Clinical Trials Update

The Heart Institute at UPMC Children’s Hospital of Pittsburgh is engaged in some of the most cutting-edge research and clinical trials in the fields of pediatric cardiology and cardiothoracic surgery. Below are summaries of several important open trials, for which patients are currently being recruited, that hold promise for evolving aspects of cardiac care.

Compassion XT Clinical Trial

Site Principal Investigator: Jacqueline Kreutzer, MD, FAAC, FSCAI

The Heart Institute at UPMC Children’s Hospital of Pittsburgh is a participating site in the Edwards Lifesciences SAPIEN XT Transcatheter Heart Valve System clinical trial. This prospective multicenter investigation is designed to examine the safety and efficacy of the valve in patients who have dysfunctional right ventricular outflow tract conduits, and who are in need of treatment for pulmonary regurgitation as evidenced by positive transthoracic echocardiograph results.

At the time of writing, UPMC Children’s was one of the top enrolling sites for the study, with five patients enrolled to date.

As a corollary to the study, UPMC Children’s recently reached a procedural milestone with its 100th percutaneous pulmonary valve implant in a young patient in October 2018. “Our ongoing successes with these procedures are a testament to the skills and devotion of our entire staff at the Heart Institute,” says Dr. Kreutzer.

XPLORE2 Study

Site Principal Investigator: Victor Morell, MD

UPMC Children’s Hospital of Pittsburgh is one of eight centers participating in a national, multicenter trial sponsored by Xeltis. The Xeltis Bioabsorbable Pulmonary Valved Conduit Early Feasibility Study (XPLORE2) is a single-arm, prospective, open label study designed to determine the efficacy of the Xeltis Bioabsorbable Pulmonary Valved Conduit in patients who are in need of right ventricular outflow tract correction, or those who are in need of reconstruction due to a congenital heart malformation. Some of the congenital conditions that may be candidates for the device are Tetralogy of Fallot, pulmonary atresia, truncus arteriosus, and others.
Heart Institute News and Notes

- Five faculty members from the Heart Institute’s cardiology group received the Department of Pediatrics Chair’s Distinction Award: Gaurav Arora, MD; Mousumi Moulik, MBBS; Lan Nguyen, MD; Sara Trucco, MD; Shawn West, MD, Msc.

- Allison Black, MD, pediatric cardiology fellow was appointed as chair-elect for the American Academy of Pediatrics (AAP) Section on Pediatric Trainees.

- On January 18, UPMC Children’s and the Heart Institute played host to the 27th American Heart Association Fellows Research Day. Chairing the 2019 event was Bernhard Kuhn, MD, Scholar, Richard King Mellon Foundation Institute for Pediatric Research, and associate professor and director of Research in Cardiology, Department of Pediatrics, University of Pittsburgh School of Medicine.

- Gaurav Arora, MD, and Mira Trivedi, MD, published a case report in Cardiology in the Young at Cambridge.org/cyt under the title “Prophylactic Pacemaker Placement at First Signs of Conduction Disease in Kearns-Sayre Syndrome.”

- Pediatric cardiology fellow Defne Magnetta, MD, presented at the AHA Scientific Sessions 2018 on the topic of Waitlist Characteristics and Outcomes Following the 2016 Revision of United States Pediatric Heart Allocation Policy.

CICU Expansion Nears Completion

The Cardiac Intensive Care Unit at UPMC Children’s is nearing the completion of a significant expansion. The former 12-bed unit is growing in size to a 33-bed-unit with expected physical renovations to be completed by early 2019. In addition to the physical expansion of beds, the Heart Institute is recruiting a substantial influx of new clinicians to treat and staff the expanded unit.

Plans are in progress to add four new CICU physicians, eight CICU advanced practice providers, and three new advanced practice providers with the Heart Institute.

New CICU chief, Justin Yeh, MD, who joined UPMC Children’s and the Heart Institute in August 2018, is overseeing the expansion during its final phases of implementation.

New Quality Initiative

UPMC Children’s is a participating member of PAC3, the Pediatric Acute Care Cardiology Collaborative. (Evonne Morell, DO, from the Heart Institute currently sits on the PAC3 executive committee). UPMC Children’s recently took part in the collaborative’s QI project on reducing chest tube duration in pediatric patients after cardiothoracic surgery. This project examined how long chest tubes were left on patients at each partner institution, and what parameters were used to determine when to discontinue their use.

“It became clear that we were quite conservative in our criteria, using a 2mL/kg/24-hour period of chest tube output compared to other partner sites that were using a 10mL/kg/24hr).” By changing our practice and adopting this alternative criterion, we saw a significant reduction in the time to removal — 2.3 days versus 3.5 days — and our patients are able to be discharged sooner, four days using the new criteria versus eight days under our old standard of care,” says Vivek Allada, MD, executive director of the Heart Institute at UPMC Children’s.

Save the Date: Master Class in Congenital Cardiac Morphology

The 12th Master Class in Congenital Cardiac Morphology will be held on October 9-11, 2019, at UPMC Children’s Hospital of Pittsburgh. World-renowned morphologist Robert H. Anderson, MD, PhD, FRCP, visiting professor, pediatrics, Medical University of South Carolina, will again be one of the course directors alongside Heart Institute Executive Director Vivek Allada, MD.
Research Update From the Heart Institute

Faculty and staff from the Heart Institute at UPMC Children’s are engaged in a continual effort to advance the basic science understandings of the cardiovascular system, and to develop new and novel clinical and translational investigations to improve patient care. Below is a sample of recent manuscripts, book chapters, reviews, and scientific statements authored by Heart Institute faculty members.

Manuscripts


 Ranked #6 in the Nation and Best in Pennsylvania for Cardiology and Heart Surgery by U.S. News & World Report


Christopher A, Kreutzer J, Ezon D. DVHTi is Associated with Aortic Coarctation Gradient at Catheterization Independent of Echocardiographic and Clinical Blood Pressure Gradients. Accepted for publication Congenit Heart Dis. 2018.

UPMC Physician Resources

For the latest CME courses, videos, news, and events for physicians, visit

UPMCPhysicianResources.com/Pediatrics.

Current CME Courses in Cardiology and Cardiothoracic Surgery

Frontiers in Cardiac Intensive Care: Critical Illness and Neurodevelopment

Presented by Justin Yeh, MD

In this presentation, CICU Chief and Heart Institute Co-Director Justin Yeh, MD, discusses neurodevelopment outcomes in pediatric patients with congenital heart disease, and he provides insights on interventions in the CICU that may improve outcomes.


Christopher A, Kreutzer J, Ezon D. DVHTi is Associated with Aortic Coarctation Gradient at Catheterization Independent of Echocardiographic and Clinical Blood Pressure Gradients. Accepted for publication Congenit Heart Dis. 2018.

Scientific Statements and Editorials


Books and Book Chapters


Heart Institute Attains STS Three-Star Rating

The Heart Institute at UPMC Children’s Hospital of Pittsburgh attained a Society of Thoracic Surgeons (STS) overall three-star rating for its congenital heart surgery program in the latest rankings that analyzed program data from participating health care systems for the four-year period from January 1, 2014 to December 31, 2017.

UPMC Children’s was one of 41 high-volume centers out of the 129 reporting institutions during the latest reporting period. Only 12 programs in North America received a three-star designation in the latest survey period, and this is the fourth consecutive reporting period in which UPMC Children’s has received the three-star designation.

UPMC Children’s overall non-risk adjusted mortality rate of 1.9 percent was lower than all but six of the 41 high-volume centers, with the overall mortality rate for the 129 STS institutions being 2.94 percent.

With respect to the observed-to-expected mortality ratio, the UPMC Children’s program’s overall ratio was 0.56, with an adjusted mortality rate of 1.6 percent.

In the highest-risk congenital heart disease neonatal surgical cases, UPMC Children’s mortality rate was five percent compared to the national average of 16.1 percent. The UPMC Children’s program specializes in treating the highest-risk cases. In the last three years, the program has experienced no mortalities in any of its Norwood procedure cases.

In heart transplant outcomes, UPMC Children’s ranks first in the United States with a 100 percent three-year pediatric graft and patient survival rate.

“The STS rating our cardiothoracic surgery program has achieved is a real tribute to the leadership of Victor Morell and the entire UPMC Children’s team,” says Vivek Allada, MD, executive director of the Heart Institute.

For complete ratings details and methodology, visit the STS website at https://publicreporting.sts.org.

UPMC Children’s Hospital of Pittsburgh Launches New Pediatric Research Podcast Series

UPMC Children’s Hospital of Pittsburgh has launched a new medical podcast series for physicians, scientists and other health care professionals featuring the hospital’s leading researchers and clinicians.

Episodes of “That’s Pediatrics” will include compelling interviews with scientists at UPMC Children’s Hospital who are performing innovative basic, translational and clinical research. New episodes will be released every two weeks.

“Going back to the polio vaccine, Pittsburgh has always been a hub of very innovative research, and in recent years has really become a nexus for some groundbreaking research in pediatric medicine,” said John Williams, MD, chief of the Division of Pediatric Infectious Diseases at UPMC Children’s and one of the podcast hosts.

“This is a spirit of collaboration here in Pittsburgh that makes it somewhat unique nationally and we really want to explore the research that is happening here and how we have a real opportunity to change the way pediatric medicine is practiced around the world.”

Current episodes of “That’s Pediatrics” include:

“Gene Therapy” with George Gittes, MD, director of the Richard King Mellon Foundation Institute for Pediatric Research and co-scientific director, UPMC Children’s Hospital

“Don’t Rule Out Brain Injuries” with Rachel Berger, MD, chief, Child Advocacy Center, UPMC Children’s Hospital

“All About Acute Flaccid Myelitis” with John Williams, MD, chief, Division of Pediatric Infectious Diseases, UPMC Children’s Hospital

In addition to Dr. Williams, “That’s Pediatrics” hosts are:

Carolyn Coyne, PhD, director of the Center for Microbial Pathogenesis, UPMC Children’s Hospital

Stephanie Dewar, MD, director of Pediatric Residency Training Program, UPMC Children’s Hospital

Brian Martin, DMD, vice president, Medical Affairs, UPMC Children’s Hospital

Subscribe to “That’s Pediatrics” in iTunes or Google Play Music to have new episodes automatically download to your phone for free when they become available.
Clinical Trials Update

Continued from Page 1

The study seeks to enroll a total of 10 patients in the trial and will follow patients for a total of 60 months to assess primary outcomes measures of device failure and associated mortality events or the need for another surgery or intervention at six- and 12-month intervals. Patients between the ages of 2 and 21 years are eligible for the study who meet the other inclusion/exclusion criteria.

Victor Morell, MD, division chief of Pediatric Cardiothoracic Surgery and co-director of the Heart Institute is serving as the site principal investigator for the study at UPMC Children’s.

About UPMC Children’s Hospital of Pittsburgh

Regionally, nationally, and globally, UPMC Children’s Hospital of Pittsburgh is a leader in the treatment of childhood conditions and diseases, a pioneer in the development of new and improved therapies, and a top educator of the next generation of pediatricians and pediatric subspecialists. With generous community support, UPMC Children’s Hospital has fulfilled this mission since its founding in 1890. UPMC Children’s is recognized consistently for its clinical, research, educational, and advocacy-related accomplishments, including ranking 13th among children’s hospitals and schools of medicine in funding for pediatric research provided by the National Institutes of Health (FY2017).

Other Cardiology Clinical Trials In Progress at UPMC Children’s

Tacrolimus/Everolimus vs. Tacrolimus/MMF in Pediatric Heart Transplant Recipients Using the MATE Score (TEAMMATE)

*Site Pl: Brian Feingold, MD, MS*

Melody® Transcatheter Pulmonary Valve Post-Approval Study: Implantation of the Medtronic Melody® Transcatheter Pulmonary Valve Using the Ensemble® Transcatheter Delivery System in Patients With Dysfunctional RVOT Conduits.

*Site Pl: Jacqueline Kreutzer, MD*

Study to Evaluate Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of LCZ696 Followed by a 52-week Study of LCZ696 Compared With Enalapril in Pediatric Patients With Heart Failure.

*Site Pl: Brian Feingold, MD, MS*