AHA SCIENTIFIC STATEMENT

Telemedicine in Pediatric Cardiology

A Scientific Statement From the American Heart Association

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Advancements in technology and broadband have revolutionized the current practice of medicine. The field of pediatric cardiology is no exception given the need for prompt diagnosis and reliance on cardiac imaging to identify infants and children with potentially life-threatening cardiovascular disease. As the relationship between telemedicine and pediatric cardiology has advanced, it has created a need to develop a broad, comprehensive document reviewing all the various aspects of telemedicine in pediatric cardiology. For more than a decade, a significant body of literature has been published describing individual experiences and practices, yet there remains no comprehensive statement or document summarizing this rapidly advancing field. In an effort to describe the collective experience and to provide structure and guidance for pediatric cardiology practitioners and healthcare providers, we have developed a scientific statement on the use of telemedicine in pediatric cardiology.

Specific areas explored in this document include both neonatal and fetal tele-echocardiography, implications for training community sonographers, pulse oximetry programs, qualitative improvement and appropriate use criteria initiatives, and remote electrophysiological monitoring. This document also includes teleconsultation and teleausculation, direct-to-consumer and home monitoring programs, and a look into the use of telemedicine and pediatric cardiology in the intensive care setting. Furthermore, a detailed review of the legislative, public policy, and legal aspects of telemedicine is provided, along with financial and reimbursement information.

Several terms are used in the literature interchangeably; a brief explanation is provided to help readers of this document. The term telehealth is defined as the use of technology to bridge distances in any aspect of medicine; telemedicine is the specific application of technology to conduct clinical medicine at a distance. The term telecardiology is defined as the broad application of telemedicine in the field of cardiology specifically, and tele-echocardiography is the most common application used within this field.

ECHOCARDIOGRAPHY AND TELEMEDICINE

Echocardiography is the most commonly used noninvasive cardiovascular imaging modality and is considered to be both safe and cost-effective. Tele-echocardiography can be described as a process in which a provider or a technician obtains cardiovascular ultrasound images from a given patient and these images are subsequently transmitted to an offsite location where a cardiologist can provide further analysis and interpretation. Thus, tele-echocardiography enables expert interpretation and consultation in a rapid and potentially geographically disparate fashion, enabling prompt and accurate decision making involving triage, transport, and therapeutic priorities. Tele-echocardiography is now routinely used across the age and subspecialty spectrum in pediatric cardiology.

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Clinical Scenarios: Fetal Echocardiography and Fetal Cardiac Monitoring

Fetal tele-echocardiography increases prenatal detection of critical congenital heart disease (CCHD). Sharma et al[1] reported that adequate screening for fetal heart disease is feasible and that community acceptance for telemedicine-assisted fetal cardiac screening and counseling is not adversely affected by a lack of direct personal contact with a specialist. Prenatal detection of CCHD in turn has been shown to improve postnatal surgical[2–4] and heart transplantation outcomes.[5] Most commonly, fetal tele-echocardiography is used to refer delivery to a place where a neonatal intervention can be performed. A few centers in North America also use tele-echocardiography for referral for fetal intervention. However, fetal tele-echocardiography is also used across all links of the referral chain, from the primary obstetrician's office to the quaternary fetal healthcare facility. It is routinely performed by obstetricians, maternal-fetal medicine specialists, and pediatric cardiologists to screen for congenital heart disease and fetal arrhythmias. If pathology is suspected or detected, these providers can refer patients to a higher level of care. Commonly, a referring clinic or hospital uploads the fetal ultrasound or echocardiogram images to a secure virtual network or a computer server of a tertiary care fetal health center. The tertiary care center then provides consultation and management recommendations. Occasionally, study image disks or videotapes of echocardiograms are sent for interpretation and reporting. In the current era of the gigabit Internet, secure digital transfer is much quicker and hence the preferred method of delivery. Some tertiary care fetal health centers offer a remote fetal tele-echocardiography service, which enables a hospital or clinic to transmit live echocardiographic images over the Internet to an attending cardiologist at an external facility. This allows instant feedback and counseling via audio or both audio and video. Because access to fetal cardiac expertise is limited for people in remote or rural locations, fetal tele-echocardiography is felt to be very helpful in these populations. As telemedicine becomes more frequently used in the delivery of maternal fetal medicine consultations, the use of fetal ultrasound to detect CCHD can also help pediatric cardiologists prepare families for delivery and treatment options.[6–8]

In cases of fetal arrhythmias, fetal tele-echocardiography can be diagnostic. In the case of fetal bradycardia secondary to atrioventricular block, tertiary care fetal health centers can use fetal tele-echocardiography to guide and monitor pharmacotherapy. Periodic fetal tele-echocardiography monitoring of fetuses with heart block may be useful in determining the optimal gestational age for a cesarean section at a center where postnatal permanent pacemaker implantation will occur.[9] Fetal tele-echocardiography similarly can play a critical role in diagnosing and treating fetal tachycardia. Transplacental or direct fetal antiarrhythmia treatment, follow-up evaluations, and delivery plans can be appropriately determined on review of the images. Of note, several commercial and US Food and Drug Administration (FDA)–approved handheld Doppler fetal heart rate monitors are readily available for use. Prospective parents can purchase them at low cost on the Internet. These devices hold promise, especially if they have Bluetooth or network connectivity. However, more data are needed to assess the utility of these devices for future home monitoring.[10] Physician input is critical because inappropriate use of home monitoring can do more harm than good.[11]

Clinical Scenarios: Neonatal Cardiology

Table 1 provides a comprehensive list of 33 publications in pediatric tele-echocardiography, 16 of which are from institutions outside the continental United States, reflecting the global interest in telemedicine in pediatric cardiology. Single-center studies on neonatal telecardiology have shown this technology to be accurate and cost-effective, to have a positive impact on patient care, and to prevent unnecessary transports.[12,15,16,18,25,27,28,36,37] When not diagnosed prenatally, newborns with congenital heart disease are often delivered or present to a primary care setting where expert cardiovascular evaluation may not be available. Management decisions based on incomplete or delayed diagnostic information may result in morbidity and mortality or unnecessary transfer. The diagnosis, clinical management, and triaging of a sick newborn with suspected congenital heart disease can be done quickly with tele-echocardiography. Randolph et al[26] reported that using tele-echocardiography resulted in a complete diagnosis for 132 (99%) of 133 patients and a clinically adequate diagnosis for the remaining patient (1%). In their study, patient transfer was recommended or avoided in 7 patients, an immediate change in local medical management occurred in an additional 25 (19%) of 133 neonatal patients, and congenital heart disease not requiring immediate treatment was noted in 47 (35%) infants.

Rendina and colleagues[22,23] evaluated the impact of telecardiology on the length of stay of low-birth-weight infants in a regional level III neonatal intensive care unit (ICU) in North Carolina. They found a reduction in length of stay of 5.4 days in the first 6 months of their study compared with the 6 months before telemedicine. They projected that the cost savings over a 1-year period would be $1.3 million. The cost attributable to telemedicine in their model was $33 per echocardiogram. Additional monetary benefits of telemedicine that are more difficult to quantify include cost savings from the prevention of delayed or incorrect management and the avoidance of the financial burden of travel and lost wages for the patient's family.[46] In a large study of 500 echocardio-

Table 1. History of Pediatric/Congenital Tele-Echocardiography Publications

Author	Location	Year	Key Findings
Finley and colleagues[12–14]	Nova Scotia	1989, 1997, 2004	Real time over POTS, cost savings, tele-education
Sobczyk et al[15]	Kentucky	1993	Store and forward over POTS
Fisher and colleagues[16,17]	Chicago, IL	1996	Real time over single ISDN line
Casey and colleagues[18–21]	Ireland	1996, 1998, 2008	Real time over low-bandwidth connection
Rendina et al[22–24]	North Carolina	1997, 1998	Outcomes and reduced length of stay
Houston et al[25]	Glasgow, UK	1999	100% accuracy requires 3 ISDN lines
Randolph et al[26]	Minnesota	1999	Accuracy, management over T1
Sable et al[27]	New Orleans, LA	1999	Accuracy, proficiency, cost savings over 3 ISDN lines
Scholz and colleagues[28,29]	Iowa	1999, 2001	Minimal difference: cardiologist vs pediatrician ordering echocardiograms in children <1 y of age
Sable et al[30]	Washington, DC	2002	500 studies/3 ISDN lines/impact on practice
Sharma et al[1]	New York	2003	Efficacy of fetal tele-echocardiography
Widmer et al[31]	Switzerland	2003	Real time over 3 ISDN lines/feasibility and accuracy
Munir et al[32]	Hawaii	2004	Live and store and forward between Hawaii and Guam
Sahn et al[33]	Portland, OR	2004	Remote real-time image control and optimization
Woodson et al[34]	Washington, DC	2004	Forward-and-store tele-echocardiography
Castela et al[35]	Portugal	2005	1761 consultations over 5 y, mostly elective
Lewin et al[36]	Seattle, WA	2006	769 studies/3 ISDN lines/99% accurate
Awadallah et al[37]	South Dakota	2006	Neonatal tele-echocardiography triage
Sekar and Vilvanathan[38]	India	2007	Real time/small aperture satellite bandwidth
Kosutic et al[39]	London, UK	2007	Belgrade to London conference over single ISDN line
Gomes et al[40]	Portugal	2010	Fetal, neonatal, and pediatric consultations in real time
McCrossan et al[8,41]	Ireland	2011, 2012	Fetal tele-echocardiography accuracy and skill transfer
Haley et al[42]	Arizona	2012	Real time telemedicine more accurate than recorded echocardiograms
Dehghani et al[43]	Canada	2013	Videoconferencing for ACHD management
Webb et al[44]	United States (9 sites)	2013	Multicenter prospective case-control study: tele-echocardiography decreases transports, length of stay, and high-risk medications
Krishnan et al[45]	Washington, DC	2014	Technology transition, >10 000 studies/15 y

ACHD indicates adult with congenital heart disease; ISDN, Integrated Services Digital Network; POTS, plain old telephone systems; and T1, Terrestrial-1.

grams by Sable et al,[30] comparison of final videotape interpretation with the initial tele-echocardiography diagnosis resulted in 1 minor diagnostic change (membranous versus inlet ventricular septal defect). The diagnosis was altered in 3 patients. Tele-echocardiography had an immediate impact on patient care in 151 studies.

A multicenter study from 9 centers across the United States evaluated 338 pairs of babies (with and without access to telemedicine) with no or minor heart disease matched for study indication, diagnosis, gestational age, birth weight, and sex.[44] This study showed a statistically significant reduction in percentage of babies transferred to a tertiary care hospital (10% versus 5%) and in total and ICU length of stay. Additionally, the use of indomethacin to close a patent ductus arteriosus and the use of inotropic support were less in the telemedicine group, thereby showing that telemedicine both is diagnostic and can reduce exposure to risky, unnecessary treatments and transports.

CCHD Screening and Pulse Oximetry

In recent times, pulse oximetry has been found to be an effective screening mechanism for CCHD in the newborn nursery.[47] The American Heart Association, American College of Cardiology, and American Academy of Pediatrics all have endorsed CCHD screening.[48] Since 2011, CCHD screening has been adopted by legislation or regulation in 43 of the 50 states. A 2009 scientific statement by the American Heart Association and American Academy of Pediatrics thoroughly examined the role of pulse oximetry in examining newborns for CCHD.[49] In addition to defining the scope of the problem and science behind screening with pulse oximetry, this statement was the first to identify access to pediatric subspecialists as a barrier to implementation of CCHD screening and to suggest telemedicine as a potential solution. It is estimated that 15% of births occur in nonmetropolitan areas where there is limited access to pediatric echocardiography or sonographers trained in pediatrics.

Strategies for implementing screening for CCHD were discussed at a stakeholder meeting in 2011 and published in *Pediatrics*.[50] Once again, the potential role of telemedicine was stressed in providing access to pediatric cardiologists for the discussion of positive screens and performance/interpretation/reporting of echocardiograms, which are necessary for both false-positive and true-positive screens. Telemedicine has been shown to be useful in the assessment of the newborn with suspected CCHD by either symptoms or physical findings in the newborn nursery.[30]

The greatest potential for telemedicine is in the confirmatory testing. Once a positive screen is obtained, telemedicine can provide timely access to pediatric subspecialists in neonatology or cardiology for assessment and recommendation. The current recommendations are for immediate assessment by a licensed, independent practitioner to determine whether there are noncardiac or cardiac causes of low blood oxygen saturations. Verbal communication, chest x-rays, laboratory assessments, and echocardiograms can all be shared by telemedicine technology. Whether in a rural setting with limited pediatric subspecialists or a suburban setting where there is need for rapid decision making, telemedicine can expedite movement to more precise cardiac care or prevent unnecessary care or transport to tertiary centers.

Initially, there was great concern about the number of potential false-positive screens for CCHD by pulse oximetry and the burden on pediatric cardiologists to respond to increased demand. It has been shown that the increase in cardiology consultations or echocardiograms to a delivery service is negligible compared with the number of false-positive echocardiograms resulting from heart murmurs.[51] In the United Kingdom, not all positive screens result in an echocardiogram because transitional circulation and infectious and pulmonary processes have been found to be the cause of the majority of positive screens in the first day of life. Finally, in calculations of the find rate of CCHD for echocardiograms performed on the basis of reason for referral, 1 CCHD is identified per 100 echocardiograms for murmur versus 1 CCHD identified per 6.8 echocardiograms for pulse oximetry screening.[51]

Clinical Scenarios: Pediatric Age Group

Outside the neonatal period, pediatric tele-echocardiography continues to offer value and convenience. Urgent evaluations are usually performed in acute care facilities; that is, emergency rooms or ICUs that do not have immediate access to onsite cardiologists. Tele-echocardiography may provide additional crucial information about cardiac function, valvular disease, pericardial effusions, and wall motion in critically ill children and can also be used for the diagnosis or exclusion of congenital/critical heart disease.[46] Widmer and colleagues[31] prospectively validated remote interpretation of echocardiograms performed in a remote hospital by a sonographer experienced in pediatric echocardiography. The quality of transmitted echocardiographic images was sufficient for evaluation except in 1 case. In 191 (98%) children, he remote echocardiographic diagnosis was correct, as confirmed by follow-up face-to-face consultations. The authors postulated that the reasons for inaccurate diagnoses may include inadequate or incomplete clinical examination by the referring physician, inability of the pediatric cardiologist to examine the child, lack of experience of the examining technician, and lack of clarity in visualizing heart structures. A few of these limitations will be overcome by sonographer training and the use of other telemedicine technologies such as videoconferencing.

Clinical Scenario: Adult Congenital Heart Disease

The first recommendation from the 2008 American Heart Association/American College of Cardiology guidelines for the management of adult congenital heart disease (ACHD) is as follows: "An individual primary caregiver or cardiologist without specific training and expertise in ACHD should manage the care of adults with complex and moderate congenital heart disease only in collaboration with level 2 or level 3 ACHD specialists."[52] In a recently published, population-based Canadian study, there was a clear reduction in mortality after publication of these guidelines and subsequent care coordination with specialized ACHD care centers.[53] However, the number of specialized ACHD care centers and providers across the world is limited. Increasing geographical distance between the patient and the ACHD referral center explains the existing care gap for patients with ACHD. Hence, collaborative care between the local primary care and specialized ACHD referral center is a model of care with potential advantages for both the patient and healthcare institutions. Telemedicine and tele-echocardiography can provide that bridge quite easily and prevent loss to specialty follow-up and resultant adverse outcomes.

Dehghani and colleagues[43] reported their model of tele-echocardiography and videoconferencing for patients with ACHD. In their system, all pertinent investigations and interventions, including past surgical operative reports and disks of imaging studies, were received by the host institution a week before the scheduled patient care meeting. During meetings, clinical presentations and display of pertinent imaging were live and in real time, allowing commentary from all those attending the videoconference. From their study, Dehghani et al concluded that telehealth is a feasible medium for arriving at consensus recommendations in the management of patients with ACHD living in geographically remote areas.

Evolution of the Technology

Solutions for live and store-and-forward telemedicine have evolved significantly. Most early telemedicine studies used point-to-point ISDN (Integrated Services Digital Network) and T-1 (Terrestrial-1) connections for live telemedicine.[16,17,25,27,30,34,54] Although ISDN provided acceptable bandwidth and image quality, developments over the past 5 years have made this technology obsolete. IP (Internet Protocol) allows multipoint connectivity from anywhere on any device that is connected to a network that is able to run videoconferencing software. Today, this includes room and desktop telemedicine systems, personal computers, tablets, and smartphones. Store-and-forward telemedicine is also greatly enhanced by modern technology and high-speed connections. Studies can be transmitted over secure FTP (file transfer protocol) and VPN (virtual private network) or accessed via remote connection to PACS (picture archiving and communication system) networks through client or Web-based programs. Cloud servers are enabling echocardiograms to be transmitted and accessed from anywhere in the world.[55,56] This expansion of technology mandates a need for diligent attention to security and a dramatic increase in dependence on technical support staff.

For some, real-time or interactive (live) tele-echocardiography is recommended/preferred.[19,30] The advantage of this approach is that additional real-time images can be obtained by interactive scanning, with the sonographer following the directions of the reviewing cardiologist.[19,37,57] This approach may allow the tele-echocardiography to be more informative in terms of the amount of information obtained, but it can be more time consuming given the commitment of time and attention needed in real time. It has been reported that when sonographers become proficient at obtaining pertinent details related to the pathology, the need for real-time expert cardiology feedback wanes. In the alternative and most commonly used store-and-forward model, the institution where the patient is records the images and then transfers the study via the Internet to the tertiary care institution using the recipient's image database server.[34] At present, many believe the store-and-forward model works just as well as live interactive tele-echocardiography. Either way, clear communication between the 2 sites on urgency, symptoms, and the clinical question at hand is critical to the success and accuracy of tele-echocardiography.

Krishnan et al[45] reported the technology transition at a single center with >10 000 telemedicine transmissions from 24 sites in 7 states and territories between 2001 and 2012. Abnormalities were detected in >40% of the studies, including >100 patients with life-threatening defects. More than 150 patients were transported for surgical, catheter-based, or medical intervention. Critical heart disease was ruled out in >75 patients, thus preventing unnecessary transports. Medical management or outpatient follow-up was recommended in approximately half of the studies. After IP expansion, a significant increase in telecardiology use took place, with no adverse effect on efficiency or diagnostic accuracy. IP expansion paralleled a change from a predominance of live transmissions to store-and-forward transmissions.

Implications for Training of Sonographers at Community-Based Settings

Although there are several published guidelines for the training and practice of pediatric echocardiography, these guidelines are targeted to those physicians and sonographers who are practicing in pediatrics full-time at institutions that have pediatric cardiologists on site.[58–61] These documents are very comprehensive and beyond the scope of the community sonographer who has not undergone formal training. This section has thus been created to provide the collective authors' pragmatic or real-world approach to providing pediatric echocardiography experience to community sonographers, who are often limited in time allowed for education and training given their day-to-day work responsibilities.

Although having pediatric transthoracic echocardiography available in all community-based settings is ideal, a number of barriers currently challenge comprehensive implementation of this service. These include equipment issues, sonographer training and skill, and rural center volume.

Community hospitals may not have the ability to upgrade ultrasound equipment as frequently as large tertiary care institutions. Their ultrasound equipment may not be specific for cardiac examinations, and 1 machine may be required to function for the examination of multiple organ systems. In preparing a community hospital to serve a triage function for pediatric heart disease, it is important to work with the equipment manufacturer to install a pediatric cardiac preset into whatever ultrasound equipment is available. In addition, transducers specific for cardiac ultrasound are imperative. For pediatric patients, transducers ranging in frequency from 5 to 12 MHz are most commonly used today. Depending on the manufacturer of the equipment, several frequencies may be combined into 1 transducer.

In terms of training and skill, sonographers in community hospital settings are usually trained in adult echocardiography. They are proficient in scanning adult-sized patients who have predominantly normal intracardiac anatomy but may have valvular heart disease or cardio-

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myopathy. These sonographers often lack specific training and experience in working with infants and children in both the hospital and outpatient settings. This usually includes suboptimal exposure to and knowledge of congenital heart defects and their unique imaging needs. Newborn babies and crying toddlers are an intimidating challenge to a sonographer who is used to scanning cooperative adults. Having an uncooperative patient challenges a sonographer to obtain the normal ultrasound views, but the challenge is compounded when that patient, whether infant, child, or adult, has abnormal intracardiac anatomy.

Additional training for community sonographers to perform a triage echocardiogram in patients with congenital heart disease requires explanation of how to visualize shunts at the atrial, ventricular, and ductal levels from several different echocardiographic views and a basic understanding of aortic arch abnormalities. It should also incorporate the ability to image ≥1 pulmonary vein connections to rule out total anomalous pulmonary venous return. In general, adult sonographers are less likely to be familiar and comfortable with suprasternal notch and subcostal views; therefore, it is suggested that teaching or training would include methods of obtaining these 2 families of ultrasound planes. It is also helpful to include instruction in instrumentation and "knobology" for pediatric studies, preferably with pediatric specific presets. Often, a standardized pediatric imaging protocol exists that has been developed by the tertiary care facility that is collaborating with the community site. It can be very helpful to develop a simple worksheet that can be filled out by the sonographer after each study has been completed. This ensures that the sonographer develops a routine pattern of thinking when performing a pediatric echocardiogram in terms of cardiac anatomy, septal integrity, myocardial function, and valvular and aortic arch issues.

Ideally, a representative from the collaborating tertiary center should initiate training in real time with one-on-one instruction. In cases when a pediatric cardiologist has a clinic at the community hospital, the pediatric cardiologist may be able to provide instruction and supervision for the sonographer the same day that the patients are seen in clinic. Alternatively, in another training pattern, a pediatric sonographer from the tertiary care institution can travel to the community hospital for regularly scheduled instructional/scanning sessions. This can be helpful even if the subjects scanned are unlikely to have abnormal cardiac anatomy.

Finally, community sonographers can visit or rotate to the tertiary care institution for several days with the goal of in-depth scanning of pediatric patients, preferably those with congenital heart disease. This training can occur under the tutelage of one of the pediatric sonographers who has been designated as an educator or is accustomed to teaching others. Obtaining permission for visiting sonographers to perform hands-on scanning at the tertiary care center can be problematic in some institutions and usually requires the involvement of and clearance with hospital administration. After the initial training experiences, the best way to advance and maintain community sonographer skills in pediatric echocardiography is for a pediatric cardiologist or senior tertiary care sonographer to supervise each of the echocardiograms in real time via telemedicine. This provides instant feedback to the sonographer and minimizes the probability of missing a significant abnormality. If real-time interaction with the sonographer is not feasible, because of either a lack of real-time technology or limited physician (or tertiary sonographer) supervisory time, then the physician reading the telemedicine study should be encouraged to provide feedback to the sonographer once the study has been read, preferably on an ongoing basis. This builds sonographer confidence and provides continuous quality improvement.

The benefits of distance education are outlined above; the most important benefit is that sonographers can gain the skills necessary to provide a critically important service. However, distance education cannot completely replace hands-on training and more frequent direct exposure to pediatric pathology. Ongoing interaction between the tertiary care center and spoke sites that include quality improvement initiatives is important to narrow this gap as much as possible.

Tele-Echocardiography Program Development

As opposed to the training required for competency in either adult or pediatric echocardiography, a very different approach is needed in crafting a high-quality pediatric tele-echocardiography program. Although this affects primarily the training of the sonographer, educating the referring physician and the interpreting pediatric cardiologist is critical to achieving the best possible patient outcomes. As an illustrative example, the pediatrician caring for an irritable child 2 years of age with fever, conjunctivitis, and mucous membrane changes with a concern for Kawasaki disease requests a tele-echocardiogram on a Sunday night to assess for coronary artery involvement. The study is performed by an early-career adult-trained sonographer who has performed only a limited number of pediatric echocardiograms. The on-call pediatric cardiologist at the referral center expects pristine coronary artery imaging. This is a scenario destined for failure, likely avoidable with prior programmatic structure developed around training, education, and coordination. It is this structure that creates a sustainable program that provides the best possible care to the child with putative heart disease.

The sustainable program providing high-quality care must have a structured approach to incorporating new sites. A successful algorithm might include the following:

1. Initial planning
   A. Well-delineated information technology support at the remote site and at the pediatric echocardiography laboratory site
   B. Documentation of training methods/expectations of the adult sonographer by the pediatric team
2. Clinical care model
   A. Intake data made available to the pediatric referral center (eg, patient demographics, referring physician contact information for effective communication, transparency around study urgency, sonographer preliminary interpretation of findings)
   B. Well-defined information feedback loop (robust method of delivering echocardiography report from the pediatric site to the referring physician/clinic/hospital)
3. Ongoing quality assessment
   A. Quality metrics established (clinical information availability, study performance completeness, timeliness of image transfer, stability of connectivity, ongoing training availability/use)
   B. Quality assessment/action plan: method of report dissemination internally and back to regional tele-echocardiography sites; internal/external method of instituting change

For well-constructed programs, the viability of a high-quality pediatric tele-echocardiography program has been validated. Many centers participating in pediatric tele-echocardiography have gone through a transition in which a high proportion of studies were viewed live early on to ensure study quality and completeness.[30] Over time, with improvements in the speed of study transmission and the confidence that comes from experience, many programs have transitioned to a store-and-forward approach. The accuracy of both the earlier and the more recent approaches has been validated.[36] In addition, the diagnostic accuracy between studies recorded to videotape and subsequently forwarded to the pediatric laboratory compared with live image transfer via broadband tele-echocardiography was studied by the University of Arizona,[42] and again, high degrees of accuracy were demonstrated.

Appropriate Use Criterion

With the recent release of pediatric echocardiography appropriate use criteria,[62] we now have in place a set of principles that provide guidance for the use of echocardiography to provide the most effective and cost-efficient care to our patients. Although many of these appropriate use criteria are based on expert consensus rather than scientific method, they provide us with a decision-making framework. As applied to pediatric tele-echocardiography, there are several constraints to consider. One consideration surrounds the care of patients at distant locations where scarce medical resources are available. There remain locations in the United States and other high-income countries where the nearest pediatric cardiologist is several hundred miles away. It should be a reasonable expectation in these circumstances that telemedicine use contributes to maintaining, not violating, these appropriate use criteria. The availability of telemedicine alone should not result in scenarios such as children with benign murmurs, episodes of noncardiac chest pain, or bouts of syncope automatically receiving inappropriate echocardiograms solely because the technology is available and the in-person cardiologist is not. In addition, the appropriate use criteria were developed on the basis of the performance of echocardiograms of the highest technical quality.[58,59] This level of quality should be sought and, we hope, achieved at most tele-echocardiography programs given that one of most important goals of pediatric tele-echocardiography is to exclude dangerous congenital heart disease in newborns. This does not mean that telemedicine is always the answer just because it is available. By way of example, such criteria as abnormal barium swallow in which a vascular ring is being excluded and family history of hypertrophic cardiomyopathy have been deemed to be appropriate reasons to obtain a pediatric echocardiogram. However, in these scenarios, the knowledge base and experience of the regional sonographer, the level of urgency of study acquisition, or other nuances (eg, the availability of safe pediatric sedation for the uncooperative toddler) may mean that these types of studies should be deferred in the typical pediatric telemedicine program in favor of a referral for pediatric cardiac hands-on care. These are the types of decisions that each program must make individually in that center-specific issues surrounding distance to referral site, the skill set of the sonographer, and the comfort level of the referring provider will often take precedence over published guidelines of care. A key component of building a telemedicine program should be direct communication between the tertiary care pediatric cardiology team and the community pediatricians who will be ordering echocardiograms. Education on the role of echocardiography is paramount in achieving a high-quality, successful program.

Future Technology in Echocardiography

The next phase of pediatric tele-echocardiography is emerging. New technology is allowing more rapid, more portable, and innovative uses of tele-echocardiography. These include newer data compression technology,[63] novel training methods for international support,[64] the use of personal devices such as smartphones for nearly instantaneous image review,[65] and the application to prenatal cardiac diagnosis.[1,66] More speculative is whether such tools as remotely controlled echocardiography probes with robotic arms can be applied in clinical prac-

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tice so that the lack of a trained sonographer is removed as a limiting factor in the effective implementation of a high-quality tele-echocardiography program.[67] In the meantime, it has been demonstrated[33] that high-quality images can be obtained in very remote pediatric populations without the availability of a certified sonographer through the training of other members of the care team (nurses, primary care providers, and others). Questions will need to be answered as to whether these new methods, patient populations, and technologies allow tele-echocardiography diagnostic testing comparable to that performed on site and in the end allow more effective patient care.

ELECTROPHYSIOLOGY AND TELEMEDICINE

External Rhythm Monitoring

In the early 1900s, Einthoven had a telephone cable laid to the hospital a mile away and demonstrated the ability to make recordings remotely.[68] These days, digital electrocardiography and Holter monitor data are shared via fax, Internet, and mobile devices with high resolution.. Starting in the 1990s, digital telemetry systems allowed computerized electrocardiography signal recording, storage, and retrieval[68,69] and now are standard of care for patients in the ICU. This has led to the establishment of tele-ICUs and facilitates remote real-time monitoring and recommendations by pediatric electrophysiologists.

Cardiac arrhythmias in newborns and children can be evaluated and treated with pediatric telecardiology by providing access to pediatric cardiologists or other specialists familiar with these arrhythmias and their management.[70,71] The applications can include transfer of the ECG or viewing of the rhythm on cardiac monitoring at the originating site connected to the pediatric patient.[72–75] Often, treatment can be started with telecardiology supervision and monitoring that allows the arrhythmia to be converted. Other electrophysiology abnormalities, including prolonged QT syndromes, can be evaluated and managed in this fashion.[75]

Mobile monitoring devices are now commonly used for patients for up to 30 days of ambulatory telemetry. These devices provide telemetry monitoring 24 hours/day via the small sensor and monitor the patient wears as the patient continues with his or her normal daily routine. As events occur, patient activity is instantly transmitted to a central monitoring center via a cellular signal for analysis and response. In 1 study, mobile telemetry was superior in confirming the diagnosis of clinical significant arrhythmias compared with memory loop recorders.[76] Two recent studies showed that a single-lead, FDA-approved adhesive patch monitor for continuously recording and detecting cardiac arrhythmias in an ambulatory setting detected more arrhythmias than conventional Holter monitors.[77,78]

Cardiovascular Implantable Electronic Devices

Implantable devices such as pacemakers and cardioverter-defibrillators have an inherent ability to store and transmit data on cardiovascular events. Most devices now have the ability to allow automated and manual remote monitoring (RM) from a patient's home. In this method, the cardiovascular implantable electronic device communicates with a monitor/communicator device, which in turn communicates with a central monitoring station via a landline or cellular connection. The standard guidelines published by the Heart Rhythm Society and European Heart Rhythm Association recommend that the maximum interval between transmissions of cardiovascular implantable electronic device RM should be 3 to 12 months.[79]

RM harnesses the power of telemedicine for early identification of arrhythmias and device malfunctions, prompting earlier corrective measures for pediatric patients. RM has been reported to improve the care and safety of patients in multiple studies. In a pediatric study, 13% of remote transmissions for routine follow-up were found to be true events, whereas 27% of remote transmissions for a specific indication were found to be true events. Of these, 11% of transmissions prompted clinical intervention.[73] By providing early detection of patient and system problems, RM reduces the volume of device clinic visits. There are no significant ongoing patient costs for RM, and patients can have international coverage with these portable systems. With these benefits, automated RM intuitively appears to have the potential to provide information on cardiovascular implantable electronic device performance that is timelier than and nearly identical to that obtained in a traditional in-person interrogation. It is foreseeable that RM will become the standard of care, if it is not already. This will allow patients and their families to pursue their lives safely and with fewer interruptions by hospital visits.

Implantable loop recorders are subcutaneous, single-lead, electrocardiography monitoring devices used for diagnosis and long-term monitoring in patients with arrhythmia.[80] These also have RM capabilities like other pacemaker devices. For arrhythmia diagnosis, children sometimes undergo placement of insertable cardiac monitoring systems. Despite their miniature size, these devices have the same rhythm detection, recording, and remote transmitting capabilities as pacemakers.[81] Varieties of implantable pacemakers with additional heart failure monitors with RM capabilities are also available on the adult cardiology side.[82] The additional sensors in these devices include accelerometers, impedance monitors, heart rate derivatives, Doppler, oxygen saturation monitor, and heart sound sensors, among others. It is quite likely that some of these implantable heart failure monitors will be beneficial to a subset of patients with

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pediatric cardiomyopathy and patients with heart failure in the future and will improve their care with RM.

Personal Tele-Electrophysiology

As available personal health applications increase exponentially, the line between entertainment and health care continues to blur. Approximately one third of the >25 000 healthcare mobile health applications are specifically for physicians.[83] Examples in cardiology include texting programs for teenagers living with congenital heart disease[84] and several examples to improve lifestyle and to decrease risk in adults with cardiovascular disease.[85,86] Mobile health applications for personal monitoring of cardiac electrical activity exist for the detection of arrhythmias and myocardial infarction. In a prospectively recruited cohort of 76 participants undergoing cardioversion for atrial fibrillation, a novel algorithm analyzing signals recorded with a smartphone accurately distinguished pulse recordings during atrial fibrillation from sinus rhythm with excellent sensitivity (0.96), specificity (0.98), and accuracy (0.97).[87] The FDA has cleared an automated algorithm for identifying atrial fibrillation from its single-lead electrocardiographic tracing. This is based on the SEARCH-AF trial (Screening Education and Recognition in Community Pharmacies of Atrial Fibrillation to Prevent Stroke in an Ambulant Population Aged ≥65 Years) from Australia evaluating nearly 1000 patients with a single-lead electrocardiographic device built into a smartphone case. The technology was accurate and cost-effective and has the potential to prevent stroke.[88,89]

A modification of the existing smartphone case single-lead device was used in a recent study for the assessment of ST-segment–elevation myocardial infarction. Six patients for whom the hospital ST-segment–elevation myocardial infarction protocol was activated were evaluated with traditional 12-lead ECG followed immediately by a smartphone ECG using right (VnR) and left (VnL) limb leads for precordial grounding. There was agreement in all 6 patients (4 with ST-segment–elevation myocardial infarction and 2 with non–ST-segment–elevation myocardial infarction).[90] One study from St. Louis, Missouri reported that this technology can generate tracings of diagnostic quality in children with positive user satisfaction and could be used to manage children with supraventricular tachycardia and atrial fibrillation.[72]

TELEMEDICINE IN THE PEDIATRIC CATHETERIZATION LABORATORY

Interventional catheterization often requires important on-the-spot decision making that would benefit from expert consultation if immediately available. Telemedicine applications have the potential to bridge this gap. Seckeler et al[91] reported high rates of use among early-career pediatric and congenital interventional cardiologists for consultation on catheterization procedures. Three quarters of mentees reported using smartphone or tablet applications for remote consultation, one quarter of them using it for nearly every case, with 45% of communication occurring during a procedure. There are also many examples of using live case demonstrations for distance learning of catheterization techniques.

TELECONSULTATION AND TELE-AUSCULTATION IN THE OFFICE

Teleconsultation

Teleconsultation can serve the nonhospitalized patient as well, particularly patients with new cardiac signs or symptoms suggestive of cardiac disease. Teleconsultation programs use telecommunication technologies, along with various degrees of supplementary multimedia (still imaging of chest x-ray and ECG, tele-echocardiogram). Teleconsultation can occur between providers (typically primary care providers requesting specialty advice) or directly between the cardiologist and the patient/family. Synchronous and asynchronous (store-and-forward) approaches have been used, ideally tailored to the particular clinical, geographic, and technical situation.

The simplest asynchronous (store-and-forward) provider-to-provider consultative services use e-mail or Web-based platforms to facilitate specialty advice for primary care providers. Several groups have reported improved access and quality with reduced costs for both adult and pediatric cardiology outpatient evaluations.[92–94] Such systems aim to replicate the classic "curbside" consultation for remote providers, thereby extending the reach of the specialist into underserved areas. These programs reduce the need for face-to-face evaluations but can increase the overall number of contacts with the specialist, likely as a result of ready specialist access for primary care providers.[95] One Spanish synchronous provider-to-provider consultation with multimedia support had similar success; only 10% of patients undergoing teleconsultation required travel to the tertiary care facility.[40] Finally, teleconsultation between cardiologists for complex cases has further extended the concentrated expertise of large tertiary facilities.[13,39]

Direct provider-to-patient teleconsultation represents the more frequently used delivery model, although reports are limited primarily to countries with national health services. A rare US report found telecardiology evaluation useful for evaluating both new referrals and recent postoperative cases, with the added potential benefit of knowledge transfer to local primary care providers who were present for the tele-encounter.[96] In Canada, synchronous teleconsultation has been useful for remote preprocedural counseling and evaluation of new patients with syncope and supraventricular tachy-

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cardia.[13] In the United Kingdom, a broad range of both inpatient and outpatient telecardiology services are available to the district hospitals using various technologies.[97–99] This approach improved access, was cost-neutral, and was appreciated by patients.[100] The authors stressed that this approach supplemented, but would not replace, regularly scheduled outreach clinics. Successful sites had dedicated clinical champions and were designed by local clinicians to meet their specific needs. Failing to recognize these requirements has caused others to fail.[101]

Tele-Auscultation

Most murmur referrals in healthy children >1 year of age reveal no cardiac pathology but nevertheless generate significant parental distress and represent a burden to the healthcare system.[102,103] Rural patients are disproportionately affected because of the heterogeneous distribution of specialty services, requiring some families either to wait for outreach visits or to travel significant distances for what is most often a normal result. As discussed previously, tele-echocardiography is one solution to this problem. However, this approach requires equipment, trained personnel, and adequate transmission bandwidth, which can limit its use in some areas. In face-to-face pediatric cardiology practice, auscultatory evaluation of the otherwise healthy child with a murmur by a pediatric cardiologist has long been shown to be both accurate and more cost-effective than simply performing echocardiography on all murmur referrals.[104–108] It would therefore seem that tele-auscultation would represent a cost-effective alternative to routine tele-echocardiography for the evaluation of heart murmurs in this population.

To date, tele-auscultation reports have focused primarily on the accuracy of remote interpretation of pediatric heart sounds. Over the past 2 decades, several investigators have evaluated different hardware and software solutions for remote murmur evaluation. Belmont and colleagues[109,110] used the synchronous approach incorporating both digital and analog systems. They found significant differences in heart sound characterization compared with face-to-face evaluation by a pediatric cardiologist using an analog stethoscope. However, when used to classify overall findings as either normal/innocent or pathological, their tele-auscultation was not different from face-to-face evaluation. Therefore, they concluded that tele-auscultation was best suited for triage purposes when used by experienced tele-auscultation providers in children >3 to 5 years of age. Patients with abnormal or equivocal findings by tele-auscultation, it was suggested, should be referred for face-to-face evaluation.

McConnell et al[111] also used a synchronous tele-auscultation approach with similar accuracy. Patients were satisfied with the results, and compared with face-to-face cardiology evaluation, the use of ancillary testing (electrocardiography and echocardiography) was no different for the tele-auscultation group. The authors concluded that a synchronous video teleconference cardiology evaluation using tele-auscultation could be performed safely without the need for costly tele-echocardiography.

Other investigators have focused on the asynchronous (store-and-forward) tele-auscultation approach, that is, having heart sounds recorded at the patient site for transmission to the remote cardiologist for later review.[112–114] These studies have combined a variety of digital recording stethoscopes with electronic transmission via e-mail or a web-based platform. Overall accuracy was similar to face-to-face evaluation as reported in the literature.[106,115] Cardiac pathology misclassified as normal/innocent in these studies was rare and mild and would not have required intervention (hemodynamically insignificant small ventricular septal defects and mild semilunar valve stenosis). Two of these studies[112,114] relied primarily on the heart sound recordings to make diagnostic decisions, and thus, the authors postulated that the real-world addition of historical, physical examination, and chest x-ray/electrocardiographic data would improve sensitivity. With regard to specificity, 10% to 15% of innocent murmurs were misclassified as pathologic via tele-auscultatory review, representing false-positives that would require face-to-face evaluation. The majority of innocent murmurs, however, were correctly classified.

The available literature on real-world clinical use of tele-auscultation is limited to reports of overall telecardiology programs using several telemedicine technologies (video teleconference for patient/provider interaction, document cameras for electrocardiography/chest x-ray, and tele-echocardiography). An early report found tele-auscultation useful in rural Georgia[96] but suggested the need for technical improvements. In the United Kingdom, the inclusion of tele-auscultation did serve as a useful check on the tele-echocardiographic diagnosis.[98] However, tele-auscultation was underused because of technical issues. These technical issues did not improve with time, and subsequent clinicians concluded that tele-auscultation was not necessary for remote evaluation.[99]

Despite the accuracy and theoretical appeal of tele-auscultation, this approach has not proliferated in practice. There are likely several reasons for this. First, several technical and device issues must be overcome for successful tele-auscultation. Because of the small size and the limited cooperation of infants and children, they require devices with small sensor footprints, short acquisition times, and extraneous noise reduction capabilities.[116] Because most of the acoustic energy of the heart is of very low frequency, simply recording and reproducing these sounds can be technically challenging.[117] Digitally acquired heart sounds must first be filtered to reproduce the familiar frequency characteristics of acoustic stethoscopes. This often results in sound characteristics that are not entirely familiar to clinicians and may be responsible for the variable tele-auscultation accuracy between clinicians.[118] Asynchronous review of low-frequency heart sounds is further hampered on most computer-based systems that are optimized for much higher-frequency music playback. Second, any telemedicine system is bound to fail if it is not practical and simple to use. To that end, successful implementation of any telemedicine system requiring remote data acquisition must address the issues of data capture, transfer, playback/viewing, and reporting. Reimbursement also plays a role in the proliferation of such an approach. Tele-auscultation of children with murmurs can improve access for remote patients, but in a fee-for-service healthcare system, this can provide a negative incentive to telecardiology providers and their employers. Therefore, tele-auscultation may be best suited financially for government-based healthcare systems with the specific purpose of augmenting outreach clinics.[97,113] Finally, despite the increased costs, many providers and patients simply prefer or expect echocardiography for murmur evaluation.[103,119]

Digitally recorded heart sounds also provide the opportunity for computerized analysis of this physiological data, referred to as computer-aided auscultation, and could be incorporated into an asynchronous tele-auscultation program. Several groups have applied a variety of signal processing techniques to pediatric heart sound recordings and report sensitivity and specificity values approaching 100%.[120–124]

Automatically generated computer-aided auscultation interpretation can also provide immediate decision support to the primary care provider.[125] With computer-aided auscultation used this way, the referral sensitivity and specificity of primary care providers increased, with the potential to significantly reduce unnecessary and costly referrals.[126] If the recorded heart sounds are subsequently "overread" by a pediatric cardiologist, this process is similar to the current practice of electrocardiographic interpretation: An automated report provides initial decision support followed by specialist verification for safety and quality control. Despite the potential, computer-aided auscultation has not yet been widely adopted despite at least 1 FDA-approved system currently available. As with tele-auscultation, this is likely the result of a combination of technical, practical, and financial disincentives.[116]

Direct-to-Consumer Telemedicine

There is an exponential growth in demand for medical care in the home via web-based direct-to-consumer applications that include tablet and smartphone applications.[127] Many payers are embracing this technology as a way to provide lower cost care for common problems that might otherwise result in an emergency department (ED) visit.[128] Most of these applications rely solely on video and audio connections with additional software for scheduling, billing, sharing of still-frame images, and documentation. However, some peripherals such as a smartphone-compatible heart rhythm detection devices[90] and otoscopes[129] may be available for purchase for a low price. One could imagine that this technology could be used to manage children and adults in follow-up of syncope, chest pain, obesity, hypercholesterolemia, and chronic heart failure.

This rapidly growing field of direct-to-consumer telemedicine creates great opportunities and, at the same time, some threat to the delivery of high-quality care. To begin to address this concern, the American Telemedicine Association (ATA) has created and is implementing an accreditation program for consumer-directed telehealth services provision.[130] Additionally, as the use of these devices grows, careful attention must be paid to patient safety and privacy. Other unanswered questions include the role of the FDA in creating streamlined approval categories and the challenge for device manufactures as they move from consumer grade to medical grade.

HOME TELEMEDICINE

There is a large and growing body of literature describing a wide variety of approaches to home monitoring for diseases that incorporate more automated telemedicine technology.[131] The most common applications are for adults with diabetes mellitus,[132] chronic respiratory disease,[133] congestive heart failure,[134] and hypertension.[131] There are reports of pediatric home telemedicine programs for children with asthma that combine standardized management with patient and parent education modules.[135] The most common home telemedicine devices consist of small units weighing <5 lb that are tablet size and connect to a variety of medical devices (hard wired or wireless), including scales, heart rate and pulse oximeter monitors, blood pressure devices, glucometers, and peak flow meters. Data can also be manually entered. These devices then transmit data (via analog phone line, cellular network, or wired or wireless Internet connection) to a medical team for review. The devices also have education modules on a wide range of disease processes. The medical team has the ability to review data with software that allows serial comparisons and has red flags for outlying or missing data. The medical team can set the frequency of transmissions.

Several home telemedicine models for adult patients could be translatable to patients with congenital heart disease, including those with single ventricles. Benatar et al[136] reported a home telemonitoring program for adults with congestive heart failure that used an automated device that captured weight, blood pressure,

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heart rate, and oxygen saturation daily and transmitted that information to a nurse practitioner. They showed that patients using this device had fewer admissions, shorter lengths of stay during admissions, lower health-care costs, and improved quality of life. A meta-analysis of home telemedicine monitoring of patients with congestive heart failure showed that telemonitoring reduced mortality, lowered the number of hospitalizations and the use of other health services, and improved quality of life.[134]

Strategies to reduce interstage morbidity and mortality for patients with a single ventricle after stage 1 palliation include standardization of care protocols to reduce practice variability; focused high-risk outpatient clinics for patients with a single ventricle after stage 1 palliation; home surveillance monitoring, including equipment such as pulse oximeters and infant scales; and a dedicated team of professionals who focus on these fragile patients' unique needs.[137–139] Family education and access are very important components of any single-ventricle program. A wide range of options are available for home monitoring of infants; pulse oximetry and weight are the 2 most important variables cited. The national collaborative for interstage care for single ventricles has had a significant impact on outcomes.[140–144]

Ghanayem et al[137] from the Children's Hospital of Wisconsin reported in 2003 that initiation of a program that asked parents to record daily weight and oxygen saturation at home improved survival in patients with hypoplastic left heart. The group also asserts that home monitoring plays a critical role in determining the ideal timing of the bidirectional Glenn.[145] Cross et al[146] reported that the use of a telemedicine solution for interstage single-ventricle care that incorporated automated transmission of pulse oximetry, weight, and formula intake, along with answering questions about the status of the infant, resulted in better nutritional status than in patients who did not use home monitoring. This home telemedicine solution included a website with automated warning alerts and a patient dashboard for easy access to subtle changes over time.

GLOBAL TELEMEDICINE

Telemedicine can be a very powerful tool to facilitate care and disease prevention in low- and middle-income countries,[147] with important similarities to and differences from telemedicine practices in high-income countries. There are numerous examples of "north-south" collaborations between experts in high-income countries and cardiology and cardiac surgery programs in low- and lower middle–income countries. These include sharing images via store-and-forward technology and live patient care conferences. Educational webconferences (both live and stored content) have had a significant impact on improving outcomes for congenital heart surgery in resource-poor countries.[148] Sharing of images via cloud imaging can advance research collaboration for endemic heart disease such as rheumatic heart disease.[149] Unique challenges to successful implementation of global telemedicine include time zone differences, language and cultural characteristics, local government telemedicine policies, Internet security, and equipment availability and maintenance. Limited bandwidth and lack of access to broadband connectivity are important barriers that must be considered and addressed in the design of global telemedicine partnerships.

TELEMEDICINE IN THE INTENSIVE CARE SETTING

There are many examples of the meaningful use of telecardiology in the neonatal ICU,[22,27,150,151] the pediatric ICU,[70,71,152–155] and the ED.[156–158] With telecardiology, pediatric patients can more quickly be evaluated, stabilized, and triaged to determine the need for transport and more advanced treatment or even surgery.[159] Furthermore, telecardiology can be used in all of these settings for case reviews, education, and quality improvement, in conjunction with originating referral sites.[160]

The types of telecardiology applications include the visual "virtual" bedside patient evaluations with videoconferencing and sharing of echocardiograms, cardiac ultrasounds, and ECGs.[97,161] With these technologies, data support the fact that telecardiology can result in high patient and provider satisfaction and improved monitoring, clinical evaluations, and treatment decisions, as well as more appropriate transport/transfer decisions, when connecting to an originating site where the pediatric patient is located. As noted previously, telemedicine has been particularly useful for newborns when evaluating for possible CCHD, particularly when the infant is cyanotic or in extremis, and, for example, differentiating CCHD from persistent pulmonary hypertension of the newborn. These positive impacts of telemedicine on avoiding unnecessary transports and cost savings have been consistently found among published reports, including evaluations done internationally.[27,161,162]

Intensive Care

Telemedicine has proven useful for newborns, infants, and children in general when distance and time create challenges in accessing pediatric cardiology expertise in a timely, efficient, and effective manner to provide just-in-time service at the point of care.[30,44,98] Pediatric cardiology specialty expertise can be provided to an originating site where the patient is located such as in a nursery or level II newborn unit, a general pediatric ward, a general ICU, or an ED where pediatric cardiology specialty services may not be available locally. Telecardiology can be a critical adjunct to current models of care when there is suspected CCHD or acquired cardiac abnormalities such as cardiomyopathy or congestive heart failure and cardiac arrhythmias.

Published data from an international telecardiology critical care program have demonstrated high levels of satisfaction and improvements in clinical outcomes, including length of stay and mortality.[70,71,152,163,164] When telemedicine has been used to care for children with a broad range of medical and surgical diagnoses, including cardiovascular disease, research demonstrates high levels of satisfaction among remote providers and parents/guardians, high quality of care, and reductions in healthcare costs as a result of more appropriate transports and decreased use of the more costly regional ICU.[155,165–168]

In certain situations, cardiac catheterization recordings can be transmitted from one neonatal ICU or pediatric ICU to another higher-level neonatal ICU, pediatric ICU, or pediatric cardiology program for a second opinion and assistance in determining the best management strategies and even definitive cardiac surgery at a higher-volume center where outcomes may be improved. Furthermore, pediatric telecardiology can be used for follow-up of those patients treated at another center without the patient needing to return to that center if the patient is progressing satisfactorily.

Hospitalized pediatric patients may benefit from pediatric cardiology expertise, reducing the tendency to "overtriage" and transport patients to a regional center for pediatric cardiology specialty services.[169] In fact, many pediatric patients, including those with mild or chronic cardiac disease, can be managed at a level II (lower acuity) pediatric ICU[170] (as defined by the 2004 report from the American Academy of Pediatrics and Society of Critical Care Medicine) or a general ICU with pediatric expertise.[155,171] Using telemedicine to assist in the management of some of these less ill children can result in high-quality care provided with shorter lengths of stay, less resource use, and lower costs.[70,172,173] It is therefore logical that some mildly or moderately ill children (eg, a child with a ventricular septal defect with asthma or a child with Kawasaki disease) can be cared for by local pediatric nurses and physicians with supervision from a regional children's hospital pediatric cardiology team using telemedicine and RM.[30,70,159,173]

Telemedicine can be used by pediatric cardiologists through a broad range of applications to assist in the care of hospitalized children in a variety of clinical scenarios.[165,174] Physician consultations, nurse and physician monitoring, and medical oversight can range from a simple model of intermittent, need-based consultations (reactive model) to a model that integrates continuous oversight via monitoring and proactive medical decision making (continuous model).[175] In a reactive model, a pediatric cardiologist can evaluate and provide recommendations on diagnostic studies, medications, or other therapies.[70,71,152] The consultation may also conclude that the patient should be transported to the regional pediatric cardiac center. Such models require compliance with critical care best practices and maintenance of training, including advanced life support certifications and participation in quality assurance programs.

Telecardiology in the ED

It is well documented that critically ill children presenting to EDs without pediatric expertise receive poorer quality of care compared with the care provided in EDs with that expertise.[164,176–179] This is especially true for infants and children with cardiovascular disease or illness.[180] In addition, the staff working in smaller, general EDs, including physicians, nurses, pharmacists, and support staff, are often less experienced in caring for children with congenital heart disease or other acquired cardiac conditions. The benefits of using telemedicine technologies as opposed to using the telephone (the current standard of care) is that the pediatric cardiologist can have a virtual presence at the patient's bedside. Previous studies have demonstrated that the use of telemedicine in the ED to deliver critical care consultations is similar to in-person consultations when diagnostic accuracy, treatment plans, and plans for disposition are compared.[173,181–183]

Although large, randomized trials are lacking, there are increasing acceptance and anecdotal evidence that providing pediatric critical care and telecardiology consultations to remote EDs for children with suspected or known cardiovascular disease is feasible and of clinical utility.[156,158,183] Overall, although more research is needed, it is logical that pediatric telecardiology consultations to rural and underserved EDs through telemedicine can be used to help address disparities in access to specialists and, in doing so, improve the overall quality of care. It is also likely that, because of better care and the reduction in unnecessary transports, telemedicine consultations to rural and underserved EDs can be provided in a cost-efficient manner that reduces the healthcare costs that would otherwise be encountered if telemedicine were not used.

LEGISLATION, PUBLIC POLICY IMPERATIVES, AND TELEMEDICINE GUIDELINES AND STANDARDS

Demand for innovative solutions in health care has been broadly driven by an aging population, high rates of chronic illness, and geographic and sociodemographic disparities in access to care, coupled with increasing numbers of insured Americans seeking care and consumer and provider demand for choice. Advancements

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in public policy related to telehealth apply equally to pediatric populations and to adults. As discussed above, in pediatric cardiology, the incorporation of store-and-forward digital imaging modalities such as tele-echocardiography or live interactive videoconferencing for consultation and care and the use of patient monitoring technologies improve the evaluation and management of pediatric patients with cardiovascular disease. The movement toward increasing newborn screening for CCHD with oxygen saturation monitoring has provided additional demand for the use of telehealth. Extensive evidence published in the peer-reviewed literature has demonstrated that telemedicine improves clinical outcomes for infants and children with congenital and acquired heart disease.

Public Policy Imperatives

Technological innovation most often outpaces advancements in policy. Health professionals and healthcare systems seeking to engage in telehealth must be aware of the legal, administrative, and regulatory framework that underpins the use of advanced technologies applied to health care.[184–186]

On a federal level, 26 different federal agencies report engagement in telehealth, affecting such issues as clinical service delivery and payment, credentialing and privileging, online prescribing, health information exchange, HIPAA (Health Insurance Portability and Accountability Act) privacy and security rules, research and grant funding opportunities, workforce, Stark and antikickback laws, the deployment of communications networks, and device development and regulation. States play an equally important role, with policies and regulations that affect Medicaid coverage, private pay mandates, licensure, scope of practice, prescribing regulations, malpractice, and in some states additional regulations addressing credentialing and privileging, health information exchange, and broadband communications infrastructure. Practitioners are advised to be aware of all relevant laws, regulations, and policies that affect medical and telehealth practice.[187,188]

Telemedicine Standards and Guidance

The April 2014 Federation of State Medical Boards (FSMB) Appropriate Regulation of Telemedicine work group's "Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine" proposed a common framework and language for adoption by states.[189] By providing a model policy for use by state medical boards, the FSMB proposed to reduce regulatory barriers to more widespread adoption of telemedicine technologies while ensuring what the working group deemed is the appropriate use of telemedicine. Shortly after the release of the FSMB publication, in collaboration with various specialty societies, the ATA published its "Core Operational Guidelines for Telehealth Services Involving Provider-Patient Interactions," which updates the ATA's February 2008 guidance to enhance guidance on patient education, to address the need to verify patient/provider identity and service delivery location, to include guidance related to mobile devices and services delivered to patients in nonfacility settings, and to further develop the existing recommendations on privacy and security.[190]

On the heels of the FSMB model policy and the ATA guidelines, the American Medical Association issued its telemedicine guiding principles document in June 2014. These guiding principles relate to the establishment of a patient-physician relationship and the coordination of patient care among providers, which may go beyond what is contemplated in the business models of telemedicine companies, arranging for episodic telemedicine visits with on-call providers.[191] The FSMB, American Medical Association, and ATA policy/guideline documents offer guiding principles to ensure patient safety and choice, quality of care, licensure, and privacy of patient information. In particular, the FSMB model policy clearly states that prescribing as a result of a telemedicine encounter should follow all current standards of practice in terms of indications, appropriateness, and safety considerations. It also establishes that, in accordance with the guidelines, a virtual face-to-face visit can establish a bona fide doctor-patient relationship.

Medical specialty societies have developed guidelines that address certain clinical and technological aspects of telemedicine[192,193] such as the practice parameters for telepsychiatry with children and adolescents from the American Academy of Child and Adolescent Psychiatry, guidelines for the surgical practice of telemedicine from the Society of American Gastrointestinal and Endoscopic Surgeons, and practice guidelines for electronic medical information privacy and security from both the American College of Radiology and the Society for Imaging Informatics in Medicine. The American Medical Association's guiding principles encourage collaboration between medical specialty societies to develop more comprehensive practice parameters, standards, and guidelines to address the clinical and technological aspects of telemedicine. The American Academy of Pediatrics issued a telemedicine guidance document in June 2015,[194] followed by the American College of Physicians in November 2015.[195] It is our hope that other pediatric specialty societies review this guidance as a source of comparison and insight when preparing their own guidelines. There are no specific policy statements governing the use of telemedicine in pediatric cardiology; the wealth of literature and widespread use of this technology certainly warrant the development of policies and procedures and the inclusion of these in future accreditation requirements.

Broadband Connectivity

Broadband communications services and wireless technologies, the underpinning of connectivity for telehealth, have been expanded with the establishment of the Federal Communications Commission's Rural Healthcare Support Mechanism. Administered by the Universal Services Administrative Corporation, this fund makes available millions of dollars in connectivity for eligible healthcare entities.[196,197] Although access to broadband continues to increase, widespread access for telemedicine still remains a challenge, especially in underserved rural areas.

FINANCIAL AND REIMBURSEMENT CONSIDERATIONS

Telemedicine services are currently reimbursed by federal and state governmental payers, by private payers, as contracted services, and by the patients themselves. Self-insured organizations may choose to offer the benefits of telemedicine services for their employees as well. However, reimbursement remains a balkanized conglomeration of policies at both the federal and state levels.

Federal Reimbursement Policies

Although in general relatively few children with heart disease are Medicare beneficiaries, coverage policies by other payers often parallel those of Medicare. Historically, Medicare coverage of telemedicine services began with the Balanced Budget Amendment of 1997 and the 2000 Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act, which authorized reimbursement for telemedicine services provided to rural Medicare beneficiaries for a broad range of diagnostic and treatment services.[198] At that time, the paradigm was established that aligned coverage with the geographic originating site of the patient.

The Affordable Care Act of 2010 did not expand eligible originating sites within the traditional Medicare program, in part because the Congressional Budget Office overestimated the cost of telemedicine services.[199,200] Although pilot programs have been launched through the Center for Medicare & Medicaid Innovation, even the regulations for Medicare Shared Savings Program accountable care organizations still require the patient originating site to conform to the regulations set forth in Section 1834(m) of the Social Security Act. Annually, in its physician payment schedule, the Centers for Medicare & Medicaid Services (CMS) reviews payment policy and, on the basis of the evidence and in alignment with the statute, may expand coverage decisions.[201] In 2014, CMS expanded its operating definition of rural from nonmetropolitan counties only to include those regions defined as rural by the Office of Rural Health Policy. Medicare covers live interactive telemedicine services when the patient is located in a specifically defined type of originating site when located in a rural area. Medicare has also defined the eligible distant site provider (the consulting practitioner) and the Current Procedural Terminology codes for which reimbursement may occur. Medicare pays an originating site fee. Medicare does not pay for store-and-forward telemedicine services other than by statute in Alaska and Hawaii. Medicare does not pay for data collection obtained through remote patient monitoring tools, although home health agencies may choose to use telehealth tools through capitated services. Physician-provided services, such as the interpretation of ECGs or echocardiograms transmitted electronically, are not considered telehealth services by Medicare and therefore are covered, much like teleradiology. CPT (Current Procedural Terminology) codes have been assigned for the remote assessment of pacemakers and the collection and assessment of data from cardiac event recorders.

Recently signed into law, H.R.2, the Medicare Access and CHIP Reauthorization Act of 2015, provides the following: "Nothing in the provisions of, or amendments made by, this title shall be construed as precluding an alternative payment model or a qualifying APM participant from furnishing a telemedicine service for which payment is not made under section 1834(m) of the Social Security Act." Thus, the stage is set with federal language to allow the expanded coverage of telemedicine services provided to children through the development of alternative payment models. The Center for Medicare & Medicaid Innovation has funded initiatives that include broader demonstration projects using telemedicine, store-and-forward, and remote patient monitoring services, including for Medicaid beneficiaries.

The statutory barriers placed on telehealth programs are borne out by the meager reimbursements reported by Medicare for telemedicine services. In 2014, CMS reported <$14 million in reimbursements for "allowable charges" nationwide for both originating sites (location of the patient) and distant sites (location of the consultant or telemedicine provider).[202] Other federal payers, including the US Department of Defense and the Veterans Health Administration, offer telemedicine services to their patients. The federal government employee benefit plans cover telemedicine services as well.

State Reimbursement Policies

The states have greater flexibility to adopt policies that provide expanded payment coverage through Medicaid, private payment mandates, state employee benefit plans, and other delivery mechanisms.[203] Two comprehensive references from the ATA that are updated frequently serve as an excellent reference and

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resource for the information provided in the following sections on Medicaid, private payer, standards of care, licensure, use and quality of equipment, and informed consent.[187,188]

Medicaid

Currently, nearly all state Medicaid programs provide some form of reimbursement for the delivery of telehealth-facilitated care to Medicaid beneficiaries, but there is no consistency in coverage across those programs. Most Medicaid programs pay for transportation of patients, yet in many states, there are still considerable limitations on coverage for telehealth. Medicaid coverage decisions may, in some states, require statutory change; in others, however, administrative change may occur by actions taken within the agency. Some Medicaid programs have implemented originating site restrictions that reflect Medicare rules, whereas others have expanded both geographic and originating site facilities (beyond healthcare facilities to include schools and the home). The proliferation of capitated managed care services in Medicaid provides an opportunity for the managed care organizations to integrate telehealth services in addition to what is offered for the Medicaid fee-for-service populations. State Medicaid agencies are encouraged to contract with the managed care organizations to include such services for their beneficiaries.

Private Payers

As of November 2015, 28 states plus the District of Columbia have passed parity reimbursement legislation. A significant number of commercial payers support coverage of telemedicine services even in the absence of a state mandate. Others have developed or adopted direct-to-consumer home or workplace telehealth models as either a benefit to members or an additional payment option.

LEGAL, REGULATORY, AND WORKFORCE ISSUES

Telemedicine in the United States touches on multiple legal and regulatory issues at the state and federal levels, including professional licensure, fraud and abuse, privacy and security, informed consent, reimbursement requirements, and standard of care requirements.[186] The requirements for complying with these legal and regulatory issues are often complex and unclear. This lack of clarity is due largely to the rapid proliferation and evolution of telemedicine services in recent years, which has left regulators struggling with how to effectively regulate this fast-paced and quickly evolving mode of care delivery, and the fact that existing legal, regulatory, and industry guidance is focused largely on the use of telemedicine in traditional care delivery settings. The ATA has been a strong advocate for providing clarity on these issues. However, state medical boards and the American Medical Association do not always follow the position of the ATA, adding further confusion for practitioners (Table 2). Legal counsel advising healthcare providers and institutions on the use of telemedicine pediatric cardiology needs to understand these complex regulatory issues and how they intersect with industry standards applicable to telemedicine programs.

Standard of Care and Limitations on Prescribing

There is a general consensus among state regulatory bodies and courts that the care provided through telemedicine technologies must meet the same standard of care as care provided in person. This requires an established patient-physician relationship before any prescriptions are issued. In most states, a physical examination of the patient must be performed before the physician's issuance of a prescription. However, what constitutes a valid physical examination varies from state to state. Although a small number of states require an in-person examination, other states explicitly allow physical evaluations to be performed via telemedicine technologies. As a result of the variation between states, a state-by-state analysis is necessary.

Licensure

When the physician and the patient are located in different states, the physician may also need to be licensed or registered (depending on the state) in the state in which the patient is located before providing services in that state. This requirement varies from state to state; some states require full medical licensure, and others require only a telemedicine-specific license or registration, which is a more streamlined process than full medical licensure.[188,189]

The fact that telemedicine providers are often (and with growing frequency as a result of the growth of national direct-to-consumer telemedicine programs) located in a different state from the patient may create the obligation for the telemedicine provider to hold a medical license in multiple states, which is expensive and time-consuming. For this reason, medical licensure requirements are frequently cited as one of the largest barriers to multistate telemedicine programs. That said, there are efforts currently underway on multiple fronts to reduce or streamline the licensure requirements. One example is the adoption of the Interstate Medical Licensure Compact by states, which allows physicians who are licensed in a compact-member state to participate

CLINICAL STATEMENTS AND GUIDELINES

Table 2. Comparison of Guidance Addressing Physician Engagement in Telemedicine

Category		AMA Guiding Principles[191]	FSMB Model Policy[189]*	ATA Guidelines[190]	Other Comments
1	Definitions of telemedicine and telehealth	According to the AMA, there is no consensus on the definition of either term.	Telemedicine means the practice of medicine using electronic communications, information technology, or other means between a licensee in 1 location and a patient in another location with or without an intervening healthcare provider. Telemedicine is not an audio-only, telephone conversation, e-mail/instant messaging conversation, or fax. It typically involves the application of secure videoconferencing or store-and-forward technology to provide or support healthcare delivery by replicating the interaction of an in-person traditional encounter between a provider and a patient.	Telemedicine is the use of medical information exchanged from 1 site to another via electronic communications to improve a patient's clinical health status.[205] Telehealth includes a growing variety of applications and services using 2-way video, e-mail, smartphones, wireless tools and other forms of telecommunications technology.	Notably, the FSMB definition of telemedicine states that telemedicine typically involves the use of video-based physician-patient interaction. In the ATA's comments to the FSMB policy, the ATA recommends the deletion of this statement because the use of telephone and secure e-mail to deliver care is common and "state policies that prohibit any such use could set back the practice of medicine and limit the delivery of care."
2	Patient-physician relationship	Before services are delivered via telemedicine, a valid patient-physician relationship should be established through (1) a face-to-face examination, if a face-to-face encounter would otherwise be required in the provision of the same service not delivered via telemedicine; the face-to-face encounter could occur in person or virtually through real-time audio and video technology; (2) a consultation with another physician who has an ongoing patient-physician relationship with the patient and supervises the patient's care; or (3) meeting standards of establishing a patient-physician relationship included as part of evidence-based clinical practice guidelines on telemedicine developed by major medical specialty societies. Exceptions to these requirements exist.	The relationship is established when the physician agrees to undertake diagnosis and treatment of the patient and the patient agrees to be treated, regardless of whether there has been an encounter in person between the physician (or other appropriately supervised healthcare practitioner) and patient. An appropriate physician-patient relationship has not been established when the identity of the physician may be unknown to the patient. When appropriate, a patient must be able to select an identified physician for telemedicine services and not be assigned to a physician at random (see Other Comments).	Health professionals using telehealth must be cognizant of the establishment of a provider-patient relationship within the context of a telehealth encounter, whether interactive, store-and-forward, or other mode of communication/interaction is used, and they must proceed accordingly with an evidence-based standard of care.	AMA delineates the 3 methods in which a valid patient-relationship may be established, whereas the FSMB describes the point in time that marks the onset of the relationship.

(*Continued*)

Table 2. Continued

Category		AMA Guiding Principles[191]	FSMB Model Policy[189]*	ATA Guidelines[190]	Other Comments
3	Informed consent and disclosures	The telemedicine service must be delivered in a transparent manner to include, but not be limited to, the identification of the patient and physician in advance of the delivery of the service, as well as patient cost-sharing responsibilities and any limitations in drugs that can be prescribed via telemedicine.	Evidence documenting appropriate patient informed consent for the use of telemedicine technologies must be obtained and maintained. Appropriate informed consent should, as a baseline, include various components, including the identification of the patient, the physician and the physician's credentials, types of transmissions permitted with telemedicine technologies, and details on security measures taken with the use of telemedicine technologies.	Organizations and health professionals providing telehealth services must ensure compliance with relevant local, state, and federal (or international if appropriate) legislation, regulations, accreditation, and ethical requirements for supporting patient/client decision making and consent.	The ATA offered significant revisions to the FSMB informed consent guidelines. The ATA argues that informed consent is not required for patients who are seeing a physician in an office setting and that the majority of state medical boards do not have any informed consent requirements.
4	Clinical standards, quality of care, and patient rights	Policies H-480.974, H-480.968, and H-480.969 encourage national specialties to develop appropriate and comprehensive practice parameters, standards, and guidelines to address the clinical and technological aspects of telemedicine.	A documented medical evaluation and collection of relevant clinical history commensurate with the presentation of the patient to establish diagnoses and identify underlying conditions or contraindications to the treatment recommended/provided must be obtained before treatment is provided, including issuing prescriptions, electronically or otherwise.	Organizations providing services via telehealth must follow the standard operating policies and procedures of the governing institution.	The level of detail pertaining to clinical standards, quality of care, and patient rights varies between organizations. The AMA, FSMB, and ATA all recognize that existing discipline guidelines and standards must be maintained regardless of the medium through which care is provided.
		The delivery of telemedicine services must be consistent with state scope of practice laws. The standards and scope of telemedicine services should be consistent with related in-person services. In addition, the delivery of telemedicine services must follow evidence-based practice guidelines, to the degree they are available, to ensure patient safety, quality of care, and positive health outcomes. Other recommendations on this topic exist.	Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (encounter in person) settings. Treatment, including issuing a prescription based solely on an online questionnaire, does not constitute an acceptable standard of care.	The health professionals providing care via telehealth must be aware of pertinent professional discipline guidelines and standards that must be upheld in the telehealth encounter, with consideration of the specific context, location, timing, and services delivered to the patient. Health professionals must be guided by professional discipline and national existing practice guidelines when practicing via telehealth, and any modifications to specialty-specific clinical practice guidelines for the telehealth setting must ensure that clinical requirements specific to the discipline are maintained.	

(*Continued*)

CLINICAL STATEMENTS AND GUIDELINES

Table 2. Continued

Category		AMA Guiding Principles[191]	FSMB Model Policy[189]*	ATA Guidelines[190]	Other Comments
5	Technological standards	AMA reaffirms policies H-480.974, H-480.968, and H-480.969, which encourage national medical specialty societies to develop appropriate and comprehensive practice parameters, standards, and guidelines to address the clinical and technological aspects of telemedicine.	Not addressed.	All efforts must be taken to use communication modes and applications that have appropriate verification, confidentiality, and security parameters necessary to be used properly. The ATA has adopted specific guidelines on this topic.	The ATA is heavily focused on technological standards and the interaction between patient and physician using said technology. The ATA intends for the physician to set expectations for the use and constraints of technology within the provision of telemedicine service.
6	Coordination of care and emergent care	The provision of telemedicine services must include care coordination with the patient's medical home or existing treating physicians. Physicians, health professionals, and entities that deliver telemedicine services must establish protocols for referrals for emergency services.	Patients should be able to seek, with relative ease, follow-up care or information from the physician (or physician's designee) who conducts an encounter using telemedicine technologies. Physicians providing services using only telemedicine technologies should make documentation of the encounter with telemedicine technologies easily available to the patient and, subject to the patient's consent, any identified care provider of the patient immediately after the encounter. An emergency plan is required and must be provided by the physician to the patient when the care provided with telemedicine technologies indicates that a referral to an acute care facility or emergency department for treatment is necessary for the safety of the patient. The emergency plan should include a formal, written protocol appropriate to the services being rendered via telemedicine technologies.	Patient location information is needed if an emergency arises and a management protocol must be implemented.	

(*Continued*)

Table 2. Continued

Category		AMA Guiding Principles[191]	FSMB Model Policy[189]*	ATA Guidelines[190]	Other Comments
7	Prescription standards	Before a telemedicine service is provided, the patient must be notified of cost-sharing responsibilities and limitations in drugs that can be prescribed via telemedicine. Physicians and other health practitioners delivering telemedicine services must abide by state medical practice laws concerning prescribing.	Telemedicine technologies, when prescribing may be contemplated, must implement measures to uphold patient safety in the absence of traditional physical examination. Prescribing medications, in person or via telemedicine, is at the professional discretion of the physician. The indication, appropriateness, and safety considerations for each telemedicine visit must be evaluated by the physician in accordance with current standards of practice and consequently carry the same professional accountability as prescriptions delivered during an encounter in person. However, when such measures are upheld and the appropriate clinical consideration is carried out and documented, physicians may exercise their judgment and prescribe medications as part of telemedicine encounters.	When prescribing, the clinician should be aware of the availability of specific medications in the geographic location of the patient. Other ATA telemedicine practice guidelines contain recommendations specific to prescribing.	

This chart compares the guidance issued by the Federation of State Medical Boards (FSMB), American Telemedicine Association (ATA), and American Medical Association (AMA) on the use of telemedicine by physicians to deliver patient care.

*The FSMB model was drafted to provide recommendations to state medical and osteopathic boards in evaluating the appropriateness of care as related to the use of telemedicine.

in a streamlined licensure process in compact-member states.

In short, although compliance with the medical licensure/registration requirements of the state in which the patient is located before providing telemedicine services may be challenging, compliance is essential to avoid potential serious penalties.

Credentialing and Privileging for Telehealth

To ensure patient safety and high-quality care, credentialing and privileging remain important elements of telehealth practice, much as they are with in-person practice. The process of credentialing and privileging a practitioner is very time-consuming and can be costly and impractical when large numbers of providers seek to provide telehealth-facilitated services in multiple hospitals. Telehealth was incorporated into The Joint Commission Standards for Credentialing and Privileging beginning in 2000 and in its revised standards in 2004. In 2011, CMS published new regulations in its hospital Conditions of Participation standards that include proxy credentialing and privileging arrangements as a viable option to further facilitate the delivery of telemedicine services. These standards allow, through an agreement between hospitals and critical access hospitals, originating sites to accept the telemedicine practitioner's credentials and privileges, and require the sharing of quality data and adherence to state licensure requirements.

Use and Quality of Equipment

Telemedicine providers have a responsibility to use quality telemedicine equipment and technology and to use such telemedicine equipment and technology in a way that protects patient safety. Some states explicitly regulate the types of technologies used or may mandate that telemedicine equipment and technology be capable of providing, at a minimum, the same information to the physician as available in an in-person encounter to enable them to meet or exceed the prevailing standard of care for the practice of medicine.

Informed Consent

Certain states statutorily require the informed consent of patients before receiving care via telemedicine. This requirement may apply to a specific specialty, all telemedicine encounters that occur in the state, or just the Medicaid program. In these states, the patients often must be informed, through a consenting process before services are rendered via telemedicine, of both the risks and benefits of different treatment or procedure options and the risks and benefits related to receiving care via telemedicine, among other things. If the patient is a minor, written informed consent by the parent or guardian may be required.

Privacy and Information Security

Telemedicine models implicate state privacy and informed consent standards and the federal requirements under the Health Insurance Portability and Accountability Act of 1996 and other laws related to the preservation of the integrity and safeguarding of the security of patient health information. If the program extends across state lines, multiple state privacy standards may apply. These laws require careful assessment in light of the facts specific to the telemedicine arrangement. Additionally, to comply with the applicable state and federal laws and to limit liability exposure, it is essential to define how patient health information may be used, shared, stored, and transmitted in agreements (eg, entity-specific business associate agreements, confidentiality and privacy agreements) and policies and to integrate mechanisms and processes into existing operational procedures to confirm that patients are aware of their rights and responsibilities with respect to receiving care via telemedicine technologies and for obtaining the appropriate consent for treatment.[206]

Patient Identity and Location Authentication

Effectively verifying the identity and location of the patient can have billing implications and various compliance and liability implications such as privacy compliance and malpractice liability and may be necessary for obtaining a valid and binding informed consent. Telemedicine providers must identify and comply with laws governing authentication through electronic means and any payer requirements that apply to the particular telemedicine arrangement.[189]

Medical Record Documentation

The laws of certain states explicitly require that services provided via telemedicine must be properly documented by the physician and that such documentation must be maintained in accordance with the provider's policies and procedures and any applicable laws and regulations. The ATA provides specific guidance: "Documentation should adhere to all medical-legal standards of care, and if appropriate, insurance requirements for future review and audit."[207]

FDA Device Approval

The FDA plays a lead role in ensuring the safety and effectiveness of medical devices and software applications used for telehealth. The FDA defines a medical device as any instrument, apparatus, implement, machine, or contrivance used to diagnose a disease or to cure, treat, or prevent disease. This definition is very broad and includes a significant amount of the equipment and technology used to deliver telemedicine services.

In February 2015, the FDA issued a guidance document to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms.[208] Although mobile applications may be subject to FDA regulation, it is worth noting that they are subject to a widely varying spectrum of regulatory requirements.

Potential Fraud and Abuse Implications

As with every other transaction involving the delivery of healthcare services, telemedicine arrangements must comply with state and federal fraud and abuse laws. Section 1877 of the Social Security Act (42 USC 1395nn), also known as the physician self-referral law and the Stark law, prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies; prohibits the entity from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third party payer) for those referred services; and establishes a number of specific exceptions for financial relationships that do not pose a risk of program or patient abuse. The federal antikickback statute [42 USC § 1320a-7b(b)] prohibits individuals or entities from knowingly offering, paying for, soliciting, or receiving remuneration that induces referrals for services covered by Medicare, Medicaid, or any other federally funded program. In addition to these laws, there are state laws that have similar objectives. The majority of the fraud and abuse issues potentially implicated by telemedicine arrangements relate to the provision of the equipment, support, and infrastructure necessary to implement a successful telemedicine program from one healthcare

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provider or entity to another (eg, collaborations between independent physicians and hospitals as part of a telemedicine network or 2 distinct hospitals collaborating in a specific telemedicine program). Various antikickback safe harbors and Stark law exceptions may apply to telemedicine arrangements, including those for the rental of office space or equipment, personal service arrangements, and electronic health records items and services. Advisory opinions issued by the Office of Inspector General addressing telemedicine-related fraud issues also provide valuable guidance for providers and entrepreneurs when structuring telemedicine arrangements.[209,210]

Malpractice

Although few malpractice cases have been reported in conjunction with telehealth practice, providers are advised to be aware of all relevant specialty society practice guidelines and consensus statements and state regulations and to notify their malpractice carrier of their desire to incorporate telehealth into their practice to confirm that their insurance policy covers telemedicine services and services provided in the states in which the patients are located.

Monitoring Compliance With Accreditation, Laws, and Policies/Procedures

Telemedicine providers must monitor telemedicine programs to confirm that the program operates in a way that complies with the applicable laws and regulations identified in this overview, as well as any applicable accreditation requirements (such as The Joint Commission) and CMS Conditions of Participation for hospitals and critical access hospitals (if applicable), and meets the appropriate standard of care. In addition, because the laws and regulations for telemedicine efforts are in a state of development, policies and procedures must be reviewed regularly to ensure continued compliance with the law.

International Legal and Practical Issues

If the patient is located in a foreign country, many of the same kinds of issues implicated by cross-state telemedicine programs will apply to the practice of telemedicine across national boundaries, but often with an additional layer of complexity. Many foreign countries do not have laws or regulations that govern telemedicine or do not address what is required when such care is provided by a physician from another country. Furthermore, there is often a lack of a tradition in the enforcement of regulations, which contributes to the uncertainty. In addition, US laws and regulations that govern US businesses conducting activities abroad may also apply. (These laws include the Foreign Corrupt Practices Act of 1977, as amended [15 USC §§ 78dd-1, et seq], and the prohibition against providing material support to terrorists or terrorist organizations [18 USC §§ 2339A and 2339B].) In sum, the foreign and domestic laws implicated by telemedicine arrangements that cross national boundaries are complex and require advance assessment by legal counsel with experience in international transactions. A more detailed discussion of telemedicine legislation in other countries is also very important but beyond the scope of this publication.

Workforce and Training

There are very limited data on the pediatric cardiology workforce needs in the United States. Telemedicine has the potential to alter the equation. Although no data have been published that suggest telemedicine will increase the use of echocardiography,[30,45] the potential for this to happen certainly exists. Additionally, telemedicine could decrease the need of pediatric cardiologists in more remote areas, allowing tertiary care centers to hire more cardiologists, who can then provide echocardiography interpretation remotely. The evolution of reimbursement, licensure, and credentialing regulations will have a significant effect on just how profound the impact of telemedicine on the workforce will be. Finally, there is no formal telemedicine component or requirement in most training curriculums despite most pediatric cardiology fellowship training programs having active telemedicine practices. As a result, very few graduating fellows are entering the workforce with a good understanding of how telemedicine could fit into their careers.

SUMMARY

Increasingly, a large body of literature and real-world experience has developed, demonstrating that telemedicine increases pediatric cardiologists' capacity to provide high-quality care to a greater number of patients by increasing the methods and efficiencies in which expert evaluation can be provided without geographic restriction. Specifically, the application of telemedicine has proven very useful in diagnosing and triaging critically ill patients, as well as stable outpatients, newborns, infants, and children, when distance or time creates challenges or an inaccessibility to pediatric cardiac care.[30,44,98] Optimizing the use of telemedicine uniquely advances the Institute of Medicine's 6 domains of healthcare quality[211]: (1) Safe: avoiding harm to patients from the care that is intended to help them; (2) effective: providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and misuse, respectively); (3) patient-centered: providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions; (4) timely: reducing waits and sometimes harmful delays for both those who receive and those who give care; (5) efficient: avoiding waste, including waste of equipment, supplies, ideas, and energy; and (6) equitable: providing care that does not vary in quality because of personal characteristics such as sex, ethnicity, geographic location, and socioeconomic status.

Advancements in modern technology and broadband have markedly affected and enabled the progression of telemedicine to its current state. Telemedicine should be thoughtfully integrated into clinical practices and partnering institutions in a well-defined and efficient manner. In most cases, the potential advantages of telemedicine in pediatric cardiology are numerous, including improving access to care, improving quality, and saving lives. In addition, this appears to be occurring with enhanced patient and practitioner satisfaction and cost-efficient medicine. All of these factors work to the advantage of our patients, their families, clinicians, and regional healthcare systems. Continuing telemedicine studies and established outcomes in the future will help us refine where, when, and for whom the use of these technologies is most clinically and economically effective.

The rapidly evolving healthcare climate includes a growing emphasis on cost containment, quality and outcomes, patient-centered care, and technology solutions, all of which are well served by the optimal use of telemedicine. The full realization of the potential of telemedicine to improve patient care and to reduce healthcare costs is in sight, but it will require state and federal governments and private and public payers to develop legislation and policies that will allow reimbursement for telemedicine to be equal to that for traditional health care, state medical boards to work together to eliminate antiquated practices that limit practicing telemedicine across state lines, and hospital organizations to develop and accept universal credentialing by proxy procedures. The body of evidence compiled in this document must now serve as a call to action for these groups to work closely with healthcare professionals to remove these reimbursement, licensure, and credentialing obstacles and to allow telemedicine to become fully integrated into our healthcare system.

FOOTNOTES

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

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This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives $10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

Reviewer Disclosures

Reviewer	Employment	Research Grant	Other Research Support	Speakers' Bureau/ Honoraria	Expert Witness	Ownership Interest	Consultant/ Advisory Board	Other
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Telemedicine in Pediatric Cardiology: A Scientific Statement From the American Heart Association

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