chair)  
Melanie Fukui, MD  
Nina Garlie, PhD  
Santhi Konduri, PhD

Chang-Hyuk Kwon, PhD  
Amber Lacrosse, PhD  
Natalie Polinsky, MS  
Richard Rovin, MD (co-chair)  
Sarika Walla, MD

**Clinical Innovation Committee**

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Srikant Chakravarthi, MD  
Shannon Clark, MBA  
Martin Corsten, MD

Melanie Fukui, MD  
Nina Garlie, PhD  
Jonathan Jennings, MD  
Amin Kassam, MD (co-chair)

Sammy Khalili, MD  
Nathaniel Kojis  
Richard Rovin, MD (co-chair)  
Sarika Walla, MD

**Neuroscience Clinical Trials Research Committee**

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Srikant Chakravarthi, MD  
Martin Corsten, MD  
Gary Dennison, CIP  
Melanie Fukui, MD  
Nina Garlie, PhD

Carol Halliday, RN  
Tonya Hollinth, RTE (MR)  
Amin Kassam, MD (co-chair)  
Jennifer Mathieu  
Richard Rovin, MD (co-chair)  
Lori Schwingshakl, RN

Carol Tutino, BSN, MS  
Sarika Walla, MD  
Valerie Werner, BSN  
Lynda Yanny, BSN
Neurosciences volumes - systemwide

Source: Aurora Smart Chart and Medipac

<table>
<thead>
<tr>
<th>Cases*</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epilepsy</td>
<td>3,239</td>
<td>3,210</td>
<td>4,317</td>
</tr>
<tr>
<td>Stroke</td>
<td>2,394</td>
<td>2,433</td>
<td>1,645</td>
</tr>
<tr>
<td>Ischemic</td>
<td>1,316</td>
<td>1,510</td>
<td>1,094</td>
</tr>
<tr>
<td>Transient ischemic attack</td>
<td>576</td>
<td>552</td>
<td>304</td>
</tr>
<tr>
<td>Hemorrhagic</td>
<td>502</td>
<td>371</td>
<td>247</td>
</tr>
<tr>
<td>Interventional radiology**</td>
<td>339</td>
<td>387</td>
<td>446</td>
</tr>
</tbody>
</table>

*For cancers of the brain and central nervous system, see table on page 32.

**Number of patients

Neurosciences publications

2015 Aurora-authored, peer-reviewed

Journal articles/Book chapters


Abstracts


Aurora Research Institute investigators engage in strategic research that includes:

- Orthopedics
- Women’s Health
- Obstetrics/Gynecology
- Geriatrics
- Family Practice
- Population Health

**Additional strategic research**

- **23** additional strategic research clinical trials open to accrual and follow-up as of Dec. 31, 2015
  - Orthopedics: 7 (30%)
  - Humanitarian Use Device/Compassionate Use: 8 (35%)
  - Asthma: 3 (13%)
  - Sleep Medicine: 1 (4%)
  - Pulmonology: 1 (4%)
  - Emergency Medicine: 1 (4%)
  - Women’s Health: 1 (4%)

- **101** total additional strategic research clinical trial enrollments in 2015
  - Orthopedics: 69 (68%)
  - Asthma: 18 (18%)
  - Humanitarian Use Device/Compassionate Use: 11 (11%)
  - Women’s Health: 11 (11%)
  - Sleep Medicine: 1 (1%)
  - Pulmonology: 1 (1%)

**> $800,000** in external grant funding awarded for investigator-initiated additional strategic research studies

- **18%** of Aurora’s research fits in the additional strategic research category
- **75%** of Aurora’s additional strategic research is investigator-initiated
Gender prediction: Is mother’s intuition more accurate than a coin flip?

There are numerous prediction tests to determine a child’s gender before the baby is born. Is the mother carrying low? Expect a boy. Fetal heart rate more than 140 bpm? Expect a girl. A Chinese model uses the month and mother’s age at conception.

The accuracy of these methods is dubious at best.

Obstetrics sonographer Michael McFadzen, BS, ARDMS, questioned whether maternal intuition might be a more accurate predictor. Based at Aurora Sheboygan Clinic, McFadzen tested his hypothesis, presenting the preliminary findings at Aurora Scientific Day.

All patients between 17 and 23 weeks pregnant were asked if they had an intuition about the baby’s gender during their second trimester screening ultrasound. Patients with advance knowledge of fetal gender from imaging results were excluded from the study.

Ultrasound was used to confirm or debunk the mother’s intuition. Data collection wrapped up in 2015 and manuscript preparation is in progress.

David Dielentheis, MD, and Ronda Kasten contributed to the study.

Study helps patients get treatment for bowel, bladder dysfunction, then measures quality-of-life improvements

Bowel and bladder dysfunction are difficult topics to discuss, even with a health care provider. To avoid the embarrassment, many people adjust their habits and lifestyles to accommodate the management of symptoms.

A survey study measuring subject satisfaction is offering a discrete way for underserved people suffering with these conditions to get the medical care they need.

Patients arriving at an Aurora Family Practice, Internal Medicine or Women’s Health clinic will have an opportunity to fill out a questionnaire on their bowel and bladder function and indicate whether they are interested in setting up a consultation with a specialist. The questionnaire allows identification of patients who may otherwise go untreated.

Those who agree to a consultation have the opportunity to participate in a series of surveys exploring quality-of-life improvements with treatment over the course of a year.

Urogynecologist Alexis Chesrow, MD, is leading the study at Aurora West Allis Medical Center. Lori Bowhousen is serving as site coordinator.

Bowel and bladder conditions

- prolapse
- stress urinary incontinence
- urgent urinary incontinence
- fecal urgency
- fecal incontinence
- constipation
Podiatrists study new approaches to foot surgeries

Recognized as Principal Investigators of the Year during the Aurora BayCare Medical Center Fall Research and Medical Education Reception for completing two innovative studies, BayCare Clinic podiatrists J. George De Vries, DPM, and Brandon Scharer, DPM, presented their findings at the 2016 American College of Foot and Ankle Surgeons Conference.

Led by Dr. De Vries, the researchers studied outcomes of a grafting process that utilized a manufactured bone morphogenetic protein rather than a bone fragment harvested from elsewhere in the body to fuse bones in the foot and ankle, a treatment to relieve pain. With promising initial findings and inherent advantages, the researchers recommend further study.

Led by Dr. Scharer, the researchers compared two surgical approaches for treating bunions. Chevron osteotomy is the standard treatment, which corrects the alignment of the bone. With the distal oblique approach, which has not been applied to bunions, the surgeon approaches the surgery at an angle. Both outcomes and patient satisfaction between the two techniques were similar. Taylor Romdenne coordinated the studies.

Women’s Health volumes – systemwide

Source: AIM/Epic Hospital and Professional Billing Data

<table>
<thead>
<tr>
<th>Breast Health Procedures</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
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<tbody>
<tr>
<td>Mammography</td>
<td>158,709</td>
<td>154,771</td>
<td>157,283</td>
</tr>
<tr>
<td>Screening</td>
<td>131,683</td>
<td>128,289</td>
<td>126,882</td>
</tr>
<tr>
<td>Diagnostic</td>
<td>27,026</td>
<td>26,482</td>
<td>30,401</td>
</tr>
<tr>
<td>Digital (%)</td>
<td>96%</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>Breast ultrasound</td>
<td>16,155</td>
<td>17,534</td>
<td>16,826</td>
</tr>
<tr>
<td>Core biopsy</td>
<td>3,180</td>
<td>3,456</td>
<td>3,373</td>
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<tr>
<td>Ultrasound-guided</td>
<td>2,146</td>
<td>2,203</td>
<td>2,179</td>
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<tr>
<td>Stereotactic</td>
<td>1,188</td>
<td>1,096</td>
<td>1,283</td>
</tr>
<tr>
<td>MRI-guided</td>
<td>29</td>
<td>41</td>
<td>45</td>
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<tr>
<td>Breast MRI</td>
<td>1,372</td>
<td>1,419</td>
<td>1,269</td>
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<tr>
<td>Needle localization</td>
<td>391</td>
<td>412</td>
<td>451</td>
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<table>
<thead>
<tr>
<th>Obstetrics/Newborn</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital deliveries</td>
<td>12,883</td>
<td>12,327</td>
<td>12,798</td>
</tr>
<tr>
<td>C-section (%)</td>
<td>26.2%</td>
<td>27.5%</td>
<td>27.4%</td>
</tr>
<tr>
<td>Hospital newborns</td>
<td>13,246</td>
<td>12,754</td>
<td>13,221</td>
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<tr>
<td>Hospital newborn NICU admissions</td>
<td>1,425</td>
<td>1,406</td>
<td>1,476</td>
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<tr>
<td>Level III unit</td>
<td>1,101</td>
<td>1,027</td>
<td>1,114</td>
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<tr>
<td>Level II unit</td>
<td>324</td>
<td>379</td>
<td>362</td>
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<tr>
<td>Average length of stay (days)</td>
<td>15.7</td>
<td>16.0</td>
<td>16.0</td>
</tr>
<tr>
<td>Average daily census</td>
<td>62.2</td>
<td>61.7</td>
<td>64.6</td>
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</table>

<table>
<thead>
<tr>
<th>Maternal Fetal Medicine</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
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</thead>
<tbody>
<tr>
<td>Ultrasounds</td>
<td>36,850</td>
<td>37,987</td>
<td>40,893</td>
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<tr>
<td>Office visits</td>
<td>3,003</td>
<td>3,305</td>
<td>3,524</td>
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<table>
<thead>
<tr>
<th>Fertility</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVF cycles</td>
<td>291</td>
<td>297</td>
<td>420</td>
</tr>
<tr>
<td>Aurora West Alis</td>
<td>164</td>
<td>175</td>
<td>253</td>
</tr>
<tr>
<td>Aurora Green Bay</td>
<td>127</td>
<td>122</td>
<td>167</td>
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<table>
<thead>
<tr>
<th>Gynecology (Primary Diagnostic) Visits</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other disorders of female genital tract</td>
<td>107,981</td>
<td>111,818</td>
<td>112,693</td>
</tr>
<tr>
<td>Routine gynecologic exam</td>
<td>64,504</td>
<td>73,377</td>
<td>75,944</td>
</tr>
<tr>
<td>Contraceptive management</td>
<td>45,972</td>
<td>47,351</td>
<td>47,826</td>
</tr>
<tr>
<td>Benign gynecology</td>
<td>7,610</td>
<td>7,202</td>
<td>7,029</td>
</tr>
<tr>
<td>General fertility management</td>
<td>6,915</td>
<td>6,727</td>
<td>6,825</td>
</tr>
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</table>

Gynecology (Primary Procedures)

<table>
<thead>
<tr>
<th>Hospital procedures</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital procedures</td>
<td>6,227</td>
<td>6,149</td>
<td>6,236</td>
</tr>
<tr>
<td>Outpatient (%)</td>
<td>8.2%</td>
<td>7.0%</td>
<td>7.6%</td>
</tr>
<tr>
<td>Laparoscopic (%)</td>
<td>55.2%</td>
<td>58.7%</td>
<td>59.1%</td>
</tr>
<tr>
<td>Laparoscopic assist (%)</td>
<td>10.9%</td>
<td>11.2%</td>
<td>10.3%</td>
</tr>
<tr>
<td>Robotic assist (%)</td>
<td>27.8%</td>
<td>25.5%</td>
<td>26.3%</td>
</tr>
<tr>
<td>Open (%)</td>
<td>15.5%</td>
<td>14.5%</td>
<td>16.1%</td>
</tr>
<tr>
<td>Cancer (%)</td>
<td>11.7%</td>
<td>13.7%</td>
<td>10.9%</td>
</tr>
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</table>

Urogynecology

<table>
<thead>
<tr>
<th>Urogynecology surgical procedures</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolapse</td>
<td>835</td>
<td>986</td>
<td>1,092</td>
</tr>
<tr>
<td>Incontinence</td>
<td>692</td>
<td>669</td>
<td>607</td>
</tr>
<tr>
<td>Revision mesh</td>
<td>36</td>
<td>42</td>
<td>33</td>
</tr>
</tbody>
</table>

Orthopedic volumes – systemwide

Source: Aurora Smart Chart

<table>
<thead>
<tr>
<th>Admits/Visits</th>
<th>2013</th>
<th>2014</th>
<th>2015*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand/Wrist/Forearm</td>
<td>11,140</td>
<td>11,837</td>
<td>13,020</td>
</tr>
<tr>
<td>Knee</td>
<td>12,112</td>
<td>12,413</td>
<td>13,541</td>
</tr>
<tr>
<td>Lower Leg/Foot/Ankle</td>
<td>19,983</td>
<td>20,789</td>
<td>24,503</td>
</tr>
<tr>
<td>Pelvis/Femur</td>
<td>8,364</td>
<td>9,022</td>
<td>10,883</td>
</tr>
<tr>
<td>Shoulder/Elbow/Upper Arm</td>
<td>15,487</td>
<td>16,833</td>
<td>20,304</td>
</tr>
<tr>
<td>Spine/Back/Neck</td>
<td>57,109</td>
<td>61,837</td>
<td>68,413</td>
</tr>
<tr>
<td>Other</td>
<td>17,057</td>
<td>19,371</td>
<td>25,030</td>
</tr>
<tr>
<td>Totals</td>
<td>141,252</td>
<td>152,102</td>
<td>175,694</td>
</tr>
</tbody>
</table>

*2015 data annualized
Obstetrics/gynecology research

Led by Marie Forgie, DO, a randomized clinical trial comparing Foley catheter insertion techniques – stylette versus no stylette – for the induction of labor was selected as one of the Aurora Scientific Day Rieselbach distinguished papers and won the Central Association of Obstetrics and Gynecology 2015 Community Hospital Award.

Published in early 2016 in the American Journal of Obstetrics and Gynecology, the manuscript concludes that the use of a stylette to guide catheter insertion does not improve speed of insertion, reduce patient pain levels or decrease failure of catheter placement when compared to insertion without a stylette. Neither technique – stylette versus no stylette – was deemed superior.

Jessica Kram, MPH, Danielle Greer, PhD, Kiley Vander Wyst, MPH, Nikki Salvo, MD, and Danish Siddiqui, MD, contributed to the study and manuscript.

Study whether tumor diameter is an important predictor in determining whether low-risk women can avoid surgery to remove their lymph nodes after being diagnosed with endometrial cancer, the team led by Callie Cox Bauer, DO (pictured at right), won the Dr. George W. Morley Memorial Paper Award at the Central Association of Obstetrics and Gynecology annual meeting.

The study, later published in the Journal of Gynecologic Oncology, found that tumor diameter is an important predictor for identifying whether the cancer has spread. Ultimately, use of the study’s proposed risk model, which incorporated tumor diameter and myometrial invasion, may reduce the number of surgeries for lymph node removal in low-risk women.

Danielle Greer, PhD, Jessica Kram, MPH, and Scott Kamelle, MD, contributed to the study and manuscript.

Geriatrics research

The U.S. Health Resources and Services Administration awarded more than $396,000 over three years to Aurora Senior Services for its Geriatrics Scholars Program. Project director Michael Malone, MD, with assistance from co-project director Aaron Malsch, MSN, will lead the program, which will develop three teams to improve care and transitions for older adults.

The Sponsored Programs Office was instrumental in securing the grant.

Family medicine research

Winning the 2015 Aurora Quality Improvement Award and presenting findings at the Wisconsin Research and Education Network Convocation of Practices, Fabiana Kotovizic, MD, and medical resident Courtney Pokrzywa shared findings on the use of opioids for chronic pain management.

The findings fuel the fire of the controversy over this national epidemic. Opioid prescription for chronic pain management was inconsistent and did not adhere to recommended guidelines at the two clinics studied, though further research is required.

To address the problem, Dr. Kotovicz and a team of researchers developed an educational intervention to empower family medicine residents on safe opioid prescribing. The findings were presented at the Society of Teachers of Family Medicine annual spring conference in 2016.

Michael McNett, MD, Kayla Flores, MD, Stephanie McDearmon, MD, Brandon Phelps, DO, Brian Wallace, MD, Jessica Kram, MPH, and Dennis Baumgardner, MD, contributed to the study.

Ariba Khan, MD, was named to a research award for her project presented at the 2015 Delirium Boot Camp at Harvard Medical School/Beth Israel Deaconess Medical Center. The award was sponsored by the Center of Excellence for Delirium in Aging: Research, Training and Educational Enhancement.

Dr. Khan will build on the studies she led to develop an automated model using electronic health record data to identify delirium in hospitalized older adults and older adults at risk for 30-day hospital readmission and 30-day mortality. She presented the studies at the American Geriatrics Society 2015 annual scientific meeting.

Mahanraj Singh, PhD, Hina Singh, MD, Ayesha Maria, Michelle Simpson, PhD, RN, Mary Hook, PhD, RN-BC, Marsha Vollbrecht, RN, Aaron Malsch, MSN, and Michael Malone, MD, contributed to the studies.
Aurora Scientific Day, an annual conference held in May, provides a forum for research presentation by students, residents, fellows, teaching and research faculty, and other allied health professional at Aurora Health Care.

In 2015, more than 150 people supported research by attending the presentations - 21 judged posters, 16 general and student posters, 15 oral presentations and three Rieselbach distinguished paper sessions.

**Rieselbach distinguished papers**
- **Marie M. Forgie, DO** – A Randomized Control Trial of Foley Catheter Placement for Induction of Labor: Stylette Versus No Stylette
- **Mirza Nubair Ahmad, MD** – Validation of a Diagnostic Algorithm for Cardiopulmonary Exercise Testing: Usefulness in Clinical Cardiology / Rafath Ullah, MD – Operating Test Characteristics of Respiratory Exchange Ratio as a Noninvasive Measure of Anaerobic Threshold
- **Zuber S. Ali, MD** – Effects of Testosterone Supplement Therapy on Cardiovascular Outcomes in Men with Low Testosterone

**Judged posters**
- **1st place tie** – Zuber S. Ali, MD
  Androgen Deprivation Therapy for Prostate Cancer Increases Systolic and Diastolic Dysfunction
- **1st place tie** – Ariba Khan, MD, MPH
  Using an Automated Model to Identify Older Patients at Risk for 30-Day Hospital Readmission and 30-Day Mortality
- **2nd place** – Ayalew T. Muluneh, MD, MPH
  Evaluating MACE Associated with Temporary Discontinuation of Antiplatelets for Acute GI Bleeding in Patients with Coronary Stents
- **3rd place** – Yang Shi, PhD
  Echocardiographic Predictors of Admission among Patients with Heart Failure with Reduced Ejection Fraction

**Oral presentations**
- **1st place** – Dakisha N. Lewis, MD
  Model Assessment and Development of Risk Stratification of Surgical Site Infection Following Cesarean Delivery for a High-Risk, Urban Population
- **2nd place** – Callie Cox Bauer, DO
  Operating Room First Start Efficiency throughout a Large Urban Hospital System
- **3rd place** – Katherine Meyers, DO
  Assessing the Effectiveness of Implementation of Unified Workflow in Improvement of Medication Reconciliation for Aurora St. Luke’s Family Medicine Residency Outpatients

(Below) Randall Lambrecht, PhD, and biostatistician Maharaj Singh, PhD, listen as senior research scientist Ahmed Dalmar, MD, describes a study.
Center for Urban Population Health

Established in 2001, Center for Urban Population Health advances health services research, professional education and health promotion programming to improve the health of individuals and populations in urban communities. A collaboration of the University of Wisconsin-Milwaukee, University of Wisconsin School of Medicine and Public Health and Aurora Health Care, the center is an independent entity focused on identifying the determinants of health and disease, designing and implementing preventive interventions that promote the health and well-being of populations, and measuring their effectiveness.

22 grants and contracts awarded = $1.4 million

Extramural funding sources in 2015

- State and local foundations: 29%
- State and local contracts: 54%
- Federal: 17%

Linking patients to appropriate care

Through the Milwaukee Health Care Partnership’s Emergency Department Care Coordination initiative, avoidable emergency department usage has decreased with high-risk patients connected to primary care services. Patients presenting with one of five priority conditions at any of the 10 participating Milwaukee County hospital emergency departments are partnered with a social worker, who schedules an appointment for the patient with his or her new medical home – a local community clinic. Center researchers are evaluating appointment data to measure the initiative’s success.

“Aurora Family Service, in partnership with Aurora Sinai Medical Center, launched an intensive case management pilot program for patients identified as high utilizers of emergency department services,” said Robert Marrs, MS, manager of Integrated Family Support Services, Aurora Health Care. “These are patients with significant comorbidity and 11-plus visits over a 12-month period. Results of the initial pilot of 47 patients demonstrated a 57 percent decrease in hospital charges and a 50 percent decrease in ED visits after six months of enrollment.”

Increasing colorectal cancer screening

Though 72 percent of Wisconsin adults were considered up to date on their colorectal cancer screening in 2012, the rate was only 34 percent for federally qualified health centers and community clinics, which serve a high population of black, Hispanic and Hmong adults living below the poverty line in the Milwaukee area.

With funding from Centers for Disease Control and Prevention, researchers are partnering with all Milwaukee federally qualified health centers and Aurora’s Walkers Point Clinic to increase colorectal cancer screening rates closer to the National Colorectal Cancer Roundtable’s goal of 80 percent by 2018.

Assessing the health of communities

Findings from the Milwaukee Health Care Partnership’s 2015 Community Health Needs Assessment of Milwaukee County revealed that access to affordable health care services continues to rank as a pressing need, but chronic disease management and prevention rose as a high priority.

Other top issues included violence, lack of access to oral health and behavioral health care services, and difficulty in navigating complex systems of care.

“This assessment builds on more than a decade of community health survey data that has been instrumental to hospitals and local health departments in the region,” said Mark Huber, MS, senior vice president of social responsibility, Aurora Health Care, and the partnership’s assessment committee chair. “The assessment data helps us target health disparities and important health indicators. With that information, we can establish concrete goals for health education, interventions and investments.” Each hospital and local health department in Milwaukee will select priorities and develop individualized plans to improve the health of the community it serves. Center researchers analyze key informant interviews and focus group feedback, compile secondary data reports and create a summary of all the reports for the assessment every three years.

Access to affordable health care and chronic disease management are high priorities.
Nursing research

Study examines impact of bundled program for care of older adults

The Helen Daniels Bader Fund, a Bader Philanthropy, is dedicated to supporting efforts that improve the health of older adults.

HDBF awarded a $125,000 grant to Aurora Health Care. Principal investigators Michelle Simpson, PhD, RN, and Michael Malone, MD, will study ways to prevent delirium and functional decline among older adults receiving care in a rural setting.

The research project will implement the evidence-based Hospital Elder Life Program (HELP) at two rural Aurora medical centers and continue the program in the home care setting. HELP utilizes an innovative model of care to maintain physical and cognitive functioning throughout hospitalization, assist with the transition from hospital to home and prevent unplanned readmission for older adults.

Using a previous grant from the HDBF, Dr. Simpson led a study to develop an evidence-based hospital readmission risk score for older adults receiving home care. Combining HELP with the risk score model and continuing HELP in the home care setting, clinicians will intervene on vulnerable older adults who are discharged to their home with the bundled program.

Researchers will examine the impact of the bundled program in the two rural hospitals and the corresponding home care market on clinical outcomes and patient experience.

Gastrointestinal focus

The gastrointestinal department at Aurora St. Luke’s Medical Center continues to conduct clinical research.

Under the mentorship of gastroenterologist Nalini Guda, MD, the GI research team presented findings for multiple studies at the 2015 Digestive Diseases Week, an international annual conference organized by American Gastroenterology Association, American Society of Gastrointestinal Endoscopy and Society for Surgery of Alimentary Tract.

The Proficient Study, published in a Gastrointestinal Endoscopy supplement, analyzed data on the competency of advanced endoscopy trainees, establishing minimum training time and procedure volume required to successfully perform endoscopic retrograde cholangiopancreatography.

Sutyanisth Agrawal, MD, presented the findings. Brian Raja, MD, Julia Leo, MD, Veena Kumaravel, MD, Jonathan Fahler, MD, and Hershel Raff, PhD, contributed to the study.

Dr. Kumaravel also analyzed data on correlating abnormalities detected on different imaging modalities to endoscopy findings. The findings will help identify patients needing endoscopic follow-up for abnormal imaging studies.

Mohamed Mahmoud, MD, Dominic Klyve, PhD, and Lyndon Hernandez, MD, contributed to the study, which was published in the Gastrointestinal Endoscopy supplement.

2015 EXTRAMURAL AWARD RECIPIENTS

John Brill, MD
University of Wisconsin/State of Wisconsin
$140,165
Aurora Lakeland rural training track

Michelle Simpson, PhD, RN
Bader Philanthropies Inc.
$125,000
Prevention and early identification of rural older adults’ clinical deterioration: The bundled HELP at Home intervention

Michael Farrell, MD
Aurora UW Medical Group
$44,000
Rapid-throughout assessment and feedback of caregivers’ communication quality at the point of care

Michelle Simpson, PhD, RN
Bader Philanthropies Inc.
$40,000
Improving home health care for the elderly: Predicting clinical deterioration among older adults with and without dementia in the home care setting

Jessica Chapin, PhD
American Academy of Clinical Neuropsychology Foundation
$12,000
Impact of neuropsychological evaluations for dementia on health care utilization and quality indicators: a multicenter study

Ron Cisler, PhD
Center for Urban Population Health/ Medical College of Wisconsin
$1,000
Understanding, developing and measuring outcomes that matter for healthy weight in African-American women
Aurora St. Luke's Medical Center among U.S. News best hospitals

Aurora St. Luke's Medical Center was recognized as a top hospital in Wisconsin by U.S. News & World Report in its annual rankings. For 2015-16, Aurora St. Luke's is ranked number one in the Milwaukee metro area and number two in the state.

Ranked specialties:
- cardiology and heart surgery
- diabetes and endocrinology
- gastroenterology and GI surgery
- geriatrics

Aurora St. Luke's was the only program in the state nationally ranked in cardiology and heart surgery. Additionally, Aurora St. Luke's was also deemed a "high performing" hospital in the areas of cancer, gynecology, nephrology, neurology and neurosurgery, orthopedics, pulmonology and urology. U.S. News evaluated hospitals in 16 adult specialties and ranked the top 50 in most of the specialties.

Additional Strategic Research publications

2015 Aurora-authored, peer-reviewed

Journal articles/Book chapters


A $19.6 million operation in 2015, Aurora Research Institute supports more than 500 clinical trial, laboratory-based and investigator-initiated research studies throughout Aurora Health Care. Employing about 170 caregivers, the institute is focused on translating new discoveries to improve choices and outcomes that change not only the lives of individuals, but transform the health of populations. Randall Lambrecht, PhD, serves as president of the institute.

**About Aurora Research Institute**

296 clinical trials open to accrual and follow-up as of Dec. 31, 2015

- Cardiovascular (79) 27%
- Oncology (172) 58%
- Neurosciences (22) 7%
- Other* (23) 8%

208 open IIR studies as of Dec. 31, 2015**

- Cardiovascular (95) 46%
- Oncology (34) 16%
- Neurosciences (9) 4%
- Other (70) 34%

*includes orthopedics, asthma, emergency medicine, pulmonology, sleep medicine, women's health and humanitarian use device/compassionate use clinical trials

**Source: Aurora Health Care Institutional Review Board

$19.6 million expenditures in 2015

- Institutional Investment ($7,549,483) 39%
- Industry Contracts ($4,651,376) 24%
- Extramural Grants and Awards ($2,361,089) 12%
- Foundation Support ($1,423,509) 7%
- Other 18%
Research Business Services highlights

Led by: Kurt Waldhuetter, MS

Research Analytics
Led by: Andy Marek

- Continued to provide the highest-quality data possible in support of research data requests while initiating population health and clinical decision-support pilots.
- In addition to multiple carry-over projects, initiated 36 new data request projects and completed many, including a customized de-identified data extract of more than 250,000 patients and 135,000,000 total records to support the development of an advanced pharmacogenomics decision-support model.
- Received Institutional Review Board approval for and built a customized geocoding resource that will allow researchers to link geospatial characteristics to electronic health record data in a fully de-identified and compliant way.

Research Business Operations
Led by: Katie Richter

- Continued to achieve new levels of service commitment in support of all research contracting for clinical trials, grants, materials, data and other academic service and support agreements.
- Progressed toward the use of common grant and contract agreement templates containing standardized language in collaboration with legal counsel.
- Debuted multiple new tools to increase efficiency, compliance and cost-coverage, including a contract negotiation tracker, nine new standard operating procedures and a robust fee schedule.
- Implemented significant improvements to electronic health record research billing functionality and the successful resolution of multiple billing issues identified during an in-depth process mapping effort.

Research Innovation
Led by: Don Conrad

- Advanced two early-stage innovations to the prototyping and patenting stage of development by transitioning a physician-originated innovation from small evaluation to systemwide adoption and through collaboration on APN Health LLC’s Navik 3D cardiac mapping system.
- Defined processes and created willingness to support more caregiver-initiated innovations.
- Spearheaded additional support for commercially structured innovations, providing due diligence and market research that led to about $2.35 million in early-stage financing.

New intellectual property disclosures and new entrepreneurial projects engaged in 2015

- New intellectual property disclosures
  - Cardiovascular: 3
  - Oncology: 1
  - Neurosciences: 2
  - Other: 1

- New entrepreneurial projects
  - Cardiovascular: 2
  - Oncology: 2
  - Neurosciences: 2
  - Other: 3
Sponsored Programs Office highlights

Led by: Yanil Niiakantan, PhD

- Tracked awards totaling about $3.3 million, including $1 million from the Vince Lombardi Cancer Foundation to develop a neuro-oncology research program and more than $435,000 from National Institutes of Health, via Vanderbilt University, to personalize drug prescriptions with genetic testing.

- Administered four intramural award programs (Aurora Cancer Care Research Award, Cardiac Research Award, Sullivan Cardiac Research Award for Residents and Fellows and Cardiovascular Surgery Research Award), awarding nearly $700,000.

- Developed learning opportunities to simplify the grant application process, including both a hands-on workshop and an online self-paced course to create a new National Institutes of Health biosketch and SciENcv. A second workshop provided tips on winning a stress-free grant proposal and another online course provided step-by-step instructions for using EndNote to create citations and bibliographies.

- Streamlined operations with development of systemwide policies and procedures on grant management.

Clinical Trials highlights

Led by: Sara Planton, BSN
Managed by: Jan DeBartolo, MSN, Annette Paul, MAT, Wendy Schmidt, RN, and Carol Tutino, BSN, MS

- Enrolled more than 1,200 subjects in nearly 300 clinical trials available in the oncology, cardiovascular and neurosciences services lines and additional strategic areas of Aurora Health Care.

- Boosted Commission on Cancer accreditations to gold status with two research-related commendations for achieving a rate of greater than 8% in clinical trial accruals and the public reporting of outcomes, in part, through Aurora Health Care’s medical journal, Journal of Patient-Centered Research and Reviews.

- Strengthened relationships with research and industry sponsors, yielding $4.7 million in revenue, to offer new options for patients.

- Enhanced caregiver skills in coordination and regulation of clinical trials through training and educational opportunities.

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Extramural grants awarded:
$3.3 million in 2015

- Nonprofit ($1,495,414) 45%
- Industry ($707,217) 21%
- Federal ($395,485) 29%
- State ($140,165) 4%

Intramural grants awarded:
$692,599 in 2015

- Cardiovascular Surgery Research Awards ($318,267) 46%
- Sullivan Cardiac Research Award for Residents and Fellows ($194,350) 17%
- Cardiac Research Awards ($120,050) 17%
- Aurora Cancer Care Research Awards ($194,360) 28%

Clinical trial revenues:
$4.7 million in 2015

- Cardiovascular ($3,982,350) 73%
- Oncology ($948,666) 14%
- Neurosciences ($398,513) 2%

Clinical trial enrollments:
1,202 in 2015

- Cardiovascular (1,048) 29%
- Oncology (348) 29%
- Neurosciences (164) 14%
- Other** (107) 8%

**Includes orthopedics, asthma, emergency medicine, pulmonology, sleep medicine, women’s health and humanitarian use device/compassionate use clinical trials

*Supported by an extramural grant provided by Vince Lombardi Cancer Foundation
Translational Research highlights

Led by: Nina Garlie, PhD, and Vani Nilakantan, PhD
Managed by: David Krum, MS, and Bob Stoltz, MBA, MT

- With a more than $5 million capital investment, constructed a unique environment, Discovery Laboratory, for researchers to work from the molecular to cellular levels to gain a better understanding of genes and proteins and how they react to new and existing therapies.

- Expanded the animal research and care program with construction of a vivarium to provide avatars for oncology research.

- Continued to grow a multidisciplinary core team of research scientists and biostatisticians to engage in and facilitate more than 200 laboratory and investigator-initiated research studies throughout Aurora Health Care’s cardiovascular, oncology and neurosciences service lines and additional strategic areas.

- Established or developed specialty centers and programs within the service lines and strategic areas.
  - Aurora UW Medical Group Research Core
  - Biorepository and Specimen Resource Center
  - Cardio-Oncology Research Program
  - Center for Urban Population Health
  - Early Phase Cancer Research Program
  - Neuro-Oncology Research Program
  - Neurosciences Research Program
  - Precision Medicine Research Program
  - Regenerative Medicine Center
  - Sheikh Khalifa bin Hamad Al Thani Center for Integrative Research on Cardiovascular Aging (CIRCA)
  - Translational Oncology Research: Quest for Understanding and Exploration (TORQUE)

- Supported laboratory research beyond programmatic areas.
  - Endocrine Research Laboratory
  - Immunotherapy Research Laboratory
  - Neuroanatomical Laboratory

- Strengthened internal relationships to ensure quality and compliant research that protected subjects and animals.

- Offered informational presentations on myriad topics by both internal and external experts.

Research associate Geoffrey Riddell conducts an experiment in Discovery Laboratory on the Aurora Sinai Medical Center campus.

Nina Garlie, PhD, and Bob Stoltz, MBA, MT, lead Discovery Laboratory tours.

Research associate Kate Denner studies cells in Discovery Laboratory.

Senior research scientist Michael Michalikiewicz, PhD, studies severe blood transfusion reactions.

Randall Lambrecht, PhD, Arshad Jahangir, MD, and Vani Nilakantan, PhD.
More than 145,000 patients consented for their leftover biospecimens to be used for research purposes through the Biorepository and Specimen Resource Center (BSRC).

Since its inception eight years ago, the BSRC has amassed an inventory of more than 70,000 whole blood, plasma and serum samples for future research studies.

Through its partnership with ACL Laboratories, the BSRC accepts thousands of discarded samples on a daily basis. Hundreds of specimens have been used for studies conducted by Aurora Health Care researchers, and, using iSpecimen technology, thousands more have been shared with investigators throughout the country.

The BSRC also coordinates the targeted collection of tissues for specific research purposes. Examples include tumors from the breast (see story on page 26) and brain (see story on page 39).

Led by Natalie Polinski, MS, the BSRC team consists of a research lab assistant, research associate and research coordinator. Research Analytics, led by Andy Merek, supports the data collection for the BSRC.

Research lab assistant Kijana Clayton removes samples from a cryogenic freezer in the Biorepository and Specimen Resource Center, which is equipped with cutting-edge technology.

Biospecimen Utilization Committee

Diane Austin
Compliance Officer Research, Aurora Health Care

Julie Basquin, MS
Senior Research Business Analyst, Aurora Health Care

Amy Bovi, MA
Policy and Ethics Officer, Aurora Health Care

Rachel Delaney, JD
Corporate Counsel Research, Aurora Health Care

Rich Merkel
Executive Director, STEM Forward

Gary Neitzel, MD
Medical Director, ACL Laboratories

Vani Nilakantan, PhD
Director, Investigator-Initiated Research Department and Sponsored Programs Office, Aurora Research Institute

Sara Plantion, BSN
Director, Clinical Trials Department, Aurora Research Institute

Natalie Polinski, MS
Manager, Biorepository and Specimen Resource Center, Aurora Research Institute (COMMITTEE CHAIR)

2015 highlights

- Distributed more than 700 biospecimens through more than 20 biospecimen requests
- With help from the Sponsored Programs Office, won a $50,000 competitive grant from Conversant Bio to enhance BSRC operations and financial stability
- Featured in biorepository media coverage (BizTimes.com, HealthITAnalytics.com, American Association for Clinical Chemistry’s Clinical Laboratory News, wire services)
- Established Biospecimen Utilization Committee to address all key perspectives (legal, compliance, ethics, etc.) involved in the use of biospecimens
- Implemented a systemwide policy that provides guidelines for the transfer and utilization of biospecimens
- Received Research Team Award at Sixth annual Greater Milwaukee Clinical Research Recognition Event
Interdepartmental collaborations

To achieve the highest level of professional and ethical standards in research, the dedication of a diverse network of caregivers from departments throughout Aurora Health Care is required.

Among others, institute caregivers collaborated with the following Aurora departments over the past year:

- Research Subject Protection Program/ institutional review boards
- Research Compliance
- Aurora Health Care Foundation
- Service market leadership and support
- Service line leadership and support
- Hospital and clinic caregivers
- Legal
- Finance
- Accounting
- Billing
- Revenue Cycle
- IT
- Health Informatics
- Medical Group Operations
- Operations Improvement
- Operations Project Management
- ACL Laboratories
- Aurora Pharmacy
- Aurora Ventures
- Enterprise Business Group
- Human Resources
- Supply Chain

Collaboration among caregivers from these departments improves the efficiency, transparency and safety of the research conducted at Aurora. Together, these teams have invested – and will continue to invest – countless hours to allow for greater involvement by Aurora in groundbreaking research.

Senior research nurse coordinator Elsa Damian, BSN, obtains an investigational drug prescription from pharmacist Jennifer Lester, RPh, for a research subject participating in a cardiovascular clinical trial.

Council for Quality Assurance and Improvement in Research

Charged with overseeing Aurora Research Institute's Quality Management Plan, the Council for Quality Assurance and Improvement in Research ensures high-quality compliant research is conducted by Aurora researchers.

Chaired by Nina Garlino, PhD, the council includes a broad representation of the institute as well as members from the Research Subject Protection Program and Research Compliance.

The council is responsible for developing a strategic annual quality monitoring plan, assessing key performance indicators and making recommendations to improve the quality of research. Melanie Guenther, senior research quality specialist, administers the quality assurance activities and reports findings to the council on a monthly basis.

In 2015, quality monitoring activities included:
- full protocol reviews of high-risk studies.
- focus audits directed at specific aspects of research.
- self-assessments and external monitoring.

The purpose of routine monitoring is to provide objective feedback to investigators and study team members regarding study conduct in accordance with the protocol, federal regulations, good clinical practices and policies/procedures. The data derived from these monitoring activities provides insight into study management to help identify education needs, recognize best practices and track and trend performance over time.
Research Subject Protection Program/Institutional Review Boards

Led by Michelle Maternowski, Aurora’s Research Subject Protection Program is charged with the oversight of human and animal subject research conducted at Aurora. Responsibilities include management of Aurora’s institutional review boards.

The RSPP and IRBs:

- Review and approve research proposals according to the ethical principles and guidelines of the Belmont Report, the applicable sections of the Code of Federal Regulations and the International Conference of Harmonisation Good Clinical Practice guidelines.
- Safeguard the rights, welfare and dignity of the human and animal subjects who participate in the research process.
- Promote the highest ethical standards for conducting research.
- Provide a strong foundation of knowledge and cooperative education to facilitate the conduct of biomedical and behavioral research.

Acknowledgments

For research to be meaningful and impactful, the commitment of many bright and talented researchers, physicians and caregivers along with the hope and generosity of friends and donors are required.

It also requires the commitment of Aurora Health Care, the Aurora Research Institute Board of Directors and leadership at sites throughout the system, which provides the administrative fortitude and support that allows innovative research to be conducted.

But most importantly, discoveries can only be translated into patient care with the courage and involvement of patients and their families.

Thank you!
Purpose, Vision, Values

Purpose
We help people live well through innovative research.

Vision
Offer more treatment choices and improve patient outcomes through research and innovation

Values
- Every patient and community deserves the best care.
- Resources should be managed responsibly.
- A healthy workplace is built through accountability, teamwork and respect.

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