CONGENITAL CARDIOLOGY TODAY
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Building an Advanced Cardiac Catheterization Laboratory for Congenital Heart Disease: Where to Start?

Jenny E. Zablah, MD, FSCAI, FACC, FPICS, FAAP

As congenital interventional cardiologists, we are creative problem solvers, working with the tools available to bring the best outcomes to our patients, who present unique clinical challenges and who vary in size and age, from newborns of just a few grams in weight to adults. At some point in our careers, many of us will have the opportunity to help design a new cath lab, and with that privilege comes the responsibility of making decisions that will shape the care patients will receive for the next 10 to 15 years. Designing that new cath lab is not without its challenges, requiring us to navigate regulatory requirements, budget constraints, and logistical complexities without compromising on quality or patient safety.

Where to Start?

1. **Decide what are your institution's needs based on:**
    - Patient Population: Will the lab serve pediatric patients only or will it be used also for older congenital patients?
    - Operators and Intended Procedures: Who will be performing procedures in this lab? Will it be solely interventional cardiologists, or will it also be electrophysiologists, interventional radiologists, cardiothoracic surgeons, or vascular surgeons?
2. **Discuss cath lab space utilization:** Decide on the configuration based on the intended procedures and available space.
    - Procedure Area: Includes the space of the cath lab with additional space for a mechanical room (cath lab components), control room, patient holding area, and recovery room.
    - Control Room: Needs to be adjacent to the procedure room with all necessary monitoring and control equipment.
    - Equipment Storage: Sufficient storage for catheters, guide wires, balloons, stents, and other supplies.
3. **Imaging Equipment:** Consider the different variables (it can get overwhelming):
    - Monoplane vs. Bi-plane Imaging: Most congenital labs choose a bi-plane imaging as their primary system because it allows one to visualize anatomy in two planes at the same time, reducing the number of required contrast injections and allowing more accurate guidance in complex anatomy. Monoplane systems require less space and are more affordable than biplane systems, so they are often chosen to provide additional capacity, especially for hybrid procedures or in cath labs that are shared with structural/coronary interventionists.
    - Floor vs. Ceiling: If you choose a monoplane system, the next decision is floor vs ceiling mounted. Ceiling mount systems typically provide more positioning flexibility, while consuming less floor space. Keeping space free at the head of the table for anesthesia is an important consideration that favors ceiling mounted systems.

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- Size of Flat Panel Detectors: Smaller detectors can provide greater positioning flexibility and better image quality for smaller patients. Larger detectors provide a bigger field of view, which is useful for larger patients, but which may produce undesirable magnification on small patients.
- Dose Management: Minimizing radiation is critical for the safety of our sensitive patient population, as well as our own staff. Challenge vendors to provide you with detailed information of the dose savings features of their systems, including peer-reviewed evidence in real-life clinical practice.
- Table Options: Ensure the table supports a wide range of movements and has a high weight capacity. Decide if you will use a standard free-floating cath lab table or a surgical table that can be integrated with the cath lab system.
- Advanced Imaging:
  - *3D Rotational Angiography (3DRA)*
    3DRA images can be used to create a roadmap to help guide complex interventions, improve our understanding of vascular relationships with other extracardiac structures, and allow for 3D assessment of complex anatomy. Use of 3DRA also helps us to decrease the overall radiation and contrast dose.[6]
  - *CT, MR and Echo Fusion*
    Previously acquired imaging can be used to plan many of our procedures. Computed Tomography (CT)/Magnetic Resonance (MR) images can be fused with live x-ray, to provide real-time positioning guidance, reducing the need for contrast injections. Live echo imaging can also be fused with live x-ray, providing a real-time view of both soft tissue and devices and procedural guidance.

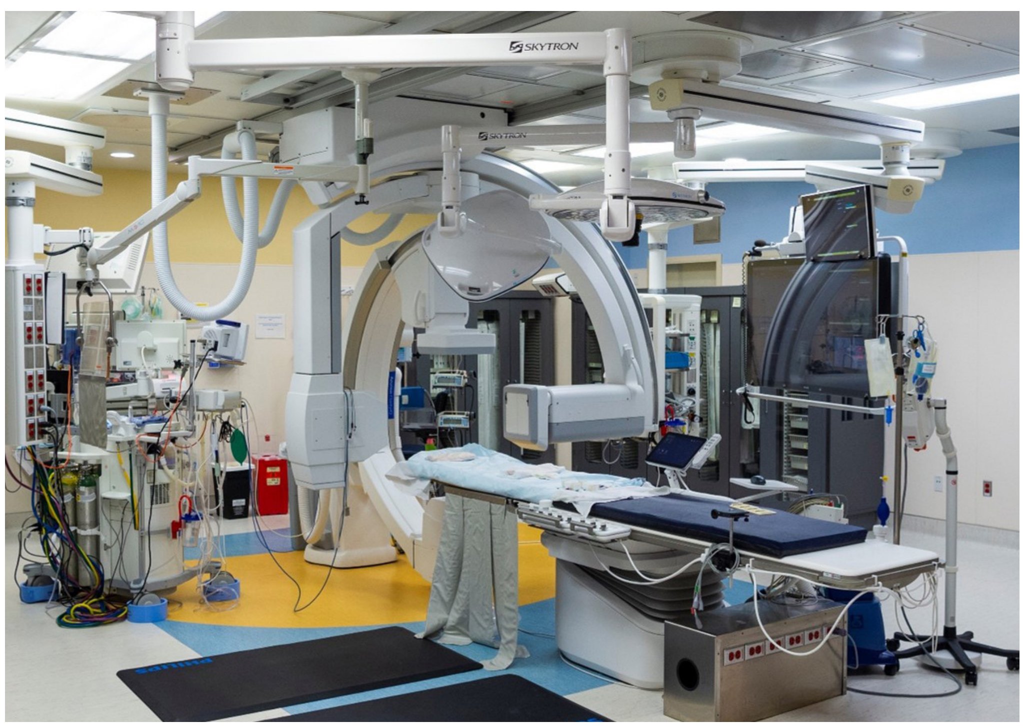
4. **Room Design:** It is important to also think beyond the interventional x-ray system and consider the other tools that aid in your desired workflow.
   - Procedure room monitors and booms: Take the time to envision what you will need to see during procedures, (e.g. hemo, echo, PACS, etc.). You will also want to decide early in the planning process whether your monitors will be mounted on booms or on monitor ceiling suspension rails and incorporate this into your room design.
   - Other equipment: Think through the other equipment needed for procedures and where that will be stored and/or moved to/for each procedure (e.g. Anesthesia, Echo, ECMO, EP mapping, EP recording, etc.).

Once you have defined the above features, meet with various vendors to evaluate their current technology, equipment delivery times, pricing, customer support, warranties, service contracts, and more. Establishing partnerships is crucial, particularly in congenital heart disease, to develop specialized tools tailored to specific requirements. Visiting cath labs like your envisioned setup aids in making informed decisions. Moreover, gathering sufficient information enables you to identify innovations that best align with your needs and budget.

Including all relevant stakeholders who may use the cath lab helps uncover specific needs that might otherwise be overlooked. Engage these individuals in early discussions, including: interventionists, electrophysiologists, surgeons, echocardiographers, nursing staff, anesthesiologists, IT personnel, risk management experts, and others.

Children's Hospital Colorado – Our Experience

We will use our institution as an example, and for that we need to bring a perspective of the program size and characteristics. Children's Hospital Colorado (CHC) is a top-ranked center for cardiology and heart surgery by US News & World Report, with outreach clinics spanning four states and over 20 locations. CHC is accredited by the Intersocietal Accreditation Commission (IAC) in more fetal, pediatric, adolescent, and adult cardiovascular diagnostic testing and intervention-based procedural areas than any other children's center. CHC performs more than 1,100 cath/EP procedures and over 700 congenital heart surgeries each



Cath Lab 1 – Philips Azurion 7 B12/12 (photo courtesy of Children's Hospital Colorado) year. CHC also hosts over 20,000 clinic visits and over 25,000 echocardiograms each year.

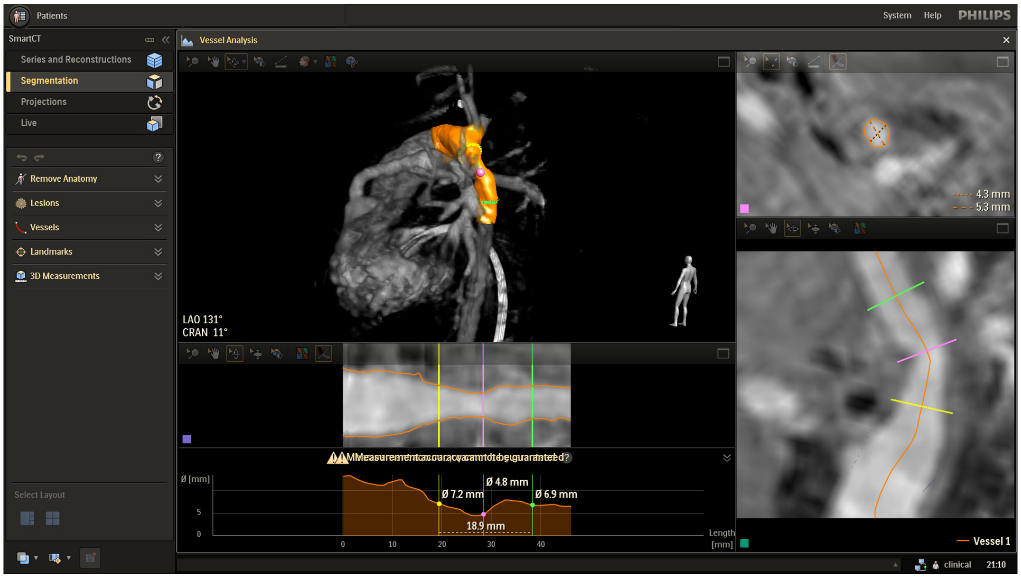
Each of our three cardiac catheterization laboratories at CHC has its own unique characteristics, providing insight into how procedure requirements impact design choices and vice versa:

- Hybrid Cath Lab/OR – Philips Azurion 7 M20 with FlexArm:
  This cath lab was built in 2023 and is used as a cath lab, for hybrid procedures, and as a CV operating room. It has a large detector measuring 47.2 cm x 36.0 cm.
  - This is our newest cath lab and the design was heavily influenced by our CV surgeons for when we perform hybrid procedures. This room was also designed to be a back-up surgical suite for open procedures.
  - The ceiling mounted FlexArm's design supports various procedures including surgical, endovascular, cardiac, peripheral, and making it adaptable for multiple specialties.
  - The FlexArm allows full freedom for staff to choose the best working positions without moving the patient table. The C-arm has a 270-degree range of movement, enabling all imaging positions while keeping the anesthesia zone free of obstruction.
  - This system is versatile and can acquire 3D images from different positions. We can perform a 3DRA Prop scan (4.1 second rotation from the head position) or Roll scan (8 second rotation from 90-degree position from either side of the table), and roadmapping of a 3D rotation can be done at three different C-arm locations including 45 degrees.
  - The two large FlexVision monitors allow us to see up to eight inputs at any given time, and we have the ability to click and control inputs like room cameras, 3D workstations, or any other personalized inputs, while remaining tableside via a mouse or touch screen.
  - In the control room the Azurion FlexSpot monitors allow us to view and control the x-ray as well as the video inputs displayed in the procedure room. This allows us to work with fewer mice and keyboards than we do in our older lab.
- Cath Lab 1 – Philips Azurion 7 B12/12:
  This biplane cath lab was built in 2018 and has two smaller detectors measuring 28.8 cm x 28.3 cm.
  - This lab is very versatile, with adequate imaging quality that can be used for premature babies to adult-size patients.
  - The smaller detector configuration of this system makes 3DRA easy to perform and provides good image quality.
  - The AP detector can reach relatively steep cranial angles, but the small detector size limits the field of view, especially for larger patients.
  - The large FlexVision Pro monitor allows us to see up to eight inputs at any given time and we have the ability to click and control inputs very similar to the FlexArm room, while remaining tableside via a mouse or touch screen.
- Cath Lab 2 – Philips Allura Xper FD20/10: Built in 2012, this cath lab is due for an update soon. It has a large detector in the AP plane and a small detector in the lateral plane.
  - With the large AP detector, the field of view and image quality is better for larger patients. This is our primary EP room where we predominantly treat larger children and adolescents, and where we also treat older patients that come for cardiac catheterization.
  - The older FlexVision monitor on this system allows for up to eight inputs for visualization, but we do not have the ability to click and control those inputs.
  - The older style control room in this lab does not have the FlexSpot capabilities, so it is more crowded with dedicated monitors, mice and keyboards.

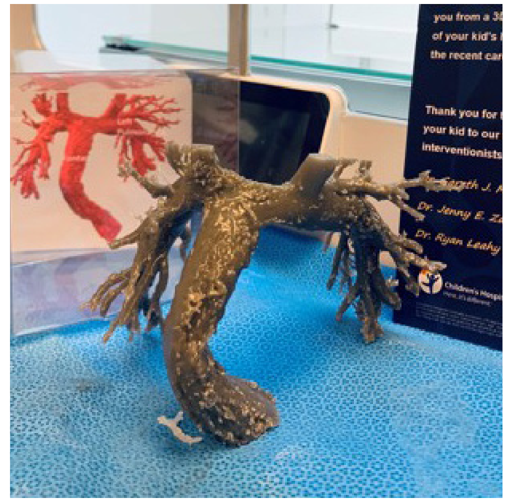
Hybrid Cath Lab/OR – Philips Azurion 7 M20 with FlexArm (photo courtesy of Children's Hospital Colorado)

The three cath labs have fusion imaging tools that support our practice and allow us to keep overall radiation and contrast doses low.

1. SmartCT Angio & SmartCT Roadmap:
These advanced tools allow acquisition of 3DRA images and 3D reconstruction of the heart and other intrathoracic structures for planning and for procedural guidance. Users are guided through the image acquisition process with on-screen prompts and can review and interact with the acquired CT-like 3D images on the system's table-side touch screen module, viewing multiplanar reconstructions and utilizing measurement tools, such as straight-line measurements.



SmartCT Angio allows acquisition of 3DRA images and 3D reconstruction of the heart and other intrathoracic structures for planning and for procedural guidance. (photo courtesy of Philips Healthcare)



Patient-specific anatomical 3D printed models using CTA, MRI, or 3DRA images[5] are utilized to educate patients both pre- and post-procedure. (photo courtesy of Children's Hospital Colorado)

- *Fun Fact:* We perform 3DRA using our center's previously published protocols[1] and the images are used for procedural planning, guidance and 3D printing of the 3DRA when exported as DICOM files. 3DRA is used for single ventricle assessments, aortic arch evaluation post intervention, coronary assessment during balloon testing prior to percutaneous pulmonary valve implantation (PPVI), etc.

2. <u>VesselNavigator:</u> This tool provides 3D views of vasculature by combining live X-ray images with pre-acquired MRI or CT images. It is designed to offer real-time visual guidance and reduce the need for additional angiography. VesselNavigator adds the ability to overlay landing zones and bifurcations using centerline ring markers onto live fluoroscopy to support catheter navigation and device positioning.
   - *Fun Fact:* This tool is the most used by our team to overlay cross-section imaging with live fluoro and guide procedures like coarctation of the aorta, PPVI and pulmonary artery stent/angioplasty.
3. <u>HeartNavigator:</u> Similar to VesselNavigator, HeartNavigator is used primarily for structural heart disease cases but can be adapted for Congenital Heart Disease. Previously acquired CT images can be used to segment and measure cardiac structures, which can be displayed as needed.
   - *Fun Fact:* This tool provides nice segmentation of the cardiac structures, which is useful for complex cases. It requires more time to segment small patients with Congenital Heart Disease, so we use it less often. In addition, just CT images can be used.
4. <u>EchoNavigator:</u> This tool fuses live echo with X-ray imaging to provide real-time guidance for precise navigation and device placement during cardiac interventions. Echo images are acquired using Philips EPIQ CVxi ultrasound system and X8-2t transesophageal echo (TEE) transducer. A new X11-4t Mini TEE is now available, which allows imaging on patients as small as 5 kgs.
   - *Fun Fact:* Especially useful in structural cases (mitral clips, mitral or tricuspid valve replacement) and complex cases like Fontan fenestration creation/closure and atrial septal stents.

Our fluoroscopy settings have been personalized for our specific needs and to keep radiation doses intentionally low for patient and staff safety. Fluoroscopy is generally performed at 3.75 frames per second which, as needed, can be increased to 7.5 frames/sec or 15 frames/sec from the control panel. Cine is performed with 15 frames/sec and 3D rotational angiography at 30 frames/sec.

Our team has published clinical outcomes from our current setup, showcasing not only reductions in radiation and contrast doses through advanced imaging tools,[2,3,4] but also innovative approaches to utilizing these images for patient education.

One of our most notable achievements is the establishment of an advanced imaging program aimed at enhancing patient education. This initiative has enabled us to create patient-specific anatomical 3D printed models using CTA, MRI, or 3DRA images,[5] which are utilized to educate patients both pre- and post-procedure. These models are provided to families as cherished memories, and since 2018, we have produced anatomical prints for 65-100 patients annually, contingent upon imaging availability.[6]

Furthermore, we have developed 3DRA protocols tailored specifically for Congenital Heart Disease using the Philips systems. This effort aims to achieve optimal image quality and serves as a blueprint for other institutions interested in implementing similar technologies, providing guidance on utilizing vendor-specific equipment effectively.

Summary

Crafting an ideal cath lab demands a delicate balance of scientific precision and clinical insight, aimed at optimizing procedural efficacy and patient outcomes, particularly for those with Congenital Heart Disease. Each decision—from the layout of procedural spaces to the selection of imaging systems—must align seamlessly with clinical workflows, enhancing our ability to deliver personalized, patient-centered care.

In conclusion, as physicians involved in cath lab design, we embrace this journey with passion and purpose. We strive not only to create functional spaces, but also to cultivate environments that inspire collaboration, innovation, and, above all, superior patient care. Our efforts in shaping these environments underscore our commitment to advancing cardiovascular medicine and improving the lives of our patients with Congenital Heart Disease.

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PICS Society 2024 Symposium Recap

Kamel Shibbani, MD; Damien Kenny, MD, FPICS; Ziyad M. Hijazi, MD, FPICS

This year's PICS Society meeting was a great success, thanks to each and every one of you! We could not be more thankful for your attendance and your thoughtful participation throughout another fantastic meeting. From the outstanding atmosphere to the live cases, the audience engagement, the plethora of learning opportunities, and the baseball game, it was all made possible by your attendance and participation and by the partnership with our industry sponsors.

This year's meeting covered a lot of ground. We had live cases broadcast from 10 different centers that spanned the North and South American continents. Cases tackled the smallest of our patient population, with premie PDA closure, to the growing and complex world of ACHD and everything in between. We had fantastic breakout sessions with excellent talks and outstanding presentations. To top this all off, we had our first PICS meeting for the inaugural class of the Early Career Academy, as well as the exceptionally well attended fellow's course.

Most importantly, there was ample opportunity to connect with colleagues, to network, to learn, and to engage with our industry sponsors in this rich academic environment amongst friends. As with every year, we end the PICS Society meeting already looking forward to the next one. The 2025 PICS Society meeting will take place in the windy city, and we cannot wait to see all of you in Chicago from August 25-28, 2025. In the interim, the PICS Society is honored to advocate on your behalf and on the behalf of our patient population!

See you all soon!

Kamel Shibbani, MD;
Damien Kenny, MD, FPICS;
Ziyad M. Hijazi, MD, FPICS
On behalf of all the PICS Directors and Co-Directors


PICS Society


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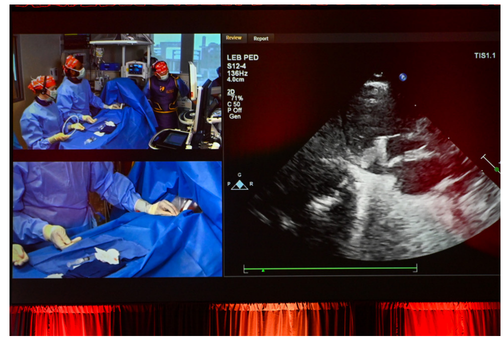
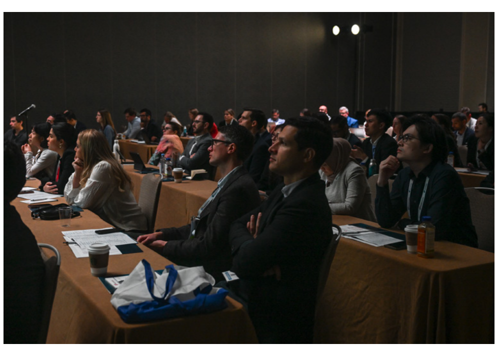
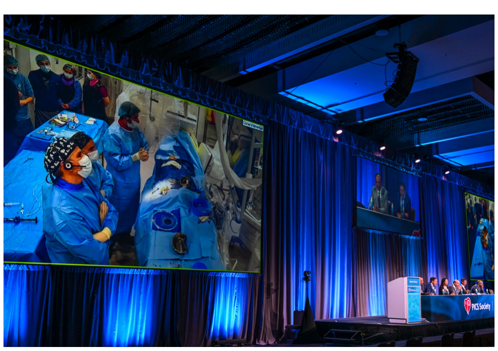






Heart Institute Researchers Awarded Major Grants to Study Congenital Heart Defects

Shelley Miyamoto, MD and Stephanie Nakano, MD, were two of five research teams selected for a $13 million grant to study biological mechanisms of rare congenital heart defects. The American Heart Association and Additional Ventures are funding the research and selected the teams for their forward-thinking approaches to research using innovative methods to challenge current knowledge and theories in search of cures for single ventricle disease. Both doctors already have extensive experience studying single ventricle heart disease as well as treating pediatric cardiology patients.

"To truly improve outcomes in single ventricle patients, we need to study their unique biology to determine personalized and effective approaches."

–Stephanie Nakano, MD

Dr. Miyamoto is leading a study called "The DEFEND Trial: Dapagliflozin or Empagliflozin for Fontan Exercise, QOL and Ketone Body Levels." Her team includes Roni Jacobsen, MD, an expert in exercise and adult congenital heart disease, and cardiac psychologist Sarah Kelly, PsyD.

Stephanie Nakano, MD and Shelley Miyamoto, MD, were two of five research teams selected for a $13 million grant to study biological mechanisms of rare congenital heart defects

The team is studying the use of two sodium-glucose co-transporter 2 (SGLT2) inhibitors used to treat diabetes and heart failure in adults to determine if these medications may also help teenagers and young adults with single ventricle disease. They hope to determine if the medications improve quality of life and the ability to exercise. People with single ventricle disease are often left out of studies of new medicines, so the DEFEND study will help address this disparity.

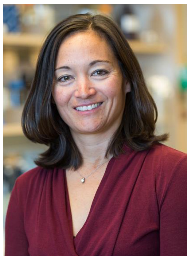
"Our goal is to advocate for the interests of patients with congenital heart disease and make sure they are part of studies on new and important treatments," says Dr. Miyamoto. "These patients need and deserve special focus, and we're honored to have the chance to represent their needs through this new research project."

Dr. Nakano is leading a study called "Consequences of Impaired T Cell Homeostasis in Single Ventricle Congenital Heart Disease." Her team includes pediatric cardiologist Anastacia Garcia, PhD, Jordan Abbott, MD, who specializes in pediatric allergy and immunology, and Julie Lang, PhD, who specializes in microbiology and immunology.

The team is seeking to learn more about the immune system of people with single ventricle disease. They theorize that children with single ventricle disease are born with abnormal immune cells, so they plan to study immune cells in patients and in animal models to learn if cell abnormalities contribute to heart failure in single ventricle patients. They hope to determine if it's possible to predict which single ventricle patients are at risk for complications and which medications may be most helpful to improve patient outcomes.

"We are finding that single ventricle patients are a distinct group and their differences may extend beyond their heart," says Dr. Nakano. "On multiple levels, we are seeing differences in the single ventricle immune system that may contribute to the development of other complications. To truly improve outcomes in single ventricle patients, we need to study their unique biology to determine personalized and effective approaches."

Featured Researchers



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Heart Defects Affect 40,000 US Babies Every Year — But Cutting Edge AI and Stem Cell Tech Will Save Lives and Even Cure Them in the Womb

Jeanette Settembre & Megan Palin, New York Post

Katie Blue-Pugh was just a few hours old when her lips turned blue and panic suddenly set in for her parents and staff in a California maternity ward.

Later that day, doctors discovered she had a major heart defect, born with a single ventricle. She was immediately sent by ambulance to a nearby hospital at University of California, San Francisco, for life-saving surgery.

By the time Katie was nine-years-old, she'd undergone multiple invasive procedures but still "couldn't run across a playground without stopping."

"My lips were blue, my nails were blue, my oxygen saturation was at 60%, it's supposed to be above 90%," Blue-Pugh told The Post.

Katie Blue-Pugh had childhood heart disease and underwent life-saving surgery at 10-years-old. However, she may one day need a full heart transplant. She is now 34 and lives in Durham, NC, with her husband, William Pugh.
(Photos courtesy of Katie Blue-Pugh)

Professor Enzo Porrello, who is a one of MCRI's top researchers and is spearheading the "Decoding Broken Hearts" initiative.
(Photo courtesy of Enzo Portillo)

The most common types of birth defects occur in the heart, according to the Centers for Disease Control and Prevention. They affect around one in every 100 live births, which is equivalent to 40,000 babies born in the US each year, or one child born every 15 minutes, according to the Murdoch Children's Research Institute (MCRI).

Blue-Pugh is now 34-years-old and thriving in Durham, North Carolina. While the Fontan procedure to "re-do the plumbing" in her heart has dramatically improved her quality of life, she still may need a heart transplant one day, according to doctors.

"Thinking of one's own mortality is scary," she said.

"I'm very grateful to be here. I live a pretty much normal life. But thinking I might one day need a transplant and that my body can reject it gives me a lot of anxiety."

Groundbreaking new research in stem cell and Artificial Intelligence [AI] technology has raised hopes of eliminating all of these worries, and treat conditions like hers — even before birth.

Top health researchers from MCRI in Australia have teamed with those from the Gladstone Institutes in San Francisco on a new program to develop cutting-edge technologies to treat the underlying causes of childhood heart disease more effectively.

Current treatment options such as transplants are inadequate as donor heart supply is limited, patients have a lower medium-to-long-term chance of survival and they require lifelong immunosuppression, according to MCRI.

Professor Enzo Porrello at MCRI is spearheading the new research which focuses on developing personalized treatments to prevent the progression of the disease and, ultimately, to avoid the need for transplantation.

The initiative, dubbed "Decoding Broken Hearts," leverages MCRI's stem cell technologies and Gladstone Institutes' advanced AI capabilities to "understand human disease biology." "Transplantation is not a cure, it's really a last resort," Porrello said.

The partnership aims to be able to offer personalized treatments to young patients.

Porrello and his team pioneered the stem-cell field in 2017 when they created the most complex 3D mini-models of human heart tissue in the world. They can now mimic the human heart in a lab dish and perform breakthrough experiments to create treatments.

"We can produce thousands of these miniature human heart tissues from stem cells every week," Porrello explained.

"These types of studies generate enormous data sets. We need to be able to mine those data sets to pinpoint the underlying cause of the heart disease – this is where AI comes in."

"It allows us to predict how an individual patient might respond to a particular therapy."

"Potentially the approach we're developing can apply to all forms of heart disease, not only children, but adults."

MCRI's researchers are working with cardiologists and heart specialists to get to a point where they can eliminate defects before they even have time to develop.

"By going in and editing these genes early – first it'll be at birth – the way they use their AI is you can go in and snip these genes at different stages. (Then it'll be) going to the mother and preventing the diseases from happening in the first place," said MCRI Global Ambassador, Sarah Murdoch, who is the wife of Lachlan Murdoch, the Chairman of The

Post's parent company, News Corp, and Chief Executive Officer of Fox Corporation.

They are carrying on the legacy started by world-leading philanthropist Dame Elisabeth Murdoch — the late mother of media mogul, Rupert Murdoch, who founded the original Murdoch Institute for Research in Birth Defects in 1986 alongside genetics pioneer Professor David Danks.

Since then it has grown from a genetics research institute to a global leader in children's health.

MCRI is now ranked among the top three best child health research institutes in the world for the quality and impact of its work.

A living example of the leaps forward in heart research by MCRI and Gladstone Institutes can be seen in the case of Ebony and Kyle Mallison.

Their daughter, Amelia, was 2-years-old when she suddenly suffered heart failure.

She was diagnosed with LVNC cardiomyopathy after waking up on Mother's Day 2015 with a "face was so swollen that she could barely open her eyes," Ebony said.

"She was in the ICU for a week and then on the cardiac ward for another week before she came home," Ebony, a 31-year-old receptionist in Melbourne, Australia, told The Post.

Later that year, an organ donor became available and Amelia had a heart transplant at just 3-years-old.

But the Decoding Broken Hearts' initiative's research will hopefully mean now 11-year-old Amelia's brother, Elijah – who has the same heart condition – will not have to undergo a transplant at all.

"Eli is currently stable, but our hope is, if he ever does become unwell, the work that MCRI is doing would be very beneficial in any treatment that he needed," Ebony said.

Sarah Murdoch has seen first-hand the heartbreaking reality of what children affected by heart disease and their families go through.

"I visited a child who was an 18-month-old toddler, who had the tubes coming out of her chest to a machine that pumps her blood for her. Bed bound," Murdoch told The Post.

"You think of a toddler – I'd never seen a child in that condition at that age. She just sat there. And she'll be sitting there waiting until she can have a heart."

"It's extra hard when you have young children yourself – that's what motivates us."

"Some months ago we pioneered being able to map an entire human genome of a child – a rapid diagnosis in three days. We're doing it in four hours now. This is where we're going to be able to map an entire baby genome. Find the genetic problem, before it causes an issue."
Another area where MCRI has excelled is in developing a life-saving vaccine for newborns to prevent rotavirus – a highly infectious virus which caused over 400,000 deaths per year in developing countries in the 90s and early 00s, according to the National Institutes of Health (NIH).

The World Health Organization (WHO) now recommends the vaccine for all children and it has been introduced to 114 countries, where it has been up to 90% effective in preventing severe rotavirus, according to the NIH.

Ebony says that the research and leaps forward made by MCRI make her whole family feel reassured and hopeful.

"It's good to know that there are people working on things that will help the lives of my kids and other kids around the country," she said.

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