

INTO the HEARTLAND CAMPAIGN

SITE: CHELYABINSK
DISTRICT: URALS
COLLABORATION LAUNCHED: 2015

APRIL 7 – 19, 2015
SURGICAL-EDUCATIONAL
MISSION 1



Treating patients with advanced valvular disease Dr. Nilas Young (left) has extensive experience performing open heart surgery to treat valvular disease. In Chelyabinsk, he worked side by side with new colleague Dr. Vladislav Aminov (foreground), providing more than 40 hours of hand-in-glove mentoring in the operating room. Cardiologist Thomas W.R. Smith, an expert in diagnostic imaging, complemented the OR training by presenting 8 lectures to an audience of over 100 specialists.

DESTINATION CHELYABINSK: TREATING VALVULAR DISEASE IN CHILDREN AND ADULTS

Valvular heart disease refers to any disease process that involves one or more of the heart's valves and negatively affects the heart's function. Valvular conditions afflict tens of millions of people of all ages. Valve abnormalities can be present at birth (congenital) or appear later in life as the heart ages (acquired). In the United States, nearly all patients with significant valvular disease receive surgical treatment that substantially lengthens and improves the quality of their lives. Globally, however, millions of children and adults lack access to life-saving care for valvular disease.

On our launch surgical-educational mission to the Chelyabinsk Federal Cardiac Center (CFCC), Heart to Heart's focus was on teaching and training our Russian colleagues to surgically treat the backlog of patients with valvular disease throughout the Urals Federal District. More than 100 specialists from all

across Russia traveled to Chelyabinsk to participate. These included dozens of doctors and nurses from several hospitals within the Urals District, as well as specialists from many other districts – some traveling as far as 1,500 miles.

The Heart to Heart team of 19 medical volunteers and support staff spent nearly two weeks on the ground. The team included two cardiologists, a cardiac surgeon, an anesthesiologist, a surgical technician, two echosonographers, a pediatric cardiac intensive care specialist, a senior pediatric cardiac ICU nurse, and five expert medical interpreters.

This report looks at how valvular disease affects children and adults, and how Heart to Heart is expanding treatment for valve patients of all ages – currently in the heartland of Russia and, beginning in 2016, in other areas of the world.

PROGRESS TOWARD NATIONWIDE ACCESS TO CARDIAC CARE



Where Europe and Asia meet Situated at the foot of the Urals, the city of Chelyabinsk is 1,100 miles southeast of Moscow. The Ural Mountains are the geographical dividing line between the European and Asian continents. The district surrounding Chelyabinsk has a population of 12 million. The city recently made international headlines when an enormous meteor landed there in 2013. (Yes, we saw a piece of the meteor and visited the site where it landed!)

Launching the Chelyabinsk collaboration

Chelyabinsk is the site of Heart to Heart's eighth cardiac collaboration – and this trip marks our 46th surgical-educational mission to Russia. This cardiac center offers medical and surgical therapies to children and adults who make up a sizeable backlog of heart patients living in the Urals District. Established in 2011, the Center is federally funded and mandated to perform 5,000 cardiac procedures annually.

On this mission, Heart to Heart provided teaching and training to both pediatric and adult cardiac specialists. Our patients ranged from a one-day-old baby girl to a 78-year-old grandmother, and included a young boy from an indigenous tribe living on an island in the Arctic Circle, more than 800 miles away.

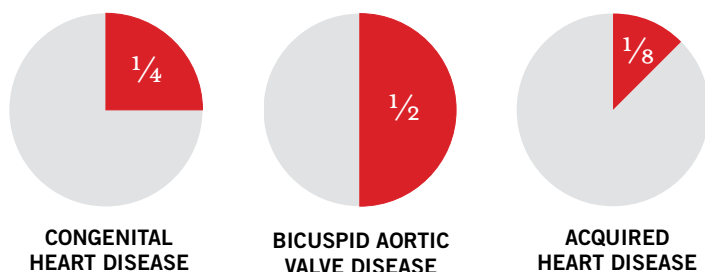
In eight working days, veteran volunteers Elaine Shea and David B. Adams performed echocardiograms on 69 adults and 45 children who had been pre-screened by the Chelyabinsk team. Of these, 60 adult patients (87%) and 25 pediatric patients (55%) showed signs of valvular disease. Echocardiograms were performed in a group setting, enabling dozens of Russian cardiologists to benefit from the expertise of Heart to Heart's nationally-recognized specialists.

Under the guidance of Founder & Medical Director, Dr. Young, the joint Heart to Heart-Chelyabinsk team selected eight adult patients for open heart surgery during the mission. All eight cases presented excellent opportunities to effectively demonstrate state-of-the-art surgical techniques for treating valvular disease.

Additionally, the joint team recommended seven children for diagnostic catheterizations in order to more fully assess each patient's condition prior to planning their best course of treatment. Three of these children subsequently underwent open heart surgery performed by the Chelyabinsk team, with Heart to Heart's intensive care team assisting in their post-operative care.

Heart to Heart's patient-centric approach consistently emphasizes the importance of teamwork along the continuum of care. Pre-op exams and diagnoses, potential surgical approaches, and post-op considerations are always discussed in conference settings. Such high-level open forums provide rare opportunities for specialists to "think out loud" with their peers and learn from one another.

ETIOLOGY OF VALVULAR DISEASE



■ Proportion of patients with valvular conditions requiring surgical treatment, by type of heart disease.

“A patient has a valvular condition if an abnormality of any heart valve is at least part of the reason for the patient’s surgical care or medical follow up.”

– DAVID TEITEL, MD
CHIEF OF PEDIATRIC CARDIOLOGY
DIRECTOR OF THE PEDIATRIC HEART CENTER
UCSF BENIOFF CHILDREN’S HOSPITAL, SAN FRANCISCO

Heart disease with valvular conditions

As stated earlier, valve conditions are generally divided into two categories, congenital or acquired. However, a very common congenital condition exists whose categorization remains ambiguous. Known as bicuspid aortic valve, this condition is directly linked to valvular disease among adults. Because patients born with a bicuspid aortic valve typically do not show symptoms until adulthood, some hospitals associate this congenital heart abnormality with acquired disease. For clarity and simplicity, we will discuss bicuspid aortic valve separately from congenital heart disease and also separately from acquired heart disease. In this report, we will take a look at valvular disease through the real-life stories of three of our Chelyabinsk patients.

Congenital heart disease (CHD) and valvular conditions

Worldwide, 1% of all babies are born with CHD, totalling over 1.3 million children each year. Approximately one-quarter of their cases involve life-threatening valvular conditions. For these babies, prompt diagnosis and access to treatment is critically important; most children diagnosed with congenital valve abnormalities require early surgical intervention in order to live. This was the case for four-year-old Lyosha, who underwent his first open heart procedure at the age of three months. (Read Lyosha’s story on page 4.)

Bicuspid aortic valve (BAV) disease An additional estimated 1-2% of babies are born with a bicuspid aortic valve (instead of the normal three-cusp aortic valve) – technically making BAV

the most common birth defect worldwide. When symptoms do develop, most commonly in adulthood, BAV is revealed as the underlying cause of the patient’s valvular disease. Regardless of the debate over BAV’s categorization, we know that over 50% of babies born with BAV will need surgical intervention – either valve repair or replacement – in adulthood. **The BAV cohort translates to more than one million babies being born worldwide each year who will ultimately need valve surgery.** Ivan, one such BAV patient, was recently diagnosed and underwent his first surgical intervention at the age of 23. Importantly, many BAV patients develop aneurysms of the aorta, which may also require concomitant surgical treatment. (Read Ivan’s story and see BAV inset on page 5.)

Acquired heart disease (AHD) In 2002, heart disease became the leading cause of death among adults worldwide. This has been the case for nearly a century in the U.S., where today an estimated one out of three people is affected by heart disease – and an estimated 2.5% of the general population have been diagnosed with a valvular condition (also known as acquired valvular disease). To repair or replace their heart valves, cardiac surgeons in the U.S. perform about 150,000 valve procedures per year. Additionally, rheumatic heart disease is a very common cause of valvular disease in the developing world. Patients with rheumatic heart disease are likely to require valve replacement surgery as adults.

We do not know what the incidence of valvular disease is in Russia, but we do know that heart disease is the leading cause of death there. With a population roughly half that of the U.S., cardiac surgeons in Russia perform less than 15,000 procedures annually on valvular disease patients – only 10% of the volume performed in the U.S.

Although the incidence of valvular disease among adults varies around the world, it is widely acknowledged that in most countries it is neither well understood nor effectively treated. Vera, 48, is an example of the growing number of underserved heart patients worldwide living with undiagnosed and untreated valve conditions. (Read Vera’s story on page 6.)

On the next pages, you will meet three Heart to Heart patients – Lyosha, Ivan, and Vera – who represent the valvular conditions detailed above: CHD, BAV, and AHD.

Valvular disease profile	Lyosha Age: 4	Ivan Age: 23	Vera Age: 48
Congenital heart disease (not including BAV)	x		
Bicuspid aortic valve (BAV) (congenital valve abnormality)		x	
Acquired valve disease			x
Needs surgery in childhood	x		
Needs surgery in adulthood	x	x	x



Patient	Lyosha, 4 years old
Disease type	Congenital heart disease with valvular condition
Diagnosis	Tetralogy of Fallot (TOF), pulmonary and tricuspid valve insufficiency
Previous interventions	Shunt (2011); complete TOF repair with transannular patch, shunt takedown, VSD closure (2011); diagnostic catheterization (2015)
Open heart surgery	Pulmonary valve replacement, tricuspid valve repair, pulmonary artery plasty (April 2015)

Lyosha’s story: congenital heart disease with a valvular condition

Every year in Russia more than 19,000 babies are born with CHD. Lyosha is one of these children. He was born prematurely, at 28 weeks, and was immediately diagnosed with a common form of CHD called Tetralogy of Fallot (TOF). In the U.S., it is customary to surgically treat TOF between the ages of three and twelve months, depending on the severity of the case.

Lyosha underwent his first surgery when he was three months old, a palliative procedure to give him some time to grow and gain strength. His second surgery, when he was seven months old, was a complete TOF repair. Now four years old, Lyosha and his mother were scheduled for a follow-up appointment to coincide with Heart to Heart’s mission.

TOF is a combination of heart defects, one of which is obstruction of the pulmonary valve. This means that TOF patients typically need pulmonary valve repair or replacement in childhood – and many need subsequent valve replacements in adulthood as well. Lyosha’s native pulmonary valve had become increasingly regurgitant (leaky), and his family had been informed he would likely need surgery soon. Heart to Heart examined Lyosha first by echocardiogram; to further confirm his condition, we performed a diagnostic catheterization. These studies revealed that Lyosha needed immediate surgical intervention to address his valvular disease.

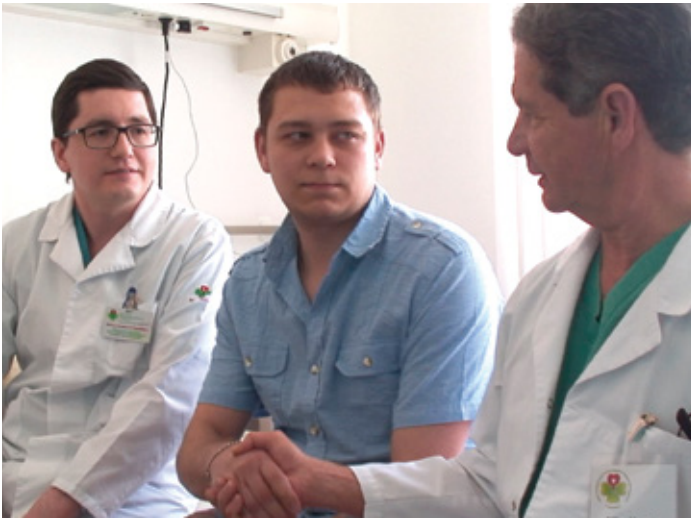
Lyosha’s was one of several complex cases presented for discussion in a conference setting. Once the best surgical approach had been determined jointly by the Heart to Heart-Chelyabinsk team, little Lyosha’s third open heart surgery was scheduled. Days later, the Chelyabinsk surgical team replaced his pulmonary valve, repaired his tricuspid valve, and reconstructed his pulmonary artery.

At four years of age, Lyosha’s heart is still quite small: over time his heart will grow and his recently implanted artificial pulmonary valve will need to be switched out with a larger one to accommodate growth. As Lyosha’s heart grows and strengthens, he will need annual cardiac follow-up exams. As an adult, he will also need to be monitored annually to assess valvular function. Throughout his lifetime, Lyosha is likely to require additional surgeries to replace his pulmonary valve as each artificial valve wears out over time. With today’s technology, children with artificial valves require replacements every 5-8 years; for adults the range is 10-20 years.

In the meantime Lyosha is doing well. He recovered quickly and was able to leave the pediatric cardiac ICU three days after his open heart surgery. He and his mother returned home to his father and siblings. Heart to Heart looks forward to checking up on Lyosha again in a year when we return to Chelyabinsk for our next surgical-educational mission.

Overview: worldwide incidence of CHD with a valvular condition

- 1 CHD is widely considered the most common human birth defect.
- 2 Each year, over 1.3 million babies worldwide are born with CHD (1% of all births.) In order to live, half of these children will need surgical intervention by the age of 3.
- 3 About one-quarter of all children with CHD – 325,000 new cases each year – have a valvular condition. Nearly all of these children will need valve surgery at some point in their lives.
- 4 Only about 15% of children worldwide have access to life-saving heart surgery.



Dr. Vladislav Aminov, Ivan, and Dr. Nilas Young, the day before Ivan's open heart surgery – the Center's first David procedure on a BAV patient.

Patient	Ivan, 23 years old
Disease type	Congenital bicuspid aortic valve (BAV) with valvular condition
Diagnosis	Bicuspid aortic valve with aortic insufficiency and large aortic aneurysm
Previous interventions	No previous interventions
Open heart surgery	Valve-sparing aortic root replacement and aortic valve repair, also known as the David procedure (April 2015)

Ivan's story: congenital BAV with a valvular condition

Ivan, 23, lives with his fiancée in Chelyabinsk Oblast. He works at a chemical plant as a technician. He holds a technical A.S. degree, but would like to go back to school to pursue a B.S. in engineering and advance in his field. He hopes that surgery will improve his overall health so that he can lead a more active life.

Ivan was born with BAV, which remained undetected until fairly recently, when he was diagnosed with aortic valve insufficiency. Ivan's undetected heart disease had progressed to the point that the root of his aorta had been adversely affected. Saving his life would require open heart surgery. During Heart to Heart's mission, Dr. Young recommended to Dr. Aminov that Ivan undergo a valve-sparing aortic root replacement and aortic valve repair operation. Developed by innovators Tirone David and Magdi Yacoub, this procedure – also known as the David procedure – replaces part of a patient's aorta with a graft into which the patient's native aortic valve is reimplanted, avoiding replacing it with an artificial valve.

The joint Heart to Heart-Chelyabinsk team performed the David procedure on Ivan. This was the first time Dr. Aminov (or anyone at the Center) had performed this operation on a patient with a bicuspid aortic valve. Ivan's case is a classic example of how both congenital heart disease and valvular disease can affect young adults. This was the best treatment option for Ivan – this repair may potentially last him the rest of his life.

“Under Dr. Young’s guidance we performed our first ever valve-sparing surgery on a patient born with a bicuspid aortic valve. Having such an experienced specialist standing next to me, to give me immediate and precise instruction when needed, was incredible. If Dr. Young hadn’t been there, I might not have tried to perform this very complicated surgery [the David procedure]. But we did it – with excellent results.”

– VLADISLAV V. AMINOV, MD
CHIEF, ADULT CARDIAC SURGERY DEPARTMENT #2
CHELYABINSK FEDERAL CARDIAC CENTER

Overview: worldwide incidence of BAV with a valvular condition

- 1 Each year, about 2 million babies are born with BAV (1-2% of all births) – technically making BAV the most common human birth defect worldwide.
- 2 People with bicuspid aortic valves are much more likely than those with normal (three-cusp) aortic valves to develop aortic valve stenosis and/or aortic valve insufficiency. Both potentially life-threatening conditions can be treated surgically via valve repair or replacement.
- 3 Very few people born with BAV require surgical intervention in childhood, however the **majority of BAV patients – about 1 million new cases each year – will require valve surgery in adulthood.**



Patient	Vera, 48 years old
Disease type	Acquired heart disease with valvular condition
Diagnosis	Dilated cardiomyopathy, mitral and tricuspid valve insufficiency, pulmonary hypertension
Previous interventions	No previous interventions
Open heart surgery	Mitral valve replacement with bioprosthesis and tricuspid valve annuloplasty (April 2015)

Vera’s story: acquired heart disease with a valvular condition

In the United States, 2.5 out of every 100 Americans suffer from acquired valvular heart disease, which is characterized by damage to or a defect in one or more of the heart’s four valves. The function of valves is to ensure that blood flows in only one direction through the heart, therefore significant valve disease is life-threatening. Left untreated, advanced valvular heart disease almost always results in severe disability and ultimately death – but timely diagnosis and surgery can greatly enhance a person’s quality of life and lifespan.

Forty-eight-year-old Vera lives with her husband, Sergey, in Kurgan Oblast, a four-hour bus ride from the Chelyabinsk Center. She has two adult children, Dmitriy and Natalia, and two grandchildren – a seven-year-old boy who just started elementary school, and a three-month-old baby girl. Vera used to work as a mail carrier. Now she, health permitting, and her husband spend their days at home tending their vegetable garden and helping out with the grandkids. Vera enjoys reading detective novels, knitting, crocheting, and cooking delicious meals for her family.

Vera has acquired heart disease. She was diagnosed with mitral valve insufficiency two years ago, in 2013. Vera has been hospitalized three times in the recent past, although she had not had any surgical interventions prior to Heart to Heart’s arrival. During her pre-operative consultation, surgeons Dr. Young and Dr. Aminov agreed that Vera’s mitral valve needed to be replaced and that the best option was to implant a biological prosthetic valve. Cardiac specialists recommend repairing or replacing heart valves depending on many factors, including the severity of valve disease; age and general health. In Vera’s case, a biological valve made of calf pericardium was recommended over a mechanical valve replacement. Her medical team believes the repair will

bring Vera a better quality of life – with no more extended hospitalizations and no need for lifelong dependency on anticoagulants.

The joint Heart to Heart-Chelyabinsk team operated on Vera on April 15, 2015. She underwent a mitral valve replacement and a tricuspid valve annuloplasty – using donated Edwards Lifesciences medical devices. She recovered well in the CICU. Vera’s family was not able to afford an extended hotel stay to be near her, so Vera was on her own in the hospital. During her post-operative recovery, Heart to Heart volunteers brought Vera a large bouquet of bright flowers to cheer her up.

Vera’s new biological valve should last her 15-20 years. She is not expected to need surgical intervention in the near term. In the future, Vera may be a good candidate for a transcatheter valve replacement.

Overview: worldwide incidence of acquired valvular heart disease

- 1 In the United States, 2.5% of the population (over 5 million people) have been diagnosed with acquired valvular disease. The worldwide incidence is not clear.
- 2 The chances of developing valvular disease increase with age. Fewer than 2% of 40-year-olds are affected, while more than 13% of those who are 75 years old or older are affected.
- 3 A variety of treatment options exist for acquired valvular disease, including valve repair and replacement through open heart or catheter-based procedures.
- 4 Valvular disease treatment is not readily understood or available in most countries.

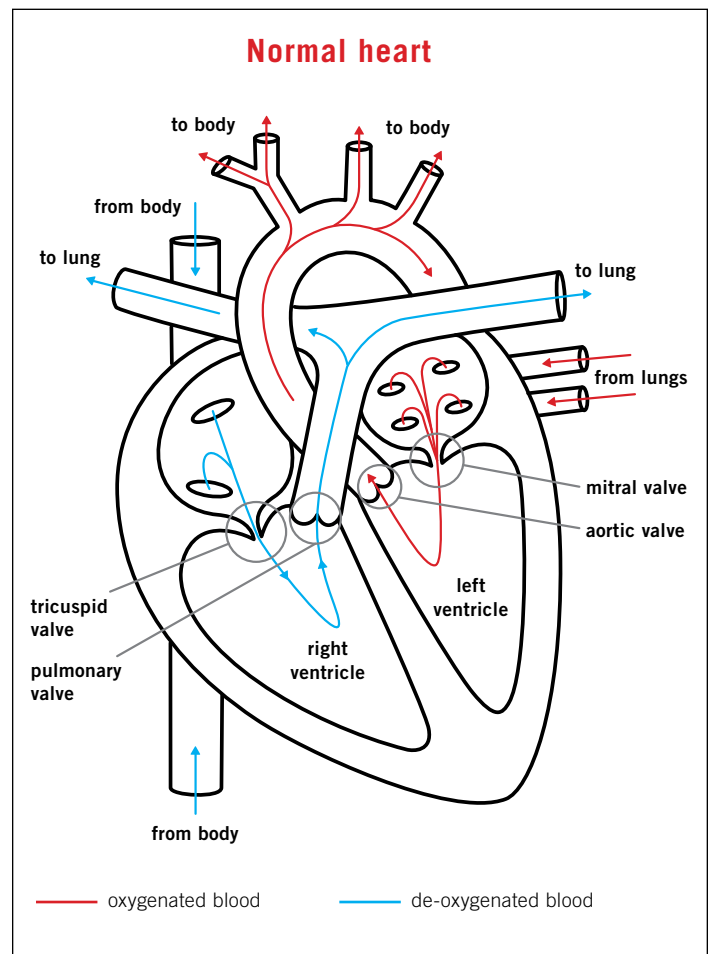
Surgically treating valvular disease: a master class in real time

A life-threatening valvular condition can strike at any age: you can be born with a heart defect affecting a valve, or with an anatomical valve abnormality that predisposes you to disease later in life, or you can acquire heart disease affecting one of your valves in midlife or later.

Repairing the heart valve is generally preferable to replacing it, in order to preserve the strength and function of the heart muscle. However, valve repair is not widely available in most countries, partly because its complexity is greater than a replacement. Additionally, some valves cannot be surgically repaired. Mitral valves can often be repaired, whereas aortic and pulmonary valves often have to be replaced. Repair options are ideal for some patients, as in the case of Ivan.

In Russia, for the past several decades, doctors have overwhelmingly recommended implantation of mechanical valves for patients with valvular conditions. Traditionally, little consideration has been given to repairing valves or to replacing a native valve with either a homograft or a biological valve. On this mission, we reviewed key concepts in every setting – from the lecture hall, echo lab, and cath lab, to the operating room and ICU – to help our colleagues better understand a broader range of valvular disease treatment options.

Over the course of five consecutive days, Dr. Young's mentoring in the OR served as a 40-hour master class in surgical approaches to treating valvular diseases, including responding to associated intraoperative challenges. Dr. Aminov, working as the lead surgeon on cases such as Ivan's and Vera's, learned important nuances of complex surgical techniques. Under Dr. Young's hands-on guidance, Dr. Aminov performed three valve-sparing root procedures, two additional root procedures with valve replacement (Bentall procedures), and two additional isolated valve replacements. Dr. Aminov, who can now perform valve surgery on a wider range of heart patients, summed up his week with Dr. Young as "an incredible opportunity to learn from a master in the operating room."



As the team in Chelyabinsk continues to learn and utilize innovative new surgical approaches, their young, technically skilled surgeons will be able to perform increasingly complicated procedures widely utilized in the West. The stories of Lyosha, Ivan, and Vera illustrate how Heart to Heart can positively affect surgical outcomes for thousands of underserved valve patients half a world away. We are privileged to play a role in advancing cardiac medicine around the globe.

HEART TO HEART 2015 CHELYABINSK TEAM Alta Bates Summit Medical Center: Elaine Shea, echosonographer Children's Healthcare of Atlanta: Brenda Jarvis, senior PCICU nurse; Dr. Michael Wolf, PCICU intensivist Duke University Medical Center: David B. Adams, echosonographer Edwards Lifesciences: David Williams,* IT support Samara Regional Cardiac Center: Dr. Anton Avramenko,* lecture & OR interpreter; Dr. Dina Vozdvizhenskaya,* cardiology interpreter Mechnikov Northwestern State Medical University, St. Petersburg: Dr. Anastasia Kuzmina-Krutetskaya,* cardiology interpreter; Dr. Svetlana Kuzmina-Krutetskaya,* cardiology & lecture interpreter Tomsk Cardiology Institute: Irma Ozashvili,* lecture & ICU interpreter UC Davis Medical Center: Olesya Dushkova,* surgical technician; Dr. Anna Kowalczyk, adult anesthesiologist; Dr. Thomas W.R. Smith, adult cardiologist; Dr. Nilas Young, adult cardiothoracic surgeon and Heart to Heart founder & medical director UCSF Benioff Children's Hospital, San Francisco: Dr. David Teitel, interventional pediatric cardiologist Heart to Heart: Ellie Bastian,* videographer; Jackson Everett, assistant videographer & photographer; Josie Everett,* executive director; Albina Popova,* administrative coordinator.

*Russian-English bilingual

FINANCIAL OVERVIEW

Financial support

Edwards Lifesciences Foundation	41,862
TSFRE	37,500
Saluja Family	25,000
St. Jude Medical Foundation	15,000
Other individual donations	21,020
Total Financial Support	\$140,382

In-kind support

In-kind medical services	471,758
Non-medical in-kind (see Expenses below)	37,860
Total In-kind Support	\$509,618

Total program value

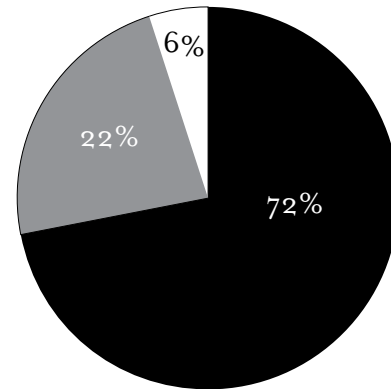
Donated medical services	471,758
Expenses (excl. non-medical in-kind)	140,382
Non-medical in-kind donations (Russian)	37,860
Total Program Value	\$650,000

Expenses

Ground transportation, in-kind	1,800
Interpreters, in-kind	3,300
Lodging, in-kind	25,600
Meals, in-kind	4,800
Program supplies	314
Pre- and post-trip coordination + logistics	62,169
Travel	27,033
Travel insurance, in-kind	1,080
Visas, in-kind	1,280
Year-round program development	50,866
Total Expenses	\$178,242

CHELYABINSK PROGRAM YEAR 1

Total Program Value: \$650,000



- Heart to Heart in-kind medical services \$471,758
- Expenses (excl. non-medical in-kind) \$140,382
- Non-medical in-kind donations (Russian) \$37,860

PROCEDURES PERFORMED APRIL 2015

Patient exams (9)	3,771
Echo studies + readings (114)	107,085
Cath lab - diagnostic (7)	54,348
Cath lab - study review (17)	4,100
Adult open heart surgeries (8)	102,900
Anesthesia (8)	66,440
Intraoperative TEE studies + readings (13)	6,300
Post-op exams / readings (8)	7,424
ICU post-op care, MD (8)	41,528
RN/tech support (ICU + OR)	5,812
Professional consulting + lectures	21,750
Donated supplies (Edwards Lifesciences)	50,300
Total In-kind Medical Services	\$471,758

Data compilation as of June 30, 2015

78% of the total program value consisted of goods and services donated in-kind to Heart to Heart and utilized in Chelyabinsk in Program Year 1. The remaining 22% consisted of financial support from our major sponsors and individual donors.

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



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