## CONGENITAL CARDIOLOGY TODAY

Timely News & Information for Congenital/Structural Cardiologists & Cardiothoracic Surgeons Worldwide

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# **Exploring Resilience in Adult Congenital Heart Disease**

Jill M. Steiner, MD, MS; J. Randall Curtis, MD, MPH; Abby R. Rosenberg, MD, MS, MA

Major medical and surgical treatment successes in Congenital Heart Disease have increased life expectancy and, in some populations, decreased the physical impacts of the underlying disease. Yet patients with Adult Congenital Heart Disease (ACHD) live daily with a lifelong chronic illness. Emotional and psychosocial impacts of this illness are known to adversely affect quality of life. Contributing factors include physical and cognitive limitations, altered familial and social relationships, prognostic uncertainty, and the presence of mood and anxiety disorders. <sup>1-3</sup> Patients report feeling inadequately equipped to effectively cope with their illness, navigate healthcare decisions, and plan for the possibility of early mortality. <sup>4.5</sup>

Early in the history of ACHD clinical care, clinicians and researchers focused on physical health problems in order to improve longevity and decrease physical morbidity. Now that we have made progress in addressing these physical health needs, it is time to address the high prevalence of emotional distress and other mental health issues in this patient group.

# Tools to Address the Emotional Wellbeing of Patients with ACHD: Resilience, Sense of Coherence, and Palliative Care

In the moment, life's challenges can be stressful and initially perceived as negative experiences. However, such experiences may provide opportunity for people to evaluate their perspectives and learn over time. This includes managing a chronic illness like ACHD. Resilience is the process of harnessing personal resources to sustain physical and emotional well-being in the face of stress.<sup>6,7</sup> While some level of resilience is generally innately present, resilience can be developed and strengthened, through experience or targeted intervention.<sup>8,9</sup> Indeed, several "resilience resources" have been associated with improved quality of life among patients with chronic diseases. These tend to fall into three reproducible categories: internal characteristics (i.e., stress-management skills), external characteristics (i.e., social supports), and existential characteristics (i.e., spirituality or meaning-making skills).<sup>6,10</sup> Different resources work better for different people in different situations, such as whether someone prefers to use internal skills in stress management versus external reliance on family support or versus existential processes of meaning making.

An overlapping but distinct concept from resilience is sense of coherence (SOC). In the 1980s, Antonovsky described his salutogenic theory, which involved focusing on resources and capacities rather than disease. <sup>11</sup> SOC is a major component of this theory, the idea that people can develop internal and external resources and experience life events that allow them to better cope with stress. In turn, they may have better quality of life and clinical outcomes. In this manner, SOC seems to be one of the key personal resources for fostering resilience among patients with serious illness. <sup>12-14</sup>

People with a strong SOC perceive the world as comprehensible, manageable, and meaningful. In 2006, Moons et al proposed SOC as a pathway to improving quality of life in ACHD.<sup>15</sup> They provided examples of how parents and clinicians can help patients with ACHD develop SOC. Education about their heart condition could alleviate uncertainty and enhance comprehensibility; provision of support from the challenges of living with ACHD could create manageability through balance

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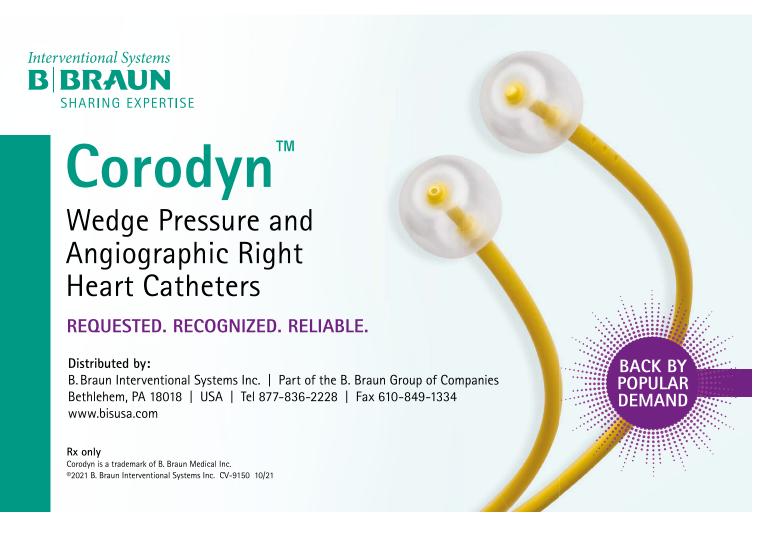
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#### **EXPLORING RESILIENCE IN ADULT CONGENITAL HEART DISEASE**



between stressors and perceived resources; and including the patient in decisions about their care and addressing existential issues could help life make sense, fostering meaningfulness.

Other studies of SOC in ACHD have shown that SOC is positively associated with perceived physical and psychosocial health and quality of life, and that degree of personal control is a major determinant in developing SOC. 14,16 In some ACHD studies, increased SOC has been associated with increased age, education, and employment, as well as partnered status, better heart failure functional class, and higher ACHD severity. SOC is thought to be a universal concept, but intercountry variability in SOC has been described, characterized at least partially by degree of cultural individualism.<sup>17</sup>

Encompassing both the broader process of resilience and specific individual resources like SOC is the practice of palliative care. The goal of palliative care is to alleviate suffering and improve quality of life for patients with serious illness and their families. 18,19 As resilience and SOC can both help achieve this goal, both have been adopted as targets for palliative care intervention and support. However, while the idea has been raised that promoting resilience may have promise in ACHD, to our knowledge, it has not yet been widely studied in this population. In adolescents<sup>20</sup> and adults<sup>21</sup> with CHD, pilot interventions targeting psychological distress and resilience have been found to be feasible, however no single intervention has been proven effective. In addition, these programs were delivered in group format, which may be undesirable for patients who are less comfortable sharing personal information. There are not studies defining the relationships between resilience and key psychosocial outcomes in ACHD that might explain how best to approach these issues. We therefore proposed to evaluate in further depth the concept of resilience in ACHD, including the application of a proven, one-on-one resilience intervention.

#### **PRISM**

The Promoting Resilience in Stress Management, or PRISM, intervention is built on the foundations of Resilience and Stress-and-Coping Theories.<sup>22</sup> The latter posits that personal appraisals of stress influence emotional, physical, and functional outcomes. PRISM's overarching hypothesis is that resilience works similarly: if someone believes they have the resources to be resilient, perhaps they will experience better health and psychosocial outcomes. Thus, PRISM was designed as a reproducible, skills-based training program that teaches common resilience resources endorsed by adolescents and young adults with serious illness and caregivers of patients with serious illness: skills in stress-management, goal-setting, positive reframing, and meaning-making.

PRISM was created using the ORBIT model for translating behavioral and social science theory to health-related interventions. 23,24 It was initially developed by and for adolescents and young adults with cancer,9 and in efficacy studies found to improve resilience, hope, psychological distress, and quality of life compared to usual care. It was iteratively adapted for patients with type 1 diabetes<sup>25</sup> and cystic fibrosis,<sup>26</sup> as well as parents of children with cancer.<sup>27</sup> Each adaptation process again followed ORBIT guidelines to hone intervention language, timing, and approach for use in different patient groups. Additionally, modules were added based on specific patient population needs. For example, a module on advance care planning, the process of considering future healthcare preferences

in the event the patient is unable to make their own decisions, was added at the request of patients with CF and advanced cancer.<sup>28</sup>

#### Evaluating and Building Resilience in ACHD

We had previously been studying palliative care in ACHD, with the stance that tailored palliative care interventions may address unmet psychosocial needs by both increasing sense of control and decreasing psychological distress. We found that patients were interested in participating in advance care planning and learning more about palliative care, however there were also a number of barriers to incorporating this into regular ACHD care, including not feeling sick enough to discuss care during serious illness and uncertainty about what their preferences might be if sicker.<sup>29</sup> In addition to systems-level issues, we identified several patientlevel factors. Specifically, patients were not sure how or when advance care planning would apply to them personally, and there seemed to be substantial concerns around lack of skills to cope with chronic illness and to manage uncertainty. 30,31 This led to the idea of exploring the role of resilience in addressing these concerns.

The foundation of PRISM is not disease specific, so we hypothesized that a tailored approach might be useful in ACHD, as it has been in other disease groups. One major difference is that our patients are slightly older and perhaps in a different stage of life than the young patients for which PRISM had been designed. At the same time, we recognized that some patients with ACHD have lower psychosocial maturity than their physical age due to the challenges they have faced, and we were encouraged by findings that PRISM was also impactful in parents of ill children.

With research funding from the Adult Congenital Heart Association, we began by interviewing patients with ACHD, asking about their ways of coping with heart-related stress and experiences with resilience. We also asked how they felt about a program like PRISM, specifically eliciting feedback on acceptability, appropriateness, and suggestions for revisions. We used purposive sampling to ensure a diverse group based on key characteristics, such as age, sex, race, ethnicity, and severity of ACHD. We then analyzed all interview transcripts using qualitative methods. Specifically, we developed a codebook and performed inductive coding to identify recurrent themes and the relationships among them in an iterative fashion. After 15 interviews, we noticed few to no new themes from patient interviews and thus concluded we had gathered adequately representative patient perspectives about PRISM. Currently, we are continuing interviews to more deeply explore the concepts of coping and resilience from the patient perspective; this second phase of analysis will help us determine if patients with ACHD would like additional components in their PRISM than the standard core modules.

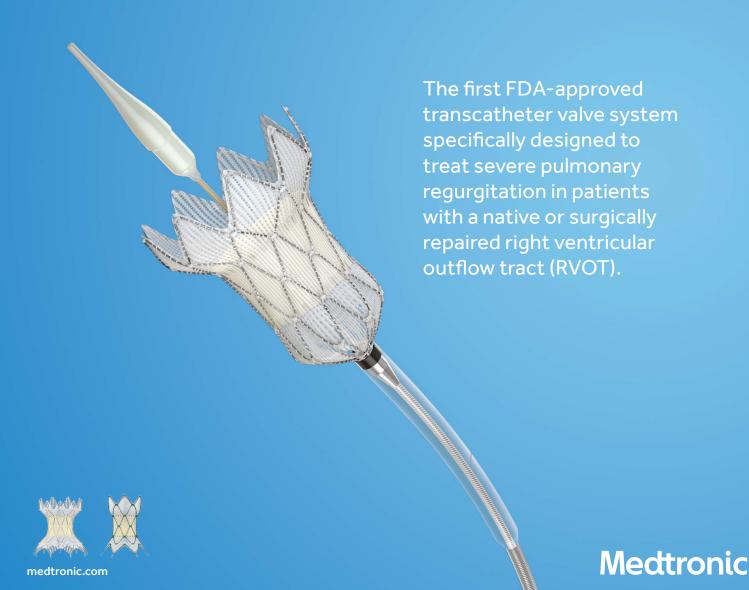
Interview participants were overwhelmingly interested in participating in PRISM or a program like it, if offered the opportunity. Some specifically asked us to contact them if the opportunity arose. Participants reported feeling that anyone with ACHD could benefit from participating (14/15 participants), and that people most likely to benefit may be younger adults who have yet to develop similar life-skills (6/15), those who are struggling with management of their ACHD (8/15), or those with newlyrecognized life- or illness-related challenges (3/15). Participants also identified several facilitators and barriers to participation (Table).

# NOW FDA APPROVED.



Harmony<sup>™</sup>
Transcatheter Pulmonary Valve (TPV)





#### Indications

The Harmony  $^{\mathbb{M}}$  transcatheter pulmonary valve (TPV) system is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation (i.e., severe pulmonary regurgitation as determined by echocardiography and/or pulmonary regurgitant fraction  $\geq$  30% as determined by cardiac magnetic resonance imaging) who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement.

#### Contraindications

The following are contraindications for the use of this device: active bacterial endocarditis or other active infections, known intolerance to Nitinol (titanium or nickel), or an anticoagulation/antiplatelet regimen.

#### Warnings

General. Implantation of the Harmony TPV system should be performed only by physicians who have received Harmony TPV system training. The transcatheter pulmonary valve (TPV) is to be used only in conjunction with the Harmony delivery catheter system (DCS). This procedure should only be performed where emergency pulmonary valve surgery can be performed promptly. Do not use any of the Harmony TPV system components if any of the following has occurred: it has been dropped, damaged, or mishandled in any way, or if the use-by date has elapsed.

Transcatheter pulmonary valve (TPV): This device was designed for single use only. Do not reuse, reprocess, or resterilize the TPV. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Do not resterilize the TPV by any method. Exposure of the device and container to irradiation, steam, ethylene oxide, or other chemical sterilants renders the device unfit for use. The device is packaged with a temperature sensor. Do not freeze the device. Do not expose the device to extreme temperatures. Do not use the device if the arrow on the sensor points to the symbol that indicates that the temperature limit has been exceeded. Do not use the device if any of the following have occurred: the tamper-evident seal is broken, the serial number tag does not match the container label, the arrow on the sensor points to the symbol that indicates that the temperature limit has been exceeded, or the device is not completely covered by the storage solution. Do not contact any of the Harmony TPV system components with cotton or cotton swabs. Do not expose any of the Harmony TPV system components to organic solvents, such as alcohol. Do not introduce air into the catheter. Do not expose the device to solutions other than the storage and rinse solutions. Do not add or apply antibiotics to the device, the storage solution, or the rinse solution. Do not allow the device to dry. Maintain tissue moisture with irrigation or immersion. Do not attempt to repair a damaged device. Do not handle the valve leaflet tissue or use forceps to manipulate the valve leaflet tissue. Do not attempt to recapture the device once deployment has begun. Do not attempt to retrieve the TPV if any one of the outflow TPV struts is protruding from the capsule. If any one of the outflow TPV struts has deployed from the capsule, the TPV must be released from the catheter before the catheter can be withdrawn. Do not attempt post-implant balloon dilatation (PID) of the TPV during the procedure, which may cause damage to or failure of the TPV leading to injury to the patient resulting in reintervention.

Delivery catheter system (DCS): This device was designed for single use only. Do not reuse, reprocess, or resterilize the DCS. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Do not reuse or resterilize the DCS. If resistance is met, do not advance the guidewire, DCS, or any other component without first determining the cause and taking remedial action. Do not remove the guidewire from the DCS at any time during the procedure.

#### Precautions

General: Clinical long-term durability has not been established for the Harmony TPV. Evaluate the TPV performance as needed during patient follow-up. The safety and effectiveness of Harmony TPV implantation in patients with pre-existing prosthetic heart valve or prosthetic ring in any position has not been demonstrated. The Harmony TPV system has not been studied in female patients of child-bearing potential with positive pregnancy.

Before use: Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the chemical vapor. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water (for a minimum of 15 minutes) and seek medical attention immediately. The TPV and the glutaraldehyde storage solution are sterile. The outside of the TPV container is nonsterile and must not be placed in the sterile field. The TPV and DCS should be used only in a sterile catheterization laboratory (cath lab) environment. Ensure that sterile technique is used at all times. Strictly follow the TPV rinsing procedure. For TPV 25: Ensure that all green sutures have been removed from the attachment suture loops on the TPV before loading onto the DCS. Prevent contamination of the TPV, its storage solution, and the DCS with glove powder. Verify the orientation of the TPV before loading it onto the DCS. The inflow end of the TPV

with attachment suture loops must be loaded first. Do not place excessive pressure on the TPV during loading. Inspect the sealed DCS packaging before opening. If the seal is broken or the packaging has been damaged, sterility cannot be assured. Proper functioning of the DCS depends on its integrity. Use caution when handling the DCS. Damage may result from kinking, stretching, or forceful wiping of the DCS. This DCS is not recommended to be used for pressure measurement or delivery of fluids. Carefully flush the DCS and maintain tight DCS connections to avoid the introduction of air bubbles

During use: The TPV segment is rigid and may make navigation through vessels difficult. Do not advance any portion of the DCS under resistance. Identify the cause of resistance using fluoroscopy and take appropriate action to remedy the problem before continuing to advance the DCS. Careful management of the guidewire is recommended to avoid dislodgement of the TPV during DCS removal. Once deployment is initiated, retrieval of the TPV from the patient is not recommended. Retrieval of a partially deployed valve may cause mechanical failure of the delivery catheter system or may cause injury to the patient. Refer to the section below  $\,$ for a list of potential adverse events associated with Harmony TPV implantation. During deployment, the DCS can be advanced or withdrawn prior to the outflow struts protruding from the capsule. Once the TPV struts contact the anatomy during deployment, it is not recommended to reposition the device. Advancing the catheter forward once the TPV struts make contact with the anatomy may lead to an undesired deployment or may cause damage to or failure of the TPV and injury to the patient. Refer to the section below for a list of potential adverse events associated with the Harmony TPV implantation. Physicians should use judgment when considering repositioning of the TPV (for example, using a snare or forceps) once deployment is complete. Repositioning the bioprosthesis is not recommended, except in cases where imminent serious harm or death is possible (for example, occlusion of the main, left, or right pulmonary artery). Repositioning of a deployed valve may cause damage to or failure of the TPV and injury to the patient. Refer to the section below for a list of potential adverse events associated with the Harmony TPV implantation. Ensure the capsule is closed before DCS removal. If increased resistance is encountered when removing the DCS through the introducer sheath, do not force passage. Increased resistance may indicate a problem and forced passage may result in damage to the device and harm to the patient. If the cause of resistance cannot be determined or corrected, remove the DCS and introducer sheath as a single unit over the guidewire, and inspect the DCS and confirm that it is complete. If there is a risk of coronary artery compression, assess the risk and take the necessary precautions. Endocarditis is a potential adverse event associated with all bioprosthetic valves. Patients should make their healthcare providers aware that they have a bioprosthetic valve before any procedure. Post-procedure, administer appropriate antibiotic prophylaxis as needed for patients at risk for prosthetic valve infection and endocarditis. Prophylactic antibiotic therapy is recommended for patients receiving a TPV before undergoing dental procedures. Post-procedure, administer anticoagulation and/or antiplatelet therapy per physician/clinical judgment and/or institutional protocol. Excessive contrast media may cause renal failure. Preprocedure, measure the patient's creatinine level. During the procedure, monitor contrast media usage. Conduct the procedure under fluoroscopy. Fluoroscopic procedures are associated with the risk of radiation damage to the skin, which may be painful, disfiguring, and long term.

#### **Potential Adverse Events**

Potential risks associated with the implantation of the Harmony TPV may include, but are not limited to, the following: = death = valve dysfunction = tissue deterioration = hematoma = heart failure = cerebrovascular incident = perforation = rupture of the right ventricular outflow tract (RVOT) = compression of the aortic root = compression of the coronary arteries = sepsis = pseudoaneurysm = erosion = stent fracture = arrhythmias = device embolization or migration = pulmonary embolism = occlusion

- arrive in this a device of a pulmonary artery laceration or rupture of blood vessels device misorientation or misplacement valve deterioration regurgitation through an incompetent valve physical or chemical implant deterioration paravalvular leak valve dysfunction
- leading to hemodynamic compromise residual or increasing transvalvular gradients progressive stenosis and obstruction of the implant hemorrhage endocarditis
- thromboembolism thrombosis thrombus intrinsic and extrinsic calcification
- bleeding bleeding diathesis due to anticoagulant use fever pain at the catheterization site allergic reaction to contrast agents infection progressive pulmonary hypertension progressive neointimal thickening and peeling leaflet thickening hemolysis. General surgical risks applicable to transcatheter pulmonary valve implantation: abnormal lab values (including electrolyte imbalance and elevated creatinine) allergic reaction to antiplatelet agents, contrast medium, or anesthesia
- exposure to radiation through fluoroscopy and angiography permanent disability.

Please reference the Harmony TPV system instructions for use for more information regarding indications, warnings, precautions, and potential adverse events.

**Caution:** Federal law (USA) restricts these devices to the sale by or on the order of a physician.

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#### **EXPLORING RESILIENCE IN ADULT CONGENITAL HEART DISEASE**



TABLE Facilitators and Barriers to Participation in a Program Like PRISM

#### **Facilitators to Participation**

- · Flexibility of the intervention (length, format, location)
- Comforting environment, support for participants to say what they need to say
- Check-ins between modules to make sure they understand the skills
- Knowing they are not alone in needing help
- Having awareness of some of these skills, wanting to develop
- Free coaching opportunity
- Positive prior experiences with healthcare

#### **Barriers to Participation**

- If program is too fast-paced or too demanding on time, too much "homework"
- If participants must travel far
- Hard to find ACHD-related examples (i.e., finding meaning in going to doctor visits)
- Hard to engage people not focused on these issues, especially if too young
- If people don't recognize they need this or that these skills could help them
- If people feel like they are already so positive/resilient this is not needed

When asked about delivery preferences, participants preferred in-person sessions, feeling the program would be more personal and they could feel more engaged. However, they found the option of virtual sessions appealing because of the flexibility this provided. A few stated they were recently more comfortable with the idea of a virtual format, having had virtual medical visits during the COVID-19 pandemic. Interestingly, no one specifically stated they preferred one-to-one format over a group setting, and some participants (6/15) wished there would be a group component of the program. Participants also asked whether the instructor could be someone with ACHD (3/15). For both of these suggestions, participants cited a desire to connect with other people with ACHD, who shared similar experiences.

With regard to content, the module including relaxation and meditation skills was most appealing, and no module was identified as undesirable. There seemed to be some equipoise about the advance care planning module, with some participants concerned it could carry a negative connotation. Suggestions for additional sessions included mental health and "healthy habits" like nutrition and exercise.

#### **Using This Information to Plan Next Steps**

Participants' interest in PRISM, appraisal of the modules, and suggestions for new material will allow us to move forward with plans for tailoring and testing the program in ACHD. It is exciting to support positive psychology and mental health, and to holistically improve the patient experience while considering these palliative care and quality-of-life goals. In line with our anticipated findings, participants were interested in a program that was supportive in addressing their emotional concerns yet flexible enough to fit their schedules. The appeal of an opportunity to connect with other patients reflects their expressed desire to feel less alone in uncertainty. We will partner with patients to identify the ideal program format, including how much out-of-session practice will be recommended and how a group component may be offered. These interviews also provided insight into a potential need to develop ACHDspecific examples for some of the modules. Questions remain about how best to engage patients who are less aware of their needs or the role of resilience in supporting psychosocial health - which we will explore further in other concurrent studies.

#### **Acknowledgements**

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#### References

- Kovacs AH, Saidi AS, Kuhl EA, Sears SF, Silversides C, Harrison JL, Ong L, Colman J, Oechslin E, Nolan RP. Depression and anxiety in adult congenital heart disease: Predictors and prevalence. Int J Cardiol 2009;137:158-164. Available at: https://www.sciencedirect.com/science/article/pii/ S0167527308008401?via%3Dihub. Accessed September 10, 2019.
- Ferguson M, Kovacs AH. An Integrated Adult Congenital Heart Disease Psychology Service. Congenit Heart Dis 2016;11:444-451. Available at: http://doi.wiley.com/10.1111/chd.12331. Accessed January 19, 2019.
- Deng LX, Khan AM, Drajpuch D, Fuller S, Ludmir J, Mascio CE, Partington SL, Qadeer A, Tobin L, Kovacs AH, Kim YY. Prevalence and Correlates of Post-traumatic Stress Disorder in Adults With Congenital Heart Disease. Am J Cardiol 2016;117:853-857. Available at: https://linkinghub.elsevier.com/ retrieve/pii/S0002914915023590. Accessed April 28, 2019.
- Kovacs AH, Moons P. Psychosocial Functioning and Quality of Life in Adults with Congenital Heart Disease and Heart Failure. Heart Fail Clin 2014;10:35-42.
- Kovacs AH, Landzberg MJ, Goodlin SJ. Advance care planning and end-of-life management of adult patients with congenital heart disease. World J Pediatr Congenit Heart Surg 2013;4:62-9. Available at: http://journals.sagepub.com/ doi/10.1177/2150135112464235. Accessed January 19, 2019.
- Rosenberg AR, Syrjala KL, Martin PJ, Flowers ME, Carpenter PA, Salit RB, Baker KS, Lee SJ. Resilience, health, and quality of life among long-term survivors of hematopoietic cell transplantation. Cancer 2015;121:4250-4257. Available at: http://www.ncbi.nlm.nih.gov/pubmed/26288023. Accessed October 14, 2018.
- Luthar SS, Cicchetti D, Becker B. The Construct of Resilience: A Critical Evaluation and Guidelines for Future Work. Child Dev 2000;71:543-562. Available at: http://doi.wiley. com/10.1111/1467-8624.00164. Accessed June 26, 2018.
- Steinhardt M, Dolbier C. Evaluation of a resilience intervention to enhance coping strategies and protective factors and decrease symptomatology. J Am Coll Health 2008;56:445-453. Available at: http://www.tandfonline.com/doi/abs/10.3200/ JACH.56.44.445-454. Accessed April 28, 2019.
- Rosenberg AR, Bradford MC, McCauley E, Curtis JR, Wolfe J, Baker KS, Yi-Frazier JP. Promoting resilience in adolescents and young adults with cancer: Results from the PRISM randomized controlled trial. Cancer 2018;124:3909-3917. Available at: http://www.ncbi.nlm.nih.gov/pubmed/30230531. Accessed December 22, 2018.





## Pediatric Heart Failure / Transplant Cardiologist

#### Overview

Children's Minnesota is seeking a dynamic, fellowship-trained pediatric heart transplant cardiologist to lead the Heart Failure Heart transplant (HFHT) program. This physician would have the benefit of collaborating with a comprehensive multidisciplinary team that includes: surgeons, cardiologists, transplant coordinators, dieticians, pharmacists, therapists and social workers. The HFHT program also offers a growing Ventricular Assist Device program as well as a well-established ECMO program.

Our Transplant program partners closely with The Children's Heart Clinic (CHC). Annually, the CHC cardiologists see more than 16,000 patients and surgeons perform over 400 surgical interventions. The CHC's state-of-the-art facilities include a dedicated pediatric cardiovascular intensive care unit, one of 30 approved pediatric cardiac catheterization laboratories in North America for transcatheter pulmonary valve placement, a complete pediatric arrhythmia service including the latest technology for ablation and devices, a collaborative fetal program for diagnosing and managing congenital heart disease in-utero, a collaborative adult congenital cardiology program, an ICAEL-accredited echocardiography lab and a rapidly growing congenital cardiac MRI/CT program.

#### **Program Description**

Children's Minnesota's cardiovascular program provides comprehensive pediatric cardiovascular services and on average, we annually perform:

- 425+ cardiac surgeries
- 400+ cath procedures
- 12,000 + echos (1,200+ fetal)
- 370+ cardiac CT/MRIs

Children's Minnesota and Mayo Clinic Children's Center collaborate in the care of children with congenital heart disease and build on each organization's passion for children as well as the complementary strengths of both programs. The Mayo Clinic - Children's Minnesota Cardiovascular Collaborative is one of the largest and strongest pediatric cardiovascular collaborations in the country.

This exciting opportunity is open for a pediatric cardiologist with heart failure heart transplant experience to lead our recognized program. Candidates should have a strong commitment to patient care, teaching and clinical research.

#### Requirements of the position include:

- Board Certified in Pediatric Cardiology from the American Board of Pediatrics
- Advanced Heart Failure/Transplant fellowship training in a program certified by the American Board of Pediatrics.
- Physicians should have clinical competency and expertise in caring for patients who are candidates for or are recipients of advanced heart failure therapies including mechanical circulatory devices.
- Must have an M.D., D.O. or equivalent degree from another country with a current Minnesota Medical License or the ability to obtain one.
- Ability to be successfully credentialed by both Hospital and 3rd Party Payers

#### Children's Minnesota

Children's Minnesota is the seventh largest pediatric health system in the United States and the only health system in Minnesota to provide care exclusively to children, from before birth through young adulthood. An independent and not-for-profit system since 1924, Children's Minnesota serves kids throughout the Upper Midwest at two free-standing hospitals, 12 primary and specialty care clinics and six rehabilitation sites. Additionally, Children's Minnesota is Minnesota's only Level I pediatric trauma center inside a hospital dedicated solely to children. Children's Minnesota maintains its longstanding commitment to the community to improve children's health by providing high-quality, family-centered pediatric services and advancing those efforts through research and education

#### Minneapolis - St. Paul (Twin Cities)

The Twin Cities has an estimated population of 3.5 million making it the 13th most populous metropolitan area in the US. The Twin Cities are known for their extraordinary quality of life, thriving economy, outstanding educational system and vibrant cultural amenities. The large numbers of colleges and universities, as well as the strong economy account for the high per-capita attendance at theatrical, musical and comedy events making the Twin Cities the capitol for arts in the upper Midwest. There are numerous lakes in the region and cities in the area have expansive park systems for recreation. Major sports teams include the Minnesota Twins (MLB), Vikings (NFL), Timberwolves (NBA), Wild (NHL) and the University of Minnesota (Big 10).

#### For inquires please contact:

Rvan Berreth Physician Recruitment Manager Children's Minnesota Ryan.berreth@childrensmn.org 952.797.6660

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- 10. Ring A, Jacoby A, Baker GA, Marson A, Whitehead MM. Does the concept of resilience contribute to understanding good quality of life in the context of epilepsy? Epilepsy Behav 2016;56:153–164.
- 11. Antonovsky A. The salutogenic perspective: Toward a new view of health and illness. Advances 1987;4:47–55.
- 12. Southwick SM, Bonanno GA, Masten AS, Panter-Brick C, Yehuda R. Resilience definitions, theory, and challenges: Interdisciplinary perspectives. Eur J Psychotraumatol 2014;5:1–14.
- 13. Apers S, Moons P, Goossens E, Luyckx K, Gewillig M, Bogaerts K, Budts W. Sense of coherence and perceived physical health explain the better quality of life in adolescents with congenital heart disease. Eur J Cardiovasc Nurs 2013;12:475–483.
- Apers S, Luyckx K, Rassart J, Goossens E, Budts W, Moons P. Sense of coherence is a predictor of perceived health in adolescents with congenital heart disease: A cross-lagged prospective study. Int J Nurs Stud 2013;50:776–785. Available at: http://dx.doi.org/10.1016/j.ijnurstu.2012.07.002.
- 15. Moons P, Norekvål TM. Is sense of coherence a pathway for improving the quality of life of patients who grow up with chronic diseases? A hypothesis. Eur J Cardiovasc Nurs 2006;5:16–20.
- Apers S, Rassart J, Luyckx K, Oris L, Goossens E, Budts W, Moons P. Bringing antonovsky's salutogenic theory to life: A qualitative inquiry into the experiences of young people with congenital heart disease. Int J Qual Stud Health Well-being 2016;11.
- 17. Moons P, Luyckx K, Thomet C, Budts W, Enomoto J, Sluman MA, Wang JK, Jackson JL, Khairy P, Cook SC, Chidambarathanu S, Alday L, Oechslin E, Eriksen K, Dellborg M, Berghammer M, Johansson B, Mackie AS, Menahem S, Caruana M, Veldtman G, Soufi A, Fernandes SM, White K, Callus E, Kutty S, Apers S, Kovacs AH. Patient-Reported Outcomes in Adults With Congenital Heart Disease Following Hospitalization (from APPROACH-IS). Am J Cardiol 2021;145:135–142. Available at: https://doi.org/10.1016/j.amjcard.2020.12.088.
- 18. Anon. What is Palliative Care | Definition of Palliative care | CAPC. Available at: https://www.capc.org/payers-policymakers/what-is-palliative-care/?gclid=Cj0KCQiA37HhBRC8ARIsAPWoO0y2eW1yZvzUV8pOo3ozW3UAuDA1VxXan7ECsu49QVslnEfSjoWVUgEaAtoCEALw\_wcB. Accessed January 2, 2019.
- 19. Anon. WHO | WHO Definition of Palliative Care. World Heal Organ 2012. Available at: https://www.who.int/cancer/palliative/definition/en/. Accessed January 2, 2019.
- 20. Lee S, Lee J, Choi JY. The effect of a resilience improvement program for adolescents with complex congenital heart disease. Eur J Cardiovasc Nurs 2017;16:290–298.
- Kovacs AH, Grace SL, Kentner AC, Nolan RP, Silversides CK, Irvine MJ. Feasibility and Outcomes in a Pilot Randomized Controlled Trial of a Psychosocial Intervention for Adults With Congenital Heart Disease. Can J Cardiol 2018;34:766–773.
- 22. Folkman S, Greer S. Promoting psychological well-being in the face of serious illness: when theory, research and practice inform each other. Psychooncology 2000;9:11–9. Available at: http://www.ncbi.nlm.nih.gov/pubmed/10668055. Accessed April 25, 2019.
- Czajkowski SM, Heart N, Powell LH, Adler N, Francisco S, Naarking S, Reynolds KD, Hunter CM, Diseases K, Laraia B, Olster DH, Perna FM, Peterson JC, Epel E, Francisco S, Boyington JE,

- Heart N, Charlson ME, Levoy E, Lazaridou A, Brewer J, Fulwiler C, Do C, Ara N, Avalia JO, Kristeller J, Wolever RQ, Sheets V. From Idea to Efficacy: The ORBIT Model for Developing Behavioral Treatments for Chronic Diseases. Heal Psychol 2015;34:971–82.
- Rosenberg AR, Steiner J, Lau N, Fladeboe K, Toprak D, Gmuca S, O'Donnell MB, Smith K, Brown CE, Yi-Frazier JP. From Theory to Patient Care: A Model for the Development, Adaptation, and Testing of Psychosocial Interventions for Patients With Serious Illness. J Pain Symptom Manage 2021;00. Available at: https://doi.org/10.1016/j.jpainsymman.2021.02.036.
- Rosenberg AR, Yi-Frazier JP, Eaton L, Wharton C, Cochrane K, Pihoker C, Baker KS, McCauley E. Promoting Resilience in Stress Management: A Pilot Study of a Novel Resilience-Promoting Intervention for Adolescents and Young Adults With Serious Illness. J Pediatr Psychol 2015;40:992–999. Available at: http:// www.ncbi.nlm.nih.gov/pubmed/25678533. Accessed January 2, 2019.
- Toprak D, Nay L, McNamara S, Ong T, Rosenberg, AR Rosenfeld M, Yi-Frazier J. Resilience in Cystic Fibrosis: a pilot feasibility study of the Promoting Resilience in Stress Management (PRISM) intervention. Pediatr Pulmonol 2019:1–8. Available at: http://dx.doi.org/10.1002/ppul.24574.
- Rosenberg AR, Bradford MC, Junkins CC, Taylor M, Zhou C, Sherr N, Kross E, Curtis JR, Yi-Frazier JP. Effect of the Promoting Resilience in Stress Management Intervention for Parents of Children With Cancer (PRISM-P): A Randomized Clinical Trial. JAMA Netw open 2019;2:e1911578.
- 28. Fladeboe KM, O'Donnell MB, Barton KS, Bradford MC, Steineck A, Junkins CC, Yi-Frazier JP, Rosenberg AR. A novel combined resilience and advance care planning intervention for adolescents and young adults with advanced cancer: A feasibility and acceptability cohort study. Cancer 2021:1–8.
- Steiner JM, Stout K, Soine L, Kirkpatrick JN, Curtis JR.
   Perspectives on advance care planning and palliative care among adults with congenital heart disease. Congenit Heart Dis 2019;14:403–409. Available at: http://www.ncbi.nlm.nih.gov/pubmed/30575286. Accessed December 24, 2018.
- 30. Steiner JM, Dhami A, Brown CE, Stout KK, Randall Curtis J, Engelberg RA, Kirkpatrick JN. Barriers and Facilitators of Palliative Care and Advance Care Planning in Adults With Congenital Heart Disease. Am J Cardiol 2020;00:1–7. Available at: https://doi.org/10.1016/j.amjcard.2020.08.038. Accessed October 16, 2020.
- Steiner JM, Dhami A, Brown CE, Stout KK, Curtis JR, Engelberg RA, Kirkpatrick JN. It's part of who I am: The impact of congenital heart disease on adult identity and life experience. Int J Cardiol Congenit Hear Dis 2021;4:100146. Available at: https://doi.org/10.1016/j.ijcchd.2021.100146.



#### **EXPLORING RESILIENCE IN ADULT CONGENITAL HEART DISEASE**





JILL M. STEINER, MD, MS

Division of Cardiology, Department of Medicine, University of Washington Cambia Palliative Care Center of Excellence, University of Washington Palliative Care and Resilience Lab, Seattle Children's Research Institute Seattle, WA, USA 206.221.8240 jills8@uw.edu



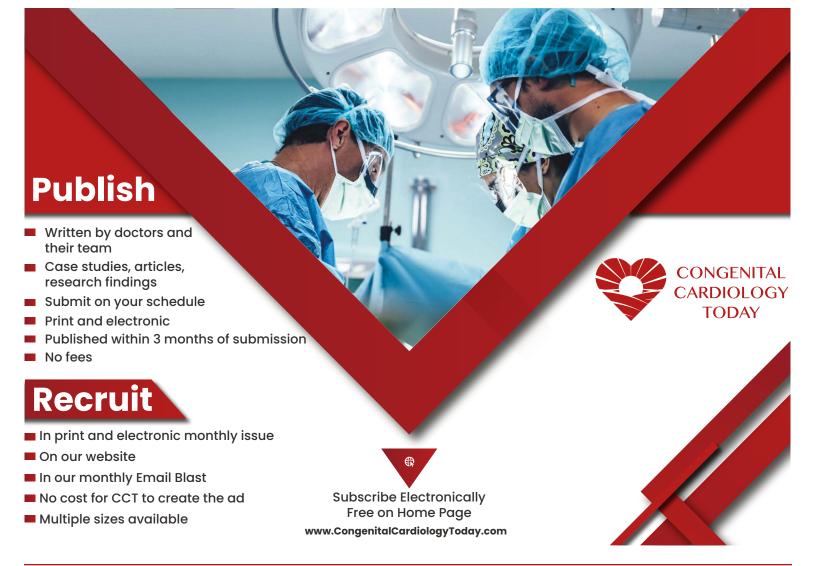
#### ABBY R. ROSENBERG, MD, MS, MA

Cambia Palliative Care Center of Excellence. University of Washington Palliative Care and Resilience Lab, Seattle Children's Research Institute Division of Hematology/Oncology, Department of Pediatrics, University of Washington Seattle, WA, USA



#### J. RANDALL CURTIS, MD, MPH

Cambia Palliative Care Center of Excellence, University of Washington Division of Pulmonology, Critical Care, and Sleep Medicine, Department of Medicine, University of Washington Seattle, WA, USA









### **Pediatric Cardiologist**

# University of North Carolina at Chapel Hill Wilmington, NC

The Department of Pediatrics at the University of North Carolina School of Medicine is seeking an open rank, fixed term, clinical faculty position for the Division of Pediatric Cardiology. The successful candidate will live and work primarily in Wilmington, NC, to join our team to provide pediatric and fetal care in communities throughout southeastern NC in partnership with Novant Health – New Hanover Regional Medical Center (NH-NHRMC). This facility houses a community-based, multispecialty practice and a children's hospital that includes a 45 bed Level III NICU, Pediatric Intensive Care Unit and inpatient unit. The faculty member will also be expected to develop and perform clinical activities in surrounding outreach locations in Southeastern NC.

As a top-tier academic medical center, UNC Children's upholds a four-tiered mission to "CARE," aligning clinical care, advocacy, research, and education to deliver world-class family-centered care. Novant Health and UNC Health formed a partnership in early 2021 to broaden and enhance pediatric care in Southeast NC and expand medical education at the Wilmington branch campus of the School of Medicine. Through this collaboration, NH-NHRMC will become the tertiary care referral hospital for children in Coastal and Southeastern NC.

The successful candidate will ideally have excellent outpatient pediatric cardiology skills with preferred fetal echocardiography expertise. The candidate must be board certified / eligible in Pediatric Cardiology. This is an excellent opportunity to be part of and build a community-based practice in Pediatric Cardiology while being part of an academic group. The faculty member will be expected to participate in faculty meetings and case management conferences virtually with Chapel Hill. The faculty member will join The UNC Children's Heart Center encompassing a dynamic faculty, which care for the fetus through adulthood along the continuum of comprehensive care. Clinical research and quality improvement interests will be encouraged and the faculty member may participate in the education of medical students and house staff.

Wilmington, NC, is a charming, coastal city of ~125,000, known as the Port City, located in the southeastern corner of North Carolina between the Cape Fear River and the Atlantic Ocean. It is a popular destination because of its moderate, four-season climate, historic preservation district, annual cultural events, and numerous championship golf courses. The historic downtown offers a 1.75-mile River walk and the nearby Wrightsville, Carolina and Kure Beaches are all within half-hour drives from downtown Wilmington.

For consideration, apply online at https://unc.peopleadmin.com/postings/194945

Applicants, please send CV and cover letter to: Timothy M. Hoffman, MD Division Chief, Pediatric Cardiology UNC Children's 101 Manning Drive, CB # 7232 Chapel Hill, NC 27599-7232 tmhoff@email.unc.edu

The University of North Carolina at Chapel Hill is an equal opportunity and affirmative action employer. All qualified applicants will receive consideration for employment without regard to age, color, disability, gender, gender expression, gender identity, genetic information, national origin, race, religion, sex, sexual orientation, or status as a protected veteran.



# ACHA Debuts New Website, Mission, and 13th Edition of the ACHD Travel Directory

We are thrilled to share our updated website today, which has been refreshed with usability and simplicity in mind for our supporters and the greater Congenital Heart Disease (CHD) community. We know that people across the country are accessing our website for a wealth of information, but especially in some key areas—such as defect-specific educational resources and the ACHD Clinic Directory. With that in mind, we have made these areas and other priority program content the core of our homepage, and easily accessible with fewer clicks.

We heard your feedback on our educational webinars, and have made this area of our website searchable (by keyword, category, or date) so you can easily find presentations in our library. The website also has been refreshed with a new, clean look and is much simpler to use on a mobile device or tablet than ever before.

"One of the pillars that ACHA was founded on was being a source of easy to access, credible information for all people living with CHD," said President and CEO Mark Roeder. "With enhanced navigation and resources on our website, we've now made it easier than ever for patients and medical providers to locate the information they need."

Alongside the website launch, we are also debuting our new ACHA logo today. As you'll see, along with our Walk for 1 in 100 logo, this now completes an overall refreshed look of ACHA.

"We're an organization that is about connecting people," said Roeder. "We are proud to be represented by an identifier for our organization that encompasses this notion, as well as CHD care across the lifespan."

Finally, ACHA Board of Directors, Medical Advisory Board, and staff came together earlier this year to review our current mission and where ACHA's work has taken us since we last updated this important, fundamental purpose of our organization. With our updated website and new look, we are excited to debut ACHA's vision, as well as an updated mission, that incorporates our value of lifelong care for CHD and our more than 20 years of work in the CHD field and support to patients, family members, and medical providers.

**Our Vision:** Every adult with Congenital Heart Disease receives specialized cardiac care.

**Our Mission:** To empower the Congenital Heart Disease community by advancing access to resources and specialized care that improve patient-centered outcomes.







The 13<sup>th</sup> Edition ACHD Travel Directory is free for ACHA members! If you're planning a trip or going away to college, this resource can help you find specialized Adult Congenital Heart Disease care in an emergency. The directory includes Adult Congenital Heart Disease (ACHD) programs across the globe and lists each clinic's name, location, and contact information.

If you would like one of these resources for your personal use, please email <a href="mailto:orders@achaheart.org">orders@achaheart.org</a> with your name and mailing address. Or click download a printer-friendly PDF version from the website:

https://www.achaheart.org/media/3080/traveldirectory13thedition.pdf?bblinkid=252555521&bbemailid=32515012&bbejrid=2023546307.

If you are a medical professional and would like to order multiple copies for your patients, please visit <a href="https://shop.achaheart.org/products/achd-travel-directory?bblinkid=252545967&bbemailid=32515012&bbejrid=2023546307">https://shop.achaheart.org/products/achd-travel-directory?bblinkid=252545967&bbemailid=32515012&bbejrid=2023546307</a>.





**CONGENITAL HEART INTERNATIONAL PROFESSIONALS** 



### New Heart Regeneration Study Provides Never-Before-Described Process

There is a ground breaking study, <a href="https://www.pubstemcell.com/epub/uploads/016010300010EPA121120.pdf">https://www.pubstemcell.com/epub/uploads/016010300010EPA121120.pdf</a>, that could speed up the effort to defeat heart disease, a major health epidemic that kills over 650,000 Americans each year, and that continues to increase because of COVID-19.

The peer-reviewed study written by Dr. Ian White, President and CSO of regenerative medicine researchers Neobiosis, <a href="https://neobiosis.com/">https://neobiosis.com/</a>, explains how a never-before-described process may be used to help regenerate damaged human hearts.

Dr. White and colleagues from the Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine said the research can be especially useful to those stricken by COVID-19.

The virus is known to cause inflammation in the heart. That poses health risks for so called "long-haulers", who have not fully recovered from COVID-19 weeks or even months after first experiencing symptoms. Among many other applications, the research could be a long-term solution to study the cardiovascular effects of COVID in a way never possible before.

#### The Study

- The scientists studied neonatal mouse hearts in a petri dish.
- Most mammalian hearts have between one and seven days where they retain primordial regenerative abilities.
- In a controlled environment, the team extended that period for a month.
- This gave them time to learn how different therapies or drugs can repair or regenerate the damaged organ.

"We took a neonatal heart from a baby mouse and studied it in a petri dish. We studied it under a controlled environment and designed a method to keep the heart alive and keep the regenerative process active long enough to study the biology behind it." This work is unprecedented as it has not been possible, until now, for scientists to keep a whole heart alive long enough in the lab to make significant scientific discoveries about the regenerative process" — Dr. Ian White, President and CSO of Neobiosis

White's paper explains that neonatal cardiac repair is mediated by the epicardium, which is a single layer of cells that covers the heart. The cells activate in response to injury by proliferating before actively migrating to the site of damage.

It is the first demonstration that whole, intact mammalian hearts can be cultured long-term without coagulative necrosis and that the innate regenerative mechanisms remain intact when afforded a conducive environment.

Dr. Keith March, Professor of Medicine and Director of the Center for Regenerative Medicine at the University of Florida, emphasized the major clinical implications of prolonging the viability of hearts in the absence of blood flow, such as is experienced by donor hearts on the way to transplantation.

"We have been excited to discover that novel biological therapies from adult stem cell secretome could markedly improve cardiac transplantation, and Dr. White's new finding could amplify this therapeutic benefit. We would be interested in testing this concept together with Dr. White's team," said Dr. Keith March.

"This study gives us an unprecedented window on how hearts heal and how we can enhance their regeneration," said Dr. Anthony Atala, Director of the Wake Forest Institute for Regenerative Medicine. "The insights from this work will have a major and lasting impact in the development of new therapies for patients with heart disease."

#### The Benefits of Regenerative Therapy

Regenerative medicine has the potential to fight disease and revolutionize healthcare, <a href="https://neobiosis.com/about-neobiosis/">https://neobiosis.com/about-neobiosis/</a>. The therapies center on treatments that support the body in repairing, regenerating and restoring itself. Some of these benefits include:

- Delivering biochemical instructions and raw biomaterials to damaged tissues and organs stimulating the body's own repair mechanisms to functionally heal previously irreparable tissues or organs.
- Modulating inflammation to facilitate recovery and tissue repair.
- Treating injuries and disease naturally without surgery and opioids.

Dr. White is eager to share his work with the world. He has called on colleagues to use the same neonatal heart preservation method for their own experiments. The sharing of this research is one example of how Neobiosis leads the way in the field of regenerative science.

"Now other scientists can use our methods to employ these technologies and use it for drug interactions and studying COVID in the heart. The more minds on this subject the better. Others can use this tool, apply their own specialties to further the knowledge of the mechanisms of cardiac regeneration to reduce the impact of heart diseases." – Dr. lan White

#### Dr. Ian White can speak to the following:

- How regenerative medicine is advancing studies in cardiology
- How he and his team were able to regenerate cardiac tissue in a neonatal mouse heart and what that means for human beings.
- How these findings help people suffering from COVID-19 and for the "long-haulers" still battling the after-effects.
- How COVID-19 damages the heart.
- How regenerative medicine works.

#### **About Neobiosis**

Neobiosis, LLC is a clinical-stage contract development and manufacturing organization (CDMO) run by scientists focused on the science of regenerative medicine. They produce regenerative medicines from perinatal tissues, cells and extracellular vesicles (EVs) for research and clinical trials. Regenerative medicine taps into the body's innate ability to heal itself relieving pain without opioids, being more cost effective and safer than many surgical alternatives. Neobiosis is an FDA-registered CDMO operating under current Good Manufacturing Practice (cGMP) standards with cleanroom laboratories located in Alachua and Gainesville. Visit <a href="https://neobiosis.com/">https://neobiosis.com/</a>.





# Pacífic Pediatric Cardiology Medical Group, Inc.

### **Pediatric Cardiologists**

Los Angeles, California

Pacific Pediatric Cardiology Medical Group is offering two positions as clinical pediatric cardiologists with emphasis on Interventional Cardiac Catheterization and fetal echocardiography starting January, 2022. Applicants should be board eligible/certified, have completed their fellowship in pediatric cardiology and have interest in providing outpatient and inpatient care.

The first position will require fourth year training in interventional cardiac catheterization.

The second position will require full competence and ability to work independently in fetal echocardiography.

Our Group is the largest and longest established community-based pediatric cardiology practice serving the Los Angeles metropolitan area. Our patient base is diverse and served by a network of offices in both Los Angeles and San Bernardino counties. The practice is managed exclusively by the physician partners with full input from all clinicians free of external governance. Strong affiliations are maintained with multiple tertiary centers where group physicians are actively involved as attending physicians providing clinical, interventional, and post-operative care on a daily basis participating fully in educational and research activities.

This position offers a competitive salary and full benefits with a rapidly expanding preestablished patient and referral base. Newly hired full time clinicians will be potentially eligible for future partnership.

Please visit our website at Pacificpediatriccardiology.com for more patient-based information regarding our practice and facilities.

Interested applicants may send their CV and Cover letter to:

Carmen Hayes, Practice Manager chayes.pacpeds@yahoo.com or contact any of the practice partners by phone at 626.796.9259



Front row: Irving R. Tessler, MD, Elizabeth R. De Oliveira, MD, Lennis P. Burke, MD Back row: Christiana Tai, MD, John Ho, MD, Joseph Ahdoot, MD



# Biosense Webster Announces Completion of Atrial Fibrillation Cases Using Novel HELIOSTAR™ Balloon Ablation Catheter

HELIOSTAR™ Balloon Ablation Catheter is the First-Ever Radiofrequency Balloon Ablation Catheter and Supports More Efficient Cardiac Arrhythmia Ablation Procedures

Biosense Webster, Inc., part of the Johnson & Johnson Medical Devices Companies¹ today announced post-approval procedures were successfully performed with the first-ever radiofrequency balloon ablation catheter at sites across Europe with Biosense Webster's HELIOSTAR™ Balloon Ablation Catheter. In Europe, the HELIOSTAR Balloon Catheter is indicated for use in catheter-based cardiac electrophysiological mapping of the atria and for cardiac ablation.

Europe is home to more than 11 million people living with atrial fibrillation (AF), and estimates state that by 2030 the number of people with AF is projected to increase by up to 70%. In Europe, catheter ablation is a recommended first-line treatment option<sup>2,13</sup> and is associated with a significant improvement in quality of life and significant reductions in AF burden and AF-related complications. III, IV, V

The HELIOSTAR Balloon Ablation Catheter, with the LASSOSTAR™ Catheter and CARTO® 3 System, allows physicians to provide more efficient ablation procedures, with lower procedure times and reduced fluoroscopy time and exposure³, potentially benefitting both the patient and physician. VI,VII,VIII Shorter procedure time may require less anesthesia and radiation and may result in less nursing and facility time. These time savings may also enable more procedures per day facilitating patient access. IX,X

The novel HELIOSTAR Balloon Ablation Catheter features ten gold-plated, irrigated electrodes that can be tailored based on anatomical location and known tissue thickness<sup>4</sup> enabling personalized ablation procedures for unique patient anatomies and arrhythmias.xi The amount of power delivered to each electrode can be controlled independently to provide electrophysiologists with greater customization, control and the ability to achieve pulmonary vein (PV) isolation in approximately ten seconds.\*

"Pulmonary vein isolation is a technically complex and time-consuming procedure so it's important that advancements in balloon ablation systems help electrophysiologists quickly and easily isolate the pulmonary veins, while maintaining safety," said Ahmed Abdelaal, Senior R&D Director and HELIOSTAR Project Leader at Biosense Webster. "The HELIOSTAR Balloon Ablation Catheter was developed with electrophysiologists in mind giving them the ability to perform personalized ablation procedures to better meet patient's needs."

In a multicenter single-arm study, SHINE, the HELIOSTAR™ Balloon Ablation Catheter was an effective treatment for paroxysmal atrial fibrillation (AF) and electrophysiologists isolated targeted pulmonary veins (PV) in 98.8% of patients without the need for focal touch-up.<sup>5</sup> On average, time to isolation of the pulmonary vein was approximately ten seconds, total procedure time was less than 90 minutes and dwell time was less than 40 minutes.\*6

"HELIOSTAR™ Balloon Ablation Catheter reaffirms our commitment to partnering with physicians to advance the practice of electrophysiology and to help change the lives of patients suffering from atrial fibrillation," said Uri Yaron, Worldwide President of Biosense Webster, Inc. "With CE mark approval and the first commercial procedures completed, we have made significant progress in providing electrophysiologists with another novel option for the safe and efficient treatment of this burdensome disease."

In Europe, full commercial availability is expected in 2022. In the United States, HELIOSTAR is an investigational device and is not approved by the U.S. Food & Drug Administration.

#### **About Biosense Webster**

Biosense Webster is the global market leader in the science and technology behind the diagnosis and treatment of cardiac arrhythmias. Part of the Johnson & Johnson Family of Companies, the specialized medical-technology company is headquartered in Irvine, Calif., and works across the world to advance the tools and solutions that help electrophysiologists identify, treat, and deliver care. Learn more at <a href="https://www.biosensewebster.com">www.biosensewebster.com</a> and connect on LinkedIn <a href="https://www.linkedin.com/company/biosense-webster">www.linkedin.com/company/biosense-webster</a> and Twitter <a href="https://twitter.com/biosensewebster">https://twitter.com/biosensewebster</a>.

# About Johnson & Johnson Medical Devices Companies

At Johnson & Johnson Medical Devices Companies, we are helping people live their best lives. Building on more than a century of expertise, we tackle pressing healthcare challenges, and take bold steps that lead to new standards of care while improving people's healthcare experiences. In surgery, orthopaedics, vision and interventional solutions, we are helping to save lives and paving the way to a healthier future for everyone, everywhere. For more information, visit <a href="https://www.injmedicaldevices.com">www.injmedicaldevices.com</a>.

#### Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding HELIOSTAR Balloon Ablation Catheter. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Biosense Webster, any of the other Johnson & Johnson Medical Devices Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of regulatory approvals; uncertainty of commercial success; challenges to patents; competition, including technological advances, new products

#### CAREER OPPORTUNITY





### Clincial Echocardiography Faculty

The Heart Institute (HI) at Cincinnati Children's Hospital Medical Center (CCHMC) seeks applications for a BE/BC Pediatric Cardiologist at the Assistant or Associate Professor level. The position will be clinically focused as part of the non-invasive imaging subsection with responsibilities primarily in echocardiography with fetal echocardiography responsibilities possible if desired by the candidate.

The HI is an internationally recognized academic center of excellence for Pediatric (congenital and acquired) and Adult Congenital Cardiac Care, and clinical and basic science research. The HI incorporates the Divisions of Congenital Heart Disease, Cardiothoracic Surgery and Molecular Cardiovascular Biology. It offers the full range of Pediatric Cardiac services within a free-standing not-for-profit tertiary care medical center. The HI also serves to train categorical Pediatric Cardiology and sub-specialty fellows in all areas of congenital heart disease practice (including 2 Advanced Imaging fellows). Academic appointment within CCHMC is through the Department of Pediatrics at the University of Cincinnati College of Medicine.

The Echo lab includes 13 imaging faculty and 22 cardiac sonographers and performs over 15,000 transthoracic, 500 transesophageal and 2500 fetal echocardiograms annually. The facility includes a state-of-the-art reading room as well as the necessary technology to perform all current advanced imaging techniques.

#### The applicant would be expected to participate in clinical service including (but not limited to):

- Perform/interpret transthoracic and transesophageal echocardiograms.
- Perform a single out-patient clinic on a weekly basis
- Provide limited periods of in-patient and/or consult service coverage
- Participate in all HI clinical and management conferences
- Perform teaching and instruction commensurate with the training mission of the HI/CCHMC

The Heart Institute and the Non-invasive Imaging Service pride themselves on excellent clinical outcomes. The acceptable candidate would be expected to maintain similar high standards of clinical service.

#### **Skills & Competencies**

- Knowledge of growth and development
- Understands and support family-centered care
- Professional knowledge and clinical ability sufficient to provide evaluation and treatment of complex patients in one or more specialty areas
- Knowledge of pathophysiology and pharmacology
- Knowledge and skill in patient and/or family education
- Understanding and showing respect and appreciation for the uniqueness of all individuals; leveraging differences in others' perspectives and ideas; appreciating cultural differences and adjusting one's approach to successfully integrate with others who are different from oneself
- Strong organizational and project management skills to handle projects independently.
- Excellent verbal, written and/or interpersonal communication skills

#### Required

- MD, DO, or equivalent degree
- Current active medical license issued by the State of Ohio or eligible for license
- Appropriate medical credentialing through the Medical Staff Services offices
- Completion of all required pre-employment activities
- Assistant or Associate Professor appointment or eligibility required

#### Preferred

Board certification

Interested candidates should submit a cover letter of interest and CV to: Andrew Redington, MD, Co-Director The Heart Institute, Cincinnati Children's Hospital Medical Center Andrew.Redington@cchmc.org

#### **MEDICAL NEWS**

and patents attained by competitors; manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of health care products and services; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither the Johnson & Johnson Medical Devices Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

- The Johnson & Johnson Medical Devices Companies comprise the surgery, orthopaedics, vision and interventional solutions businesses within Johnson & Johnson's Medical Devices segment
- Recommended first-line treatment for patients with symptomatic Paroxysmal AF episodes or persistent AF without major risk factors for AF recurrence, of as an alternative to AAD class I or III, considering patient choice, benefit, and risk.
- In a multicenter single-arm study, SHINE (n=95), fluoroscopy time was 10.9 ± 9.1 minutes in per-protocol population while in a multicenter single-arm study RADIANCE (n=40), fluoroscopy time was 17.4 ± 10.1 minutes without using LASSOSTAR™ Diagnostic Catheter.
- Tissue thickness is known per anatomical location or measured via intracardiac echocardiography.
- This data is based on 7 operators. PV isolation is defined as sustained PV entrance block on adenosine/ isoproterenol challenge. PV isolation is defined as sustained PV entrance block on adenosine/isoproterenol.

 SHINE study (n = 95, roll-ins = 8 patients). Per SHINE protocol, a roll-in phase of up to 3 patients per physician was implemented. Total procedure time: 87.6 ± 22.25 min. and dwell time: 40.3 ± 16.69 min.

\*In a multicenter single-arm study (SHINE, n=95), pure single shot isolation was achieved by one initial RF application (regardless of the duration of ablation). Time to isolation (mean  $\pm$  SD, sec) was 9.0  $\pm$  6.46 (LIPV), 12.0  $\pm$  11.58, (LSPV), 9.1  $\pm$  4.95 (RIPV), 8.9  $\pm$  6.22 (RSPV).

- Global Burden of Disease Collaborative Network (2016) Global Burden of Disease Study 2016 (GBD 2016) Results. Seattle, United States: Institute for Health Metrics and Evaluation (IHME), 2017. Accessed 2018-04-20. Available from http://ghdx. healthdata.org/gbd-results-tool.
- Zoni-Berisso M, Lercari F, Carazza T, Domenicucci S (2014) Epidemiology of atrial fibrillation: European perspective. Clin Epidemiol. 6: 213-220.
- iii. Walfridsson, Håkan, et al. "Radiofrequency ablation as initial therapy in paroxysmal atrial fibrillation: results on health-related quality of life and symptom burden. The MANTRA-PAF trial." EP Europace. 17.2 (2015): 215-221.
- iv. Blomström-Lundqvist, Carina, et al. "Effect of catheter ablation vs antiarrhythmic medication on quality of life in patients with atrial fibrillation: the CAPTAF randomized clinical trial." JAMA. 321.11 (2019): 1059-1068.
- v. Journal of Nursing: June 2019 Volume 119 - Issue 6 - p 18 doi:10.1097/01. NAJ.0000559795.09114.0b.
- vi. Calkins et al, 2017HRS/EHRA/ECAS/ APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation, Europace (2018) 20, e1–e160.
- vii. Schilling, R., Dhillon, G., Tondo, C., et al. Safety, Effectiveness, and Quality of Life Following Pulmonary Vein Isolation with a Multi-Electrode Radiofrequency Balloon Catheter in Paroxysmal Atrial Fibrillation: One Year Outcomes from SHINE. Europace (2021) 23, 851-860.
- viii. Dhillon G, Honarbakhsh S, di Monaco Antonio et al. Use of a multi-electrode radiofrequency balloon catheter to

- achieve pulmonary vein isolation in patients with paroxysmal atrial fibrillation: 12-Month outcomes of the RADIANCE study. J Cardiovasc Electrophysiol. 2020 Jun;31(6):1259-1269.
- ix. Klein G, Lickfett L, Schreieck J, Deneke T, Wieczorek M et al. (2015) Comparison of 'anatomically designed' and 'point-by-point' catheter ablations for human atrial fibrillation in terms of procedure timing and costs in German hospitals. Europace. 17 (7): 1030-1037.
- x. Yildiz M, Yilmaz Ak H, Oksen D,
   Oral S. Anesthetic Management In
   Electrophysiology Laboratory: A
   Multidisciplinary Review. J Atr Fibrillation.
   2018;10(5):1775. Published 2018 Feb 28.
   doi:10.4022/jafib.1775.
- xi. HELIOSTAR™ Balloon Ablation Catheter Clinical Evaluation Report 100503977 Rev 3; CO:100610371.
- xii. Grimaldi et al., Impact of Workflow Modifications in Atrial Fibrillation Ablation for Reducing the Incidence of Silent Cerebral Lesions with a New Multi-Electrode Radiofrequency Balloon Catheter, ESC 2019.
- xiii. Hindricks G et al. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): The Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. Eur Heart J. 2021 Feb 1;42(5):373-498.



# NEONATOLOGY TODAY Peer Reviewed Research, News and Information in Neonatal and Perinatal Medicine

Neonatology Today is interested in publishing manuscripts from Neonatologists, Fellows, NNPs and those involved in caring for neonates on case studies, research results, hospital news, meeting announcements, and other pertinent topics.

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#### **CAREER OPPORTUNITY**





### Interventional Pediatric Cardiologist

#### Successful Pediatric Cardiology Practice - Tropical Florida Coast

Pediatric Cardiology Associates, located in Tampa Bay on Florida's Gulf Coast, is seeking a BC Interventional Pediatric Cardiologist with advanced fellowship training and experience in Congenital Intervention.

- Ideally seeking candidates with a minimum of 5 years of experience post-fellowship
- Large, experienced, well-established team of 14 pediatric cardiologists and 3 NPs with offices and clinics located throughout the Tampa/St. Petersburg area
- Offer comprehensive congenital cardiac care from fetal life through adulthood
- The team includes members of all pediatric cardiology sub-specialties including: fetal, advanced imaging (CT, MRI, 3D echo), intervention, electrophysiology, cardiomyopathy/heart failure, prevention, and adult congenital
- The interventional team performs over 400 catheterizations per year, about 60% of which are interventions
- Recent interventional team accomplishments include:implanting their 150th transcatheter pulmonary valve, Summer 2019
  - First program in Florida to implant the Gore Cardioform ASD Occluder, Fall 2019
  - Only program in Tampa Bay currently offering PDA device closure for premature newborns, first implant, Winter 2016
- Sub-specialty clinics include general pediatric cardiology, intervention, pulmonary hypertension, cardiomyopathy, ACHD, electrophysiology, and prevention
- Our ACHD program is the ONLY certified Adult Congenital Heart Association program in central Florida
- This position also offers:
  - Full time interventional duties with expected procedural volume of 200+ catheterizations per year
  - No expectation of inpatient service coverage
  - 24/7 collaboration with our excellent pediatric cardiac surgical and pediatric cardiac intensive care teams at St Joseph's Children's Hospital
- Our center offers a unique depth of hospital infrastructure:
  - Two state of the art 1000+ square foot hybrid capable catheterization labs/ORs (one biplane, one single plane)
  - Two additional biplane catheterization labs
  - Two EP labs
- We have the added benefits of a children's hospital inside a large tertiary adult hospital simplifying care across all patient ages with easy access to consultants from all pediatric and adult specialties
- Pediatrix, as a national pediatric cardiology group with over 125 pediatric cardiologists, provides opportunities for quality initiatives that can have national impact
- We offer an attractive schedule allowing freedom to enjoy a great quality of life
- Generous compensation package offered

Tampa Bay's warm weather affords plenty of opportunities to relish the great outdoors year-round. You will live in a region others only get to enjoy on vacation. Golf at one of nearly 100 courses or relax on one of the many pristine white-sand beaches. The area offers an assortment of family venues such as zoos, aquariums, theme parks, and state parks. Additionally, Tampa Bay offers access to world-class museums, professional sporting events and the performing arts. There is a wide range of residential choices to fit every budget and lifestyle – whether you are looking for big city downtown living, golf course communities, waterfront lifestyle, majestic horse farms or historic neighborhoods.

#### **Benefits**

Our clinicians enjoy a competitive compensation package with many locations offering sign on bonuses, relocation and tuition reimbursement. \*Our benefits include:

- Health (various options), life, vision, dental and disability insurance
- 401(k) with annual matching program
- Advanced and continuing medical education
- Leadership training and advancement opportunities
- Employee stock purchase plan at a 15% discount
- Professional liability insurance
- Support and payment for mandatory license/s and hospital credentialing

\*These benefits are for full time employees, employees in other types of employment classifications may be eligible for some of these benefits.

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Mednax Services, Inc. is a national medical group. Over the last 40 years, through our network of over 3,500 clinicians in 39 states and Puerto Rico, we have reshaped care delivery within women's and children's specialties and subspecialties. Our clinical teams care for the unique population of high-risk pregnancies and critically ill infants and children in both hospital and ambulatory clinical settings. Over the years, clinicians practicing as part of Pediatrix™ and Obstetrix™ Medical Groups have used evidence-based tools, continuous quality initiatives, clinical research, and telemedicine to enhance patient experience, outcomes and provide high-quality, cost-effective patient care. Our nationwide team of almost 8,000 employees, including physicians, advanced practitioners, clinical leaders, business and operational experts, work together every day to fulfill our mission to take great care of the patient®. We invite you to join the Mednax family and help shape the future of health care. Find additional information at www.mednax.com.

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# Hackensack University Medical Center Heart Doctors are First in New Jersey to Perform Innovative Heart Failure Treatment

#### Promising Therapy is Offered Through Multicenter International Study

Interventional cardiologists and heart surgeons at Hackensack University Medical Center were the first in New Jersey to treat a patient with heart failure after a heart attack using a unique device that makes a weak, enlarged heart smaller — enabling it to pump blood more efficiently, relieving heart failure symptoms, and improving quality of life. The procedure is being evaluated through a clinical trial called ALIVE (American Less Invasive Ventricular Enhancement). Hackensack University Medical Center is participating in this study and is now enrolling eligible patients with heart failure and left ventricular scars and/or aneurysms.

Heart failure occurs when the heart becomes inefficient and weak, making it difficult for organs throughout the body to receive enough oxygenated blood to work effectively. Patients may experience shortness of breath, fatigue easily, have swelling in their legs, and develop other symptoms. When someone has had a major heart attack that causes scarring of tissue in the left ventricle of the heart (the chamber responsible for propelling freshly oxygenated blood out of the heart), the ventricle can become enlarged. An aneurysm can result, where part of the ventricle wall bulges out. In both cases, it becomes very difficult for the ailing heart to do its job.

The ALIVE study is evaluating the LIVE procedure (left invasive ventricular enhancement) in patients with heart failure who have left ventricular scars or aneurysms on the front of the heart and whose symptoms are not responding well to medical treatment. An interventional cardiologist and surgeon work together, taking a hybrid approach to implant the device components through a catheter threaded into the heart via a vein in the neck and a probe inserted through a 1-inch incision in the chest. Multiple anchors inserted into the heart pinch the area of dead tissue closed, excluding the non-functioning scar tissue from the rest of the heart and reshaping the healthy part of the heart to a more normal size.

This procedure is a promising alternative to traditional open-heart surgery to remove scarred heart tissue, which requires a large incision in the chest, attachment to a heart-lung machine, and a two-week hospital stay. "With the LIVE procedure, there is just a one-inch chest incision and the patient stays in the hospital for only two days," noted cardiologist Joseph E. Parrillo, MD, chair of the Heart and Vascular Hospital at Hackensack University Medical Center. "If successful, the patient experiences a relief of heart failure symptoms."

The LIVE device was approved in Europe and has been shown to improve function, such as a better ability to walk. At Hackensack University Medical Center, doctors performed the procedure in July 2021 in a 63-year-old man, reducing the volume of his left ventricle by 30% to a more normal size and already relieving his shortness of breath. Tests also showed that his heart is beating more effectively and that his ejection fraction (a measure of the strength of the left ventricle) has improved, too.

"This approach is very promising. It is not for everyone with heart failure, but for those with scar tissue in the heart, it offers another option," explained Tilak K.R. Pasala, MD, interim director, Structural and Congenital Heart Program and the structural interventional cardiologist involved in the first LIVE procedure at Hackensack University Medical Center.

"This minimally-invasive procedure has the potential to treat heart failure patients whose disease is beyond medications but not severe enough for

heart transplant or implantation of an external left ventricle assist device," added Mark B. Anderson, MD, the cardiac surgeon who participated in the groundbreaking LIVE procedure.

The ALIVE study is recruiting patients who:

- Have symptomatic heart failure (New York Heart Association functional class III or ambulatory class IV)
- Are referred for treatment of left ventricular scars/aneurysms on the front of the heart that are contiguous
- Have a left ventricular ejection fraction under 45%
- For more information or to inquire about being considered for this study, please contact 551.996.2136 or email <a href="mailto:Ann.TownsendSolis@hackensackmeridian.org">Ann.TownsendSolis@hackensackmeridian.org</a>

#### About Hackensack University Medical Center

Hackensack University Medical Center, a 771-bed nonprofit teaching and research hospital located in Bergen County, is the largest provider of inpatient and outpatient services in New Jersey. Founded in 1888, it was the county's first hospital. It was the first hospital in New Jersey and second in the nation to become a Magnet®-recognized hospital for nursing excellence, receiving its sixth consecutive designation in 2019 from the American Nurses Credentialing Center. The academic flagship of the Hackensack Meridian Health network, Hackensack University Medical Center ranked #1 in New Jersey and #7 in the New York metro area by U.S. News & World Report's 2021-2022 "Best Hospitals" Honor Roll. Hackensack University Medical Center is also rated as High Performing in 14 procedures and conditions, and sets the standard for all New Jersey hospitals in several specialties including New Jersey's only nationally-ranked Neurology & Neurosurgery and Urology programs; ranked nationally in Cardiology & Heart Surgery; New Jersey's Best Urology and Neurology & Neurosurgery programs since 2013; with Cardiology & Heart Surgery, Gastroenterology & GI Surgery, Geriatrics and Orthopedics ranked among the top in New Jersey. This award-winning care is provided on a campus that is home to facilities such as John Theurer Cancer Center, a consortium member of the NCI-designated Georgetown Lombardi Comprehensive Cancer Center and recognized as the #1 hospital for cancer care in New Jersey by U.S. News & World Report's 2021-22 "Best Hospitals" Honor Roll; the Heart & Vascular Hospital; and the Sarkis and Siran Gabrellian Women's and Children's Pavilion, which houses the Joseph M. Sanzari Children's Hospital and Donna A. Sanzari Women's Hospital, recognized as being in the top 1% of children's hospitals in the nation and #1 children's hospital in New Jersey by U.S. News & World Report's 2021-22 "Best Hospitals" Honor Roll; as well as the Deirdre Imus Environmental Health Center. Hackensack University Medical Center is listed on the Green Guide's list of Top 10 Green Hospitals in the U.S. Our comprehensive clinical research portfolio includes studies focused on precision medicine, translational medicine, immunotherapy, cell therapy, and vaccine development. The hospital has embarked on the largest healthcare expansion project ever approved by the state: construction of the Helena Theurer Pavilion, a 530,000-sq.-ft., nine-story building, which began in 2019. A \$714.2 million endeavor, the pavilion is one the largest healthcare capital projects in New Jersey and will house 24 state-of-the-art operating rooms with intraoperative MRI capability, 50 ICU beds, and 150 private patient rooms, including a dedicated 50-bed Orthopedic Institute.







# Chief of Pediatric Interventional Cardiology

The Heart Center at Driscoll Children's Hospital is recruiting for a Chief of Interventional Cardiology to lead and guide a robust program engaged in providing the highest standard of care for its patients.

The ideal candidate will be board certified in Pediatric Cardiology with at least five years of clinical experience in pediatric interventional cardiac catheterization and a proven history in a leadership role with vision and strategic planning.

This is a full-time employed position with the multispecialty group, Children's Physician Services of South Texas (CPSST). The position offers a sign-on bonus, highly competitive compensation package, medical benefits, disability, life insurance, excellent retirement plans, generous paid vacation days, paid holidays, CME allowance and malpractice insurance.

Driscoll Children's Hospital is a freestanding children's hospital in Corpus Christi, Texas. The Driscoll Heart Center team includes inpatient and outpatient cardiologists specializing in Echo, Fetal, CMR, Imaging, electrophysiology, interventional cardiology, congenital cardiac surgeons, cardiac anesthesiologists and intensivists. Driscoll is a regional referral center for South Texas with supporting practices in Laredo, McAllen, and Brownsville.

Corpus Christi, Texas is a wonderful place to work, live and play! This is a dynamic coastal city with miles of beautiful beaches, world-class sailing, fishing and windsurfing. The mild climate allows for year-round outdoor family activities such as golf, cycling, and tennis. The cost of living is low, and there is no state income tax.

#### Contact information:

Lori Smith Director of Physician Relations and Recruitment D. 361.694.5906 M. 361.331.1311 Lori.Smith@dchstx.org



# AngelMed Announces FDA Approval of Enhanced Real-Time Cardiac Detection Monitor

Monitor for Acute Coronary Syndrome (ACS) Events, AngelMed Guardian® System, Prompts High-Risk ACS Patients to Seek Medical Care

Angel Medical Systems, Inc., (dba AngelMed) a proactive diagnostics company focused on the advancement of long-term management of high-risk coronary disease, announced today the FDA approval of the second-generation AngelMed Guardian® device. The AngelMed Guardian System is the world's first implantable cardiac detection monitor and patient-warning system for acute coronary syndrome (ACS) events, including silent heart attacks. The new, second-generation device is enhanced with ease-of-use adaptations and an updated, long life battery that could potentially double the life of the implanted device.

The AngelMed Guardian device is implanted subcutaneously by a cardiologist during a low-risk, outpatient surgical procedure. Using a patented algorithm, the AngelMed Guardian continuously records the heart's electrical activity, 24 hours a day, monitoring for electrical changes that can indicate an impending ACS event. The AngelMed Guardian device provides a more effective diagnosis of a life-threatening condition when compared to patient symptoms alone.<sup>1</sup>

"Patients who have had a prior ACS event often remain at high-risk for a recurrent event. Even those patients who are on alert for another potential cardiac event may delay seeking treatment," said Dr. C. Michael Gibson, MD, Boston Clinical Research Institute. "The AngelMed Guardian System has demonstrated the ability to identify the earliest signs of an ACS event, including heart attacks, more effectively than patients' symptoms alone, and in patients who do not experience symptoms at all."

"The improved AngelMed Guardian device will have a meaningful effect on the current standard of patient cardiology care for ACS events. Our dedicated team and supporting physicians have worked tirelessly to bring this disruptive technology to market," said AngelMed Chief Executive Officer, Brad Snow. "As the first real-time detection device for high-risk heart attack patients, the AngelMed Guardian System provides critical data at the point of care, along with peace of mind for physicians and patients alike."

"Our key learnings based on hundreds of thousands of hours of clinical monitoring data for many ambulatory patients with



cardiovascular disease provides a technology platform for future offerings. Our patientcentric approach will drive our research and development," said Dave Keenan, AngelMed chief operating officer.

Every 40 seconds, someone in the U.S. suffers a myocardial infarction or heart attack.<sup>2</sup> The most important risk factors for another cardiovascular event in post-heart attack patients are age, medical history, comorbidities, and the severity of their first ACS event.<sup>3</sup> Despite proactive ongoing efforts over the last decade from the medical community to better educate the public on signs and symptoms of a heart attack, the time from symptom onset to arrival at a hospital remains static at eight hours.<sup>4</sup>

For more important safety information, please visit: <a href="www.angel-med.com/">www.angel-med.com/</a>.

#### About Angel Medical Systems, Inc.

Angel Medical Systems, Inc., is a proactive diagnostics company committed to advancing life-sustaining, personalized patient care, including the long-term management of highrisk coronary disease. Angel Medical Systems maintains a robust portfolio of U.S. patents relating to detecting cardiac events, including silent heart attacks.

- 1. Food and Drug Administration Website. Summary of Safety and Effectiveness Data. https://www.fda.gov/media/96475/ download. Accessed May 6, 2021.
- Centers for Disease Control and Prevention. (2012, August). NCHS data brief: Prevalence of Uncontrolled Risk Factors for Cardiovascular Disease: United States, 1999–2010 (No. 109). Retrieved from https://www.cdc.gov/nchs/data/ databriefs/db103.pdf.
- 3. Amsterdam EA, Wenger NK, Brindis RG, et al. 2014 AHA/ACC guideline for the management of patients with non-ST-elevation acute coronary syndromes: executive summary: a report of the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines. Circulation. 2014;130(25):2354-2394. doi: 10.1161/CIR.000000000000000133.
- Holmes DR, Krucoff MW, Mullin C, et al. Implanted monitor alerting to reduce treatment delay in patients with acute coronary syndrome events. J Am Coll Cardiol. 2019;22:2047-2055. doi: 10.1016/j. jacc.2019.07.084.



#### CAREER OPPORTUNITY







#### Outpatient Pediatric Cardiologist Opportunity – Northeast Ohio

Ohio-based Akron Children's Hospital seeks a *Pediatric Clinical Cardiologist* to join its expanding Heart Center. Akron Children's Hospital is the largest pediatric healthcare system in Northeast Ohio and is ranked among the best children's hospitals by US News and World Report.

This integrated healthcare delivery system includes:

- Two free-standing pediatric hospitals
- More than 800 providers, who manage over 1.1 million patient visits annually
- A network of more than 60 primary and specialty care locations
- Robust research and innovation endeavors

The successful candidate will provide Cardiology care at the Beeghly campus, expanding the services of the dedicated Heart Center team, which includes 16 pediatric cardiologists, 5 nurse practitioners and 2 cardiothoracic surgeons who provide a complete spectrum of coordinated, compassionate, cardiac care to over 10,000 patients annually. Services include: advanced diagnostics, complex surgical procedures, an adult congenital heart disease program, a fetal imaging program and a cardiac MRI program. Enjoy practicing in a comfortable community setting.

#### This position offers opportunities for:

- Partnership with an established team of Cardiologists affording exceptional work-life balance
- Active involvement in medical student and resident education; academic appointment at Northeast Ohio Medical University is available and commensurate with experience
- An attractive compensation plan that includes bonus compensation

Requirements include board eligibility/certification in Pediatric Cardiology and the ability to obtain an active medical license in the state of Ohio.

The Mahoning Valley is an exciting and vibrant place to live...outstanding parks, museums, theaters, art galleries, sport events, golf courses, country clubs, live concert and event venues, biking and hiking trails, lakes and much more provide residents with a dynamic choice of recreational opportunities. This area is successfully transitioning to a technology and knowledge-based economy by leveraging its industrial and academic strengths. In just the last two years, 107 businesses have invested \$682 million here, creating over 4500 new jobs!

Interested candidates may contact Jane Hensley, Physician Recruiter at 330-543-3015 or ihensley@akronchildrens.org. To learn more, visit our website at www.akronchildrens.org.

One Perkins Square | Akron, OH 44308 | akronchildrens.org





Division of
Pediatric Cardiology
Saint Louis University
School of Medicine
SSM Health
Cardinal Glennon
Children's Hospital

# Electrophysiologist

We are seeking a pediatric electrophysiologist to direct invasive and non-invasive electrophysiology services at our institution. Participation in outpatient clinic and inpatient care is also required. An interest in clinical research is encouraged. Academic rank will be commensurate with qualifications and experience.

The cardiology division is housed within the Dorothy and Larry Dallas Heart Center at SSM Health Cardinal Glennon Children's Hospital. The Heart Center opened in 2009 and underwent significant expansion in 2016. An active congenital heart surgery program exists, and the hospital houses state-of-the-art operating rooms, neonatal intensive care unit, pediatric intensive care unit, and a hybrid cardiac catheterization lab/operating suite. There is a dedicated bi-plane electrophysiology lab with 3-D mapping capabilities as well as trained lab staff, and a nurse practitioner dedicated to the EP service. SSM Cardinal Glennon Children's Hospital is a free-standing children's hospital and is staffed by faculty members of Saint Louis University School of Medicine.

Interested candidates may submit a cover letter and current CV to:

#### Renuka Peterson, MD

Associate Professor, Pediatric Cardiology Saint Louis University School of Medicine 1465 South Grand Blvd, St. Louis, MO 63104 T. 314.577.5633 F. 314.268.4035 E. renuka.peterson@health.slu.edu

#### **DECEMBER**

#### 03-04

CSI America 2021

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ICI for All 21 – Innovation in Cardiovascular Interventions Award

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https://icimed.org/ici-award/

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#### **FEBRUARY**

17-19

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11502 Elk Horn Drive Clarksburg, MD 20871 USA

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