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Understanding Heart Failure in Children After Single Ventricle Surgery

Shelley Miyamoto, MD; Stephanie Nakano, MD; Anastacia (Tasha) Garcia, PhD

A team of doctors at Children's Hospital Colorado's Heart Institute is working to uncover the exact mechanisms that lead to heart failure for some children after single ventricle surgery. The hope is to not only identify potential drugs to slow the progression, but ultimately prevent the need for a heart transplant all together.

The University of Colorado Anschutz Medical Campus is home to one of the largest IRB-approved cardiac tissue biobanks in the country, where Shelley Miyamoto, MD, and her team receive freshly explanted heart tissue to study. This area of pediatric research is particularly valuable because what we know about heart failure in adults is vastly different than what we know about heart failure in children. As Dr. Miyamoto puts it, "There's something different about pediatric heart failure," and the team at Children's Colorado is determined to figure out what.

One of the most common severe congenital heart diseases is single ventricle disease, where a baby is born with only one pumping chamber of the heart. The most common treatment path for single ventricle babies is a series of three surgeries over the first five years of the child's life to reroute the heart's blood flow. After the third surgery, known as the Fontan procedure, an entire team of experts in the Children's Colorado Fontan multidisciplinary clinic partner with the child's primary cardiologist to support the child through the next hurdles. The team watches for complications in the lungs and liver, tests for neurodevelopmental issues and monitors patients for the signs of heart failure that could require an eventual heart transplant.

Dr. Miyamoto and her team are working to understand why heart failure happens to these young children. She has spent nearly two decades at Children's Colorado and is the top-funded child health research investigator at the Heart Institute. She is also a valuable mentor to Anastacia "Tasha" Garcia, PhD, Stephanie Nakano, MD, and Kathryn Chatfield, MD, PhD, among others. Together, they are making significant contributions to this area of research.

The Link Between Single Ventricle Heart Disease and Mitochondrial Dysfunction

When Dr. Garcia arrived at Children's Colorado nearly eight years ago, Dr. Miyamoto saw an opportunity to bridge the world of basic science and clinical translational research for single ventricle heart disease. At the time, researchers knew that adults with heart failure typically have mitochondrial dysfunction, where the energy factory of the cells is not functioning properly. But that was never proven true for single ventricle pediatric patients — until now.

"Until recently, very little was known about the transition to heart failure in this unique population," Dr. Garcia explains. "But over the past several years, our lab and others have really characterized what happens at a molecular level."

Dr. Garcia has worked her entire professional career to identify mechanisms of heart failure progression and to assess if there is mitochondrial dysfunction in these failing single ventricle hearts. And according to Dr. Miyamoto, Dr. Garcia's latest paper, published earlier this year in Journal of the American College of Cardiology **https://www.sciencedirect.com/science/article/pii/S2452302X22003758?via%3Dihub**, is the first to show proof of this. Her team found that failing single ventricle hearts have dysregulated metabolic pathways and impaired mitochondrial function. They also found an intermediate metabolic phenotype in single ventricle hearts prior to the onset of heart failure, suggesting even nonfailing single ventricle hearts are vulnerable to metabolic dysfunction and eventual heart failure.

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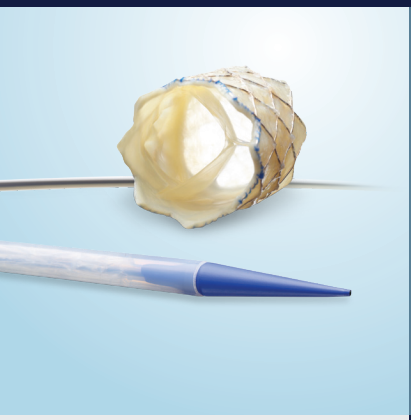

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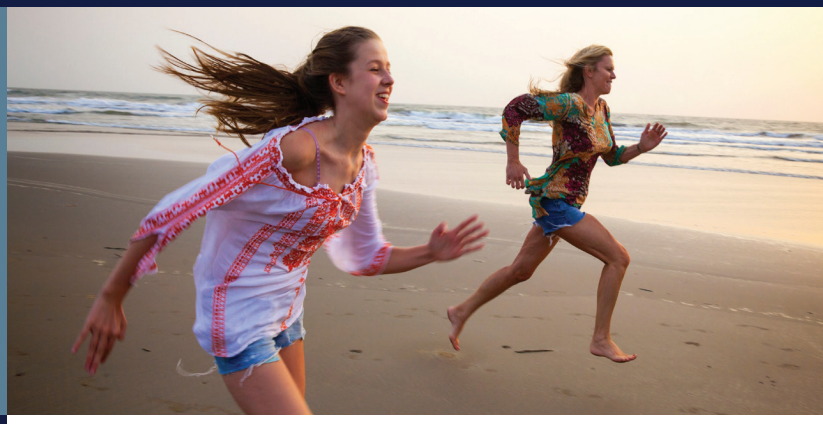

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*The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

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- Venous anatomy unable to accommodate a 22 Fr size introducer sheath
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- RVOT unfavorable for good stent anchorage
- Severe RVOT obstruction, which cannot be dilated by balloon
- Obstruction of the central veins
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- Active endocarditis
- Known allergy to aspirin or heparin
- Pregnancy

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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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Preparing for Mitochondrial Research Studies

These kinds of studies are possible thanks to the cardiac tissue biobank on the CU Anschutz Medical Campus. This is an essential tool for pediatric researchers studying heart failure because they are not able to conduct many of the invasive studies researchers perform to study heart failure in adults, such as heart muscle biopsies. Once a child needs a heart transplant, the researchers get permission from the families to take part of the diseased heart for this biobank. The challenge with mitochondrial studies like the one Drs. Miyamoto and Garcia have been working on is timing.

"These mitochondrial studies have to be done in the moment, because once you freeze the mitochondria, they burst and they aren't going to function anymore," Dr. Miyamoto says. "Some of these studies need to be done in the middle of the night or the middle of the week. If it's Christmas Day, it's done on Christmas Day."

Once the team is notified that a heart transplant is taking place, they spring into action to complete their mitochondrial studies immediately, they then freeze the rest of the heart tissue to study later.

"That freezes that piece of tissue in time. So, it preserves things like enzymes, proteins and genes so we can go back and look later," Dr. Miyamoto says.

Mitochondrial Function as a Therapeutic Target

With this understanding of the mitochondria's role in heart failure for single ventricle patients, Drs. Miyamoto and Garcia and their team have turned to studying different, promising therapeutic options that target the mitochondria's function.

"This is highly impactful, because there are now drugs that target the mitochondria," Dr. Miyamoto explains. "If this is one of the reasons the heart is failing, then there are therapies that can target that mitochondria and hopefully help the mitochondria function better."

Along with their collaborator, Denver Health's Head of Cardiology Brian Stauffer, MD, Drs. Miyamoto, Garcia and Chatfield have performed investigations to investigate the drug elamipretide (which is not yet FDA approved for any indication in the U.S.) as a helpful option to improve mitochondrial function in a failing heart. In addition to this drug, Dr. Miyamoto's current R01 grant is looking into a drug called sildenafil, which could also improve mitochondrial function in this population.

"We need to think about different targets of therapy and identifying different drugs that work in our [pediatric] population and not just assume that all these drugs that are great for adults with heart failure are going to help children," Dr. Miyamoto says.

The location of Children's Colorado on a major medical campus with researchers studying the entire lifespan on all corners of campus offers a unique opportunity for collaboration. Dr. Miyamoto says all this work would not be possible without the valuable collaboration with adult cardiology colleagues on the CU Anschutz Medical Campus who started this group with her back in 2007: Kika Sucharov, PhD, a molecular biologist and Dr. Stauffer. Dr. Chatfield is also on the pediatric team as one of Dr. Miyamoto's mentees, and she is an expert in cardiac genetics and mitochondrial function, who plays a key role in bringing these research studies to life. She has also been essential to the team's research on the drug elamipretide and mitochondrial function over the years.

Advancing Heart Disease Research

Pediatric cardiologist Dr. Nakano collaborates closely with Drs. Miyamoto and Garcia and is continuing to push this research forward with a $2.4 million award from the Department of Defense (DOD) to study a specific kind of single ventricle heart disease, hypoplastic left heart syndrome (HLHS). HLHS is a condition where the left side of the heart is underdeveloped and nonfunctional. This study generates heart muscle cells from circulating white blood cells in HLHS patients, known as human-induced pluripotent stem cell-derived cardiomyocytes.

Dr. Nakano will explore three different areas with the DOD's Investigator-Initiated Research Award funding. The first area is focused on better understanding the changes in HLHS heart muscle cells that predispose them to failure, which could ultimately help delay or erase the need for a heart transplant. Next, the study will investigate the effects of having low oxygen levels for an extended period of time, as many single ventricle patients are exposed to low oxygen for the first years of their life. The third part of this research will test various drug therapies by screening thousands of potential compounds to see if any improve heart muscle cell contraction.

Over the years, these Heart Institute doctors have shifted their work together from a mentor-mentee relationship to now researching side-by-side to advance this research.

"They are brilliant scientists," Dr. Miyamoto says about her colleagues. "I get more joy, and I'm more proud of the success they have than my own success. It just feels so much bigger to me." Their collaborative efforts are accelerating our understanding of why and how these young hearts fail for the smallest patients.

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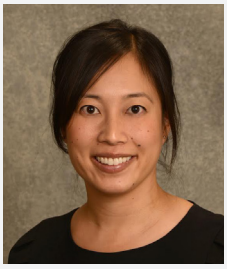

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Another Matter of the Heart and Mind

Neil Wilson, MBBS, DCH, FRCPCH, FSCAI

Apologies for the pretentiousness in my previous effort in these pages. I've given up on Latin. As the saying goes: "Pretentious? Moi? I come out with it every blue moon thanks to Mr. Elias, my first Latin teacher. My mother, in a misguided effort to encourage my enthusiasm at school, persuaded me that knowledge of Latin would be essential in my eleven years of age ambition to be a doctor. Don't worry, no Doogie Howser here. Besides, Doogie was ten when he entered medical school. But Ne Gloriemur Ne Blateremus have endured. No boasting no bull***t. See nightmare sessions. Thank you, Mr Elias.

Let's go to Denver. About eight years ago. Johnson was eleven and from out of state, Nebraska. He had Tetralogy anatomy, had a repair in the first year of life, and subsequent reoperation with a homograft to the right ventricular outflow tract at age six. A good candidate for revalvulation, an ugly but perfectly valid term coined by our Belgian colleague Marc Gewillig (he knows a bit about percutaneous pulmonary valve implantation). I had done some in Great Ormond Street in the Bonhoeffer era, in Oxford and indeed beyond. The technology was catching on in the US (at last). This looked straightforward. A couple of disclosures; moderate calcium deposition in the homograft, much as expected. The coronaries looked remote. We were trying to develop some sort of algorithm regarding risks of coronary compression but right then we were still very much accumulating data. And… cut to the UK some years previously. I, in particular, was twitchy about coronary compression after a very scary procedure at Great Ormond Street with a Melody Valve implant in a similarly aged patient. Slightly more complicated anatomy as it was in a patient with 'congenitally corrected transposition' who had undergone a Rastelli type repair and had subsequently developed pulmonary homograft dysfunction. The valve implantation went technically very smoothly, rapidly followed by profound ST segment changes and severe hypotension. The left anterior descending coronary artery disappeared. After about thirty seconds of discombobulation… short story - chest compressions flattened the valve stent, the left coronary reappeared in its entirety and Victor Tsang was the saviour in the OR and everything was happy ever after thanks to Victor and his team. Especially poignant to me was that this was a family who had 'followed' me from Glasgow, where I'd previously worked and where I had stented the homograft. They had trusted me to take good care of their daughter. Sheesh…that hurt. To their credit we are still on Christmas card terms today. I think I won myself a presentation in a Nightmare Case session with that case. Ne Gloriemur Ne Blateremus.

Back to Johnson, the anatomy and physiology were in great shape for a percutaneous valve. The day before the procedure I was sitting with Johnson and Mom and Dad, describing the procedure and discussing, as I would say "The risks and imponderables" associated with it. Imponderables? What do I mean? I guess an imponderable is a problem/outcome we hadn't yet come across. Read on dear reader… Mom and Johnson listened intently. Dad, much to my disappointment and suppressed indignation was preoccupied with a game on his phone. I did politely bring him into the discussion. The phone disappeared and the consent agreement was completed. Day of the procedure. He was first case, it went like a dream, coronary challenge with an 18mm high pressure balloon in the outflow tract, the coronaries were 'miles away' and unequivocally unaffected. There was certainly some disruption / fracture of the homograft. Angiography: no mediastinal leaks. Valve on an 18mm balloon slides in and deploys nicely. RV pressure 35mmHg, maybe 10-12 mmHg gradient. Angio negligible regurgitation. Almost all of the procedure was performed by the senior fellow. Fluoro time 23 minutes. Commendable. Pat on the back. Overnight observations and predischarge X Ray, Echo and EKG look perfect. Back to Nebraska. We're all happy.

Three weeks later. It's early Friday morning. I'm finishing off a bowl of legendary Wilson overnight oatmeal enjoyed also by The Pengster, the surgical senior fellow who lives 300 yards away. We car share and put the World to rights in the 20 minutes it takes to get to the hospital. We walk on to CICU where I am met by one of the CICU fellows. "We admitted one of your valves with chest pain last night." It is Johnson… He's sitting in his room, no mom or dad, an aunt I learn later is at his side. He looks pretty good if a little scared but hell, he's eleven and his mom and dad are not with him. I didn't think to ask. I'm met with, "He's had chest pain since Wednesday evening, EKG no change, Troponin normal, chest X Ray normal, echo no change since discharge, no hints of poor function, CT scan no mediastinal concerns, no effusions, nothing to suggest pulmonary emboli." I am told, much to my irritation, "He needs an angiogram to check his coronaries." I mumble politely. We do the CICU round in the usual clockwise direction. Johnson is in the last room. Nobody has any new ideas, I feel the pressure to shoot his coronaries but resist. I say, "I'll come back." We move on to the floor and complete the round, picking up a cup of coffee and a slice of zucchini bread on the way to the surgical conference. The zucchini bread is for Jim Jaggers. Surgeons rarely eat breakfast. I can't quite focus on the cases. I'm still thinking about Johnson. So much so that I let my usual idiosyncratic insistence to correct clumsy English grammar from the presenting fellows ('Off of the ventilator', 'to be honest' 'over exaggerated' 'literally…') pass me by. I feel the disappointed sharp intakes of breath from my loyal colleagues Gareth Morgan and Michael Ross who think I've missed a trick. Thanks team.

Back to CICU, Johnson is sitting up, monitored, playing something on his phone. 'Grand theft auto?' I wouldn't know. After a short chat, no trauma to the chest, no pain anywhere else, breathing is comfortable. Groin wound looks great and I move to examine his chest. He adopts a protective flinch and utters a mini cry of pain as my hand approaches his precordium but doesn't actually touch. Is that a clue? I distract him with some chat about The Cornhuskers, (I still have a Cornhuskers sweatshirt gifted to me many years ago by our own John Cheatham), by which time I am pressing quite hard on his chest and there is clearly no discomfort. Auscultation heart and lungs appropriate. I am stumped. The lady sitting by his bed is his aunt. Her perception is that I am going to catheterise him and check the coronaries. I explain why I don't think that is necessary and Johnson and she look relieved about that. "I'm still thinking, enjoy some breakfast Johnson" I say and move to leave the room. The aunt follows me outside into the CICU corridor. She wants to talk… 'Doctor…I have to tell you, Johnson's dad was shot in the chest in the family home and died in the hospital on Wednesday."

Johnson's monitoring came off and at lunchtime he was transferred to the floor where he stayed the weekend. I never did catheterise him. I saw him a month later, all good from my side. His heart will take much longer to recover without his dad.

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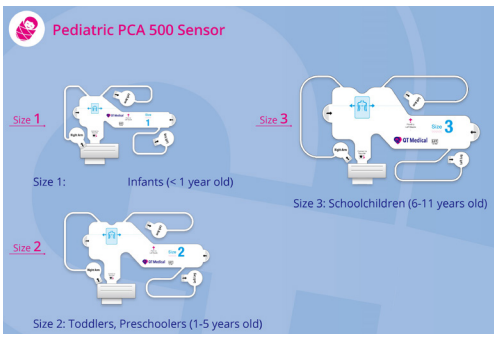
PCA 500 from QT Medical is the Only 12-Lead ECG Optimized for Pediatric Use

Ruey-Kang Chang, MD, MPH

Electrocardiogram (ECG or EKG) is the most frequently used test in cardiology practice beyond the initial auscultation using a stethoscope. The standards for 12-lead resting ECG use in clinical practice were established by the American Heart Association in 1954.[1] Over the past 70 years, not only has the way how an ECG test is performed not significantly changed, but the ECG machines and the technologies have also remained relatively the same.[2]

Performing an ECG test on a pediatric patient, especially an infant, can be quite difficult. There were no ECG machines or leadwire cables designed for use on babies. The operator, an ECG technician or a bedside nurse, often have to cut the electrodes smaller to fit on the body of a baby. Doing an ECG on a baby could be a three-person operation—one person to hold the baby's arms, the second person to hold the legs, and the third person to place the electrodes. Placing the electrodes on an uncooperative baby proves to be challenging, and more manipulation of the baby is only met with more kicking and crying, leading to discomfort and distress.

Now there is a 12-lead ECG system designed and optimized for pediatric use—the PCA 500 by QT Medical.



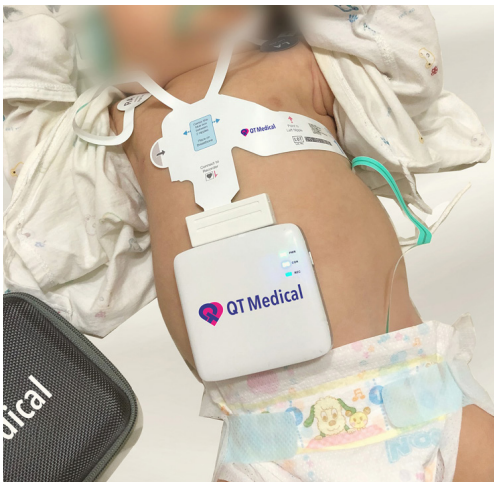
The PCA 500 was designed by a pediatric cardiologist, Dr. Ruey-Kang Chang. In his 25 years of practice, Dr. Chang has seen the significant challenges and struggles associated with getting ECG electrodes properly placed on pediatric patients. With grant funding from the National Institutes of Health (NIH), Dr. Chang's team developed a baby-friendly 12-lead ECG technology and conducted a clinical trial of 2,582 babies screening for long QT syndrome.[3] Dr. Chang founded QT Medical to commercialize this ECG platform. In a study comparing PCA 500 with Philips's flagship ECG Pagewriter TC70, it was shown that the prepositioned electrodes produced ECGs equivalent to ECGs recorded by conventional, individual electrodes when judged by three blinded cardiologists.[4] In 2022, the PCA 500 received FDA clearance for use on patients of all ages, including infants, and children.

This revolutionary product offers a digital, wireless, mobile-friendly, and cloud-based ECG management solution. With its single-use pre-positioned sensor and compact recorder, the PCA 500 is cleared by the FDA for use by both healthcare professionals and laypeople (patients or parents). Since its market launch, the PCA 500 has been widely used by: hospitals, physician offices, airlines, telehealth practices, clinics, skilled nursing facilities, and in clinical trials and schools for ECG screening of student athletes for risks associated with sudden cardiac arrest.

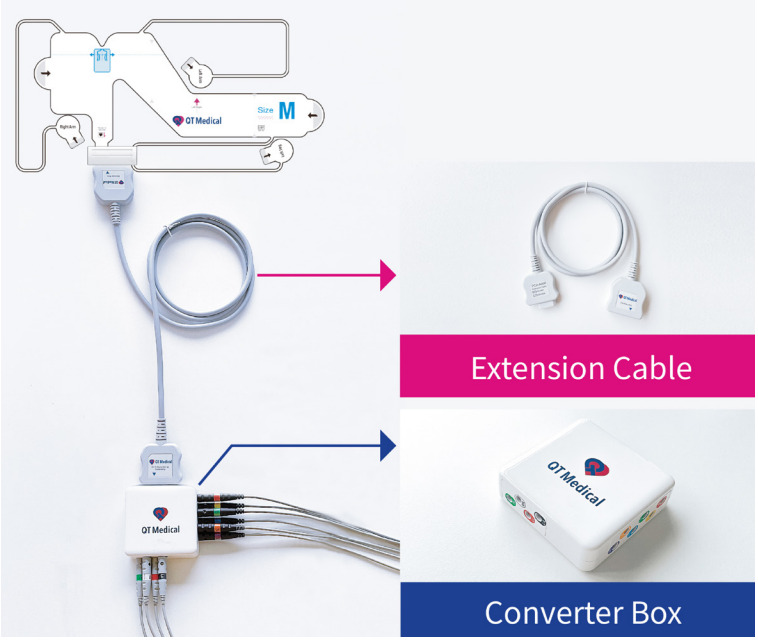
The single-use pre-positioned and preconnected electrode sensors offer many advantages. Because of its efficiency, accuracy, consistency, and lower risk of disease transmission, PCA 500 sensors can greatly streamline workflow, decrease the need for personnel training, and lower the overhead costs. The electrode sensors are available in three sizes for pediatrics—Size one for one for one-month-old to 12-months-old, Size two for ages one to five years, and Size three for ages six to 11 years. Children 12 years and older can utilize adult sensors, which are available in four sizes (S, M, L, XL).

The apparent advantages of the patented PCA 500 sensors are:

- ***Efficiency*** The proper placement of electrodes can require a significant amount of time. Then, the untangling of the leadwires and matching to each of the electrodes is cumbersome and requires additional time and patient interface. Using the PCA 500 electrode sensors eliminates the steps of matching and connecting the leadwires with electrodes and reduces the electrode placement process from 20 steps to four steps (sensor strip placement on the chest plus pulling out three limb electrodes). The electrode placement time can be reduced by over 70% using the PCA 500 sensor.
- ***Accuracy*** The sensor eliminates opportunities for lead placement errors. With its elongated asymmetric design and limb leads located in the proximity of the destined placement sites, the chance for limb leads reversals and chest leads misplacements are virtually eliminated. In fact, it would be almost impossible to reverse the limb leads or not place V1-V6 in the ordered sequence as the sensor itself would not accommodate for this placement.
- ***Consistency*** The electrode placements on the same patient will be consistent across different tests at different visits. Consistent leads placement is important in detecting early and subtle changes in the ECG.
- ***Lower Risk for Disease Transmission*** Eliminating cables, wires, and making the electrode sensor single use also helps to reduce the risk of disease transmission via ECG hardware. Previous studies have shown that ECG cables can be a source of infection outbreaks in the hospital.
- ***Minimal Training is Needed*** The PCA 500 system enables people with minimal or no training to do a standard 12-lead ECG test. This device is cleared by the FDA for use by healthcare professionals and laypeople (patients). In a study of



over 2,500 babies, more than 94% of parents were able to complete an ECG test on their own babies with only written instructions. In a study of the first 1,000 patients using the home delivery ECG testing service (Xpress ECG™), 92.9% completed their tests with good quality ECGs, and the technical failure rate was less than 2%.



The PCA 500 system is so compact and user-friendly that it can be mailed to patients for at-home ECG testing. In a study of the first 1,000 patients who used PCA 500 for at-home ECG testing, over 92% patients completed their ECG tests with a technical failure rate <2%.[5] When reviewing the results of 31 pediatric patients (mean age 13 years) who performed their own ECG tests at home, it was found that all patients had recordings suitable for clinical decision-making with 68% graded as 'excellent' 32% as 'good,'[6] 77% of patients found it 'easy' or 'extremely easy' to perform, and 80% were 'confident' or 'moderately confident' in the recording.

"We are extremely excited about the potential of the PCA 500 to improve heart health for millions of children. As a pediatric cardiologist, I know how difficult it is to get a 12-lead ECG on a child. With the PCA 500 technology, we can make ECG testing widely available and easily accessible to all children. We truly believe it will make a difference in many lives. This is the exact reason why I founded QT Medical," said Dr. Chang in an interview.

To introduce the PCA 500 to the pediatric market, QT Medical showcased its new products at the 8th World Congress of Pediatric Cardiology and Cardiac Surgery (WCPCCS) in Washington, DC, in August, 2023. It was met with very high levels of enthusiasm by nurses and cardiologists who are excited to adopt this new technology in multiple locations of care including ward and outpatient settings. Many clinicians are also planning to use the PCA 500 in telehealth practices, homecare, and for various other remote monitoring and screening applications.

QT Medical plans to announce two new initiatives at the American Academy of Pediatrics National Conference and Exhibition in October 2023. First, the Youth Xpress ECG™ screening service, in partnership with Who We Play For, a 501© organization, dedicated to preventing sudden cardiac arrest of athletes. Youth Xpress ECG is a mail delivery 12-lead ECG testing service for children aged 12-18 years old who participate in sports. The ECG results will be interpreted by expert pediatric cardiologists. Second, is the Baby Xpress ECG™, an at-home ECG screening service for infants with increased risks for long QT syndrome. In the Baby Xpress ECG service, when a baby with a prolonged QT interval is identified on the ECG, a genetic test kit will be used for collecting the baby's saliva to check for genetic mutations known for causing long QT syndrome. Long QT syndrome, occurring in one in every 2000 babies, is a known cause for sudden death (including SIDS).

QT Medical is making the patented pre-positioned ECG sensors available for use by ECG machines made by other manufacturers. The ECG sensors, called QHeart™ sensors, can be used with existing ECG machines through a cable connection (available for GE and Philips ECG machines) or a converter box (which receives banana plug inputs from the majority of existing ECG devices currently in use globally). The QHeart™ sensors can offer the same advantages of efficiency, accuracy, and consistency regardless of the ECG machine that is being used to conduct the test. QHeart™ sensors will make performing an ECG test using any ECG machines much faster, easier, and with superior signal quality.

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The Employee Retention Credit: Advancing Patient Care & Financial Wellness

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Why Read About Tax Credits?

Tax law topics are not commonly highlighted in the pages of medical journals. Even less common are those concerning payroll tax credits. While most cardiologists do not delight in the intricacies of tax law, and while they might (rightly) expect such discussion to be complex and even tedious, consideration must be given to the Employee Retention Credit. This credit has proven a powerful tool for employers in healthcare, resulting in significant refunds that practices, hospitals, and other organizations may use at their discretion. These refunds have finally resourced providers to show tangible appreciation to the staff who worked tirelessly during the pandemic, to retain and recruit critical team members, to improve the technology and facilities by which they care for their patients, and in some cases, to maintain their practice during even more difficult financial times than during the COVID-19 pandemic itself. The opportunity to claim both the 2020 & 2021 Employee Retention Credits expires April 15th, 2024. While the ability to claim 2021 credits will extend into 2025, those who have not yet considered the credit should do so urgently.

What is the Employee Retention Credit?

The Employee Retention Credit (ERC) is a refundable tax credit of up to $26,000 per employee, developed by Congress in March 2020 as part of the CARES Act.[1] At the time, our nation was experiencing the first weeks of a global pandemic, and fears of an unprecedented unemployment crisis loomed. Congress released ERC alongside the Paycheck Protection Program (PPP) to support employers in keeping employees on payroll. The credit has suffered from much misunderstanding and difficulty in administration, both of which have deterred many eligible organizations from benefiting from the credit.

What is the Employee Retention Credit? The Nitty-Gritty…

The Employee Retention Credit is a return of wages paid during the COVID pandemic and is worth up to $26,000 per employee for qualifying organizations. While this article focuses on the medical field, ERC is not limited to any specific industry or specialty. Many non-profit employers may be eligible for ERC, along with those in home care, hospitality, entertainment & recreation, manufacturing, and a host of other industries. Unlike PPP, however, ERC is not a loan. ERC is a credit paid to a qualifying organization as a refund check, to be used at the discretion of its owner(s).

ERC is available from March 13th, 2020 through September 30th, 2021 for organizations that were in operation before the pandemic. Organizations that began operations after February 15th, 2020, may have extended eligibility through December 31st, 2021.

Who Can Claim the Employee Retention Credit?

An organization must be an "eligible employer" to qualify for ERC. An "eligible employer" is an employer who was carrying on a trade or business during the COVID pandemic, and who also passes at least one of three tests. The first two tests apply to organizations in operation before the pandemic. These tests look for a significant decline in gross receipts or a more-than-nominal impact on operations due to government mandates. Both tests must be considered to ensure appropriate due diligence, resulting in the maximum potential credit.

Test #1 – Decline in Gross Receipts

The first test, the Decline in Gross Receipts Test, is an accounting question. This test looks at an organization's receipts quarterly during the pandemic and compares the receipts in each quarter with receipts in the same quarter in 2019.

- If the organization experienced a decline in gross receipts of at least 50% in a quarter in 2020 compared to the same quarter in 2019, the organization will be eligible for ERC in that quarter.
- If the organization experienced a decline in gross receipts of at least 20% in a quarter in 2021 compared to the same quarter in 2019, the organization will be eligible for ERC in that quarter.

For example, if an organization had $250,000 of gross receipts in 2019 Q1, and had $120,000 of gross receipts in 2020 Q1, the organization experienced more than a 50% decline in gross receipts in 2020 Q1 and is an eligible employer for this quarter. Similarly, if the organization had $199,000 of gross receipts in 2021 Q1, the organization experienced more than a 20% decline in gross receipts in 2021 Q1 compared to 2019 Q1 and is an eligible employer for this quarter.

While this test may seem straightforward, Congress included various adjustments to the commonly expected gross receipts definition, as well as a complicated "Alternate Quarter" rule. This rule extends eligibility to the quarter following an eligible quarter and can cause the 2021 20% decline threshold to apply to 2020 Q4 for purposes of determining eligibility for 2021 Q1. As a result, this first test is often misunderstood and commonly misapplied.

TABLE 1 *Example of Qualifying Decline in Gross Receipts*

YEAR	Q1 RECEIPTS	% CHANGE	RULE	ELIGIBLE?
2019	$ 250,000			
2020	$ 120,000	-52.00%	50% Decline in Revenue	Y
2021	$ 199,000	-20.40%	20% Decline in Revenue	Y

Test #2 – Government Mandate Test

The second test, the Government Mandate Test, is a test considering the facts and circumstances of an organization. This test looks for a more-than-nominal impact on operations due to COVID-19 government mandates limiting commerce, travel, or group meetings. Healthcare providers were subject to targeted mandates from more governing bodies than almost any other industry. As a result, healthcare providers are often very strong candidates for ERC.

Examples of operational impact on healthcare providers due to these mandates include the impact of quarantine requirements, increased cleaning and sanitation standards, capacity and social distancing restrictions, and the prohibition of group activities. The result of complying with these mandates was often an increase in the time required to provide care, increased work hours, reduction in the level of care provided, or complete elimination of certain procedures or types of services and care. All of these represent a decrease in a provider's ability to offer its services and care to its patients.

Properly determining eligibility under the Government Mandate Test depends on the answers to three questions:

- Who are the appropriate governing bodies?
- What operational changes did these governing bodies require due to COVID-19 and for what period?
- Was there a more-than-nominal impact on operations because of these government mandates?

These questions again seem straightforward on the surface, but quickly become involved on closer inspection. For example, it's often clear when Federal, State, County, and City governments have authority, but when might requirements other Federal or State authorities be applicable? A careful review of the language in these mandates is also critical. By nature, mandates include only language that conveys requirements (i.e. 'must', not 'should') and are relevant for ERC purposes only for the period during which they were effective.

Each one of these questions requires specific analysis beyond the scope of this article. It is clear, however, that the high volume of mandates issued during COVID-19 frequently had a significant impact on the ability of healthcare providers to provide care, interact with their patients and teams, and care for patients in the same amount of time required pre-pandemic.

All of the operational changes driven by government mandates aggregate as an organization evaluates whether it experienced a more-than-nominal impact on operations due to COVID-19 government mandates. (The phrase "more-than-nominal" or "more than a nominal" comes directly from IRS interpretive guidance of the CARES Act.) The specific dates during which an organization experienced a more-than-nominal impact on its operations due to COVID-19 government mandates are its dates of eligibility for ERC under this test.

Test #3 - Recovery Start-up Businesses

The third test applies only to an organization that began carrying on a trade or business after February 15, 2020. This type of organization is dubbed a "Recovery Start-up Business" or an RSB. RSBs have ERC eligibility in 2021 Q3 & Q4, regardless of either of the other two tests so long as its average annualized gross receipts do not exceed $1M in the taxable year ending before the quarter for which the credit is claimed.

What is ERC Worth?

Because the credit was designed to support employers in keeping employees on payroll during the COVID-19 pandemic, the credit is based on qualified wages paid during an organization's eligibility period and could be worth up to $26,000 per employee.

- 2020: 50% of qualified wages paid, up to $5,000 credit per employee per **year**.
- 2021: 70% of qualified wages, up to $7,000 credit per employee per **quarter**.

Practically speaking, an employee who is paid $10,000 of qualified wages during 2020 could maximize the 2020 credit, and an employee who is paid $10,000 of qualified wages during any quarter of 2021 could maximize the 2021 credit for that quarter.

This, however, raises the question: what are "qualified wages"? These are generally wages paid to employees (as determined by Medicare taxation) plus the cost of health insurance paid on behalf of each employee. Wages paid to majority owners and certain blood relatives will not be eligible for ERC, and careful consideration of PPP funds received and forgiven is also required. One of the many changes Congress made to ERC since its inception was to allow employers to claim both PPP and ERC. Employers who do so must ensure that they do not "double dip," that is, they are not permitted to consider wages paid with PPP dollars for ERC purposes.

Special Considerations

Like every tax credit, ERC has a variety of special considerations for certain organizations and unique rules for handling organizations with common ownership or control. For ERC purposes, organizations must measure their number of full-time employees (not full-time equivalent employees) to determine whether they are small or large employers. Large employers are those with more than 100 or 500 full-time employees in 2019 for 2020 and 2021, respectively. This classification carries great significance as it determines whether the organization may consider all wages paid to an employee as qualified wages (if a small employer), or if it may consider only wages paid to the employee while they were not providing services (if a large employer). Large employers should not be discouraged by the adjusted definition of their qualified wages – many large employers provided quarantine pay and other generous COVID leave benefits to their employees. Large employers regularly provided sufficient qualified wages to their employees to drive millions of dollars in ERC refunds.

Other situations that require specific tax technical analysis include organizations with common ownership or control, or those receiving specialized COVID-19 funding (such as Restaurant Revitalization Funds, or Shuttered Venue Funds). These facts do not make organizations ineligible for ERC – they simply require attention to the complexities of applicable tax codes that drive appropriate revenue measurements, employee counts, etc.

Red Flags

While ERC was intended to support employers as they navigated the challenges of the COVID-19 pandemic, quick and successive changes to the program and administrative challenges suppressed proper understanding and awareness of the credit. As a result, many potentially eligible organizations have not evaluated their eligibility, or have been inaccurately advised that they are not eligible.

In addition, organizations have struggled to identify trustworthy providers. Where confusion reigns, opportunity for fraud and bad actors abounds. ERC has been no exception. While confirming that ERC is a legitimate credit, the IRS has regularly warned organizations about the risks of working with ERC Mills to claim the credit. ERC Mills are unlicensed organizations that often produce unfounded ERC claims while frequently employing aggressive and even deceptive marketing techniques. The IRS has identified several key characteristics of these ERC Mills that are warning signs to their potential customers:

- Charging a % of the ERC refund
- Requiring payment in advance
- Requiring a signed agreement before disclosing the fee
- Preparer does not sign the amended returns
- No documentation for eligibility exists
- Self-qualifying questionnaires are required

The IRS has urged organizations to seek the advice of tax professionals[2] in evaluating their ERC eligibility, to avoid later being subject to penalties and interest on improper claims. Even so, organizations must move quickly to maximize their potential ERC refund. Due to the time limits for filing amended payroll tax returns, organizations have only until April 15th, 2024 to claim 2020 ERC credits, and until April 15th, 2025 to claim 2021 ERC credits.

Who Has Benefitted from ERC?

Healthcare providers are generally quite strong candidates for ERC, so examples of solo practices, multi-location practices, surgical centers and hospitals that have benefited from the credit are numerous. A favorite example is that of a physician leading a multi-site group of practices in the Southeast. This physician employed almost three hundred people before the pandemic. During the pandemic, he was forced to cease providing non-emergent care to patients. Once allowed to resume, the number of patients the practice could see in a week dropped significantly. Fewer patients were allowed to be in the building at one time as social distancing and capacity limitations required reductions in waiting room occupancy. It took longer for patients to complete a health screening before entry, to arrive in the practice once called in from waiting in the parking lot, and then for staff to spend additional time sanitizing in between patients. These operating changes drove a more than nominal impact on the practice's ability to provide care. Overall eligibility for ERC resulted in over $3,800,000 of refunds, all paid to the practice via checks from the IRS.

Another practice with multiple physicians had a similar experience. The constraints of their physical space, combined with capacity restrictions, caused them to only have three patients in the office at any one time, compared to 10 or 12 patients before the pandemic. This significant decline in capacity severely reduced their ability to provide care. In addition, gathering restrictions prohibited their physicians from attending certain critical continuing education events that were unique to their specialty. No replacement for these trainings was available. The lack of training prevented their physicians from completing scheduled training which would have allowed the practice to have uninterrupted staffing for specialized procedures. The restrictions on scheduled training disrupted the practice's ability to provide these procedures. As a result, based on wages paid to 27 employees, the practice was eligible for over $558,000 of ERC, all of which was available for use at the practice's discretion.

A third practice experienced similar restrictions to those mentioned above but responded differently. Capacity and social distancing restrictions reduced their ability to see patients. Additional sanitation took more time during a standard shift. This practice, with six employees, adapted by increasing shift length, adding appointment hours, and increasing their time investment to meet the needs of their patients. As a result, gross receipts did not generally decline. Rather, receipts increased somewhat as the cost of providing care increased. The practice paid more for labor and medical supplies, as well as costs to implement their patient health screening process and other operational adjustments. This practice, with only six employees, benefitted from over $118,000 of ERC, an amount that equipped the practice to reward the employees who worked so diligently to provide care throughout the COVID pandemic.

These are only a few examples of practices that have benefited from the Employee Retention Credit. While many similarities exist among practices, hospitals, and centers in healthcare, each organization has its own set of facts and circumstances that must be individually analyzed in the context of the mandates under which it operated.

Taking Action: Unlocking the Potential of the Employee Retention Credit

Healthcare organizations, regardless of size, specialty, or location, should seriously consider exploring their eligibility for the Employee Retention Credit. Even if you have already assessed your eligibility, a second look will reveal eligibility not yet seized, present an opportunity to safeguard against compliance risk, or provide comfort that your prior claim was both accurate and maximized. Physicians and surgeons, particularly those within larger healthcare organizations, can play a pivotal role by encouraging their finance teams to reach out to a tax professional to claim the credit. They can also have significant impact on their community as they raise awareness with nonprofit organizations, or for-profit businesses of friends and family, whether in healthcare or another industry.

As demonstrated earlier, substantial refunds await those who qualify based on a significant decline in gross receipts or operational impact due to government mandates. While navigating the ERC's complexities demands due diligence and substantiation, the rewards can be transformational.

The deadline to claim 2020 ERC credits is fast approaching, so time is of the essence. Reach out to tax professionals equipped with the necessary accounting and legal expertise to accurately assess your eligibility. Strategic Tax Planning, a licensed CPA firm, specializes in tax credits requiring this unique expertise. Our team of CPAs, Juris Doctorates, and other professionals excels at navigating the ERC's intricate requirements. We have helped thousands of employers across the nation, including entities owned outside of the United States.

We regularly uncover additional eligibility opportunities when reviewing prior ERC claims and we are pleased to offer a complimentary analysis—whether a first or second look—of your practice's ERC eligibility. To discuss ERC or request an estimate, please contact either author or visit https://info.smartertaxplanning.com/congenitalcardiologytoday.

The information above does not constitute tax or legal advice. Please seek the help of a tax professional experienced in the specific technical requirements of the Employee Retention Credit as they apply to your particular facts and circumstances.

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Announcing the PICS Early Career Development Academy

OVERVIEW OF THE ACADEMY

The PICS Early Career Development Academy will advance professional development of early career pediatric/congenital interventional cardiologists globally. The Academy is an innovative global two-year program blending mentor supervision and team-based learning. This new program meets a need expressed by training directors for such a program following completion of formal training programs (or equivalent according to local training pathways and board committee evaluation).

WHO SHOULD APPLY?

If you trained as a pediatric/congenital interventional cardiologist and completed formal training within the past 5 years, this program has been designed for you.

HOW IS THE ACADEMY STRUCTURED?

- Hybrid program: online & in-person
- Didactic instruction plus team activities
- 25 early career physicians to be selected
- 70 faculty from centers worldwide
- 5 teams: 5 participants and 1 mentor per team. Participants from around the globe
- Program Directors: Drs. Gianfranco Butera & Aimee Armstrong
- Each team will be assigned a 2-year research project
- Mentors: Drs. Lee Benson, Mario Carminati, John Cheatham, Ziyad Hijazi, & Sir Shakeel Qureshi
- Two challenges: interim review paper & final case presentation
- Winning team declared at end; recognition of all participating early career physicians

Didactic content will cover clinical topics, resilience during difficult situations, team building, medical reasoning, research methodology, industry relationships and much more.

APPLY TODAY: at CHDinterventions.org or email, info@CHDinterventions.org

PICS Society

ACHA Announces 2023 Research Grants

With the latest round of Adult Congenital Heart Association (ACHA) research grants, announced at our Virtual Research Symposium on September 23, 2023, we have now invested more than $500,000 over the past four years to fund 18 research investigations specifically focused on adult congenital heart disease (ACHD).

Since the launch of our emerging research program in 2019, ACHA has been the only national patient advocacy organization focusing solely on ACHD research. Through the research grants funded, we emphasize the importance of partnership between patients, their families and the medical field.

"Research is one of the noblest duties of the modern physician and provides the impetus to change the practice of medicine," said ACHA Medical Advisory Board Chair Richard Krasuski, MD. "We have come so far in the field of ACHD based on the prior efforts of researchers. Success in this area requires creative thoughts, flexibility and perseverance. It also requires a source of funding. That is why I am so proud of ACHA, our ACHD community, and most importantly our donors for supporting these research projects."

All research grant awardees were chosen through our double-blind process with two teams of reviewers—one comprised of Medical Advisory Board members, including ACHD cardiologists, nurse practitioners and nurses, and the other of patients and family members across the country, including peer mentors, board members, fundraisers, and more.

"We are thankful for the generosity of our research donors who allowed us to launch our research initiative and fund 18 investigations over the past four years," said ACHA President/CEO Mark Roeder. "We are proud to be the only national patient advocacy organization solely dedicated to funding ACHD studies. **And we are also proud that our review process includes both patient and medical reviewers to ensure that the patient voice is included in all our research funding decisions."**

Dr. Krasuski reports that the two teams of reviewers received several interesting research proposals covering a variety of topics this year, which were critically reviewed according to scientific merit and relevance to the ACHD population. Scoring included areas such as significance and innovation, approach and methodology, and investigator track record and qualifications.

The following one-year ACHD early investigator grants will begin in October 2023:

- In Silico Evaluation of a Dual-Impeller Single-Drive Fontan Circulation Assist Device, Christopher Broda, MD, Adult Congenital Heart Disease Program at Texas Children's Hospital/Baylor College of Medicine; and co-investigators Yaxin Wang, PhD, and Katharine Fraser, MPhys, PhD
- Leveraging Wearable Technologies for Arrhythmia Detection in Adults with Congenital Heart Disease – The ACHD Apple Watch Study, Brynn Connor, MD, ACHD Fellow, ACHD Program at Stanford University and Scott Ceresnak, MD, Director of Pediatric Electrophysiology, Stanford University

In addition to the two traditional research grants, the brand new Pulmonary Vascular Disease Award, funded in part by Janssen Pharmaceutical Companies of Johnson & Johnson, will also begin in October 2023. This grant was awarded to:

- Investigating the Genes Involved in Pulmonary Arterial Hypertension in Congenital Heart Disease, Kali Hopkins, MD, Adult Congenital Heart Disease Fellow with the ACHD Program at Mount Sinai and Maria Giovanna Trivieri, MD, PhD, Director of the Pulmonary Hypertension Program at Icahn School of Medicine at Mount Sinai

Finally, the Meil Family Foundation Research Award for Neurocognitive Studies was awarded to Adam R. Cassidy, PhD, LP, ABPP (Mayo Clinic), and Michelle Gurvitz, MD, MS (Boston Children's Hospital/Brigham and Women's Hospital). ACHA will work with Drs. Cassidy and Gurvitz, along with leading experts from the Cardiac Neurodevelopmental Outcome Collaborative (CNOC), ACHD providers, patients, and family members, to convene a conference in early 2024. The goals of this conference will be to identify critical gaps in knowledge; to propose an agenda for the next decade of neuropsychological, neurocognitive, psychosocial research focusing on adults with CHD; and to develop recommendations for the neuropsychological and psychosocial evaluation and management of adults with CHD. **This will be the first conference of its kind to identify research and clinical priorities to optimize neuropsychological and psychosocial outcomes for adults with CHD.**

"With the core of ACHA's program in traditional research grant funding, as well as the continual additions of new focus areas for ACHD research as the program grows, we look forward to the results and impact of our current funded studies—and with the support of the entire ACHD community, we can't wait to see where the future takes us," said Roeder. "A special thanks goes to the Meil Family Foundation for allowing us to continue to increase our research focus on neurodevelopmental issues, and to Janssen Pharmaceutical Companies of Johnson & Johnson for expanding its longstanding partnership with ACHA by adding research to the list of mission activities they support for the ACHD community."

ACHA would also like to thank the following donors for their contributions in support of our Research Fund: Anne Stapleton Reilly, Brad's Heart of a Jayhawk Research Fund, the Dale Amorosia Heart Fund, Diana J. Kalman, Janssen Pharmaceutical Companies of Johnson & Johnson, the Jim Wong Memorial Fund, Laurie Rae Graham Bennett, the Meil Family Foundation, the Robby Klaber Research Fund, Susan Timmins, and Ted and Donna Wagner.

To learn more about ACHA's research program and research projects, as well as how to contribute to the ACHA Research Fund, https://www.achaheart.org/your-heart/programs/research/.

ACHA is the only nonprofit in the country dedicated solely to the unique needs of nearly two million adults born with heart defects, the most common birth defect in the United States, diagnosed in one in 100 births. These adults are living longer today with one of the many varying types of congenital heart defects that range among simple, moderate, and complex—which was not a reality 20 years ago.

NOVEMBER

10TH-11TH

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15TH-17TH

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22ND-23RD

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07TH-09TH

UF International Aortic Symposium
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08TH-09TH

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FEBRUARY

22ND-24TH

Innovations in Heart Valve Reconstruction: A Master Class - 8th Annual Advances in Congenital Heart Disease Summit
Lake Buena Vista, Florida, USA
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