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Advancing Children's Healthcare Research through the Project K: Legacy Grant

Jenny E. Zablah MD, FSCAI, FACC, FPICS, FAAP; Sanjay Daluvoy, MD, FACS; Pratheepan Gulasekaram, JD; Mickie Okamoto, MPA

Cutting-edge research, contributing to advancing technology, healing under-resourced children, and bringing people together. These were the qualities that defined the professional and personal ethic of the late Dr. Kanishka Ratnayaka, internationally renowned pediatric interventional cardiologist. Dr. Ratnayaka served as the director of the new Dickinson Image-Guided Intervention Center and co-director of research at the Heart Institute at Rady Children's Hospital-San Diego and as Clinical Professor of Pediatrics at UC San Diego School of Medicine, after a lengthy tenure as an interventional pediatric cardiologist at Children's National Medical Center. During that time, he was also a researcher at the National Institutes of Health, where his path breaking work on MRI-based imaging paved the way for earlier detection of disease while reducing radiation exposure for pediatric patients. His research yielded more than fifty peer-reviewed articles and several patents for novel cardiovascular devices.



Dr. Kanishka Ratnayaka



Dr. Kanishka Ratnayaka guiding Dr. Lubega Sulaiman at the Ugandan Heart Institute

Dr. Ratnayaka was also a relentless advocate for children who lacked resources and access to healthcare. In the course of his career, he donated his time and expertise traveling to countries in Africa and Asia to train other pediatric cardiologists, and transforming the lives of thousands of children. Foundational to philanthropic work was his creation of the non-profit organization, World Children's Initiative (WCI) in 2005. Along with his two close friends, Dr. Sanjay Daluvoy (Plastic & Reconstructive Surgeon in Raleigh, NC) and Pratheepan Gulasekaram (Professor of Law, Univ. of Colorado), Dr. Ratnayaka founded WCI to improve healthcare access and infrastructure for children in developing areas domestically and worldwide. As a capstone of his work with WCI, Dr. Ratnayaka led the design of the Uganda Heart Institute's pediatric catheterization lab, and trained the local physicians who now perform hundreds of interventional procedures



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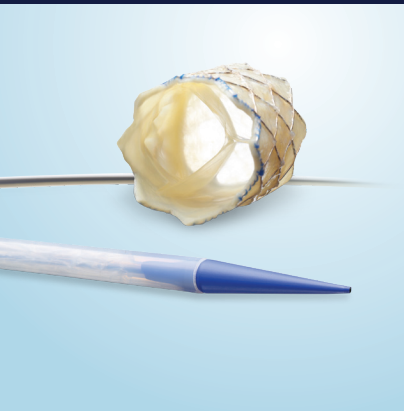
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- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.
- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilatation of the intended site of deployment, or for deployment of the TPV.
- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.
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*The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions for Use provided with the product or available on <http://manuals.medtronic.com>.

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- Patients with stenotic prosthetic RVOT conduits or bioprostheses where the risk of worsening regurgitation is a relative contraindication to balloon dilatation or stenting

Contraindications

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- Implantation of the TPV in the left heart
- RVOT unfavorable for good stent anchorage
- Severe RVOT obstruction, which cannot be dilated by balloon
- Obstruction of the central veins
- Clinical or biological signs of infection
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Potential Complications/Adverse Events: Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, pain, swelling or bruising at the catheterization site. Potential device-related adverse events that may occur following device implantation include the following: stent fracture, stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

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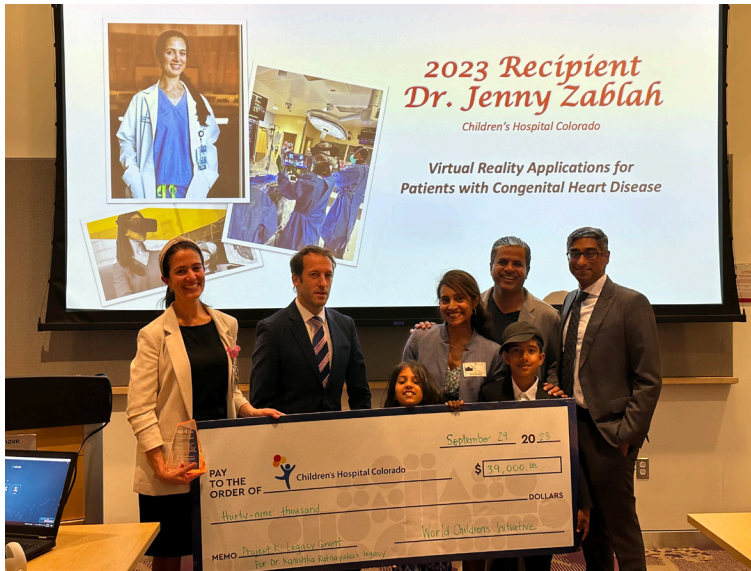
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The Melody Transcatheter Pulmonary Valve and Ensemble II Transcatheter Delivery System has received CE Mark approval and is available for distribution in Europe.

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2023 Project K: Legacy Grant check presentation to Dr. Jenny Zablah and Dr. Gareth Mortan at Children's Hospital Colorado. Check presented by (left to right) Dr. Amy Dewar, Dr. Sanjay Daluvoy, Pratheepan Gulasekaram and Dr. Kanishka Ratnayaka's children.

on children without foreign assistance. Tragically, Dr. Ratnayaka passed away in 2021, the untimely victim of colorectal cancer.

To honor his dedication to his craft and to serving the underserved, WCI created the Project K: Legacy Grant. Named for the affectionate moniker used by his close friends ("K"), the grant seeks to recognize and promote the work of an individual who embodies Dr. Ratnakaya's commitment to cutting-edge research with the potential to improve healthcare access for children. In September 2023, WCI awarded the inaugural The Project K: Legacy Grant in the amount of \$39,000 to Dr. Jenny Zablah at Children's Hospital Colorado.

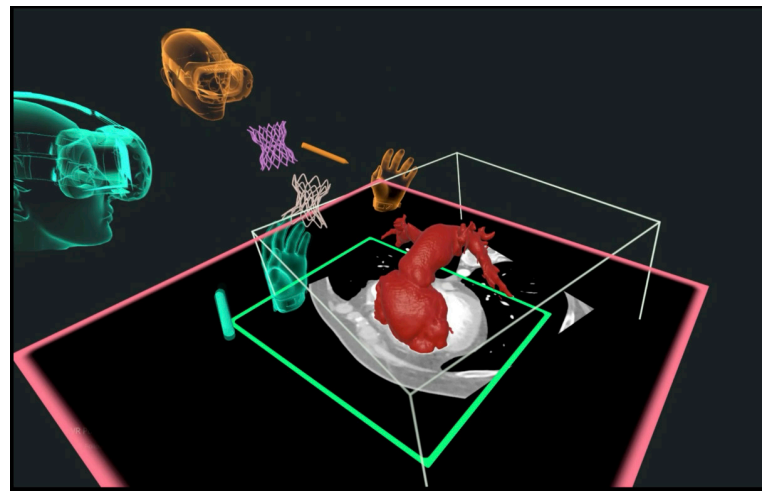
First Project Funded by The Project K: Legacy Grant

In 2019, Dr. Jenny Zablah established the Cardiac Catheterization Laboratory Advanced Imaging Program at Children's Hospital Colorado. This program has successfully devised and implemented a sustainable workflow for 3D printing, specifically tailored for patient education and procedural planning. Furthermore, it has seamlessly incorporated fusion imaging and 3D rotational angiography (3DRA) as routine practices within the cardiac catheterization laboratory, resulting in notable reductions in radiation doses, contrast volumes, and procedural times.

Since 2020, Extended Reality has become a big part of the program with partnership with software developers that have now come a long way since then, with Congenital Heart Disease specific tools that allow not only case planning but also patient and family education. This clinical and educational approach aligns with the vision of Dr. Ratnayaka's legacy work.



Dr. Jenny Zablah using Virtual Reality Headset



Multicenter collaboration in virtual reality

The research project being supported by the WCI Project K: Legacy Grant is a prospective study with several sub-studies, evaluating the benefit of virtual and augmented reality from the planning to the procedural guidance and performance of transcatheter and surgical cardiac procedures like: Transcatheter Pulmonary Valve Implantation, Sinus Venous Defect Percutaneous Closure, Left Ventricular Assist Device Implantation and Surgical Patches Design. The specific aims of the study include:

1. To evaluate the feasibility and accuracy of virtual reality (VR) for procedural planning.
2. To develop a reproducible workflow for VR planning of common transcatheter procedures in vendor neutral softwares.
3. To determine the influence of VR for procedural planning on radiation exposure, complications, and procedure time.
4. To explore the use of VR for training and for the continuing education of physicians.

The project includes multiple specialties and researchers in different levels of training to augment the impact of the project. Participants in our project include congenital interventional cardiologists, cardiothoracic surgeons, pediatric cardiology/ cardiac catheterization fellows, modern human anatomy master students and medical students.



Using Augmented Reality Intraoperative

Immediate Impact of the Legacy Grant in the VR Project

Thanks to the generosity of WCI and their Project K: Legacy Grant, the project received complete funding, enabling the initiation of five concurrent projects. In support of these endeavors, essential equipment has been procured, including a state-of-the-art computer and additional virtual reality (VR) headsets. The acquisition of these resources is aimed at providing additional workstations for our students and researchers, thereby expanding capacity for in-depth studies.

Furthermore, this grant affords students the opportunity to secure financial support for travel, enabling them to present their research at conferences and actively promote the work. This aligns seamlessly with Dr. Ratnayaka's vision, which extends beyond the enhancement of imaging techniques in the cathlab with reduced radiation. It also underscores the commitment to empowering new generations and elevating the standards of education in our field.

Commenting on Dr. Zablah's selection for the grant, WCI Founder and President Dr. Daluvoy reflected, "Her research and commitment parallel the ideals Kanishka stood for. I'm sure he would have been truly excited to support her work." Speaking directly to Dr. Zablah's VR innovations, Dr. Daluvoy noted that it is "hard for children and their parents to understand what a hole in the heart means. Seeing it in virtual reality is both a powerful way for physicians to explain what's going on and allows them to simulate treatment plans and plan procedures." Important to legacy grant, both Drs. Zablah and Daluvoy expressed optimism at the promise of VR technology for planning, collaborating, and

treating the vulnerable populations that so deeply motivated Dr. Ratnayaka.

More than just honoring Dr. Ratnayaka, the award presentation reflected his warmth and spirit. Joining Dr. Daluvoy and Professor Gulasekaram were Dr. Ratnayaka's widow (Dr. Amy Dewar) as well his young children, his brother and his infant nephews. The ceremony at Colorado Children's Hospital provided them with a chance to hear about their father's brilliance, charisma, and selflessness, as well as an opportunity to play with and experience the VR technology used by Dr. Zablah. The award ceremony itself and its celebrant, Dr. Zablah, exemplified WCI's and Dr. Ratnayaka's credo to help children "Live Longer and Play Harder."

Inquiries about supporting future grant cycles or applying for WCI's Project K: Legacy Grant can be directed to info@wciprojects.org. For more information regarding Dr. Zablah's VR research, please direct inquiries to Jenny.zablah@childrenscolorado.org.

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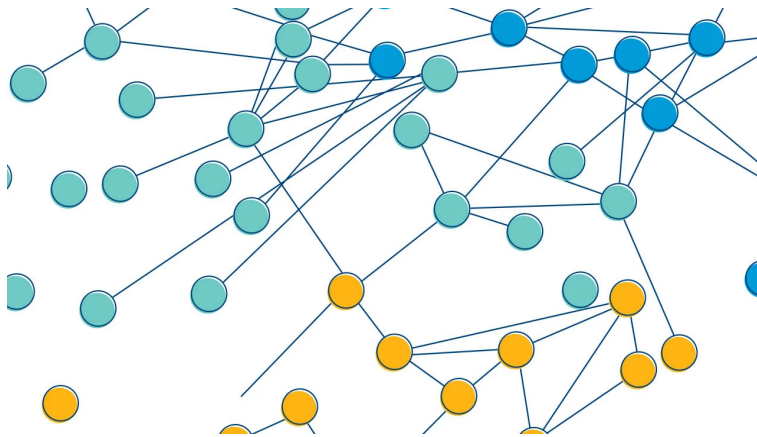


Speeding Up Cardiac Disease Research with Big Data

How Can Adopting Big Data Strategies From the Business World Help the Medical Field Advance Research?

Benjamin Frank, MD & Jesse Davidson, MD, MPH

The business world has used big data to drive decisions for years. Now, doctors are bringing this approach from the board room to the lab bench, using data to inform research questions. Investigators in Children's Hospital Colorado's Heart Institute, childrenscolorado.org/doctors-and-departments/departments/heart/, are using big data and multiomics profiling as a launchpad to uncover new information and hypotheses about pediatric heart disease. This technique can point researchers toward new areas of study and accelerate the research process to impact patients faster. As Ben Frank, MD, puts it, "Sometimes you don't know what you don't know until you find it."



Inductive Research Approach for Cardiac Research

Jesse Davidson, MD, and his team started exploring this inductive research approach at Children's Colorado in 2018 with a metabolic profiling study of infants under four months old who underwent cardiothoracic surgery. At the time, Dr. Davidson says, this was one of the first major pediatric medical studies to use the data-driven approach. The team's work showed significant dysregulation in many of the metabolic pathways, pubmed.ncbi.nlm.nih.gov/30561257/, pointing them to areas of further research.

The big data process looks slightly different each time, but the research typically starts with blood tests. If Drs. Davidson and Frank are using a metabolomics approach, that means measuring anywhere from 200 to 250 biomarkers. If they are employing a proteomics approach, that involves measuring closer to over 1,500 markers in each patient. Then, the researchers plug that data into a machine-learning algorithm that sorts through what might be significant depending on how the researchers are dividing up the population they are studying, such as kids with heart disease compared to kids who do not have heart disease. The software can also help the team identify how the individual dysregulated metabolites and proteins fit into key biologic systems.

"Zooming out to see the truth can help you see things you weren't expecting," Dr. Davidson says. "Science has traditionally been a hypothesis-driven product. You make a hypothesis about a next experience, test that hypothesis, come up with more data, make your hypothesis, test that, etc. It has blinders on to just about everything else that's going on. It is extraordinarily challenging to work down a very linear path and expect that you'll know a lot about the rest of the system."

While Dr. Davidson says this more traditional, hypothesis-driven approach is still extremely important in the research process, using data to drive the hypotheses can account for more complexity.

As Dr. Davidson, Dr. Frank and their colleagues started seeing clinical research yield more complex and intricate data, they realized this type of big data approach would be ideal, especially for their work with patients with Single Ventricle Heart Disease. The team treats children with this condition regularly, so there's a trove of clinical data to analyze.

"There's a lot of room to do better, and there's a lot of room to help their lives, to help their survival and to help their day-to-day experience," Dr. Frank says. "We are at a unique and powerful moment to be at the forefront of trying to figure out how to leverage this new data, and how to use it to help kids."

Dr. Davidson agrees: "Cardiology and cardiac surgery are ripe for this reverse strategy. If you start with an inductive approach, are there ways to find smarter ways forward and also to speed up the discovery process?"

The Orchestra Behind Big Data Analytics

Big data analytics would not be possible without a team of experts working together across the University of Colorado (CU) Anschutz Medical Campus. For example, as part of this work, it was necessary to engage with statisticians, and CU is home to the Center for Innovative Design and Analysis — an invaluable tool for researchers partnering with biostatisticians,



computational biologists and data scientists on complex data sets. Drs. Davidson and Frank also work closely with a team of research coordinators, research nurses and regulatory support teams.

“Sometimes I think Dr. Davidson and I are conductors of a big orchestra. Without all the instruments, though, you wouldn’t get any music,” Dr. Frank says. “That kind of collaborative, team-based approach has been essential to our success.”

This collaborative style of research allows the team to follow the path laid out by the data. Dr. Davidson and his team are taking this work one step further, by not just generating new hypotheses after analyzing the data, but also dedicating time and studies to test those new, specific hypotheses to see what they learn.

“I think that’s where Dr. Davidson has really led,” Dr. Frank says. “If you look at the machine-learning literature, there’s a lot out there about using these strategies to do hypothesis-generating studies in different populations, but there are fewer people who are pushing to take the next step: hypothesis-testing validation of their findings. That next step is the crucial piece to move our work closer to improving outcomes for kids at the bedside.”

Metabolomics and Phenotypic Approach

Dr. Davidson’s 2018 Journal of the American Heart Association study laid the groundwork for this type of data analysis research to blossom in the Heart Institute. Through that research, which took a metabolomic approach, Dr. Davidson and his team found a profound shift in the metabolic fingerprint of infants undergoing cardiothoracic surgery with cardiopulmonary bypass. They also noted a global deficiency in amino acid levels, which is a finding that can lead to quick, direct changes to the care patients receive and an area the team will focus on next.

The team also used metabolomic profiling in a 2022 paper in the American Journal of Renal Physiology, pubmed.ncbi.nlm.nih.gov/35532069/, where they explored acute kidney injury, a common cause of morbidity after congenital heart disease surgery. Using animal models, the researchers were able to identify novel evidence of dysregulated tryptophan catabolism, among additional findings, opening the door to explore these pathways for diagnostic and therapeutic targets.

In a 2023 Journal of the American College of Cardiology: Advances paper, pubmed.ncbi.nlm.nih.gov/36875009/, Dr. Frank analyzed how kids with single ventricle heart disease are different than other populations, such as those without heart disease, and how doctors can be more personalized in their approach to treating these children. The findings suggested an association between increased pre- and post-operative circulating methionine and tryptophan metabolite levels, as well as difficulty recovering from heart surgery. These three examples are just a handful of many research projects the Heart Institute team has conducted with this big data approach.

“I think taking the big data approach allows you to build this really deep phenotype of who these kids are at these different key, crucial moments of leverage in their life,” Dr. Frank says. “This type of approach really allows you to blend the acute and the chronic. It really allows you to ask questions about both how we can help you get through this moment of crisis in your life, and also when you are OK, how we can help you maintain that functional status? How can we make you feel even better than you thought was possible?”



This article was originally published by Children's Hospital Colorado;

<https://www.childrenscolorado.org/advances-answers/recent-articles/big-data-for-cardiac-research/>



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Congenital Track at 2024 SCAI Scientific Sessions Offers Learning, Development, and Connection

Gavin Stern, MPH, MS, Director of Public Relations & Communications, SCAI

Every year, SCAI Scientific Sessions brings together the interventional cardiology community from around the world to share the latest clinical data, procedural guidance, and advanced expertise. This year's conference has lots to offer for those specializing in Congenital Heart Disease treatments, with more than 15 sessions offered in the program's Congenital Heart Disease Track.

"With the rapid development of new transcatheter devices and techniques for treating Congenital Heart Disease, I'm excited about this year's program," said SCAI's Congenital Heart Disease Program Chair, Dr. David T. Balzer, MD, MSCAI. "The sessions and live cases will focus on a broad range of topics, beginning with the basics (invasive hemodynamics) and progressing to the more unusual (i.e., interventions in middle aortic syndrome). In addition, we will cover many of the hottest topics in interventional cardiology."

The track is dedicated to congenital interventional cardiology and will employ didactic and case-based sessions to enhance expertise through collaborative and interactive learning. Attendees will acquire take-home knowledge for navigating complex cases, maximizing procedural success, and minimizing complications.

"SCAI has been a very strong proponent of Congenital Heart Disease and interventions. The congenital track at the Annual Scientific Sessions provides an excellent opportunity for congenital cardiologists to receive updates on cutting edge Imaging, interventions, currently available and upcoming devices," added Dr. Zahid Amin, MD, MSCAI, FAHA, Associate Chair of the Congenital Heart Disease program. "Industry representatives and stakeholders are onsite to discuss future endeavors and carve pathway for future improvement in this field."

In addition to educational sessions, attendees can look forward to live cases, scientific and clinical research abstracts, a poster competition, SCAI Women in Innovation, the Fellows Summit for Complex Cases, an international case exchange, and a special induction ceremony for those receiving the MSCAI and FSCAI honors.

The congenital heart disease track in 2024 focuses on:

- Invasive physiology.
- PDA stenting in ductal-dependent pulmonary blood flow.
- Complex Congenital Heart Disease cases.
- Tricuspid valve interventions.
- Pulmonary vein stenosis.
- Pulmonary valve implantation.
- Atrial septal interventions.
- Unusual interventions in CHD.
- An 'I blew it session' of case-based discussions of complications during CHD interventions.

"Prepare to be impressed! Our meeting this year is full of exciting talks, education, and thrilling cases. We will touch on hot topics from the basics on invasive hemodynamic physiology to the most dreaded pulmonary vein stenosis to the new techniques of utilizing flow restrictors and electrosurgery," said Dr. Howaida El-Said, MD, PhD, FSCAI, Assistant Program Chair.



SCAI President Dr. George D. Dangas, MD, PhD, MSCAI gives remarks at SCAI Scientific Sessions

Additional highlights include:

- The Pediatric and Congenital Interventional Cardiology Early-career Society (PICES) group detailing ventricular assist device (VAD) cannula stenting and how to place adult-size stents in small children.
- The Mullins lecture, which will go back to the origins of congenital interventions and what the field has learned along the way.
- A pulmonary valve session focused on what is new in the field.
- A patent ductus arteriosus session to teach tips and tricks of the craft.
- The "forgotten" tricuspid valve.

"And, of course, our favorite 'I blew it' session to pump up our adrenaline and keep us humble," El-Said said. "We look forward to seeing all of our friends while we learn together and share our knowledge and rekindle our friendship!"

This track will appeal to trainees, early-career physicians, and experienced practitioners of congenital interventional cardiology.

Attendees at Scientific Sessions can include:

- An invasive, interventional, or general cardiologist.
- Pediatrician specializing in congenital heart disease.
- Cardiology or interventional cardiology fellow-in-training.
- Cath lab nurse practitioner, physician assistant, nurse, technologist, radiologic technologist, or technician.

Registration includes on-demand access to meeting content for three months after the meeting ends so you can catch up on anything you missed after the event.

For more information and to register, visit: www.scai.org/SCAI2024.





Calling All Trainees: Join the Trainee Committee of the AAP Section on Cardiology and Cardiac Surgery

Dean Karahalios, DO, FAAP & Andrew Headrick, MD, MPH, FAAP

The American Academy of Pediatrics (AAP) is the home for all pediatric trainees. The Trainee Committee of the AAP Section on Cardiology and Cardiac Surgery (SOCCS) is a dynamic group of medical students, residents, and fellows collaborating to meet the needs of trainees pursuing a career in pediatric cardiology. Drawing on the resources of both SOCCS and the AAP Section on Pediatric Trainees (SOPT), the SOCCS Trainee Committee develops programming and resources for trainees at all levels. This committee aims to expand your knowledge base and enhance your training experience through collaboration at regional and national levels. The group devotes itself to accomplishing this goal through four different workgroups: Career Planning, Medical Education, Advocacy, and Communication.

There is no group that understands the needs of trainees like trainees themselves. As such, previous feedback from trainees regarding their training experience has been crucial in driving several different initiatives under the career planning workgroup. In one such example, the Committee is working to enhance mentoring opportunities and connections in a streamlined fashion utilizing the AAP Mentorship Program. In addition, this year the Committee will host the third annual webinar titled, "What Comes After Fellowship: Preparing for Fourth Year Fellowship or Your First Attending Job." This webinar focuses on educating trainees about pediatric cardiology job market characteristics and preparing for a job or senior fellowship search. It features breakout rooms dedicated to each subspecialty of pediatric cardiology, where faculty and current fourth year fellow panelists will offer specialty-specific insights on the fellowship and job application processes. Breakout rooms feature faculty and current fourth year fellows in trainees' respective fields of interest, and help fellows gain specialty-specific insights on the fellowship and job application processes. The SOCCS Trainee Committee has also organized a financial wellness webinar for pediatric cardiology trainees and has been involved in SOPT webinars devoted to preparing residents for the pediatric cardiology fellowship application process.

Another chief concern of trainees across the country is developing the knowledge needed to become a competent pediatric cardiologist. Responding to feedback about the paucity of board review materials in pediatric cardiology, the SOCCS Trainee Committee has partnered with Heart University (www.heartuniversity.org) to start an exciting new monthly board review initiative as well as multidisciplinary educational modules related to neonatology and cardiology. Additionally, the Committee will host its inaugural webinar titled, "Difficult Cases in Pediatric Cardiology: Navigating Management Without a Consensus." This webinar will feature a complex clinical case with dynamic attendee involvement, will be moderated by attendings with varying practice patterns, and conclude with a didactic and debate segment reviewing the merits of each practice approach.



Join our WhatsApp group!

Network and get involved in career planning, education, advocacy, and communication projects to launch your career.

Virtual Meetings on the 4th Wednesday of every month. Trainees at all levels welcome!

From an advocacy and communications standpoint, the SOCCS Trainee Committee is collaborating with the SOCCS Advocacy Committee to develop a webinar titled, "Perinatal Mental Health and Congenital Heart Disease." Moreover, the Committee constantly works to enhance membership and bring relevant AAP resources locally, appropriate to the training program level of each trainee. This past year has included in-person social gatherings at each pediatric cardiology conference, allowing for sharing of resources, and helping trainees expand their network outside their respective institutions.

All trainees at every level of training—medical students, residents, and fellows—are welcome to join the SOCCS Trainee Committee to contribute to all of the above initiatives and more. AAP membership is a requirement and can be accessed at www.aap.org/join. In most scenarios, national AAP membership is either paid for by training programs or eligible for reimbursement. After obtaining national AAP membership, training fellows can join SOCCS at no cost. Residents are currently charged a \$10 fee to join SOCCS, though the section is working to remove that soon. Ultimately, the SOCCS Trainee Committee is a rewarding group that enriches the early careers of so many trainees. It provides countless opportunities to network and pursue extra-clinical initiatives specific to each individual's interest. If you have any questions about joining this vibrant, active group, do not hesitate to reach out to the SOCCS



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Camp is Good Medicine

Sara Meslow, Executive Director, Camp Odayin

At Camp Odayin, we provide fun, medically safe and emotionally supportive camp experiences and community building opportunities for young people with heart disease and their families. Our goal is to improve the quality of life, mental health, and overall well-being of our campers. Young people with heart disease often experience high levels of anxiety, depression, and trauma and Odayin provides a safe and supportive environment to lessen these mental health challenges. We provide a sense of belonging, community bonding, connection to nature, and a ton of campy fun! Fifty-four percent of our campers said that attending Odayin has improved their mental health. Camp is good medicine!



Our former camper, now volunteer camp counselor, Elena, shares her Odayin story:

I am a former camper and current heart patient. I genuinely cannot count how many cardiac procedures I've had, and I have no memory of a life without heart disease since my condition was discovered when I was 2 months old. What I do remember, what it all felt like before I went to camp.

While I was growing up with serious cardiac illness, well-meaning adults tended to treat me like I was made of glass. I grew accustomed to being sequestered, separated, having to constantly explain to both peers and adults why I couldn't fully participate in certain everyday activities because of the fatigue those activities would induce, eat certain foods because of their conflicts with my medications, or even walk through a metal detector because I had a pacemaker.

It was kind of a stressful lifestyle for a 12-year-old. I glowered enviously at those big-name with diseases with well-publicized 5Ks and people wearing pink for a whole month, and trendy rubber bracelets. On the occasions people did mention 'heart disease', it was all old people and something about cholesterol, which meant they obviously weren't talking about me. Nobody knew anything about kids like me. My diagnosis was cardiomyopathy. My disease was loneliness.

Then, in 2005 during one of my many cardiology appointments, I picked up a brochure sitting on one of the side tables in the waiting room. It described a summer camp, a real sleepaway summer camp, for kids with heart disease. But I was overjoyed, because prior to that moment, camp had just been another thing on the long list of stuff I could never do. After much pleading and very diligent research, my parents agreed, piled the family into our SUV, drove six and a half hours, and nervously hand-delivered me to Camp Odayin.

The rest, as they say, is history. At camp, for the first time in my life, I met a lot of other kids who were just like me. I met other kids who had also had countless surgeries and proudly sported the telltale "zipper" scar on their torso. I met older teens, and counselors who served as role models who truly "got me" in a way few others did. I tried new things that my thoroughly urban environment simply couldn't have introduced me to – horseback riding, tubing, kayaking, and roasting marshmallows over a bonfire (we usually just used the microwave at home).

For five glorious days, I was introduced to myself, and to who I might be outside of hospital rooms and surgeries and anxiety. For five days the most salient detail about me to most adults, that is to say my heart problem, just didn't matter. I also gained really important perspective on my life and the severity of my condition, as I met many other kids multiple diagnoses of equal severity to my own.

When I returned, my parents were floored. I overheard my mom telling her sisters how much more confident I seemed, no small feat for a middle school girl. They happily sent me again and again and again, and soon my friends became theirs too. When I "graduated" from camp, the support didn't stop there, as the young adult retreat reconnected many old camp friends and provided valuable information about how we might best manage our transitions into the world of adult cardiac care.

I went for fun and I gained a family, a community, and the sense of identity that so many chronically ill people are robbed due to circumstance. My parents could connect with others who could truly understand their worries and hopes for their child. I met one of my lifelong best friends at camp that very first year.

I simply do not know who I would be if I hadn't had that chance at 12-years-old. Each year at camp I could see bright, technicolor flashes of the adult I might become. Historic civil rights activist Marian Wright Edelman said, "You cannot be what you cannot see," and through camp I could finally see so much. Camp Odayin allows heart warriors, families, and friends to see and be seen.





66 Hospitals Unite Under ACTION to Bridge Gaps in Pediatric Cardiac Care

Sixty-six hospitals across the country have joined forces to enhance outcomes for pediatric heart patients. While specialized devices for heart disease significantly benefit adults, the pediatric realm faces a challenging reality: the lack of dedicated medical devices tailored for children. Consequently, physicians are often compelled to adapt adult-sized FDA-approved devices for pediatric use, leading to prolonged hospital stays and, in some cases, children being tethered to monitors for years.

Heartbreaking Statistics and Unprecedented Collaboration

In the United States, pediatric heart failure, with over 14,000 hospitalizations annually, surpasses those due to pediatric cancer. Despite these staggering numbers, research and innovation in this critical area are grossly underappreciated and underfunded. Presently, therapies for managing pediatric heart failure largely derive from adaptations of adult treatments, forcing healthcare providers into a challenging situation where medications and devices not originally intended for children are employed without adequate evaluation.

Enter ACTION, www.actionlearningnetwork.org/, the Advanced Cardiac Therapies Improving Outcomes Network, a pioneering collaboration among pediatric heart failure hospitals nationwide. Consisting of physicians, nurses, patients, families, and researchers, ACTION is a united force dedicated to improving outcomes and enhancing the quality of life for young heart failure patients. This collaborative effort signifies an unprecedented milestone, replacing traditional approaches.

"As we reflect on the journey, February's Heart Health Month spotlights persistent challenges," says Angela Lorts, MD, MBA, and Co-Executive Director of ACTION. "Beyond celebrating achievements, we recognize a critical imperative – the desperate need for tailored medical devices for children."

ACTION Achievements in 2023 and Future Innovations in 2024

In 2023, ACTION launched the first FDA-regulated trial for a pediatric ventricular assist device registry with Berlin Heart, Inc. This expanded health literacy, published impactful research, established

new guidelines for patients, and launched a Heart Healthy Video Series featuring celebrity ambassador Julian Lerner.

"I had been wanting to contribute in a meaningful way to an organization that focuses on helping children. Once I learned about ACTION's mission to keep kids' hearts healthy, I knew that I had found just the right place – a place where I could make a tangible, positive difference for kids and their families," says ACTION's celebrity ambassador Julian Lerner.

For 2024, ACTION anticipates FDA approval of the Berlin Heart Active Driver, which is expected to revolutionize pediatric heart care. Collaborating globally, ACTION aims to enhance patient quality of life and advocate for pediatric-specific devices, transcending national boundaries.

About ACTION

To explore ACTION's initiatives, achievements in 2023, and plans for 2024, kindly visit www.actionlearningnetwork.org.

ACTION (Advanced Cardiac Therapies Improving Outcomes Network) is a global organization dedicated to enhancing outcomes for heart failure patients, with a particular focus on children. Since 2017, ACTION has fostered international collaboration among patients, families, clinicians, researchers, payors, and industry stakeholders. Based in Cincinnati, OH, ACTION deploys a quality improvement and research-based approach, uniting 66 network sites and 1,185 members to share data, develop solutions, and drive innovations.

Discover more at www.actionlearningnetwork.org.



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FDA Grants Breakthrough Device Status to Toku's Patented Cardiovascular Risk AI (CLAiR) Platform

Toku's AI (CLAiR) technology platform has received FDA Breakthrough Device status, and if cleared by the FDA will deliver real-time cardiovascular disease (CVD) risk assessments through routine eye exams. FDA's Breakthrough Device designation expedites the development and review process, shortening the time until Toku's AI technology is able to reach the market. Consequently, patients, especially those in lower socioeconomic groups who may lack access to robust healthcare, will benefit from earlier access to non-invasive and point-of-care CVD risk assessments, which in turn can lead to early prevention and improved outcomes. The patented CLAiR AI technology platform, if cleared for marketing, will integrate seamlessly into existing retinal cameras to allow widespread access to CVD assessments through eye care clinics, primary care, and pharmacies. Toku recently joined the Innovator's Network of the American Heart Association's Center for Health Technology & Innovation, a group dedicated to fostering development of innovative and scalable healthcare solutions. Toku plans to reach the US market by mid-2025.

(BUSINESS WIRE)--Toku, Inc., a commercial medical device company specializing in imaging technology and AI, announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device designation to its patented CLAiR technology. The CLAiR platform, if cleared by the FDA, will be the first medical device in the US market that can provide affordable, point-of-care and non-invasive evaluation for risk of cardiovascular disease (CVD) using fundus retinal images through a routine eye exam. Working with its partners, Toku is aiming to establish the largest network for CVD risk assessment across the US and then globally. Toku recently joined the Innovator's Network, part of the American Heart Association's Center for Health and Technology & Innovation. Inclusion in this group will enable Toku to collaborate easily with other cutting-edge companies creating the next generation of high-tech healthcare solutions as the Company works to bring the CLAiR platform to scale commercially, pending clearance from the FDA.

The retina, located in the back of the eye, is the only transparent part of the vascular system and can be photographed easily and non-invasively. The CLAiR technology is designed to integrate readily with existing retinal imaging cameras, to provide real-time CVD risk assessments with accuracy comparable to traditional cardiovascular risk assessment tools (which typically include multiple measurements and blood tests and can take weeks). The AI-powered CLAiR technology can interpret the many tiny signals conveyed through retinal images of blood vessels to identify elevated cardiovascular risk that may be caused by genetics or risk factors such as hypertension or high cholesterol. These results can then be shared with the patient's primary care physician, who can initiate a comprehensive cardiovascular evaluation. Retinal imaging is routinely performed in a variety of eyecare settings

and is increasingly being implemented in primary care clinics and pharmacies across the US. Once cleared by the FDA, the CLAiR technology will provide healthcare professionals across multiple settings with the ability to check for elevated cardiovascular risk before the onset of clinical disease.

"Toku's mission is to make identifying disease accessible for everyone, everywhere, all the time. The Breakthrough Device designation that the FDA has granted to our CLAiR technology platform is a validation of the tremendous potential our CLAiR AI technology can provide to the tens of millions of patients who may unknowingly be at risk of a devastating cardiovascular condition," said Associate Professor Ehsan Vaghefi, CEO and Co-Founder of Toku. "This designation greatly de-risks our clinical development and regulatory pathway for the technology, as the FDA's Breakthrough Devices program offers medical device companies accelerated review processes, enhanced guidance, and prioritized evaluation, facilitating quicker market access for innovative technologies and encouraging the development of devices that significantly improve patient care."

"I am excited by the potential of Toku's CLAiR technology as it can help improve health equity both in the United States and elsewhere in the world," said Michael V. McConnell, MD, MSEE, Clinical Professor of Preventive Cardiology, Stanford University and author of Fight Heart Disease Like Cancer. "As a clinician, I see broadening access to quality care and prevention as a critical issue, and the CLAiR retina scan technology may help improve the cardiovascular health of more people worldwide."

"Predictive analytics technology, provided it has been proven to be accurate and applicable to the population using it, has tremendous potential to benefit patients by identifying those at highest risk so treatments and preventive measures can be initiated quickly. The medical literature has published many examples using different types of eye imaging to predict risk of other systemic conditions beyond cardiovascular disease, such as neurologic or kidney disease. Therefore, further developing this type of technology is very exciting as cardiovascular disease remains a significant cause of morbidity and mortality in the whole country," said April Maa, MD, Professor of Ophthalmology, Emory University School of Medicine.





New Combination of Techniques May Improve Stent Expansion for Patients Undergoing Percutaneous Coronary Intervention

Principal Investigator: Samin Sharma, MD, Director of Interventional Cardiology for the Mount Sinai Health System

Conference: Transcatheter Cardiovascular Therapeutics (TCT 2023) – Featured Science Presentation

Title: Rotational atherectomy combined with cutting balloon to optimize stent expansion in calcified lesions – Primary Results of the ROTACUT Trial

Bottom Line of the Study: Rotational atherectomy (RA) is an established technique for PCI of moderately or severely calcified coronary lesions. Currently, as the standard treatment, interventional cardiologists perform a rotational atherectomy on these patients followed by high pressure balloon dilation and then drug-eluting stents.

The hypothesis of the study was that using a cutting balloon in addition to rotational atherectomy (RA) would improve coronary stent expansion. While the minimum stent area did not significantly differ between the groups treated with RA plus cutting balloon angioplasty versus the group treated with RA plus non-compliant balloon angioplasty, there was a trend toward improving stent expansion. The important takeaway is that RA plus cutting balloon angioplasty was safe with rare procedural complications and few clinical adverse events at 30 days.

Why this Study is Important: Calcified coronary lesions remain a challenge for interventional cardiologists and are associated with procedural complications.

Why this Study is Unique: This is the first randomized control trial investigating combination of two ablative techniques with serial intravascular imaging assessments.

Study Findings: There was no significant difference in stent expansion between the group treated with RA plus cutting balloon angioplasty versus the group treated with RA plus non-compliant balloon angioplasty, but there was a trend toward improving stent expansion. The important takeaway is that RA plus cutting balloon angioplasty was safe with rare procedural complications and few clinical adverse events at 30 days.

How the Research was Conducted: Twenty-nine patients from two sites, including The Mount Sinai Hospital in New York City were randomized to RA plus cutting balloon angioplasty group and 31 patients to RA plus non-compliant balloon angioplasty. Procedural outcomes were assessed by an imaging core lab. Clinical follow up was obtained by phone calls.

The Results: No differences in minimum stent area or other measures of stent expansion were found on angiography or intravascular ultrasound between the groups. There were rare procedural complications and few clinical adverse events.

What the Results Mean for Physicians: The study findings have important implications. The use of a combination of RA and CBA appears safe in clinical practice and is associated with high procedural success. This study can be the foundation of larger trials to see if outcomes can be improved for patients with calcific lesions using this strategy.

What the Results Mean for Patients: If patients need to undergo PCI for calcified coronary lesions, they there is now an additional strategy that has been proven to be safe to treat these complex abnormalities.

Quote: “Calcific lesions are amongst the most complex lesions for patients undergoing PCI. The ROTACUT study sought to investigate the safety and efficacy of two approved ablative technologies in combination compared with Rotational atherectomy alone. While we did not show improvement of the Stent area by imaging, we did observe trend toward improving stent expansion, and observed no safety issues at all. This will set the stage for a larger randomized trial to evaluate how best to treat calcific lesion,” says Samin Sharma, MD, Director of Interventional Cardiology for the Mount Sinai Health System.

For more information, visit www.mountsinai.org or find Mount Sinai on Facebook, Twitter and YouTube.



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