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## Upcoming Medical Meetings

**PICS-AICS 2019**
*Sept. 4-7, 2019; San Diego, CA USA*
www.picsymposium.com

**2019 North American Society for Cardiac Imaging**
*Sept. 14-17, 2019; Seattle, WA USA*
www.nasci.org/Future-Meetings

**8th Annual Adult Congenital Heart Disease in the 21st Century**
*Oct. 4-5, 2019; Bethesda, MD USA*
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# Development of an Osteopenia Protocol in a Pediatric CVICU

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### Case Presentation

We had a six-month-old patient with Heterotaxy Syndrome and associated Complex Congenital Heart Disease, including: dextrocardia, malposition of the great vessels, hypoplastic pulmonary valve, tricuspid atresia, bilateral superior vena cavae, right aortic arch. He was admitted for a bilateral cavopulmonary anastomosis. Due to morbidity associated with his illness, he was hospitalized for three months. Midway through his stay, his daily x-ray was significant for healing rib fractures without any associated cause. Laboratory values showed significant hypovitaminosis D. Supplementation was started and the plan of care was changed to gentle handling. A week later, the nurse noticed he appeared to be in significant pain with movement. A femur x-ray demonstrated a healing proximal femur fracture. After ruling out all other causes for bone weakness, he was diagnosed with osteopenia. A multidisciplinary group at Children's Minnesota Cardiovascular Intensive Care Unit convened to discuss how to identify and treat this fragile patient population.

### Definitions

Once considered an "old person's disease," threats to bone health are increasingly common due to genetic illnesses affecting the bone, chronic illnesses and their medical treatments. Patients with osteopenia are at risk for inappropriate absorption and decreased bioavailability of essential electrolytes for bone growth, decreased bone mineral density, and if severe, fractures.

**Osteopenia** is defined as a decrease in the amount of organic bone matrix. There are not sufficient amounts of elemental materials to create strong bones.

**Osteomalacia** is defined as a lack of mineralization of the organic bone matrix. A sufficient amount of elemental materials to create bones exists, but it is not effective in creating strong bones.

**Rickets** is when the lack of mineralization involves the growth plate, stunting a child's growth.

**Osteoporosis** is a decrease in bone mineral density >2.5 SD from the norm. Unfortunately, the norm is poorly defined for pediatrics. The reason why a definition of "normal" has not been possible is the rates of bone growth and mineral accrual are more closely linked to pubertal and skeletal

maturation than to chronological age. The DEXA scan, which is the gold standard in diagnosing osteoporosis in adults, only provides a two-dimensional measurement of the three-dimensional skeleton. Several methods have been developed to account for bone size and create a "normal," for pediatrics; none of them have been effective.

Lastly, metabolic bone disease is the preferred term for osteopenia in pediatrics.

**Project Goals**

1. Identify risk factors which make patients more susceptible to osteopenia
2. Follow laboratory values to monitor these patients
3. Physical and occupational therapy for patients identified as high risk for osteopenia
4. Prevent future bone fractures

**Introduction**

The body of literature that describes osteopenia in the pediatric cardiac population is based primarily on expert opinions and a few case studies. What we learned was extrapolated from adult or premature infant literature. Cheng et. al assessed fractures in pediatric patients with Congenital Heart Disease and found patients with osteopenia had an increased mortality rate; hyperparathyroidism was present in the majority of their patients and low Vitamin D was present in almost half their population[1]. They found the creation of a protocol to identify and treat patients resulted in decreased numbers of fractures. Cross et. al discussed nursing implications for osteopenia in the premature patient, supporting the difference nursing interventions can make[2]. This study addressed nursing interventions to guide handling patients with osteopenia. Marrani et. al has a well-defined description of osteopenia: "all patients are 'at risk' of osteopenia until they have a fracture, when a definitive diagnosis can be made"[3]. The true incidence of pediatric osteopenia is difficult to assess, because there are very few effective methods of assessing bone demineralization. Bachrach et. al described what a comprehensive bone assessment should include in their study[4]. Khosla et. al discussed the risks and benefits of bisphosphonate use in children, which is an accepted treatment for osteoporosis in adults. Bisphosphonates lower fracture risk in large part by reducing the rate of bone remodeling as well as by increasing bone mass. Treatment with this medication class is not without risks, however. Some of the risks of bisphosphonate use include: electrolyte imbalances, renal toxicity, atrial fibrillation, osteonecrosis of the jaw, and subtrochanteric fractures[5]. Umass et. al explained how different chronic pediatric diseases contribute to the development of secondary osteoporosis[6].

| | Patient Distribution | % Distribution |
|---|---|---|
| **Gender Distribution** | Males 15<br>Females 15 | 50% Male<br>50% Female |
| **Age Range** | 27 Patients <1 yr of age<br>3 Patients >1 yr of age | 90% <1 yr of age<br>10% >1 yr of age |

*Table 1. Demographic Data*

| Patient Diagnosis | Total Patients with Diagnosis | % of Patients with Diagnosis |
|---|---|---|
| Balanced AV Canal | N = 5 | 17% |
| Hypoplastic Left Heart Syndrome | N = 5 | 17% |
| Tetralogy of Fallot with Absent Pulmonary Valve | N = 3 | 10% |
| Tricuspid Atresia | N = 3 | 10% |
| Dextro-Transposition of the Great Arteries | N = 3 | 10% |
| Double Outlet Right Ventricle | N = 3 | 10% |
| Total Anomalous Pulmonary Venous Return | N = 2 | 7.66% |
| Shone Complex with Aortic Arch Hypoplasia | N = 1 | 3.33% |
| Coarctation of the Aorta | N = 1 | 3.33% |
| Unbalanced AV Canal | N = 1 | 3.33% |
| Interrupted Aortic Arch | N = 1 | 3.33% |
| Atrial Septal Defect | N = 1 | 3.33% |

*Table 2. Patient Diagnosis*

**Team Development**

This information was shared with a multidisciplinary group charged with the creation of an algorithm to identify and treat these patients. The multidisciplinary group was comprised of representatives from cardiac intensive care nursing, cardiac intensive care medicine, pediatric endocrinology, pediatric radiology, nutrition, pharmacy, physical and occupational therapy, pediatric orthopedics and information technology. Everyone brought a unique perspective to the group and contributed different information to help better refine various aspects of the algorithm.

# RIGHT DESIGN.

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**Contraindications:**

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath
- Implantation of the TPV in the left heart
- RVOT unfavorable for good stent anchorage
- Severe RVOT obstruction, which cannot be dilated by balloon
- Obstruction of the central veins
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- Active endocarditis
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- Pregnancy

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**Step 1 - Patient identification**

Based on the available literature and expert opinions, we were able to identify medical conditions or treatments that would put a patient "at high risk" for osteopenia. Risk factors were weighted to reflect contribution toward bone demineralization. Each week, the unit dietitian evaluates patients and assigns an osteopenia risk score. Patients who receive an "at-risk" score are initiated on the protocol.

**Step 2 - Screening laboratory and radiologic tests to establish the patient's baseline values**

We test for serum calcium, phosphorus, alkaline phosphatase, urine calcium/creatinine ratio, vitamin D and assess a skeletal survey. We found that wrist/knee x-rays were not sufficient to identify bone demineralization; therefore, we switched to full skeletal surveys. While not without risks, it was found to be the most comprehensive radiologic test and provides the most complete information about the patient's bone health. The initial lab results dictate which treatment arm of the algorithm each patient follows. These are management of calcium, phosphorus and vitamin D abnormalities and assessment of underlying calciuria. Endocrinology is consulted on patients with a diagnosis of osteopenia. Special handling signage is posted at the bedside of all patients initiated on the protocol as a visual reminder to all caregivers that special handling precautions must be observed. All patients receive a physical and occupational therapy consult for gentle stretching and joint compression exercises. Patient and Family Education materials are provided as well. If we identify bone fractures, orthopedics is consulted.

| Findings | | |
|---|---|---|
| Hypovitaminosis D | 16 patients | 53% |
| Hypophosphatemia | 14 patients | 47% |
| Elevated Urine Calcium: Creatinine ratio | 11 patients | 37% |
| Expired | 8 patients | 27% |
| Hypocalcemia | 2 patients | 7% |
| Fracture Incidence of Patients off Protocol | 2 patients | 0.4% |
| Nephrocalcinosis | 1 patient | 3% |
| **Opportunities for Improvement** | | |
| Fracture Incidence of Patients on Protocol | 6 patients | 20% |

*Table 3. Clinical Data of Patients on Osteopenia Protocol.*

**Results**

Between January 2017 and April 2019, 30 patients were initiated on the osteopenia protocol. The algorithm went through multiple revisions in order to avoid triggering unnecessary laboratory tests and adding cost to patient care. The most common risk factors for triggering the protocol were: long term diuretic use, total parenteral nutrition and steroid use. The gender distribution was even, see Table 1. The age range was predominantly <1 year of age, with 28 patients under a year triggering the protocol. The most commonly utilized treatment arm of the protocol was the hypovitaminosis D arm. Thirteen patients followed multiple treatment arms. Patients who triggered the protocol were the sickest patients on the unit. This is reflected in the mortality data. Eight patients or 27% expired while on the protocol.

**Discussion**

Developing an osteopenia protocol is an important tool to identify and treat patients with demineralization in the Cardiac Intensive Care Unit. This patient population has the highest morbidity amongst pediatric cardiac patients. Input of a multidisciplinary team is essential in this process. The osteopenia protocol trial has provided many opportunities for continued education and improvement. Two patients with osteopenia were diagnosed with a fracture before they were initiated on the protocol. Six patients in two years were diagnosed with fractures while being treated on the protocol. There were no common denominators found regarding the type of fractures patients were experiencing. Fractures of the humerus, femur and vertebrae were the most commonly diagnosed. Our first intervention to address the fractures was

| **Treatment Arm** | Hypovitaminosis D | Nephrocalcinosis | Hypophosphatemia | Elevated Urine Calcium: Creatinine Ratio |
|---|---|---|---|---|
| **Length of Stay Mean** | 86 days | 135.4 days | 20.3 days | 34.2 days |
| **Fracture** | 3 patients | 0 patients | 1 patient | 2 patients |
| **Number in Treatment Arm** | 16 patients | 1 patient | 16 patients | 11 patients |
| **Morality** | 2 patients | 0 patients | 7 patients | 4 patients |

*Table 4. Fracture and Mortality Results per Treatment Arm. Thirteen patients followed multiple treatment arms.*

# Osteopenia Protocol

## Risk Factors

Risk Factor Score is noted in parenthesis

- Hx atraumatic bone fracture **(12)**
- Rickets **(12)**
- Osteogenesis Imperfecta **(12)**
- Current ALL/Leukemia **(6)**
- Crohn's Disease **(6)**
- Rheumatoid Arthritis **(6)**
- Hx of solid organ transplant **(6)**
- Anorexia Nervosa **(6)**
- Previous osteopenia diagnosis **(4)**
- >5 days of glucocorticosteroids **(4)**
- TPN > 4 weeks **(4)**
- Severe malnutrition **(4)**
- Immobility ≥14 days **(4)**
- >4 wk 3x normal creatinine or dialysis **(4)**
- Heparin use for >4 weeks **(3)**
- Loop diuretics/fluid restriction≥4wk **(3)**
- VACTERL, DiGeorge, 22q11 or FISH microdeletion **(3)**
- J-tube fed **(3)**
- < 1 year corrected age or weight <2000gm **(3)**
- Chylothorax - current **(3)**
- History of NEC or malabsorption **(3)**
- Chronic use of phenytoin, pheobarb, or carbamazepine **(3)**

**Any patient scoring ≥ 10 points should be discussed for risk and ≥ 12 points should progress to screening for further assessment. All patients designated as at-risk should receive the precautions outlined below.**

## Precautions/ Preventative Treatment

For all patients identified as at-risk

- RN/Provider/Parent education regarding careful handling (RN to educate parents)
- https://www.childrensmn.org/educationmaterials/childrensmn/article/17174/osteopenia/
- Post "Careful Handling" sign on bed
- Dietitian to note Osteopenia Risk on the Nutrition Assessment - Pediatric
- RN to ensure staff outside unit are aware of risk when applicable (MRI, off-unit procedures)
- PT/OT consults (ROM exercises, use of Z-flo to create resistance boundaries, Joint Compression Protocol)

## Screening Tests

Values listed are the normal ranges

- **Alkaline Phosphatase: <**668 males <12mo. and <610 females <12mo.
- **Serum Phosphorus: >**5mg
- **Serum Calcium: >**8mg/dl
  - If low, check iCa and PTH. Always check PTH if DiGeorge or VACTERL
- **Vitamin D (25-OH): >**32ng/ml
- **Urine Calcium/Creatinine Ratio**: <7mo <0.86; 7-18m < 0.6, 19m - 6y <0.42, adult < 0.21
- **Skeletal Survey**

### Treatment Instructions

Once screening tests have been completed, proceed to appropriate treatment option (next page). If patient does not meet one of the defined treatment categories, provider to use their discretion on best treatment course and communicate plan with dietitian.

Owner: Heidi Shafland. Last Modified: 05/26/17 by A. Franz. *Disclaimer: This guideline is designed for general use with most patients; each clinician should use his or her own independent judgment to meet the needs of each individual patient. This guideline is not a substitute for professional medical advice*

Children's MINNESOTA

*Figure 1. Children's Minnesota Osteopenia Algorithm*

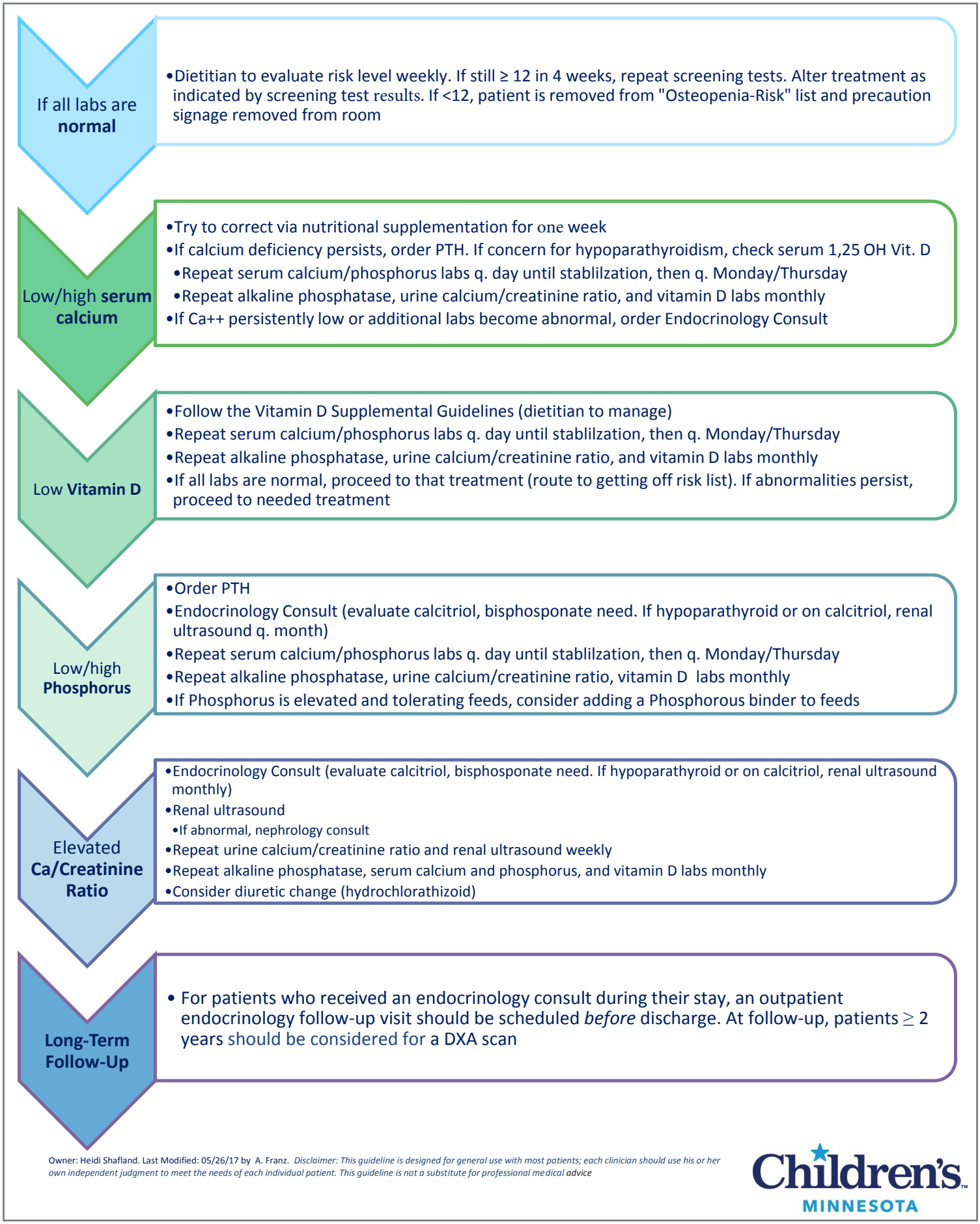


*Figure 1 continued. Children's Minnesota Osteopenia Algorithm*

an educational push to clarify what safe patient handling means. How should diapers be changed on these patients? How should they be lifted? Due to the paucity of literature supporting one intervention over another, we used an innovative approach to stabilize and mobilize patients, by physical and occupational therapy, providing bedside charts and daily instructions to the nursing staff and parents. We recommend two people for nursing care, log rolling for diaper changes and scooping the body when lifting.

One identified trend is, some patients' laboratory values were within normal limits, while still experiencing fractures. This led us to revisit our calcium and phosphorus management in total parenteral nutrition as well as Vitamin D administration protocol. It is common practice to provide post-pyloric feeds to critically-ill infants. Vitamin D is primarily absorbed in the duodenum; therefore, by administering it jejunely, it is not being absorbed to its fullest extent. Our patient population, depending on their severity and chronicity of illness, fluctuate between periods of feeding and being NPO. During NPO periods, we have advised Vitamin D to be continued. Lastly, weekly osteopenia rounds were initiated. The dietitian, intensive care physician, occupational therapist and clinical nurse specialist round on all the children who were on the protocol to ensure their initial and follow-up labs were ordered, their vitamin D was being administered per protocol, and there was signage for the nurses and families present in the room.

**Next steps**

Education regarding safe patient handling for this fragile patient population continues. We are in the process of rolling out the protocol to the Pediatric ICU and Neonatal ICU, then to the rest of the hospital floors. We continue gathering data and assessing whether the identified risk factors correlate with disease severity and are in the process of creating a bisphosphonate treatment protocol. Creating the protocol has positively impacted the health of critically-ill patients in our cardiac intensive care population.

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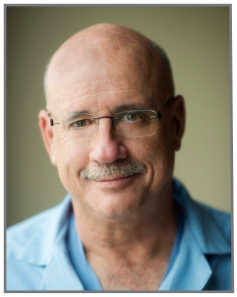

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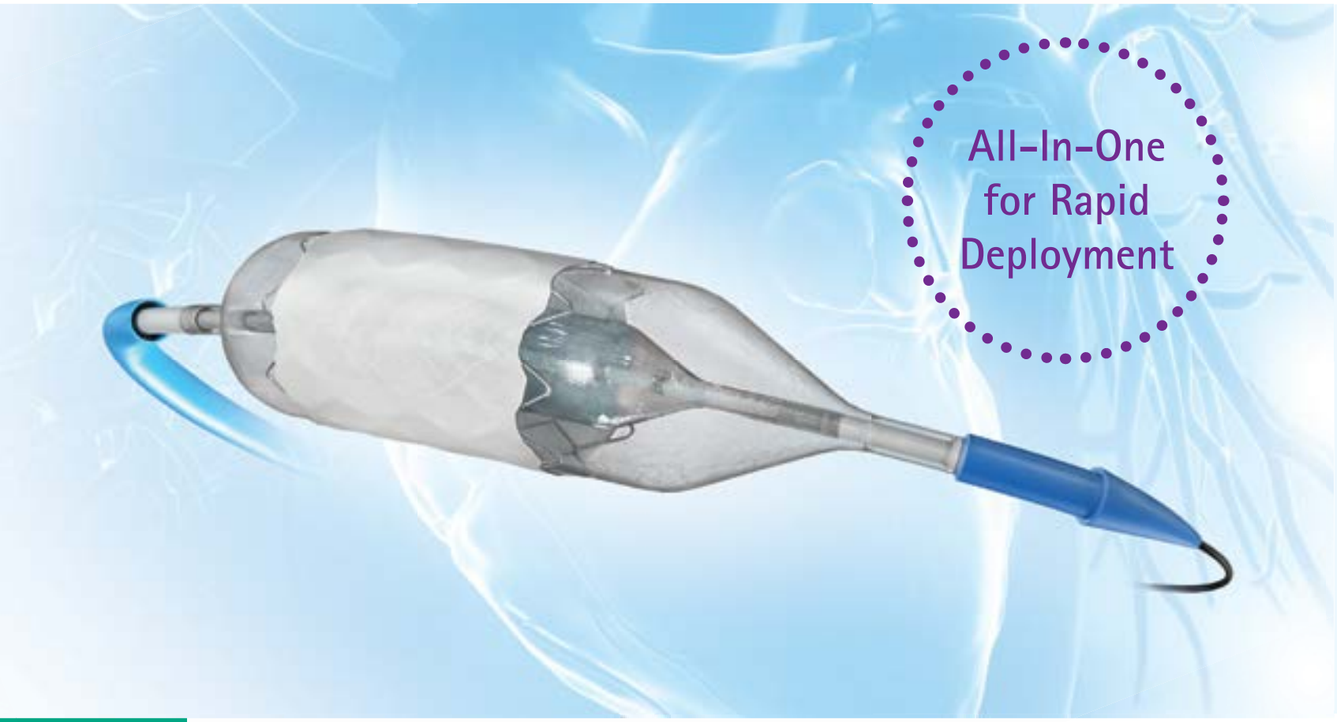


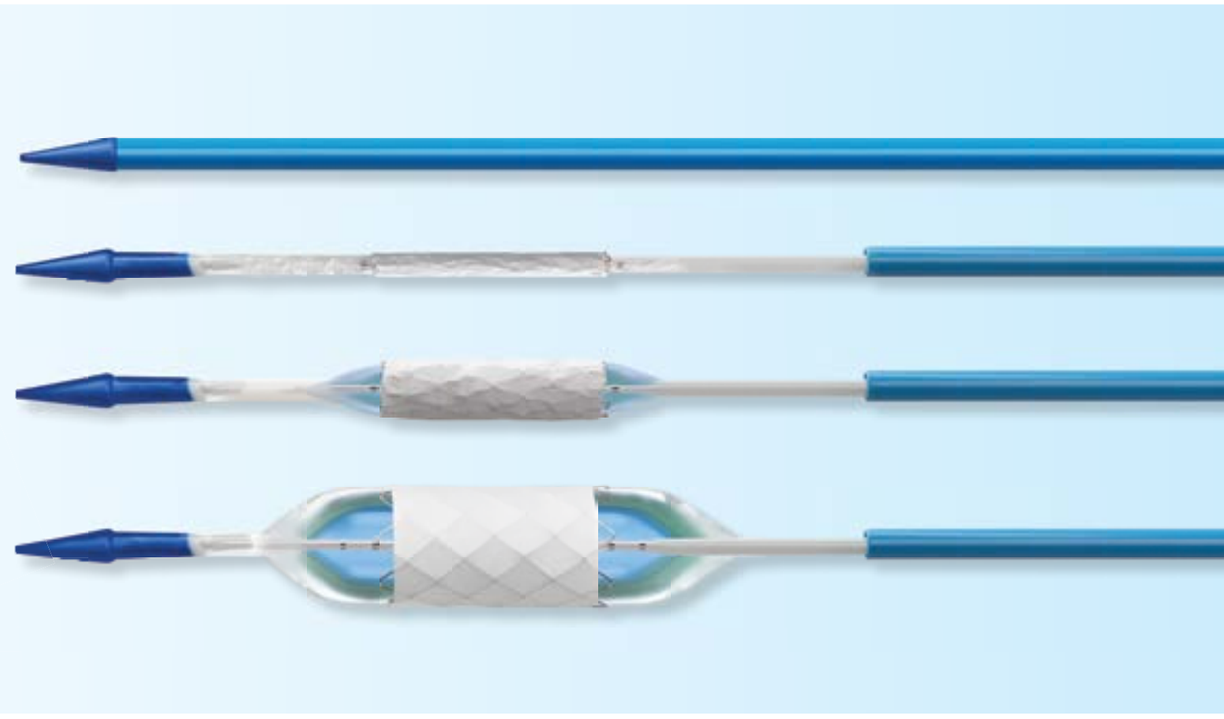

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**Indications for Use:** The NuDEL is indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta where there is adequate size and patency of at least one femoral artery associated with one or more of the following: acute or chronic wall injury; nearly atretic descending aorta of 3 mm or less in diameter; a non-compliant stenotic aortic segment found on pre-stent balloon dilation; a genetic or congenital syndrome associated with aortic wall weakening or ascending aortic aneurysm.

**Indications for Use:** The NuDEL is indicated for use in the treatment of right ventricle to pulmonary artery (right ventricular outflow tract) conduit disruptions that are identified during conduit pre-dilatation procedures performed in preparation for transcatheter pulmonary valve replacement.

**Caution:** Federal (USA) Law restricts this device to sale by or on the order of a physician. **Contraindications:** Clinical or biological signs of infection. Active endocarditis. Pregnancy. **Contraindications (CoA only):** Patients too small to allow safe delivery of the stent without compromise to the systemic artery used for delivery. Unfavorable aortic anatomy that does not dilate with high pressure balloon angioplasty. Curved vasculature. Occlusion or obstruction of systemic artery precluding delivery or the stent. Known allergy to aspirin, other antiplatelet agents, or heparin. **Contraindications (RVOT only):** Patients too small to allow safe delivery of the stent without injury to a systemic vein or to the right side of the heart. **Warnings / Precautions:** Administer appropriate anticoagulation therapy to reduce potential thrombosis. If the patient is not appropriately anticoagulated, thrombus formation may occur. The sheath must be flushed with heparinized saline via the proximal side port prior to introducing the delivery system into the body. The inflated diameter of the stent should at least equal the diameter of the intended implant site. Excessive handling and manipulation of the covering while crimping the stent may cause the covering to tear off of the stent. Retracting the covered stent back into the sheath may cause the covering to catch and tear off of the stent. Do not exceed the RBP. An inflation device with pressure gauge is recommended to monitor pressure. Pressure in excess of the RBP can cause balloon rupture and potential inability to withdraw the catheter into the sheath. Confirm that the distal end of the introducer sheath is at least 2.5cm back from the most proximal image band before inflating the outer balloon. Failure to do so may stretch the outer tubing and severely hinder balloon deflation. Exercise caution when handling the stent to prevent breakage. The NuDEL system, especially at the stent, is rigid and may make negotiation through vessels difficult. The inflation diameter of the balloon used during stent delivery should approximate the diameter of the obstructive vessel and the intended implant site. If resistance is encountered upon removal, the whole system (balloon, guidewire and sheath) should be removed as a single unit, particularly if balloon rupture or leakage is known or suspected. **Warnings / Precautions (CoA only):** Coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta should be confirmed by diagnostic imaging. The NuMED CP Stent has not been evaluated in patients weighing less than 20kg. The platinum/iridium stent may migrate from the site of the implant. As with any type of implant, infection secondary to contamination of the stent may lead to aortitis, or abscess. Over-stretching of the artery may result in rupture or aneurysm formation. **Warnings / Precautions (RVOT only):** During the Premarket Approval study the Medtronic Melody valve was used for valve restoration. The safety and effectiveness of the Covered CP Stent for pre-stenting of the right ventricular outflow tract (RVOT) landing zone (i.e. prophylaxis or prevention of either RVOT conduit rupture or TPVR fracture; use as a primary RVOT conduit) in preparation of a transcatheter pulmonary valve replacement (TPVR) has not been evaluated. As with any type of implant, infection secondary to contamination of the stent might lead to endocarditis, or abscess formation. The Covered Stent can migrate from the site of implant potentially causing obstruction to pulmonary artery flow. Over-stretching of the RVOT may result in rupture or aneurysm of the RV-PA conduit or the native pulmonary artery. **Reference the IFU for a complete listing of indications, contraindications, warnings and precautions. www.bisusa.org**

**Rx only**


CV-9107 6/19

# SCAI 2019: Congenital Track Hosted a Blowout in Las Vegas!

*By John Moore, MD, MPH, FSCAI*

Hey! If you weren't in Las Vegas on May 19th to 22nd, you missed it.… You will definitely want to come to Atlanta next year to join this Party! We were having so much fun, that the adult interventionists were lined up to peek into our room to find out what all the laughter and applause was about. Yes, there was virtual reality, and there were songs, games and libations. We rolled in a full bar during the Jeopardy Session, just to fuel the party.

We had an airline pilot tell us about check lists and safety in his industry, an interventional radiologist teach us about embolization procedures beyond coiling, and a neonatologist talk about the role of device PDA closure in preemies. There were lots of out of the box ideas to expand our thinking. We learned the results of the late breaking Harmony, Altera, and Piccolo Trials from trial investigators Lee Benson, Vivian Dimas, and Brian Morray. Matt Crystal and Frank Ing ran a great 'I Blew It' session. Dennis Kim blew past the competition with his 'Elephant Trunk' Case. Imagine using two vascular grafts, two transcutaneous pulmonary valves and all the associated stuff; and have the case go South!

Dennis "pulled it out," but after eight hours. The Clap Meter registered off the scale. Dennis won this, hands down!

And Neil Wilson gave a most memorable Mullins Lecture: "The Agony and the Ecstasy of the Interventional Cardiologist—Bomb Disposal for Cowards." His message: We do high-risk complex stuff; if things go well the patient gets defused, if not the patient may suffer an explosion; and we get to feel the ecstasy of success or suffer the agony….

To punctuate his message, Neil accompanied by Dan Gruenstein, serenaded the audience with Neil's original song:

**The Cath Lab Calypso**

*If life in the clinic is getting you down so bad you just can't mention.*
*Come to the cath lab, lose that frown, with intervention.*

***Refrain: Intervention, Intervention balloon and stent a coarctation. Come on get with it, just inflate it!***

*I went to the cath lab, went to see, Zahid Amin close an ASD.*
*T'was the biggest hole you ever did see, oh the agony and ecstasy!*

***Refrain: Intervention, Intervention...***

*I said Zahid take Shak's advice, be sure to use a big device.*
*But he'd seen erosions more than twice, and sadly chose a small device.*

***Refrain***

*Device was released with echo guide, quickly moved and embolised.*
*That's OK, get the gooseneck snare! But we couldn't find the Amplatz anywhere!*

***Refrain***

*Amongst the looks of consternation we found the device at the bifurcation.*
*Good Zahid said 'I don't care' he got it out with the gooseneck snare!*

***Refrain***

*Thanks for hearing our cath lab tale, we hope your time in the lab don't fail,*
*Go to the lab, go there soon, keep kids out of the operating rooms.*

***Refrain***

In addition, to the new and fun stuff, the Track provided a comprehensive congenital interventional curriculum and lots of 'bread and butter' sessions for practitioners. The meeting was organized by age with Monday devoted to infants, Tuesday to kids and Wednesday to adolescents and adults. Topics were introduced by experienced operators who showed videos of live cases. The cases were followed by full discussions of the community's historical experience with the procedure and of what's new in the areas touched by the cases.

Our Track featured a workshop on PDA Closure in Premies. This procedure, pioneered by in large part by Evan Zahn, was new to many of the Track attendees. The workshop provided by Brian Morray, Shyam Sathanandam, John Breinholt, and Darren Berman was, in essence, a detailed course on “how to do” the procedure and “how to select” patients for it. There was lots of interest….

Another highlight of the Program was the live case provided by Jasvindar Singh, John Lasala and David Balzer from Washington University in St. Louis. They demonstrated implantation of a Sapien 3 Valve in an adult with Tetralogy of Fallot, status post Trans-annular Patch repair.

And this year for the first time; *PIECES* (*The Pediatric Interventional Cardiology Early Career Society*) organized its own session (as part of the main program) about ‘Getting Out of Trouble.’ Ryan Callahan and Sara Trucco led a great case-based session with words of wisdom from Frank Ing.

Take my word for it, there was a lot more in the Congenital Track at *SCAI 2019 Scientific Sessions* that you want to know about! One way to get access to the entire program if you are a *SCAI* member is to use the On Demand Portal. If you’re not a member, find one, or better yet, join up!

Keep an eye out for news of *SCAI 2020* Congenital Track being organized by Lee Benson, Dan Gruenstein and Julie Vincent!


**John Moore, MD, MPH, FSCAI**

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# CME Spotlight: Treating Adult Congenital Heart Disease

*By Anitha S. John, MD, PhD*

A two-day Continuing Medical Education (CME) conference for physicians and clinicians treating patients with Adult Congenital Heart Disease (ACHD) will be held Oct. 4th-5th, 2019, at the Bethesda Marriott in Bethesda, Maryland.

The eighth annual conference, *Adult Congenital Heart Disease in the 21st Century*, hosted by Children's National Health System and MedStar Washington Hospital Center provides a comprehensive review of the evaluation, diagnosis and management of ACHD, including guidelines to help ACHD patients manage a healthy pregnancy and clinical guidance about the progression of Congenital Heart Disease (CHD) treatment from adolescence through adulthood.

Two tracks accommodate these themes, with the first track focusing on a multidisciplinary approach that clinicians, can use to help manage patients with Complex Heart Disease through pregnancy. The second track focuses on cardiac defects, starting with anatomical cardiac lessons with 3D heart models, then moving to imaging review and examining echocardiograms and MRI's; it ends with a clinical management review.

"This conference brings together the best science and the most innovative approaches to treatment with questions doctors receive in the exam room," says Anitha John, MD, PhD, the conference organizer and Director of the Washington Adult Congenital Heart Program at Children's National. "We're also inviting patients to join us the afternoon of October 5th to support shared knowledge of these concepts, which supports lifelong treatment and education." Dr. John planned this year's conference with the November 6th ACHD board exams in mind, integrating topics that will appear on the third ACHD certification exam issued by the American Board of Internal Medicine.

At this year's CME conference, more than a dozen faculty members, including several physicians and nurses from Children's National, will guide lectures to help attendees meet 13 objectives, from understanding the prevalence of Congenital Heart Disease and its complications, to learning about when surgical interventions and referrals to specialists are necessary.

Attendees will review new and innovative PAH therapies, mechanical support therapies and catheter-based procedures, as well as appraise the use of pacemaker and defibrillator therapy among adults with CHD.

Patients and families attending the patient sessions, held from 12:30 to 3:45pm on Saturday, October 5th, have a chance to participate in three sessions that support the medical and social needs of ACHD patients. Topics range from workshops that address the neurodevelopment and psychosocial factors of living with a congenital heart defect to sessions that focus on reproductive options for patients and personalized lifestyle recommendations, including fitness and exercise guidelines.

"To support cardiovascular health throughout the lifespan, it helps to educate patients about their heart's structure and unique needs," notes Dr. John. "We want to spark a dialogue now and have future conversations with patients, especially while they are young."

*Dr. Anitha John, third from right, Director of the Washington Adult Congenital Heart Program, hosts the Eighth Annual "Adult Congenital Heart Disease in the 21st Century" Conference.*

The American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines updated ACHD treatment recommendations in August 2018, the first time in 10 years, and many of these guidelines manifest as panel discussions and interactive lectures presented at the *2019 Adult Congenital Heart Disease in the 21st Century Conference*.

Attendees can receive up to 12.5 credits from the Accreditation Council for Continuing Medical Education, the Accreditation Council for Pharmacy Education, the American Nurses Credentialing Center and the American Academy of PAs.

Those interested in starting their own ACHD program can attend an evening symposium, entitled "ACHD Program Building 101," hosted by representatives from the Mid-Atlantic ACHD Regional Group. Topics in the six-session panel range from managing ACHD patients in a pediatric hospital setting to the role of clinical nurse coordinators in ACHD care.

To learn more about or to register for the conference, visit www.CE.MedStarHealth.org/ACHD.

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# Medical News, Products & Information

*Compiled and Reviewed by Kate Baldwin and Tony Carlson*

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**Digisonics Receives ASE Certification for the ImageGuideEcho™ Registry**

The *American Society of Echocardiography (ASE)* is pleased to announce that Digisonics has received Certification as a Software Reporting Vendor for the ImageGuideEcho™ Registry. Practitioners utilizing the Digisonics Cardiovascular Information System, DigiView, will be able to seamlessly transmit real-time data to the ImageGuideEcho™ Registry and thereby avoid manual data entry and workflow modification.

"Seamless data submission through Certified Software Reporting Vendors is critical to the success of the ImageGuideEcho Registry," says Registry Committee Chair Sherif F. Nagueh, MD, FASE. "Digisonics' certification represents a key in the registry's growth and allows Digisonics' customers to participate in the registry with minimal impact on workflow – a goal identified early on by registry participants and *ASE*. Ease of data submission combined with free *ASE* member participation in ImageGuideEcho will only expedite the registry's tremendous growth to date."

"Digisonics strives to provide the 'best of class' clinical interpretation solutions for PACS and structured reporting for the field of echocardiography," says Digisonics CEO Diana McSherry, PhD. "By partnering with *ASE* and the ImageGuideEcho™ Registry through Software Vendor Certification, Digisonics is pleased to provide its customers with this integrated solution for improving quality through registry participation for the benefit of practices and patients alike."

ImageGuideEcho exists to assess specific quality metrics and patient outcomes as a vehicle to drive technology application and quality improvement within the field of Echocardiography for the benefit of patients, physicians, researchers, and other stakeholders. Participation in the Registry is free for *ASE* members in 2019. *ASE*, together with the support of its partners Lantheus Medical Imaging, Bracco Diagnostics, and the National Board of Echocardiography, is underwriting the cost of the enrollment to benefit the field of cardiovascular ultrasound.

Those who are interested in participating in the ImageGuideEcho™ Registry through *ASE's* partnership with Digisonics DigiView Software can visit www.Digisonics.com or contact info@digison.net. For more information on the registry itself and enrollment, please visit www.ImageGuideEcho.org or contact info@imageguideecho.org.

*About ASE*

*ASE* is the *Society for Cardiovascular Ultrasound Professionals™*. Over 17,000 physicians, sonographers, nurses, and scientists are members of *ASE*, making it the largest global organization for cardiovascular ultrasound imaging and as such the leader and advocate, setting practice standards and guidelines for the field. The Society is committed to improving the practice of ultrasound and imaging of the heart and cardiovascular system for better patient outcomes. For more information about *ASE*, visit www.ASEcho.org.

*About Digisonics*

Digisonics provides top-rated clinical image management and structured reporting systems for Cardiology (CVIS), Radiology, and Obstetrics & Gynecology. Digisonics structured reporting solutions combine high performance image review workstations, a powerful PACS image archive, an integrated clinical database, comprehensive analysis capabilities and highly configurable reporting for multiple modalities. Key applications are complemented with interfaces to information systems and 3rd party vendors, providing facilities with a seamless, efficient clinical workflow. To learn more, please visit www.Digisonics.com.

**InfoBionic: Cardiac Monitor Disrupts Current Remote Monitoring with "Full Disclosure Beat-to-Beat" Technology**

Legacy devices could only record segments of data over short periods of time – providing only partial data and having it downloaded and analyzed by a third party. A new generation of remote cardiac monitors allows for near real-time full disclosure remote monitoring of every single heartbeat for improved physician review, diagnosis and reporting.

More than 50% of clinically significant cardiac arrhythmias are recorded after the typical 48-hour monitoring period typical for Holter monitors. These legacy monitors rely on the patient to activate the device when they experience symptoms, but nearly 90% of patients cannot recognize themselves as being at high risk prior to an actual heart attack. Without a continuous 24-hour capability, doctors often miss the critical minutes before the patient activates the device.[1] According to Stuart Long, CEO of InfoBionic, a leading digital health company, new developments in remote cardiac monitoring are enabling cardiologists to see a complete readout of cardiac data in near real time – as it's happening – while shaving valuable days off of the time-to-diagnosis.

About 610,000 people die of Heart Disease in the US every year and 47% of sudden cardiac deaths occur outside a hospital.[2] Tests such as electrocardiograms enable a cardiologist to look at a patient's heart activity at rest and at one point in time. But abnormal heart rhythms and cardiac symptoms may come and go most often without the patient even knowing it. The main purpose of an event monitor is to record the heart rate and rhythm during a symptom ("event"). They work only

when a person interacts with the device to log the symptom they feel. The doctor may recommend an event-monitor when symptoms are infrequent – less than daily.

A Holter monitor provides a more complete picture of heart activity but requires the patient to return the unit to the physician's office after a period of days and wait for results while the cardiologist sends the data to a third-party diagnostic for analysis.[3] In a scenario where the monitor diagnosis eventually shows evidence that an arrhythmia has occurred, the delay puts the patient at risk.

Thanks to advances in data storage, transmission and machine learning, a new generation of remote cardiac monitors enables 24/7 monitoring, combined with sophisticated data analysis to help physicians cut through large amounts of data. Cardiologists can now monitor a patient's every heartbeat over extended periods and identify potentially dangerous arrhythmias as they happen — all via convenient HIPAA-compliant access through any internet connected device such as a PC or mobile device.

Now doctors can fit a patient with a device and get immediate and current data over a secure cell phone connection. If a patient calls experiencing symptoms, the cardiologist can quickly see the patient's up-to-the-minute data on a cell phone, tablet or PC – and make a critical cardiac arrhythmia diagnosis instantly. This is a dramatic alternative to having a patient return with a legacy cardiac monitor, then uploading the data to a third-party provider. "What we developed is a non-emergency, virtual telemetry-type station – that doctors can hold in their hand," described Stuart Long, CEO of InfoBionic. "The ability to interpret and diagnose a cardiac event as it happens and get help for the patient immediately is a clear win for both the physician and more importantly for the patient."

Long points out that, as one of the next generation of non-invasive, remote cardiac monitors now being placed in service, the MoMe® Kardia monitoring system from InfoBionic effectively aids cardiologists by providing:

- Anytime access to 24-hour patient data – cardiologists can verify possible cardiac events, map symptoms to actual arrhythmias and help provide assistance to patients that require intervention.
- Full disclosure data in a variety of formats, with sophisticated display algorithms — allowing doctors to quickly sort through vast reams of data and identify and focus on important cardiac events.
- Expanded data over much longer periods, which may capture smaller events that may otherwise go unrecorded, diagnosing faster and more accurately.
- Elimination of an expensive middleman – the traditional heart-monitoring device service – by offering complete ownership of their remote cardiac monitoring service line.
- Devices like the MoMe® Kardia threaten to thoroughly disrupt the cardiac monitoring process—from faster, more accurate diagnosis to vastly improved efficiency within the practice.

*References*


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**Cardiologs CEO Named European Innovator of the Year**

Cardiologs Co-founder & CEO named to MIT Technology Review's 'Innovator Under 35' and BNP Paribas' 'European Innovator of the Year'.

Cardiologs, a medtech company transforming cardiac diagnostics using medical-grade artificial intelligence (AI) and cloud technology, announced today that co-founder and CEO, Yann Fleureau, has been named one of MIT Technology Review's Innovators Under 35 Europe 2018. He was honoured during an award ceremony in Paris on December 4, 2018. Additionally, Yann Fleureau has been selected among the 35 laureates as BNP Paribas European Innovator of the Year.

Yann Fleureau, Co-founder of Cardiologs, was selected from a pool of more than 1,000 candidates. The 35 innovators were awarded as part of a community of leaders that are changing the future of technology. Yann was specifically recognised for revolutionising cardiac care through his work developing a cloud-based AI platform that can quickly and accurately analyse electrocardiograms (ECGs).

"I'm deeply honoured to be selected to receive this prestigious award and am humbled to be included among the many talented innovators who are using technology to benefit humankind," said Yann. "This technology not only improves cardiac diagnostic efficiency and analysis of ECGs, but also democratises access

to make expert cardiac diagnostics more available in developing countries and emerging markets. I'm proud of the work our team has done. We're excited to build on this recognition and continue to extend our solution's reach and data collection to serve a greater community of doctors and patients."


*Yann Fleureau, Co-founder of Cardiologs*

Cardiologs' technology, which can be universally accessible from any device, supports doctors by helping identify patterns and predicting irregularities the heart's electrical activity – empowering physicians to better diagnose and address patients' heart conditions. It's the first commercially-available algorithm for analysing ECGs based on deep learning technology, and among only a few AI solutions to have received regulatory clearance for clinical use. The system is currently CE-Marked in Europe and has received FDA clearance to aid physicians in screening for arrhythmias such as atrial fibrillation using ambulatory ECG recordings. The solution is now in clinical use across four continents.

"With Cardiologs and their use of AI in cardiac diagnostics, Yann Fleureau proposes a technological revolution in a tool that has been used in clinical practice for many years, but whose potential is now growing exponentially with the availability of new devices capable of recording ECGs," said Innovators Under 35 Europe's organising team. "With Cardiologs, we now have a scaleable expert analysis solution that can help make sense of this new flow of valuable clinical information and can form a key building block in the medicine of the future".

*About Cardiologs*

Cardiologs is a medical technology company committed to transforming cardiac diagnostics using medical-grade artificial intelligence and cloud technology. Developed in partnership with leading physicians, the Cardiologs ECG Analysis Solution empowers clinicians worldwide to deliver expert cardiac care faster and more efficiently. CE-Marked and FDA cleared for detection of 14 cardiac arrhythmias, the Cardiologs ECG Analysis Solution is built on a growing database of more than 600,000 ECG recordings and is supported by a number of clinical publications.

**Decolonization Protocol can Prevent Dangerous Infections Among Discharged Hospital Patients**

*Antiseptic soap, mouthwash, and nose ointment after hospital discharge reduced infections and infection-associated hospitalizations due to MRSA in high-risk patients*

*Rush University Medical Center*

Hospital patients who have Methicillin-Resistant Staphylococcus Aureus (MRSA) can prevent future MRSA infections by following a standard bathing protocol after discharge, according to research results published in the February 14 issue of the *New England Journal of Medicine*.

The Changing Lives by Eradicating Antibiotic Resistance, or CLEAR, trial divided 2,121 adult patients at random into one of two groups. All patients in both groups were "colonized" with MRSA; that is, they carried MRSA silently on their bodies. One group received education in infection prevention measures related to personal hygiene, laundry and cleaning in the home, and the other group received the same education along with instruction in decolonization -- that is, a treatment regimen to remove MRSA bacteria from their bodies. The decolonization regimen included bathing or showering with an over-the-counter antiseptic soap, rinsing the mouth and throat with a prescription mouthwash, and applying an antibiotic ointment to the nose. The patients were taught to self-administer the decolonization regimen daily for five days, twice a month, for six months.

"Our goal was to understand whether removing MRSA from the skin, nose and throat was better than hygiene education alone in reducing MRSA or other infections and associated hospitalizations," said Dr. Mary Hayden, Professor of Internal Medicine and Pathology, Chief of the Division of Infectious Diseases, and Director of the Division of Clinical Microbiology at Rush University Medical Center.

In the group that received education alone, one out of every 11 (9.2%) participants developed a MRSA infection and one in four (23.7%) developed a serious infection from any pathogen, with most infections (85%) leading to hospitalization.
The decolonization plus education regimen reduced MRSA infections by 30%, compared to the group that only received education, and reduced all types of infections by 17%. Patients who did not miss any doses of decolonization had 44% fewer MRSA infections and 40% fewer infections overall.

Participants in the study were recruited from 17 hospitals and seven nursing homes in Southern California (Orange County and Los Angeles County). The participants were adults who were able to bathe or shower (either by themselves or with caregiver assistance), had been hospitalized in the previous 30 days, and tested positive for MRSA while in the hospital or 30 days before or afterward. (California mandates MRSA screening at hospital admission in high-risk patients).

The researchers followed the patients for 12 months after they were discharged from the hospital, meeting with them in their homes or in a research clinic four times and conducting an exit

interview at the end of the year. They also contacted the participants monthly, asked them to report any hospitalizations or clinic visits for infection and reviewed their medical records from the study period.

National data from the Centers for Disease Control has shown that MRSA carriers who are discharged from hospitals are at high risk of serious disease due to MRSA in the year following discharge. Approximately 5 to 10% of hospitalized patients are MRSA carriers.

"With an issue this large, we wanted to find best practice strategies to prevent these infections and associated hospitalizations," said Hayden. "This large clinical trial helped determine that there is a way to help prevent infections after patients go home and it can prevent readmission."

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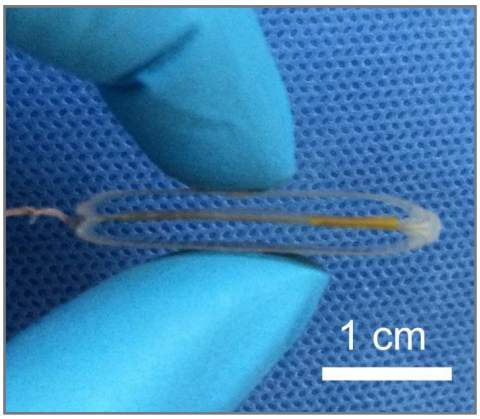
**Powering a Pacemaker with a Patient's Heartbeat**

*American Chemical Society*

Implantable pacemakers have without doubt altered modern medicine, saving countless lives by regulating heart rhythm. But they have one serious shortcoming: Their batteries last only 5 to 12 years, at which point they have to be replaced surgically. Now, researchers have surmounted this issue by designing a pacemaker powered by the energy of heartbeats, according to a report in ACS Nano. The device was successfully tested in pigs, which have a similar physiology to humans.

A conventional pacemaker is implanted just under the skin near the collarbone. Its battery and circuitry generate electrical signals that are delivered to the heart via implanted electrodes. Because surgery to replace the battery can lead to complications, including infection and bleeding, various researchers have tried to build pacemakers that use the natural energy of heartbeats as an alternative energy source. However, these experimental devices aren't powerful enough because of their rigid structure, difficulties with miniaturization and other drawbacks, so Hao Zhang, Bin Yang and colleagues searched for ways to improve the technology.




First, they designed a small, flexible plastic frame. Next they bonded the frame to piezoelectric layers, which generate energy when bent. They implanted the device in pigs and showed that a beating heart could, in fact, alter the frame's shape, generating enough power to match the performance of a battery-powered pacemaker. The study is a step toward making a self-powered cardiac pacemaker, the researchers say.

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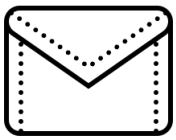
**ACC/AATS/AHA/ASE/ASNC/ HRS/SCAI/SCCT/SCMR/STS 2019 Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in NonValvular Heart Disease**

The *ACC/AATS/AHA/ASE/ASNC/HRS/ SCAI/SCCT/SCMR/STS2019* Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in NonValvular Heart Disease was published online in January 2019.

This document is the second of two companion Appropriate Use Criteria (AUC) documents. The first document addresses the evaluation and use of multimodality imaging in the diagnosis and management of Valvular Heart Disease, whereas this document addresses this topic with regard to Structural (nonvalvular) Heart Disease. While dealing with different subjects, the two documents do share a common structure and feature some clinical overlap. The goal of the companion AUC documents is to provide a comprehensive resource for multimodality imaging in the context of Structural and Valvular Heart Disease, encompassing multiple imaging modalities.

The *American College of Cardiology* envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The *ACC* bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned *JACC Journals*, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions. For more, visit www.acc.org.



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