

# Recommendations for the Implementation of Telehealth in Cardiovascular and Stroke Care

## A Policy Statement From the American Heart Association

**ABSTRACT:** The aim of this policy statement is to provide a comprehensive review of the scientific evidence evaluating the use of telemedicine in cardiovascular and stroke care and to provide consensus policy suggestions. We evaluate the effectiveness of telehealth in advancing healthcare quality, identify legal and regulatory barriers that impede telehealth adoption or delivery, propose steps to overcome these barriers, and identify areas for future research to ensure that telehealth continues to enhance the quality of cardiovascular and stroke care. The result of these efforts is designed to promote telehealth models that ensure better patient access to high-quality cardiovascular and stroke care while striving for optimal protection of patient safety and privacy.

### INTRODUCTION

#### Telehealth: Opportunity to Reduce the Costs and Burden of Cardiovascular Disease and Stroke

The United States finds itself at a pivotal moment in the history of medicine when the annual growth in US healthcare spending increased to 5.3% in 2014, up from 2.9% in 2013, after 5 consecutive years of historically low growth.<sup>1</sup> Spending on federal healthcare programs continues to grow significantly.<sup>2</sup> Regardless, the need to provide high-quality care continues. More than 85 million Americans (~26% of the US population) suffer from cardiovascular disease (CVD), and nearly 7 million (2.2%) are stroke survivors. CVD and stroke cost the US healthcare system more than \$320 billion and \$33 billion, respectively, each year, and by 2030, annual costs of CVD and stroke are projected to balloon to nearly \$1 trillion.<sup>3</sup> Now more than ever, strategies are needed to increase the value of health care by increasing the quality of care and lowering costs.

Enhancing patient access to care via telehealth is an important strategy to help address this challenge. Telehealth, as defined by Office for the Advancement of Telehealth, comprises the use of telecommunications and information technologies to share information and to provide clinical care, education, public health, and administrative services at a distance.<sup>4</sup> Telehealth is a broad term that encompasses many digital health technologies, including telemedicine, eHealth, connected health, and mHealth. Telehealth is a new method of enabling care delivery that has the potential to help transform the healthcare system, to reduce costs, and to increase quality, patient-centeredness, and patient satisfaction.<sup>5-7</sup> In particular, telehealth may increase access and convenience for patients with CVD and stroke.<sup>8</sup> This is especially true for vulnerable patients with CVD or stroke who, because of their geographical location, physical disability, advanced chronic disease, or difficulty with

Lee H. Schwamm, MD,  
FAHA, Chair  
Neale Chumbler, PhD  
Ed Brown, MD  
Gregg C. Fonarow, MD,  
FAHA  
David Berube, PhD  
Karin Nystrom, MSN,  
APRN, FAHA  
Robert Suter, DO, MHA,  
FAHA  
Mirian Zavala, DNS, RN  
Daniel Polsky, PhD  
Kavita Radhakrishnan, RN,  
MSEE, PhD  
Nathaniel Lacktman, JD  
Katherine Horton, RN,  
MPH, JD  
Mary-Beth Malcarney,  
MPH, JD  
John Halamka, MS, MD  
A. Colby Tiner, MA  
On behalf of the American Heart Association  
Advocacy Coordinating  
Committee

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securing transportation, may not otherwise access specialty healthcare services.<sup>6,7</sup> Yet, telehealth is underused for the management of CVD and stroke, and several barriers to the successful implementation of telehealth interventions for CVD and stroke exist, including cultural, financial, and legal or regulatory constraints.<sup>9</sup> Substantial implementation of telehealth will likely transform the practice of medicine, just as other major innovations such as electronic health records and payment reform have, and may increase pressure on solo practices or small groups to adopt new technology and methods of practice.

In addition, there are many ways in which patients and experts may be brought together through telehealth, including transfer of health information from patient to doctor or vice versa, transfer from a remote area to a centralized site of expertise within the same country or between countries, and transfer to a distributed network of experts. However, health information can also flow between providers or patients in the form of tele-education, which may be a direct aim of the encounter (as in telementoring) or an indirect byproduct of physician-to-physician consultation (learning at the bedside or “Webside”).

### Goals of the Policy Statement

The goals of this policy statement are to articulate for clinicians, policymakers, and other key stakeholders the benefits of existing telehealth interventions for CVD and stroke and to delineate the barriers that currently limit their broader application. This document provides the evidence and background that will help the reader address the following critical questions:

- What current telehealth interventions have been shown to increase patient access to or to enhance the quality of CVD and stroke care?
- What are the current barriers to implementation of these evidence-based telehealth interventions at the federal, state, and local levels?
- Where are gaps in the evidence supporting the use of telehealth in CVD and stroke care? What emerging telehealth technologies have the potential to address these gaps, and where is new research needed?
- What should be done to overcome the barriers and to better facilitate telehealth?

### Defining Domains of Quality in Health Care Relative to Telehealth Implementation

In *Crossing the Quality Chasm*, the Institute of Medicine defined 6 domains of quality of care that provide an excellent lens through which to evaluate and monitor innovations such as telehealth.<sup>10</sup> The STEEEP acronym reflects the 6 quality domains:

- **Safe:** Telehealth should contribute to preventing harm from care. Frequent or continuous monitoring of patients with specific, well-defined conditions may improve health outcomes.
- **Timely:** Telehealth should reduce barriers and delays in access to care that can be harmful for patients. Telehealth interventions may increase access to important health information between traditional visits and permit the earlier detection of adverse health trends.
- **Effective:** Telehealth should provide services based on scientific knowledge and avoid services that are not likely to be of benefit. Telehealth alternatives to traditional care should not be embraced simply because they are intuitively appealing or because they can collect large quantities of data. Instead, they must deliver evidence-based care. New scientific research will be needed to achieve this goal and to prove that telehealth interventions are at least as effective as their traditional counterparts.
- **Efficient:** Telehealth should avoid waste. Replacing in-person visits with remote monitoring and virtual encounters has the potential to reduce the use of transportation, real estate, and energy while saving hours of missed work by patients and caregivers. Monetizing these savings and using them to reduce overall healthcare spending will require new economic models of cost sharing among providers, insurers, and patients, untethered from traditional fee-for-service models.
- **Equitable:** Telehealth should deliver care that does not vary in quality because of the personal characteristics of the patient or provider, including sex, race or ethnicity, geographic location, and socioeconomic status.
- **Patient-centered:** Telehealth should deliver care that is respectful and responsive to individual patient's preferences, needs, and values, including the patient's values in clinical decision making.

If telehealth is to achieve its full potential, it should be integrated into the traditional ambulatory and hospital-based delivery models and leveraged to foster deeper patient engagement and patient-centered care. To do so will require re-evaluating the traditional healthcare encounter with a clear understanding of patients' and providers' expectations and the implementation of evidence-based telehealth interventions. Important to the effective sustained implementation of telehealth will be the development of quality metrics and management programs. These could be stand-alone programs, or they could be integrated into existing quality measurement and certification programs for CVD and stroke. One such example is inclusion of standards for telestroke into The Joint Commission certification of stroke centers for acute or subacute stroke care. Consensus recommendations for

quality standards in telestroke care should be developed and promulgated.

### Section Summary

- CVD and stroke are a significant public health burden.
- Telehealth can reduce this burden and make care more accessible and affordable while reducing many widespread disparities in access to care, particularly those attributable to geography or provider shortages.
- Telehealth is a broad term that encompasses many digital health technologies. It should be widely integrated into traditional healthcare delivery systems, including electronic health records.
- When implemented, telehealth should optimize quality of care as defined by the Institute of Medicine (STEEEP). Consensus recommendations should guide the development of quality management programs specific to disease-based use of telehealth.
- Substantial implementation of telehealth will likely transform the practice of medicine
- Goals of this policy statement include providing clinicians, policy makers, and other key stakeholders with the knowledge to address and eliminate barriers to telehealth, especially as it applies to CVD and stroke care.

## EFFECTIVE TELEHEALTH INTERVENTIONS THAT INCREASE ACCESS TO OR ENHANCE THE QUALITY OF CARE

Providing affordable accessible care for individuals with chronic health conditions will continue to be a daunting challenge for the US healthcare delivery system. Telehealth modalities are at a unique position to improve processes within delivery systems of care:

- Reducing transportation costs. Rural or low-income populations may struggle with the significant transportation costs, time, and effort required to visit practitioners at healthcare facilities; telehealth (especially home based) can be an affordable alternative to meet the healthcare needs of vulnerable populations who have multiple comorbid conditions requiring frequent healthcare services.<sup>11</sup>
- Improving patient safety. Because telehealth can offer continuous monitoring and the transmission of real-time data between providers and patients, it improves patient safety.
- Enhancing patient engagement. Telehealth can provide an effective platform for patients to be involved in their own decision making.<sup>12</sup> For instance, the Veterans Health Administration introduced a national home telehealth program, Care Coordination/

Home Telehealth. This model empowers patients to manage their own conditions via telehealth, and a nurse plays a coordinating care role and navigates patients through the care continuum.<sup>13</sup> Some key studies have found that the Veterans Affairs model of shared decision making lowered hospitalization rates.<sup>14</sup>

- Reducing overuse. Telehealth can reduce unnecessary or inappropriate use of services.<sup>15</sup>
- Increasing access to care. Telehealth services may increase patient access to medically necessary services such as emergency department care, specialty care, and intensive care monitoring.<sup>16-19</sup>
- Improving medication adherence. Telehealth programs can reduce nonadherence to medication protocols, a common cause of preventable harm in CVD and stroke.<sup>20</sup>
- Enhancing provider-to-provider communication. Telehealth can improve delivery systems of care by streamlining the flow of information vertically from patient to primary care provider and specialist and horizontally between practitioners.<sup>21</sup> Nurses using telehealth-supported visits are able to make more effective medical recommendations to patients on behavioral issues, including medication compliance, diet, and exercise.<sup>21</sup>

### Current Effective Telehealth Interventions in CVD

CVD can be challenging to manage because it typically affects older patient populations, it occurs with comorbid conditions, and effective treatment typically requires lifestyle changes, medication regimens, and laboratory monitoring.<sup>22,23</sup> Conventional outpatient management of patients with CVD involves office-based follow-up visits, and the therapy provided is most often adjusted only in response to new complaints by the patient.<sup>24</sup> Because there is not typically an opportunity for monitoring between scheduled visits, recurrent cardiovascular events and hospitalizations are relatively frequent.<sup>13</sup>

Although multidisciplinary CVD management programs have been found to be successful in reducing clinical event rates and associated hospitalizations, these interventions do not involve telehealth and thus are not available to all patients.<sup>25-28</sup> Telehealth interventions can continuously monitor patients with CVD and may include anything from structured telephone support to remote monitoring of implantable devices, which can favorably affect CVD burden (such as significantly reducing blood pressure), progression of disease, and healthcare expenditures.<sup>27-30</sup> However, uptake by physicians is limited, especially in primary care and family practice. In a recent report, only 15% of family practitioners used telehealth to provide health care.<sup>31</sup>

One adaptation of multidisciplinary disease management has been to use telephone calls. This strategy may

lift some of the burden of geographic or funding barriers limiting in-home visits. Information about the patient's condition is gathered through a structured telephone conversation, and patients are directed to follow up with their physician if there is evidence of deterioration.<sup>32</sup> Meta-analyses of structured telephone support programs for heart failure suggest that telephone support may reduce rehospitalization by ~25% but has no significant impact on either all-cause readmission rates or all-cause mortality.<sup>33,34</sup>

Patient monitoring can go beyond just telephone calls. Telemonitoring involves the transfer of physiological data such as blood pressure, weight, electrocardiographic signals, or oxygen saturation through technology such as telephone lines, broadband, satellite, or wireless networks. By incorporating more data, telemonitoring also promises to detect CVD deterioration earlier, allowing prompt and more effective intervention. Meta-analyses have suggested that telemonitoring in ambulatory patients with heart failure can improve mortality by 17% to 47% during 6 to 12 months of follow-up and reduce hospitalizations by 7% to 48%.<sup>35–38</sup> However, 3 large, multicenter, randomized controlled trials in heart failure found neutral results.<sup>39,40</sup> Furthermore, research on the effects of telemonitoring is lacking long-term outcome data.<sup>41,42</sup> In TELE-HF (Telemonitoring to Improve Heart Failure Outcomes), a telephone-based interactive voice-response system that obtained symptom and weight information provided no significant benefit over usual care in terms of all-cause rehospitalizations rates or death.<sup>43</sup> The Telemedical Interventional Monitoring in Heart Failure Study also did not demonstrate a significant impact of telemonitoring on heart failure–related rehospitalization rates or on mortality.<sup>44</sup> The BEAT-HF (Better Effectiveness After Transition–Heart Failure) randomized trial tested telemonitoring with electronic equipment that collected daily information about blood pressure, heart rate, symptoms, and weight with centralized registered nurses conducting telemonitoring reviews, protocol-driven actions, and telephone calls for patients hospitalized with heart failure. The intervention had no impact on 30- or 180-day readmission rates. These studies highlight that to be clinically effective, telemonitoring programs need to have timely transmission of data, receipt of the information by the appropriate staff who can analyze and act on it, a feedback loop to the patient with directions, and sufficient patient empowerment to understand and implement the instructions.<sup>45</sup>

Implantable devices that automatically record and transmit data can be used for enhanced home-based monitoring.<sup>46</sup> These implantable devices can take the form of permanent pacemakers, implantable cardioverter-defibrillators, or cardiac resynchronization therapy devices that have been placed for other indications, or they can be specially designed implantable hemodynam-

ic sensors and monitors that can measure such parameters as intracardiac pressures.

Remote monitoring of these devices generally involves the transmission of recorded data through an external transmitter to the manufacturer's central database. Information is transferred on a regular basis, and alerts are forwarded to the clinical team. Such monitoring may lead to more timely recognition of serious arrhythmias, worsening heart failure, or problems with the device.<sup>46–49</sup> Daily data transmissions improve clinical outcomes, reduce the number of in-home follow-up or clinic visits, and save patient and provider time without compromising patient safety.<sup>47–49</sup> Given these demonstrated advantages, remote monitoring of implantable devices has been endorsed by national and international guidelines.<sup>50</sup> In heart failure, elevations in left ventricular filling pressures and pulmonary artery pressures are closely correlated with clinical congestion, functional limitation, and prognosis in patients with heart failure.<sup>23</sup> These increases in intracardiac and pulmonary artery pressures can be detected several days to weeks before the onset of symptoms that typically trigger hospital admissions and readmissions.<sup>23,51–53</sup> Ambulatory hemodynamic monitoring can provide an early warning of potential decompensation and facilitate the day-to-day management of patients with heart failure by allowing the titration of medications on the basis of reliable physiological data.<sup>23,51–53</sup> Additional advantages of implantable devices include the ability to track measures longitudinally over time, to average these values over the course of a day, and to more accurately reflect a patient's clinical status.<sup>23</sup>

A pulmonary artery sensor (heart sensor, CardioMEMS/St. Jude Medical) is now approved by the US Food and Drug Administration (FDA) to reduce heart failure hospitalizations.<sup>54</sup> A study of its safety and efficacy, the CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients trial, demonstrated that the device can reduce heart failure hospitalizations by 30% among patients in New York Heart Association class III with a heart failure hospitalization in the previous 12 months.<sup>54</sup>

However, more studies on the efficacy and cost-effectiveness are still needed, as is research on factors influencing the use of implantable remote monitoring devices. Provider, institutional, and patient-related factors appear to influence the use of telemonitoring.<sup>55</sup> Although patient satisfaction may increase with telehealth, researchers need to explore patient and provider perspectives for the use of telemonitoring, including incentives designed to improve its perceived value.<sup>56</sup>

### Current Effective Telehealth Interventions in Stroke

Telestroke is the largest, most substantive, and fastest-growing telehealth intervention of the past decade for

acute stroke treatment, in which lack of access to stroke expertise placed thrombolytic therapy out of reach for many patients.<sup>57–59</sup> Telestroke can provide an effective solution for many small or underresourced hospitals to access acute stroke expertise on demand through its ability to promote the use of thrombolysis, which greatly reduces the risk of long-term disability and its attendant costs.<sup>30,60,61</sup> Telestroke-assisted thrombolysis therapy compares favorably with face-to-face approaches, with no significant differences between survival and intracerebral hemorrhage in patients at risk for strokes.<sup>62</sup> The use of telestroke is evidence based and recommended as a Class I intervention by the American Heart Association (AHA).<sup>63</sup> A recent survey of active telestroke programs in the United States and the growth of for-profit companies providing these services demonstrates the increasing adoption of this telehealth intervention.<sup>64</sup> Although telestroke has increased access to thrombolysis for many patients, disparities in access continue. Many hospitals and communities in the United States are still without appropriate acute stroke care, and the AHA has called for policy interventions to increase the use of telehealth for improved access to stroke care across the continuum of care.<sup>65</sup>

## Section Summary

- Effective telehealth interventions exist already in CVD and stroke, and examples in different health systems and payers are provided.
- Telemonitoring in ambulatory patients with heart failure has improved mortality and reduced hospitalization in some studies, although the 3 largest trials have shown outcomes comparable to usual care. Effective programs need timely data, appropriate staff, and a feedback loop to patients with sufficient empowerment to understand and implement instructions.
- Trials of implanted cardiac devices with remote monitoring have demonstrated a reduction in time to diagnosis and clinical decision, as well as improved clinical outcomes, and some are now FDA approved.
- Telestroke is an evidence-based and accepted method of delivering expert stroke care that has seen rapid growth and adoption over the past 2 decades.
- Although many telehealth studies have shown high rates of patient satisfaction, convincing evidence of clinical benefit is limited to specific applications.

## CURRENT BARRIERS TO IMPLEMENTATION OF TELEHEALTH INTERVENTIONS

A variety of barriers impede the effective implementation of telehealth. They can be broken down into 3 large

areas of legal/regulatory, technological, and financial barriers.

## Legal and Regulatory Landscape

### Reimbursement

A significant impediment to widespread telehealth adoption is a lack of meaningful reimbursement under Medicare, many state Medicaid programs, and commercial health insurance plans. This is most glaring in fee-for-service payments because Medicare covers only a narrow set of service codes and the patient must be located at a qualifying originating site (a health facility) in a rural area. New Medicare payment models, however, such as accountable care organizations stress movement toward a value-based fee-for-performance system. In fact, in 2015, the Centers for Medicare & Medicaid Services (CMS) created the Next Generation accountable care organizations program, under which providers can apply to have the geographic limitation on telehealth reimbursement waived.<sup>66</sup>

Although 48 states have some sort of Medicaid reimbursement for telehealth services, coverage varies widely with no well-developed design. In addition, unless mandated by law, many commercial health plans have historically not covered telehealth-based services as a patient-member benefit. Thus, many telehealth programs have been built around cost-savings models, patient self-pay, or employer-sponsored payments.

Change is afoot as states have begun to enact laws requiring commercial health plans to cover medical services provided via telehealth to the same extent that they cover medical services provided in person. These laws are intended to promote innovation and care delivery in the private sector by encouraging practitioners and health plans to invest in and use the telehealth technologies available in the marketplace. Currently, 29 states plus the District of Columbia have enacted commercial payment statutes.<sup>67</sup> Similar bills are in process in several states.

A number of states, particularly those that have enacted telehealth payer laws in the past few years, have elected to expand on telehealth coverage with 2 additional concepts: requiring health plans to cover remote patient monitoring in the benefit package and requiring health plans to pay providers for telehealth services at the same or equivalent rate that the health plan pays the provider when the service is provided in person (known as payment parity).<sup>66</sup>

Although some hospitals and providers already offer telehealth services, it remains in development for the majority of healthcare providers. These new requirements are expected to drive the commercial insurance market, allowing telehealth to be enjoyed by more patients across the states. Successes in these states will signal the promise of telehealth coverage and payment

parity to the remaining 21 states as they consider their own legislation. Limited reimbursement continues to be a daunting challenge for telehealth expansion, although telehealth payment policies are advancing nationally.<sup>68</sup> Medicare payment for telehealth services has increased since the late 1990s, but use has remained low.<sup>69,70</sup>

### **Compliance With Multiple State Laws Remains a Significant Barrier**

A physician who treats a patient via telehealth across state lines must observe the local laws in the state where the patient is located at the time of the consult.<sup>67</sup> Providers would benefit from legislation that establishes a national practice standard for telehealth to clarify the confusion from myriad state policies. Earlier this year, the National Advisory Committee on Rural Health and Human Services recommended that CMS revise a number of regulatory provisions to leverage the full value of telehealth.<sup>67</sup> Nine state medical boards offer special-purpose licenses or certificates that allow physicians to treat patients in another state via telehealth services.<sup>71</sup> Additionally, many state laws contain a consultation exception to licensure, permitting an out-of-state physician licensed in another state to consult on a peer-to-peer basis with an in-state licensed physician.<sup>71</sup> Under some limited circumstances, there is a licensure exception for a physician lawfully licensed in one state to practice in a border or adjoining state.

Another challenge has been the Medicare Conditions of Participation requiring originating site hospitals to use primary-source credentialing of distant-site practitioners, a time-consuming and complex administrative process. However, this issue was largely resolved in 2011 when CMS issued regulations permitting hospitals to use a credentialing-by-proxy process for telehealth-based services.<sup>72</sup>

### **Differing Telehealth Practice Expectations Among States**

Although some states have given thought to telehealth-based practices, publishing guidance or regulations to facilitate adoption and to promote standardization, there are notable variances across states of what various medical boards expect in connection with telehealth practice. Many states do not require an in-person examination as a prerequisite to a valid doctor-patient relationship or before issuing a diagnosis, treatment recommendation, or prescription.

A minority still require an in-person examination or a patient-side telepresenter, leading to difficulties in standardized practice protocols when a physician has a multistate telehealth practice. Some states require the patient to give written informed consent when the service is provided via telehealth, even if such written consent would not be required for an equivalent in-person exami-

nation. Similar differences exist across states with peer-to-peer consultations, disclosures to the patient of the physician's credentials, and other practice standards.

As states continue to promulgate guidance, there is a trend to follow model guidelines and practice standards for telehealth such as those issued by the Federation of State Medical Boards, the American Medical Association, and the American Telemedicine Association.<sup>71,73,74</sup> These are useful to promote standardization across states, and we would like to see more cohesiveness in this regard.

### **Lack of Multistate Telehealth Licensure**

With a virtual health platform, geographic restrictions of brick-and-mortar clinical practices begin to lose their meaning. Telehealth providers can seamlessly offer medical services across state and national borders, sharing their expertise with patients and other practitioners. The lack of a robust multistate licensure system represents an administrative burden because physicians must obtain and manage licenses (and Continuing Medical Education requirements) in 50 different states.

Change is coming, and 2015 saw the fruition of efforts to streamline and simplify physician licensing across state lines. Under the Federation of State Medical Boards Physician Licensure Compact, participating state medical boards would retain their licensing and disciplinary authority but would agree to share information and processes essential to the licensing and regulation of physicians who practice across state borders.<sup>75</sup> The compact has received notable support, and many states have completed the legislative process necessary to bring it to adoption when it becomes effective.<sup>76</sup>

### **Patient Privacy and Confidentiality**

Concerns about the privacy and security of telehealth systems remain a barrier to broader use of telehealth and may undermine the potential success of telehealth if not adequately addressed. To realize the full potential of telehealth, patients and providers must trust that the information being transmitted is private and secure.

Currently, no single federal agency has the authority to regulate patient privacy, confidentiality, and data security as they relate to telehealth. The Health Insurance Portability and Accountability Act (HIPAA) regulates the privacy and security of health information.<sup>77</sup> HIPAA regulations provide protection for identifiable health information but only when it is collected and shared by "covered entities," which include healthcare plans, healthcare clearinghouses, and any healthcare provider who transmits healthcare information electronically.<sup>73</sup> HIPAA regulates provider-to-provider communication and requires that providers implement appropriate security safeguards.<sup>73</sup> However, in some telehealth models in which communication may be directly with the patient,

this transmission may fall outside of the scope of HIPAA. Although the Health Information Technology for Economic and Clinical Health Act extended HIPAA to “business associates,” many questions remain about the adequacy of the protections of this law pertaining to telehealth.<sup>78</sup> In addition, in the case when a provider communicates directly with a patient using telehealth, a number of security threats exist, including possible breach of confidentiality during transmission of the data and unauthorized access to the data, among others.<sup>79</sup>

### Data Accuracy and Ease of Use

The accuracy of data transmission may also present a barrier to effective treatment of patients using telehealth. The precision of data depends on the optimal operation of multiple technological resources, which can vary in quality and predictability.<sup>80</sup> For example, a study evaluating the accuracy of measuring physical function found that the choice of Internet bandwidth affects measurement validity and reliability for fine-motor tasks, with some speeds falling far below quality and community standards.<sup>81</sup> As a result, healthcare providers not well versed in the technological differences between systems could possibly make clinical treatment decisions and recommendations based on potentially inaccurate patient data. One of the areas that has been most successfully implemented in telehealth is the transfer and interpretation of radiological images. This is likely attributable to the early evolution of clear and consistent data standards of the Digital Imaging and Communications in Medicine (DICOM) format, which is an international standard for medical images and related information (International Organization for Standardization 12052). It defines the formats for medical images that can be exchanged with the data and quality necessary for clinical use and interpretation. DICOM is implemented in almost every radiology, cardiology imaging, and radiotherapy device (x-ray, computed tomography, magnetic resonance imaging, ultrasound, etc) and increasingly in other medical devices.

Although studies have determined that there is a high level of accuracy in domains such as radiological image interpretation, reviews of diagnostic validity and management outcomes focusing on a variety of medical conditions have not provided sufficient information on data accuracy of telehealth in general.<sup>82</sup>

Although the technology continues to improve and evolve at a rapid rate, most providers still use custom software solutions that can be challenging to deploy and do not adequately interface with electronic health record systems. Rapid evolution also means that systems have a very short life cycle and must be replaced frequently to take advantage of new features or better stability. Stable, high-quality systems are needed to

make the use of telehealth a seamless activity within care delivery networks.

### Costs Associated With Technology

Lack of capital for the purchase and maintenance of telehealth equipment and infrastructure continues to be a barrier for more widespread implementation of telehealth.<sup>83</sup> This is particularly true for many safety-net providers (eg, community health centers and public hospitals) or solo/small practices that may lack the necessary resources and often have competing demands for available funds. Although purchasing costs associated with telehealth equipment and infrastructure can be significant, they have dropped dramatically in recent years as a result of technology advances. This is particularly true for implementations that do not require high-end equipment, pan-tilt-zoom cameras with far-end camera control, or additional peripheral devices for integration (stethoscopes, otoscopes, handheld high-definition cameras, etc). Additional costs are often incurred for these higher-end systems because existing technology must be upgraded or replaced and ongoing maintenance is required. Other costs associated with a telehealth program include technician salaries, administrative support and supplies, training programs, and initiatives to promote the program to patients.<sup>84</sup> There may be additional personnel costs for trained individuals to assist during some consultations, and lack of interoperability either increases costs or limits the pool of providers available to perform consultations. With the rise of mobile connectivity, smartphones, and video compression, the costs to implement straightforward telehealth interactions have come way down, and the dominant costs are now those associated with the labor (providers and technical support personnel).

A national cost projection done in 2007 by the Center for Information Technology Leadership estimated installation and annual costs for low-end systems, midrange systems, and high-end systems for physician offices.<sup>85</sup> It identified 4 types of data transmission that could take place during a telehealth encounter: textual, still images, video, and audio.<sup>85</sup> Textual data include the patient record and any text-formatted laboratory results for the patient. Still images include x-rays, photographs, and any visual laboratory results such as pathology slide pictures. Video images consist of general examination room images and any video from medical scopes such as an ophthalmoscope. Audio data consist of sounds captured from a stethoscope, microphone, or other audio capture device. The cost model includes 4 different types of facilities: physician offices, emergency departments, nursing home facilities, and correctional facilities.<sup>85</sup> All 4 types of facilities require the same type of equipment to conduct near-side encounters, whereas only the physician offices and emergency departments require extra equipment to participate in the far-side encounters. The study found ac-

quisition costs beginning at \$305 000 for a low-end system and ranging up to \$7 820 000 for a high-end system, excluding installation fees, which ranged from \$156 000 to \$625 000.<sup>85</sup> The annual costs to maintain a telehealth program within a physician's office ranged from \$61 000 to \$1 560 000.<sup>85</sup> Table 1 illustrates the various costs associated with various encounter types for a midrange system. However, the rapid advancement of technologies now allows providers to deliver care with such low-cost equipment as Web cameras, personal tablets, or smartphones, rendering these cost estimates obsolete except for the most sophisticated applications requiring peripheral devices or very high-end cameras and connectivity. Savings can also accrue to health systems that operate under shared financial risk contracts once they get telehealth visits to scale because the cost of individual healthcare encounters can be much lower through telehealth than in person. For-profit companies have found a niche in urgent care delivery for which patients are willing to pay out of pocket for convenience and access.

### Lack of Technological Infrastructure in Underserved Areas

Members of underserved populations often do not have the same access to care as other individuals.<sup>86</sup> In rural areas, it is difficult to maintain adequate numbers of clinical staff and specialists to serve the population.<sup>87</sup> Telehealth has the potential to improve health outcomes for the underserved, although challenges exist, particularly for individuals in rural or remote areas who may be uninsured or underinsured.<sup>82</sup> These challenges include technological access and increased concerns about security and privacy, among others.<sup>83</sup> Telehealth has the potential of introducing a new form of disparity in access to care by replacing geographic isolation with digital isolation. Communities and patients who are not technologically engaged, who live on the other side of the "digital divide," and who have limited capital to invest in telehealth infrastructure (at the community or pa-

tient level) may face challenges to access care as telehealth offerings are increasingly used to reduce cost and increase access. This will be a critical aspect that must be monitored by hospitals, public health officials, and insurers.

### Congressional Budget Office

Although some private health plans, Medicaid health plans, and Medicare Advantage plans use telehealth, challenges remain related to coverage of telehealth services in the fee-for-service Medicare program. Although Congress has considered broadening the use of telehealth in Medicare, cost estimates from the Congressional Budget Office (CBO) have been prohibitive. For example, during the recent debate on the sustainable growth rate (the formula used to pay physicians treating Medicare patients), attempts were made to broaden telehealth coverage in the Medicare fee-for-service program.<sup>88</sup> Ultimately, inclusion of the telehealth provision was not successful as a result of CBO estimates related to cost.<sup>89</sup> However, the Furthering Access to Stroke Telemedicine Act, introduced in 2015, and the Creating Opportunities Now for Necessary and Effective Care Technologies for Health Act would extend Medicare reimbursement to telestroke beyond rural areas.<sup>90,91</sup> The Medicare Telehealth Parity Act, also introduced in 2015, would extend Medicare to telemedicine in general beyond rural areas.<sup>92</sup>

Central to the CBO concern about broadening coverage for telehealth in Medicare fee for service is whether telehealth services would be provided in addition to currently covered services (thus increasing Medicare spending) or whether telehealth services would instead prevent or substitute for the use of more expensive services such as emergency room services, producing cost savings for the Medicare program. CBO notes that it does not have the data needed to project how expanding telehealth coverage would affect healthcare spending in the Medicare

**Table 1. Total Cost of Telehealth Installations by Type of Site: Midrange Estimated in 2007 in 2007 US Dollars**

	Sites, n	Acquisition Costs, \$				Annual Costs, \$		
		Store and Forward	Real-Time Video	Hybrid	Installation Costs	Store and Forward	Real-Time Video	Hybrid
MDs	312 400	477 000	4 180 000	4 430 000	312 000	95 500	835 000	887 000
EDs	4516	0	60 400	64 100	4520	0	12 100	12 800
NFs	16 100	24 600	214 000	228 000	16 100	4920	42 900	45 500
CFs	1668	2550	22 200	23 600	1670	510	4440	4720
Total	334 684	504 150	4 476 600	4 745 700	334 290	100 930	894 440	950 020

Current costs are substantially lower because of major advances in video compression, camera technology, and large-scale adoption of compressed video formats and will likely continue to fall. CF indicates correctional facility; ED, emergency department; MD, physician office; and NF, nursing facility.

Source: Center for Information Technology Leadership. "The Value of Provider-to-Provider Telehealth Technologies."<sup>85</sup> Reprinted with permission. Copyright © 2007, Center for Information Technology Leadership.

program and is calling for additional studies to help inform its estimates.<sup>93</sup>

## Section Summary

- Barriers to the effective implementation of telehealth across broad populations of patients and providers can be broken down into 3 large areas of legal/regulatory, technological and financial barriers.
- Lack of reimbursement by most major carriers is a major impediment, particularly under Medicare because CVD and stroke disproportionately affect patients  $\geq 65$  years of age.
- States are increasingly requiring coverage for telehealth services but with significant variability across states with regard to restrictions on eligible providers, eligible originating sites, and the need for a prior in-person encounter.
- Outdated licensure, privileging, and credentialing requirements by state medical boards place undue administrative burden on providers.
- Privacy regulations did not anticipate current telehealth activity, and concerns about data accuracy, privacy, and security inhibit adoption.
- Startup and ongoing costs can be significant and discourage adoption at a small scale.
- The CBO continues with very conservative estimates of the cost savings of telehealth and therefore projects cost estimates so large as to prohibit successful legislative passage.

## EMERGING TELEHEALTH TECHNOLOGIES

### Toolkits and Platforms

In 2015, devices that monitor body parameters in the home such as heart rate, blood pressure, and glucose level monitors, pulse oximetry, and even electrocardiography have become mainstream. In part, Apple catalyzed the evolution of the industry with Healthkit, which significantly reduces the interface burden to collect patient data by providing a simple patient-controlled container for device data. Innovations on the horizon involve new ways of connecting healthcare partners through data standardization and interoperability protocols, of connecting patients and caregivers via remote and self-monitoring, of developing health intelligence by sharing data along care stages, and of promoting business incentives via insurance parity laws, bundled payments, service line expansion, and more.<sup>94</sup> Already here and experiencing rapid development are tool sets such as health spot kiosks in work, schools, and other locations<sup>95</sup>; handheld Medweb kits<sup>96</sup>; rural school-based telehealth clinics<sup>97</sup>; low-bandwidth tablet-based communication systems<sup>98</sup>; online portals to generate second opinions<sup>99</sup>; integrated wireless

continuous and noninvasive detection and life safety systems with proactive alerts<sup>100,101</sup>; online health education<sup>102</sup>; and more, 4 categories of which are detailed below.

### Wearable Nonimplanted Monitoring Devices

The wearable cardioverter-defibrillator is an external device capable of automatic ventricular tachyarrhythmia detection and defibrillation. It is often used during transitional periods as a bridge to left ventricular improvement or implantation of a cardioverter-defibrillator.<sup>103–105</sup> Although retrospective studies of clinical registries have found a survival benefit with the use of wearable cardioverter-defibrillators comparable to that obtained with implantations in short-term monitoring of patients at risk for sudden cardiac death, sufficient high-quality evidence is lacking.<sup>103,105,106</sup> There is also a lack of clear criteria for identifying patients who can benefit most from this therapy. Evaluation of the usability of wearable monitoring devices is needed, especially since it has been found that improper use and noncompliance with wearables are associated with mortality.<sup>106</sup> Although wearable monitoring devices have been shown to be more cost-effective than a stay in a hospital or skilled nursing facility in protecting patients against sudden cardiac arrest while waiting for implantation,<sup>107</sup> more studies evaluating the cost-effectiveness and survival benefit of wearable monitoring devices are needed.

### Telerehabilitation via Robotic, Virtual Reality, and Gaming-Based Devices

Telerehabilitation delivered via robotic, virtual reality, or commercial gaming devices (eg, Kinect, Microsoft Corp; Wii, Nintendo) is a rapidly advancing field that holds promise for improving functional outcomes for patients after stroke.<sup>108–110</sup> These therapies can improve upper limb function, walking speed, balance, and mobility in people with stroke by enhancing traditional poststroke treatment through simulated practice of therapy-related tasks at a higher dose, for longer periods, consistently and precisely without fatigue.<sup>110–113</sup> However, because of the lack of high-quality evidence, both clinical and cost-effectiveness, the benefits and risks of robotic, virtual reality, and gaming-based rehabilitation compared with conventional therapies remain unclear.<sup>112–115</sup> Large, well-designed, multicenter studies evaluating the benefits and risks of robotic, virtual reality, and gaming therapy are clearly needed. Research that provides information on optimal dose, appropriate time to initiate such therapies, and criteria for identifying patients who will benefit most from such therapies is especially needed. A multicenter, randomized, clinical trial of telerehabilitation, Telerehabilitation in the Home Versus Therapy In-Clinic for Patients With Stroke, has just started in the National Institutes of Health-funded StrokeNet network and promises to

provide important information about the efficacy of this approach.<sup>116</sup> The acceptability and satisfaction with such therapies by older adults who could benefit most from improved rehabilitation remain understudied because most of the trials have been conducted with younger participants.<sup>110</sup> In summary, current available evidence limits the translation of these types of telerehabilitation therapies into day-to-day clinical practice.

### Mobile Platforms and Connected Health

Mobile devices, smartphones, and distributed medical devices have the potential to provide preemptive, proactive care to patients who are geographically isolated or removed from access to their healthcare providers. In-hospital providers increasingly provide care directly from their mobile devices, increasing efficiency and decreasing their reliance on a limited number of desktop devices.<sup>117</sup>

The future of healthcare delivery will likely involve increased reliance on mobile computing or communication platforms ranging from handheld smartphones to small form factor tablets that can support a variety of operating systems and healthcare applications. Stand-alone applications and those that mobilize traditional medical instruments such as stethoscopes, otoscopes, or cameras and diagnostic equipment such as portable ultrasound or electrocardiogram machines will transform our consumption of medical information and enable better point-of-care decision making.

When diagnosing new-onset hypertension, clinicians often want to distinguish between situational hypertension (white coat syndrome), caffeine excess, stress-related blood pressure changes, and metabolic causes. Cumbersome monitors that capture data and require a visit to the clinician's office for download are no longer needed because new FDA-approved blood pressure monitors connected to smartphones are inexpensive. The patient can capture blood pressure before or after commuting, on waking, or after stressful events. The data can be sent automatically to personal health records or electronic health records, without the need for an office visit, aiding the diagnosis and treatment of hypertension.

In the past, Holter monitors, stress tests, and office-based electrocardiography studies were used to evaluate patients with suspected arrhythmias. In an era when every smartphone will be able to have an FDA-approved electrocardiography device built into the protective case or the wrist strap of a smartwatch, the role of this legacy equipment will evolve. As patients experience symptoms, they can touch their phone and capture a single-lead ECG, and it can be sent electronically to their clinician via secure e-mail, text, or electronic health record upload. The likelihood of capturing arrhythmias through a distributed network of inexpensive monitoring may change the paradigm and cost-effectiveness of cardiac monitoring.

Notably, however, such mobile technologies stand to shift the focus of healthcare delivery by engaging the patient more at every step of the delivery process. By allowing patients continuous access to their own health data and by prompting patients for their engagement at all steps of the healthcare process, mobile technologies can strengthen the provider-patient relationship.

### Mobile Stroke Units

Mobile stroke units are emergency medical services vehicles equipped with a computed tomography scanner, tissue-type plasminogen activator, and a means to access stroke expertise either on board or via telehealth that can be used to diagnose and treat acute ischemic stroke in the field.<sup>118</sup> Early attempts at mobile ambulance-based telehealth were hampered by inadequate bandwidth and reliability, but recent advances in telecommunications technology have enabled newer more robust solutions. The TeleBAT intervention from the team at University of Maryland used wireless cellular technology in ambulances to transmit visual and auditory data to a stroke neurologist in real time at very low frame rates and was neither practical nor scalable.<sup>119</sup> More recent studies examined the paradigm again and showed that the transmission of video data reached acceptable levels of quality and reliability.<sup>118,120</sup> However, the most compelling evidence comes from the STEMO (Stroke Emergency Mobile) project in Berlin in which the use of a mobile stroke unit with onboard neurologist but remote teleradiologist has led to more rapid alarm-to-needle times with no increase in the rate of complications and improvement in outcomes estimated at €32 456 per quality-adjusted life-year.<sup>121,122</sup> In the United States, several ongoing pilot studies of mobile stroke units suggest that the model is robust and that a teleneurologist may be able to substitute for an onboard neurologist.<sup>123,124</sup> If proven effective and generalizable, these mobile stroke units have the potential to transform acute stroke care.

### Section Summary

- New tool kits and platforms from major information technology companies have emerged recently that will make integration of remotely monitored health data into electronic health record systems routine.
- Effective evaluation of wearable devices is critical because inappropriate use may lead to harm.
- Telehealth-enabled rehabilitation (telerehabilitation) for stroke patients is promising, and a large National Institutes of Health study is underway. This is an area of convergence between the personal computer gaming industry and federal agencies that could serve as a model.

- The future of healthcare delivery will likely involve increased reliance on mobile computing (eg, smartphones) that can support a variety of operating systems and healthcare applications (eg, FDA-approved blood pressure monitors).
- If proven effective and generalizable, telehealth-enabled mobile stroke units have the potential to transform acute stroke care and to bring stroke experts to the prehospital care arena routinely.

## GAPS IN EVIDENCE AND RESEARCH NEEDS

### Usability and Other Human Factors

Usability is the “acceptability of a system for a particular class of users carrying out specific tasks in specific environment” and has 5 attributes: learnability, efficiency, memorability, errors, and satisfaction.<sup>125,126</sup> The success of telehealth programs will depend on the degree to which devices are usable and useful. Determining the usability of telehealth programs will be paramount to ensuring positive health outcomes.<sup>127–129</sup>

Human factor engineering is a discipline that examines the capabilities and characteristics of end users’ interactions with the designs of tools and systems.<sup>130</sup> Considering human factors, engineering (ergonomics) is necessary to design telehealth care that is safe, patient-centered, and equitable.<sup>131</sup> Device and systems designers must be cognizant of human factors such as aging. Sensory changes and patient comorbidities such as diabetes mellitus and vascular diseases compound the human factors in telehealth.<sup>132,133</sup> According to Chen et al,<sup>134</sup> the digital divide that exists in the older adult population is getting smaller, and this population is interested in using technology.

Recognizing and mitigating potential system failures caused by human factors is an important part of a robust telehealth application. These failures can cause harmful delays in diagnosis or treatment, lead to incorrect diagnosis, or reduce provider or patient confidence in the method. Thus, developing prespecified fail-safe methods for consultations or data transfer can help mitigate the potential negative impact of human factors. The AHA policy recommendations for telestroke include language for such fail-safe procedures, and national authorities recommend usability testing to avoid common patient safety issues.<sup>65</sup>

### Efficacy and Cost-Effectiveness Data

More studies are needed to establish the clinical efficacy of new telehealth models of care and to address concerns that reimbursement for these activities will lead to overuse of healthcare resources. Eradicating barriers to care will likely lead to increased use, which may be cost-effective but still result in higher short-

term costs. With increasing scrutiny at the local, state, and federal levels of annual healthcare expenditures, stronger economic models and data are needed to demonstrate the financial benefits of telehealth. In addition, broader application of remote monitoring and outpatient care delivery will require new research funding to test these applications in rigorous, well-controlled studies to demonstrate proven benefit. Traditional funding agencies have been slow to embrace the type of studies that will be needed, although the Patient-Centered Outcomes Research Institute reflects a promising new avenue in contrast to more traditional research funding organizations. Another likely mechanism to help support telehealth research is the changes in the health system economy introduced by the Affordable Care Act. As healthcare systems shift from volume to value and develop population health management strategies, telehealth becomes an attractive method to help maintain or increase quality while lowering cost. Strong evidence will be necessary to help convince these organizations and third-party payers to make the initial substantial investments required to widely disseminate telehealth interventions across patients and providers. These studies will need to be performed in selected populations with CVD or stroke and be subjected to the same standards as other studies that seek to validate new models of care delivery or devices. Wherever possible, cost-effectiveness should be evaluated along with efficacy when new telehealth interventions are studied because not all interventions achieve the same outcomes or do so at the same cost.

A recent report to Congress by the Medicare Payment Advisory Commission devotes a chapter to telehealth services and the Medicare program, concludes that there is evidence demonstrating cost savings for telestroke, and recommends that Medicare consider expanding coverage for this telehealth service for all Medicare patients.<sup>135</sup>

### Section Summary

- Telehealth interfaces must incorporate features of usability that assess the capabilities and characteristics of end users’ interactions with the designs of tools and systems.
- This will be especially important for older users or those with clinical conditions that impair sensation, vision, dexterity, or cognition.
- Robust home-based or mobile telehealth applications will require reliable, high-quality communications infrastructure and interfaces beyond traditional healthcare facilities.
- More research is needed to determine the cost-effectiveness of telehealth interventions that are shown to be efficacious in treating CVD and stroke.

- Increased federal funding is needed to promote high-quality research in these areas, to support rigorous cost-effectiveness research, and to ensure the safe dissemination of telehealth interventions.

## STRATEGIES TO OVERCOME THE BARRIERS TO BROAD DISSEMINATION OF TELEHEALTH

Increasingly, federal lawmakers are advancing telehealth proposals in attempt to address these barriers. Telehealth has attracted bipartisan interest in Congress; in the 113th Congress alone, 57 bills were introduced.<sup>136</sup> Current federal legislative proposals include efforts to create federal standards for telehealth<sup>137</sup>; to enable Medicare patients to be treated by physicians across state lines through the use of telehealth<sup>138</sup>; to enhance data collection at the Medicare Payment Advisory Commission to study telehealth payment<sup>139</sup>; to expand patient access to remote monitoring and telehealth<sup>91,140</sup>; to allow flexibility in the coverage of telehealth by accountable care organizations<sup>141</sup>; and to allow additional sites to be considered originating sites for the purposes of payments for telehealth services under Medicare.<sup>141</sup> The CMS is also revising federal regulations to expand telehealth services under Medicare<sup>142</sup> and to improve access to telehealth services within accountable care organizations.<sup>142</sup>

Within state legislatures, there currently are telehealth-related proposals that aim to enhance Medicaid reimbursement for telehealth, to extend the definitions of telehealth providers, to broaden the list of qualifying originating sites, to establish physician practice standards and measurable metrics, to promote parity with face-to-face encounters, and to require private insurance plan coverage of telehealth.<sup>143</sup>

According to an analysis by the American Telemedicine Association, many of the proposed state and federal policies would serve to fill gaps in coverage and reimbursement for telehealth, but given the many policy proposals with implications for the delivery of telehealth services under consideration, it is important to evaluate which of these proposals will best advance patient health.<sup>67</sup> The Center for Connected Healthcare Policy has recently been funded by the Office for the Advancement of Telehealth within the Health Resources and Services Administration to serve as the National Telehealth Policy Resource Center both to provide technical assistance for policy development and to “collaborate with policymakers, researchers, industry leaders, health advocacy organizations, and other influential groups to advance valuable telehealth policy solutions based on non-partisan research.”<sup>144</sup>

Although policy analyses from Center for Connected Healthcare Policy will be instructive, stakeholders should

**Table 2. Principles for Evaluating Proposed Telehealth Legislation or Regulation**

Does the proposed policy define telehealth and telemedicine appropriately?
Are the standards and scope of the telehealth communication the policy establishes consistent with in-person encounters?
Does the policy establish a valid provider-patient relationship for the delivery of telemedicine to occur?
Are the policies proposed supported by sufficient evidence? In other words, can the metrics established for in-person healthcare delivery be achieved with telehealth care delivery?
Does the policy maintain the optimal privacy and confidentiality of the patient and his/her health data?
Does it maximize patient engagement and collaboration in healthcare decisions or management?
Does it maintain the optimal accuracy of the data being transmitted?
Does the proposed policy remove disparities in access to quality health care?
Does the policy create opportunities for data collection and evaluation that would support future policy development?
Does it enhance professional coordination and interoperability of data among care teams?
Does it increase the overall value of health care being delivered in terms of cost and outcomes?
Is it consistent with the medical and licensure laws of the state in which the patient is receiving the services (originating site)?

also consider a series of questions when evaluating proposals to determine whether a particular proposal achieves the goal of increasing access to telehealth technologies to support acute, rehabilitative, preventive, or routine care for patients with CVD and stroke (Table 2). Additional selected resources for those seeking to design or implement telehealth interventions are listed in Table 3.

If the ultimate goal is to make effective telehealth interventions broadly available to patients with CVD and stroke, then the AHA should partner with other organizations to achieve the following 6 objectives:

1. Ensure that a coverage mandate exists in all states so that third-party payers must offer specific, evidence-based telehealth interventions as covered services
2. Ensure that all properly trained providers are deemed eligible providers for telehealth interventions without restricted networks that would limit reimbursement by the provider
3. Encourage the development of simpler, less expensive technology platforms that allow interoperability between systems and keep the patient burden and costs for healthcare systems as low as possible

**Table 3. Selected Online Telehealth Resources**

Nongovernment Associations	Government Agencies
American Health Information Management Association ( <a href="http://www.ahima.org">www.ahima.org</a> )	Agency for Healthcare Research and Quality ( <a href="http://www.ahrq.gov">www.ahrq.gov</a> ) (telehealth)
American Hospital Association ( <a href="http://www.aha.org">www.aha.org</a> ) (telehealth)	Health Resources and Services Administration. Telehealth Programs. ( <a href="http://www.hrsa.gov/ruralhealth/telehealth/">www.hrsa.gov/ruralhealth/telehealth/</a> )
American Medical Informatics Association ( <a href="http://www.amia.org">www.amia.org</a> ) (policy priorities)	Office of the National Coordinator for Health Information Technology ( <a href="http://www.healthit.gov">www.healthit.gov</a> )
American Telemedicine Association ( <a href="http://www.americantelemed.org">www.americantelemed.org</a> )	Federal Communications Commission ( <a href="http://www.fcc.gov">www.fcc.gov</a> ) (telehealth)
American Medical Association ( <a href="http://www.ama-assn.org">www.ama-assn.org</a> ) (digital health)	Federal Office of Rural Health Policy ( <a href="http://www.hrsa.gov">www.hrsa.gov</a> ) (telehealth programs)
Center for Connected Health Policy ( <a href="http://www.cchpca.org">www.cchpca.org</a> )	Food and Drug Administration ( <a href="http://www.fda.gov">www.fda.gov</a> ) (digital health)
Center for Telehealth and e-Health Law ( <a href="http://www.ctel.org">www.ctel.org</a> )	Office of Advancement of Telehealth ( <a href="http://www.hrsa.gov/telehealth">www.hrsa.gov/telehealth</a> )
College of Healthcare Information Management Executives ( <a href="http://www.chimecentral.org">www.chimecentral.org</a> )	Veterans Affairs ( <a href="http://www.telehealth.va.gov/">www.telehealth.va.gov/</a> )
eHealth Initiative ( <a href="http://www.ehdc.org">www.ehdc.org</a> )	Federal Trade Commission ( <a href="http://www.ftc.gov">www.ftc.gov</a> )
Federation of State Medical Boards ( <a href="http://www.fsmb.org">www.fsmb.org</a> ) (interstate licensure compact)	Food and Drug Administration ( <a href="http://www.fda.gov">www.fda.gov</a> )
Healthcare Information and Management Systems Society ( <a href="http://www.himss.org">www.himss.org</a> )	Health Resources Services Administration ( <a href="http://www.hrsa.gov">www.hrsa.gov</a> )
Home Care Technology Association of America ( <a href="http://www.hctaa.org">www.hctaa.org</a> )	Veterans Affairs ( <a href="http://www.va.gov">www.va.gov</a> )
National Association of Health Data Organizations ( <a href="http://www.nahdo.org">www.nahdo.org</a> )	

4. Ensure that large electronic health record systems incorporate telehealth and make it compatible with traditional health records to promote a single integrated health record for all patients
5. Encourage the development of improved education for providers to simplify the process of delivering telehealth and to increase adoption among providers
6. Ensure that adoption of telehealth does not sacrifice quality in the name of cost savings such as by restricting patient access to limited networks

of telehealth specialists rather than in-person specialty care and promotes high-quality care delivery as outlined by the Institute of Medicine (ie, STEEEP)

### Section Summary

- Legislators and regulators in many states and the US Congress are attempting to advance telehealth initiatives.
- Through innovation grants and alternative payment contracts, CMS is encouraging health systems to explore telehealth as a method for generating shared cost savings.
- Many organizations that promote the adoption of telehealth provide guidance on model legislative language and scorecards that grade states on their current performance.
- To make concrete progress toward the goal of expanding telehealth for CVD and stroke, the AHA should partner with other organizations and focus on specific policy objectives to eradicate barriers to adoption.

### CONCLUSIONS AND SUMMARY

CVD and stroke are a significant public health burden, and telehealth interventions can reduce this burden, making care more accessible and affordable while reducing many widespread disparities in access to care, particularly those attributable to geography or provider shortages. Regardless of how it is collected, stored, or analyzed, the practice of telehealth should be integrated into traditional healthcare delivery systems and electronic health records. When implemented, telehealth should optimize quality of care as defined by the Institute of Medicine and ensure that patient-centered care is never sacrificed to cut costs.

Effective telehealth interventions already exist across many diseases such as diabetes mellitus, in pain management and medication adherence, and in CVD and stroke in particular. Telehealth monitoring (telemonitoring) in ambulatory patients with heart failure and in those with implanted cardiac devices with remote monitoring has been most extensively studied and has demonstrated benefits. Telehealth in acute stroke (telestroke) is an evidence-based and well-accepted method of delivering expert stroke care with rapid adoption. Many publications have shown reproducible results across different platforms, countries, and health systems. Across all these diseases, many telehealth studies have shown high rates of patient satisfaction.

Despite this promising evidence, little research is ongoing, and many barriers to effective implementation remain. Barriers to the effective implementation of telehealth across broad populations of patients and providers can be broken down into 3 large areas of legal/regulatory, technological, and financial barriers.

Lack of reimbursement by most major carriers is a major impediment, particularly under Medicare because CVD and stroke disproportionately affect patients  $\geq 65$  years of age. States are increasingly requiring coverage for telehealth services, but there is significant variability across states with regard to restrictions on eligible providers, eligible originating sites, and the need for a prior in-person encounter. Outdated licensure, privileging, and credentialing requirements by state medical boards place undue administrative burden on providers, and privacy regulations did not anticipate current telehealth activity. Lingering concerns about data accuracy, privacy, and security inhibit adoption, and the significant startup and ongoing costs discourage adoption at a small scale. Lastly, the CBO continues with very conservative estimates on the cost savings of telehealth and therefore projects cost estimates so large as to prohibit successful legislative passage.

### Future Scientific Research

Despite these barriers, new tool kits and platforms from major information technology companies have emerged recently that will make integration of remotely monitored health data into electronic health record systems routine. Effective evaluation of wearable devices is critical because inappropriate use may lead to harm.

Telehealth-enabled rehabilitation (telerehabilitation) for stroke patients is promising, and a large National Institutes of Health study is underway. This is an area of convergence between the personal computer gaming industry and federal agencies that could serve as a model. The future of healthcare delivery will likely involve increased reliance on mobile computing (eg, smartphones) that can support a variety of operating systems and healthcare applications (eg, FDA-approved blood pressure monitors). However, to be successful, telehealth interfaces must incorporate features of usability that assess the capabilities and characteristics of end users' interactions with the designs of tools and systems. This will be especially important for older users or those with clinical conditions that impair sensation, vision, dexterity, or cognition. Robust home-based or mobile telehealth applications will also require reliable, high-quality communications infrastructure and interfaces beyond traditional healthcare facilities. More research is needed to determine the cost-effectiveness of telehealth interventions that take into consideration equipment- and personnel-related costs and to identify the telehealth interventions that are efficacious in treating CVD and stroke. Increased federal funding is needed to promote high-quality research in these areas and to ensure the safe dissemination of telehealth interventions.

### Future Legislative Processes

Legislators and regulators in many states and the US Congress are attempting to advance telehealth initiatives, and CMS is encouraging health systems to explore telehealth as a method for generating shared cost savings. To facilitate legislative progress, many organizations that promote the adoption of telehealth provide guidance on model legislative language and scorecards that grade states on their current performance. However, to make concrete progress toward the goal of expanding telehealth for CVD and stroke, the AHA should partner with other organizations and focus on specific policy objectives to eradicate barriers to adoption.

### 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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**DISCLOSURES****Writing Group Disclosures**

Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/Advisory Board	Other
Lee H. Schwamm	Harvard Medical School, Massachusetts General Hospital	None	None	None	None	None	None	None
David Berube	North Carolina State University	None	None	None	None	None	FDA Risk Communication Advisory Committee*; Genetic Engineering and Society Center Fellowship†; investigator, laboratory analytic sciences/NSA† (grant)	Salary, North Carolina State University†
Ed Brown	Ontario Telemedicine Network; director, OntarioMD; past-president, American Telemedicine Association (Canada)	None	None	None	None	None	None	Salary, CEO of Ontario Telehealth Network†; board director, OntarioMD*
Neale Chumbler	Dean, College of Health and Human Sciences, Western Kentucky University	None	None	None	None	None	None	None
Gregg C. Fonarow	UCLA	NIH/NHLBI (examining the effects of high-protein diet on outcomes in patients with heart failure)†; NIH/BWH (novel therapies to improve renal and cardiac allograft outcomes)†; NIH/NINR (central autonomic nervous system regulation in heart failure)†	None	None	None	None	Consults on Steering Committee for Novartis†; Medtronic*, Johnson & Johnson*, Boston Scientific*, Medtronic*, Gambro*	Employee of UCLA/ director of the Ahmanson-UCLA Cardiomyopathy Center/holds the Eliot Corday Chair of Cardiovascular Medicine and Science†
John Halamka	Beth Israel Deaconess Medical Center; Harvard Medical School; New England Health Electronic Data Interchange Network, MA-SHARE (the Regional Health Information Organization); US Healthcare Information Technology Standards Panel	None	None	None	None	None	None	None

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## Writing Group Disclosures Continued

Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/Advisory Board	Other
Katherine Horton	George Washington University	None	None	None	None	None	None	None
Nathaniel Lacktman	Foley and Lardner LLP	None	None	None	None	None	None	None
Mary-Beth Malcarney	George Washington University	None	None	None	None	None	None	None
Karin Nystrom	Yale–New Haven Stroke Center	None	None	None	None	None	None	None
Daniel Polsky	University of Pennsylvania	None	None	None	None	None	None	None
Kavita Radhakrishnan	University of Texas	None	None	None	None	None	None	None
Robert Suter	American Heart Association, University of Texas–Southwestern	None	None	None	None	None	None	None
A. Colby Tiner	American Heart Association	None	None	None	None	None	None	None
Mirian Zavala	College of Mount Saint Vincent	None	None	None	None	None	None	None

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\*Modest.

†Significant.

## Reviewer Disclosures

Reviewer	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/Advisory Board	Other
Rene P. Handschu	University of Erlangen-Nuernberg (Germany)	None	None	None	None	None	None	None
Sophie I. Mavrogeni	Onassis Cardiac Surgery Center (Greece)	None	None	None	None	None	None	None
David Z. Wang	OSF St. Francis Medical Center/University of Illinois	None	None	None	None	None	None	None
Shadi Yaghi	Brown University	None	None	None	None	None	None	None

This table represents the relationships of reviewers that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all reviewers 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.

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## Recommendations for the Implementation of Telehealth in Cardiovascular and Stroke Care: A Policy Statement From the American Heart Association

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