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### Harnessing Teams and Technology to Improve Outcomes in Infants With Single Ventricle.

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## Harnessing Teams and Technology to Improve Outcomes in Infants With Single Ventricle

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**Abstract**—Infants with single ventricle require staged cardiac surgery, with stage I typically performed shortly after birth, stage II at 4 to 6 months of age, and stage III at 3 to 5 years of age. There is a high risk of interstage mortality and morbidity after infants are discharged from the hospital between stages I and II. Traditional home monitoring requires caregivers to record measurements of weight and oxygen saturation into a binder and requires families to assume a surveillance role. We have developed a tablet PC–based solution that provides secure and nearly instantaneous transfer of patient information to a cloud-based server, with the capacity for instant alerts to be sent to the caregiver team. The cloud-based IT infrastructure lends itself well to being able to be scaled to multiple sites while maintaining strict control over the privacy of each site. All transmitted data are transferred to the electronic medical record daily. The system conforms to recently released Food and Drug Administration regulation that pertains to mobile health technologies and devices. Since this platform was developed in March 2014, 30 patients have been monitored. There have been no interstage deaths. The experience of care providers has been unanimously positive. The addition of video has added to the use of the monitoring program. Of 30 families, 23 expressed a preference for the tablet PC over the notebook, 3 had no preference, and 4 preferred the notebook to the tablet PC.

**Key Words:** caregivers ■ congenital ■ mortality ■ survival ■ telemedicine

### Goals and Vision of the Program

Babies who are born with hypoplastic left heart syndrome require staged surgical palliation, which involves 3 operations, the first of which (the Norwood procedure) is performed shortly after birth.<sup>1</sup> A second operation (the superior cavopulmonary anastomosis) is typically performed between 4 and 6 months of age, and a third operation (the Fontan procedure) between 3 and 5 years of age. Hospital mortality after the Norwood procedure remains the highest among common congenital heart procedures, ranging between 7% and 19%.<sup>2,3</sup> An analysis of resource utilization for common structural heart defects has shown that the Norwood procedure is associated with the highest cost, and the third longest length of stay.<sup>4</sup>

### The Interstage Period

The period between discharge after the Norwood procedure and completion of the second stage surgery—the interstage period—is one during which these babies are at risk for sudden death at home. Before 2000, interstage mortality after the Norwood procedure ranged between 15% and 20%.<sup>5</sup> In 2000,

Ghanayem et al<sup>6</sup> initiated a program of home surveillance for babies who had undergone the Norwood procedure. Families were discharged with a weight scale, pulse oximeter, and a binder for logging daily measurements. Although home monitoring was associated with improved interstage survival, interstage mortality remains a significant problem, comparable in incidence to the mortality of the Norwood procedure. Today, interstage mortality ranges between 2% and 20% with almost 75% of deaths occurring suddenly.<sup>2,7,8</sup> In recognition of this, in 2011, the National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) focused on improvement in interstage mortality.<sup>9</sup> Today, a large majority of programs use home monitoring during the interstage period.<sup>9</sup> The interstage period is now known to be strongly associated with mortality, morbidity, and hospitalizations in babies with all forms of single ventricle, including those who have undergone forms of initial surgical palliation other than the Norwood procedure.<sup>10</sup> Consequently, many programs have expanded the scope of their interstage monitoring programs to include children with all forms of single ventricle. During the past few years, the focus

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of interstage monitoring has also expanded from improving survival to improving growth and nutrition.<sup>11</sup> These changes to the care model have already led to some improvements in outcomes.<sup>12,13</sup>

### Limitations of the Existing System

The system of interstage monitoring that was proposed by Ghanayem et al<sup>6</sup> places the responsibility for monitoring, interpretation of monitoring data, and contacting providers on patients' families. This has the potential for missing important clinical cues that can delay care, in addition to potentially adding to the psychological burden for parents. In response, some teams have taken on an active role where they initiate phone calls, text messages, or other similar mechanisms to contact families, obtain information from the families' log books, and then transcribe it into a spreadsheet. The teams review the spreadsheets periodically to guide management. Delays and redundant data entry are implicit to this process. Nevertheless, it lays the conceptual foundation for systematically collecting data on multiple patients, with the potential for generating new knowledge.

### The Vision

Although the past decade has seen paradigm shifts in mobile technology, interstage monitoring has not changed, barring a few exceptions with varying results.<sup>14,15</sup> To improve interstage outcomes in a manner that harnesses the power of teams, technology and automation, we conceived of a solution that was based on remote monitoring and ensured continuous, connected care for patients and their families. Our vision was that instead of a binder, the family would enter data (pulse oximetry, weight, and other information) into a mobile device with near-instant connection to an enterprise database and the ability to perform automated analytics and graded notifications to the care team, while also, as a secondary objective, laying the foundation for future outcomes research.

### Local Challenges in Implementation

The concept of re-engineering home monitoring required a full understanding of all of the components and workings of the current model, the articulation of a clear vision for an idealized future state, and the development and implementation of a solution that would duplicate all of the desirable features of the current model, remove the less-desirable features, and augment the process with new capabilities. While this process started as an idea in 2012, it remains ongoing and iterative and continues to evolve in scope over time and in response to field testing and feedback from end-users.

An interstage monitoring program had existed in our center since 2011, but it had deficiencies that we addressed while the new platform was being developed. The team and care model for managing the interstage period were structured loosely and relied on individuals who had many other unrelated responsibilities. There was no consistency in terms of the nature of home monitoring, and the availability of equipment was dictated by whether insurers would cover the costs. Our concept was for a care team that would be focused on the specific area of interstage mortality, potentially with secondary

responsibilities in complementary areas. The program also needed a unique identity, with a name that made sense and supported team cohesiveness and purpose.

To move the new platform from concept to execution, it was critical to obtain institutional support and funding. Decisions such as the choice of the operating system for the mobile platform, the specific device(s) that would be used, regulatory issues around patient enticement, confidentiality, compliance, types of data transmission, nature and capabilities of the database that would receive and interpret the data, specifics of data visualization by the clinical team, and the nature of integration with the electronic medical record all had to be addressed. A particularly important feature sought by the team was to add in daily high-definition videos of the babies. The goal was to enable teams to have access to longitudinally collected virtual physical examinations, to potentially help detect subtle changes in the baby's appearance and breathing pattern. Because our electronic medical record does not provide the ability to store videos, we had to decide where the videos would be housed.

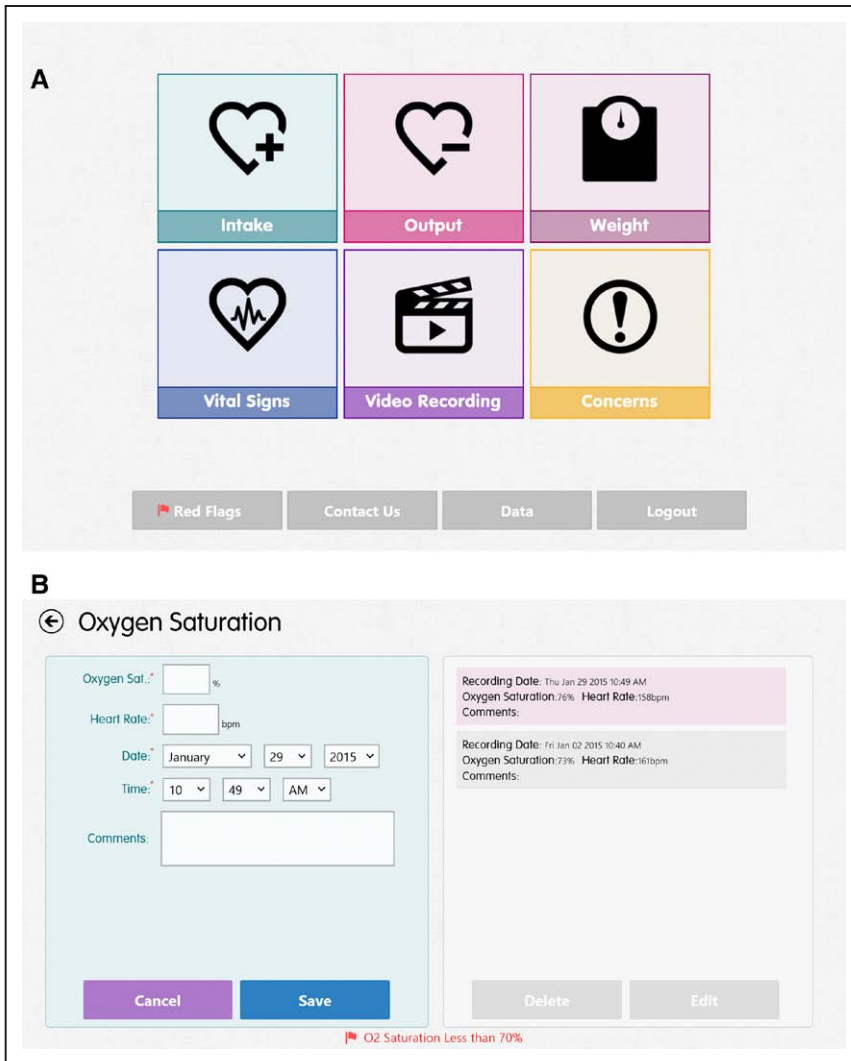
### Design of the Initiative

In early 2013, we started working toward a new model of care named Cardiac High Acuity Monitoring Program (CHAMP). Programmatic goals included ensuring that these patients' families would receive uniform education before discharge, and that they would be cared for by a dedicated, focused group of providers who called families on a weekly basis, in addition to proactive contact for any emerging clinical problems. This team initially consisted of an advanced practice registered nurse and a nurse coordinator. Over time, other key components were added, including 2 dedicated pediatric cardiologists, a Medical Director, a social worker, and a dietician. We ensured that all patients consistently went home with a pulse oximeter and a weight scale. The contemporaneous focus on the interstage period by NPC-QIC provided us with the framework to institute—and periodically revisit and modify—best practices.<sup>11,12</sup>

We were fortunate to obtain funding from a philanthropic source (the Claire Giannini Fund (<http://www.clairegianninifund.org/>)) for the development and implementation of the tablet PC platform. Our presentations of the tablet PC concept to institutional leadership were well-received, which was critical to insure ongoing support after grant funding ended. To develop a solution that would combine technical and clinical practicality, we built a team that combined both medical informatics and clinical expertise, with input on an as-needed basis from our legal office, hospital compliance leadership, and other key stakeholders.

### Decisions and Reasoning

We decided to maintain complete control over hardware and software, and to limit ourselves to a single platform. We determined that a Windows-based tablet PC would provide the necessary functionality while allowing us to benefit from our years of experience with Microsoft Windows software development. At this stage of design and feasibility testing, we also did not want to deal with the burdens of developing



**Figure 1.** This figure provides examples of the caregiver interface for the Cardiac High Acuity Monitoring Program tablet PC. **Top.** Screen shot of the home page for the touch screen interface. Each of the 6 icons is touch-responsive and opens up the appropriate screen for data entry. **Bottom.** The contents of the screen that pertains to oxygen saturation. This screen defaults to the current time and date stamp, but the caregiver can change those if they are making a late entry for a previous measurement. The Comments box provides for the entry of free text, where the caregiver can type in any comments that they decide are relevant. The caregiver has the opportunity to delete or edit an entry for 5 minutes after they save it; after 5 minutes, the data automatically uploads to the web server. A static, pre-programmed reminder is seen in red at the bottom of the screen. This serves to remind the caregiver that the red flag for low oxygen saturations is 70%. Regardless of what number the caregiver enters, the tablet does not interpret the entry; it passes information on to the HeartCenter database. The database is programmed to identify values that are out of range and to send appropriate alerts to the coordinator or care-provider who is on call.

our software on numerous operating systems (iOS, Android, etc.) and compatibility testing for every new software release of each platform. To minimize potential disparities in access and to ensure that all patients would qualify for our program without requiring their own wireless internet or cellular service, we selected tablets with built-in cellular capability at no charge to the family. This form of internet access is used regardless of whether the family has alternative methods to access the internet. Consistency of the route of transmission ensured that we were able to maintain security of transmitted data. To address the issue of patient enticement, the tablet PC was programmed into kiosk mode, which only allows it to be used for a single purpose (interstage monitoring). Our choice of cellular service provider was driven by the quality and extent of coverage in our geographic area, although this is configurable to different carriers and environments. We used feedback from the clinical team, parents, and from our institution's office for family-centered care to refine and optimize the appearance and flow of the user interfaces for both the families and the CHAMP clinical team. We then developed a Spanish version of CHAMP to meet the needs of our Spanish-speaking families. Examples of the CHAMP tablet user interface for families are shown in Figure 1.

### Use of Wireless Technologies

Next, we addressed the question of whether to use Bluetooth (or other wireless) peripheral devices, such as weight scales and pulse oximeters, to simplify the transmission of pulse oximetry and weight data to the tablet PC, or to use manual entry of data. There were limited choices for wireless transmission of data from peripheral devices. We initially used a pulse oximeter with Bluetooth capability, but the only such model that could be used for babies was one that did not have an audible alarm system or a visible waveform, and it had not been validated for cyanotic infants. We could only find 2 manufacturers of Food and Drug Administration-approved wireless digital baby weight scales. Of these, 1 company would not allow direct access to patient data; instead, they wanted us to use data that were routed through their servers, which raised issues of cost, confidentiality, speed, and reliability. Another manufacturer used proprietary wireless technologies that proved unwieldy for daily use by caregivers. We were also aware of emerging Food and Drug Administration guidance about the nature of mobile monitoring devices, which led to a level of uncertainty about the level of Food and Drug Administration oversight that may be needed if we were to opt for wireless transfer of data from peripheral devices.<sup>16</sup> For all of these reasons, we decided not to use any peripheral devices and

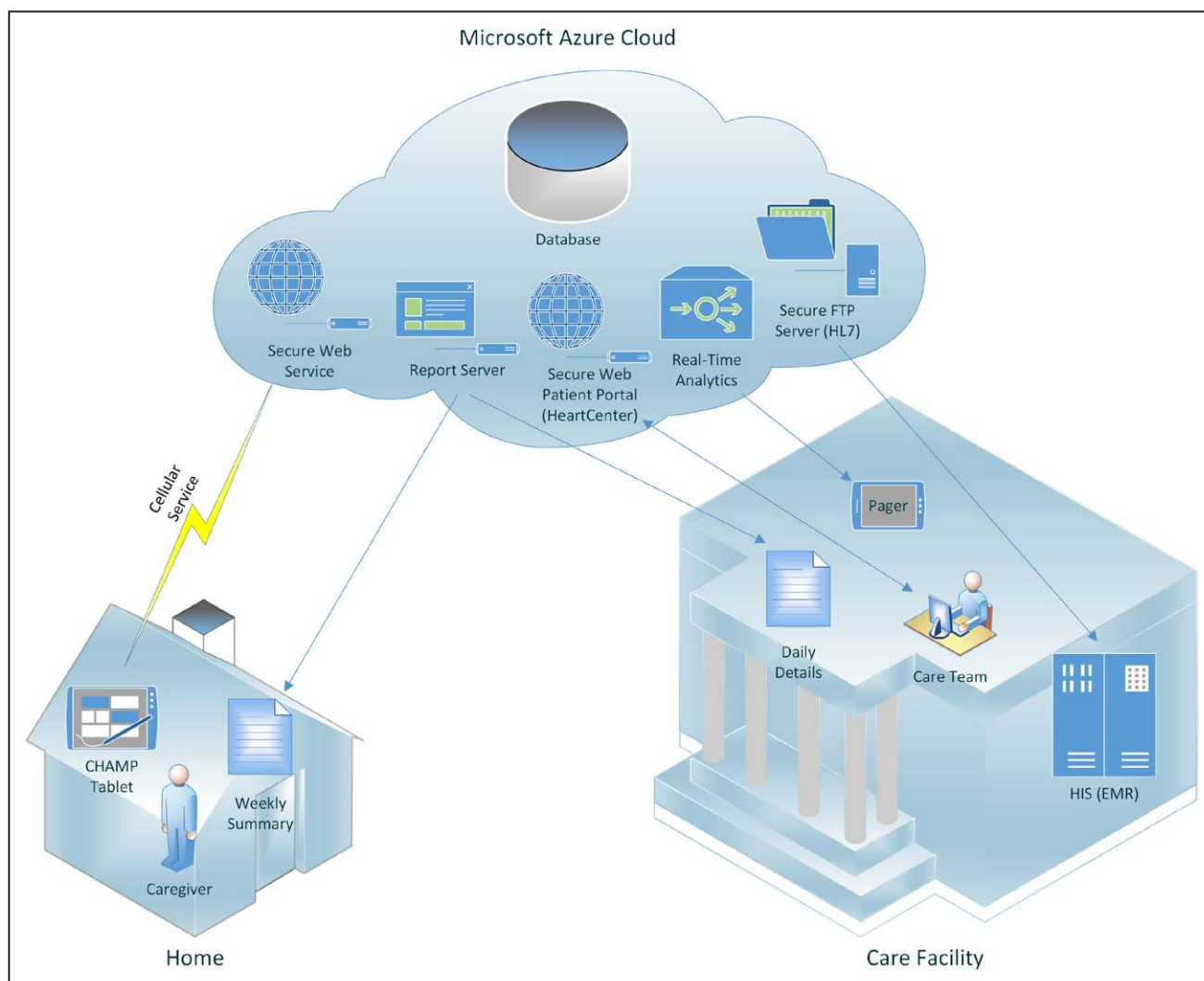
to limit the scope of the CHAMP tablet to being a passive conduit for patient monitoring, using manual entry into data fields.

### Data Encryption and Warehousing

Our informatics team developed highly encrypted methods for the transmission and storage of data in a manner that is Health Insurance Portability and Accountability Act compliant. To be able to extend the application of CHAMP beyond the confines of our own center, we developed secure mechanisms for the transfer of data that would maintain the confidentiality of each participant and site, while enabling seamless analysis of cumulative data. We ultimately selected the Microsoft Azure

platform, an industry-standard cloud-based solution that lends itself well to high levels of security and encryption.

Several years ago, we began developing a proprietary and patented software and data warehouse solution known as HeartCenter. Its main purpose is to collect information from a number of other hospital systems, manage business processes associated with a large congenital cardiology and cardiovascular surgery department, and allow users to visualize and analyze all data in a coherent and consistent fashion. Information such as patient demographics and visit details from our hospital information system, laboratory results, measures from our cardiology picture archiving and communication system, operating room



**Figure 2.** This illustration depicts details of the flow of information between the home caregiver, cloud-based web service, and care teams. Connection between the tablets and the web service occurs through a secure Secure Sockets Layer (SSL) connection. The web service accepts data from the tablets and stores it in the cloud. It does not provide any data to the tablet except an acknowledgment that the data were successfully saved. Each data point is hashed to verify the identity of the source. The database where data are stored resides in the Azure cloud, and all protected health information is encrypted. A secret encryption/decryption key is created for each facility (Rijndael cipher), and each row of data is individually encrypted by a uniquely generated Initialization Vector. This eliminates the possibility of deducing the value of frequently repeating patterns within data sets, such as male/female or letter-based frequency distributions, even if unauthorized access to the data were gained. The Cardiac High Acuity Monitoring Program (CHAMP) website is password protected, and each institutional user, once validated, is restricted to seeing his/her institution's patients only. Users' passwords are uniquely salted and hashed so that all passwords saved in the database are unique and unrecoverable. All access to the site is forced to a secure (SSL) channel. All communication between tiers is secured with SSL encryption using a 4096-bit certificate. HL7 transactions are restricted to secure file transfer protocol. Communication of alerts to devices that cannot be secured—such as text pagers, e-mail, and short message service—is limited to only as much information as is necessary for the clinician to be able to identify the subject of the alert. An HL7 interface provides for all CHAMP data to be uploaded daily into the electronic medical record.

**Table 1. List of Red Flag Clinical Concerns and Instant Alerts**

Red flags
Any behavior or bodily change that worries the caregiver
Temperature >101°F
Does not gain an average of 20 g/d >7 days or has 3 days of weight loss
Increased work of breathing or stopping to breathe during feeding
Bloody stool
Feeding difficulty, increased sweating during feeds, or excessive spitting up
Vomiting or diarrhea (>3 episodes in 24 h)
Irritability/wont calm or decreased response to you
Low oxygen saturations (<70%)
Fewer than 4 wet diapers per day
Problems with the child's feeding pump or pulse oximeter
Instant alerts
Oxygen saturations <70% or >93%
Heart rate <90 bpm or >180 bpm
Bloody stool
Three episodes of emesis in 24 h
Three diarrheal stools in 24 h
Concerns: Caregiver is concerned because the baby is:
Just not him/herself
Having a fever >101°F
Working harder to breathe
Having feeding trouble or sweating during feeds
Looking swollen with fewer wet diapers
Looking bluer or needing oxygen
More tired today or not waking up well
In pain despite all the normal interventions

CHAMP indicates Cardiac High Acuity Monitoring Program. Caregivers are trained to contact the CHAMP team if their child exhibits any red flag. The CHAMP team is instantaneously notified in the event of an instant alert.

and perfusion details, and a host of other data are collected and displayed in real time and then stored in our data warehouse for quality improvement and research purposes. We determined early on that HeartCenter was an ideal infrastructure within which to store and visualize CHAMP measures, alerts, and videos. An interface was developed between HeartCenter and CHAMP. As a result, we gained access to a large amount of associated patient data for each patient who was monitored at home. A web-based version of the HeartCenter software was designed, and the cloud-based architecture was then developed in preparation for our plans to enable other sites around the country to be able to use the CHAMP system. The specifics of data transmission and warehousing are demonstrated in Figure 2.

The addition of video recordings posed a challenge. Our initial plan had been to house videos in our echocardiography image management system (Xcelera, Philips Medical Systems). Unfortunately, the addition of a Digital Imaging and Communications in Medicine wrapper, which is required

to view videos within Xcelera, excluded the soundtrack from the recordings. In field testing, the CHAMP team found significant added value in hearing the sound of the baby breathing. Therefore, we changed the plan and decided to house the video as a standard AVI file in the HeartCenter database itself, within each patient's individual folder.

We collected all data under an Institutional Review Board-approved protocol, with an additional consent form that pertains to assignment of rights and release of images for the video recordings that are retained in the CHAMP system.

As designed, the CHAMP tablet PC serves as a passive collector of data that is sent to the enterprise database (HeartCenter), where analytics are performed to designate appropriate alerts to the CHAMP team. It does not interact with the family or the patient, and does not respond to any values that are entered. Every 24 hours, HeartCenter automatically outputs all CHAMP data to our electronic medical record (Cerner) using an HL7 interface.

### Analytics and Alerts

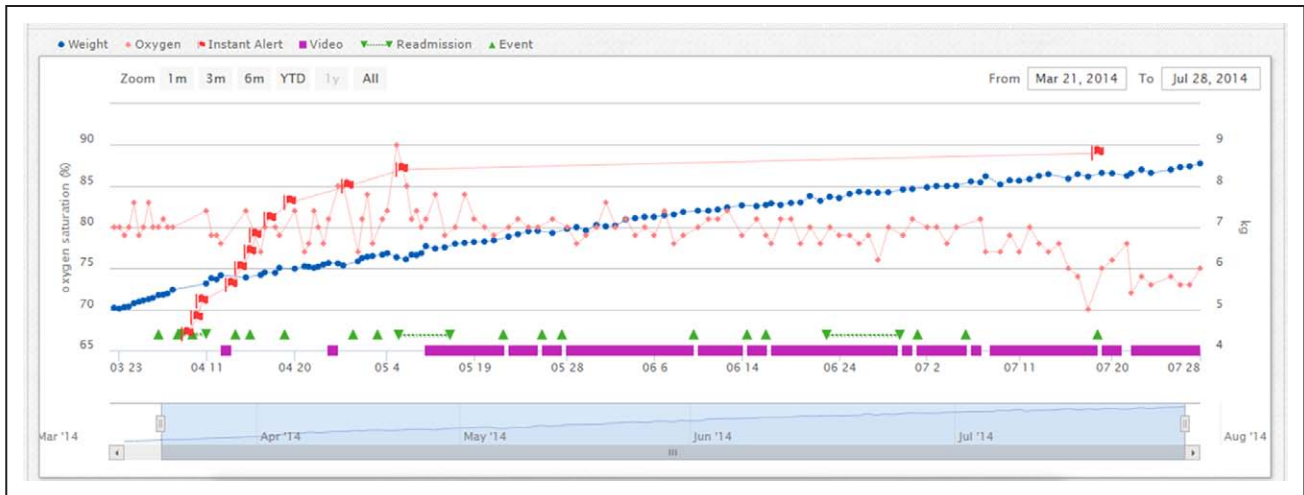
Our program uses the red flag alerts that have been adopted by NPC-QIC.<sup>12</sup> These are listed in Table 1. CHAMP team members noted that while each of these red flags is an important indicator of an underlying problem, some are more urgent than others. The connection of the CHAMP tablet to an enterprise database provides the ability to instantly alert the care team about specific issues. In taking advantage of this capability, a short list of alerts, termed instant alerts, was developed (Table 1). In addition, an instant alert is triggered if the caregiver indicates that they are concerned for any of the reasons listed in Table 1.

### Implementation of the Initiative

It took 2 years to move CHAMP from concept to reality. Once the platform was developed and stable, the first step was to prove feasibility and reliability. This was done in early 2014 by asking 2 families to volunteer to perform dual entry of home monitoring data: once into CHAMP, and, separately, into the (then state-of-the-art) logbook. At the end of 1 month, each field of information in the logbook was matched with the corresponding field that had been received through the tablet PC. This study revealed that data transfer was feasible and reliable, as there were no errors detected. The development of automated reporting and calculations, presenting data in a manner that was the most efficient for the clinical team, was an iterative process driven primarily by dialog between the clinical team and the informatics team. It resulted in the type of graphic display that is demonstrated in Figure 3, with multiple overlays of data from CHAMP that were designed in a manner that makes clinical sense. In addition, the CHAMP team now receives an automated Summary Report of all data received on all patients every morning. This report has computer-generated highlights for every value that is out of a configurable, predefined range. It enables the clinical team to rapidly review all active patients for any potential problems. Specifics about the exact values for each field that would trigger an instant alert to the CHAMP team were discussed, implemented, and refined until they were optimized.

### Response to Caregivers's Input

Caregivers are instructed in the use of the tablet PC in the last few days of their initial hospitalization, before assuming



**Figure 3.** Data visualization using CHAMP (Cardiac High Acuity Monitoring Program). Each dot represents a discrete data element that was received. Time is on the x axis, oxygen saturation is on the left-sided y axis (red dots) and weight is on the right-sided y axis (blue dots). Each of the purple dots represents a video. Each red flag is charted. The first (upright) green triangle on the left represents a clinic visit that was initiated based on clinical cues. Each pair of inverted green triangles, connected by dotted lines, represents an inpatient admission. In infants with single ventricle who are interstage, baseline oxygen saturations are typically around 80%. In this case, saturations started in the mid to high 80%, stabilized around 80% and were then elevated significantly in late April and early May 2014. This was associated with a slowdown in weight gain. At the end of the first week of May, the baby was diagnosed with recoarctation of the aorta and underwent balloon angioplasty of recoarctation. Oxygen saturations dropped to baseline, and weight gain improved almost immediately thereafter.

responsibility for monitoring. Families have had varying levels of interest in knowing what the graphic trends on their babies look like; of those who have wanted data, some have wanted to see graphs, whereas others have preferred tables. In response, we have implemented the capability for automatic

e-mails that send both graphic and tabular summary data on a weekly basis to those families who express a desire to receive this information. The majority of caregivers have readily accepted the CHAMP platform regardless of their level of technical sophistication or language preference. There are

**Table 2. Interstage Outcomes and Resource Utilization Before and After Initiation of CHAMP**

	Before Initiation of CHAMP	After Initiation of CHAMP	P Value
Total number of patients discharged with interstage monitoring (n=83)	53	30	
Age at neonatal discharge in months, median (IQR)	1.43 (0.95, 1.93)	1.2 (0.67, 2.1)	0.365
Age at the end of interstage period (stage II surgery, death, or transplant), median (IQR)	7.23 (5.63, 9.6)	5.85 (4.93, 7.33)	0.021
No. of interstage days per patient (mean±SD)	190±99	143±55	0.006
Total number of interstage days	10095	4275	
Interstage mortality for all single ventricles (%)	9 (17%)	0 (0%)	0.023
Interstage mortality for HLHS (%)	6/33 (18%)	0/14 (0%)	0.159
Total number of unplanned readmissions	91	43	
No. of unplanned readmissions per patient per 100 interstage days, median (IQR)	0.63 (0, 1.64)	0.73 (0.46, 1.41)	0.75
Total number of unplanned readmission days	1174	481	
No. of unplanned readmission days per patient per 100 interstage days, median (IQR)	3.05 (0, 18.6)	4.85 (0.52, 13.9)	0.613
Total number of unplanned readmission ICU days	633	233	
No. of unplanned readmission ICU days per patient per 100 interstage days, median (IQR)	0 (0, 8.4)	1.39 (0, 5.49)	0.52
Total unplanned inpatient charges (US\$)	13 200 000	5 665 285	
Unplanned inpatient charges per patient per 100 interstage days, median (IQR) (US\$)	20 486 (0, 178 762)	41 712 (1924, 164 311)	0.805
Total number of visits to the emergency room	104	33	
No. of emergency room visits per patient per 100 interstage days, median (IQR)	0.7 (0, 1.64)	0.63 (0, 1.38)	0.41
No. of patients who underwent stage II (Glenn) during unplanned readmission	7	3	

CHAMP indicates Cardiac High Acuity Monitoring Program; HLHS, hypoplastic left heart syndrome; ICU, intensive care unit; and IQR, interquartile range.



ongoing studies of caregivers' feedback for both the logbook and the tablet PC.

### Success of the Initiative

Starting in May 2014, the CHAMP tablet PC became the standard of care for interstage monitoring of babies with single ventricle at our institution. We have followed 30 babies interstage using CHAMP. These consist of 14 babies with hypoplastic left heart syndrome who underwent a Norwood or hybrid procedure, 12 with right ventricular hypoplasia and pulmonary atresia who underwent an aortopulmonary shunt, and 4 who had a balanced circulation and were discharged without requiring neonatal surgery. Input from families has been used to refine the capabilities of CHAMP. Details on the quantity of data collected are summarized in Table 1 (Appendix I in the Data Supplement).

We compared outcomes and resource utilization with CHAMP tablet monitoring (April 2014—current, 30 patients) to the preceding 3 years, during which the interstage monitoring team and program were being optimized (January 2011 to March 2014, 53 patients). Clinical data were collected using chart review, and charge data were obtained from our hospital's financial system (GE Centricity Business). Outcomes and resource utilization for each of these periods are summarized in Table 2.  $\chi^2$  and Fisher exact test were used to compare categorical variables. Either the *t* test or the Mann–Whitney *U* test was used to compare continuous variables. Neither the distribution of diagnostic subtypes of single ventricle nor the age at neonatal discharge differed between phases. Contemporaneously with the use of the CHAMP tablet, median age at the end of the interstage period decreased significantly from 7.23 months to 5.83 months ( $P=0.026$ ), and therefore, so did the duration of the interstage period per patient. Interstage mortality has decreased in all patients with single ventricle (17%–0%,  $P=0.025$ ) as well as in patients with hypoplastic left heart syndrome (18%–0%,  $P=0.159$ ) since the initiation of CHAMP. Although markers of resource utilization such as number of unplanned readmissions, readmission days, intensive care unit days, inpatient charges, and emergency room visits per patient have improved with the use of the CHAMP tablet, these improvements do not meet statistical significance. We conducted additional analyses of these markers of resource utilization by controlling for the varying duration of the interstage period (by calculating each marker of

resource utilization per 100 interstage days per patient), which also did not reveal significant differences between groups. We recognize that there are serious limitations to this retrospective study. Given our results on the feasibility of the system, further studies are needed to critically compare CHAMP to paper, as well as to evaluate human–computer interaction from both the caregiver and the care-provider perspectives.

Anecdotally, CHAMP clinical team members report that they spend less time collecting data and more time making decisions. The summary report provides rapid access to information and better time management, enabling the team members to focus their efforts on subjects with concerning trends. The addition of video has been perceived to be an important advantage. Not only does it enable the CHAMP team to evaluate the baby's breathing pattern but it also provides an unanticipated glimpse into the interactions between the baby and the caregiver in the baby's home environment: an interaction that has, until now, not been part of the diagnostic toolset. Information obtained from viewing the video was found to be helpful in determining the disposition in >80% of all instant alerts or red flag events. An example of the additive value of video, which pertains to the patient who is profiled in Figure 3, is provided in Movies 1 to 3 in the in the Data Supplement.

Caregivers have reported nearly unanimous positive experiences with CHAMP. Of 30 families, 26 continued with CHAMP tablet monitoring through the study. The remaining 4 families returned the CHAMP tablet and went back to monitoring using the notebook. When given the choice, 23 of 30 families who used both the notebook and the CHAMP tablet stated that if they had to continue monitoring, they would use the CHAMP tablet in preference to the 3-ring binder; 3 families had no preference and 4 families would use the notebook in preference to the CHAMP tablet.

Our outcomes differ from those reported recently by Black et al<sup>15</sup> in recent study of a project for interstage monitoring. They found that while remote monitoring was feasible in this population, there were challenges with compliance and with the reliability of hardware and software, and they terminated their study earlier than planned because telemedicine did not affect interstage mortality. In contrast, we have found no evidence of increased admissions and a suggestion of decreased mortality. We did not have any problems with families' compliance. The observed differences in outcomes may well reflect differences relating to team structure and the specifics of the equipment used.

**Table 3. Estimated Costs of the Program**

	Year 1	Year 2	Year 3
Cost of tablet PCs	\$600/tablet=\$120 000		
Cost of cellular coverage	\$40/mo/tablet=\$96 000	\$40/mo/tablet=\$96 000	\$40/mo/tablet=\$96 000
Total annual costs	\$216 000	\$216 000	\$216 000
Cumulative costs	\$216 000	\$312 000	\$408 000
No. of patients	400	400	400
Cumulative number of patients	400	800	1200
Cost per patient	\$540	\$390	\$340

The estimated cost for 200 tablets over a 3-year period is \$408 000. This would provide the ability to extend the program to ≈1200 interstage patients (\$340/patient).

To date, we have collected >27 000 data points on our 30 patients >18 months. Perhaps the most exciting feature of the structure of CHAMP is that with this approach, wherein individual patient data is linked to clinical outcomes within the HeartCenter database, each patient who is recruited becomes part of a cohort of patients—in a manner akin to a registry—albeit one with built-in, real-time analytic capabilities, as well as the potential for predictive capabilities that are likely to become more robust as data from more patients are collected over time. Our vision for this aspect of CHAMP is that of a live registry that would provide dynamic prediction of risk of an adverse event for a given patient at a given time, based on continuously updating and increasing data from the individual patient as well as from the entire cohort.

### Summary, Future Directions, and Challenges

CHAMP represents a step in the evolution of the model of care for chronic disease from episodic care toward the ideal of continuously connected and continuously improving care. We have successfully developed and implemented CHAMP in our center with good results and planned to deploy the platform in other centers. The development and implementation of CHAMP is currently supported by philanthropy, with additional philanthropic support obtained to distribute 200 tablet PCs to sites around the country at no charge. We plan to achieve this during the next 18 months. Our estimate for the cost of hardware and cellular service for the program is provided in Table 3. Costs for CHAMP development, program administration, and data analytics are not included in this estimate. We assume that the tablet PCs will be reused during the entire period, thus providing for coverage of 1 patient every 6 months, and that any losses because of damage or theft will be minimal (we have had no such losses to date). This should allow the accumulation of daily data at a rapid pace; within one year, with full use of 200 tablets, we should have ≤200 years' worth of daily monitoring data on >400 patients. Deployment to multiple sites will test the scalability of the platform and support generalizability of analyses from the emerging registry. Although the integration between Heart Center and our electronic medical record system has enabled the creation of linkages between CHAMP data and clinical events for individual patients in our center, the implementation of CHAMP in other centers will be challenged by the need for data entry to create such linkages with other electronic medical record systems. We have built an HL7 output that enables all CHAMP data to be sent to any electronic medical record system every 24 hours through the cloud-based system. The development of robust databases and mechanisms for automated data export from the electronic medical record or other enterprise databases would be a significant advance to minimize—if not eliminate—the need for redundant data entry. We have already built in features to allow seamless export of >98% of variables that are already being collected via Research Electronic Data Capture for the NPC-QIC initiative, thus decreasing the data burden for future sites participating in the CHAMP program. We think that those types of linkages will be crucial to progress toward developing more robust and data-driven algorithms for predicting, and by extension, preventing interstage mortality and morbidity. We hope that the

perceived value of the information obtained from CHAMP and the improved efficiency of the team would engage hospitals in supporting CHAMP without philanthropic support. Our experience points to the need for studies to test the value proposition to hospitals and payers, using robust study designs that are designed to critically examine survival, resource utilization, and timeliness of care.

The development and evolution of wearable physiological monitors for babies (or implantable monitors, placed at the time of neonatal surgery), coupled with robust, unconditional wireless capabilities for connection to the tablet PC, would represent yet another step in the evolution toward continuously connected care. The use of machine learning as applied to video of the baby could add another dimension to the potential for predictive algorithms. It would seem that the platform that we have built for CHAMP has the potential for many applications in various field of pediatric and adult medicine. The user interface of the CHAMP tablet and the secure cloud-based data warehousing architecture that has been created are customizable to enable entry of information that is pertinent to other disease states. For example, the ability to record and transmit blood pressure, weight, and heart rate may be of value in adults with hypertension or heart failure. Similarly, the ability to enter data from glucometers or spirometers may enable improved monitoring for adults or children with diabetes mellitus or asthma. Pertinent instant alerts could be programmed for any of these conditions. When coupled with a vigilant and responsive team of care-providers, the CHAMP platform enables prompt and targeted clinical care, which may prove to be important as medicine evolves to a value-based model with a focus on outcomes.

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### Disclosures

None.

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