

Department of Pediatrics

The Science of Health. The Art of Compassion.



University Hospitals



Rainbow Babies & Children's

Cleveland | Ohio



UH Rainbow Babies & Children's

Internationally renowned, UH Rainbow Babies & Children's is a full-service children's hospital and pediatric academic medical center with experts in 16 medical divisions and 11 surgical specialties. Nationally ranked care not available at other institutions in the region includes a center dedicated to adolescent and young adult cancer treatment and Northeast Ohio's only single-site provider of advanced maternal fetal medicine and neonatology services. An affiliate of Case Western Reserve University School of Medicine and the only Level I Pediatric Trauma Center in the region, UH Rainbow Babies & Children's offers novel therapies, advanced technologies and clinical discoveries to children long before they are available nationwide. Our pediatric specialists – all of whom also serve on the faculty at the School of Medicine – are engaged in today's most advanced clinical research and are widely regarded as the best in the nation – and in some specialties, the best in the world.

UH Rainbow Babies & Children's offers the most expansive pediatric care network in Northeast Ohio with more than 130 service locations. The vast network includes nationally ranked UH Rainbow Babies & Children's Hospital – Cleveland's only full-service, freestanding children's hospital with a medical staff of more than 745 physicians – along with a primary care network with more than 200 pediatric and family medicine providers at 85 locations, three inpatient hospital locations, 14 pediatric emergency departments, six urgent care centers, five surgery centers, 20 medical and surgical specialty clinics, and seven advanced newborn and maternal/fetal medicine service locations.

To learn more, visit UHRainbow.org

Current research at University Hospitals
Cleveland Medical Center encompasses more
than 2,600 research studies, more than
\$160 million in research funding and more
than 70 medical innovation disclosures.

UH Rainbow Babies & Children's Hospital is ranked one of America's Best Children's Hospitals in eight pediatric specialties by U.S. News & World Report, including Neonatology, Pulmonology and Orthopaedics.

Learn more at UHRainbow.org/USNews

Visit CME.UHhospitals.org for the latest in live, webinar and on-demand Continuing Medical Education events.



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UH Cleveland Medical Center

Among the nation's leading academic medical centers, UH Cleveland Medical Center is an affiliate of Case Western Reserve University School of Medicine.

With more than 1,000 registered beds, UH Cleveland Medical Center provides primary, specialty and subspecialty medical and surgical care. Located in the heart of Cleveland's University Circle on a beautiful 35-acre campus, UH Cleveland Medical Center includes general medical, intensive care and surgical units as well as three major hospitals:

UH SEIDMAN CANCER CENTER

UH MACDONALD WOMEN'S HOSPITAL

UH RAINBOW BABIES & CHILDREN'S HOSPITAL

Our physicians and researchers – who also serve as faculty at Case Western Reserve University School of Medicine – are leaders in their respective fields, and their ongoing clinical research programs push the boundaries of medical progress.

To learn more, visit UHhospitals.org

HARRINGTON DISCOVERY INSTITUTE

Accelerating Breakthrough Discoveries Into Medicines

The Harrington Discovery Institute at University Hospitals is the nonprofit arm of The Harrington Project for Discovery & Development, a national initiative supporting breakthrough research by physician-scientists. The Harrington Project is a powerful approach to address the challenges of advancing discoveries into medicines.

To learn more, visit HarringtonDiscovery.org

ADVANCING THE SCIENCE OF HEALTH AND THE ART OF COMPASSION.

It is through this vision that UH Rainbow Babies & Children's Hospital adapts, changes and looks for the best ways to deliver the most advanced care. We earned high recognition in U.S. News & World Report's Best Children's Hospitals annual rankings. UH Rainbow is ranked among the nation's top 50 children's hospitals in eight specialties, four of which -- cancer, orthopedics, endocrinology and gastroenterology rank in the nation's top 25

Our pediatric experts are recognized leaders in clinical care, research and discovery. Well-known for our pioneering work in adolescent and young adult cancer care, and as Northeast Ohio's only single-site provider of advanced maternal fetal medicine and neonatology services, our physicians are involved in the most advanced clinical research and widely regarded as the best in the nation – and in some specialties, the best in the world.

Advancing the Science of Health and the Art of Compassion means providing the latest diagnostic tests, medications and technologies to care for patients with complex conditions. It was also evidenced by the opening of a new model of care in the heart of Cleveland, Ohio – the UH Rainbow Center for Women & Children. This center applies evidence-based research to address social services with the goal of closing the health care disparity gap prevalent in many urban communities.

UH Rainbow is also training the next generation of pediatric providers through comprehensive education programs, helping to shape tomorrow's standard of care while fulfilling our mission as a community-minded, full-service children's hospital and pediatric academic medical center.

Providing compassionate care is centric to everything we do. For more than 130 years, University Hospitals Rainbow Babies & Children's Hospital has been advancing its mission: To Heal. To Teach. To Discover. UH Rainbow is evolving as a pediatric powerhouse by pioneering research, developing new technologies and educating the next generation of care providers, while delivering compassionate patient care.



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Changing the Face of Cancer Care for Adolescents and Young Adults

The Angie Fowler Adolescent & Young Adult Cancer Institute combines the expertise of pediatric oncologists at UH Rainbow Babies & Children's with specialists in medical, surgical and radiation oncology at UH Seidman Cancer Center to eliminate barriers to treatment, develop early diagnosis strategies and improve access to lifesaving clinical trials.



The Angie Fowler Institute was designed to change both the treatment experience and outcomes for adolescents and young adults, ages 15 to 30, with cancer. Often caught between pediatric and adult oncology, adolescents and young adults face unique challenges. Their cancers, treatments and social needs are very different from young children and older adults.

The Angie Fowler Institute promotes early diagnosis and offers nurse navigator services, survivorship programs and psycho-social supportive services that address fertility preservation, isolation, lack of insurance and other issues that impact this age group. Age-appropriate facilities provide a comfort zone that includes bright, uplifting spaces, a rooftop respite garden and digital technology.

Today, physician-scientists at Angie's Institute are shepherding several promising projects from bench to bedside.

UH Rainbow pediatric hematologist Sanjay Ahuja, MD, who leads the hemostasis and thrombosis program and holds the Dominic Piunno Endowed Chair in Hemophilia and Bleeding Disorders, is working to develop a device that tests different aspects of the coagulation pathways that may be impaired or defective in complex coagulopathies, which are common in children who are critically

ill as a result of cancer, traumatic injury or blood disorders. He and his team are also among the first in the U.S. to enroll patients in a novel gene therapy trial for patients with hemophilia B, delivered through a new adeno-associated viral vector made by Freeline.

In the cancer space, pediatric oncologist Alex Huang, MD, PhD, who holds the Theresia G. and Stuart F. Kline Family Foundation Chair in Pediatric Oncology, is tackling the intractable problem of refractory and metastatic pediatric osteosarcoma from novel directions. One involves a drug that has long been approved for patients with multiple sclerosis and inflammatory bowel disease – natalizumab.

As a result of Dr. Huang's research, a Phase I trial of natalizumab in recurrent, refractory or progressive pulmonary metastatic osteosarcoma is now open at UH Rainbow Babies & Children's Hospital. Dr. Huang and Mei Zhang, PhD, an Assistant Professor of Biomedical Engineering at Case Western Reserve University, have also identified a naturally derived compound from oat bran as a potential novel cancer therapeutic. The compound, BG34-200, was shown to be highly effective when administered intravenously in reducing early pulmonary metastatic osteosarcoma in immune competent mouse models. If pre-clinical research progresses as expected, the goal is to offer a Phase I clinical trial for osteosarcoma patients at UH Rainbow in late 2021 or early 2022.



ADVANCING THE ART OF COMPASSION THROUGH BEST-IN-CLASS CLINICAL CARE

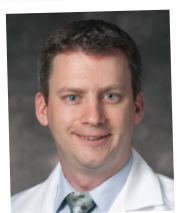
Neurology: Pediatric neurologist Max Wiznitzer, MD, who treats patients with autism at UH Rainbow Babies & Children's Hospital, has collaborated with colleagues around the world on a definitive look at the best evidence-based approaches for supporting people with autism across the lifespan. Writing in *Lancet Neurology*, Dr. Wiznitzer and his colleagues highlight the need for more rigorous research into the effectiveness of different autism interventions, while pointing to some noteworthy approaches. Evidence suggests, they say, that comprehensive, naturalistic early intervention with active caregiver involvement can facilitate early social communication, adaptive functioning, and cognitive development, while targeted intervention can help to enhance social skills and aspects of cognition.

Most evidence is available for specific models of naturalistic early intervention that actively involve caregivers, targeted interventions for the building of social skills, and specific treatments for co-occurring mental health challenges, they write. With all interventions, the authors argue, the details matter. When the correct intervention is paired with the correct patient, the results can be dramatic, "In some cases when interventions are being done, you can actually see a rise in IQ points," Dr. Wiznitzer says. Dr. Wiznitzer and his colleagues also argue for creating more autism-friendly environments for people of all age groups – something which is currently lacking for many adults with autism. If more autism-friendly change were to occur, Dr. Wiznitzer says, it could lead to measurable improvements in quality of life not only for people with autism, but also for those with other developmental disabilities.



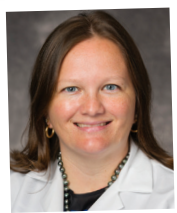
Orthopaedics: A successful, complex vertebral column resection surgery, likely the most complex ever performed in Northeast Ohio, and the addition of state-of-the-art X-ray technology are among the recent developments in the Division of Pediatric Orthopaedic Surgery at UH Rainbow Babies & Children's Hospital. Over 12 hours, Michael Glotzbecker, MD, Division Chief of Pediatric Orthopaedic Surgery at UH Rainbow and holder of the George H. Thompson, M.D., Chair in Pediatric Orthopedic Surgery, and his team rebuilt the spine of a 15-year-old boy diagnosed with congenital kyphosis and scoliosis as an infant, removing all of the bone 360 degrees around the spinal cord and deploying an expandable cage to remove the curvature from the patient's spine.

Ultimately, bone will grow within and around the cage, encasing it in new bone and bridging the gap in the spine where it once curved. Aiding in surgeries like this in the future will be the next-generation X-ray system that recently came on line at UH Rainbow – a first in Northeast Ohio. EOSedge delivers exceptional 2D/3D frontal and lateral full body images, while providing a profound reduced radiation exposure compared to traditional X-rays. Dr. Glotzbecker says the new system will be used from a research perspective to gain a better understanding of the underlying pathology of spinal curvature and what the UH Rainbow team is able to achieve through corrective surgery.



James Strainic, MD

*Director, Fetal Heart Program
Division of Pediatric Cardiology
UH Rainbow Babies & Children's Hospital*



Ellie S. Ragsdale, MD

*Director of Fetal Intervention
Department of Obstetrics & Gynecology
Division of Maternal Fetal Medicine
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Aimee K. Armstrong, MD

*Director, Cardiac Catheterization
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Cardiology: **James Strainic, MD**, director of the UH Rainbow Fetal Heart Program, **Ellie S. Ragsdale, MD**, director of Fetal Intervention at UH MacDonald Women's Hospital and **Aimee K. Armstrong, MD**, director of Cardiac Catheterization and Interventional Therapies at Nationwide Children's Hospital, have built a team of experts from their respective hospitals to form the Fetal Heart Intervention team at the Congenital Heart Collaborative. Maternal fetal medicine specialists and the Congenital Heart Collaborative team can offer the full continuum of care for rare cases. The board-certified and fellowship-trained team has both congenital cardiac imaging and congenital cardiac catheter-based intervention expertise and is skilled in treating the most complex structural cardiac conditions, including: fetal aortic valvuloplasty, fetal pulmonary balloon valvuloplasty and fetal atrial septal intervention.

UH Rainbow Babies & Children's Hospital is home to the most advanced hybrid cardiac catheterization and surgical suites. The two 900-square-foot advanced hybrid cardiac catheterization surgical suites

are equipped with next generation Canon Infinix-i Biplane technology and advanced imaging capabilities to perform complex interventional cardiac catheterization procedures, minimally invasive hybrid operations and complex bypass surgeries. The suites are designed to provide the safest interventions while delivering the best possible patient outcomes. This advanced imaging technology provides the very highest imaging resolution at the same time it improves patient safety through reduced radiation doses and real-time dose tracking. This advanced technology also offers fusion of previous cardiac CT or MRI imaging, allowing the team to review 3-D assessments without any additional radiation exposure to patients. The angiography suites offer the highest resolution imaging capability with noise filtering processing and 3-D rotational capability – all while delivering optimal patient comfort.

Community Health: UH Rainbow Babies & Children's recently introduced a new model of care in the heart of Cleveland, Ohio – the UH Rainbow Center for Women & Children. This center applies evidence-based research to address social, economic and environmental factors that influence health by integrating medical care with behavioral and social sciences. In doing so, UH Rainbow aims to close the health care disparity gap prevalent in many urban communities. The center provides an oasis of health care, education and support for families in Cleveland's vibrant Midtown neighborhood. Brought together in one convenient location – a 40,000-square-foot, three-story urban center – are OB/GYN, pediatric primary care and adolescent health services, integrated mental and behavioral health services, nutrition education and counseling, full service vision clinic, dental screening/cleaning, legal aid and compounding pharmacy. In addition to education and advocacy as its core mission, the center is also a primary training site for the next generation of pediatric and OB/GYN clinicians.

Plastic Surgery: Advanced technologies in the Jeannette and Frank Zagara Pediatric Specialty Suite and the Center for Cranio-Maxillofacial Surgery, Pediatric Dentistry and Orthodontics at UH Rainbow Babies & Children's Hospital offer a patient-centric and patient-focused experience for a customized solution. Custom virtual surgical planning takes patient data via low-dose computerized tomography (CT) scanning, 3-D orbital capture photography, and advanced intraoral digital scanning, and combines it into a single digital platform to plan and treat complex problems of the face. Surgeons can create 3-D personalized titanium plates, fixation guides, splints and screws, planning the exact position, depth and length for patient-specific precision in facial surgery.



Pediatric Critical Care

Medicine: Researchers at UH Rainbow are involved in local, national and global efforts to better understand how the novel coronavirus affects children.

Steven L. Shein, MD, Division Chief of Pediatric Critical Care Medicine, who also holds the Linsalata Family Chair in Pediatric Critical Care and Emergency Medicine at UH Rainbow, and colleagues mobilized an existing global network of physician-scientists studying pediatric bronchiolitis to launch a COVID-19 study in children, looking specifically at severe cases that required a stay in the PICU.

The CAKE study, published in Pediatrics, now involves over 65 centers in nearly 20 countries from the Americas and Europe and more than 200 patients.

At the same time, UH Rainbow pediatric hospitalist Amanda Lansell, MD, and colleagues across the U.S. have conducted an early surveillance study on MIS-C, reporting data on 186 MIS-C patients in 26 states, with data collection ongoing.

Locally in Cleveland, University Hospitals is also building its own database and biologic samples for COVID-19 research. Led by Grace McComsey, MD, Division Chief of Pediatric Infectious Disease at UH Rainbow and holder of the Rainbow

“There are several embedded studies within the biorepository looking to see if we can understand COVID and kids, how it affects the immune system and how much virus they shed, if any.”

Babies & Children’s Foundation John Kennell Chair of Excellence in Pediatrics, the COVID-19 biorepository is currently enabling more than 130 ongoing studies into different aspects of COVID, including several studies in children.

“There are several embedded studies within the biorepository looking to see if we can understand COVID and kids, how it affects the immune system and how much virus they shed, if any,” Dr. McComsey says. “We’re trying to get samples on every pediatric patient we have and try to understand the effect of COVID, not just acutely, but also at three, six, nine, 12 months after the diagnosis to see how the immune system disturbances and inflammation that we see during the acute illness translate over the long term.”

ADVANCING THE SCIENCE OF HEALTH THROUGH PIONEERING RESEARCH

UH Rainbow Babies & Children's Hospital is a pediatric affiliate of Case Western Reserve University School of Medicine. Physician-scientists at UH Rainbow, all members of the faculty of Case Western Reserve University School of Medicine, are among the world's most innovative researchers in diseases such as cancer, blood disorders, cystic fibrosis, asthma, diabetes, GI and orthopaedic conditions. Their groundbreaking research has given UH Rainbow a rich legacy of leadership and innovation in neonatology and other pediatric specialties.

Neonatology: Neonatologists from UH Rainbow Babies & Children's Hospital have been working since 2014 as part of the Ohio Perinatal Quality Collaborative (OPQC) to improve outcomes for Ohio infants exposed to opiates in utero, with much to show for it in terms of improvements in length of hospital stay.

The group recently turned its attention to non-pharmacologic measures aimed at improving care for infants with neonatal abstinence syndrome (NAS), addressing the question of which type of formula is the best choice for these infants – low-lactose formula (LLF) or high-calorie formula (HCF).

Surveying hospitals across the state, the researchers found that 47 sites in Ohio caring for 546 NAS infants self-selected into the four formula groups, with the two variables of lactose level and calorie content.

The benefit of HCF for NAS infants was seen in terms of reducing weight loss, preventing treatment failure and reducing length of stay.

Given these results, the OPQC updated its non-pharmacologic treatment bundle to recommend HCF when breastfeeding was not possible. During implementation of this change, HCF use increased, and length of stay decreased for NAS infants from 17.1 to 16.4 days across the OPQC. "There's been a lot published about the benefits of breastfeeding when it's appropriate, and by far that is our first recommendation for NAS infants," says UH Rainbow neonatologist Moira Crowley, MD.

"But with what we've found, when breastfeeding is not an option, then you should consider using a higher calorie formula."

– Moira Crowley, MD



Pulmonology: Kristie Ross, MD, Division Chief of Pediatric Pulmonology at UH Rainbow Babies & Children's Hospital, is leading her asthma research colleagues across the U.S. to better understand the course of severe asthma in children and teens.

She was first author of a recent study, the first in the NIH-funded Severe Asthma Research Program (SARP) to follow patients over time, which found that fully half of children and adolescents being treated for severe asthma will improve over a three-year period with proper treatment, lending credence to the idea that some children and teens may "grow out of" severe asthma.

The decrease in asthma severity found in the study was not driven by improvement in any one parameter;

Dr. Ross says, however, one factor did predict patients' asthma improvement status: eosinophil count. Patients with a peripheral eosinophil count of greater than 436 cells/ML were 2.75 times more likely to have their severe asthma resolve than were patients with an eosinophil count below that number.

With this research, Dr. Ross and her colleagues are able to provide clinicians with important new information for managing children and teens with severe asthma. They plan to follow the patients in this longitudinal study into adulthood, while enrolling new others. "This third iteration of SARP is the first time that the subjects were followed over time," she says. "So there's great interest in continuing that as we move into the fourth SARP study."

Neonatology: Cynthia Bearer, MD, PhD, Division Chief and William and Lois Briggs Chair in Neonatology at UH Rainbow Babies & Children's Hospital, has spent her career merging the fields of biochemistry and neonatology, teasing out the mechanisms behind neurotoxic insults to developing brain and how best to prevent or ameliorate them.

She's delved deeply into the biochemical mechanisms by which alcohol – and other neurotoxicants -- affect brain development, looking closely at the vitally important L1 cell adhesion molecule.

The important concept, she says, is the lipid raft – a specialized microdomain of the plasma membrane that serves as a platform for protein-protein interactions. "At very low levels of alcohol, L1's ability to stimulate neurite outgrowth is impaired," she says. "So we began to ask ourselves why. It turns out that L1 has to traffic through a part of the leading edge of those nerve cells as they're trying to find their synapse partner. We found that alcohol disturbed L1's trafficking through the lipid raft and disrupted all the downstream signaling events that L1 needed to do. At the same time, we found that if we supplemented experimental animals with choline, we could prevent these effects on L1 and improve the animals' behavior."

Currently, Dr. Bearer has funding from the National Institute of Child Health and Human Development to examine whether a similar mechanism might be at play with hyperbilirubinemia, which occurs in nearly all preterm newborns. Preliminary results show that bilirubin inhibits lipid raft function using L1 as a reporter, but by supplementing experimental animals with choline, behavioral difficulties resulting from excess bilirubin are ameliorated. Ultimately, this research will move to looking at whether babies are getting enough choline and how to address any deficiency. "Working with nutritionists on how we can deliver more choline to our babies and improving outcomes that way -- that's what I'm interested in," Dr. Bearer says.

Endocrinology: Researchers with the UH Rainbow Babies & Children's Hospital are part of important new clinical trial of continuous glucose monitoring (CGM) in young children.

The new multicenter, randomized controlled trial included 143 youth with type 1 diabetes between the ages of 2 and 8 years, followed over six months.

Results show that CGM can be an effective tool for even very young children with type 1 diabetes and is even more helpful to parents when introduced with a short but structured education program.

This is among the first studies to show a benefit of CGM for this young age group, says investigator Jamie Wood, MD, Medical Director of Pediatric Diabetes, who also holds the Mary Blossom Lee Chair in Pediatric Diabetes at UH Rainbow.

Site principal investigator Sarah MacLeish, DO, attributes the success of CGM in this age group to the psychologists, social workers, and physicians on the study team who designed the family behavioral intervention to address family feelings, attitudes and behaviors that can be barriers to CGM use.

Pediatric Emergency Medicine:

Hospitals that score in the top quartile in readiness for pediatric emergencies have about a third the rate of mortality for severely ill children.

To enhance readiness to care for ill or injured children who present for emergency care, UH Rainbow Babies & Children's Hospital is establishing a Pediatric Disaster Care Center of Excellence – one of just two in the country. Funded with a \$3 million grant from the U.S. Department of Health and Human Services' Office of the Assistant Secretary of Preparedness and Response (ASPR), the Eastern Great Lakes Pediatric Consortium for Disaster Response, led by UH Rainbow and accompanied by five other children's hospitals in Michigan and Ohio, is developing a multi-pronged approach to address gaps across the disaster cycle spectrum of mitigation, preparedness, response and recovery for nearly 7 million children.

"We face threats from disasters every day, which is why it is so important for hospitals, health care infrastructures, government and private entities to work together to create a coordinated emergency response model," says Charles Macias, MD, MPH, Division Chief of Pediatric Emergency Medicine and Chief Quality Officer at UH Rainbow.

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