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 1 and Adult 1, 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 preemies 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 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

May 2015, Peru & California
- On-the-ground site assessment at three potential partner sites in Lima
- Week of in-person meetings in Lima with key stakeholders
- Heart to Heart governing board approves proceeding to protocol negotiations

January 2016, Peru
- Adult Surgical-Educational Mission 1 at INCOR, Lima. Focus: valvular disease
- In-person meetings with INCOR director plus adult and pediatric cardiac chiefs to confirm mutual goals
- In-person meetings with President of ESSALUD to confirm mutual goals
- Pediatric Surgical-Educational Mission 1 at San Borja National Children’s Hospital, Lima. Focus: CHD
- In-person meetings with San Borja National Children’s Hospital CEO and pediatric cardiac leadership to confirm mutual goals
- Major media event with Peruvian Minister of Health and U.S. Ambassador to raise awareness re CHD

June 2016, Lima
- Pediatric Surgical-Educational Mission 2 to take place at INCOR, Lima. Focus: CHD
- Adult Surgical-Educational Mission 2 to take place at INCOR, Lima. Focus: valvular disease

Summer / Fall 2016, Peru
- Protocol signing among collaborative partners: ESSALUD, INCOR, and Heart to Heart
- Initial research/site assessment of ESSALUD affiliates in the provincial cities of Trujillo and Chiclayo

Late 2014/Early 2015, California
- Research conducted re cardiac care in Latin America
- Peru emerges as likeliest country for successful Heart to Heart collaboration
- Seed funding secured from long-time supporters

February 2016, California
- Begin refinement of protocol agreement with ESSALUD and MINSA

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

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

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

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

4 The 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.
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.
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.
¡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.

Youth 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.

PEDIATRIC PROCEDURES PERFORMED JAN. 2016

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<thead>
<tr>
<th>Procedure</th>
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<td>Patient exams</td>
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<td>Professional consulting + lectures</td>
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<tr>
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<tr>
<td><strong>Total In-kind Medical Services</strong></td>
<td>$410,820</td>
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PEDIATRIC FINANCIAL OVERVIEW

**Financial support**
- Edwards Lifesciences Foundation: $110,656
- The Stan and Jan Berenstain 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: $59,036
- Travel: $35,461
- Travel insurance, in-kind: $3,210
- Year-round program development: $49,939
- **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.
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 1 – 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 Itland, 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**

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**ADULT FINANCIAL OVERVIEW**

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Data compilation as of May 6, 2016
“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

“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

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 Calhoon*, 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. Nillas 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; Joyce Leventhal, photographer; Adam Neville, videographer; Albina Popova, administrative coordinator.

*Spanish-English bilingual