Telehealth and Home Monitoring

Course IX.

Content for CPHIE

 Health IT Certification

Welcome to the Health IT Certification program on Health Information Exchange (HIE) Course on Telehealth and Home Monitoring. This is the fifth of the six courses in the Certified Professional in Health Information Exchange (CPHIE) track. Other courses in this track cover:

V – HIE Goals and Governance
VI – HIE Architecture
VII – Data Stewardship
VIII – Personal Health Records
X – Nationwide Health Information Network

Introducing . . .

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Objectives

- Upon completion of this course, participants should be able to:
  - Define the scope of telehealth, telemedicine, home monitoring, and other collaborative techniques and technologies for clinical and non-clinical use
  - Describe the technologies used in telehealth and home monitoring
  - Identify the major barriers that exist to using telehealth
  - Explore the wide range of applications for telehealth and home monitoring and the impact these have had
  - Discuss how telehealth and home monitoring holds potential for use within health information exchange

The objectives of this Course are to appreciate the scope of telehealth and home monitoring and, recognizing the barriers that exist, explore how telehealth and home monitoring fit within health information exchange.

Topics

Part 1. Scope of Telehealth and Home Monitoring

Part 2. Telehealth and Home Monitoring Technologies

Part 3. Barriers to Telehealth and Home Monitoring

Part 4. Applications and Benefits of Telehealth and Home Monitoring

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Topics covered in this Course describe telehealth and home monitoring in general, identify various technologies used, discuss barriers, and illustrate applications and benefits, especially as they may be facilitated and enhanced through a health information exchange service.

Telehealth and Home Monitoring

Part 1. Scope of Telehealth and Home Monitoring

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Part 1 addresses the scope of telehealth and home monitoring, including defining key terms.

Content Part 1.

- History of Telehealth and Home Monitoring
- Definitions of Key Telehealth Terms
- Telehealth Project Taxonomies
- American Telehealth Association Core Standards for Telemedicine Operations
- Resources

Part 1 of this Course describes the continuing emergence of telehealth, defines key terms, provides taxonomies that may help describe types of telehealth projects, introduces standard-setting activities, and identifies resources for keeping up-to-date on activities.

History


1875


1950


1978


1987


1993


1994

2001

- From quill pens and papyrus through the early days of telephones and closed circuit TV,
- the predictions of science fiction writers are coming true today, enabled by sophisticated telecommunications, robotics, and other “star trek” technology, made both large and small, personal and professional
- There are many telehealth applications; many of which are can be enabled by HIE

Some have suggested that telehealth has existed for longer than even the telephone – perhaps as an exchange of letters between physicians about an unusual case. Others identify the first formal telehealth implementations as occurring in the 1950s, when closed circuit TV was used to monitor patients remotely. In 1978 the first electrophysiological monitoring of a heart was recorded; and in 1987, Life Alert and Life Call started marketing pendants linked to an automated dialer that allowed people to be connected to an operator without a phone line. Most telehealth activities probably date from approximately the 1980s and 1990s when the first PCs became popular and the Internet began to be more widely used by consumers. Today, video-conferencing and pacemaker monitoring is fairly commonplace, robotic surgery is coming into its own, and consumer monitoring and diagnostic devices are fairly commonplace. Despite its history, however, telehealth is still considered an emerging application of collaborative techniques and technologies that facilitates team-based decision-making in a virtual workplace (Gartner Group, Inc. 1998). With the addition of consumer empowerment and home monitoring tools, it is expanding in scope and interest. Its emerging status may well be attributed more to significant barriers to adoption than to technology.

Definitions

- Telemedicine – "use of medical information exchanged from one site to another via electronic communications to improve, maintain, or assist patients' health status"
- Telehealth – closely associated with telemedicine, "often used to encompass a broader definition of remote health care that does not always involve clinical services"

American Telemedicine Association

Definitions from "Core Standards for Telemedicine Operations"

- **Store and forward** transmission of medical images for diagnosis (consultation)
- **Real time** health service and remote monitoring vital signs
- Health advice in emergent cases (triage)
- Distance education
- Administrative meetings
- Research
- Online health data management
- Health maintenance and prevention reminders

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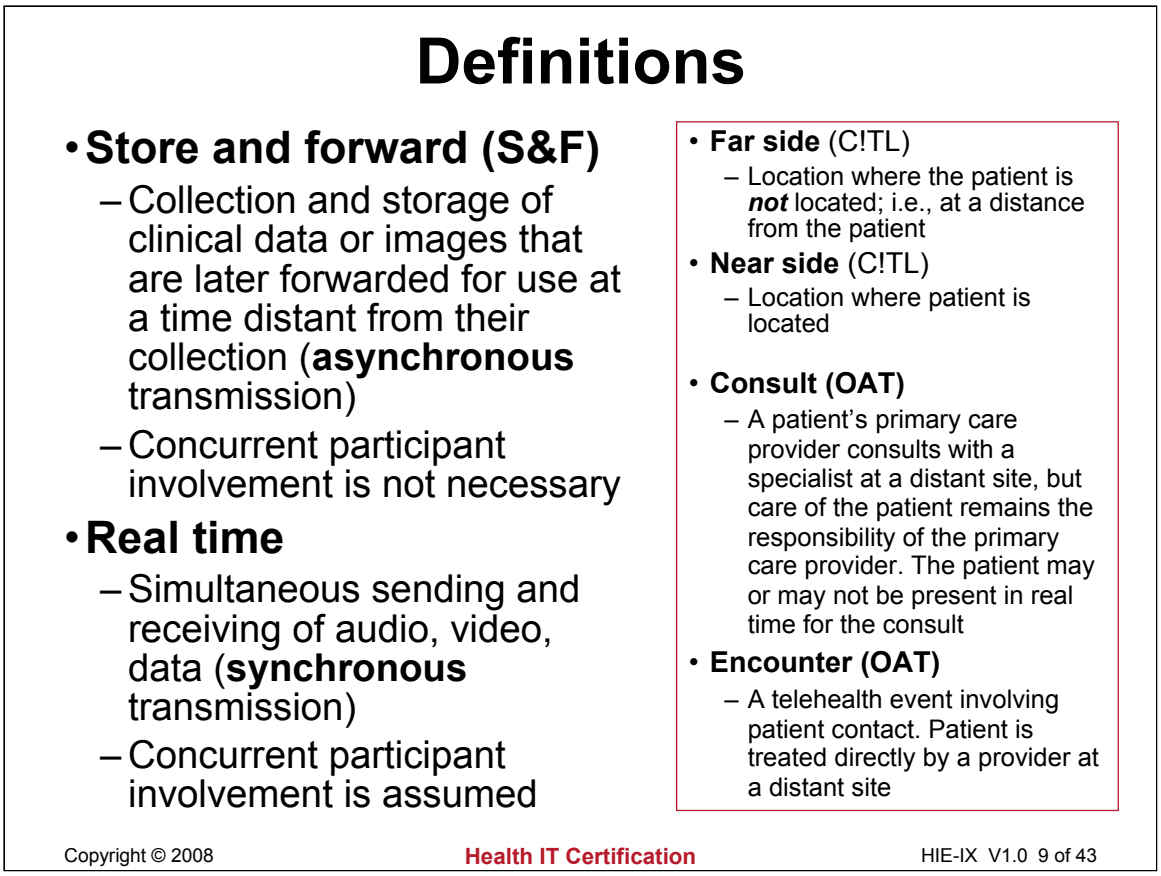
As with those who attempt to distinguish between electronic *medical* record (EMR) and electronic *health* record (EHR), telemedicine and telehealth may carry separate connotations or be used synonymously. Certainly, the lines between the terms become blurry as examples are considered. Use of the broader term of telehealth seems to be gaining momentum. The definitions provided here are those included in the "Core Standards for Telemedicine Operations," proposed for adoption in 2007 by the American Telemedicine Association (ATA).

For purposes of this Course, except where specific reference is made to "telemedicine" by an author, the term "telehealth" is used, partially as a matter of convenience, but also to convey the notion that the fullest scope possible of electronic collaboration in health care is being referenced.



Although we cover technology in more depth in Part 2 of the Course, two terms that are frequently used in association with telehealth definitions are store and forward (S&F) and real time. Store and forward refers to the collection and storage of clinical data or images that are later forwarded for use at a time distant from their collection. It should be observed, however, that the time between collection and use may be very short (including a matter of seconds) or long (which may be a relative concept). Some references use the terms asynchronous and synchronous synonymously with store and forward and real time, respectively, to convey the process the technology utilizes rather than merely time of use. Asynchronous transmissions occur in one direction at a time; where as synchronous transmissions are interactive, occurring in both directions at the same time.

In addition to these primary types of technology, terminology to provide a geographic reference point can be helpful. The Center for Information Technology Leadership (C!TL) utilizes the terms "far side" and "near side" to describe the location of the provider and patient respectively. The Office for the Advancement for Telehealth (established by the Health Resources and Services Administration [HRSA] of the U.S. Department of Health and Human Services [HHS]) also distinguishes between two key terms: consult and encounter, which can be particularly meaningful when considering licensure and reimbursement.

Telehealth Services and Functions

Functions: in relationship to Services:	**Shared Ideas**: People share ideas over geography and time	**Shared Space**: People work interactively regardless of location	**Shared Creation**: People use technologies for real time creation
Monitoring: remote acquisition of physiological data to base			X
Encounter: real-time or store-and-forward facilitation of communication with patients	X	X	X
Consultation: capture clinical tests or procedures for consultation between providers	X	X	X
Distance learning: real-time synchronous or classroom or asynchronous online computer-based training		X	X

Adapted from Gartner Group, Inc. "Relationship Between Collaborative Services and Telemedicine Functions"

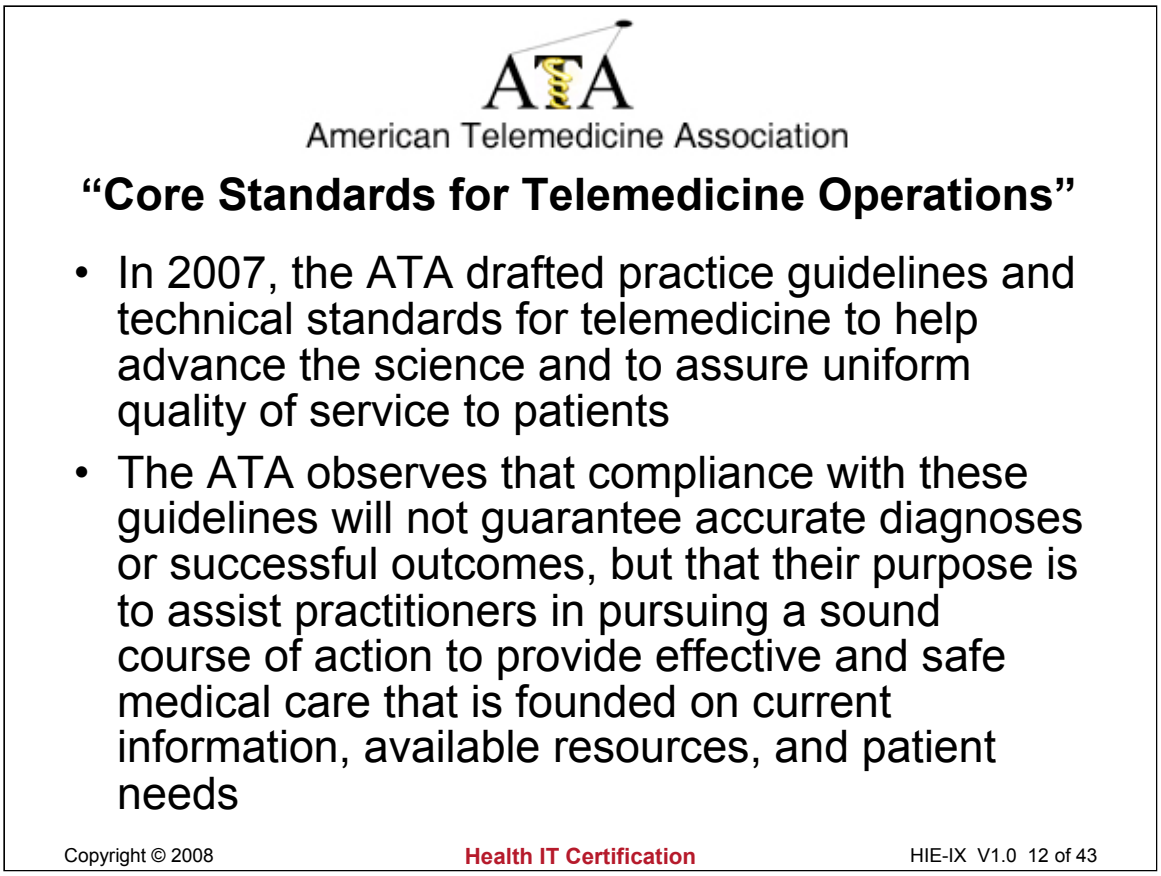
There are several organizations that have categorized telehealth services, functions, and projects for various purposes. The Gartner Group, Inc., in 1998, described the relationship between collaborative services and telehealth functions. This categorization is useful in appreciating the nature of how people relate to one another while using collaborative technologies even today.

Telehealth Projects

Simple	Complex	Integrative	Transformational
Interaction between two people over a distance	Use of technology as a physical extension of caregiver	Use of technology to integrate clinical services	Restructuring of care, including patient-centric medicine
Examples: telephone, email to exchange referral information	Examples: range of synchronous and asynchronous technologies for teleradiology, etc.	Examples: PACS and teleradiology are integrated and support multiple locations	Examples: Physical location of specialist no longer a concern, and all data available (via HIE)
Usually single function to share ideas	Multiple functions to share and create information	Many functions that integrate services across distances	Many integrated functions
Provider to provider, or provider to patient	Specialist to many providers	Multi-specialists to many providers	One patient to many providers

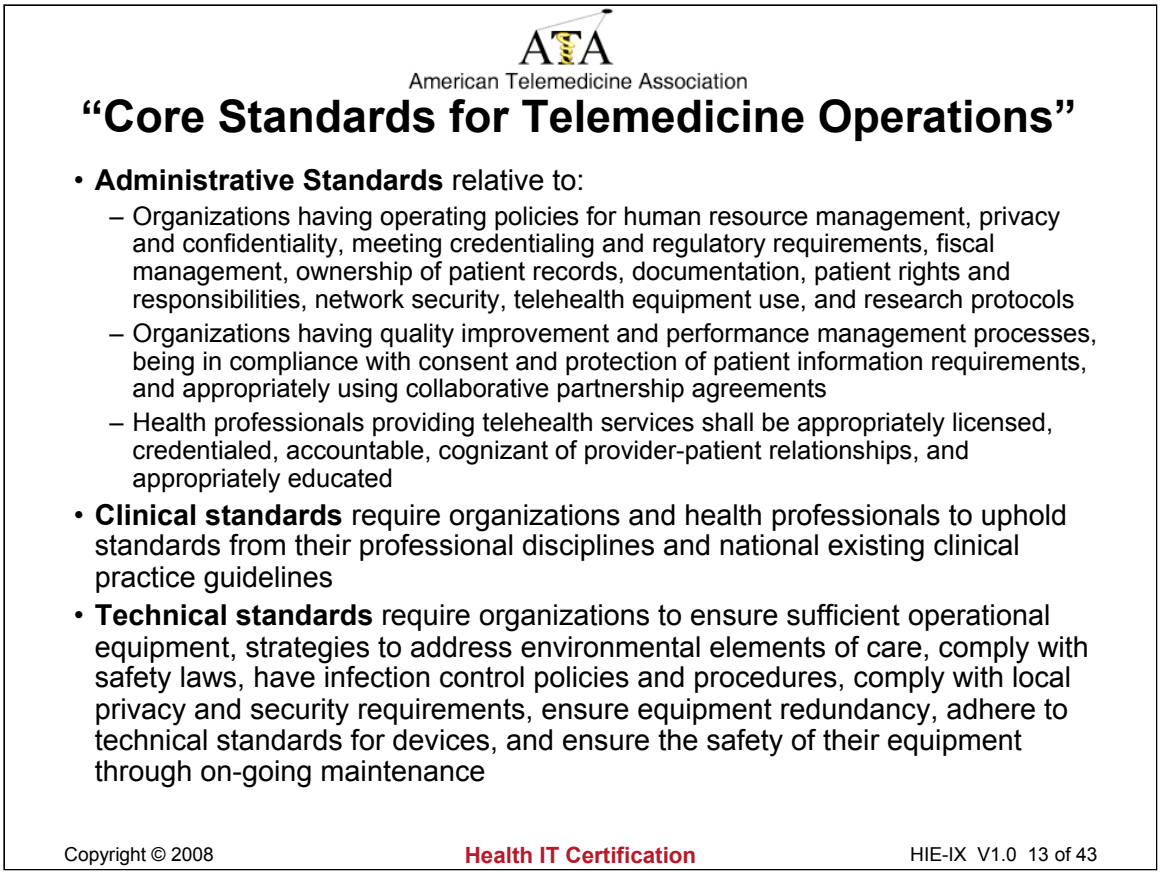
Adapted from Gartner Group, Inc. "Relationship Between Collaborative Services and Telemedicine Functions"

Also suggested by the Gartner Group, Inc., there is clearly a continuum of sophistication with respect to telehealth projects. However, the intent is not to suggest that simple projects are not useful, as they must be accommodated within a construct that may also be more complex, integrative, or transformational. Although HIE was not on most organizations radar screens in 1998, the transformational class of telehealth projects certainly describes what we have come to know today as HIE.



The American Telemedicine Association (ATA) is a "nonprofit organization that seeks to bring together diverse groups from traditional medicine, academia, technology and telecommunications companies, e-health, allied professional and nursing associations, medical societies, government, and others to overcome barriers to the advancement of telemedicine through the professional, ethical, and equitable improvement in health care delivery."

The ATA initiated the drafting of "Core Standards for Telemedicine Operations" to provide an operational reference and educational tool for organizations and health professionals engaged in telehealth activities. Panels of experts from the field and other strategic stakeholders were used to draft the standards, which are undergoing a thorough consensus and rigorous review process, ultimately to be approved by the ATA Board of Directors.



The ATA Core Standards for Telemedicine Operations that have been proposed are summarized here. It may be observed that the standards are not intended to replace existing professional standards of health care practice, rather, relying heavily on incorporation of such standards. The ATA standards address roles and responsibilities for both organizations sponsoring telehealth and professionals engaged in providing care via telehealth.

Home Monitoring

- Also called “remote monitoring”
  - Transmission of biometric data from sensors applied to patient in any remote location
  - Personal physiological/ medical monitoring
  - Home-based provision of care
  - Telehealth in the home
  - Personalized diagnostics
  - Disease management
  - Patient reminders
  - Chronic care diaries

Home Monitoring Devices

- Pedometers
- Thermometers
- Scales
- Heart rate monitors
- Blood pressure monitors
- Blood glucose meters
- Fluid status monitors
- Pulse oximeters
- Peak flow
- ECG/rhythm strip recorder
- Spirometers

HL7 Device Formatted Medical Device Interface is protocol for information systems to receive discrete alphanumeric data from monitoring systems

“Home monitoring” has come to refer to a wide range of functions. Most often it refers to personal physiological/medical monitoring – used with or without the consultation of a health care professional. Sometimes the devices are standalone; others are integrated with a personal health record (PHR); and still others are used to transmit data to a provider. Commercial monitoring devices often used without health care professional intervention include pedometers, scales, thermometers, heart rate monitors, blood pressure monitors, and even “smart toilets” (reportedly sold in Japan to check blood pressure, temperature, and blood sugar) and “smart fabrics” (that are interactive textiles that may monitor heart rate and body temperature, can be fitted into a sneaker designed to adjust sole support, or into an office chair that can detect tension and apply massage). Many of these are sold directly to consumers; some are available for use in drug stores and other locations; and some are still in the research stage. Home monitoring may also include direct provision of care in the home, such as home-based dialysis or other services entailing transmission of biometric data from sensors applied to the patient. An increasing number of wearable and even implantable devices are being used to monitor diabetes, asthma, pacemaker functioning, location of individual, etc.

Though not monitoring devices in the sense of producing a continual assessment of physiology, there are certainly a number of “home testing” kits or “personalized diagnostic” devices to test for pregnancy, HIV, Hepatitis C, cholesterol, etc.

Other forms of home monitoring may be more focused on simply information dissemination and/or data gathering for which personal interaction is required. These may be “low tech” disease management calls from a health plan reminding patients to visit their physicians. They may utilize smart phone technology, such as to call or text message to remind Type 1 diabetic teens that it’s time to test their blood sugar and give themselves an insulin shot. Some may be in the form of “smart pill boxes” that sound an alarm when it is time to take a medication. In other cases, it may be a Web site for Type 2 diabetic adults or their caregivers to record a diary of their blood sugars, or someone on a diet regimen to record caloric intake (although there are also scales that will weigh food and transmit this information to a computer).

Resources
for information and advocacy

- Advanced Medical Technology Association (www.advamed.org)
- American Telemedicine Association (www.atmeda.org)
- Association of Telehealth Service Providers (www.atsp.org)
- Center for Aging Services (www.agingtech.org)
- Center for Telehealth and E-Health Law (www.ctel.org)
  - Formerly Center for Telemedicine Law
- National Rural Health Association (www.ruralhealthweb.org)
- National Telehealth Resource Center, Office for the Advancement of Telehealth
  - Established by Health Resources and Services Administration (HRSA), Dept. of Health and Human Services (HHS)

Universal Service Program for Rural Health Care Providers

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A variety of organizations represent the interests of telehealth stakeholders. Those listed here are the most frequently cited for their national reach, advocacy interests, and broad focus. Many telehealth organizations have special interests in rural communities and the aging population. There are also a number of organizations with very specific focus, such as the Community for Teledermatology.

Some examples of recent advocacy interests of these groups include urging Congress to pass the Medicare Telehealth Improvement Act, S. 2812 that would expand the existing Medicare telehealth program. There is also a Remote Monitoring Access Act that has been introduced into the House of Representatives that would require Medicare to cover remote monitoring services used to manage care for patients with congestive heart failure and cardiac arrhythmia.

In addition to professional organizations and trade associations, the federal government has centered its telehealth focus within the Health Resources and Services Administration of the Department of Health and Human Services. There are also telehealth interests within the Federal Communications Commission of the Department of Commerce, especially with respect to providing discounts to public and non-profit health care providers in rural areas, paid for through the Universal Service Fund (USF) to which telecommunications service providers contribute based on a percentage of their revenues.

Telehealth and Home Monitoring

Part 2. Telehealth and Home Monitoring Technologies

While much of the technology used in telehealth is familiar computing and telecommunications technology, there are special combinations and modifications of their use within a telehealth networking environment. A broad review of these are provided in Part 2.

Content Part 2.

- Basic Technical Infrastructure
- Devices and Software
- Broadband Technologies
- Bandwidth

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Specifically, Part 2 addresses the basic technical infrastructure required for telehealth, identifies the types of devices and software that may be suitable for different types of telehealth applications, describes broadband technologies – including the potential for their enhancement, and specifically with respect to the speed with which they can transmit data, voice, video, and images.

Basic Technical Infrastructure

- "Capture" devices, such as digital and video cameras, imaging devices, and physiologic monitors
- Basic telecommunications and devices for networking of computer systems
- Communication software, including email and browsers
- Forms of telecommunications, including videoconferencing, remote data monitoring, and file transfer, applicable to medical care in remote or rural areas
- Electronic data storage facilities
- Physical facilities, especially for videoconferencing but also for mobility

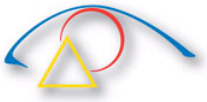
Not unlike other uses of health information technology (HIT), electronic health records (EHR), and health information exchange (HIE), telehealth requires the ability to capture and transmit the content of the telehealth activity. In the case of telehealth, the content, however, is greatly enhanced with use of not only data, but voice, video, and images. Therefore, there is the inclusion of microphones, speakers, video monitors, cameras, and telephones – all of which have special considerations for use in telehealth.

In addition, there are also special considerations relative to the physical facilities in which the telehealth activity is conducted. For videoconferencing, for instance, lighting, color, noise in general, and sound reflection in particular are of concern. There are also more general physical facility concerns depending on the location of the telehealth activity. Some of these may include those for privacy or general space to work and place equipment, such as in a home. Other physical location considerations may include those needed in a military theater or on an airplane or in an ambulance. These considerations should not be underestimated, as they make a difference between what is possible and what will actually be accepted.

Telehealth Equipment

- Videoconferencing equipment
  - Analog devices: Microphones, speakers, video monitors, cameras, telephones
  - Digital devices: CODEC (Coder/Decoder, a.k.a. compressor-decompressor), Multipoint Control Unit (MCU), routers, etc.
- Camera technology
- Monitors
  - Types, connections, and video frame rates
- Audio technologies
- Auxiliary equipment
  - Video medical scopes

Standardization Sector & Technology Watch



Free downloads:
Remote collaboration tools
Ubiquitous Sensor Networks
ICTs and Climate Change
Telepresence: High-performance video-conferencing
Intelligent Transport Systems and CALM

Symposia:
14-15 Feb 2006: Networked RFID
15-16 April 2008 and 17-18 June 2008: ITU Symposia on ICTs and Climate Change
July 2008: Networked Robotics
Other ITU-T Workshops
ITU New Initiatives Workshops

Archives:
Techwatch general forum
Ubiquitous Sensor Network (USN)
Ubiquitous Networks
Grid Computing
Next-Generation Networks

Audio and video equipment produces analog signals that enable people to see and hear; but digital signals are required to transmit these across a digital network. CODEC (coder/decoder, also known as a compressor-decompressor) converts signals used in videoconferencing so they may be transmitted as video protocols, audio protocols, far end camera control, and file transfers. The International Telecommunication Union Telecommunication (ITU-T) Standardization Sector develops standard protocols for video (H.261, H.263, and H.264), audio (G.711 and G.722), camera control (H.281), and data transfer (T.120). The ITU was founded in 1865 and is based in Geneva Switzerland. Its ITU-T sector was established in 1993 and through its Technology Watch program researches new technologies and assesses their implications for standardization. Its interests certainly impact HIEs and telehealth.

Considerations for telehealth use of this equipment includes:

- Cameras should be equipped with pan-tilt-zoom (PTZ), auto white balance, and auto focus.
- Monitor resolution is constrained by connectivity to CODEC. S-video connections provide 500 lines of resolution; component connections provide 2000 lines of resolution. Video frame rate needs to be high enough to prevent jerkiness. Many desktop units use 15 frames per second (fps), while clinical quality videoconferencing should use a minimum frame rate of 30 fps (typical for videoconference calls) and ideally 60 fps when near TV broadcast quality is required.
- Acoustic echo cancellation (AEC) is used to reduce echo in microphones.
- Multipoint Control Unit (MCU) allows multiple locations to be brought together in a single videoconference. MCUs may be hardware (more expensive and reliable) or software (cheaper and less reliable) based. To create a “virtual meeting room” by managing the audio, video, and data streams from each participant, however, the total bandwidth of all connection points must be less than the desired available network connection. (For example, if 5 sites each have 384 Mbps, totaling 1.920 Mbps, but the only available line to the MCU is a T1, at 1.54 Mbps, the connection will fail).

Auxiliary equipment includes may include high resolution cameras for teledermatology, cameras connected to a microscope for telepathology, or fiber optic videoscope systems for teleotorhinolaryngology. Stethoscope and other equipment used to transmit heart and lung sounds may be needed for telecardiology.

Devices and Software

Technology	Devices & Software	Application Examples
Remote Monitoring	Physiological sensors and algorithmic databases, remote monitoring instruments	Telehomecare, Bio-defense
Diagnostics	Scopes (e.g., stethoscope)	Consultations, Telehomecare
Videoconferencing	Videocams, webcams, desktops, portable communications systems	Consultations, Tele-dermatology, Telementalhealth
Digital Imaging	Digital imaging acquisition devices, 3D medical data and image analysis and displays, virtual workbench	Telepathology, Teleradiology, Teledentistry
Robotics	Instruments, controls, viewers	Telesurgery
Store-and-Forward	Data/image/video/audio card capture/scanners; computer camera/microphone & image management software	Electronic health record, Report Generator, Teleradiology, Telepathology
Simulation and Training	Multi-media graphics, computer-aided instruction/medical simulation analysis, virtual reality, digitally enhanced mannequins	eLearning, Curriculum, Conferencing

Adapted from *Innovation, Demand, and Investment in Telehealth*, OTP, February 2004

A useful reference was published in February 2004 by the Office of Technology Policy (OTP) within the U.S. Department of Commerce, entitled *Innovation, Demand, and Investment in Telehealth*, that provides a comparison of devices and software used for various telehealth applications. This comparison has been adapted and updated here. In addition to describing technology, the OTP work observed that much innovation in technology has come about through local improvements in currently operating programs and lessons learned, often without attention to intellectual property protection – often due to constraints of time and expense. It has suggested the need for improvements in the U.S. Patent and Trademark Office rules for "fast track " petitioning for patents that would allow innovative technologies to reach the marketplace and healthcare consumer sooner.

This same work identified other policy findings, including that convergence of telehealth technologies, healthcare informatics, eHealth, and perhaps assistive technologies, warrants a more comprehensive, systematic, and coordinated approach to research, development, testing, and evaluation. It also observed that the nation's civilian, private, and other public sector healthcare communities are not fully benefiting from the Departments of Defense and Veterans Affairs' achievements in telehealth technologies.

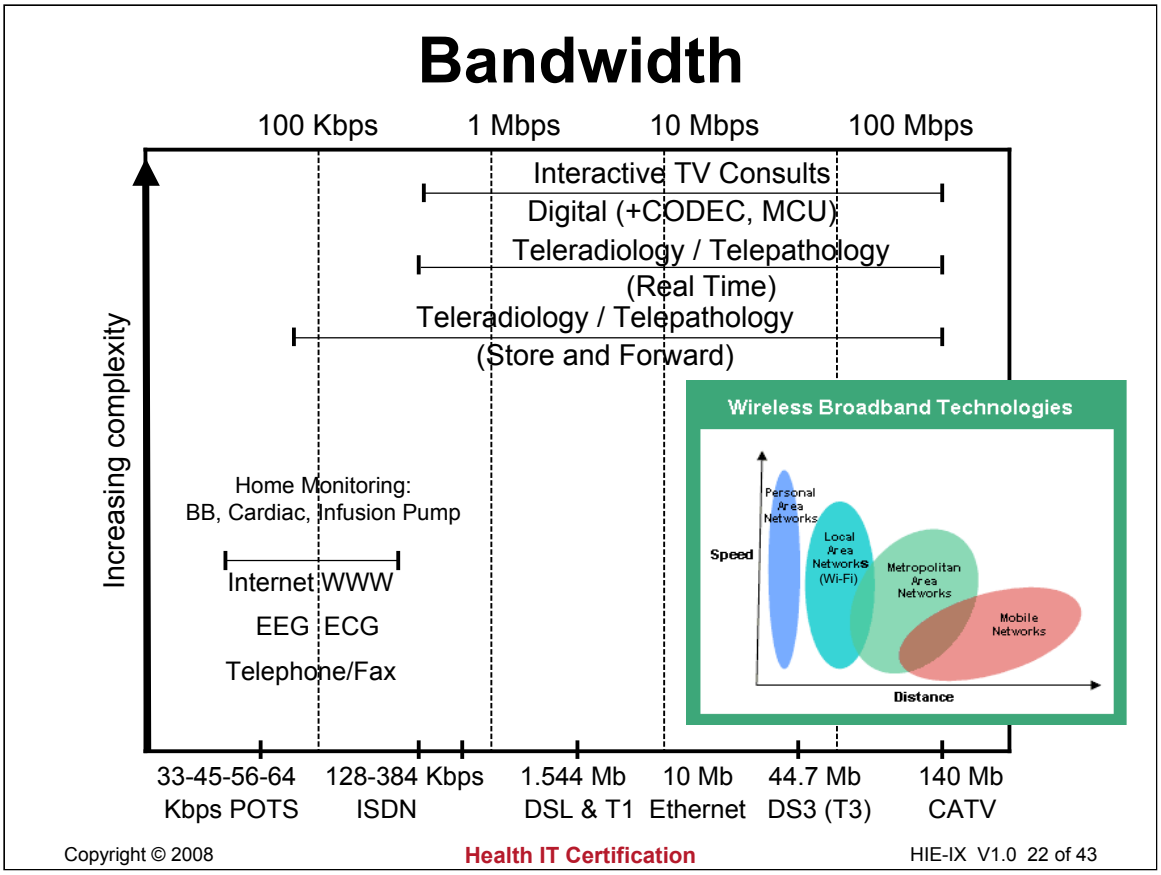
Broadband Technologies






- Broadband over Power Line (BPL) uses existing electric power lines with radio frequency (RF) energy
- Digital Subscriber Line (DSL) electronically enhances conventional copper telephone voice line to provide both voice and data
- Satellite signals have the potential to provide ubiquitous broadband service
- Cable television (CATV) transmits signals via coaxial cable. Hybrid networks of optical fibers and coaxial cable provides video and data
- Fiber optic cables transmit data, voice, Internet access, and video from a distribution frame to a customer; next generation services could provide download speeds in excess of 100 Mbps
- (Terrestrial) Wireless provides a radio link between a service provider and a customer. Wireless can be mobile or fixed
  - Personal area network technologies, such as Bluetooth, ZigBee, and Ultra-Wideband (UWB) transmit data over very short distances

The Federal Communications Commission (FCC) defines broadband as data transmission speeds exceeding 200 kilobits per second (Kbps) in at least one direction: downstream (from the Internet to the user's computer) or upstream (from the user's computer to the Internet). Essentially, this is high-speed Internet access. The FCC identifies six main types of broadband technologies, some of which are widely available today and others of which have still not been fully enabled or widely deployed.



Bandwidths range from those in plain old telephone service (POTS) to cable TV (CATV), and many other services in between, not all of which are available in all parts of the country.

- Integrated Services Digital Network (ISDN) is a broadband dial-up for digital wide area network (WAN) connection that uses a series of channels capable of carrying data from one point to another.
- Digital Subscriber Line (DSL) provides a constant connection, purchasable in a variety of forms, including symmetric (SDSL), asymmetric (ADSL), high bit rate (HDSL), very high speed (VDSL), multi-rate symmetric (MSDSL), rate adaptive (RADSL), power line DSL (PDSL), and ISDN DSL (DSL).
- T-carriers include any of several digitally multiplexed telecommunications systems (in North America) which may be provisioned to use various communication protocols, such as Frame Relay, Asynchronous Transfer Mode (ATM), etc. The original speed of the T1 line is 1.544 Mbps
- Ethernet is a networking technology for local area networks, standardized as IEEE 802.3.
- DS3 (Digital Signal 3) is a digital signal level 3 T-carrier (T3) offering a higher data rate and larger payload than a T1, largely used between both wired and wireless telephony carriers.

Wireless broadband technologies transmit various forms of data at high speeds via wireless links using mobile, fixed, or portable technologies. They can transmit data over short, medium, or long ranges. **Mobile network** technologies enable subscribers to access the Internet with speeds ranging in excess of 400 Kbps, such as CDMA 1x EV-DO (EV-DO) or Wideband CDMA (WCDMA) with High Speed Downlink packet Access (HSDPA). Technologies for **Metropolitan Area Networks** (MAN), such as Orthogonal Frequency Division Multiplexing (OFDM), enable portable services at speeds from 768 Kbps to 1.5 Mbps, with networks extending from 5 to 30 miles. Wireless services over fixed networks require a direct line-of-sight (e.g., rooftop antenna) between the wireless transmitter and receiver, at speeds of about 1 Mbps with a range of 1 to 5 miles. These are often used in rural areas not served by cable or wireline (e.g., T1) networks. Wireless **Local Area Networks** (WLANs) have a range of 100 to 300 feet and use the IEEE 802.11 family of standards, commonly known as Wi-Fi with speeds of up to 54 Mbps, often used to provide service for the “last mile” of access. **Personal Area Networks** transmit data over very short distances, with speeds ranging from 300 Kbps with ZigBee, to 100 Mbps with UWB.

Telehealth and Home Monitoring

Part 3. Barriers to Telehealth and Home Monitoring

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Many suggest that, despite the need for interoperability standards (previously discussed in CPHIE VI HIE Architectures), some technology incompatibility issues, and the need for scalability, accessibility, and reliability assurances, most barriers to use of telehealth and home monitoring are not technical. Part 3 identifies the primary barriers in gaining widespread adoption.

Content Part 3.

- State licensure and accreditation of providers
- Liability
- FDA and State Regulations for Medical Devices
- Privacy and Personal Concerns
- Security
- Documentation
- Reimbursement
- Broad-based Acceptance Issues

Specifically, Part 3 discusses the primary telehealth barriers of state licensure and accreditation of providers, liability, FDA and state regulations for medical devices, privacy and personal concerns, security, documentation, reimbursement, and other broad-based acceptance issues. It should be noted that generally no attempt has been made to priority rank these, although state licensure is probably the biggest barrier. The ranking of other barriers may vary significantly by type of telehealth activity, the provider of the telehealth services, or even the recipient of the telehealth services.

State Licensure and Credentialing

- Consulting exception
  - Upon request of and in consultation with a near side referring physician. Some states permit a specific number of consulting exceptions per year
- Endorsement
  - Licenses granted to health professionals in states with equivalent standards
- Reciprocity
  - Agreement to recognize license without further review
- Mutual recognition
  - Agreement to accept licensure of a licensee's home state, depending on home state, host state, and harmonization of standards (Nurse licensure compact is based on this model)
- Registration
  - Health professional informs authorities of other states and agrees to operate under the authority and jurisdiction of the states
- Limited licensure
  - Health professional obtains a limited licensure for delivery of specific services under particular circumstances (AL, MT, CA, OR, TN, TX)

- National licensure
  - Could be adopted on a state or national level for universal practice
- Federal licensure
  - Health professionals could be issued one license by federal government, valid throughout U.S.

The Joint Commission

Credentials telehealth providers under certain circumstances

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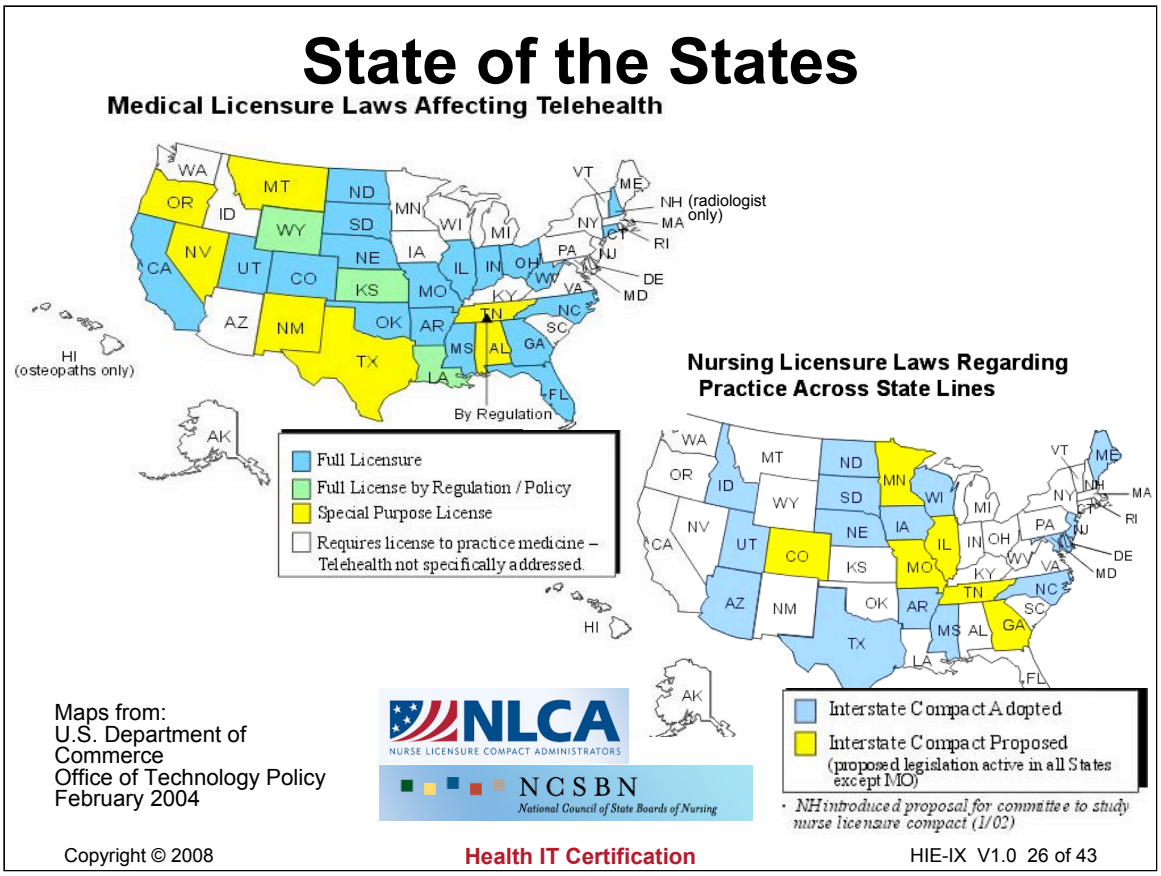
Licensure is a state function, and licensure of health professionals (especially physicians and nurses) working in telehealth has been all over the map with respect to states. Different states have adopted different models of telehealth licensing, so any one engaging in a telehealth activity that crosses state boundaries needs to understand the requirements of both the far state and near state. Some have proposed a national or federal licensure, but these have not come to fruition.

The Joint Commission has recognized the importance of telehealth, but has also been conservative in its credentialing. Its basic premise is that the place where the patient resides retains responsibility for "overseeing the safety and quality of services offered to its patients," but may credential telehealth providers at distant sites under certain conditions.



The variation in medical and nursing licensure laws are clearly evident from these maps. States with no color require license to practice medicine or nursing and telehealth is not specifically addressed. Reasons given by state medical boards for restricting telehealth activities include patient safety, jurisdiction (e.g., how would providers be sanctioned), and the fear that patients will be drawn away by out-of-state providers providing more attractive or lower cost services. In most cases, the penalties for examining a patient in another state or recommending treatment are severe, and may be prosecuted as tantamount to practicing without a license. However, it is observed that patients have the right to travel to another state to be treated in that state instead of their state of residency. One argument on behalf of telehealth is essentially the patient's right to "travel" by video or other form of telecommunications.

A number of states have adopted an interstate compact for nursing (both RN and LPN), and still others have legislation proposed to do so. The Nurse Licensure Compact (NLC) is an agreement that allows a nurse to have one license (in his or her state of residency) and to practice in other states (both physical and electronic), subject to each state's practice law and regulation. Once a compact is enacted, the National Council of State Boards of Nursing in each compact state designates a NLC Administrator to facilitate the exchange of information between the states relating to compact nurse licensure and regulation.

Liability

- Medical malpractice liability requires the existence of a physician-patient relationship
  - A consult with a physician about an anonymous patient will usually not implicate the consultant
  - The patient's primary care physician is likely to be the main target of legal action in the event of malpractice or other wrongdoing
  - As a consultant becomes more directly involved in the treatment relationship, the more likely the consultant will be subject to action
- Criteria courts may look for to determine **physician-patient (i.e., treatment) relationship** include:
  - Review of patient's medical record
  - Knowledge of patient's name
  - Receipt of fee for consultation
  - Exertion of control over patient's care

Although many believe the "liability" barrier to telehealth is no different than any other form of liability that exists in practicing medicine, the nature of a physician-patient relationship may either be harder to define, or perhaps harder to prove (especially where an attempt is made to prove to such a relationship did not exist).

Criteria courts may look for to determine the physician-patient relationship include that the physician under question in a liability situation reviewed the patient's medical record, had knowledge of the patient's name, received money for the consultation, and the extent to which the physician exerted actual control over the patient's care. We have inserted the word "treatment" in reference to this relationship because the existence of a treatment relationship is also pertinent in matters of privacy and whether, under HIPAA, a treatment relationship exists.

FDA and State Regulations

- Hardware and software used in a telehealth encounter may be regulated by the U.S. Food and Drug Administration as medical devices
  - *Example:* First FDA approved Bluetooth-to-Public Switched Telephone Network gateway links home monitoring devices to provider, based upon prescription of a licensed physician
- Use of Internet, email, and other technologies may be regulated by state rules

RTX Telehealth Gateway

Website:http://www.rtx.dk/

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Another barrier that has been raised is the fact that hardware and software used in a telehealth encounter may be regulated by the U.S. Food and Drug Administration (FDA) as a medical device. For example, a Danish company is the first to receive FDA approval for a wireless Bluetooth-to-Public Switched Telephone Network (PSTN) gateway designed for home use by patients. It is intended to be used in combination with a variety of home monitoring devices upon the prescription of a licensed physician or other authorized health care provider.

In addition to the device regulation, there are also some concerns about state regulations pertaining to use of the Internet, email or other transmission technologies – especially surrounding privacy and security.

The issue as to whether a telehealth hardware or software application is regulated is largely related to the creation of telehealth products themselves. In many cases, telehealth applications are those of modification to existing products. But such modification is often not rendered in the form of a new product, submitted through a rigorous process of FDA approval, patenting, etc. In some respects, this is a Catch 22, because the small volume of telehealth services and, therefore, lack of rigorous business case analyses, has made it difficult for innovators to justify public funding or developing mainstream applications for telehealth. In addition to impacting not only telehealth in the U.S., this also impacts U.S. competitiveness in the global marketplace.

Privacy and Personal Concerns

- Health professionals (from HIPAA covered entities) may be unknown to patient, that may require time for building a trusting relationship
  - –Notice of privacy practices, authorizations, and consent forms from near side, but new, health care provider organizations may be confusing to patients
- Those assisting in setting up technology may not typically be health professionals
  - –Even if they are HIPAA business associates fully trained to respect patients' privacy, patients may not be aware of non-traditional role requirements and be uncomfortable with their presence
- Caregivers with typically minimal exposure to private health information may be placed in a position to receive more than patient anticipated

- Personal space of home may be violated
  - – Obstruction or impediment in physical space
  - – Aesthetic incongruence
  - – Lack of accessibility
  - – Suboptimal technical capabilities
- Perceptions of obtrusiveness
  - – Threat to replace in-person visits
  - – Lack of human responsiveness
  - – Detrimental effects on existing provider relationships
  - – Symbol of loss of independence, cause of embarrassment or stigma
  - – Interference with daily activities
  - – Concerns about affordability, future needs and abilities

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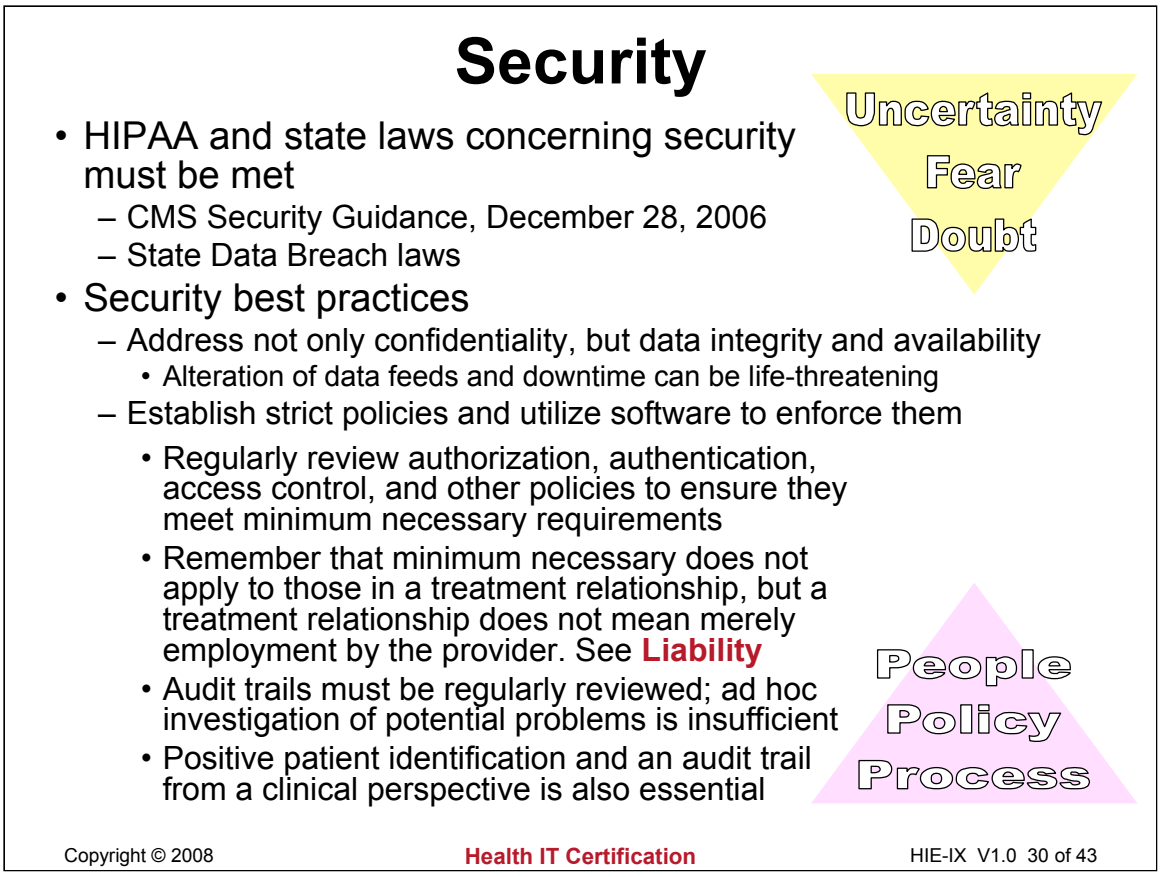
Privacy and personal concerns as barriers to telehealth are very much on the minds of telehealth providers, despite that results of a number of surveys have indicated that patients who are recipients of telehealth services very much appreciate them and generally do not believe their privacy has been violated. Still, attention to potential privacy issues should be uppermost in providers' minds. The HIPAA Privacy Rule should be followed in a telehealth activity the same as in any other provision of care. The presence of caregivers and others who may be present, however, often adds to the complexity of sorting out privacy issues.

In addition to protecting health information, and of course personal privacy, there may also be personal space concerns, such as where patients may feel their home environment is being dismantled to accommodate the telehealth equipment and personnel. Special care should be taken to ensure that physical distance does not distance the provider from the patient in a relationship sense. Harris Interactive pollsters have recently identified that an increasing number of U.S. adults are disregarding doctors' course of treatment due to perceptions of overly aggressive treatment (April 10, 2007). While this survey did not explicitly focus on telehealth, it is one more sign that consumer empowerment is taking hold, and as was discussed in the CPHIE VIII Personal Health Records, consumers want to be more engaged in conversation with their providers, and not be merely the object of a healthcare encounter. Telehealth has the potential to make distances seem both nearer as well as farther – and this human factor of consideration for the personal space of the patient is important.



Obviously, as electronic transmission of data occurs, there is always the need to heighten attention to security. In addition to the basic HIPAA Security Rule, additional CMS guidance and state data breach laws have been issued or enacted.

Many embarking upon telehealth, as well as HIE in general, seek answers on what security is required. As we know, HIPAA is highly risk-based. Covered entities are expected to take steps necessary to mitigate their risk, and each entity's risk may vary due to a number of factors. However, this risk-based approach is clearly open to interpretation. HHS stayed away from specificity in the HIPAA regulations due to concerns that "one size does not fit all" and new technology is always being developed, which would make it impossible for regulations to keep up with technology. We observed in the CPHIE VII Data Stewardship course that "uncertainty, fear, and doubt" with respect to the lack of specificity in HIPAA, however, has made an otherwise conservative industry even more conservative.

A number of industry observers have also noted that security is often identified as a barrier – not because of lack of technology or even lack of uncertainty about what technology to use, but the unwillingness on the part of the health care industry to adopt the needed technology. People, policy and process factors are more likely to impede use of security best practices than lack of either technology or regulatory guidance. Strict policies must be adopted and enforced – by covered entities. An example is the common practice in health care to use access controls that enable virtually any health professional employed by or having medical staff privileges from the covered entity to have access to any patient's health record, often over concern for lack of ability to get to information in an emergency treatment situation. As a result, products have not been designed with stronger controls. However, "break-the-glass" (BTG) emergency access technology is widely available in other industries' applications and in some health information technology applications that often goes unused.

Documentation

- Is a recording of a telehealth encounter part of the "**legal health record**"? Must continuous feeds of monitoring devices be retained?
  - AHIMA observes that an equivalent recording of an in-person encounter is not usual as a part of the legal health record
  - Other professional requirements may exist for retention of physiological monitoring data – which would likely be treated the same irrespective of the distance of the monitoring
- Is there a requirement for **retention** of such recordings for E-Discovery?
  - E-discovery may seek and find any additional information and a plea for its introduction determined by the court
  - Store and forward technology will necessarily make a recording; real time technology may also make a recording as a matter of contingency planning – but these could be routinely destroyed unless desired for research purposes
- Within whose medical record, as the business record of care, is **documentation** of the encounter recorded?
  - Routine documentation of encounters and consultation records
- In all cases,
  - Check with the licensure **laws of the states** in which telehealth is occurring
  - Establish and follow written **policy** for all situations, including the handling of exceptions for research, potential litigation, etc.

Another matter that may pose a barrier is the issue of documentation, including: What constitutes documentation of a telehealth encounter relative to the legal health record, what needs to be retained and may be subject to e-discovery rules, where does the documentation reside when the provider is in one location and the patient in another, and what state regulations must be addressed.

Obviously, again, states regulate medical record documentation and regulations may vary. Documentation standards of practice, however, are less different among states than professional licensure, but still must be checked. Written policy with respect to all matters relating to documentation is critical. Each provider needs to define its legal health record in accordance with state law, HIPAA designated record set, accreditation requirements, etc. Following policy consistently is also key to ensuring that practices for telehealth are not singled out as exceptional.

Reimbursement

- Medicare
  - Recognizes telemonitoring as an allowable cost
  - Reimbursement for certain telehealth consultations under strict requirements for Medicare beneficiaries in rural areas qualifies for reimbursement
    - Know the nature of services and strictly follow the requirements
    - Seeking reimbursement for non-reimbursable services may lead not only to no reimbursement but criminal and civil penalties for Medicare fraud
- Medicaid
  - Payment provided only under the fee-for-service Medicaid plans in 23 states (2002 CTL), usually at both ends of a consultation, with an interactive communication. Line-charges, use of equipment, and technical support are usually not reimbursed
- Private insurers
  - Survey of 72 programs offering billable services found 38 programs in 25 states reimbursed by private payers (2002 AMD Telemedicine, Inc.), with BlueCross BlueShield generally taking the lead in defining coverage determinations

Probably no topic is more often identified as an “issue” or a “barrier” in telehealth than reimbursement for encounters. The state of reimbursement for telehealth by Medicare, Medicaid, and private insurers is dismal. Although third party reimbursement is essential to long term sustainability of telehealth programs, providers have largely been compensated for telehealth services by other institutions (federal and state government grants, non-profit foundations, and universities) to date.

Broad-based Acceptance

- Technical knowledge and technical problem-solving skills required to use
- New workflow routines and organizational support required
- Physician resistance
- Viable business model required to acquire technology
- Lack of information on efficacy and cost/benefit for product development

Finally, there are a number of other issues that may play more minor roles as barriers to broad-based acceptance of telehealth, but are nevertheless important in their own way. At an individual level, technical knowledge and skills, new workflow routines, and general resistance to new technology are barriers; although there are also barriers where more technology is expected than exists. For instance, several telemedicine specialists who provide exclusively house calls indicate that medical devices need better outfitting with Bluetooth technology to upload data to computers, and speeds of broadband access cards used to upload data back to a home base need to be faster. More widespread adoption would help overcome these issues, but as with many of the barriers, all have interdependencies that make it difficult to breakthrough in any one area.

The telehealth community has also had a very difficult time proving efficacy and producing cost effectiveness data through high-quality, peer-reviewed clinical studies, although this is changing, especially as much more experience is available through the Department of Defense and Veterans health Affairs. Lack of a viable business model restricts innovation, although thankfully, many continue to push for investment and utilization.

Telehealth and Home Monitoring

Part 4. Applications and Benefits of Telehealth and Home Monitoring

So despite the barriers, there are an increasing number of applications of telehealth and home monitoring that are showing clear benefits. The final Part of this Course provides some examples of such applications. It should be stressed that there are many other examples!

Content Part 4.

- Markets for Telehealth
- General Application Areas and Benefits
- Application Case Studies

Part 4 covers the various markets for telehealth, general application areas and benefits, and several case studies – again observing these are only just a very few examples of many in the literature.

Markets for Telehealth

- Homeland security
  - Military
  - First responders
  - Public health and surge capability
- Access: New Populations and Settings
  - Maldistribution of health professionals
  - Rural
  - Remote
  - Correctional facilities
  - Mental health
  - Elderly
- Consumer “on demand”
  - Workplace/school-based services
  - Recreational areas
  - Transportation centers and modes
    - Aircraft
    - Cruise ships
- Continuum of care
  - Trauma and emergency
  - Rehabilitation
  - Disease management
- Home health care
- International
- Health information exchange

Current and emerging markets for telehealth have been cited in the literature for Homeland security; providing access to health care for new populations and in new settings – in part to overcome the maldistribution of health professionals, but also to reach out to those who have or present difficulty in reaching health care services; supplying consumer “on demand” services; ensuring continuity of care; and addressing consumer empowerment for individuals at home. In addition, the international market is open for telehealth, especially where medical tourism may present transportation obstacles.

Not explicitly identified in the literature to date, but starting to be linked, is the market for telehealth in health information exchange (HIE). It is clear that in connecting communities for information exchange, part of that information will be from monitoring devices, and part of the information exchange could well be telehealth consultations. If only to set up or enable piggybacking on broadband connectivity enhancements, HIEs could get greatly facilitate adoption of telehealth.

Clinical Application Areas

- Radiology
- Pathology
- Dermatology
- Psychiatry
- Cardiology
- Intensive care
- Endocrinology
- Optometry
- Infectious medicine
- Pediatrics
- Surgery
  - Cardiac
  - Gastrointestinal
  - Neurosurgery
  - Orthopedics
  - Urology

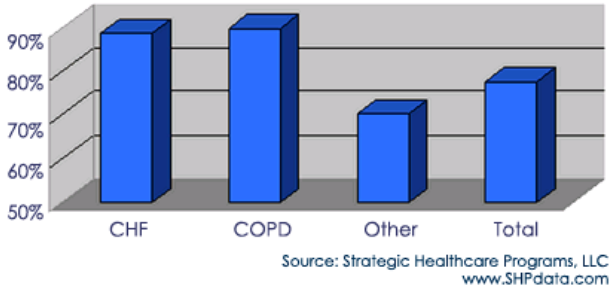
- Chronic illness
  - Diabetes
  - Hypertension
  - Congestive heart failure
  - Chronic obstructive lung disease
  - Asthma
  - Obesity
  - Depression
- Cardiovascular disease, cancer, COPD, and diabetes account for 72% of all deaths each year (CDC National Center for Chronic Disease Prevention and Health Promotion, 2005)
- About 3,500 hospitals, clinics, schools and other facilities are estimated to use some form of telemedicine, representing an increase of 75% between 2000 and 2006 (American Telemedicine Association)
- Sales of devices and digital services for home monitoring are projected to grow from $461 M in 2005 to over $2.5 B in 2010 (Parks Associates, 2006)

It is very likely that almost any health care specialty may utilize telehealth and home monitoring. Probably the first implementations widely used were in radiology, then pathology. Other, highly visual-oriented specialties, such as dermatology and some psychiatry services are well-suited to telehealth. Intensity of monitoring needs makes cardiology, intensive care, and endocrinology prime candidates for telehealth and monitoring – both within a provider setting and from home. But other specialties, such diabetic retinopathy screening, wound management, and pediatrics all present unique opportunities for telehealth services. The literature also supports use of robotics in cardiac, gastrointestinal, neurosurgical, orthopedic, and urological surgery.

The focus of much home monitoring for the management of chronic disease has focused on the most widespread and critical conditions of diabetes, hypertension, congestive heart failure (CHF), chronic obstructive lung disease (COPD), asthma, obesity, and depression – often using a combination of physiological monitoring with automated reminder systems.

General Benefits

- Avoidance of transportation costs
  - Between emergency departments (ED)
  - From correctional facilities to EDs, physician offices
  - From nursing facilities to EDs and offices
- Less invasive surgery and less post-surgical infection using surgical robotics and wound care monitoring
- Reduction in hospitalization



Although cost is certainly a benefit from avoiding transportation of patients, less invasive surgery, and reduction in hospitalization, these and other benefits also have significant patient safety, quality, and patient satisfaction elements.

Video Interpretation (Holy Name Hospital, Teaneck, NH)

- Treat high percentage of non-English speaking, deaf, and hard of hearing patients, including 46 different languages and American Sign Language (ASL)
- Since early 1980s, utilized primarily telephone interpreters who were not always sure of the patient's understanding (or family, who often have difficulty interpreting medical terminology or magnitude of patient's medical complaints, or staff who may not always be available or clinically oriented)
- Pioneered use of video interpretation by "medically trained" interpreters for both non-English and ASL:
  - Average cost about $3 per minute in comparison to $2.20 to $3.00 per minute telephone interpretation
  - Well-informed patient more likely to cooperate with treatment
  - Faster response time to interpretation needs and faster recovery reduced average length of stay
  - Patient satisfaction significant
  - Expect to move to video interpretation on demand at the bedside

Describing their experience in Health Management Technology (March 2007), Hirsh and Marano identified their need for a solution that would offer:
•On-demand non-English and ASL interpretation
•One device to handle all interpretations (integrated speakers, microphone, camera and screen with minimal wires or wireless)
•High-quality picture and sound for the patient and the interpreter (12.1 inch LCD screen, H.264 video compression standard for broadcast quality video to ensure all facial, lip, and hand movement can be seen to ensure message is understood, and ability to connect to other devices at 768 kilobits-per-second for smoother picture and enhanced audio was used for ASL)
•Encrypted transmission (utilize AES/DES secret-key encryption
•Ease of use
•Accessibility
•Interpretation by "medically trained" interpreters
•Cost effectiveness
•Staff training

Home Telemonitoring (VNA Western Pennsylvania)

- Monitor 150-200 patients/day
  - Video visits
  - Daily vital sign monitoring
- Emergent care dropped 38%
- Hospitalizations dropped 24%
- Re-hospitalization rates for congestive heart failure patients dropped 33%

- Clinical effectiveness conclusions for home telemonitoring:
  - Patients see results and recognize the cause and effect relationship between their actions and health consequences
  - Patients and their families feel empowered by the experience
  - Telemonitoring allows for early clinical interventions to prevent exacerbations

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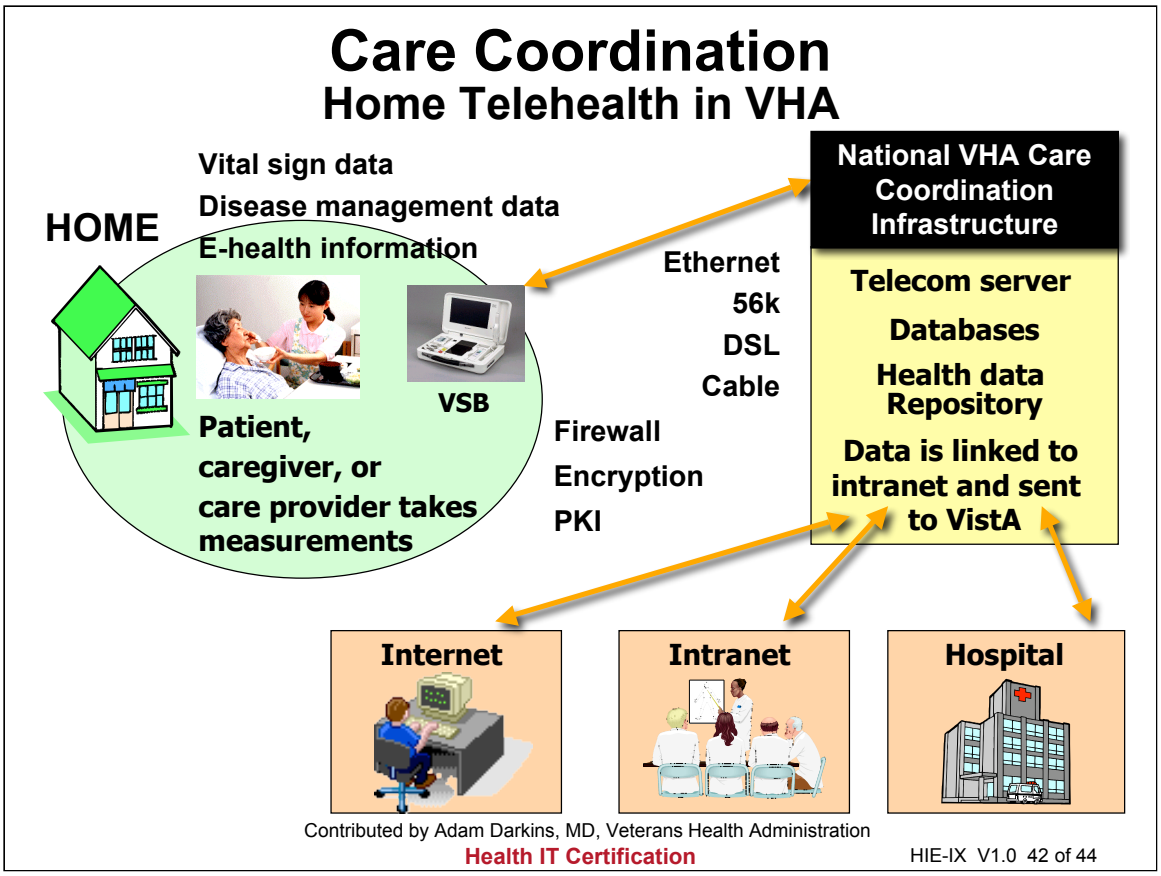
The VNA (Visiting Nurse Association) Western Pennsylvania reported very positive results with its VNA telemonitoring activities. Since 1991, home health nurses had been using lap tops to record medical record documentation, and by 1999 had become totally paperless. In August 2002, they started home telemonitoring. At the Telehealth Leadership Conference in 2005, Kristy Wrights, President/CEO of VNA Western Pennsylvania, describes significant results for the period January 2003 through June 2004 from their home telemonitoring program. In addition to conclusions nurses observed, Wrights also identified future considerations, including the need for national definitions and standards, that less nursing resources will require more efficient use of nurses, that there will increasingly be more emphasis on patient outcomes, and that there is an increased need to extend cost effective health care into the home.

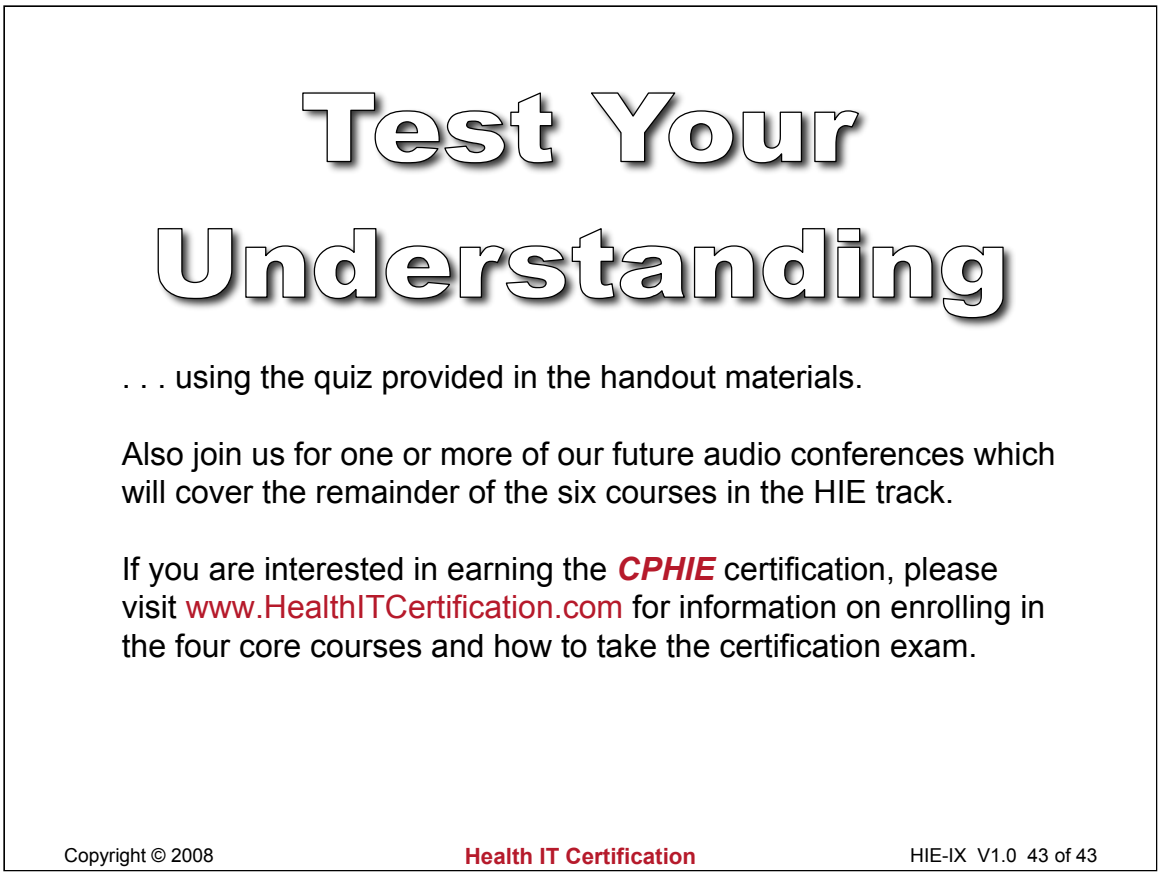
Advanced ICU Care
(St. Mary's Health Center, Jefferson City, MO

- 167-bed hospital with extensive cardiology and open-heart surgery services had difficulty retaining intensivists
- Clinical management software combined with patient data and video feeds enabled intensivists and critical care nurses to care for patients from St. Louis, MO
- After one year:
  - ICU mortality dropped by 24%
  - ICU length of stay shortened by 6%
  - Overall length of stay for ICU patients decreased 14%

Another unique example of a telehealth activity is the case of a small hospital wanting to take advantage of the benefits of intensivist services, but unable to attract such individuals who are very much in short supply. Instead, they built a telehealth service directly into their ICU and utilized intensivists from their regional health system. Similar findings have been found using "tele-intensivists" in other facilities as well.



The use home telehealth, informatics, telehealth and disease management technologies in the Veterans Health Administration (VHA) enhances and extends care and case management. This improves access of veteran patients to care and helps veteran patients to remain living independently in the least restrictive setting.



This course has covered the waterfront on telehealth and home monitoring. While not necessarily an inherent element of HIE, it certainly presents an opportunity for HIE as well as potentially a responsibility for an HIE as part of a broader mission of connectivity.

Use the quiz in the handout materials to test your understanding of the content just presented. Answers are provided following the quiz.