



GOING heart TO heart GLOBAL

LOCATION: TWO SITES IN LIMA, PERU
COLLABORATIONS LAUNCHED: 2016

JANUARY 6–19, 2016
SURGICAL-EDUCATIONAL MISSIONS
PEDIATRIC 1 & ADULT 1



Municipal Palace, Plaza Mayor Also known as Plaza de Armas, Lima's main square was constructed in the mid-sixteenth century, shortly after the city's founding. The bright yellow municipal buildings lining the square were built over the following centuries and completed in 1944.

GOING GLOBAL: EXPANDING ACCESS TO CARDIAC CARE IN SOUTH AMERICA

Heart disease continues to be the main cause of death globally. Every year, millions of adults around the world are diagnosed with various forms of acquired heart disease – from atherosclerosis (hardening of the coronary arteries) to arrhythmias (irregular heartbeats) to valvular conditions (restricted or leaky blood flow). Effective surgical treatment for people suffering from acquired heart conditions is readily available in the United States (and Western Europe, Japan, and several other countries), but not for most people around the globe.

In the U.S., the notion of heart disease and its routine treatment is widely associated with middle age. In recent years, treatment for adult heart patients has become increasingly effective, and recovery less prolonged. Today in the U.S., heart patients are living longer, thanks in part to less invasive new medical technologies.

A lesser known fact is that worldwide each year at least 1.3 million babies are born with heart disease. Unfortunately, at least 75% of children and adults around the globe still lack access to life-saving cardiac care. Heart to Heart's quarter-century of work in Russia has expanded access to timely heart treatment for tens of millions of people on two continents, Asia and Europe. We are thrilled to be in a position to extend our work to a third continent, South America – beginning in Lima, Peru.

This report presents: a timeline of our research, site assessment, and work-to-date in Peru; a preview of our strategy for simultaneously advancing both pediatric and adult cardiac care throughout the country; and summaries of our first two surgical-educational missions to Lima, Pediatric I and Adult I, conducted concurrently in January 2016.

To transfer knowledge, first see the cardiac community as a whole

For decades, cardiac specialists in the U.S. have had the collective knowledge and expertise to treat everyone – from the tiniest newborn premies to great-grandparents. With advanced diagnostic technologies, some heart defects can even be detected in utero. Teams in the U.S. perform tens of thousands of open heart surgeries and endovascular interventions each year. English-language cardiac journals publish extensive data-driven studies on: leading-edge surgical approaches, the efficacy of new post-operative medications, evolving diagnostic catheterization techniques, surveys of programmatic and departmental best practices, and scores of other highly advanced topics.

For over 25 years, Heart to Heart’s approach has been to identify, collaborate with, and advance medical communities

The successful transfer of knowledge and experience to medical communities in underserved areas is key to reducing the global burden of heart disease.

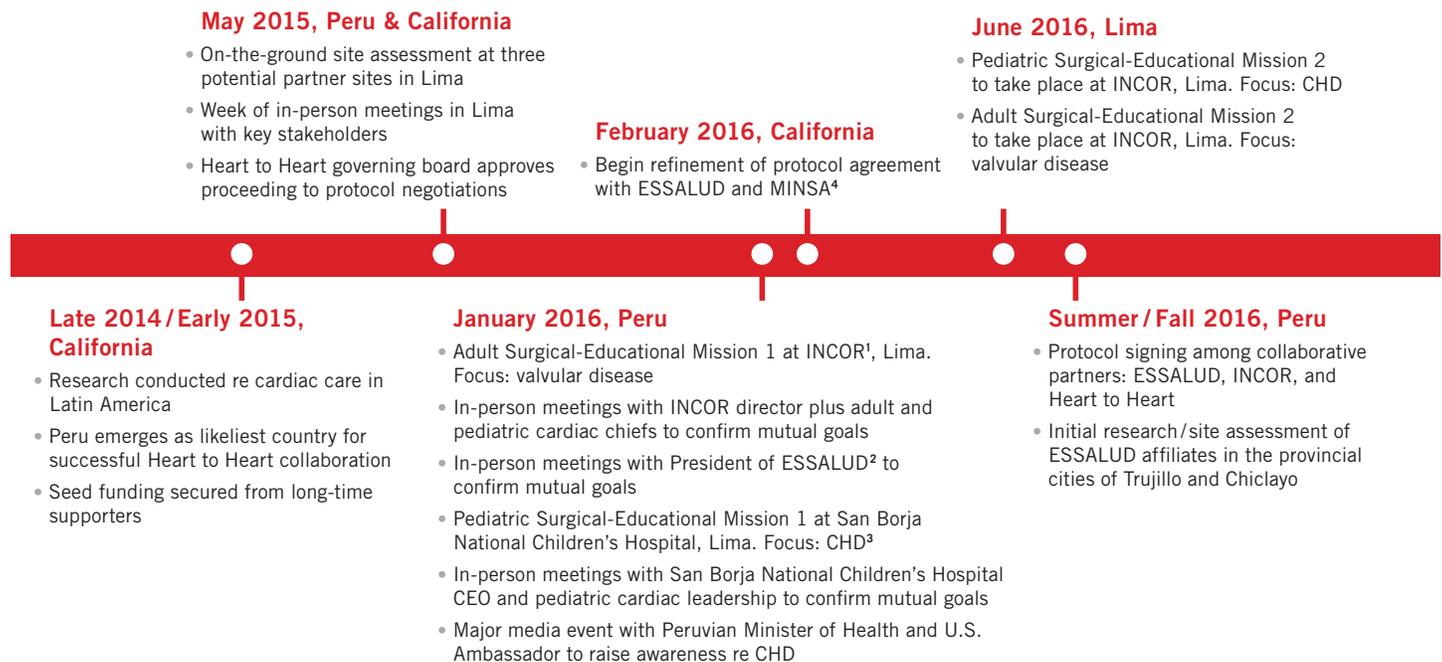
that are *ready* for a transfer of knowledge. Our stepwise teaching and training methodology empowers communities in areas of need to fully integrate the surgical treatment of heart disease

into their existing medical infrastructure in a relatively short period of time.

Heart to Heart excels at assessing our new colleagues’ level of proficiency to confirm an appropriate starting point for our multidisciplinary collaboration. Our transfer of knowledge then proceeds concurrently along three pathways: hands-on training, didactic education, and integration of best practices. Our program model has resulted in five self-sustaining cardiac programs throughout the Russian Federation – with three more on track to “graduate” within the next few years.

In regions of the world where resources are scarce and medical care is underdeveloped, Heart to Heart approaches a cardiac community’s needs as a whole. We know from experience that establishing a new children’s heart program requires us to draw from the resources of the cardiac community, in whatever form they may exist. The reality is that in underserved areas, cardiac care is first available to adult patients with acquired heart disease. By the time an adult cardiac program is “on its feet,” the adult team has been repeatedly approached by desperate parents seeking life-saving heart surgery for their children. After having to turn many families away, inevitably surgeons begin to consider operating on children with less complex forms of congenital heart disease.

STRATEGIC FIRST STEPS IN SOUTH AMERICA



¹The leading cardiac center in the ESSALUD provider network, the National Cardiovascular Institute (INCOR, Lima) is a stand-alone cardiac center serving children and adults.

²ESSALUD is one of the two principal healthcare providers in Peru, administering a nationwide network of medical institutions for workers and their families.

³Congenital heart disease is widely referred to as congenital heart defects; it is also known as childhood heart disease.

⁴The Peruvian Ministry of Health (MINSA) administers a nationwide network of medical institutions for the uninsured, unemployed, low-income, and indigent. San Borja National Children’s Hospital is a MINSA affiliate.



Machu Picchu, 2016 Peru is rooted in the ancient Incan culture and has only been a modern sovereign nation since 1821. Today, it is home to 30 million people, about one third of whom live in metropolitan Lima, the country's capital. Modern Peru is on an excellent path forward, with an impressive literacy rate of 94.5%. Over the last decade, the national poverty rate has decreased from 56% to 22%.

Heart to Heart has always recognized the vital role that adult cardiac specialists play in a community's initial efforts to treat children with heart defects. If the leaders of an adult cardiac center decide to develop a dedicated pediatric program, they select doctors and nurses from among their talent pool to begin specializing in pediatric cardiac medicine. And, because cardiac equipment and supplies are costly, the adult team will need to share their material resources – such as operating rooms, heart-lung machines, cath labs, echo machines, and post-op monitors – with the nascent pediatric team.

Having the capacity to treat heart patients of all ages with all forms of heart disease is an important part of any country's healthcare system. Heart to Heart's network of volunteers is comprised of specialists who collectively provide patient care in all aspects of cardiac medicine available for children and adults. The breadth and depth of our expertise means we can advance the work of any cardiac subspecialty team.

Laying the groundwork in Peru

The Peruvian government administers multiple healthcare delivery systems and is working toward ensuring accessible healthcare for all residents. The two largest and most advanced systems are Seguro Social de Salud del Perú (ESSALUD) and the Peruvian Ministry of Health (MINSA). Funded through payroll deductions and employer contributions, ESSALUD provides healthcare to the country's workforce and their families, serving approximately 11 million people. MINSA provides healthcare to people who are uninsured, unemployed, low-income, or indigent, serving approximately 17 million people. Approximately 87% of Peruvians are covered under these two systems.

Since March 2015, Heart to Heart has been conducting a series of in-depth discussions with key stakeholders in Peru regarding how to collaboratively advance cardiac medicine for children and adults nationwide. We have met with leaders from

both ESSALUD and MINSA; we have also met with hospital administrators and cardiac specialists from Peru's leading centers. All parties have expressed great enthusiasm about a long-term collaboration with Heart to Heart.

Lima, the capital, is one of the few cities in Peru where adults can undergo open heart surgery and the only city where children can undergo open heart surgery. To effectively advance heart care throughout Peru, we have launched in Lima, to:

- (1) increase the capacity of their basic medical infrastructure, which already serves a large number of Limeñans with heart disease, but cannot meet current need;
- (2) help cardiac specialists in Lima to achieve surgical outcomes comparable to the U.S. and Europe, within a few years;
- (3) "train the trainers," who will join us to expand access in Peru's provinces during the second phase of our collaboration.

Our vision dovetails perfectly with ESSALUD's current five-year strategic plan to expand heart care nationwide.

Peru at a glance

Country population: 30 million
 Area: 496,200 square miles (nearly twice the size of Texas)
 Capital city: Lima, population 9.9 million
 Children born annually with CHD: 6,000

Physicians: 1.13 per 1,000 (U.S.: 2.45 per 1,000)
 Poverty: 22% on average, but as high as 55% in rural areas
 GDP per capita: 12,300 USD (U.S.: 56,300 USD, Russia: 23,700 USD)
 Average monthly salary (middle class): 325 USD
 25% of the labor force works in agriculture

Literacy: 94.5%
 Life expectancy: 73 years
 Fertility rate: 2.18 children/woman

*Most data from *CIA World Factbook*, updated 2015.



Operating side by side Our pediatric team, led by pediatric cardiac surgeon John Calhoun, spent nearly two weeks at San Borja National Children's Hospital. During each surgical procedure, Dr. Calhoun and the other Heart to Heart volunteers worked side-by-side with their Peruvian counterparts to provide patient care. The Heart to Heart team included six more pediatric specialists from his home institution, University of Texas Health Science Center, San Antonio: Cindy Eckhardt, RN; Rachel Lopez, surgical technician; Clinton Pietz, MD, critical care specialist; Deborah Rasch, MD, anesthesiologist; Joshua Walker, perfusionist; and Cathy Woodward RN, DNP. Our pediatric team was rounded out by veteran Heart to Heart cardiologists, Frank Cetta and David Teitel.

Pediatric track: teaching timely treatment for CHD

Childhood heart disease (also known as congenital heart defects, or CHD) is the most common birth defect worldwide, affecting 1 in every 100 babies. In the second half of the 20th century, amazing breakthroughs in cardiac medicine made headlines around the globe. For children in the U.S., these advances have translated to life-saving heart care for nearly every baby and child born with CHD – with a stunning 97% successful treatment rate.

On the continent of South America, 65,000 babies are born annually with CHD. Of the 6,000 born in Peru each year, 3,000 will need surgical intervention by the age of three if they are to survive. The cardiac community of Peru currently has the annual capacity to perform surgery on approximately 750 children suffering from less severe forms of CHD. Although children are diagnosed in a number of clinics around the country, open heart surgery is only available in Lima. Nationwide, the unmet need for pediatric open heart surgery greatly exceeds capacity, so the backlog of young patients grows dramatically each year. Babies and children on the “waiting list” get sicker and sicker.

For some babies born with CHD, the “window of opportunity” for life-saving treatment will be measured in years; for others, it is measured in months; and for babies with the most severe forms of CHD, it is measured in days, or even hours. If the window of opportunity is missed, they become so sick that heart surgery can no longer save them.

Pediatric cardiac medicine has progressed rapidly since its infancy. In the U.S., more than three generations of specialists have contributed to the evolution of today's best practices to: teach new physicians and nurses; collect and analyze surgical outcomes data; communicate and work as a team to provide the best patient care. Heart to Heart's medical volunteers have benefitted from the collective wisdom and experience of those who came before them. By leveraging the knowledge the cardiac community has accumulated over the last several decades, we are able to leapfrog nascent teams forward, considerably abbreviating their learning curve.

Heart to Heart has used two paths to develop pediatric cardiac programs: one is to start at a multi-profile children's hospital and integrate the subspecialty of pediatric cardiac surgery. The other is to start at an existing stand-alone cardiac center that treats adults, with the intent to expand services to treat pediatric patients. There are challenges specific to either path. Heart to Heart has already developed multiple self-sustaining programs in both types of medical institutions. Our institutional knowledge in pediatric cardiac program development readily enables us to design a blueprint for either scenario – this is what we mean by replicability.

In either medical setting (cardiac center or children's hospital), Heart to Heart's rigorous site assessment process enables us to set an appropriate starting point for our educational collaboration.



Young Peru The Republic of Peru is a young nation – 27% of residents are 14 years of age or younger, and only 7% of residents are 65 years of age or older. In contrast, in the U.S., 19% of the population are 14 or under, and 15% are 65 or older.

¡First pediatric surgical-educational mission to Peru!

We conducted Pediatric Surgical-Educational Mission 1 at San Borja National Children’s Hospital in Lima. Working side-by-side with our new colleagues along the continuum of care – to examine patients, perform procedures, and provide post-op intensive care – confirmed our site assessment findings. Demographic trends show that modern Peru is well positioned to expand cardiac care nationwide. We are fortunate to have the opportunity to collaborate with many of the dedicated specialists determined to make this a reality.

PEDIATRIC PROCEDURES PERFORMED JAN. 2016

Patient exams (9)	5,355
Echo studies (4)	3,716
Echo readings (10)	3,000
Cath lab - diagnostic (1)	8,064
Cath lab - interventional (1)	35,000
Open heart surgeries (6)	199,123
Intraoperative TEE studies + readings (5)	6,000
Anesthesia (7)	61,243
Perfusion (6)	18,000
Post-op exams /readings (8)	3,072
ICU post-op care, MD (7)	15,036
RN/tech support (ICU + OR)	10,461
Professional consulting + lectures	27,750
Donated supplies	15,000
Total In-kind Medical Services	\$410,820

PEDIATRIC FINANCIAL OVERVIEW

Financial support

Edwards Lifesciences Foundation	110,656
The Stan and Jan Berenstein Healthy Kids Foundation	20,000
Total Financial Support	\$130,656

In-kind support

In-kind medical services	410,820
Non-medical in-kind (see Expenses below)	5,670
Total In-kind Support	\$416,490

Total program value

Donated medical services	410,820
Expenses (excl. non-medical in-kind)	130,656
Non-medical in-kind donations (Peruvian)	5,670
Total Program Value	\$547,146

Expenses

Ground transportation, in-kind	1,100
Interpreters, in-kind	2,150
Meals, in-kind	1,100
Program supplies	4,220
Pre- and post-trip coordination + logistics	50,036
Travel	35,461
Travel insurance, in-kind	1,320
Year-round program development	40,939
Total Expenses	\$136,326

Data compilation as of May 6, 2016

76% of the total program value consisted of goods and services donated in-kind to Heart to Heart and used at San Borja in Program Year 1. The remaining 24% consisted of financial support from our major sponsors and individual donors.



Teamwork times two In the cath lab, two teams of adult cardiac specialists synchronize their efforts to implant an artificial human heart valve. While the team in the background confirms the patient's heart anatomy via x-ray technology in order to select the appropriate-sized valve, the team in the foreground is at the ready, with several valves to select from. Preparing the valve, which will be threaded through the patient's femoral artery on up to the heart, is its own highly specialized procedure.

Adult track: enhancing and extending life for patients with valvular disease

In the same way that Heart to Heart works with new pediatric teams to determine the best starting point, we work with already-established adult cardiac teams to determine what type of collaboration will take patient care to the next level. The adult care team at the National Cardiovascular Institute (INCOR) in Lima – the site of Adult Surgical-Educational Mission I – leads Peru in the treatment of heart disease. They perform fairly advanced surgical procedures, including cardiac transplantation, and they routinely treat valvular disease both surgically and endovascularly (via minimally-invasive catheter-based interventions).

Heart to Heart proposed introducing advanced technology to INCOR's adult team, and we mutually agreed to focus on transcatheter aortic valve replacement (TAVR), the newest therapy option for treating patients with valvular disease. This technology, only available since 2010, is an exciting breakthrough for patients with severe valvular disease. Historically, a significant number of such patients were considered too high-risk for open heart surgery. Studies have shown that without valve replacement, their prognosis is poor. For more than 50% of patients with severe symptomatic aortic valve stenosis, the average life expectancy is less than two years – and for some of them, it is often less than 12 months.

Heart to Heart assembled a team of specialists from UC Davis Medical Center (UCDMC) in Sacramento, California – one of the most experienced TAVR programs in the U.S. Since

2011, the UCDMC team has performed roughly 300 TAVR procedures. The team was very enthusiastic to share the new technology and their clinical expertise. Working side-by-side with our new colleagues, the UCDMC team guided the INCOR team to:

- (1) evaluate as a team which treatment option – open heart surgery (valve repair or replacement) or transcatheter valve replacement – will best serve a patient's needs;
- (2) perform the complex TAVR procedure on patients.

Every cardiac surgical procedure demands effective and precise teamwork. Performing the TAVR procedure actually requires three high-performing teams – two teams synchronizing their work to implant a valve in the cath lab (see photo above), and a back-up surgical team prepared to perform open heart surgery should the patient require it.

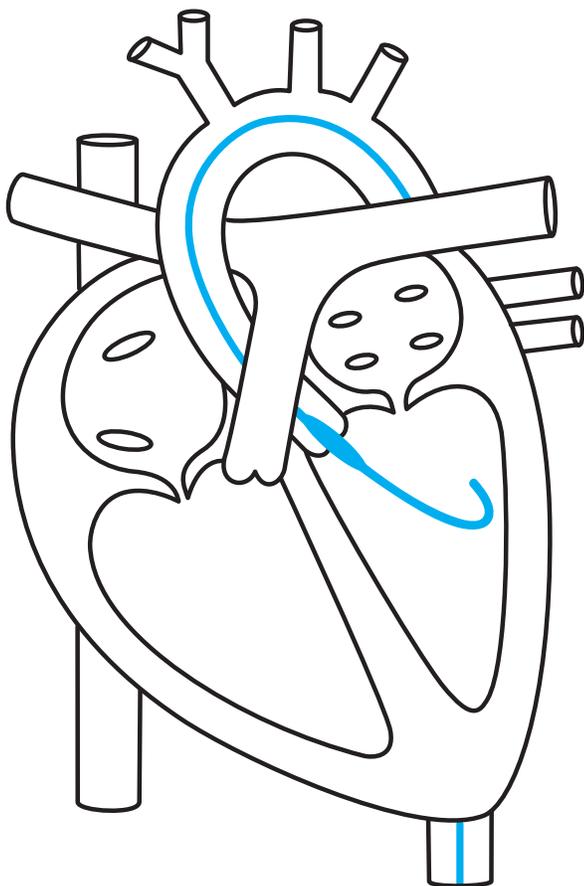
First, the joint Heart to Heart-INCOR team reviewed CT scans and echocardiographic images of about 20 potential TAVR patients. Then, over the course of five days, the team successfully implanted TAVR valves into nine patients. The response from the Peruvian interventional cardiology team was spontaneous and unanimous – they had never seen such strong cohesive teamwork, and they were inspired at the prospect of achieving this level of “team think” to benefit all their patients.



Team TAVR On the last day of the mission, Dr. Bertha Gonzales, INCOR's chief of interventional cardiology, shares some esprit de corps with her new colleagues from UC Davis Medical Center. From left: Harmeet Bhullar, MD; Thomas W.R. Smith, MD; Luke Ifland, Heart to Heart staff; Nilas Young, MD; Bertha Gonzales, MD; Garrett Wong, MD; Andrew Studin, RN; Jeff Southard, MD; surgical technician Debbie Lewis.

Transcatheter valve replacement

Shown here: catheter inserted into the heart to deliver and implant an artificial heart valve (TAVR valve). The artificial valve takes over the function of the incompetent native aortic valve.



As we age, our heart valves can “wear out.” In the United States, 1 in 50 adults will suffer from valvular disease. But even in the U.S., this condition often remains undiagnosed. Recently, guidelines have been established to address this public health issue.

88% of the total program value consisted of goods and services donated in-kind to Heart to Heart and used at INCOR in Program Year 1. The remaining 12% consisted of financial support from our major sponsors and individual donors.

ADULT PROCEDURES PERFORMED JAN. 2016

Patient exams (12)	4,764
Cath lab - interventional, TAVR (9)	41,139
Open heart surgeries (1)	6,000
Anesthesia, TAVR (9)	36,270
Intraoperative TEE studies + readings (12)	9,600
Post-op exams /readings (10)	2,560
RN/tech support (ICU + OR)	4,650
Professional consulting + lectures	24,375
Donated supplies (Edwards Lifesciences)	300,000
Total In-kind Medical Services	\$429,358

ADULT FINANCIAL OVERVIEW

Financial support

Edwards Lifesciences Foundation	59,145
Total Financial Support	\$59,145

In-kind support

In-kind medical services	429,358
Non-medical in-kind (see Expenses below)	10,100
Total In-kind Support	\$439,458

Total program value

Donated medical services	429,358
Expenses (excl. non-medical in-kind)	59,145
Non-medical in-kind donations (Peruvian)	10,100
Total Program Value	\$498,603

Expenses

Ground transportation, in-kind	1,200
Lodging, in-kind	6,360
Meals, in-kind	1,820
Program supplies	1,213
Pre- and post-trip coordination + logistics	27,662
Travel	7,637
Travel insurance, in-kind	720
Year-round program development	22,633
Total Expenses	\$69,245

Data compilation as of May 6, 2016

PERSPECTIVES ON ADVANCING COMPREHENSIVE CARDIAC CARE

“We help advance our international partners’ programs in a variety of ways, based on what is needed to improve patients’ access to excellent care. This may involve teaching new techniques or addressing the management of challenging clinical problems.”

– NILAS YOUNG, MD
FOUNDER & MEDICAL DIRECTOR, HEART TO HEART
CHIEF OF CARDIOTHORACIC SURGERY,
UC DAVIS MEDICAL CENTER

“When doctors from the U.S. first started coming to Lima, we gave them our most difficult cases, cases we could never have attempted. We couldn’t even imagine how to do such cases — but those children’s lives were saved. All we did was watch. After a few years, we started giving visiting American doctors the kind of cases we actually thought we might be able to perform in the future. Again, we watched. Now, we have come to realize that education for the whole team and learning-by-doing is what will enable us to move forward.”

– PERUVIAN CARDIAC SPECIALIST
PARTICIPANT, HEART TO HEART
SURGICAL-EDUCATIONAL MISSION 1

“Heart to Heart is in a unique position: we can tailor cardiac education and training to help cardiac teams in areas of need provide all forms of life-saving heart care for patients of all ages — from newborn babies to great-grandparents.”

– JOSIE EVERETT
EXECUTIVE DIRECTOR, HEART TO HEART

“Heart to Heart’s approach is by far the best way to build a program. There is no way that, in a week, we can take care of all the children needing heart care in Peru. The smart way to do this is to train people who will be staying in Peru — the specialists who live in Peru. It is their country, and they want to take care of their own children.”

– CATHY WOODWARD, RN, DNP
PEDIATRIC CARDIAC NURSE
UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER,
SAN ANTONIO

Thank you to our major sponsors, whose support continues to fuel our progress



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HEART TO HEART LIMA JANUARY 2016 TEAM **Mayo Clinic, Rochester, MN:** Dr. Frank Cetta, pediatric cardiologist **UCSF Benioff Children’s Hospital, San Francisco:** Dr. David Teitel, interventional pediatric cardiologist **University of Texas Health Science Center, San Antonio:** Dr. John Calhoun*, pediatric cardiac surgeon; Cindy Eckhardt, PCICU nurse; Rachel Lopez*, surgical technician; Dr. Clinton Pietz, ICU intensivist; Dr. Deborah Rasch*, anesthesiologist; Joshua Walker, perfusionist; Cathy Woodward, PCICU nurse **UC Davis Medical Center:** Dr. Harmeet Bhullar, anesthesiologist; Debbie Lewis, surgical technician; Dr. Thomas W.R. Smith, adult cardiologist; Dr. Jeffrey Southard, adult interventional cardiologist; Andrew Studin, cath lab nurse; Dr. Garrett Wong, adult interventional cardiologist; Dr. Nilas Young, adult cardiothoracic surgeon and Heart to Heart founder & medical director **Heart to Heart:** Jack Everett, assistant videographer; Josie Everett*, executive director; Lucie Everett*, interview interpreter; Luke Ifland*, administrative coordinator; Joye Leventhal, photographer; Adam Neville, videographer; Albina Popova, administrative coordinator.

*Spanish-English bilingual