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ARTICLE

Feasibility of Digital Stethoscopes in Telecardiology Visits for Interstage Monitoring in Infants with Palliated Congenital Heart Disease

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Abstract

Infants with staged surgical palliation for congenital heart disease are at high-risk for interstage morbidity and mortality. Interstage telecardiology visits (TCV) have been effective in identifying clinical concerns and preventing unnecessary emergency department visits in this high-risk population. We aimed to assess the feasibility of implementing auscultation with digital stethoscopes (DSs) during TCV and the potential impact on interstage care in our Infant Single Ventricle Monitoring & Management Program. In addition to standard home-monitoring practice for TCV, caregivers received training on use of a DS (Eko CORE attachment assembled with Classic II Infant Littman stethoscope). Sound quality of the DS and comparability to in-person auscultation were evaluated based on two providers' subjective assessment. We also evaluated provider and caregiver acceptability of the DS. From 7/2021 to 6/2022, the DS was used during 52 TCVs in 16 patients (median TCVs/patient: 3; range: 1–8), including 7 with hypoplastic left heart syndrome. Quality of heart sounds and murmur auscultation were subjectively equivalent to in-person findings with excellent inter-rater agreement (98%). All providers and caregivers reported ease of use and confidence in evaluation with the DS. In 12% (6/52) of TCVs, the DS provided additional significant information compared to a routine TCV; this expedited life-saving care in two patients. There were no missed events or deaths. Use of a DS during TCV was feasible in this fragile cohort and effective in identifying clinical concerns with no missed events. Longer term use of this technology will further establish its role in telecardiology.

Keywords Single ventricle · Telemedicine · Telecardiology visits · Stethoscopes · Auscultation · Quality improvement · Remote patient monitoring · Digital stethoscopes

Introduction

Infants with staged surgical palliation for congenital heart disease are at high-risk for interstage morbidity and mortality. These patients are fragile with critical clinical changes that can occur over short periods of time. It has been reported that up to 18% of infants with single ventricle physiology die unexpectedly after being discharged to home [1], although home-monitoring programs have lowered interstage mortality in infants with HLHS and related variants [2, 3]. Telehealth has been used in this population in an asynchronous manner [4–7] and more recently, feasibility of synchronous telecardiology visits (TCV) has been demonstrated [6, 7], including the experience of our center. [8] Since 2010, the Children's Hospital of Philadelphia (CHOP) home-monitoring program, The Infant Single Ventricle Monitoring & Management Program (ISVMP), has cared for over 800 infants requiring staged surgical palliation for congenital heart disease, with a low incidence of morbidity and mortality [9]. Since 2019, we successfully included TCV in interstage home-monitoring, creating a hybrid care model. We found this care model to be feasible, sustainable, and effective in identifying clinical concerns and preventing unnecessary emergency department (ED) visits [8].

However, one significant limitation of TCV has been the inability to conduct a remote cardiac examination [10].

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Cardiac auscultation is at the core of cardiology practice and the stethoscope, introduced by Rene Laennec in 1816, [11] is the iconic, universally accepted medical instrument. Although first reported in 1956 [12], electronic stethoscopes were not used in clinical practice until 1995 [13]. As sounds are transmitted electronically and converted to a digital signal, digital stethoscopes (DSs) can provide noise reduction and signal enhancement as well as produce both audio and visual output, the latter which can be displayed on a screen and saved digitally. The ability to transmit a wide spectrum of sound waves is a benefit of DSs compared with acoustic stethoscopes. Currently available models vary in shape, size, quality, complexity, and cost [14].

As with conventional acoustic stethoscopes, sound interpretation with a DS remains subjective, as diagnosis is still dependent on the listener's expertise. In pediatrics, telemedicine with cardiac auscultation recordings from DSs has been shown to be feasible and effective for diagnosis, distinguishing between innocent and pathologic murmurs[15–19] as well as assessing pulmonary artery hypertension [20, 21]. These prior studies have focused on store-and-forward (asynchronous) recordings in older children; to our knowledge, there are no published data on auscultation using a DS in synchronous TCV for high-risk interstage infants.

In mid-2021, we added use of a DS during routine TCVs for this high-risk population. We hypothesized that use of a DS in TCVs would be feasible, potentially impact interstage care, and provide high provider and caregiver satisfaction. Here, we describe our experience with use of a DS in our ISVMP. This article was written according to Standards for Quality Improvement Reporting Excellence guidelines [22].

Methods

Context

Our ISVMP consists of a dedicated nurse practitioner (NP), 9 designated cardiologists, and a nutritionist, with support from case managers and individuals with expertise in quality improvement from the CHOP Cardiac Center. ISVMP monitors all infants in the interstage period (defined as discharge from Stage 1 palliation to admission for Stage 2 palliation). It includes infants who have shunt-dependent single ventricle physiology (surgical shunt placement or patent ductus arteriosus (PDA) stenting as part of staged palliation), patients with single ventricular physiology and a pulmonary artery band, patients with aortopulmonary shunts or PDA stents in anticipation of eventual biventricular repair, as well as patients with stable neonatal physiology with either single ventricle physiology or those with undetermined candidacy for biventricular repair with the above interventions. On average, we follow approximately 70 patients (range: 62–89) per year, of which about 40 are on an outpatient basis. Roughly 50% are infants with hypoplastic left heart syndrome (HLHS).

ISVMP has been described in detail previously [8]. Briefly, the program involves a standardized approach to discharge criteria, daily home-monitoring of weight, nutritional intake, oxygen saturations by caregivers, and frequent, regularly scheduled follow-up (in-person, TCV and telephone). Caregivers record and upload monitoring data to the Epic Care Companion app in MyChart or communicate (through email, text or phone) to the ISVMP NP. Caregivers receive weekly telephone calls from the ISVMP NP, and patients are seen regularly in-person and via TCV at intervals based upon diagnosis. Patients with HLHS attend biweekly visits with their cardiologist alternating with TCVs. Patients who required an isolated aortopulmonary shunt or PDA stent attend monthly cardiology and TCV visits. According to the established protocol, if concerns are raised during the NP or a caregiver telephone contact or via entries in the Care Companion app, an "urgent" consultation with a cardiologist is conducted to determine the appropriate course of management. Moreover, caregivers can call the ISVMP NP or come to the hospital with their infant at any time. Prior to discharge, caregivers are provided with equipment (digital baby scales, pulse oximeters) and receive standardized education including instructions with specific parameters to prompt communication to the ISVMP team.

Intervention

Selection of a Digital Stethoscope

An ISVMP pediatric cardiologist (TJP) initially tested various DS models clinically both in-person and remotely in ISVMP patients. We purchased Eko CORE stethoscopes (Eko Devices, Berkeley, California, USA). We found that the sound quality of the Eko DS was equivalent to analog stethoscopes used during in-person visits and allowed the user to distinguish nuances of heart sounds and significant cardiac murmurs in this high-risk population. It was easy to use with minimal training required for caregivers to operate. The Eko CORE DS is a hybrid device which can operate as a traditional acoustic stethoscope or as an electronic stethoscope. We used an Eko attachment connected to a neonatal 3 M Littman US stethoscope head (3 M Littman, St. Paul, MN) (Fig. 1). The device has been approved by the US Food and Drug Administration for use in pediatric and adult patients. Sounds can be transferred to an accompanying mobile application ("app") for storage and sharing. The Bluetooth capability allows users to transmit sounds through their smartphones. The connection system is secure, confidential, and Health Insurance Portability and Accountability Act (HIPAA)-compliant.

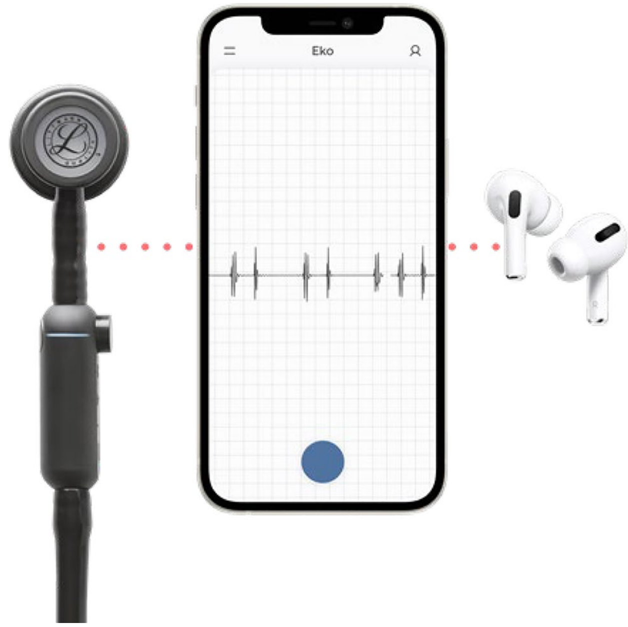

Fig. 1 Eko digital stethoscope (Eko CORE attachment assembled with Classic II Infant Littman stethoscope, 3 M, USA) and iPod with Eko app downloaded (Eko, Berkeley, CA). Reproduced with permission from Eko Health, Inc. and 3 M

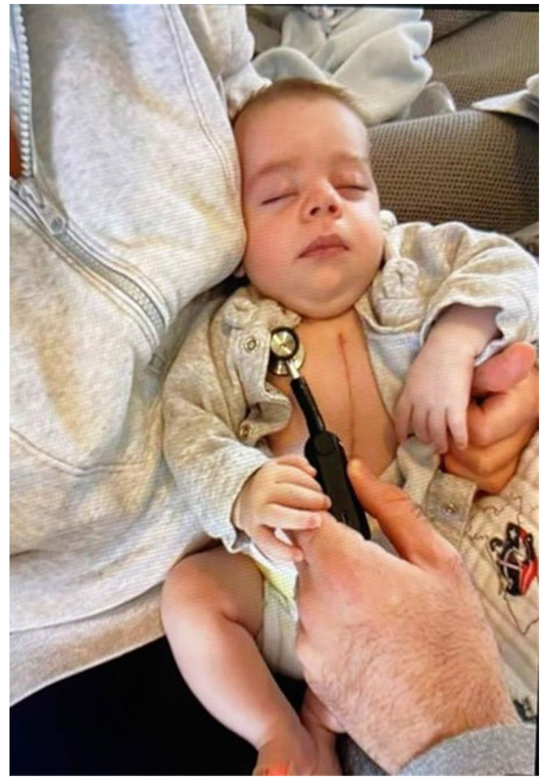

Fig. 2 Patient undergoing cardiac exam with DS during a synchronous telecardiology visit. DS, digital stethoscope

Implementation in Telecardiology Visits

Beginning in July 2021, caregivers of ISVMP patients were offered a DS and an iPod Touch with the Eko app installed. We initially purchased 5 DSs and provided them sequentially based upon availability to patients being discharged, regardless of diagnosis or preferred language. As the initiative progressed, we purchased 10 additional DSs and again offered them sequentially. The ISVMP NP (AS) trained caregivers in-person on use of the DS and iPod Touch. Conducting TCVs with the DS required caregivers to have access to WiFi and a mobile device (e.g., smartphone, tablet). An iPad was available in cases where a caregiver did not have a personal device. Further, caregivers needed access to the MyCHOP patient portal application in the electronic health record (EHR). When needed, staff assisted and ensured caregivers could access the portal prior to discharge. Interpreter services were provided for caregivers with a preferred language other than English.

TCVs were conducted by ISVMP pediatric cardiologists and the ISVMP NP. Visit frequency did not change with the introduction of the DS for TCVs. Clinicians used software embedded in the EHR (Epic Systems Corporation; Verona, Wis.) to conduct TCVs. The visit protocol mirrored our previously reported approach [8] and included: tracking of clinical concerns and ED visits or hospitalizations, visual assessment of color, activity, work of breathing and respiratory rate, oxygen saturation and heart rate (via direct visualization of the pulse oximeter). As previously described [8], it also included discussion of daily weights, nutrition, and medications (including need for refills), identification of equipment malfunction, confirmation of immunizations status including palivizumab, and identification of health-associated social and developmental needs and additional subspecialty evaluations.

A cardiac and lung exam was performed using the DS. Caregivers were asked to ensure that the devices (DS, iPod touch, caregiver's smartphone or tablet) were charged prior to initiating the TCV. At the start of the visit, we ensured that the DS was connected via Bluetooth. During the visit, we also guided caregivers on the use and placement of the DS and obtained cardiovascular data synchronously. Caregivers positioned the DS while remote auscultation was performed with the providers wearing ear pods or acoustic noise-canceling headphones. A standard cardiac and pulmonary exam was performed over the precordial locations (mitral, tricuspid, aortic, pulmonary) with the patient in both sitting and supine positions, as well as auscultation on the back (Fig. 2). For each TCV, routine auscultation was performed both by our ISVMP NP and 1–3 of the ISVMP cardiologists. In patients with concerning oxygen saturations, we confirmed an accurate heart rate with the DS to see if it agreed with the pulse oximeter. The potential presence of a thrill was confirmed by caregiver palpation.

Clinicians documented the TCV through a templated note with a modified physical examination which included a cardiac exam and fields to document need for the visit, identification of visit participants, and appointment duration. All findings were communicated to the patient's primary care provider and primary cardiologist if not in attendance.

Study of the Intervention and Measures

After each TCV, two independent reviewers (TJP, AS) evaluated each cardiac exam for murmur type, sound quality and presence of any technical difficulties. Murmur grade and type were described in the clinical note. Clarity of the heart sounds and the murmurs were independently subjectively assessed by each provider on a three-point scale: very clear, moderately clear, or unclear. In addition, for each TCV, reviewers noted ease of use (yes/no) and their perception of whether the DS enhanced the overall quality of the TCV (yes/no).

At the end of each TCV, caregivers were asked about ease of the DS (yes/no). Upon completion of their interstage monitoring period, caregivers were queried regarding their perception of whether use of the DS during the visits provided reassurance. These questions were asked verbally by the ISVMP cardiologist to maximize response rate. Caregivers were encouraged to candidly critique their experience with the DS. We tracked outcomes with respect to use of the DS, specifically if it led to escalation of care or reassurance, the latter thereby preventing an ED visit. We also tracked non-urgent issues identified at TCVs, such as equipment or medication concerns, nutrition, education, and additional required subspecialty referrals.

Analysis

Descriptive analyses are reported with frequencies and percentages for total completed TCVs with DS and caregiver responses to the verbal survey. For continuous variables, median with range is provided. Inter-rater agreement on subjective sound quality at each TMV was analyzed by calculating overall percent agreement.

Results

From July 2021 through June 2022, 16 patients were examined with a DS during 52 TCVs (median: 3 TCVs/patient; range: 1–8 TCVs/patient) (Table 1). The median duration of TCVs was 30 min (range: 20–60), with the inclusion of the DS adding an average of 5 minutes to the TCV.

Table 1 Patient characteristics, $N=16$

Diagnosis *n* (%)	
HLHS[a]	7 (43.8)
Other single ventricle[b]	3 (18.8)
Anticipated biventricular[c]	6 (37.5)
Age at initial discharge, days (median, range)	24.5 (8–85)
Monitoring duration[d], days (median, range)	104 (35–298)
Birth weight, kg (median, range)	3.3 (2.6–3.6)
Distance from CHOP, miles (median, range)	54.4 (7–243)

[a] *HLHS* Hypoplastic Left Heart Syndrome; *CHOP* Children's Hospital of Philadelphia

[b] Other Single Ventricle: includes DORV, TGA, straddling mitral valve, unbalanced AV canal with arch hypoplasia; Tricuspid atresia, VSD, pulmonary stenosis; d-TGA, VSD, pulmonary stenosis

[c] Anticipated Biventricular: includes TOF/PS; TOF/PA; IAA, VSD, aortic valve hypoplasia; and d-TGA, VSD, pulmonary stenosis

[d] Monitoring time is number of days in the interstage monitoring period, defined as discharge from stage 1 palliation through admission for stage 2 palliation

All scheduled DS TCVs were completed with concurrent use of DS except one secondary to a technologic issue which was resolved for the subsequent visit. The system was reported as easy to use by providers in all the visits (52/52) and by caregivers in 94% (49/52) of visits; caregivers all found the visits to be reassuring. Auscultation of the first and second heart sounds as well as delineation of their murmurs was achieved with the DS in 51/52 visits (98%). Comprehensive lung examinations could be achieved in 80% (41/51) of visits. Providers judged the DS to be on par with respect to the sound quality found with in-person examinations with an acoustic device. The quality of heart sounds and murmur auscultation was judged as "very clear" or "moderately clear" with excellent inter-rater agreement (98%). In all visits, providers agreed that incorporation of the DS was helpful in medical decision-making and agreed that using DSs enhanced the overall quality of the TCV.

Use of the DS provided additional significant information in 12% of TCVs (6/52) as compared to our routine TCV; in two cases this expedited life-saving care. There were no missed events or deaths. Furthermore, there were no false positives where the DS led to patients being directed to the ED unnecessarily. During TCVs for two patients (described below), we were able to discern through use of the DS a significant change in a murmur in the setting of hypoxemia, prompting urgent hospitalization and subsequent surgical intervention. In four TCVs, the use of the DS provided reassuring auscultatory findings to avoid emergency care visits and/or hospitalizations in the setting of cyanosis, increased respiratory effort and/or intercurrent illness.

Most Impactful Cases

Patient 1: 25-day-old neonate with single ventricle heart disease (tricuspid atresia with normally related great arteries and pulmonary stenosis) who did not require any post-natal intervention. There were no concerns during an in-person cardiology visit several days earlier. An expedited TCV was performed due to isolated lower trending saturations by pulse oximetry as reported by caregivers, decreasing from 80 to 75%. During this visit, lower oxygen saturations were confirmed by correlating the heart rate (measured with pulse oximeter) with the heart rate measured by auscultation with the DS. Cardiac exam via the DS also showed a change in the murmur to being higher pitched compared to the exam at the previous TCV. These findings were concerning for a more restrictive ventricular septal defect (VSD). This prompted an urgent direct admission to the hospital where our concerns were confirmed by transthoracic echocardiography and the patient underwent placement of an aortopulmonary shunt placement to augment pulmonary blood flow prior to clinical deterioration.

Patient 2: 5-month-old infant with single ventricle heart disease consisting of D-transposition of the great arteries, large VSD, hypoplastic left ventricular outflow track (LVOT) (subpulmonic) and diminutive main pulmonary artery (MPA) palliated as a neonate with a PDA stent. The patient's parents reported a saturation of 79% earlier that day via our remote patient monitoring app. During a routine scheduled TCV, the patient had fluctuating saturations but sustained periods in the 68–72% range. Although the patient was in no distress, they appeared more cyanosed compared to their previous TCV. We correlated the heart rate via auscultation with the DS to confirm accuracy. Upon cardiac auscultation, we noted diminution in the grade of the murmur via the DS as compared to the prior TCV. We directed this patient for an urgent admission with echocardiography confirming our clinical suspicion of PDA stent narrowing. The infant had expedited surgical intervention with a bilateral bidirectional Glenn shunt prior to clinical deterioration. Intraoperative inspection demonstrated a nearly occluded PDA stent.

Discussion

We report the first initiative incorporating auscultation with a DS in synchronous video visits in an established home-monitoring program for high-risk interstage infants. Use of DSs enhanced TCVs by providing a more extensive evaluation, mirroring in-person visits. This more comprehensive clinical evaluation was additive in 12% of visits; it resulted in expedited life-saving care in two. With auscultation using the DS, we monitored pulse oximetry over a longer period of time, corroborating pulse oximetry readings, and were able to identify significant clinical changes which prompted earlier intervention prior to clinical decompensation; this averted the need for cardiac critical care or surgery under higher risk circumstances.

Pulse oximetry is generally accurate even in cyanotic patients [23]; lower readings may be attributed to motion artifact, changes in body temperature, low signal quality or mechanical error. However, interpretation of pulse oximetry is not foolproof, as demonstrated by the two cases related above. There also may be a tendency to accept the highest reading obtained even if only transient. Misinterpretations may lead to the recommendation for ongoing monitoring rather than further investigation.

Data are sparse concerning the application of DS for the purpose of long-distance auscultation. Most studies compare new murmur auscultation findings to pre-recorded tele-auscultation findings in older pediatric patients. In an early study, these recordings concurred with in-person murmur characteristics in 80% of cases [24]. In comparing digital auscultation to in-person auscultation to distinguish innocent from pathologic murmurs, one study demonstrated good negative and positive predictive values [18]. While these studies have focused on interpreting heart sounds, ours is the first to evaluate the impact of this technology in care delivery in real-time and in neonates and infants. We found it feasible to obtain proper auscultation in the context of synchronous TCVs. We could optimize our examination during direct clinical care via various patient and stethoscope positions as there was ample time to maximize participation by repositioning or repeating when the infant was more cooperative and/or sleeping with examination, which also empowered caregiver collaboration. The other advantage of real-time versus a store-and-forward approach includes better clarity obtained with noise-canceling headphones. The DS was widely accepted by our caregivers for ease of use and the reassurance provided by a more detailed examination during their TCVs. In addition, we observed increasing confidence in use of the DS over time. Importantly, our strategy allowed for a heightened level of evaluation while permitting neonates and infants to remain at home as outpatients. This is significant for family dynamics compared to mandating acute or rehabilitation hospital stays for the duration of the interstage period.

There are several limitations in this study. There is inherent subjectivity in the assessment of murmurs, which can be influenced by the measurement of sound transmission and acoustic quality between the analog and digital instruments. While we found a high degree of consensus between examiners, there were a limited number of care providers and a small number of patients. We felt the former allowed for more consistency and ability to compare evaluations for this initial step of assessing feasibility. In addition, while there are several types of DS available, our findings are limited to the one used in this study. Finally, although it was not available for our initiative, in the future, we anticipate the ability to record and upload recordings in the EHR for data-sharing in patient care. This would enable comparison of examinations over time and monitoring for progression of murmurs and potentially reduce the need for repeated cardiac exams by multiple clinicians.

The COVID-19 pandemic forced an expedited expansion of virtual care, dramatically changing the way health care is delivered. With this rapid growth of telemedicine came a renewed interest and need for performing a remote physical exam, including the use of tele-auscultation devices. However, despite improvement in technology, there has not been wide adoption of DS due in part to limitations of transmitting and storing auscultatory information in a consistent, accurate and user-friendly manner, reliability of the device, potential burden to patients and the hospital system, as well as skepticism by the medical community [14]. The advantages and disadvantages of virtual care have previously been published with the inability to perform physical exams as one frequently cited limitation [25]. The familiarity of the personal stethoscope, simply augmented as in our approach, may help to remove barriers to use for many physicians.

The widespread implementation of telemedicine has been hampered by billing, reimbursement, licensing, and legal considerations [26]. There is currently no CMS telemedicine modifier code to account for real-time cardiac auscultation during telemedicine visits. These issues may discourage incorporation of DSs in the future. Compensation standards need to be established for pediatric remote patient monitoring (RPM) including pulse oximetry and DSs. In addition, there is reliance on patient-accessible Wi-Fi networks with their well-documented-associated inequities. These issues need to be addressed in light of the recently expired public health emergency to allow telemedicine to remain and evolve as an important component of health care.

The ability to perform high-quality cardiac exams with a DS has huge implications for the future of health care. It can open new avenues of health care access and equity in specialized care, particularly for vulnerable populations. It could enable home-based monitoring of cardiorespiratory conditions and clinical teaching, among others. Improvements in diagnostic accuracy, consistency, and efficiency could be realized through the development of clinical decision support based on artificial intelligence-generated diagnostic algorithms. Adult cardiology has generated large databases of recorded heart sounds [27] which contribute data to clinical decision pathways. The same could be possible for the pediatric population as well as the expanding population of adult congenital heart disease patients. Incorporation of data generated by the DS in the EHR will further facilitate the use of TCV with DSs.

The integration of clinically validated home-monitoring technologies (including DSs) could allow for greater personalization and inclusivity in health care interactions, potentially resulting in patients and caregivers being more engaged in their own healthcare and improving continuity of care in a cost-effective manner. With appropriate reimbursement and licensing regulations, healthcare systems will be able to maintain and build on the telemedicine infrastructure that evolved during the COVID-19 pandemic and greatly enhance the quality of care for infants, children, and adults with CHD.

Conclusions

Our results demonstrate use of DSs is feasible, acceptable, and effective in augmenting TCVs for home-monitoring of patients with palliated congenital heart disease. This study adds to the groundwork that has already been laid for telemedicine to remain as a key modality for cardiovascular health care delivery. Further studies are needed to investigate the impact that more widespread implementation of DS in TCVs could have in transforming management and care delivery and to understand its role in a hybrid model alongside traditional in-person care.

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Declarations

Competing interest The authors declare no competing interests.

Non-financial interests TJP is on the editorial board of *Journal of Pediatrics* and *World Journal of Pediatric and Congenital Heart Surgery*. TMG is Invited Editor-in-Chief for a 17-article supplement in *Pediatric Critical Care Medicine*: Critical Treatment Strategies for Acute Pulmonary Hypertension in Infants and Children: Pediatric Cardiac Intensive Care Society Scientific Statement, guest editors: Giglia TM, Bronicki RB, Checchia PA, Laussen PC. Pediatr Crit Care Med;11(2 Suppl):S3-S90, 2010, and a manuscript reviewer for: *Journal of the American College of Cardiology, Intensive Care Medicine, European Journal of Heart Failure, Clinical and Applied Thrombosis/Hemostasis, Cardiology in the Young, The Journal of Pediatrics, Pediatric Critical*

Care Medicine, and World Journal for Pediatric and Congenital Heart Surgery. CR is a manuscript reviewer for *Congenital Heart Disease, Journal of Pediatrics, International Journal of Artificial Organs, Cardiology in the Young, Journal of Thoracic and Cardiovascular Surgery, Artificial Organs, World Journal for Pediatric and Congenital Heart Surgery, Journal of American College of Cardiology, Circulation, European Journal of Clinical Nutrition, Critical Care Nursing, Italian Journal of Pediatrics, European Journal of Clinical Nutrition, and Journal of the American Heart Association.* JJR is Guest Editor, *Progress in Pediatric Cardiology—Transcatheter Treatment of Congenital Heart Defects* and a reviewer for: *Annals of Thoracic Surgery, Catheterization and Cardiovascular Interventions, Journal of Thoracic and Cardiovascular Surgery, Circulation, Journal of the American College of Cardiology, Journal of Pediatrics, and American Journal of Cardiology, Chest.* AS, ALS, MMG, RJS, DAH, SSN: none.

Ethical Approval This feasibility initiative was reviewed and determined to not meet the criteria for Human Subjects Research by the Children's Hospital of Philadelphia Institutional Review Board.

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