AN INTRODUCTION TO HEARTBYTES

V2 August 4, 2015

INTRODUCTION

HeartBytes is the first-of-its-kind national youth cardiac registry of seemingly healthy kids. It is inspired by Simon's Fund, a nonprofit organization dedicated to raising awareness about the conditions that lead to sudden cardiac arrest and death in children.

HeartBytes is the logical next step in a quest to prevent the sudden and unexpected death of children. Simon's Fund and several other organizations around the country conduct youth heart screenings. These groups have witnessed the benefit that an EKG exam can bring to the life of a seemingly healthy child. However, stories are not enough. A change in the standard of care requires evidence-based research.

HeartBytes is a HIPPA-compliant digital platform designed to efficiently gather and disseminate data to qualified researchers free of charge. It will promote more research and relieve organizations from many of the administrative burdens inherent in the screening process.

The data contained in HeartBytes includes: medical history, family history, vitals, electrocardiograms and echocardiograms. All of the parents have provided consent and the data is de-identified prior to distribution. It is gathered by organizations that conduct youth heart screenings. Every organization subscribes to a protocol to ensure that the data is gathered responsibly and consistently.

HeartBytes was built with the help of some very talented and generous companies. INFINITT North America, a company based in Phillipsburg, New Jersey, stores the electrocardiograms and echocardiograms on its cloud-based platform. Pulse Infoframe, a company based in London, Ontario and Philadelphia, Pennsylvania, is the architect of the registry and application, and hosts all of the data on its secure and HIPPA-compliant servers. DataMed, a company based in Atlanta, Georgia, provides the ECG translation software enabling groups to use any brand of equipment with digital storage capabilities.

If you have other questions about HeartBytes, please contact Darren Sudman, Executive Director and Co-Founder of Simon's Fund. He can be reached at darren@simonsfund.org.

USING HEARTBYTES

Thanks for your interest in HeartBytes. By joining the HeartBytes network, you are committing yourself to the greater good. While we are all engaged in lifesaving screening work at home, combining our data will facilitate lifesaving research across the country. The digital platform will also streamline your screening process and greatly reduce the administrative burden.

In the pages ahead, you will learn how HeartBytes works and what is required of organizations. In the Appendix, you will see screen shots of the desktop version.

The Protocol

There are minimum standards required of organizations that wish to use HeartBytes. In a registry, there needs to be consistency among data sets. While organizations are encouraged to provide their input for future modifications and updates, the current version requires that the following data be recorded:

Medical and Family History
Vitals: blood pressure, height (feet/inches), weight (pounds).
Murmur
ECG
Echo (can be mandatory or applied as needed)

Setting Up the Screening

HeartBytes is a fully integrated and independent web application with a connected Android application for onsite data entry built using Healthie™. Healthie™ is a cloud-based health care analytics system. Pulse Infoframe provides data management and integration systems targeted at the highly detailed requirements of medical specialists. Healthie™ will allow physicians at Screening Clinics to easily capture, organize, model, store, and share detailed administrative and medical data with patients and other health care stakeholders through a secure, web-based application. The platform provides real-time data-collection and analytics based on the customized workflow of the heart screening.

HeartBytes allows organizations to schedule, obtain consent and collect valuable historical and medical information on students.

It takes just a few minutes to create a new screening location on your computer. Through the "Site Management" screen, the user enters the screening location, sponsor, start and end times, age intervals and determines how many students will be screened and at what time intervals. This will create the site with the necessary links to create registrations of students.

Parents are invited to register for the screening via a link. Parents are first required to provide their consent. Following this, they select an appointment time. Next, they complete a cardiac specific medical and family history questionnaire, at which time, the student is assigned a unique ID. Upon completion of this process, an electronic medical record is completed for the student. The parent receives an email confirming the screening time, along with a link that can be used to reschedule or cancel the appointment.

Prior to the screening, the administrative user should create additional user accounts. The following categories have been created and vary as to rights:

- Administrative – can access all data and perform any function on the platform.
- Physician – can access all students for a specific site and for a given time period.
- Data Entry – can access all students for data entry purposes only for a specific site and for a given time period.

The ECG and Echo equipment must be able to store the studies in a digital format (more on this later). Using a USB drive, you will be required to export the studies from the machines after the screening is over, and upload them to the INFINITT server where they will be appended to the student's electronic medical record.

Using at the Screening

The HeartBytes application provides all of the administrative tools needed to conduct a youth heart screening.

Upon arrival, students are checked in with the touch of a button. Immediately following, the student is prompted to provide his/her assent to use his/her de-identified data for research purposes. Remember, the parent's already provided consent during the registration process.

As the student progresses through the heart screening, data is added to his/her electronic medical record via Android-based tablets. These tablets can be purchased at a discount at TechSoup (www.techsoup.org).

HeartBytes is designed around the following screening activities: vitals (BP, height and weight), murmur, ECG Exam, Echo and Screening Report. The medical professionals tasked with performing these functions are provided with tablets for data entry. After all of the data has been gathered and evaluated, a medical professional will complete the Screening Report which will be emailed to both parents and the pediatrician (if such info was provided) with the touch of a button.

HeartBytes has a unique feature as it alerts the medical professionals to high-risk students through a red flag system. Students who answered affirmatively to important questions have an indication next to their name. The red flag concerns are listed on a summary page making it easy for medical professionals to identify potential problems. Answers to the complete medical and family history questionnaire are available under a separate tab.

At the completion of the screening process, the student is checked out with the touch of a button.

Using After the Screening

At the conclusion of the screening, the following data will be incorporated into the student's electronic medical record:

- A complete medical and family history.
- Vital information
- Murmur information
- ECG information
- Echo information
- A completed Screening Report

The ECG and Echo images need to be added to HeartBytes. In order to complete this manual step, you will need a USB drive (64 GB recommended). Insert the drive into the port on your machine. If prompted, export the ECG data in XML format and the Echo data in a DICOM format. This process will take time as some of these files are large. Once the images are exported onto your drive, you will need to upload them to the INFINITT server.

Technically Speaking

Setting Up the ECG

- Ensure that the device is set up to save the studies so that they can be exported at the conclusion of the screening.
- Enter the student's name, birthday and Unique ID into the system.

Setting Up the Echo

- Ensure that the device is set up to save the studies so that they can be exported at the conclusion of the screening.
- Enter the student's name, birthday and Unique ID into the system.
- The technician should collect a minimum of nine heart views.
- Machine must have 2D, color flow and pulsed and continuous wave Doppler
- Machine must be Digital Imaging and Communications in Medicine (DICOM) ready with USB port or drive burning capability for transfer of studies to HeartBytes
- Machine must be currently inspected for safety compliance by appropriate department, agency

Establishing WiFi Connection

- HeartBytes is updated in real-time as the data is gathered at the screening. The week before the screening, confirm that the location has WiFi access in your screening area. If they do not, bring a 4G hotspot to ensure access to HeartBytes. The application uses very little data in the transfer however, we recommend if a hotspot is used to keep the device in a static location with strong signal strength so that connections will not be dropped.

THE FINE PRINT

HeartBytes is a collaborative effort and changes the research paradigm. Currently, a researcher must apply for grants, wait for funding to arrive (if ever), and conduct heart screenings to gather data. This takes lots of time and money. This is a tremendous barrier to advancement.

Through collaboration, HeartBytes creates a "public library" model and enables qualified researchers to spend their time doing what they do best – evidence-based science.

Data Ownership

As a HeartBytes user, your organization can collect and store all of your heart screening data and images in a unique portal. This data belongs to you and is only accessible by you. You can withdraw it at any time and use it as you wish.

As part of the HeartBytes community, you agree donate a copy of your data to the registry or "public library." In this environment, your data will be commingled and de-identified. The registry will be managed by Simon's Fund and the data can only be used by qualified researchers approved by the HeartBytes Independent Review Board.

Data Access

All researchers are encouraged to apply to HeartBytes. The applications will be submitted online and reviewed by the HeartBytes Independent Review Team (HIRT). This team was selected by Simon's Fund for their dedication to the well-being of children and experience in the medical and academic community.

Brett Anderson, MD MBA, earned her medical degree from the University of Pennsylvania and a Master's of Business Administration at the Wharton School. Her clinical interests are in the management of both congenital and acquired pediatric heart disease. Her research interests focus on improvements in costs and quality associated with the management of pediatric heart disease.

Dawn Comstock, PhD, earned her B.S. from Colorado State University, her M.S. from the University of Iowa and her PhD from the University of California San Diego. Her research interests focus on the epidemiology of injury among the

physically active, specifically the study of sports, recreation and leisure activity-related injuries among children and adolescents.

Alex Kemper, MD, MPH, MS, earned his medical degree from Duke University, an his MS and MPH at University of North Carolina - Chapel Hill. He is an active pediatrician. His research interests focus on the delivery of preventive care services and the quality of care that children receive by strengthening the linkages between primary care, specialty care, and public health services.

All research proposals deemed to have a legitimate purpose by HIRT will be considered, regardless of the researcher's viewpoint or professional affiliation.

Finances

Simon's Fund invested approximately $250,000 of cash and in-kind contributions to launch HeartBytes. As new organizations are added, and bandwidth is expanded, additional capital will be needed to compensate the service providers. Some of this capital will come from the participating organizations. There will be an upfront licensing fee and an annual maintenance fee.

A fund has been established to offset the upfront licensing fee of qualified organizations. These funds were generously donated by the family of Victor Thay.

CLOSING

You already know that you are a part of something special. Words cannot describe the feeling when a family says "Thank you for discovering a potentially-fatal heart condition in our child. You saved her life."

However, in order to change the standard of care so that every child receives a cardiac screening, we need to do more. We need to gather data.

The data collected at our heart screenings holds the answer to so many important questions like "How many children have undetected heart conditions," "how many children possess risk factors for hypertension or obesity," and "does the ECG exam when added to the physical help discover heart conditions."

Thanks for considering HeartBytes. Your participation will ensure that while you are accomplishing greatness in your community, we are working together to accomplish greatness in this country.

APPENDIX

heartbytes

Sites

Name	Start Time	End Time	Public Registration Link	View Timeslots
Second Test Site	06/02/2015 8:00 AM	06/02/2015 11:00 AM	https://simons-fund-staging.pulseinfoframe.com/consent/second-test-site-2015-06-02	View
Hank Scorpio Public School	04/30/2015 9:00 AM	04/30/2015 12:00 PM	https://simons-fund-staging.pulseinfoframe.com/consent/hank-scorpio-public-school-2015-04-30	View

inspired by Simon's Fund

pulse infoframe inc

Your unique HeartBytes home page displays all of your screening locations.

heartbytes

Consent Form For Hank Scorpio Public School Screening - Apr 30, 2015

I, the undersigned, give consent, for my child to voluntarily participate in the Heart Screening hosted by Simon's Fund (hereinafter "Screening Organization"). The Heart Screening is not a formal clearance for sports participation. Clearance for sports must be obtained from your physician.

The Heart Screening will include a few tests. My child will receive an electrocardiogram (ECG), have his/her blood pressure checked, have height and weight recorded, have a medical history form reviewed, and if required, based on findings, receive an echocardiogram (ECHO).

All of the information that you provide before and during the Heart Screening is gathered and stored in a confidential registry called HeartBytes. HeartBytes was developed and paid

Parents begin the registration process by reading and signing (electronically) the consent form.

heartbytes Sites Dashboard test Administration Logout

Registration for Second Test Site screening - Jul 2, 2015

Please review this medical history form carefullly and fill it out to the best of your ability. Your answers will be used to create medical forms, so please be mindful of spelling and punctuation. Thanks for your cooperation.

Appointment Time

Please select an appointment time:

8:00 AM	8:30 AM	9:00 AM	9:30 AM
10:00 AM	10:30 AM	11:00 AM	11:30 AM
12:00 PM	12:30 PM	1:00 PM	1:30 PM

Student Information

First Name

Last Name

Current School

Date of Birth (MM/DD/YYYY)

Student Address

Address

City

State Pennsylvania

Zip

Parents select a screening time and complete the medical and family history questionnaire. Upon completion, an electronic medical record is created for the students.

heartbytes Sites Dashboard dsudman1 Administration Logout

Students

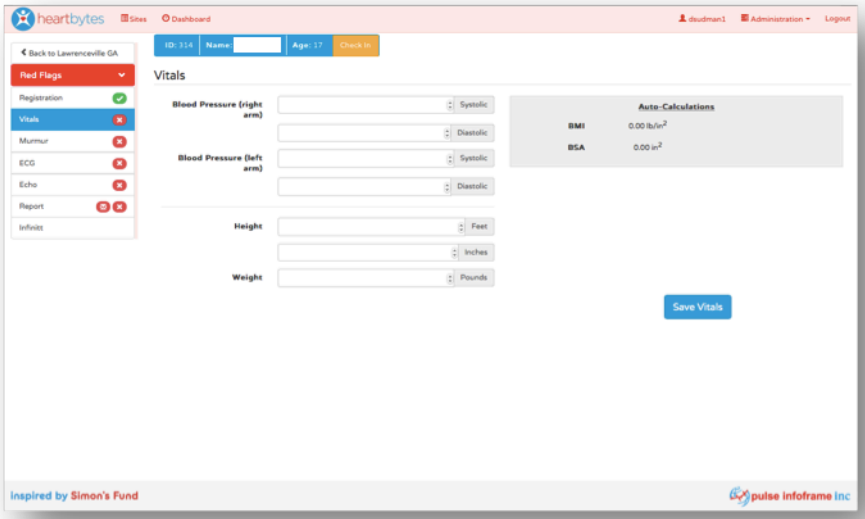
A B C D E F G H I J K L M N O P Q R S T U V W Y

Search Search

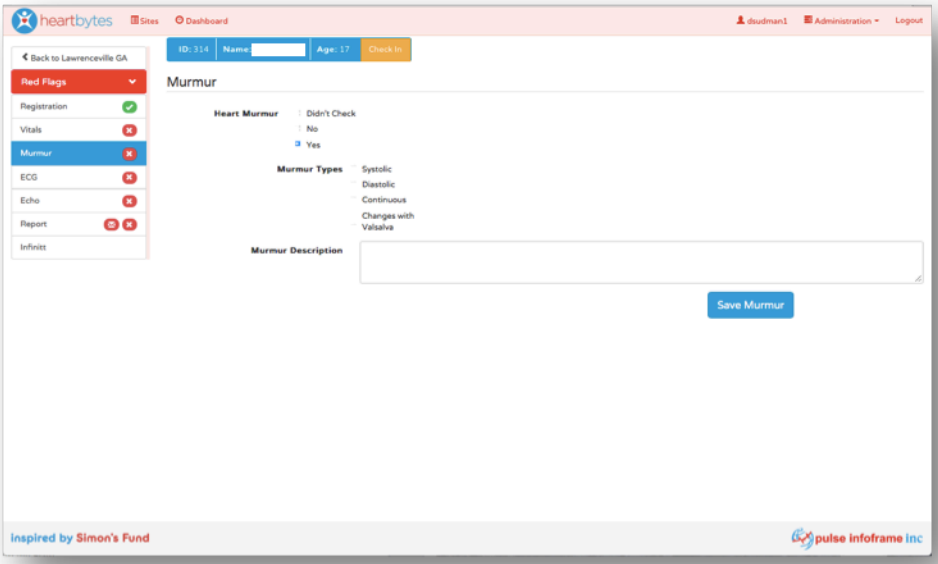
ID	Student's Name	School Name	Appointment Time			Checked In	Checked Out
Redacted for Privacy				View	Vitals Murmur ECG Echo	Check In	--
				View	Vitals Murmur ECG Echo	Check In	--
				View	Vitals Murmur ECG Echo	Check In	--
				View	Vitals Murmur ECG Echo	Check In	--
				View	Vitals Murmur ECG Echo	Check In	--
				View	Vitals Murmur ECG Echo	1:46 PM	1:46 PM

This administrative view lists every registered student alphabetically. The entire record can be seen behind "View." The red boxes represent stations at the

screening. There are forms behind each box that are filled out. Upon completion, the red box turns green or yellow if the finding is abnormal.



At the Vital Station, the student's blood pressure, height and weight are entered. The BMI and BSI are automatically calculated.



At the Murmur Station, any sounds are recorded.

heartbytes Sites Dashboard dsudman1 Administration Logout

Back to Lawrenceville GA

ID: 314 Name: Age: 17 Check In

Red Flags

Registration

Vitals

Murmur

ECG

Echo

Report

Infinitt

Electrocardiogram

Status: Didn't Check / Normal / Abnormal

Findings

- 3° Atrioventricular Block
- Arrythmia
- Atrial Tachyarrhythmias
- Brugada-like ECG Pattern
- Complete Left Bundle Branch Block
- Increased Ceptal Forces
- Intra Ventricular Conduction Delay
- Left Atrial Enlargement
- Left Axis Deviation
- Long QT Interval
- Markedly Elevated QRS Voltage
- Mobitz Type II 2° Atrioventricular Block
- Nonspecific ST T Wave Abnormalities
- Pathologic Q Waves
- Premature Ventricular Contractions
- Profound Sinus Bradycardia
- PVCs
- Right Ventricular Hypertrophy Pattern
- Short QT Interval
- St Segment depression
- T Wave Inversion
- Ventricular Arrhythmias
- Ventricular Pre Excitation

Save Electrocardiogram

Normal ECG Findings / Variants
Sinus bradycardia (> 30 bpm)
Sinus arrhythmia
Junctional escape rhythm
Ectopic atrial rhythm or wandering atrial pacemaker
1° AV block (PR interval > 200 ms)
Mobitz Type I (Wenkebach) 2° AVB
Incomplete RBBB
Early repolarization (ST elevation, J-point elevation, J-waves, or terminal QRS slurring)
QRS voltage criteria for left ventricular hypertrophy (Except: QRS voltage criteria for LVH AND any non-voltage criteria for LVH such as left atrial enlargement, left axis deviation, ST-segment depression, T-wave inversion, or pathologic Q waves)

Low Positive Predictive Value
Isolated right axis deviation > 120°
Isolated non-specific intra-ventricular conduction delay (QRS 120-139 ms)
Isolated T wave inversion in V1-V2
Complete RBBB
Short PR without a delta wave
Profound 1° AV block (PR interval > 300 ms)
QTc 440-480 ms
Single PVC per tracing

At the ECG Station, findings are recorded. Following the screening, the digital copy of the ECG (xml) is uploaded and made part of the student's electronic medical record.

heartbytes Sites Dashboard dsudman1 Administration Logout

Back to Lawrenceville GA

ID: 314 Name: Age: 17 Check In

Red Flags

Registration

Vitals

Murmur

ECG

Echo

Report

Infinitt

Echocardiogram

Finding: Didn't Check / Normal / Abnormal

Finding Description

Valves

Pulmonary Pressure

IV Septum

LV end-disatolic diam

LV posterior wall

LV end-systolic diam

Fractional shortening

Sinuses of Valsalva

Ascending aorta

Mitral Valve

Regurgitation

Stenosis

Aortic Valve

Regurgitation

Stenosis

Pulmonic Valve

Regurgitation

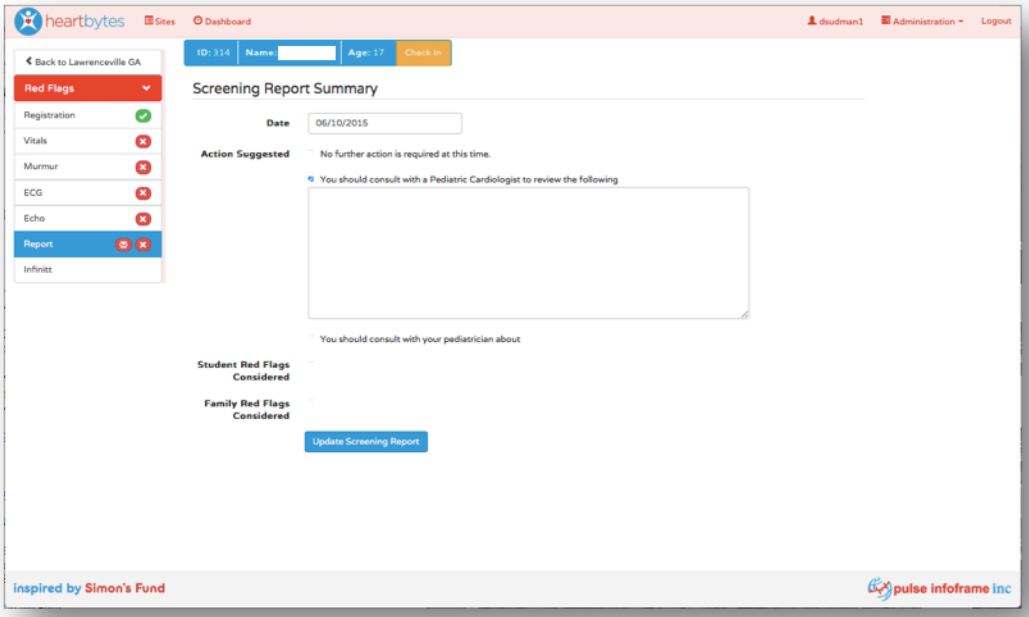
Stenosis

Right coronary ostia

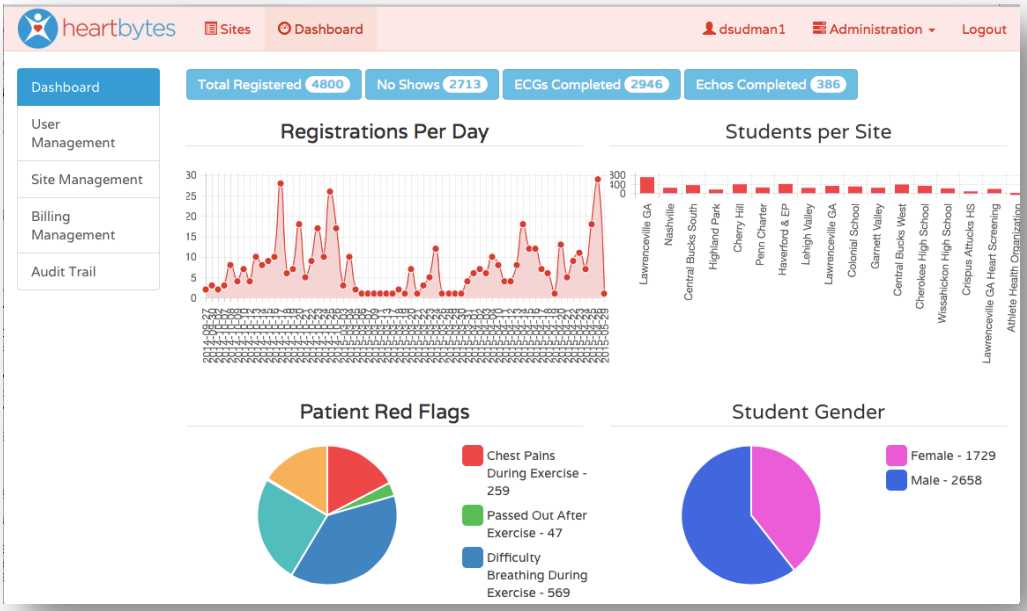
Left coronary ostia

Left main bifurcation

At the Echo Station, findings are recorded. Following the screening, the digital images of the Echo (DICOM) are uploaded and made part of the student's electronic medical record.



A Screening Report is completed for each student and it specifies the findings/recommendations/next steps. This report is emailed to both parents (mandatory) and the pediatrician (if the email address is provided).



The Dashboard provides a powerful look at the data collected at a particular screening or all of your screenings.