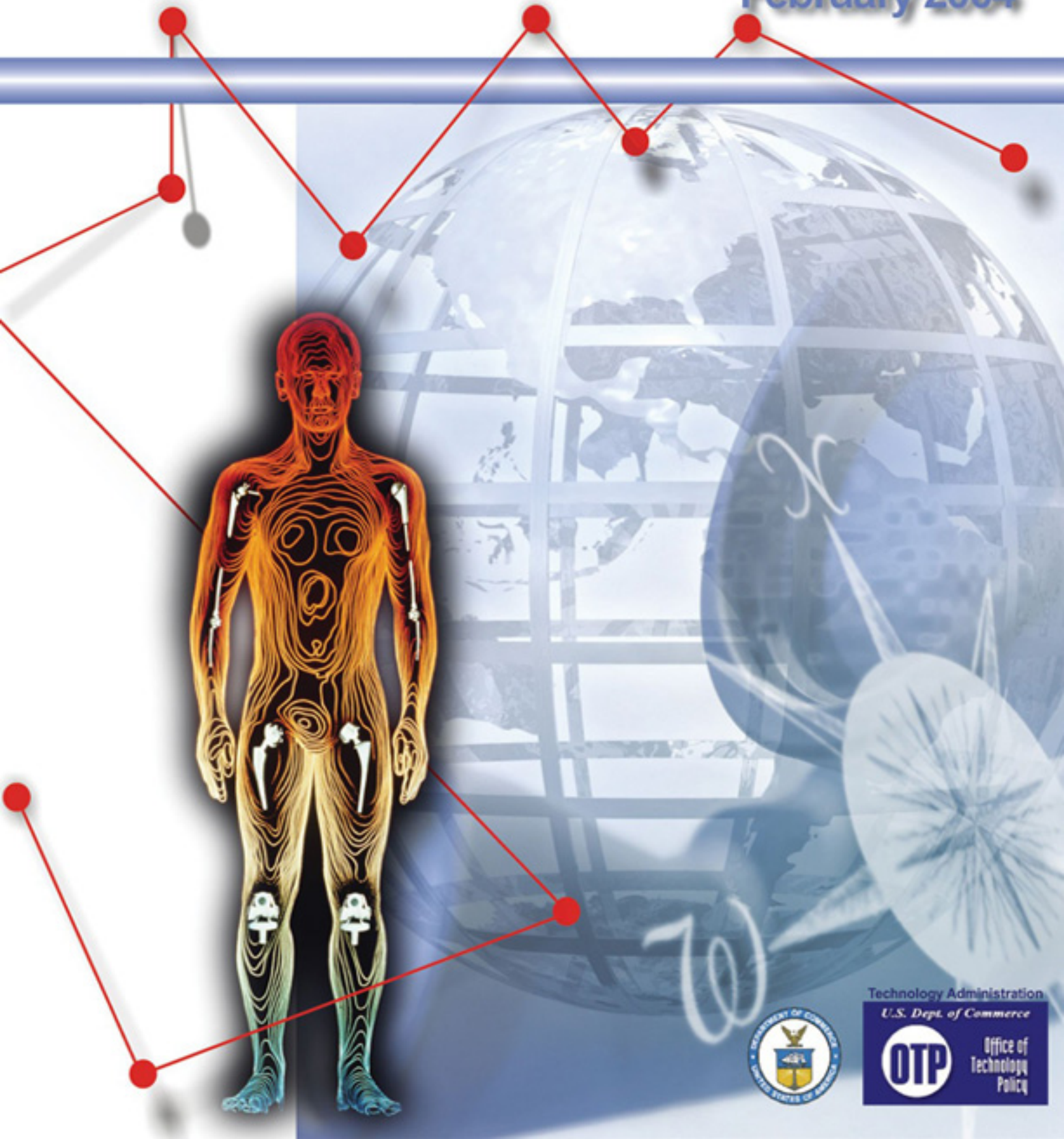
Innovation, Demand and Investment in Telehealth

February 2004



Technology Administration
U.S. Dept. of Commerce
Office of Technology Policy

FOREWORD

America's healthcare system is regarded as among the world's best. The application of new technologies to medical care has enabled significant progress. However, the wider adoption of telehealth technologies promises even greater access and higher quality care, with reduced costs. Telehealth applications have been proven effective in extending medicine's reach to remote Alaskan villages, disaster assistance teams, and ships at sea. As global demand for healthcare increases, adoption of telehealth systems and technologies can be a powerful tool to assure high quality medical care for all peoples, regardless of their location.

The Technology Administration was asked, in its role as a portal to private industry, to conduct the first comprehensive analysis of telehealth since 1997. This report focuses on the state of innovation, demand and investment in telehealth in the United States at the end of 2003. Its findings represent information collected in over 40 interviews with medical specialists, information technology innovators, healthcare consumers, etc. This report should be viewed as a baseline, presenting what is current, while offering a roadmap for achieving what is possible.

Although this report is a call to action, the Technology Administration joined with other federal, state and private stakeholders even before its release to make progress in addressing several of the impediments described herein. The information presented here can serve as a framework for advancing the adoption and application of telehealth technologies, but a strong commitment among all healthcare stakeholders is essential.

If we seize this opportunity and act, the national benefits can be great. Increased adoption of telehealth technologies offers increased access to quality health care at lower costs, while simultaneously increasing our nation's security. Please join with the Technology Administration as we continue to work to improve America's healthcare access, quality and cost through more effective "Innovation, Demand and Investment in Telehealth."

Sincerely,

Phillip J. Bond
Under Secretary for Technology

Innovation, Demand and Investment in Telehealth

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Innovation, Demand and Investment in Telehealth

Executive Summary

> **With medical knowledge expanding every day, no physician can keep up without help. By using high-tech medical communication, high-performance computers, high-resolution video, and fiber-optic information "superhighways," we have been able to put the entire world of medical science at the fingertips of even the most isolated rural family doctor.**
>
> - C. Everett Koop, M.D.[1]

This quote by a former Surgeon General encapsulates the promise and potential for healthcare technology. Tens of thousands of Americans are accessing healthcare remotely from medically underserved areas such as Arctic villages, Native American reservations, prisons, and rural communities. Many more are being diagnosed, treated and monitored from ships at sea, battlefields, urban centers, and homes. However, only a fraction of the potential for technology to increase access to, improve quality of, and reduce the cost of the nation's healthcare has been realized to date. In 2001, a major report by the Institute of Medicine stated: "The automation of clinical, financial and administrative information and the electronic sharing of such information among clinicians, patients and appropriate others within a secure environment are critical if the 21st-century health care system (envisioned by the committee) is to be realized." [2]

This report discusses factors that have affected the adoption and application of one of these technologies - telehealth - and presents findings that, if addressed, could lead to increased innovation, demand, and investment. Many of the study's findings relate to other healthcare technologies as well -- a result of their ongoing convergence with telehealth.

Some have suggested that telehealth is not a technology *per se* but rather a *technique* for delivering care remotely.[3] It is "the use of telecommunications and information technologies to provide health care services at a distance, to include diagnosis, treatment, public health, consumer health information, and health professions education." This definition[4] incorporates the concept of a comprehensive system for integrating various

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[1] From the Koop Institute web site at http://www.dartmouth.edu/dms/koop/projects/past/nnehii.shtml

[2] Crossing the Quality Chasm, A new Health System for the 21st Century," Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, Washington (2001) page 17

[3] Loane, M., and Wootton, R.. "A Review of Guidelines and Standards for Telemedicine." *Journal of Telemedicine and Telecare* 8(2):63-71. 2002.

[4] from the "2001 Report to Congress on Telemedicine," Office for the Advancement of Telehealth, May, 2002 at:
http://telehealth.hrsa.gov/pubs/report2001/intro.htm#overview

applications—clinical health care delivery, management of medical information, education, and administrative services—within a common infrastructure. Any examination of the nation's healthcare system should also acknowledge the convergence of such healthcare technologies as medical devices, healthcare informatics, IT for healthcare, telehealth and healthcare over the internet ("eHealth").

Telehealth providers characteristically apply a unique combination of innovative, technical, and entrepreneurial skills. The absence of a "national market" and the fragmentation of research and development, demand and investment have prompted the development of telehealth's pioneers and "champion" providers independently of a national or sectoral strategy or effort. To fully respond to the nation's healthcare and homeland security needs, however, telehealth suppliers (manufacturers and services firms), providers (clinics and clinicians), payers (third party insurers), and other stakeholders must be prepared to work together to address a wide array of needs, issues and opportunities.

The market for telehealth technology (products and services) is relatively small and has historically been considered a technical specialty separate from traditional medicine. One of the most important challenges to (and opportunities for) telehealth providers is the integration of technology with clinical medicine. Growing acceptance and use of advanced medical devices, information technology (IT), and the Internet by healthcare providers have contributed to greater interest in telehealth within the medical mainstream. Attention to telehealth has also grown with the surge of interest in homeland security, especially with its current emphasis on first responders, equipment interoperability, and public health information networks.

In order to evaluate the current state of telehealth, it is important to consider public policy issues that seem to act as barriers to innovation, demand and investment. As the technology evolves into its "third generation," it is also important to move the discussion of these issues to the next level, that is, to focus greater attention on designing and implementing solutions. If progress in meeting the combined challenges of access, quality, cost and homeland security is going to be made, industry leaders and policy makers must agree on and demonstrate the will to undertake appropriate solutions.

The report devotes a good deal of discussion to *organizational* or *process* issues to include several findings that focus on *coordination*. A principal finding suggests that progress in addressing public policy issues is often limited by insufficient coordination among stakeholder groups and organizations. Solutions to issues have also been hampered by lack of information, authority and organization. Examination of organizational and process issues was, therefore, included within the comprehensive "systems approach" applied to the research and analysis leading to this report.

The report contains numerous findings although only those considered most significant have been summarized below. Findings and conclusions are presented in a manner that should lead easily to follow-on actions and/or solutions. The intent of this report was to analyze the current state of telehealth and to describe the impact that policy and process issues seem to be having on its innovation, demand and investment. As such, the report should be viewed as a "baseline" for renewed effort among stakeholders to resolve

longstanding legal, financial, regulatory, organizational, and process barriers. Because the Department of Commerce has a secondary or indirect role with telehealth, the research, analysis and findings presented below are intended to be consultative and not prescriptive. Analysts within the Office of Technology Policy will, however, be pleased to discuss findings and possible recommendations with appropriate stakeholders within another venue.n

PRINCIPAL FINDINGS

Policy

Telehealth innovation, adoption and deployment have been impeded by legal, financial and regulatory barriers.

Numerous federal, state and private sector policy issues have contributed to the inability of telehealth technology to achieve enough of a critical mass needed to be fully included in national discussions of healthcare and homeland security. Although an array of potential solutions is well known within the telehealth community, a coordinated and focused effort to act on frequently compelling evidence supporting change has not been undertaken.

A framework for determining reimbursement coverage of telehealth applications that is more reflective of technology's impact on access, quality, and cost considerations is needed.

Although Medicare only accounts for a portion of healthcare reimbursement, its policies influence other payers as well as providers. The telehealth community has been generally unsuccessful in persuading Medicare to reimburse many of its applications to include such technologies as store and forward (with certain exceptions). There is also evidence that Medicare and Medicaid policies lag behind those of private payers. There is evidence to suggest that greater discussion and coordination among payers of reimbursement policies may lead to more informed consideration of technology's impact on access, quality and cost.

A recently announced process for requesting Medicare coverage and a "Medical Technology Council" may have little effect until or unless the stakeholder community can provide the Centers for Medicare and Medicaid Services (CMS) and Congress with compelling evidence of telehealth's value. Although it is a widely held belief that telehealth and other healthcare technologies can reduce the cost and increase the productivity of healthcare, additional high quality studies are needed to make the business case for expanding reimbursement.

Additional innovation may be stimulated through greater use of "fast track" protection of intellectual property.

Additional innovation may be stimulated through "fast track" protection of intellectual property. A good portion of innovation in telehealth occurs locally as a result of improvements in currently operating programs and lessons learned. Innovators in this field, however, tend to be small companies or individuals that often choose not to pursue intellectual property protection for financial reasons, among them the time and possible expense of seeking exclusive rights. As a result, the disclosure of significant advancements in telehealth may be delayed. Reducing the time for granting patents by encouraging inventors to use existing "fast track" processes would allow innovative technologies to reach the marketplace and healthcare consumer sooner. Those "fast track"

processes are available by way of "petitions to make special" which are provided for under the current United States Patent and Trademark Office rules of practice.

Acceptance of telehealth within the medical mainstream can be increased with a coordinated effort within the stakeholder community.

Greater acceptance within the medical mainstream is a long and evolutionary process, especially in a field where risk is measured in human health. There are steps that the telehealth community can take, however, to accelerate acceptance of telehealth and its integration with clinical procedures such as ensuring that a telehealth curriculum is available to medical and nursing schools and telehealth "champions" are working actively throughout the nation's healthcare delivery system.

Homeland security requirements for local, regional and national healthcare networks justify greater cooperation and coordination among licensing authorities.

Regulation of healthcare providers has traditionally been a function of the states. Even though telehealth and, more recently, healthcare over the Internet cross state lines, vendors and providers have been unable to plan for a "national market" due to a patchwork of state policies for licensure and reimbursement (i.e. Medicare, Medicaid and the State Children's Health Insurance Program). The same factors make investment and adoption of telehealth technology by clinicians less attractive due to the uncertainties and changing nature of licensing rules from state to state, and credentialing and privileging rules for healthcare networks and facilities. A "compact" among licensing authorities could help form a foundation for greater coordination and cooperation among states under certain circumstances, such as those related to homeland security.

Recent initiatives give reason to expect greater progress in resolving licensure issues in 2004. For example, an Office for the Advancement of Telehealth (OAT) contract with the Center for Telemedicine Law providing for a December 2003 workshop to examine various options, and another OAT contract with the Federation of State Medical Boards for developing workable licensure solutions should help incentivize stakeholders to move forward.

Progress in the development and adoption of industry-wide standards will contribute to resolving interoperability issues in the long term.

Following the policy roundtable organized by the Technology Administration in June 2002, representatives of the American Telemedicine Association (ATA) and the National Institute for Standards and Technology (NIST) began to work together to develop, market and gain industry acceptance of standards. Progress to date has included the development of a standards process for diabetic retinopathy as a test case. Over time, this process will routinize the development and marketing of other telehealth standards, a key requirement for addressing issues of interoperability. OAT's process for developing "guidelines" offers an interim step for focusing attention on interoperability requirements while standards are being developed.

A national discussion of the merits of, and policy and technical issues associated with national health information infrastructure is needed.

A great deal of discussion favoring a "national health information infrastructure" (NHII) has taken place to include extensive proposals by such groups as the Department of Health and Human Services, ATA, and the Rand Corporation. The complexity of and the many different interests affected by policy issues surrounding a NHII justify a national discussion of its merits, costs and benefits before investment decisions are made. The Department of Health and Human Services recently appointed an Assistant Secretary for Planning and convened the first conference to develop a national action agenda for the NHII, important first steps in shifting the focus from promoting the concept to design and cost-benefit analysis.

Organization and coordination

Progress in addressing public policy issues and improving the return on the nation's investment in telehealth can be affected by greater coordination among federal stakeholders.

Existing mechanisms for coordinating federal agency telehealth policies, investments and activities have been less than completely effective in such areas as data collection, planning for research, information exchange and policy development. More effective coordination among federal stakeholders is necessary to raise awareness, share information and increase return on investment, and parallels the need to coordinate and, where appropriate, integrate federal research, programs and resources for converging healthcare technologies. A more systematic approach to coordination might include an interagency working group for healthcare technologies with specific responsibilities and the authority to carry out those responsibilities.

More effective coordination of planning, policy-making, and allocation of resources among government, academic and private stakeholders is needed to achieve more efficient solutions and to realize telehealth technologies' potential.

Processes currently available for coordinating federal, state and private sector activities are less than completely effective. The absence of a coordinative process resulting from the fragmented nature of the telehealth community limits opportunities for technology and information diffusion, the efficiencies of a larger and more integrated market, and the kinds and levels of synergies that should lead to greater innovation, demand and investment. It has been noted that a critical mass of telehealth programs that could collaborate on research has not existed until recently. As programs gain experience and the merits and benefits of collaboration are recognized, there will be both greater need for coordination and greater opportunities for collaboration.

Convergence of such healthcare technologies as telehealth, healthcare informatics and eHealth warrants a more comprehensive, systematic and coordinated approach to research, development, testing and evaluation.

A more general description of healthcare technologies would include telehealth, medical devices, healthcare informatics, eHealth, and, perhaps, assistive technologies. Each of

these technologies shares the same policy issues as well as the same potential for transforming the nation's healthcare enterprise. Until recently, each of these technologies has innovated, grown, developed standards, and addressed policy issues independently. Coordination among planners, policy-makers, researchers and program managers is essential to insure the most efficient, integrated strategies for increasing access, improving quality and reducing costs, and for assuring that public policy reflects current technologies, issues and opportunities.

The homeland security community has not yet given significant consideration to telehealth technologies when assessing healthcare needs or available resources.

Because telehealth has not been a major player at the national level, its value to homeland security and healthcare in general has been largely overlooked. The assessment of telehealth and other healthcare research and technology needs should comprise an important and early undertaking within the Department of Homeland Security's science and technology framework.

Telehealth technologies could also contribute significantly to protecting public health. For example, development of epidemiological detection and surveillance information systems by the Centers for Disease Control and Prevention and various states should not overlook the hundreds of telehealth networks as a currently available infrastructure. Planning for surge capacity should also include consideration of remote telehealth providers as extensions of local healthcare providers and facilities.

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.

Telehealth has been widely adopted and applied by the nation's defense and veterans health enterprises for several years, having realized and demonstrated the benefits to access, quality and cost of integrating technology with healthcare. Although enthusiastic about sharing lessons learned, the civilian sector has yet to fully benefit from DOD and VA research, innovation, know-how and experience through technology transfer. Reasons for this lag may include the high cost of research, and more effective technology transfer through channels that are not exclusively telehealth or even healthcare.

Data

Innovation, demand and investment in telehealth will be impeded as long as evidence of its clinical efficacy and cost-benefit is unavailable or not widely accepted.

The telehealth community's inability to prove efficacy and produce cost effectiveness data through high-quality, peer-reviewed clinical studies is often perceived as a barrier to resolving such diverse issues as provider acceptance, third party payer reimbursement, and liability. Further, lack of rigorous cost-benefit or business case analyses has made it difficult for innovators to justify public funding for developing mainstream applications for telehealth. Direct and indirect benefits of undertaking such studies include the

identification of healthcare's technology needs and the value of technology innovations that will, in turn, justify public funding.

The varied and, in some cases, competing interests of providers, payers and technology suppliers dictate that these studies be undertaken by competent but disinterested third parties. The Department of Health and Human Service's Agency for Healthcare Research and Quality (ARHQ) seems a likely choice, but the challenge of its many research priorities competing for limited funding suggest that an ARHQ program or appropriation specifically dedicated to analyses of the efficacy, cost-effectiveness, cost-benefit and business case of telehealth and other healthcare technology applications would be most effective.

Where high quality clinical and cost-effectiveness studies are being conducted (e.g. Veterans Affairs), it is important that those results are shared with the Centers for Medicare and Medicaid Services, private third party payers, the Agency for Healthcare Research and Quality, healthcare providers, and numerous other stakeholders. A coordinated effort to catalog and distribute clinical studies for the nation's healthcare providers would also be useful.

Innovation, demand and investment data important to telehealth program managers, policy makers, exporters and investors is not readily available.

Despite the substantial amount of available research and data relating to healthcare, telehealth program managers, policy makers, exporters and investors sometimes lack fundamental data upon which to base analysis and make decisions. A primary reason for this information gap is limited public and private coordination, prioritization, and funding of data collection, research and evaluation.

Industry and trade data and market research and analysis is limited for the lack of U.S and international classifications and codes specific to telehealth and other important healthcare technologies. Although the process for adding classifications and codes is long and arduous, the additional data that could be generated as a result would assist stakeholders in conducting more accurate cost-benefit, business case and market analyses.

Competitiveness

Despite being regarded as one of the world's leading innovators and suppliers of telehealth technologies, U.S. firms' participation in international markets is limited.

The U.S. healthcare sector is internationally recognized as one of the world's most innovative and competitive, and this reputation carries over into the area of telehealth technologies. Telehealth consulting and engineering services could be as marketable as the products themselves because American know-how in designing, developing and deploying successful installations is very highly regarded. Many telehealth firms, however, have neither the resources nor the size to support significant product and services export campaigns. Other nations such as Canada, the U.K. and Japan appear to have recognized the international market potential for telehealth and other healthcare technologies, and appear to be succeeding in markets unattended by U.S. firms.

Chapter 1 – Background and Methodology

The original purpose of this study was to analyze the current state of telehealth technology and identify barriers to the development and adoption of telehealth innovations, including such longstanding policy issues as access to health care within medically-underserved areas,[5] interoperability, reimbursement, privacy, and security. Many of these same issues were highlighted in a GAO report entitled "*Telemedicine: Federal Strategy is Needed to Guide Investments.*"[6] On the surface, it would appear that little has changed since that report was issued in 1997. What limited progress there has been in resolving such issues can be attributed to a very recent and concentrated effort by such stakeholders as the American Telemedicine Association (ATA), the Center for Telemedicine Law, and the Office for the Advancement of Telehealth (OAT) within the Department of Health and Human Services (HHS).

The report's title "Innovation, Demand and Investment in Telehealth" was chosen because of the importance of all three functions. Innovation is important to telehealth because it creates the potential to increase access to, improve quality of, and reduce the cost of the nation's healthcare. Demand is important to telehealth because it encourages innovation and investment. Investment is critical because it supports both innovation and the capacity to meet demand.

The convergence of healthcare technologies and policies with those of homeland security added another important dimension to the study. The nation's inventory of telehealth networks and other technology resources offers an extensive existing infrastructure upon which to build sound and strategic healthcare defense and response capacities. Additionally, telehealth's relationships with information technology (IT) and telecommunications make it a logical and significant building block that should be included in ongoing discussions of a national health information infrastructure.

These added dimensions convergence both expanded the scope of this study and underscored the need for a "systems approach" for research and analysis.[7] A "systems approach,"[8] for example, begins with a comprehensive inventory of current and proposed national, regional, state, local and private health programs and initiatives ("systems") that might have some impact on telehealth. Integration presents one of the biggest challenges to telehealth. There are hundreds of "stovepipe" telehealth systems already in use. Within many enterprises, such as the Department of Defense, integration of these systems is a logical next step.

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[5] Also referred to as "Health Professional Shortage Area" or HPSA.

[6] "Telemedicine: Federal Strategy is Needed to Guide Investments," U.S. General Accounting Office Report GAO/NSIAD/HEHS-97-67, February 1997

[7] A "systems approach" entails close examination of healthcare and homeland security "systems" (end-to-end rather than point-of-care) and was considered necessary to address a very broad array of technical and policy issues and subjects.

[8] The study team adapted the methodology recommended by the Project management Institute in their *Project Management Book of Knowledge* to the comprehensive scope of this subject.

Table 1(a) shows a few of the more visible national initiatives, while the chart at Appendix A includes major current and proposed national and regional health information systems. There are numerous other healthcare systems managed by states, institutions, and private payers. System sponsors should continually update their awareness of what other systems are proposed or operational in order to leverage the efficiencies and cost savings that could result from integration.

Table 1a: National Healthcare Systems Initiatives, 2002

Initiative	Primary Sponsor	Status
National Information Architecture	Rand Corporation	Proposed
National Health Information Infrastructure Initiative (NHII)	HHS	Proposed
NEMCON	American Telemedicine Association	Proposed
eHealth Initiative	HRSA with eHealth Initiative	Demonstration
Bio-Defense Initiative	Southern Governors Association	Planning
National Epidemic and Disease Surveillance System (NEDSS)	Centers for Disease Control and Prevention (CDC)	Development
Health Alert Network (HAN)	CDC	Partially operational
Veterans Information Systems Network (VISN)	Veterans Affairs	Operational
Tri-Care On-Line	Department of Defense (DoD)	Operational
OASIS	Medicare (CMS)	Operational

Because each of these systems involves healthcare informatics, telecommunications networks and national policy in some fashion, each should be analyzed for how current telehealth applications and networks could be integrated.

Methodology

Over 40 interviews were conducted with individuals who are leaders and/or users of telehealth, each of whom represented the unique perspective of a specific stakeholder

group. A common factor among telehealth stakeholders interviewed, however, was their enthusiasm and belief in its efficacy and potential. "Champions" of telehealth technology have committed themselves to its diffusion. Interviews included stakeholders from each of the following categories:[9]

1. Government agencies funding telehealth
2. Non-profit industry and trade associations
3. Military
4. First respondebrs
5. Public health departments
6. Healthcare institutions
7. Clinicians
8. Manufacturers and services firms (suppliers)
9. Payers
10. Consumers

Primary sources of information were the American Telemedicine Association (ATA), a trade, industry and professional association representing different stakeholders, and the Office for the Advancement of Telehealth (OAT) of the Department of Health and Human Services. Many of the nation's "telehealth centers of excellence" receive at least some of their initial funding through OAT grants. The support and participation of these two entities will be essential to implementing solutions that might be generated by this study.

In addition to interviews, on June 19, 2002, the Department of Commerce's Office of Technology Policy, Technology Administration held a "roundtable" discussion with 28 public and private leaders in the fields of telehealth, healthcare, and homeland security. Discussion focused on issues and solutions related to innovation, demand, and investment in telehealth, and points raised are referenced in this report. Transcripts of the Roundtable discussions can be found at the Technology Administration web site at www.technology.gov.

Analysis also included an extensive literature search to include Web sites for and publications of ATA, OAT, the Association of Telehealth Service Providers (ASTP), the Telehealth Information Exchange, the journals *Telemedicine Today*, *Telehealth Journal and eHealth*, and *Telemedicine News*, and such on-line databases as *MedLine* and *PubMed*. These sources, in conjunction with primary data collection, yielded a wealth of information on stakeholders' interests, issues, and proposed solutions (see Table 1.b).

Table 1(b). **Issues of Primary and Secondary Importance to Stakeholders**

Stakeholders	*Homeland Security*	*Access*	*Quality*	*Cost*	*Innovation*	*Competitiveness*
Homeland Security	P	P	P	P	P	S

[9] There were other organizations that do not consider themselves telehealth stakeholders but perhaps should (e.g. the National Guard, the fire system, and international development agencies).

First Responders	P	P	P	P	S	S
Public Health	P	P	P	P	S	S
Military	P	P	P	P	P	S
Clinicians	S	S	P	P	S	P
Payers	S	S	P	P	S	P
Consumer	P	P	P	P	S	S
Telehealth Manfuacturers and Vendors						
Products	S	S	P	P	P	P
Services	S	S	P	P	P	P

P = Primary, S = Secondary

In the private sector, stakeholders include manufacturers and services firms (suppliers), health care providers, third party payers, and patients. The American Telemedicine Association (ATA) and several other industry groups represent manufacturing stakeholders as well as healthcare providers. Because telehealth is not considered a medical specialty but provides fairly specialized products or clinical tools for many specialties, it falls outside the fields of such influential groups as the American Medical Association and the Advanced Medical Technology Association (ADVAMED). ATA is attempting to forge strategic alliances with such groups.

ATA also represents other, non-vendor members such as clinicians, nurses, supporting industries, and business services. These stakeholders often participate in other trade and professional associations or advocacy groups that may attempt to influence policy. The Center for Telemedicine Law, for example, provides research and positions on such federal and state issues as licensure and reimbursement. Federal members of ATA may also participate in the federal interagency "Joint Working Group on Telemedicine."

Chapter 2 summarizes research, development, and innovation taking place in the field of telehealth, and attempts to identify both research and technology "gaps." Many of these gaps represent the "needs" or "requirements" of homeland security, the military, public health, clinical healthcare and other sectors of the healthcare community.

Chapter 3 describes and summarizes the "market" for telehealth technologies, and identifies what actions and policies may be necessary to unleash demand. Some of the more complex and difficult "barriers" are discussed in this chapter because of the considerable impact those issues have on demand . . . the engine that drives innovation and investment. Any issue that affects demand, therefore, will likely impact every other dimension of telehealth policy.

Chapter 4 addresses current investment and what would be required to increase access, especially for medically underserved areas. As with any investment in the development and adoption of new technologies, public and private investment decisions must consider returns or the relationship of cost to benefits, a primary focus of this chapter. The chapter also discusses alternative approaches and possible incentives for increasing investment,

and what “business models” experts in the field have suggested might be applied to grow and sustain telehealth diffusion in the private sector.

Lastly, findings have been prepared and presented to correspond with the report’s narrative discussion. These findings are intended to “baseline” a dynamic inventory of ideas directly and indirectly related to innovation, demand, and investment in telehealth. Rather than using this report to catalog all the secondary findings and recommendations, however, it was determined that the most productive way to move forward with identifying and strategizing solutions was through informal discussions with appropriate stakeholders.

It is hoped that this report and its findings will be used, built on, and improved by the many stakeholders that have an interest in telehealth to baseline the state of innovation, demand and investment in, to track progress in removing barriers to, and to serve as a reference and starting point for future studies of telehealth in the United States.

Chapter 2 – Innovation in Telehealth

> *The convergence of information technology and telecommunications, including Internet technologies, is emerging as a key tool to drive increased efficiency and effectiveness in health systems worldwide. With part of its roots in medical research for military and space applications, telemedicine is expected to make it possible to link medical expertise with patients in the most distant locations--providing clinicians with valuable new tools for remote monitoring, diagnosis, and intervention.*[10]

A 1997 Kaiser Permanente study of telehealth concluded that "technology in healthcare can be an asset for patients and providers and has the potential to save costs; therefore, this technology must be a part of continuous planning for quality improvement."[11]

It is widely claimed and often assumed that innovation in healthcare technologies can contribute to increased access to and improved quality of care, reduced costs, and better national security. With healthcare expenditures of over $1.5 trillion projected to account for 13 percent of U.S. GDP in 2002,[12] even incremental improvements in delivery can have a significant economic impact. Although telehealth technologies currently account for a small segment of all healthcare technologies (an estimated $380 million out of $71 billion nationwide and $169 billion globally), innovation in this area could spur significant improvements in sector productivity and quality of life.[13] Today, after more than 30 years of telehealth, that potential has still not been fully realized. This Chapter assesses telehealth technology and research and identifies barriers to innovation that have impeded its potential.

TECHNOLOGIES

Telehealth focuses on the transfer of basic patient information over networks and the diagnosis, treatment, monitoring, and education of patients using systems that allow access to expert advice and patient information. A technical definition of telehealth technology would include those devices and software that enable healthcare providers and educators to diagnose, consult with, monitor, treat and educate patients and consumers remotely. In order for the devices and software to be effective, however, it is necessary to integrate technology with healthcare applications and clinical procedures. The integration of devices and applications with clinical processes must then be

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[10] "Technology Forecast" from *Medical Device Link*, at http://www.devicelink.com/mddi/archive/00/01/012.html

[11] Barbara Johnston, *RN, MSNM&L;* Linda Wheeler, *RN, MSNM&L;* Jill Deuser, *RN, MBA;* Karen H. Sousa, *RN, PhD* "Outcomes of the Kaiser Permanente Tele-Home Health Research Project" from the *Archives of Family Medicine*, January 2000. View the 1997 study at: http://archfami.ama-assn.org/issues/v9n1/ffull/foc8072.html#a4.

[12] U.S. Centers for Medicare and Medicaid Services, *Health Care Financing Review*, Summer 2001.

[13] Source: Commerce Department (See Table 3.a).

integrated with provider workflow or protocols that would add value to a network of providers and patients. This innovation continuum may be characterized as:

Need identified	→	Applications developed	→	Devices developed	→	Integration with clinical protocols	→	Programs developed

Effective functioning requires proper infrastructure, to include the physical facilities, setup, and equipment used to capture, transmit, store, process, and display voice, data, and images. For example:[14]

1 "Capture" devices such as digital and video cameras, radiographs (e.g. x-ray images), and physiologic monitors (e.g. EKGs, oxygen saturation monitors);
2 Basic telecommunications and networking of computer systems;
3 Communications software, including electronic mail and browsers for the World Wide Web; and
4 Forms of telecommunications, including videoconferencing, remote data monitoring and file transfer, applicable to medical care in remote or rural areas.
5 Electronic data storage facilities (e.g. disk arrays to store patient records and/or digital images).

[14] Guler, Nihal Fatma and Elif Derya Ubeyli. "Theory and Applications of Telemedicine." *Journal of Medical Systems*, vol. 26, No. 3, June 2002. p. 202.

Table 2.a Telehealth Technologies

TECHNOLOGY	EXAMPLES OF DEVICES and SOFTWARE	EXAMPLES OF APPLICATIONS[15]	WHO INNOVATES
Remote Monitoring	Sensors Instruments Ultrasound	Bio-defense Telehomecare	Laboratories Sensor manufacturers Telemedicine centers Military/VA
Diagnostics	Otoscope Stethoscope EKG	Consultations Telehomecare	Medical device manufacturers
Videoconferencing	Cameras (Videocams, Webcams) Computer-based desktops Portable communications and data systems	Consultations Teledermatology Telementalhealth	Videoconferencing manufacturers
Digital imaging	Instruments Media (e.g. film, magnetic tape) Scanners/Viewers Digital cameras Videocams with scopes	Telepathology Teleradiology Teledentistry Teledermatology TeleENT, TeleGI	Laboratories Instrument manufacturers Media manufacturers
IT	Data storage systems Servers Software/Informatics/ Middleware	Electronic medical record Data mining Syndromic surveillance Web portals Decision-support systems Administration	IT manufacturers Systems integrators Software developers Database developers Webmasters
Networking/ Interfaces	Hubs, routers, servers "Black boxes" System software	Interoperability Internet/intranet Hub and spoke networks Mobile data transmission	IT/telecom manufacturers System integrators
Robotics/Remote Controls	Instruments Controls Viewers	Telesurgery Telepathology Homeland security	Instrument manufacturers Control manufacturers Defense Advanced Research Projects Agency (DARPA)
Store-and-Forward	Data/image/video/audio card capture/scanners Computer/camera/microphone & image management software	Electronic medical record Report generator	Card capture manufacturers Scanner manufacturers Software developers
Simulation and Training	Multi-media graphics Software Audio-visual	eLearning Curriculum Conferencing	Multimedia firms Software developers

Current telehealth technologies can be grouped into at least nine broad categories (Table 2.a), each of which includes both devices/equipment and applications. Each of these categories overlap and intersect. For example, information technology (IT) systems (hardware, software, and microprocessors) are a central component of all technologies.

Telehealth technologies may also be classified according to the point in time when the encounter is transacted: *store-and-forward* (asynchronous) and *interactive* (synchronous). *Store-and-forward* technology[16] is a lower-cost method of transmitting images by computer. This technology is currently most frequently used for transmitting radiological

[15] Applications developed to incorporate a device into the healthcare process can be defined by function, end-use, or nature of the user. For example, a stethoscope can be categorized as a listening device for a broad variety of functions, as part of a heart monitoring application as an end-use, and emergency response as the nature of the user.

[16] Store-and-forward technology allows the provider to perform a procedure, store the procedure for a later use, or forward the procedure to another location for further activity.

and dermatological pictures, and is employed by hospitals and clinics across the country. *Interactive* telehealth implies face-to-face interaction with a patient, health professional, or both, and requires audio, full-motion video, and still images. Although both categories are sometimes used in conjunction with one another, store-and-forward technologies are more widely used due to lower start-up and sustainability costs, and increased flexibility and productivity in scheduling encounters and managing workload.

This method of categorizing telehealth technology is important when discussing third party reimbursement. Because store-and-forward does not feature a "real-time" encounter between a patient and a healthcare provider, the application is not currently being reimbursed by Medicare. It is very likely that this issue will become more important as store-and-forward technology becomes more commonly-used and more cost-effective. In the meantime, this lack of reimbursement represents a barrier to further investment and a disincentive to use by clinicians. [17]

Leaders in the field of telemedicine/telehealth suggest that the current state of technology is moving from its second generation into its third.[18] The *"first generation"* can be traced as far back as far as the 1950s. "One of the earliest uses was at the University of Nebraska where psychiatric consultations were conducted on two-way closed-circuit TV using microwave technologies."[19] The *second generation* might be dated from 1989, when then Secretary Bowen of the Department of Health and Human Services directed its Health Resources Services Administration (HRSA) and the Centers for Medicare and Medicaid Services (CMS - formerly the Health Care Financing Administration) to fund a telemedicine project call "the MedNet Project (now HealthNet) at Texas Tech University. Until then, telehealth was limited to a few medical specialties such as radiology and focused on either store-and-forward or video conferencing applications. That generation was characterized by specialized devices that did not interface easily with other devices and were not well integrated with clinical protocols. This lack of "interoperability" and technical know-how frequently led to user dissatisfaction and may have created a negative image of telehealth products and services within the traditional medical community. [20]

Teleradiology was one of few technologies that developed quickly during the *first generation* of telehealth, to become the first specialty to establish a record of interoperability and sustainability. [21] A telehealth technology CEO suggested that "teleradiology is most successful because the specialty (radiology) is made up of professionals who are already technical." Other reasons for its success included the

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[17] For an in-depth treatment of this and other issues, see: "Telemedicine: Follow the Money," by Dr. Dena Puskin, *Online Journal of Issues in Nursing* September 2001, *at* http://www.nursingworld.org/ojin/topic16/tpc16_1.htm

[18] A generation is defined as a period of time in which stakeholder interests and technological development are at a similar stage. A generation changes when breakthroughs occur in technologies and innovation moves quickly to a different level.

[19] For more history of telehealth, see "Telecommunications for Nurses, 2nd Edition," Armstrong and Frueh (editors), "An Overview of Telemedicine: Through the Looking Glass," (D.S. Puskin), Springer Publishing, 2003

[20] Mark Newburger, CEO of Apollo Telemedicine and a panelist at the Technology Administration's Roundtable "Innovation, Demand and Investment in Telehealth," June 19, 2002 in Washington D.C.

[21] *Ibid.*

development of private teleradiology services that have already proven sustainability, and because x-rays, sonograms and other images have been consistently reimbursed by Medicare and other payers.

With the *second generation*, users demanded greater ability to integrate with legacy systems and peripheral devices, and manufacturers responded with multi-application systems. Successful first generation telehealth applications -- such as monitoring, radiology and video-consults - were joined by other specialty applications such as dermatology and pathology. Most first and second generation technologies were based in some way on remote monitoring, video conferencing, or digital imaging technologies.

Technological advances in videoconferencing and digital imaging are now well into a *third generation* of telehealth. Several factors account for the faster pace of innovation in these technologies and their attendant applications: the underlying technologies are multi-use, the broadcast infrastructure is stable, there is little FDA regulation, cost effectiveness is more evident, and their market is much broader than simply healthcare.

Other drivers that are moving technological innovation toward a third generation of telehealth technologies and applications include:

Technology related drivers:

1. decreasing costs of telecommunications technologies
2. decreasing costs of telehealth devices and applications
3. progress toward resolving the longstanding issue of interoperability
4. convergence of telehealth technology with telecommunications, IT and the Internet

Market related drivers:

1. increasing emphasis on reducing cost and increasing quality of healthcare
2. increasing demand for homeland security and public health technologies
3. more clinical and econometric studies concluding that telehealth meets expectations
4. rapidly increasing demand for home healthcare
5. incremental changes in payer reimbursement policies and increased levels of Medicare and other third party reimbursement
6. increasing awareness by providers and consumers as a result of government investment in "demonstration projects"
7. increasing acceptance by medical professionals and institutions

INNOVATORS

Telehealth research since 1975 includes a mix of public and private sector R&D, clinical studies, and demonstration projects. Federal departments and agencies, state and local governments, universities, private foundations, manufacturers, insurers, and other sources provide varying amounts and forms of research funding. Technology and research efforts span a wide range of organizations and medical specialties – from military medical commands to rural clinics, from major medical centers to the needs of sparsely populated regions and territories. This diversity (and fragmentation) complicates quantitative

analysis of R&D expenditures, as well as the collection of information about current and required R&D and technology transfer.

Following is an overview of research and innovation activities in three broad stakeholder groups: federal and state governments and the private sector.

Federal and State Governments

Table 2b – Federal Research and Program Funding (FY2000-01)

Department	Agency or Bureau	Nature of Research or Program	Nature of Technologies	FY2000 Funding $million	FY2001 Funding $million
Agriculture	Rural Utilities Service	Program grants	Distance learning and telemedicine	25	25
Commerce	NTIA	Demonstration Projects	Network Infrastructure	15.5	15.5
	NIST (ATP)	Tech commercial High-risk, enabling tech development	Various	3	3
Defense	DARPA	Applied		<1	<1
	Army				
	TATRC	Applied	Remote access, warfighter	100	100
	AMEDD	Applied	Web-based triage	3.1	3.6
	Navy	Applied	Shipboard applications	*	20
	Air Force	Applied	Various	*	11.5
Education		Applied	Rehab/Assistive tech	*	*
Energy	Sandia	Applied	Robotics	*	*
		Applied	Diagnostic devices	*	*
	Oak Ridge	Applied	Sensors	*	*
		Pure	Sensors	*	*
HHS	AHRQ	Evaluation		*	*
	HRSA (OAT)	Demo Projects[22]		34.5	34.7
	HRSA (ORHP and other HRSA)	Demonstration projects	AHEC, Community Health Centers, Rural development	*	13
	CMS	Demo Project		6	6[23]
	FDA	Demo Projects		*	*
	NIH NLM NIBIB**	Applied Demo projects	Next generation Internet	45	45
Justice	Bureau of Prisons	Clinical	Consultations Cost-benefit	*	*
NASA		Pure Applied	Remote monitoring	10	10
VA		Applications Clinical	Ongoing programs Efficacy Studies	45	45
FCC	USAC	Subsidies	ERate	*	18
*** Data not available** **TOTAL** **** Began telehealth initiatives in FY2003**				**287**	**332**

Public sector research and innovation are centered on applications (including software) and programs, but not devices. Federal civilian and state R&D is most often associated with "demonstration grants." Attempts have been made to quantify public investment in

[22] Amounts include Congressional earmarks.
[23] Amount for CMS represents one year of a five-year, $30 million demonstration grant managed by Columbia Presbyterian.

telehealth in the past but have been largely unsuccessful because agencies are not required to either collect or report on their telehealth investments. Although data are not easily identifiable, it is estimated that in FY2001, federal agencies spent at least $332 million for military and civilian telehealth research and programs. That amount grew in FY2003 as recent legislation included funding for telehealth infrastructure, programs, and projects, and as homeland security research, program development, and procurement were funded. Table 2.b was constructed from limited information available from federal agencies and other sources.

Within the federal telehealth community, the Department of Defense (DoD), Department of Veterans Affairs (VA), and the Department of Heath and Human Services' Office for the Advancement of Telehealth (OAT) account for most federal telehealth spending. DoD (and, more specifically, the Army) is far and away the federal research leader with such programs as:

- the Army's Telemedicine and Advanced Technology Research Center (TATRC) at Fort Detrick, Maryland, which commands a budget of over $100 million for research into a broad array of healthcare technologies.
- the Army Medical Department (AMEDD), which sponsors a "Competitive Telemedicine Program" where individual Army medical units compete with each other for funding for innovative programs. This program nearly doubled in the number of proposals submitted from FY2000 to FY2002 and currently funds 25 projects at slightly over $4 million.
- the Navy's "Global Digital Teleradiology Network" including ships at sea.
- the Defense Department's "Akamai" program in the Pacific theater.
- the Armed Forces Institute of Pathology which is currently developing a web-based telemedicine program using a browser for viewing images, and store and forward application software.

On the civilian side, the Department of Veterans Affairs (VA) operates the nation's largest telehealth program with more than three hundred thousand teleconsults annually. Like the Department of Defense, VA is considered a "closed system" that includes patients, providers and payers, and is not significantly affected by the need to annually compete for grant funding. It therefore offers the size and stability necessary to provide one of the best available "testbeds" for research, development, standards, clinical efficacy and cost-benefit studies, and needs assessment. VA is also considered unique among telehealth programs because its leadership has taken on the role of "early adopter" of healthcare technologies, and has been adequately funded to procure and integrate telehealth with clinical medicine on a very broad scale.

HHS' Office for the Advancement of Telehealth (OAT) and Agriculture's Rural Utilities Service (RUS) are the largest federal programs outside the DoD and VA with telehealth programs/networks in 43 states and 2 territories. OAT's guidance to grantees is a 40%/60% ratio of equipment to operations.[24] OAT's demonstration grants would be

[24] OAT emphasizes the development of operational infrastructure within its programs, not equipment. There is also a "symbiotic" relationship between OAT and the National Library of Medicine wherein the latter examines information requirements needed for technology to assist in a clinical diagnosis or treatment, and OAT examines the practical issues of cost-effective deployment and utilization of those technologies.

considered installations within an "open system" in which business principles such as financial planning and reporting, sustainability, and marketing apply.[25] In addition to demonstrating technological benefits, grantees are expected to demonstrate the merits, and increase provider and patient awareness, of telehealth as an effective healthcare technique.[26]

There would appear to be a symbiotic relationship among DoD, VA, and OAT. For example, DoD leads in developing technology, VA leads in both volume of encounters and in the integration of telehealth with medicine, and OAT leads in the diffusion of telehealth within the civilian sector. Additionally, the VA and DoD currently cooperate on several pilot projects and in a policy-making forum that has made significant headway in credentialing and workload credit for teleconsultation and patient-provider eMail.[27]

Greater coordination among these three agencies' telehealth programs could be expected to increase: 1) prioritization of high quality research, efficacy, and cost-effectiveness studies; 2) diffusion of telehealth information and technology between the military/veteran and civilian sectors; 3) the use of VA as a more expansive "test bed" for new devices, applications and standards; 4) the complementary roles of DoD as innovator, VA as early adopter, and OAT as diffuser. In addition to demonstration projects, federal research also touches on the very clinical (i.e. the development of robots for surgery), the programmatic (e.g. evaluating the cost effectiveness of telehomecare), homeland security (i.e. research, development, testing and integration of sensors and syndromic surveillance), and the very technical (i.e. applying Internet2 to network architectures).

Most states and some local governments fund telehealth research, programs and procurement, generally with the goal of supporting program infrastructure, project development, or feasibility studies. A number of states have developed statewide public and private strategies for increasing access to quality healthcare through telehealth technologies. In several cases, states have organized "taskforces" responsible for assessing needs and assessing factors affecting telehealth adoption and deployment. For example:

> Arizona provides money from a variety of sources to support the University of Arizona Telemedicine Network, funds pilot studies documenting whether telemedicine contains health care costs, and studies the feasibility of providing healthcare within the state corrections system via telemedicine.[28]
>
> Texas has, through its Statewide Health Coordinating Council (SHCC), conducted research on and prepared an extensive report titled "The State of

[25] Unlike a "closed system" such as VA or DoD where, for example, common business principles such as supply and demand are less relevant.

[26] Federal demonstration projects and pure and applied research are frequently managed through public/private partnerships, and vary from operational clinics to cooperative research to personnel exchanges to licensing technologies.

[27] "Workload credit" refers to a process for recognizing value added to the clinical process when performed electronically, such as when a provider (clinician) respond to a patient's eMail inquiry. The workload credit may be linked to billing as well, although capturing the value of electronic activity such as eMail is still largely a manual process.

[28] State Law Update, Center for Telemedicine Law.

Telemedicine and Telehealth in Texas." In preparing this report, the Council brought together stakeholders from throughout the state to develop a strategic plan and to explore solutions to policy and technical issues, an approach that may serve as a model for other states, localities, and the federal government. The SHCC has been conducting research through such pilot programs as telehealth and distance learning programs within rural and remote schools.

The primary mission of Florida's Center for Research on Telehealth and Healthcare Communication is to facilitate collaborative multidisciplinary research on telehealth, both within the state's university system and in health science centers across the nation. The Center is funded by a combination of grants from NIH's National Institute on Disability and Rehabilitation and Research, the Department of Veterans Affairs, the Florida Department of Elder Affairs, and the Robert Wood Johnson Foundation.

The Texas legislature also established the "Telecommunications Infrastructure Fund" (TIF) in 1995 and allocated $1.5 billion over 10 years to promote and develop a statewide telecommunications infrastructure to include grants to health care facilities and schools. The future of this program is uncertain as its initial life cycle draws to a close. In contrast, California created the "California Telehealth and Telemedicine Center" with support from private foundations.

Universities

Some of the most innovative and important research is taking place at the nation's public and private universities, frequently through "Telemedicine Centers" attached to their medical and nursing schools. University research may include both technological innovation and sociological studies focused on delivery of health care to underserved populations. It appears that universities located in states with substantial remote and rural medically underserved populations such as Texas, Tennessee, Alaska, Montana and North Carolina produce some of the nation's most active and innovative research and telehealth programs.

University telehealth programs may leverage grants from OAT as well as funding from state government and private foundations. While the focus of their funded research and innovation may be on devices and applications, the connection with academic medical centers provides a stable and significant patient population, as well as the research and teaching environment and capabilities of the university and medical schools.

- The Arizona Telemedicine Program run in conjunction with the University of Arizona's Health Science Center receives $85 million a year in research grants that enable state-of-the-art treatment for patients and up-to-date healthcare information for students. The Colleges of Medicine, Nursing, Pharmacy, and Public Health and the University of Arizona School of Health Professions participate in the program. The program has partnerships with a variety of not-for-profit and for-profit healthcare organizations and has created new interagency relationships within the state government. Additionally, the state has received grants OAT, USDA's Rural Utilities Service, Commerce's National

Telecommunications and Information Administration, HHS' National Library of Medicine and the DoD.[29]

A number of university telehealth programs also benefit from technology collaborations with private corporations. For example:

- The University of Texas (UT) joined VTEL, Sprint, and NASA to demonstrate direct visual examination of patients in remote locations, in a project designed to serve Hispanic children living in medically underserved areas of south Texas. The project used video teleconferencing, a document camera for transmitting x-rays, and a microscope camera that permits the transmission of bone marrow biopsy slides.

- UT's Medical Branch in Galveston (UTMB) also partners with the SBC Foundation in supporting a telehealth research center. A $1 million grant provided by the philanthropic arm of SBC Communications allows center researchers to evaluate the effectiveness of healthcare technologies using rigorous scientific methods. The center collects data not only to demonstrate effectiveness of technologies and applications, but also to help guide public and private insurers in developing reimbursement policies.[30]

One feature of many successful university programs is the very technical background and technological interests of the telehealth center staff and researchers.

- The Telemedicine Center at East Carolina University (ECU) in Greenville, North Carolina has emerged as a national innovation leader, largely due to the enthusiasm of its director and its willingness to recruit top-level technologists and to develop experimental technologies. For example, ECU technologists have addressed the issue of interoperability by developing a "black box" which acts as an interface to as many as twelve different devices at once.

- The Telehealth Center at the University of Tennessee (Knoxville) is another technology innovator led by an engineer who had previously designed medical devices. Research and development relating to human factors in videoconferencing has resulted in advancements in teleconsultation systems.

- The telehealth program at the University of Vermont is led by a vascular surgeon with extensive technical skills who has conducted research in using telehealth for trauma care in rural areas.

University innovations are not focused only on rural applications. For example, the interests of an ophthalmologist at Charles R. Drew University of Science and Medicine led to a research grant from the Los Angeles County Community Development Commission in 1996 for the "Urban Telemedicine Demonstration Project". This project was designed to evaluate the use of telehealth in providing increased eye care to [atients in inner city Los Angeles. The doctor established "partnerships" with private sector

[29] Source: *Federal Telemedicine News, 1/6/03*. For more information on the Arizona program, see http://www.federaltelemedicine.com/n010603.htm

[30] From "*Telemedicine Today,*" October 2002. at http://www.telemedtoday.com/newslinks/

telehealth technology companies and leveraged donations of equipment, software and connectivity to become a pioneer in the field of teleopthamology.[31]

Private Sector

In contrast to federal, state, and local research – much of which focuses on specific applications within specific, individual projects – most private sector firms concentrate their research on technological innovations in specific medical areas such as pathology and homecare.

This is a function of how telehealth firms were founded - generally by an individual who developed a product or service around a particular technical skill or interest. Business growth and consolidation require a broader approach to both research and product development, such as designing multi-use products for a broader range of customers. In successful firms, greater attention is paid to both product and market research in order to gain and maintain market share, and, if necessary, to compete with multinational corporations entering the market with considerable resources.

The following are a few examples of applied research taking place within the nation's small, medium, and large companies:

Table 2.c Examples of Private Sector Research and Development

Technology	Examples of research	Firm Size
Digital imaging	Replacing film with digital radiographs	Large[32]
Epidemiological detection and surveillance	Developing sensors and linking sensors to algorithmic databases	Medium[33]
Remote monitoring	Linking devices (e.g. pacemakers) to remote monitoring instruments	Medium
Distributed measurement and control architectures	Homecare patients completing diagnostic procedures and then transmitting results to providers	Small[34] and medium
Televideoconferencing	Telepsychiatry	Medium
Distributed diagnostics	Linking devices to information systems	Small and medium
Pathology	Linking instruments and laboratories to providers	Small

[31] For more information on this interesting project and person, visit the University's telemedicine web site at http://www.cdrewu.edu/telemedicine/Default.htm
[32] Having 500 or more employees
[33] Having more 50 or more employees but less than 500
[34] Having less than 50 employees

Research in digital imaging is being led by such large firms as General Electric, Siemens, and Kodak and is focusing on replacing film with digital radiographs for teleradiology. The practice of medicine is growing increasingly dependent on computers and networking. To be cost-effective and efficient, these networks must include x-ray images, which account for about 70% of all the imaging studies done in the United States. "Additionally, as doctors grow increasingly accustomed to the benefits of digital image display in other modalities such as MRI, CT, and ultrasound, they will demand the same from radiography and the various applications of x-ray fluoroscopy."[35] Some smaller firms also conduct research in digital imaging, focusing on monitors, application servers, and information systems.

Epidemiological detection and surveillance (i.e. "bio-defense") has gained importance and attention with the growing concern for homeland security. Although the Centers for Disease Control and Prevention (CDC) are currently engaged in a substantial undertaking to develop a nationwide system, small and medium firms are developing sensors and the kinds of algorithmic databases that would alert networks to a possible healthcare emergency situation. These technologies are also under development at federal labs, such as the Department of Energy's Oak Ridge National Laboratories which is providing leadership and public/private collaboration in the field of sensors.

Distributed measurement and control architectures allow the use of telehealth, client-server networks, and the Internet to program and receive data, and to diagnose symptoms. Small and medium-size private companies such as HealthCare Vision, Health Frontier, Health Hero, HomMed, March Networks, ATI, CyberCare, CyberNet, Cardiocom, CDX, and Creative Health Products, Inc. have emerged as early leaders in this area.

One of the nation's leaders in televideoconferencing technology, Polycom, reported that it had invested over $82 million in research and development in 2001, an amount unique to R&D spending among telehealth firms.

Research in the area of distributed diagnostics appears to be confined to a few small companies such as Apollo Telemedicine and tends to focus on incremental product improvement. Apollo's pathology network uses a subscription-based applications service provider model and remotely controlled telescopes to feed images from laboratories over a TCP/IP based network (internet or intranet) to professional pathologists.

According to DoD and VA telehealth executives, small telehealth companies are beginning to investigate funding sources for R&D such as the federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. For example, the Army's Telemedicine and Advanced Technology Research Center (TATRC) maintains 15 SBIR "topics" for which SBIR funding is available.

Some *private non-profit organizations* are also conducting telehealth research often associated with improvements in access and quality. Although new technology does not generally result from such research, studies are important in identifying research needs. One such organization undertaking prototype research is the Center of Excellence for

[35] "Digital Imaging Heralds Waning of Film Era," *Medical Device and Diagnostic Imaging*, January 1999.

Remote and Medically-Underserved Areas (CERMUSA).[36] CERMUSA is building a wireless rural telemedicine communications "test bed" at its St. Francis University facility in Pennsylvania to test and evaluate the integration of new communications technologies with cutting-edge telehealth technologies to determine the optimal means to increase access to healthcare in medically under-served areas.

> The focus of CERMUSA's prototype is, essentially, the development of a wireless communications infrastructure capable of transmitting and receiving medical information. As new communications and telemedicine technologies become available, they will be added to the "test bed." The first priority will be audio transmissions. The follow-on to audio will be to examine the ability to transmit medical data and video. This test bed will allow technologies to be tested on several different wireless frequencies and signals. This upgradeable system will examine the efficacy of communications modalities including: VHF radio, UHF radio, analog and digital cellular, 800MHz radio, and mobile satellite communications.

IDENTIFYING NEEDED TECHNOLOGIES

Needs Assessment[37]

An effective and efficient needs assessment should recognize the nation's technical, economic, and political environments. For example, increased attention to homeland security has underscored the technical and economic need for federal and private research and development to focus on "multi-use" technologies. Epidemiological surveillance and pathology are examples of much-needed public health and homeland security applications.

During a 2002 industry and provider roundtable, DoC Undersecretary for Technology, Mr. Phillip Bond asked the nation's telehealth leadership to discuss the role of the Federal government in innovation, demand and investment in telehealth. All agreed that any effort must begin with a systematic *needs assessment* or *requirements analysis.*

It would appear that, with a few exceptions, a great deal of effort or coordination has not yet been directed toward the "front end" identification of research, clinical healthcare or homeland security requirements for telehealth. This should be expected, however, since the business of healthcare is healing and not technology, and the healthcare industry has not traditionally thought in terms of "national" needs or priorities.

Events of September 11, 2001 underscored the convention that technology must meet the primary requirements of being both multi-use and interoperable. To accomplish these

[36] For more information on CERMUSA and their research, visit their Web site at http://www.cermusa.francis.edu/default2.htm
[37] Also commonly referred to in the private sector as "business analysis," "requirements identification," "requirements definition," "requirements analysis," and "requirements gathering."

requirements most effectively and efficiently, homeland security and clinical healthcare needs should be integrated at every level -- locally, regionally and nationally. Coordination of this integration project should begin with the Department of Homeland Security. The needs assessment process will not only identify current "gaps," but will also identify technology and information needs not currently being addressed and requiring additional effort and/or investment in research, development, testing, and evaluation.

Identification of areas for telehealth research requires assessment according to recognized evaluation criteria, and a prioritization which has not yet been developed nor applied. Needs assessment can play a significant role in identifying telehealth technologies (devices, applications, and program models) that can be instrumental in providing greater access to, lowering the cost of, and improving the quality and security of the nation's health. Such an assessment is also important for the development of "business models".

Needs assessment can play a significant role in identifying telehealth technologies (devices and applications) that can be instrumental in providing greater access to, lowering the cost of, and improving the quality of the nation's healthcare, increasing productivity or healthcare professionals and staff, and providing greater homeland security. A cross- or multi-specialty needs assessment could spur innovation by applying a "systems approach" to identify what new or additional technologies are needed, what technologies are available, what technologies are needed and available but not being used (and why), and strategies for researching, developing, producing, and deploying the required technologies.

Although leaders of the telehealth community generally agree on the importance of such an "assessment," there is not currently a process in place which identifies, compiles and disseminates telehealth technology needs of the nation's providers. A commonly developed and accepted collection of technology requirements beyond those identified for a few specialties and on behalf of manufacturers or customers could not be identified in the data-gathering phase of this report. The fragmentation of technology needs assessment was recognized early on, however, and stakeholders have considered this study a call for greater coordination and effort in collecting, compiling, and disseminating this information.

Some activities that might contribute to telehealth needs assessment are currently under way. The National Library of Medicine, for example, evaluates commercial telehealth, informatics and eHealth products. OAT requires its grantees to meet periodically to discuss lessons learned, and looks to the proposal process as a method of assessing technology needs. It has also developed guidance for strategic planning, technical guidelines for purchasing equipment for specific telehealth applications, and is currently developing a series of technical assistance documents for its grantees to guide them in assessing needs. Draft guidelines should be available to the public by March, 2004. Private telehealth product and services firms often routinely assess provider's needs when conducting market research prior to innovating technology solutions. How these and other efforts feed information back into the research and development process is unclear.

The ATA has made an effort to coordinate the identification of technology needs to the extent of publishing certain standards. Beginning in 2003, ATA also began to emphasize the role of its Technology Special Interest Group (Technology SIG) in identifying requirements and future technology trends. [38]

Before needs assessment can occur effectively and efficiently, it is important to understand the policy climate surrounding telehealth. Policy issues such as reimbursement and the availability of clinical studies would assist provider's decisions regarding technology needs. In addition, increased attention to homeland security has underscored a need articulated by the President that the technology be multi-use.

One of the most critical policy questions with fundamental relevance for any telehealth technology needs assessment is the need, worth and desirability of a "national health technology and information infrastructure," and attendant issues such as data privacy. For example, if providers and/or first responders are linked nationwide to sophisticated evidence-based databases, their technology needs may be quite different.

Previous efforts that might have led to a national health technology and information infrastructure include NIST's Advanced Technology Program's Information Infrastructure for Healthcare[39] (1994-1997) which focused on providing funding for infrastructural technology development to enable enterprise-wide integration of information among all sectors of the healthcare industry. By improving the quality and flexibility of the delivery of care through broad and effective access to information, the program aimed to drive down the rising costs of healthcare while raising the quality of care. It was not until the National Research Council and Institute of Medicine issued "Crossing the Quality Chasm: A New Health System for the 21st Century" [40] that the concept of a national health information infrastructure began to acquire traction. The Council's report was followed by "Information for Health: A Strategy for Building a National Health Information Infrastructure (NHII)" by the National Committee on Vital and Health Statistics. In June, 2003, HHS convened a conference to "bring together representatives of all stakeholders and to develop a consensus for a national action agenda, which will then be published and widely disseminated, and used to guide the further development of NHII." [41]

Consideration of such an infrastructure should include the converging technologies of telehealth, healthcare informatics, and eHealth as well as other healthcare devices and applications. The nation's interstate highway system, banking (ATM and credit card) network, and Internet are good examples of current national infrastructures, and may, in fact, provide models for a national health infrastructure development.

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[38] For information on ATA's Technology SIG, see http://www.americantelemed.org/ICOT/icot.htm.

[39] For more information, see Bettijoyce Lide and Richard N. Spivack, "Advanced Technology Program Information Infrastructure for Healthcare Focused Program: A Brief History," (NISTIR 6477), February 2000.

[40] "Crossing the Quality Chasm," Committee on Quality Health Care in America, 2001, Washington D.C, National Aademy Press

[41] For more information on the conference, see: http://www.nhii-03.s-3.net/welcome.htm

Approaches to Needs Assessment

There are at least three approaches to needs assessment – "top down," "bottom up," and a hybrid version of these. The "top down" approach requires high-level decisions and priorities on the direction and utilization of technologies, followed by the identification of telehealth, IT and data requirements that support those high-level goals. This approach can be undertaken with fewer resources but risks overlooking important requirements and diminishes "buy-in" by state and local stakeholders who are critical to effective implementation.

This has been the approach, for example, of the Centers for Disease Control and Prevention (CDC) in their development of the National Epidemiological Detection and Surveillance System (NEDSS) and Health Alert Network (HAN) in which they established a national framework and specifications, then funded states to develop local systems to interface with and support the national system.

The "bottom up" approach would involve surveying stakeholders at the "front lines" for their requirements, and compiling this information into a comprehensive set of national requirements. This approach develops a sense of "buy in" and participation that is important for implementation. The disadvantage is the amount of time and dollar resources required to undertake the survey, analysis and translation of clinical needs into technology requirements.

The third approach is a hybrid of the first two – a "needs assessment team" made up of professional requirements analysts and representatives of primary stakeholder groups. The team would interview leaders within each community at all levels to obtain requirements, and then compile a database of identified needs. The team would analyze needs and recommend public/private strategies for meeting those needs.

The convergence of healthcare technologies would suggest that the most efficient and cost-effective approach to needs assessment would be a comprehensive "systems approach." As such, a team should be comprised of requirements analysts familiar with devices, applications, IT, informatics and eHealth.

In April of 2003, The Army's Telemedicine and Advanced Technology Research Center (TATRC) hosted a full day "needs assessment" workshop. This session, which included 40 or more technical experts in various areas of healthcare and technology, was the first attempt at a nationwide needs assessment focusing on homeland security and bio-defense. There was productive discussion of detailed requirements and should result in a substantial step forward in understanding and identifying needs

AREAS FOR TELEHEALTH RESEARCH

Stakeholder groups with specific interests in telehealth innovation include both providers (clinicians and healthcare institutions) and suppliers (manufacturers, services firms, and systems integrators). Both groups have identified a common set of research priorities, such as the development of industry-wide technical standards integrated with medical

protocols, clinical efficacy of telehealth applications, and cost-benefit comparisons that offer compelling evidence of increased productivity and decreased costs. New telehealth technologies must also be multi-use, scalable, and interoperable with legacy systems (i.e. "plug and play") Three other common research and development requirements include interoperability, multi-use and training.

The American Telemedicine Association suggests the following seven areas as priorities for innovation and adoption. It is here that the application of current technologies and further research can significantly impact healthcare access, quality, cost, and homeland security:[42]

1. Homeland Security, CBRN/E,[43] and Public Health
2. Military
3. Convergence of Technologies
4. Interoperability and Integration/Standards
5. Medical Simulation, Training and Health Education
6. Efficacy and Cost-Benefit Analysis
7. Diffusion of Information and Technology Transfer

Homeland Security, Chemical/Biological/Radiological/Nuclear/Explosive (CBRN/E), and Public Health

A member of the President's Homeland Security Advisory Council has said:

> "A necessary first step is to more clearly define the desired outcomes—to establish national objectives for the homeland security mission. From those objectives we can devise strategies—the means to accomplish the objectives. From those strategies we can begin to identify opportunities to employ technology-based solutions. And from those opportunities, we can determine where today's products are adequate—given effective implementation—and where today's technologies fall short.
>
> Then, and only then, can we create a roadmap to guide technology investment for the homeland security mission. But rather than tasks to be completed in sequence, these steps must become elements of an ongoing process that continually adapts our homeland security posture—maintaining an asymmetric advantage over the adversaries who would threaten our homeland."[44]

[42] For more information on CERMUSA and their research, visit their Web site at http://www.cermusa.francis.edu/default2.htm
[43] Chemical, biological, radiological, nuclear, and explosion.
[44] "Homeland Security Technologies: Creating an Asymmetric Advantage," Dr. Ruth David, President and CEO — ANSER (Analytic Services Inc.) *April 2002*.

Even though the healthcare technologies industry responded early with offers of various technologies,[45] the federal homeland security community has yet to fully identify its healthcare needs, or to completely address the role of telehealth technologies in "desired outcomes," "objectives," "strategies," or "opportunities to employ technology-based solutions."

The nation's public health infrastructure was not a significant user of telehealth prior to the events of September 11, 2001 and the anthrax attacks that followed. The Centers for Disease Control and Prevention (CDC) had been developing plans and designing systems, however, to detect chemical, biological, radiological, nuclear and explosion (CBRN/E) attacks and to alert public health authorities. Prior to September 2001, the CDC had begun development of a "National Epidemiological Detection and Surveillance System" (NEDSS) and a "Health Alert Network" (HAN) applying multi-platform telecommunications networks to link the Nation's 1,300 public health sites. It was widely assumed that many local health departments did not have the basic infrastructure to either connect with a NEDSS or HAN system, or to approximate more sophisticated emergency medical response capabilities of metropolitan areas. For example:

> Weaknesses in the nation's governmental public health infrastructure were clearly demonstrated in the fall of 2001, when the once-hypothetical threat of bioterrorism became all too real with the discovery that many people had been exposed to anthrax from letters sent through the mail. Communication among federal, state, and local health officials and with political leaders, public safety personnel, and the public was often cumbersome, uncoordinated, incomplete, and sometimes inaccurate. Laboratories were overwhelmed with testing of samples, both real and false. Many of these systemic weaknesses were well known to public health professionals, but resources to address them had been insufficient.[46]

The events of September 11, 2001 underscored the need for coordinating local response to medical emergencies and highlighted the need for improved relationships between healthcare and homeland security agencies and personnel. Federal responsibilities for assessing technologies and identifying requirements for responding to CBRN/E threats and emergencies is currently diffused among the Department of Health and Human Services (HHS), the Department of Defense (DOD), and the Department of Energy (DOE). The consolidation of CBRN/E defense and preparedness responsibilities under the Department of Homeland Security is underway, although responsibility for public health will remain with HHS.

In January 2002, Congress and the Administration released the first installment of more than $1 billion in funding to the states to respond to the threat of bio-terrorism. States were expected to respond with a statewide plan to ". . . lay out how it will respond to a bio-terrorism event and other outbreaks of infectious disease, but also how it will

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[45] According to a report by the National Academy of Sciences, over 11,500 manufacturers responded to calls from Governor Ridge following his appointment in October 2001 and by the Department of Defense for technologies that would contribute to homeland defense, including dozens of telehealth suppliers. A coordinated process to interface those responses with healthcare technology requirements was not in place. It was reported that the initiative was "overwhelmed" as a result, and most private sector responses were disregarded.

[46] "The Future of the Public's Health in the 21stCentury," Institute of Medicine, The National Academies Press, 2002, page 96

strengthen core public health capacities in all relevant areas."[47] Plans are being reviewed and approved by HHS according to 17 critical criteria.[48] It is likely that at some point in the future, these plans will be used to further identify technology gaps and/or the need for a national health technology and information infrastructure. This review and (possible) integration provide unique opportunities to apply a "systems approach" to identify and assess homeland security, public health and clinical healthcare gaps and needs as an integrated whole.

Discussion of telehealth's role in and potential contribution to homeland security has been reflected in the distribution of initial homeland security-related funding. Initial emphasis on first responders and public health communities appears to miss hospitals and clinics, where most telehealth programs are deployed. Organizational responsibility for and structure of each state's homeland security planning depends on the individual or organization designated by the Governor.[49] For the most part, Governors have designated state public health officers and emergency medical directors as points of contact and responsibility. The "National Bioterrorism Hospital Preparedness Program" administered by HRSA's Office of Special Programs committed $498 million in FY2003 for grants to states for disaster planning, needs and capacity assessment, technical assistance and training although it is not yet known whether this deployment has included consideration of telehealth technologies.

A major activity of the new Department of Homeland Security's Office of Science and Technology will be directing federal research and development, coordinating research and development/science and technology activities among the multiple agencies involved, and identifying homeland security research, science, and technology requirements. Interagency teams tasked with evaluating federal needs for homeland security infrastructure have been convened in several critical functions, but not, as yet, for healthcare. It is important that any consolidation of healthcare technologies requirements for homeland security be integrated with other private and public stakeholders to include such research organizations as the Army's Telemedicine and Advanced Technology Research Center (TATRC). Cooperation among users in requirements definition as well as research and development could well result in multi-use breakthrough innovations for homeland security, public health and clinical healthcare technologies.

Telehealth technologies offer the opportunity to not only augment the "first response level" but also empower successive levels of authority in crafting an overall response network. Such a network would require: 1) updated, open-platform systems; 2) high-speed networks; 3) workstations; 4) industry-standard applications; 5) standardized nomenclatures and taxonomies; 6) data security tools and protocols; and 7) computer-

[47] "Federal Funds for Public Health Infrastructure Begins to Flow to States," DHHS Press release, January 25, 2002. see http://www.hhs.gov/news/press/2002pres/20020125a.html.
[48] "17 Critical Benchmarks for Bioterrorism Preparedness Planning," DHHS Press release, June 6, 2002, see http://www.hhs.gov/news/press/2002pres/20020606a.html.
[49] For a list of State Homeland Security Directors, go to http://www.whitehouse.gov/homeland/contactmap.html.

based patient records.[50] While each of these requirements is being addressed in some fashion by researchers and federal organizations, there has been little coordination with each other or within the telehealth community.

Homeland security technology needs include sensors and surveillance devices, related information systems for syndromic surveillance, and alert capabilities. One of the leading examples is the Real-time Outbreak and Disease Surveillance (RODS) system developed by the University of Pittsburgh's Center for Biomedical Informatics and funded by the National Library of Medicine, the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), and the Defense Advanced Research Project Agency (DARPA). RODS is essentially a proven telehealth technology that could be used as the basic platform for national CBRN/E development programs.

Research and development of sensor technology was rapidly advancing even prior to 9/11. At the 2002 Winter Olympics in Salt Lake City, for example, sensor and syndromic surveillance technologies were combined by the U.S. Air Force in conjunction with Idaho Technologies to form the Ruggedized Advanced Pathogen Identification Device, or RAPID. This innovative project provides for fast pathogen identification, using a backpack-sized portable laboratory to analyze field samples and polymerase chain reaction technology. It was designed for use in field settings like military hospitals and first-responders to detect the presence of harmful biological agents.

Beyond detection and surveillance, other areas of focus for innovation and adoption related to development of a technology infrastructure for homeland security include telecommunications, information, and training networks which link providers and institutions. Deploying these technologies and programs, and providing training to the nation's public health providers to respond to their new homeland security responsibilities presents both a financial challenge and an opportunity to increase access to quality healthcare for medically underserved areas. Linking sensors to central receivers or monitors and linking those facilities, in turn, to centralized databases requires telecommunications infrastructure that does not exist in much of the nation's rural and remote areas. Although wireless communications may provide a partial answer (Oak Ridge Laboratory's "Sensor Net" uses wireless telephony, although over a relatively limited area), most sensor research and development has yet to address interfaces or integration with CDC's public health systems.

Research and development is also underway in the area of bioinformatics for syndromic surveillance systems using algorithms to analyze symptoms for possible epidemiological and CBRN incidents and/or attacks. For example, the Lincoln Laboratory at the Massachusetts Institute of Technology (MIT) is developing a microchip combined with mouse B cells to detect individual pathogens. Efforts are under way to increase the speed, sensitivity, and cost-effectiveness of such a detector.

[50] Simpson, Roy L."Our First Line of Defense Against Bioterrorism." *Nursing Management* 2002 May 33(5):10-13. p. 12.

In a worst-case scenario, there will be a need to monitor individuals in quarantine, bringing the need for bio-detection and remote monitoring technology to the front doorstep of home healthcare. Advances have been made in this arena as well, such as the Air Advice monitoring system developed by an Oregon company of the same name. That device monitors allergens, pathogens and biogens in a room or house, then transmits collected data via telephone lines (POTS) to DOE's Pacific Northwest Research Lab (PNRL). There the data is analyzed using algorithms, then transmitted to Air Advice's database, which then alerts the subscriber. It appears that in addition to significant potential for improving the protection and healthcare provision for individuals, there is significant economic potential in linking homecare monitoring with environmental (air and water) and CBRN monitoring.

Military

Within the federal government, the DoD leads the federal research community in research and innovation related to telehealth due primarily to the Army's Telemedicine and Advanced Technology Research Center (TATRC) located at Fort Detrick, Maryland. Although TATRC research and other DoD missions are focused on military applications, their telehealth applications are clearly "multi-use". Systems can be deployed for domestic preparedness, emergency response, and homeland security, as well as combat theater uses. TATRC's technological research priorities outlined in a recent presentation include the following:[51]

- Imaging
  - Digital image acquisition devices
  - 3D Medical data and image analysis and displays
  - Virtual workbench
  - Portable Apollo Digital Mobile Radiology System
- Distance medicine
  - Predictive diagnostics
  - Radio frequency triage system
  - Image-guided therapies
- Medical informatics
  - Computerized patient record
  - Medical data mining
  - Intelligent decision systems
  - Medical data processing
- Wireless medical enterprise
  - Wireless medical systems (e.g. medical digital assistants)
  - Personal information carrier (i.e. "digital dog tag")
  - Virtual retina laser display
  - Digital EMS
- Medical modeling and simulation
  - Computer-aided instruction
  - 3D surgical simulation
  - Virtual reality

[51] "Telemedicine and Advanced Medical Technology Program," a briefing presented by Conrad Clyburn of the U.S. Army Telemedicine and Advanced Technology Research Center, November 2002

- Healthcare complex modeling
- Medical situational analysis
- Digitally enhanced mannequins
- Operating room of the future

Minimally invasive therapy
- Physiological sensors
- Microelectromechanical (MEM) systems

Sensors and robotics
- Real-time biochemical assays

Communications infrastructure

Each of these areas represents significant technology needs and may provide opportunities for project-specific "partnerships" for small private firms focusing on research, development and commercialization. Although much of the $106 million budgeted for TATRC research is designated for specific projects, the Center routinely identifies potential partners for projects that fit with their mission. In addition, TATRC manages 12-15 Small Business Innovation and Research (SBIR) topics.

One of the early breakthroughs in telehealth research and development came through a Defense Advanced Research Projects Agency (DARPA) contract to develop the "Life Support for Trauma and Transport" system -- a fully self-contained electronic stretcher. DARPA is also developing robotic models for such applications as telementoring, telepresent surgery, and laparoscopic video teleconferencing, as well a robotic transporter for moving injured personnel away from battle without endangering the attending medical specialist. DARPA reduced its telehealth research in FY2000 through FY2002, but may resume its telehealth research now that its former lead researcher has rejoined the agency.

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Convergence of Technologies

Several technologies which have developed in their own right appear to be converging and, in some cases, integrating. For example:

1. With its roots in information technology, healthcare or medical informatics is increasingly dedicated to research, simulation, modeling, education, and decision support.

2. The rapid integration of informatics and devices with eCommerce and the Internet has evolved into the field of "eHealth."

There are several similarities between these IT-based technologies and other telehealth technologies. For example, each of these face barriers of reimbursement, licensure,[52] and user acceptance. Despite advances in each of these technologies, a recent Institute of

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Medicine report maintains, "The health care sector has languished behind almost all other industries in adopting information technology."[53]

The convergence of healthcare technologies creates another dynamic for innovation. For example, the National Science Foundation, in conjunction with the Commerce Department, recommended in a 2002 report entitled "Converging Technologies for Improving Human Performance" that "the Federal Government should establish a national research and development priority area on converging technologies focused on enhancing human performance as a long-term, conferment strategy for research and education."[54]

The convergence of technologies has also been widely recognized throughout the healthcare sector. Industry associations have begun expanding their membership to include vendors and users of related technologies, and some associations have created crosscutting committees or special interest groups. The American Medical Informatics Association has, for example, created a Telehealth Special Interest Group, while the American Telemedicine Association has created new Special Interest Groups to consider the industry impact of convergence. In December 2002, Department of Commerce Undersecretary of Technology Phil Bond called for a "coalition" of like-minded healthcare and information technology associations to develop a "single voice" on important issues.

Interoperability and Integration/Standards

> *The integration of technology with medicine may be the single greatest current research need for the telehealth community.*[55]

Technology

Increasing the interoperability of devices and the integration of telehealth with clinical medicine and other healthcare technologies is another focus of telehealth innovation. Interoperability is the ability of two or more systems to interact with one another and exchange information in order to achieve predictable results. Innovations in this area include the integration of networks with programs, of devices with applications, of applications with clinical protocols, and of technologies with business processes. If telehealth is going to realize its potential for improving productivity, increasing quality and reducing cost, the following three levels of interoperability must be provided:[56]

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[53] "Fostering Rapid Advances in Health Care: Learning from System Demonstrations," Institute of Medicine's Committee on Rapid Advance Demonstration Projects: Health Care Finance and Delivery Systems, November 2002.

[54] "Converging Technologies for Improving Human Performance," a NSF/DOC sponsored report, June 2002.

[55] Jon Linkous, Executive Director, American Telemedicine Association, September 2002.

[56] Col. Ron Porapatich in speaking to the American Telemedicine Association conference, December 2002.

1. Stations or applications developed by independent vendors must be able to interact.
2. Medical devices and other "peripherals" connected to one vendor's station must be able to interact with stations developed by other vendors.
3. Individual stations should be developed as "plug and play" from components developed by multiple vendors.
4. Ideally, information systems should be developed or adapted using open standards and, just as importantly, publishing those standards widely.
5. Eventually, most applications need to link back in some fashion to electronic clinical patient record databases.

Until interoperability is fully achieved, innovators must focus on "middleware" to include hardware and software. As a result, users will likely face higher integration costs.

Standards are a means by which interoperability is achieved.

In addition to facilitating development of interoperable devices and applications, the following represent benefits to providers of adopting universally accepted standards: [57]

- The ability to plug and play devices and applications as required
- Increased safety with compliant devices and applications comply with industry requirements
- Greater satisfaction of users in knowing devices and applications are tested and compliant
- Reduction of uncertainty means better management of clinical risk
- Assuring compliance will contribute to greater credibility and, therefore to consultation volumes
- Compliant performance can assist with costing of services because of the sameness of workflow among providers
- Standard performance can support evidence-based practices

Standardization cab improve business profitability by:

- Lowering purchasing costs
- Increasing quality
- Lowering trade barriers (where standards have been internationalized)
- Decreasing design time
- Ensuring Interoperability

Standardization can improve competitive advantage by:

- Promoting innovation
- Increasing speed to market of new technology
- Creating the perception of being an industry leader
- Enabling compliance with international codes, specifications and standards

To achieve operational interoperability, a number of practical steps are recommended. These include: interoperability testing of devices and applications, clarification on

[57] Col. Ron Porapatich in speaking to the American Telemedicine Association conference, December 2002.

clinical approaches, process and workflow analysis and improvement, provider agreements, and education of providers regarding the uses (and limitations) of the technologies. In addition, operational interoperability requires buy-in from the participating organizations, technical support, training of both users and staff, and detailed staff and equipment scheduling procedures.[58]

In addition to technical issues of interoperability, other policy issues must be addressed. Looking at three areas of interoperability, one can identify both technical and policy requirements: 1) operational (e.g. ease of use, cost-benefit, privacy, and human resource/education); 2) clinical (e.g. licensure, automation of patient records, and risk management); and 3) technical (e.g. connectivity speeds and modes, technical standards, peripherals, and security).

As noted, the problems associated with interoperability are due in large part to the fragmented nature of telehealth – many participants each having different requirements or solutions and each applying different technical standards. The healthcare industry is not unique in having an excess of standards that are developed by multiple organizations. Other organizations face similar situations and challenges with respect to electronic business specifications. Healthcare is unique, however, in the diversity of standards – infrastructure standards, clinical information standards, and business information standards, as well as standards within each medical discipline – only some of which are comparable. Healthcare is also unique in that, due to the number and diversity of providers and technology suppliers, interoperability is significantly more challenging. It is also critically important, especially when considering that individuals' health and life are affected as well as the national dimension of homeland security.

Some vendors' telehealth systems are similar enough that physicians need not be fully retrained when they move to a new delivery system or combine services with another provider. But the lack of compatibility among many homegrown systems has limited just how far many telehealth services can extend. On a national level, compatibility is essential to constructing any truly useful, larger infrastructure of healthcare service. Faster connection and transmission speeds have increased the capabilities of telehealth applications overall, but without standards (or the ability to integrate patient information among various internal or external systems) many telehealth services cannot be performed within or across delivery systems. Standards form the building blocks of effective health information systems and are essential for efficient and effective public health and healthcare delivery systems.

Adoption of standards that make it easier for telehealth systems to interoperate with other hospital information systems and easier to integrate technology with routine care should encourage physicians to adopt telehealth applications. Without standards that make telehealth technologies easier to use or that enable interoperability among disparate systems, physicians are unlikely to embrace advancements in telehealth applications. [59]

[58] Canadian Society of Telehealth. "National Telehealth Interoperability Workshop Report," Feb. 2001, p. 2.
[59] Kelly, Becky. "Telemedicine Begins to Make Progress." *Health Data Management*, Jan. 2002, p. 76.

Requirements should be developed to define the level of interoperability to which different vendors or suppliers of telehealth equipment must communicate and exchange health related information. [60] Efforts to enumerate current standards and develop profiles (i.e., a stack of standards) and conformance testing methodologies, need to ensure that broad (standards) coverage exists to serve the needs of the whole community, not just one sector. [61]

There are a few initiatives underway which may contribute to improvements in interoperability and standards for telehealth devices and applications:

1. HHS, DoD and VA recently announced an effort to standardize the information exchange, part of the Consolidated Health Informatics (CHI) initiative, one of the Bush administration's 24 eGovernment initiatives. The standards, including privacy and security protections, will make it easier for health care providers to share patient information and identify emerging public health threats. It also will facilitate the creation of portable electronic medical records

2. To ensure that all agencies are working together to address common homeland security equipment issues, the Interagency Board for Equipment Standardization and Interoperability (IAB) is facilitating the development of Interagency Agreements (IAs) and Memoranda of Understanding (MOUs) among federal, non-profit, and private standards agencies. These agencies include, among others, the National Institute for Occupational Safety and Health (NIOSH), the National Institute for Standards and Technology (NIST), and the American National Standards Institute (ANSI). The IAB suggests that these IAs and MOUs are critical to the development and use of interoperability standards and regulations for military and first responders.

   The Interagency Board is organized into four equipment Subgroups and two technical Committees. The equipment Subgroups include the Medical Subgroup, the Personal Protective and Operational Equipment Subgroup, the Interoperable Communications and Information Systems Subgroup, and the Detection and Decontamination Subgroup. The two technical Committees include the Science and Technology Committee, and the Standards Coordination Committee. [62]

   Discussion with the Federal co-chair of the Medical sub-group revealed that inclusion of telehealth devices had not been considered to date.

3. The Technical Support Working Group (TSWG) is the U.S. national forum led by DoD that identifies, prioritizes, and coordinates interagency and international research and development (R&D) requirements for homeland security. The TSWG "rapidly develops technologies and equipment to meet the high-priority needs of the homeland defense community, and addresses joint international operational requirements through cooperative R&D with major allies."[63]

   Discussion with TSWG staff revealed that inclusion of telehealth devices had not been considered to date.

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[60] Ibid. p. 5.
[61] Ibid. p. 76.
[62] For more information, visit their web site at http://www.tswg.gov/tswg/home.htm.
[63] For more information, visit their web site at http://www.iab.gov/IAB.asp.

4. The Technology Special Interest Group (SIG) of the American Telemedicine Association (ATA) has also been organized with interoperability and standards as its primary objective.

5. ATA is discussing a joint effort at standards development with the Canadian Society for Telehealth.[64]

6. Following the June 2002 Roundtable organized by Technology Administration, ATA and the National Institute for Standards and Technology (NIST) developed a process leading to standards in the area of diabetic retinopathy. That "roadmap" has been completed in draft and was presented to the ATA membership for review at their December 2003 business opportunities conference.

7. The Universal Plug and Play Forum is a private, non-profit initiative designed to enable simple and robust connectivity among stand-alone devices and PCs from many different vendors. The Forum consists of more than 500 vendors, including industry leaders in consumer electronics, computing, home automation, home security, appliances, printing, photography, computer networking, and mobile products.[65]

Development of technologies such as "middleware" and "black boxes" that connect and integrate devices and/or applications from a variety of sources and between different versions of systems would speed adoption and deployment of telehealth. Many problems with interoperability are attributable to unsuccessful attempts at integration, especially during the first generation of telehealth technology. Research and development of integration models, methodologies, and innovative technologies could be instrumental in facilitating integration.

Additionally, the "gap" between the technical know-how of the user and the human factors engineering of the technologist might be narrowed with more "user friendly" technologies or features that are intuitive to providers. The DoD has been a leader within the federal government in closing this gap, as demonstrated by their "Tri-Care On-Line" which integrates numerous medical information systems into a common, user-friendly web portal.

The information technology industry has essentially solved this issue through systems analysis, systems integration, and business process reengineering. The limited number of systems analysts, systems integrators, and business process reengineers expert in

[64] A look at how Canada is addressing the issue of interoperability may also be useful. Canada has taken the issue of interoperability seriously, beginning with a "National Telehealth Interoperability Workshop" in 2001. The Canadians concluded with the need for "an inventory of interoperability activities across Canada" and "the collection and synthesis of the telehealth interoperability elements be compiled into a framework to address telehealth interoperability implementation and sustainability. This framework will provide interoperability guidelines and recommend standards to assist health care providers in their implementation and use of telehealth systems. These common sets of telehealth standards and protocols will support collaborative telehealth activity, and encourage development of the evolving telehealth industry." Another interesting comment by the Canadians is " . . . the lack of information on the tangible benefits of telehealth interoperability makes the issue difficult to prioritize, as does the lack of funding specifically targeted for this activity. They continue "The process for developing interoperability is very immature and fragmented. As such, there is a lack of clarity on accountability, governance and mandates."

[65] For more information, visit the Forum's web site at http://www.upnp.org/

telehealth often shifts the burden for integration to in-house IT staff, clinicians or vendors. Education and training in healthcare applications for "techies," and the development of in-house integrators (health care professionals with training in systems analysis and process reengineering) will contribute to resolving interoperability issues. It is equally important for manufacturers to build interoperability into systems from the outset.

Policy

While most of the attention has been focused on the interoperability of *technology*, not enough attention has been paid to the interoperability of technology with *policy*. An example is the security and privacy regulations mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Devices and applications should have become "HIPAA-compliant" in 2003, which may add another layer or dimension of interoperability, especially for legacy systems. How homeland security-related technology procurements by state and local first responder and public health organizations are integrated with other networks may also be significantly affected by interoperability concerns.

Medical Simulation and Training/Health Education

Using telehealth to increase access to education and training opportunities could also advance user adoption. The audio/video/digital nature of telehealth networks allows them to be used for simulation and training, as well as health care. Simulation technologies such as "virtual operating rooms" can be distributed to educators and healthcare providers through telehealth networks. Streaming video and other web technologies make education and training as economical and accessible as the closest computer. Technology to deliver the educational component of public health and homeland security is currently available and awaiting additional infrastructure and curriculum content.

Because of the need to link to increasing amounts of information and IT capabilities, telehealth networks may provide the infrastructure needed for continuing education. The convergence of telehealth, healthcare informatics, and eHealth will increase the levels of technical know-how required of healthcare providers at all levels and in all specialties. Medical and healthcare education curricula will be revised with greater integration of information technology and knowledge management.

The Internet and related information technologies also can enable a more efficient, quality healthcare system. The evidence-based approach to medical treatment uses knowledge about the treatments and technologies that provide the best patient outcomes under different circumstances at the point of care. Evidence-based medicine and health informatics may improve the quality of patient care. With recent concern over widely publicized medical errors, as well as rising variable costs in treatments and outcomes, the healthcare community is searching for ways to acquire knowledge that will guide them in the appropriate delivery of care. The generation and provision of such evidence could support the development of practice guidelines and the standardization of care.

Overwhelming amounts of clinical and public health information are available to healthcare and public health providers and patients. Some of that information is potentially confusing or inaccurate, in particular that found on the World Wide Web. Knowledge management technologies such as data mining and decision support systems assist in sorting good from bad information. As individuals take greater responsibility for their own healthcare, search, sort, and filter technologies which could connect the consumer to appropriate sources of diagnosis, treatment or information may become commonplace.

Process reengineering and automation of current manual transactions and processes are tasks necessary to enable a seamless continuum of care, evidence-based healthcare, and wellness and prevention. One of the key problems to be solved is providing a means for practitioners to enter data they develop during patient encounters without imposing on the clinical procedure or the practitioner's natural, individual workflow. Such unobtrusive data capture will allow for the development of resources such as longitudinal patient records, knowledge services, and clinical repositories. The DoD, with the development and early deployment of its Composite Health Care System (CHCS) II, is perhaps the leader in fielding a large system that includes a patient data repository and brings to the clinician's desktop patients' electronic health records.

There is a need to make systems and data more accessible to those outside the organization where systems and data reside. This need in the healthcare industry arises out of new business relationships among various healthcare players established to respond to paradigm shifts in healthcare delivery, and from the need to deliver information directly to the patient to meet the demand for patient involvement in his/her own healthcare decisions. Open exchange of healthcare data and information requires sophisticated technological safeguards to mitigate the risk of unauthorized access or disclosure, or a loss of information integrity.

Challenges for Healthcare Standards and Testing

The provision of simple, standardized methods to evaluate and certify online healthcare information is crucial to making healthcare safe and available to all. At the same time, the public, as well as healthcare providers, must have confidence that their online communications are secure, their privacy protected, and the digital representation and exchange of information is accurate and correct. Security and continuity of operations must also be assured. Appropriate standards for healthcare information and systems provide the cornerstone to achieving a 'healthy' healthcare infrastructure.

Efficacy and Cost-Benefit Analysis

Much of what is considered "research" in telehealth is actually devoted to efficacy and cost-effectiveness studies funded primarily by private sources. It appears, however, that such studies have not yet significantly contributed to advancing the adoption of telehealth. A primary challenge to these types of studies has been the need for a "critical

mass" of programs. OAT suggests that "We appear to be on the cusp of having enough programs in place that can be studied."

Although the conduct of peer-reviewed clinical studies in telehealth has been relatively limited, there have been some that have demonstrated promising results. For example, where telehealth was applied to managing high-risk pregnancies, there were significant reductions in premature births. [66] Other studies in Tennessee showed that hospital readmission rates for congestive heart failure patients were dramatically lower after a sustained program of telehomecare monitoring and patient education. [67]

Even though the quantity of high-quality clinical studies is relatively limited, there may have been enough to conclude that telehealth should be considered a promising application of technology in the national context and discussion of healthcare quality. It would also seem likely, then, that additional high quality efficacy studies would be sufficient to convince both providers and patients of the efficacy of a certain device or application, its contribution to improving quality of care, and its ability to increase the productivity of the provider and staff which will, in turn, lower costs.

Some studies undertaken to establish efficacy have, however, yielded contradictory conclusions. In one case study referred to frequently by telehealth leaders, Kaiser Permanente studied the effects of telehomecare on congestive heart failure patients and determined that televideo monitoring can economically replace in-home visits. The positive results of this study resulted in Kaiser's decision to reimburse and to promote telehomecare use among its providers. On the other hand, an Aetna "evidence review"[68] funded by HHS' Agency for Health Research and Quality (AHRQ) in 2001 to determine the availability of evidence of improved access and clinical efficacy in certain telehealth specialties suggested that the quality of efficacy studies was insufficient to reimburse any telehomecare application. As a result, Aetna appears to be the only major third party payer with a specific policy prohibiting reimbursement of telehealth encounters.

Despite dramatic growth in federal and private funding for medical and healthcare research (e.g. a 30% increase in funding during FY2000-02 to $23 billion for the National Institutes of Health), there appears to be little activity throughout the federal government in conducting efficacy or cost-benefit research for telehealth, even though the need has been recognized for several years.

In 1998, the predecessor to the AHRQ described the nation's needs for telehealth research and information as follows: [69]

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[66] Morrison, John, M.D. et al, "Telemedicine: Cost-Effective Management of High Risk Pregnancy," *Managed Care*, November 2001.

[67] Burgess, S., Dimmick, S., & Robbins, S. (2001). "Cost of care reductions using telehealth: A comparative analysis," paper presented at the American Telemedicine Association Annual meeting. Fort Lauderdale, FL, June 2001.

[68] See a discussion of the AETNA study at http://archfami.ama-assn.org/issues/v9n1/fful/foc8072.html

[69] Fitzmaurice, J. Michael, "Telehealth Research and Evaluation: Implications for Decision Makers," AHRQ, August 1998

1 Scientific studies - controlled trials
2 Condition-specific studies
3 Site-specific studies
4 Multiple-site studies
5 Large sample sizes
6 Studies in developed and underdeveloped areas
7 Continually updated Web site of telehealth projects
8 Continually updated Web site of telehealth evaluation studies
9 Funding for scientifically valid telehealth research and evaluation projects

In 2001, the University of Oregon published an evaluation of telemedicine research under an AHRQ grant that contained several recommendations:[70]

> The Evidence-based Practice Center team recommends that, in the future, diseases with a high burden of illness and barriers to access to care should receive the highest priority for telemedicine research. Systematic observation of the effect of a telemedicine service should begin as soon as possible with the use of patient registries, and research on telemedicine in practice networks should be encouraged.
>
> Randomized controlled trials that assess patient outcomes and costs related to entire episodes of care should be encouraged, and demonstration projects avoided. The fact that telemedicine is an emerging technology is not a reason for failing to perform randomized controlled trials. Rather, new methodologies such as "tracker trials" should be used to assess telemedicine systematically. **There is also a need for basic research in telemedicine to refine target populations for services, refine interventions prompted by them, develop standardized tools to measure effectiveness and harm, and assess the effect of different methods of delivery and payment.**
>
> Finally, journals publishing telemedicine evaluation studies must set high standards for methodological quality so that those who make decisions on coverage of telemedicine services need not rely on studies with marginal methodologies.

There has been limited progress in meeting those research needs. What federal funding may be available for clinical efficacy studies for telehealth has been largely limited to grants or contracts awarded by AHRQ for evaluative studies and by NIH Institutes such as the National Library of Medicine for technology assessment and demonstration projects. It would appear that, to date, AHRQ's efforts have been largely focused on the evaluation of existing studies rather than in creating studies of a quality acceptable to clinicians, regulators, and third-party payers.[71] What emerges is a "Catch 22" situation where telehealth cannot advance without evidence created by quality studies, but quality studies are not being undertaken because of lack of coordination, funding, or focus.

[70] Evidence Report/Technology Assessment No. 24, *Telemedicine for the Medicare Population* (AHRQ Publication No. 01-E012).
[71] Studies conducted by vendors are often discounted as not being objective.

The DoD and VA have produced and published some efficacy studies of their own programs. The Quality Interagency Coordination Task Force (QuIC) was established in 1998 in accordance with a Presidential directive to ensure that all Federal agencies involved in purchasing, providing, studying, or regulating health care services are working in a coordinated manner toward the common goal of improving quality care. It would appear, however, that efforts to coordinate federal research topics, priorities, and funding for telehealth have thus far fallen short or have fallen outside of the mission outlined for QuIC.

Without greater efforts to provide evidence of clinical efficacy and positive cost-benefit, other barriers to innovation, demand and investment in telehealth will be difficult to overcome. The Food and Drug Administration (FDA), for example, needs high quality clinical efficacy studies to evaluate and approve new devices, and the Centers for Medicare and Medicaid Management Services (CMS) require evidence of efficacy for reimbursement decisions. As importantly, clinicians expect sound, peer-reviewed research before adopting new technologies, and administrators require evidence of cost effectiveness before considering investments.

Whereas FDA requirements are generally satisfied by the firm submitting a device or application for approval, CMS and private payer efficacy requirements apply to a broader application or specialty, such as mental health or home healthcare. While it is in the interest of telehealth providers and vendors to provide CMS and private payers with clinical evidence of efficacy, the cost of such research may be prohibitive to small and medium size firms that tend to make up most of the telehealth technology sector.

Data on Efficacy and Cost/Benefits

Although there are numerous studies that claim to prove telehealth applications are cost-effective, these studies are often summarily dismissed because they are not scientifically or statistically significant. Moreover, critics of telehealth point to a lack of evidence that the technology has proven itself as an effective substitute for the traditional encounter. Primary reasons for the lack of data are the cost of surveying and collecting data as well as what would appear to be the lower priority for such studies.

Another factor is the debate over what constitutes valid measures.[72] OAT has developed some common measures of value-added for improved access that are being implemented in 2003, and some preliminary measures of outcomes for a subset of specific conditions are under development.

As mentioned earlier, teleradiology (TR) is an area that was invested in and developed early in the history of telehealth for various reasons, some of which included the specialty is made up of professionals who are already technical, private teleradiology services have already proven sustainability, and because radiological images have been consistently

[72] For example, in theory, every American already has access to quality healthcare - the only barrier being distance to and cost of travel to the provider's location. In this case, the return on investment is more an economic measure of convenience or transportation cost savings than a reflection of public policy such as increased access or improved quality. This line of reasoning argues for the home as the most cost effective location for healthcare for many Americans.

reimbursed by Medicare and other payers. Thus, many large HMOs as well as the Federal government (DoD, VA) have instituted TR to varying degrees within their enterprises. Yet, to date, there appear to be no comprehensive business-case analyses that have definitively estimated the overall economic return on investment. This may, in part, be due, to business competition concerns. In 2000, the US Air Force Telemedicine office performed a literature search and found only five (5) such studies in the medical literature that addressed cost factors and/or savings, yet each of these studies addressed only a subset of possible factors, such as costs savings from elimination of films and storage rooms. The Air Force telemedicine consultant then developed an Excel®-based model that looked into 25 separate factors, including other items such as reduced medical malpractice claims arising from lost films and the reduction in costs associated with the use of voice-recognition software for reports (thus reducing or eliminating the need for transcriptionists). While it was concluded that the "break-even point for investment would occur at 7-8 years, that duration may currently be shorter as costs for radiographic image "capture" devices have dropped dramatically in just three years.

Attempts to evaluate the impact of telehealth investment by such states as Virginia have also been hampered by the need for more and better data. There are not, for example, before and after data relating to the percent of patients in rural and medically underserved areas that have benefited from increased or improved access to additional medical services through telehealth programs.

A reason often given for the limited data on telehealth's effectiveness is the governmental focus on issues other than telehealth research. "The government's been more focused on developing the telecommunication infrastructure to provide the services rather than finding out if the services work,"[73] suggests one critic. States struggle with the same issues of lack of evaluative data and the lack of funding to carry out relevant data collection.

DISSEMINATION OF INFORMATION AND TECHNOLOGY TRANSFER

"How do you find out what is happening in the field of telehealth innovation and research?" was a question asked of individuals interviewed for this study. The most common responses were the ATA annual meeting and grantee meetings hosted by OAT. *Telemedicine Today* and the *Telehealth Journal* were also mentioned. Several of those individuals interviewed suggested the need for a "national information clearinghouse."

This raises the question of why information on telehealth research and innovation is not more available to healthcare providers (for example, why clinical research is more often found in telehealth journals but not in well-established medical journals.) The answer probably relates to a widely shared perception that telehealth exists outside the medical mainstream. Greater awareness of and familiarity with telehealth applications, healthcare informatics, and other healthcare technologies are generally followed by greater acceptance by providers and patients. This suggests that telehealth advocates need to put forth greater effort to ensure information is made more widely available using mainstream channels as well as their own.

[73] Lisa Rabasca, "Taking Telehealth to the Next Step," *Monitor on Psychology*, April 2000.

"Diffusion of information on medical and clinical research and innovation is well established within the traditional medical community. Two examples are the production of electronic, up-to-date versions of clinical references (i.e. medical journals and textbooks), and development of efficient search tools for large bibliographic databases such as Medline."[74] Electronic access to information on telehealth innovation and research is, however, limited to a few sources such as *PubMed* and the *Telemedicine Information Exchange (TIE)* operated by the Telemedicine Research Center (TRC) and funded by the National Library of Medicine.[75] While the TIE offers on-line access, its coverage of telehealth research is selective, with access to most publications limited to paying subscribers.

In a promising development, the American Telemedicine Association has said it will be surveying its members in 2003 regarding the level and extent of private sector research and development. ATA's Research and Evaluation Special Interest Group (SIG) has proposed to help benchmark and shape telemedicine research by tracking ongoing and completed research among ATA members; preparing guidelines for telemedicine research; providing a list of current resources for doing telemedicine research; generating a research agenda or priority list of current research questions; and developing a checklist or model documents. While this effort represents a significant step forward, the part-time and voluntary nature of the SIG and its need to limit its activities to ATA membership limits the scope and value of this initiative.

It would appear that the Joint Working Group on Telemedicine (JWGT), the American Telemedicine Association, the National Library of Medicine, and the TIE are best positioned to diffuse telehealth research and program best practices information. All four organizations collect and maintain useful but different information on programs, research, and policies.

Technology Transfer

The federal government is required to work with the nation's private sector to transfer technologies developed in its laboratories and other research institutions. Only anecdotal information is available to estimate how much innovation in telehealth-related technologies takes place in federal laboratories and may be available for public commercialization.

"Tech transfer" occurs using a variety of mechanisms, to include patent licensing agreements, Cooperative Research and Development Agreements (CRADAs), personnel exchange programs, etc.[76] Other mechanisms include Small Business Innovation

[74] Rick G. Kulkarni, M.D. and Justin Graham, M.D., "Information Technology in Patient Care: The Internet, Telemedicine and Clinical Decision Support," in *Current Medical Diagnosis and Treatment* (2002).

[75] The Telemedicine Research Center (TRC) is a Portland, Oregon based non-profit public service research organization founded in 1994 to promote telemedicine research and to create, manage and disseminate information about telemedicine related issues.

[76] For a good description of tech transfer, see the Air Force's Technology Transfer Handbook at the Air Force Research Laboratory's web site: http://www.afrl.af.mil/techtran/handbk/.

Research (SBIR) grants and Small Business Technology Transfer Research (STTR) grants. In FY2003, for example, TATRC has solicited SBIR and STTR grants in 15 topics, and NIH's FY2003 program includes hundreds of topics (some pertaining to telehealth). One group, the Federal Laboratory Consortium,[77] maintains a web site of available laboratory technologies although there is no category for "telehealth" and there are no telehealth technologies listed.

The Commerce Department's National Telecommunications and Information Administration (NTIA) offers the following examples of creative approaches to federal tech transfer. In 2001, NTIA's Technology Opportunity Program (TOP) awarded a grant to the District of Columbia's Department of Health to deploy the Veterans Administration's electronic medical record system at three nonprofit community clinics,[78] and, in 1997, TOP awarded a grant to Saint Vincent Hospital in Montana to integrate the Telemedicine Instrumentation Pack (TIP) unit, originally developed for space flight medical applications by the National Aeronautics and Space Administration (NASA), with a terrestrial telemedicine network linking the Crow Reservation. [79]

The prospect of technology transfer (i.e. from federal research organizations to private sector firms for commercialization) has not been widely pursued by either side. The most active tech transfer programs in telehealth would include TATRC, VA, and NASA. TATRC engages in "partnerships" with private firms to develop technology applications, with companies taking ownership of intellectual property. VA facilities are used by private firms to develop and evaluate innovations. NASA undertakes both partnerships and the more traditional channels such as licensing agreements.

INTELLECTUAL PROPERTY

Regarding special provisions for processing health-related patent applications, new applications are ordinarily taken up for examination in the order of their effective United States filing dates. Certain exceptions, however, can be made by way of petitions to "make special," which may be granted under specific conditions. Applications which have been made special will be advanced out of turn for examination and will continue to be treated as special throughout their entire prosecution in the U.S. Patent and Trademark Office (PTO). There are several petitionable conditions under which applications may be made special. The following conditions may be of particular relevance to health-related patent applications:

> I. In view of the exceptional importance of recombinant DNA and the desirability of prompt disclosure of developments in the field, the U.S. Patent and Trademark Office will accord "special" status to patent applications relating to safety of research in the field of recombinant DNA.

[77] For more information of the Consortium, visit its web site at: http://www.federallabs.org/
[78] For more information on this example, see http://ntiaotiant2.ntia.doc.gov/top/details.cfm?tiiap_no=10564.
[79] For more information on this example, see http://ntiaotiant2.ntia.doc.gov/top/details.cfm?tiiap_no=970118.

> II. In view of the importance of developing treatments and cures for HIV/AIDS and cancer and the desirability of prompt disclosure of advances made in these fields, the U.S. Patent and Trademark Office will accord "special" status to patent applications relating to HIV/AIDS and cancer.
> III Applicants who are small entities may request that their biotechnology applications be granted "special" status.
> IV. If an applicant is 65 years of age or more, and/or can make a showing that the state of their health is such that he or she might not be available to assist in the prosecution of the application if it were to run its normal course, a petition for special status can also be made. No fee is required for either petition.
> V. A new application (one which has not received any examination by the examiner) may be granted special accelerated status provided that applicant (and this term includes applicant's attorney or agent) complies with each item set forth in our Manuel of Patent Examination Practice (MPEP) section 708.

Except as provided above, these petitionable conditions require payment of the fee under 37 CFR 1.17(h) and the filing of a petition accompanied by a statement by the applicant, assignee, or an attorney/agent registered to practice before the PTO. See MPEP Chapter 708 for a concise explanation of all of the individual petitionable conditions and their associated requirements.

Additionally, the PTO's proposed 21st Century Strategic Plan provides applicants with a "rocket docket" option of choosing an accelerated examination procedure with priority processing and a pendency of no longer than twelve months. This, however, will require statutory rule changes to implement and is not yet available.

Chapter 3 - Demand for Telehealth Technologies & Services

THE MARKET

Demand is probably the most critical factor affecting the deployment of telehealth technology and programs because it drives private innovation and investment decisions. Public and private perspectives and motives differ, however.

On the public side, demand is driven by such national priorities as providing access to quality health care for all citizens and the containment or reduction of healthcare costs. Much of the demand for telehealth programs has been artificially created and maintained by millions of dollars in public grants for "demonstration projects."

On the private side, market demand for healthcare technologies and delivery systems is driven largely by the business needs of transforming traditional clinical services through technology, increasing the level and quality of services provided, increasing productivity, and reducing costs. As consumers become increasingly more technology savvy and are empowered by continually greater healthcare information, it is likely that they will also involve themselves more directly in purchasing decisions, and especially those applications which do not require a physician's prescription or are priced within reach of the individual.

This chapter analyzes market demand for telehealth programs, products, and services, and identifies the major factors that drive demand.

Estimates of Market Demand

Any discussion of market and market demand must be prefaced by identifying problems with currently available data. Because the North America Industry Code System (NAICS) and Harmonized System (HS) classifications for medical equipment do not separate telehealth from other applications, no "official" and specific market data is available. Private research firms have estimated the annual market for telehealth technologies (products and services) to be around $380 million in 2004 based on an estimated growth rate of 15-20% per year.[80] [81] There have been widely publicized

[80] This estimate is based on projections from research by the firm Frost and Sullivan which showed that videoconferencing, the largest component of telehealth equipment, had a market of $119 million in 2000 which is expected to grow to $275 million in 2007.

[81] This estimate also includes a 1999 forecast by Feedback Research Services that the combined worldwide sales of video-based home care, telemedicine, and teleradiology systems would possibly reach $172.0 million by 2004. Both the Frost and Sullivan and the Feedback research estimates have been added to arrive at a projection of around $380 million in 2004.

claims of a telehealth market in the billions of dollars, although the few private firms that have conducted actual research in this area discount such claims completely.[82] [83]

A leading market research organization studying telehealth is Feedback Research Services of Jacksonville, Oregon. In a 2000 interview, Feedback's research director summarized the difficulty with estimating the size of the telehealth market:

> "Unfortunately, in telemedicine, there are a limited number of segments for which sales data can be obtained. This is partly due to the fact that many of the larger competitors (such as Kodak in radiology and VTEL in videoconferencing) generate a relatively small portion of total corporate revenues from telemedicine-based activities. Another problem is the number of privately held competitors involved in this market (some of which can be significant players)."

Several entities have provided very general descriptions of the telehealth market by estimating the number of programs. Conclusions that can be drawn from these descriptions, however, vary noticeably. The following list represents some of the more significant efforts to quantify the nation's telehealth market.

1 In 1996/1997, HHS's Office of Rural Health Policy's former Rural Telemedicine Grant Program (now HRSA OAT's Telehealth Network Grant Program) contracted with Abt Associates to survey the extent of telehealth in rural hospitals. Although survey data is dated, it represents the best available snapshot of rural telehealth investment to date. The survey of 2,472 non-federal U.S. hospitals outside metropolitan areas had a 95% response rate, and showed that 700 or 30% of rural healthcare operations were engaged in some kind of telehealth activity.

2 In 1998, the Joint Working Group of Telemedicine completed a "Federal Telemedicine Directory" which described 188 projects in 44 states having some federal funding.[84]

3 A 1999 study conducted for HHS' Agency for Health Research and Quality identified 455 telehealth/telemedicine programs, to include 362 in the United States. Among U.S. programs, 111 were located at academic medical centers and 68 were in hospital-based health care networks; 80 were in Federal, military, or VA medical centers. Over 30 medical specialties were represented. Many programs include more than one activity. The most common telemedicine activities identified were:

- Consultations or second opinions (290).
- Diagnostic test interpretation (169).
- Chronic disease management (130).
- Post hospitalization or postoperative follow-up (102).
- Emergency room triage (95).

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[82] "In Pursuit of a Market Analysis for Telemedicine," A Telemedicine Information Exchange interview with Fran Fields of Feedback Research Services, by Bill Grigsby, June 6, 2000. For the full interview, visit TIE Web site at http://tie2.telemed.org/news/features/market_analysis.asp#about.

[83] Bauer, Jeffrey C., Ph.D., "Insights on Telemedicine: How Big Is the Market?" *Journal of Healthcare Information Management*, Spring 2002.

[84] To view the complete Directory, visit the OAT web site at http://telehealth.hrsa.gov/jwgt/teldirect98/index.html

- "Visits" by a specialist (78).
- Services in patients' homes (~50).

More programs served rural patients than any other group. Of the 455 programs catalogued in the general literature review, approximately 120 (26 percent) provided health care to rural populations. Telemedicine also serves a large number of veterans and elderly. The numbers of telemedicine encounters increased steadily throughout the 1990s.

4 The Association of Telehealth Service Providers' 2001 survey identified 206 telemedicine programs, up from 170 in 1999.[85]

5. In 2003, OAT, working with East Carolina University's Telemedicine Center developed and implemented an inventory of all of HRSA's telehealth programs. OAT is hopeful that this inventory will serve as a model for a more comprehensive inventory across all federal programs.

6. In addition, the Health Resources and Services Administration (HRSA) announced in the October 31, 2002 *Federal Register* (vol. 67, page 66404) that it is requesting comments on a proposed project to create a *HRSA Grantee Telecommunications and Telehealth Inventory and Database.* Considering the fact that HRSA presently has more than 8000 grants, many of which have some telehealth component, this database plus the three above could form the basis for the most comprehensive information on the nation's investment in telehealth (and its market) yet.

In short, there are no available or reliable data available which would allow calculation of the value of total market demand for telehealth. These market estimates have not included demand for telehealth services (e.g. number of consults or images required) or references to performance measures. As such, an alternative to measuring statistical market demand might be the identification and assessment of the telehealth needs of healthcare providers and users. A few market research firms have prepared marketing studies that estimate the market for their client's specific interests or type of equipment, but the typically small size of telehealth manufacturers limits the number of firms having the resources to purchase or undertake such research.

Markets for Telehealth

Homeland Security

The Military – The military market for telehealth products and services is large, broad and diverse. Because it is a "closed system," there is a tendency by the military medical community to consider itself largely self-sufficient in telehealth. Because each branch has traditionally supported itself, there is not a single telehealth point of coordination within DOD, the National Guard and the Coast Guard. Until now, each branch has managed its own telehealth programs with periodic, informal coordination.

[85] The 2001 ATSP Report on U.S. Telemedicine Activity, Association of Telehealth Service Providers.

For the foreseeable future, much of DoD's telehealth acquisition will be taking place on two tracks: traditional mission-essential healthcare and homeland defense. The former track will continue to develop in-house applications through such user/research organizations as Walter Reed Army Institute for Research and the Walter Reed Army Medical Center, while the demand for the latter track is already being addressed through various organizations, such as the Technical Support Working Group (TSWG) and the assignments of non-Army telehealth staff to TATRC.

The military is specifying an "all hazards response." The lead agency for the military's medical technology aspect of the homeland security program has effectively been Army's TATRC.[86] With establishment of the Northern Command, the scope of DoD's homeland security role also includes protecting the American population, which should include coordinating and integrating telehealth planning, training and procurement with the nation's clinical and public health communities. The Army will then have an increasingly important role in defining the homeland security market for healthcare technologies.

That the Chief of Telemedicine at Walter Reed Army Medical Center is also the immediate past president of the American Telemedicine Association (ATA) has resulted in unique military/ civilian and public/private relationships, and an equally unique opportunity for its government and industry members to cooperate in the resolution of longstanding issues. ATA and its members have been the primary beneficiaries of this dual leadership.

First Responders – The "first responder" segment includes police and fire, Emergency Medical Technicians (EMTs), emergency nurses, National Guard, and other emergency response teams. In the case of a natural disaster, first responders would include all of the above with the addition of Disaster Management Assistance Teams (DMATs). In the case of a chemical, biological, radiological, nuclear or explosion (CBRN/E) emergency, first responders would include all of the above plus CBRN/E teams.

However, the definition of "first responder" applied by the Federal Emergency Management Agency (FEMA) and the (earlier) Office of Homeland Security has left certain groups out of discussions and planning. One might argue, for example, that homecare nurses would be among the first to respond to local threats, and, an Emergency Medical Service (EMS) emergency room physician's response is inseparable from that of an Emergency Medical Technician (EMT). Additionally, initial first responder discussions and funding did not include EMTs employed by non-fire systems, an oversight when such personnel comprise most of the nation's emergency medical staff.

Initial responsibility for equipment purchases for "first responders" has been delegated to the states, either through public health or State Medical Director channels. It is important that decision-makers consider telehealth technologies when addressing homeland security needs. According to the Chairman of the Technology Committee of the National Association of EMS Physicians, "EMS is migrating away from transporting patients to an

[86] See further discussion of TATRC in Chapter 2.

emergency room, and toward more video and telemedicine encounters."[87] This would suggest that EMTs may be increasingly expected to provide video and telemedicine services at the site of an emergency.

Public health and surge capability – One of the communities affected most by the nation's homeland security needs has been public health. The anthrax attacks in late 2001 focused the nation's attention on the public health communities' state of preparedness to respond to potential threats.

There is also a significant public health responsibility for educating citizens in public health threats and individual responses, as well as the education and training of first responders, military, clinical, and public health professionals in CBRN/E response. The education and training capabilities offered by telehealth make this an appropriate medium, limited only by the reach and coverage of existing telehealth networks. The ATA has proposed a "network of (telehealth) networks" as a relatively quick and inexpensive method for linking legacy networks to provide clinical healthcare, health alerts, and public and professional education and training. The Southern Governors Association has adopted the ATA approach in proposing a bio-defense "network of networks" linking public health and healthcare programs across eleven states. The National Governors Association is also exploring a national network initiative.

In the discussion of public health preparedness for natural or man-made emergencies, there is a general concern that any significant disaster might overwhelm existing facilities and response systems. This concern was reinforced with experience gained from recent disaster response drills such as "Dark Winter." Telehealth technologies have the potential to significantly contribute to surge capability by linking clinical care or triage capacity from across the nation to areas of surge or higher-than-capacity demand (much like what happens when demand for electricity surges).

While the Army has integrated telehealth technologies into its rapid deployment model and Veterans Affairs has included telehealth in surge capacity planning, the public health and telehealth communities should step up their discussions of how healthcare technologies can assist with surge preparedness and first response.

For example, there is a need first to inventory the nation's institutional capacity to include intensive care unit beds and emergency rooms. Once an inventory is established, there is then a need to track capacity on a real-time basis. Protocols should be established on how to transfer patients from areas affected to surge capacity facilities. There is also a need to inventory emergency providers to include a two or three-tier system to provide for relief from fatigue. This would involve an emergency or homeland security personnel roster system, and be integrated with the newly-established "Medical Reserve Corps."[88] Each of these requirements should be addressed from a systems approach which also suggests information systems integration and IT investments.

[87] Greg Mears, Chairman of the Homeland Security Committee, National Association of EMS Physician.
[88] For more information, see: http://www.medicalreservecorps.gov/about.htm.

The recent outbreak of Sudden Acute Respiratory Syndrome (SARS) forced the issue of public health quarantine or isolation to center stage. Telehealth may be one of the safest and, therefore, most important technologies to diagnose, monitor and treat patients in quarantine for any infectious disease. Singapore, one of the early centers of SARS infection, has applied televideoconferencing to allow providers to monitor and families to "virtually" visit patients. Other applications would enable patients with communicable diseases to be isolated physically but not "virtually."

Access: New Populations and Settings

One of the traditional arguments for telehealth has been its potential for providing greater access to quality healthcare to those living in medically underserved areas. While rural areas are the focus of most discussions on access needs, the subject of medically underserved urban areas has been included in discussions more recently.

Access to healthcare is a state and local priority as well. The State of Texas, a leader in telehealth planning and coordination, has identified access to rural and urban citizens as a statewide priority, pointing to the "maldistribution of health professionals" as a major issue.[89]

Telehealth already provides access to thousands of individuals in medically underserved locations such as rural and remote areas, and "locked-in" patients at correctional facilities and at home. Successful Indian Health Service programs on reservations, telesurgery aboard aircraft carriers, and tele-consultations with diabetes patients in rural Tennessee are among the many applications which demonstrate telehealth's potential to bridge distance, culture, national borders, and very different levels of economic development. Demonstration programs in Micronesia and other territories are linking island villages to mainland specialists as well.

Some characteristics that are unique to rural, remote and some urban areas may support increased demand for the use of telehealth technologies to increase access. While primary care is generally available (although in many areas at a considerable distance), specialty providers are often not. Telehealth, therefore, should increase access to specialists through local primary care providers and facilities. Currently, HHS' Bureau of Primary Health Care funds and supports over 3000 clinics in medically underserved areas and the VA has been linking more than 400 "Community-Based Outpatient Centers" with "parent" medical centers by telehealth connections. Add to these numbers hundreds of rural, remote, and urban clinics funded by state and local governments, private institutions and other organizations and one could conclude that any discussion of "access" should not only include patient to provider but primary care provider to secondary and tertiary care providers, and home healthcare patients to primary care.

[89] See "*The State of Telemedicine and Telehealth in Texas: A Special Report of the Texas Statewide Health Coordinating Council and Recommendations for Ensuring a Strong Telehealth/Telemedicine System in Texas,*" February, 2002, see: http://www.texasshcc.org/tmreport.pdf.

To date, the cornerstone of public telehealth demand has been increasing access to care for remote or health professional shortage area populations. [90] Response to demand for increased access is most commonly a function of government funding and policy decisions by state and local governments, Congress, and such federal agencies as HHS' Office for the Advancement of Telehealth and the Bureau of Primary Health Care, Department of Justice's Bureau of Prisons, USDA's Rural Utilities Service, the Appalachian Regional Commission, Department of Veterans Affairs and the Indian Health Service. A strong Rural Health Caucus, an emerging Congressional Steering Committee on Telehealth and Healthcare Informatics, the beginnings of cooperative research, and lobbying by such groups as the ATA, eHealth Initiative, and others suggest a bright future for telehealth project funding in response to increasing demand for healthcare access.

Another aspect of demand that is likely to grow is consumer demand for convenience or quality healthcare "on demand." Settings for consumer telehealth may include the workplace, recreational areas, transportation centers and modes (e.g. resorts, cruises, aircraft, personal transportation, etc.), schools, and virtually anywhere the need arises. This demand driver may be viewed as another population seeking access for it presumes that the consumer has the ability to pay for convenience.[91]

Telehealth's "store-and-forward" technologies such as eMail and off-line storage offer the healthcare provider and patient the option of scheduling consultations at their convenience and location. The provider's ability to consult outside typical office hours also expands his or her earning potential. Developments in telehomecare not only connect home and provider, but also allow monitoring, consultation, and even treatment around the clock.

Continuum of Care

The emergence of the educated consumer wanting greater control over healthcare choices will also affect demand. One expert noted, "The United States health care industry is experiencing a substantial paradigm shift with regard to homecare due to the convergence of several technology areas. Increasingly capable telehealth systems and the Internet are not only moving the point of care closer to the patient, but the patient can now assume a more active role in his or her own care."[92]

The increasingly important role of the individual consumer in driving technology demand was underscored by another telehealth professional who suggested that " . . . remote

[90] Bashur, Rashid M.D., "Where we are in telemedicine/telehealth, and where do we go from here?" *Telemedicine Journal and e-Health*, Volume 7, Number 4; 2001, p. 273

[91] One commentator at the June 19 Roundtable warned of a trend toward "boutique healthcare" where those that can pay more received better quality and more convenience. For example, the ubiquitous and "always on" nature of the Internet as well as the shift in choice from the provider to the consumer makes such applications as "Web MD" so popular. This trend coincides with a growing population of Baby Boomers which will choose to take charge of their own care.

[92] Warren, Steve, Ph.D., Craft, Richard L., M.S., Bosna, John T., "Designing Smart Health Care Technology into the Home of the Future," Sandia National Labs, 1999

monitoring and care management using telehealth technology have great promise in redefining the health care encounter, and creating a better delivery system for chronic care, and educating patients, supporting patient behavior change, and identifying problems early which are still the fundamental prerequisites to higher quality and lower cost of care."[93] [94] In addition, the use of telehealth technologies coupled with the Internet and related information technologies may shift costs and responsibilities along the continuum of care. For example, telehealth monitoring and communications technologies enable a nearly seamless continuum of care following discharge, and may shift greater responsibility to the patient.

The use of videoconferencing for encounters[95] has been the traditional form and, to a large degree, the foundation of telehealth technology. The use of in-home closed circuit television, cable, satellite, videophone, webcasts, streaming and other technologies offer a virtually unlimited market for connecting Americans to each other, with their healthcare providers, and with first responders. "Vendors have yet to make a conscious effort to help educate the medical community and related end users on the benefits of implementation and integration of videoconferencing into their core communication networks. However, improvements in videoconferencing technologies coupled with the need to curtail spiraling healthcare costs will increasingly propel the industry to utilize and implement telemedicine solutions on a routine basis." [96] Clarification of such policy areas as digital rights, privacy, security, broadcast licensing, spectrum allocation, the quality and accuracy of content, and multi-state licensure will be necessary to fully realize the potential of televideoconferencing.

Monitoring and information exchange can improve the integration and communication between hospital and primary care services to facilitate a 'seamless continuum of care' for families. This means that the healthcare of local or regional populations can be addressed with a progressive spectrum of appropriate delivery entities such as home healthcare, ambulatory clinics, trauma centers, hospitals, or any other resource that is geographically distributed and available to that community. This prospect of instantly matching healthcare needs with the most appropriate and most cost-effective providers through intelligent information and decision-support systems may prove to be one of IT's most significant contributions to addressing the issues of access, cost, and quality. The ability to direct patients with various needs most efficiently to appropriate providers (or linking appropriate providers to patients) should also contribute to meeting homeland security's requirement for surge capabilities.

Disease management is another important aspect of the wellness and prevention paradigm, and future applications for telehealth technology. A prospective disease-specific approach to delivering healthcare, disease management includes inpatient

[93] Steve Brown, CEO of Health Hero Network, Inc. and a panelist at the Technology Administration's Roundtable "Innovation, Demand and Investment in Telehealth," June 19, 2002 in Washington D.C.
[94] Steve Brown, CEO of Health Hero Network, Inc. and a panelist at the Technology Administration's Roundtable "Innovation, Demand and Investment in Telehealth," June 19, 2002 in Washington D.C.
[95] The use of cameras and recording devices to link providers with patients.
[96] Frost & Sullivan (www.conferencing.frost.com), "U.S. Telemedicine Videoconferencing Systems and Services Market," reveals this market generated $119 million in 2000 and projects revenues to reach $275 million by 2007.

treatment, emergency services, outpatient care, and home care, and represents a new model of care that requires proactive intervention in illnesses at all disease stages in order to avoid hospitalization costs. Common features of disease management are physician guidelines, monitoring (drug and other treatment interventions), patient education, and behavior modification interventions – all applications that could be accomplished through telehealth.

Home Healthcare

Demographic trends suggest that any discussion of access should increasingly include healthcare at home as demographic trends suggest. Aging of the Baby Boomer generation combined with longer life expectancies will likely mean a larger population of fragile and chronically ill elderly, many requiring rehabilitation after hospitalization. Retiring Baby Boomers favoring independent lifestyles are also increasingly likely to demand access to medical advice and treatment from home.

Through personal health information systems, health education information and decision-support will be publicly accessible over the Internet, through email, and through telehealth. The public will also be expected to assume a greater responsibility for developing personalized health risk profiles. From this information, individual intervention programs can be developed to prevent onset of disease. A strong patient-centered lifetime wellness strategy combined with a robust patient education program could have a major impact on lifestyle-related chronic illness.

Consumer advocates seem to agree with the statement, "Consumer education needs to be an important part of the health care mission,"[97] suggests a leading professor. Wellness and prevention offer a strategy for coping with the costs associated with chronic illness, as well as with injury-related and other types of healthcare encounters. An emerging national trend is the shifting of resources to disease management, preventive care, and health promotion. By preventing incidents requiring hospitalization and the onset of disabilities that require long-term expensive treatment, significant reductions in the economic burden of healthcare can occur.

According to recent studies and workshops, homecare was the fastest growing segment of the medical device industry throughout the 1990s and the movement toward greater independence and convenience in home healthcare, telehomecare will be an important associated trend. Providing telehomecare to elderly or disabled populations using telehealth raises important policy questions about access and the reimbursement of telemedicine services for both rural and urban patients.

It can be argued that urban patients who are very elderly, chronically ill, poor, or disabled are as isolated and have as much difficulty getting access to needed health services as those living in rural areas. Most of these urban patients cannot drive to local clinics and

[97] Robert A. Greenes, MD, Ph.D. Professor of Health Policy and Management at the Harvard Medical School. "To Err is Human-Healthcare Internet Strategies in Enhancing Quality and Avoiding Medical School." Presentation before the eHealth Colloquium, Harvard University, August 2000.

many require assistance getting from point A to point B. Traveling a mile for an urban patient may be as onerous as a rural patient's two hundred-mile drive to see a specialist.[98]

"In addition to monitoring patients with chronic diseases such as congestive heart failure and diabetes, telehomecare has the potential to provide access to high-risk patients typically cared for in hospitals thus driving down costs and risks associated with transportation to and from points of care. Telehomecare has also been shown to improve healthcare access for disabled persons, connect socially isolated individuals to their care providers, and enhance caregiver effectiveness."[99]

Home may also be the lowest-cost place to deliver care, but this assumption must be proven for each situation and medical treatment needed. Such a significant shift from traditional healthcare encounters should trigger a serious and systematic reexamination of coverage and reimbursement policies among Medicare, Medicaid, and the nation's private payers.

Demand in International Markets

Although known, adopted and deployed throughout the world, globalization of telehealth technologies and services has yet to achieve its market potential. This appears to be especially true in developing countries where access to primary health care in remote and rural villages is more limited and transportation of patients to providers is more difficult.

Generally speaking, however, U.S. telehealth vendors have limited themselves to the U.S. domestic market and U.S. companies with active installations in overseas markets appear to be the exception rather than the rule. AMD Telemedicine is one exception, with activity in over 50 countries. Other than Canada, the U.K., Japan[100] and Australia, other major developers and manufacturers of telehealth technologies do not have sufficient domestic markets to justify significant research, development, and production. That currently leaves the United States with a competitive advantage for exporting telehealth technologies and services.[101]

That the U.S. leads in telehealth technologies suggests that, with effective marketing and responsiveness to sales opportunities, American firms can also lead in world market

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[98] "2001 Report to Congress," Office for the Advancement of Telehealth.

[99] Dansky et.al., "Cost Analysis of Telehomecare." Telemedicine Journal and e-Health, Volume 7, Number 3, 2001.

[100] Japan's Health, Labor and Welfare Ministry plans to set up telemedicine networks to provide specialized care to people in remote areas via information technology with in the hopes of narrowing the health-care divide between large cities and rural areas. The government will provide 500 million yen (about $4 million US) a year to form networks consisting of one large hospital and three clinics working together to supervise patients. Each patient will be equipped at home with a computer that can monitor heart rate, blood pressure and other indicators as well as a phone capable of transmitting video. They will be linked to doctors via an ISDN digital phone connection. Tokyo plans to establish 10 such networks a year from fiscal 2001, which began this month, so that all 47 districts have at least one within five years. For data see http://telehealth.net/subscribe/newsletter12.html#marketwatch.

[101] The international market for telehealth technologies and major projects has been largely overlooked by U.S. industry except for a few integrators such as AMD Telemedicine and VitalNet.

share. Economic assistance programs, such as those offered by the US Agency for International Development (USAID) and multi-lateral development banks, may lead to major telehealth projects, possibly in conjunction with broader healthcare or telecommunications projects. Even though USAID has invested heavily in primary care in many developing nations, its interest in healthcare technologies has been limited by its emphasis on technologies "appropriate" for recipient nations. Meanwhile (and ironically), medical communities in those countries are among the most enthusiastic advocates for telehealth as evidenced by their participation in international forum. For example, the launch in 2002 of the World Health Organization's (WHO) first "Collaborating Centre for Telemedicine" in Norway raises the potential for partnerships worldwide in the diffusion of U.S. telehealth technology (e.g. a "Collaborating Center" for the Western Hemisphere and other regions).

In 2003, DOC's International Trade Administration (ITA) began to target telehealth suppliers for its export promotion programs featuring four trade missions and one international exhibition in 2003. Although most events will include telehealth within the larger medical device sector, ITA featured telehealth in a "virtual" trade mission to Columbia in August, 2003.

Although ATA's own annual exhibition held in conjunction with its annual meeting may not include enough vendors to justify foreign buyer attendance, the collective know-how in designing and managing telehealth programs of those participating in a typical ATA conference would likely be considered a very attractive, exportable service. ATA's exhibitions have, until now, been planned and perceived as a service to its own 2500-3000 conference attendees (which include a few hundred foreign visitors).

It has been suggested that combining shows with a very large exhibition such as that held annually by the Healthcare Information and Management Systems Society (HIMSS) would be a cost-effective means for marketing telehealth technologies to a much broader audience. The same synergy may be useful in marketing healthcare technologies to donor agencies (e.g. USAID, World Bank, etc.).

Competitiveness

The United States has one of the most active and innovative telehealth sectors in the world. Although trade statistics are not available in enough detail to support this assumption, a review of international literature and the number of international inquiries reported by ATA suggest that the U.S. leadership role is widely recognized. It is also evident from the trade press that competitor nations are seriously attempting to catch up. Canada, Australia, Japan, and the U.K. all have active telehealth industries characterized by national associations and small to medium enterprises. A recent International Telecommunications Union study stated: "The EC[102] has its telemedicine/telehealth program squarely aimed at developing a competitive European telemedicine industry as

[102] European Community

well as improving the delivery of health care services to Europeans."[103] Japanese and German mega-firms such as Sony and Siemens are also innovating telehealth products. Japanese innovations, for example, appear to be targeting home healthcare and consumer markets.

This nation's competitive advantage in telehealth may, in the long run, be threatened by some potential trends:

- Continued engagement with such issues as reimbursement, licensure and the evidence of efficacy and cost effectiveness may distract technology firms from international market opportunities and building competitive advantage.
- Limited presence of U.S. healthcare technologies in international markets will ultimately lead to market preferences for foreign suppliers. Faced with the prospect (or appearance) of limited American interest in supplying foreign markets, buyers and providers may begin to develop preferences for and dependencies on competitor technologies.
- Outsourcing of healthcare technology research, development or production, or services to lower cost competitor nations is a relatively recent development. It has been reported, for example, that Indian, Australian and Israeli firms are already providing major U.S. hospitals with second and third shifts of radiologists interpreting images.[104] While this practice may lower healthcare costs and improve competitiveness in the short run, the economic, social and political implications of outsourcing healthcare abroad are, as yet, unknown.
- A recent development in Europe also raises the prospect of increased competitiveness through regional cooperation. The Telemedicine Alliance (TM Alliance) has been set up to pave the way for a unified system of telemedicine in Europe. This alliance links the Information Society Technologies (IST) program of the European Commission (EC), the World Health Organization (WHO), the International Telecommunication Union (ITU), and the European Space Agency (ESA).

Certain actions may be necessary to sustain the U.S. advantage in telehealth technology and competitiveness:

1. Providing timely and accurate information on telehealth research and innovation abroad
2. Increasing the commitment and capabilities of U.S. telehealth suppliers to export
3. Supporting telehealth products and services exporters in overseas markets
4. Expanding international awareness of U.S. telehealth technologies (active programs in overseas markets funded by USAID, the Millennium Challenge Account,[105] or other US Government agencies)
5. Assuring that U.S. products and services comply with international standards
6. Resolving interoperability issues essential to exportability and market share

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[103] From a report of the Plenary Meeting of the International Telecommunications Union Regional Development Conference for the Arab States. For more information, see http://www.itu.int/itudoc/itu-d/rtdc96/023e_ww2.doc.

[104] "MGH examines India for X-ray reading help," *India New England News*, January 15, 2003.

[105] The Millenium Challenge Account is defined as a new partnership between all parties involved in successful international development: donor and recipient governments, non-governmental and private voluntary organizations, businesses, and multilateral organizations all working to achieve measurable development results.

7. Assuring that the U.S. is represented in any discussion of standards and/or trade barriers which would affect export markets
8. Adding Harmonized System[106] codes that would be used to identify telehealth market opportunities
9. Assuring that the U.S. workforce has the level and quality of skills needed to compete

Factors such as the lack of technical standards, state licensure rules, and infrastructure costs affect the size and openness of telehealth markets at home and may ultimately affect competitiveness abroad. Internationally, U.S. exporters are faced with the uncertainties of exchange rates, language barriers (which affect labeling requirements), regional or national technical standards, and other non-tariff barriers. Until now, U.S. telehealth manufacturers have not been routinely represented in standards-setting fora, such as the European Union, the International Telecommunications Union, and even Underwriter Laboratories in the U.S. The eight-point "Standards Initiative" recently announced by Commerce Secretary Evans is designed to address some of these issues.[107]

Developing nations are anxious to apply technology to improve primary care delivery but need financial and technical help. USAID offers a potentially effective channel for replicating the kinds of "demonstration projects"[108] to advance awareness and adoption of U.S. healthcare technologies in developing nations. Telehealth projects organized and funded by the Millennium Challenge Account and Digital Freedom Initiative also have the potential to significantly improve primary healthcare delivery in target nations.

Continuing innovation in telecommunications will also impact markets for U.S. telehealth exporters. That some foreign markets are nearly completely connected by high-speed Internet communications (broadband) gives their healthcare providers a broader choice of technologies and range of capabilities. On the other hand, developing countries without efficient telecommunications infrastructure can leapfrog forward in delivering healthcare with the use of satellite and wireless technologies. Good market research, such as that provided by the Commerce Department, will allow would-be exporters to select markets based on estimated demand for their products and services, adapt their products and services to the distinct requirements of selected markets, and assist in securing this nation's competitive advantage.

BARRIERS TO MARKET DEMAND

The U.S. market for telehealth does not fit well with the traditional model of supply and demand because most healthcare is reimbursed by third party payers. Providers and payers (and not patients) make economic choices and, therefore, play the role of an intermediate consumer. Although individuals will almost always choose better healthcare, they have far less choice in what, when, where, by whom, and at what cost

[106] The Harmonized System is the universally-accepted classification systems for trade in products and services.
[107] The Initiative mobilizes different bureaus of DOC to focus special emphasis on assistive technology needs, such as international trade, manufacturing processes, standards and technology transfer.
[108] Such as those funded by OAT, for example.

healthcare is provided. Demand created by such national priorities as homeland security and access to quality healthcare is not economic. The market is affected by such factors as:

- Reimbursement policies of third party payers (also discussed in Chapter 4)
- Variable and exclusive state licensure requirements
- Credentialing and privileging of providers[109]
- Perceptions of legal liabilities
- Lack of information on efficacy and cost benefits (also discussed in Chapter 2)
- The need to ensure HIPAA-compliant data storage and information exchange (e.g. patient-provider e-mail)

Reimbursement

Probably no topic is more often identified as an "issue" or a "barrier" to innovation, demand and investment in telehealth than reimbursement for encounters. Since 88% of Americans do not reimburse healthcare providers directly but through "third party payers," reimbursement "policy" is determined and applied by such organizations as Medicare, Medicaid, health maintenance organizations, and employment-based insurance plans. The following table estimates how many Americans have healthcare coverage and by whom:

Table 3.a Third Party Reimbursement Patterns[110]

Type of Coverage	Total persons (millions)	Per cent	Total
Private Insurance: Self	22,945	7.38%	
Private Insurance: Employment -based	177,226	57.01%	
Total private	200,171		64.39%
Medicare	28,648	9.22%	
Medicaid	37,015	11.91%	
Military healthcare[111]	8,301	2.67%	
Total government	73,964		23.79%
Total Insured	274,135		88.18%
Not-insured or private pay	36,729	11.82%	11.82%
Total	310,864	100.00%	100.00%

[109] JCAHO is currently in the process of changing its policy on credentialing and privileging (C&P) for some aspects of teleconsultation by allowing a distant "treating clinician" specialist (e.g. dermatoligst) to be credentialed and privileged through one of three options. These are: the originating site of the consult does both the credentialing and privileging of the distant specialist, the distant site does the credentialing and originating site the privileging (current rule), and a new "proxy" method wherein the originating site would accept the C&P from the distant site. In this last instance, the originating site would be responsible for reporting to the distant site any "adverse" outcome arising from the distant specialist's treatment, leaving peer review of cases (one aspect of continued privileges) up to the distant site. Development of this process was spearheaded by a joint DoD/VA policy group who worked in concert with JCAHO. It is expected that this policy should take effect in early 2004.

[110] Table A-2, "Health Insurance Coverage Status and Type of Coverage by Selected Characteristics: 2000," U.S. Censure Bureau, can be viewed at: http://www.census.gov/prod/2001pubs/p60-215.pdf.

[111] Includes CHAMPUS/TRICARE, Veterans Affairs, and military healthcare.

Table 3.b underscores the point that healthcare providers are almost entirely dependent on third party payers for their revenue. Third party payers (Medicare, Medicaid, Workmen's Compensation, other government payers [e.g. military and veterans healthcare services], and private insurers) comprise 88.18% of all reimbursement. Given this, telehealth providers tend to prefer (demand) those services and equipment that are covered by applicable third-party reimbursement policies – and will be unlikely to provide services that will not be reimbursed. It would appear, then, that demand for telehealth devices and applications is, therefore, influenced greatly by reimbursement policies. A more accurate observation would be that, although third party reimbursement is essential to long term sustainability of telehealth programs, providers have largely been compensated by other institutions (federal and state government, non-profit foundations and universities) to date.

Table 3b. Reimbursement for Healthcare by Source and by Provider

(figures in $millions)

Who pays	Medicare	Medicaid	Other Govt.	Worker's Comp	Private insurers	Private (Self)	All other sources	TOTAL
Who benefits								
Physician offices	48,370	13,896	2,025	7,419	97,193	22,865	7,299	199,067
Other providers offices	4,225	1,542	857	2,268	12,546	8,120	2,200	31,758
Mental health practitioners	177	206	556	N/a	844	656	262	2,701
Therapists	1,368	516	n/a	1,296	2,871	803	1,331	8,185
Outpatient care centers	11,651	6,814	2,492	1,411	20,694	5,803	4,126	52,991
Other outpatient care centers	11,236	4,709	1,287	1,402	19,724	5,000	3,369	46,727
Freestanding ambulatory surgical and emergency centers	1,338	345	N/a	338	2731	670	532	5,954
All other outpatient care centers	2,983	2,912	818	1,040	6,132	1,663	1,559	17,107
Home healthcare services	9,961	7,121	443	n/a	5,145	2,465	2,282	27,417
Other ambulatory care services	1,593	466	n/a	n/a	1,893	703	3,931	8,586
Hospitals	138,843	52,305	22,687	4,720	155,206	22,928	10,622	407,311
Nursing and residential care	12,699	43,834	7,157	n/a	6,231	24,603	3,300	97,824
Community care facilities for the elderly	1,093	2,827	511	n/a	567	12,374	794	18,166
Medical and diagnostic laboratories	3,790	1,032	96	387	8,642	2,005	5,319	21,271
Totals (millions)	249,327	138,525	38,929	20,281	340,419	110,658	46,926	945,065

	26.38%	14.66%	4.12%	2.15%	36.02%	11.71%	4.97%	

One factor that influences reimbursement decisions is the definition of what constitutes a "patient encounter." An encounter has been traditionally defined as an event in which both the provider and the patient were in the same room for the purpose of providing medical care or "service." Medicare and other payers generally pay for visits, interpretations, etc, and not encounters. When Medicare pays for an x-ray, there is a facility fee and a fee to the professional for an interpretation. There is no assumption of a face-to-face visit. When Medicare began to pay for telehealth, it removed the requirement for patient and provider to be in the same "space" or room, but by requiring interactive services, maintained the requirement that the patient and provider be in the same "time." The issue now with store-and-forward technologies is that patient and provider are no longer interactive or in the same "time."

The definition is important because, traditionally, the payment structure for providers' services has defined the encounter, so there does not appear to be a single, explicit definition of encounter.

An additional dilemma is associated with the traditional practice for physician services paid under the physician fee schedule. It is the physical location of the physician providing the service that determines the place of service. For example, if a patient had an x-ray performed by a facility in Pennsylvania, and the x-ray was read by a physician in Florida, Medicare would consider the service to have been furnished in Florida. Moreover, if the patient was in Pennsylvania and the x-ray was read in Israel, Medicare would consider the service to have been furnished in Israel. [112]

The definition of encounter for Medicaid is: "face-to-face contacts between a patient and a health professional for medically necessary services and includes the recipient's visit to the center, including all services and supplies incidental to a practitioner's services ..." [113]

With the evolution and emergence of telehealth, the traditional definitions of encounter no longer apply. The critical elements of a definition could be considered the significance of what takes place between the provider and patient, not the location or timing. If the exchange of information "establishes, changes or implements a plan of care," the net effect is the same as the traditional encounter, regardless of time and place. A current definition that recognizes the role of technology is an issue that warrants more and more specific attention of third party payer and provider communities.

Until recently, there was a common assumption within the telehealth community that most third party payers were restrictive. Two recent surveys, however, one of providers and payers in all 50 states, and a second of Medicaid organizations in all 50 states,

[112] Center for Medicare and Medicaid Services, "FAQs" at http://questions.cms.hhs.gov/
[113] "Medicaid Provider Manual" Chapter 21, issued October 18, 2002

suggests that the reimbursement issue may not be as widespread or as insolvable as once thought.[114] A discussion of the major third party payers reveals why.

Reimbursement by Medicare

Like many other medical services, Medicare's reimbursement policies and regulations on telehealth have been developed to implement legislation. For example, CMS' policies to implement the "Medicare, Medicaid, and SCHIP (State Chil It appears that increasing interest in telehealth by Congress, the states and private insurers has begun to impact the longstanding issue of reimbursement. It is widely assumed that the degree of specificity contained in the "Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Benefits Improvement Act of 2000" (BIPA) was a result of growing Congressional interest with Medicare's restrictive approach to telehealth (such as what was viewed as an overly restrictive response to telehealth provisions of the Balanced Budget Amendment of 1997). In the BIPA, for example, Congress took the unprecedented step of specifying CPT codes within the legislation as well as specifying more precise provisions than those that had been interpreted more narrowly in the past.
dren's Health Insurance Program) Benefits Improvement Act of 2000" (also known as "BIPA")[115] included expanding coverage for additional applications, and eliminating such payment policies as fee-sharing.

Congress has traditionally played a central role in determinations of Medicare policy. The Beneficiary Improvement and Protection Act of 2000 ("BIPA"), for example, instructs:

> "The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician . . . to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing telehealth service is not at the same location as the beneficiary. In the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term "telecommunications systems" includes store and forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats."[116]

This legislation marked a significant change in Medicare's coverage of telehealth services. The Act:

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[114] Taken from presentations to the ATA December 2002 business conference on surveys of reimbursements policies by Medicaid and private payers by the Center for Telemedicine Law and AMD Telemedicine respectively.

[115] It appears that increasing interest in telehealth by Congress, the states and private insurers has begun to impact the longstanding issue of reimbursement. It is widely assumed that the degree of specificity contained in the "Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Benefits Improvement Act of 2000" (BIPA) was a result of growing Congressional interest with Medicare's restrictive approach to telehealth (such as what was viewed as an overly restrictive response to telehealth provisions of the Balanced Budget Amendment of 1997). In the BIPA, for example, Congress took the unprecedented step of specifying CPT codes within the legislation as well as specifying more precise provisions than those that had been interpreted more narrowly in the past.

[116] The "Beneficiary Improvement and Protection Act of 2000"

- Expanded who could receive services
- Expanded what services would be covered
- Clarified home care coverage
- Eliminated the presenter requirement for face-to-face encounters
- Changed the payment methodology
- Provided for coverage of store and forward in Hawaiian and Alaskan demonstration projects

Medicare has also relied on efficacy and cost effectiveness[117] studies for its analysis leading to determinations, but has postponed some determinations of reimbursement due to insufficient breadth of the "review" performed under an Agency for Health Research and Quality (AHRQ) contract with AETNA. It appears from the following summary of the AETNA review[118] that telehealth applications are making progress in the areas of access, quality, and cost, but that additional and better quality research is needed to confirm earlier results.

> A total of 28 eligible studies were identified. In the new clinical areas, few studies in store-and-forward telemedicine were found. There is some evidence of comparable diagnosis and management decisions made using store-and-forward telemedicine from the areas of pediatric dental screening, pediatric ophthalmology, and neonatology.
>
> In self-monitoring/testing telemedicine for the areas of pediatrics, obstetrics, and clinician-indirect home telemedicine, there is evidence that access to care can be improved when patients and families have the opportunity to receive telehealth care at home rather than in-person care in a clinic or hospital. Access is particularly enhanced when the telehealth system enables timely communication between patients or families and care providers that allows self-management and necessary adjustments that may prevent hospitalization. There is some evidence that this form of telemedicine improves health outcomes, but the study sample sizes are usually small, and even when they are not, the treatment effects are small.
>
> There is also some evidence for the efficacy of clinician-interactive telemedicine, but the studies do not clearly define which technologies provide benefit or cost-efficiency. Some promising areas for diagnosis include emergency medicine, psychiatry, and cardiology. Most of the studies measuring access to care provide evidence that it has improved. Although none of these studies were randomized controlled trials, they provide some evidence of access improvement over prior conditions. Clinician-interactive telemedicine was the only area for which any cost studies were found. The three cost studies identified did not adequately demonstrate that telemedicine reduces costs of care (except when comparing only selected costs), and no study addressed cost-effectiveness.

Since this and similar AHRQ reports are provided to the Center for Medicare and Medicaid Management Services (CMS) for use in determining reimbursement policies, it appears that additional quality research is required to determine telehealth efficacy and cost savings. Most importantly, until clinical efficacy and cost-benefit research achieves a much greater level of acceptance by HHS, providers, and payers, reimbursement for

[117] There is a current debate over whether cost is being and should be used as a criterion by Medicare.
[118] Evidence Report/Technology Assessment Supplement No. 24, *Telemedicine for the Medicare Population: Pediatric, Obstetric, and Clinician-Indirect Home Interventions* (AHRQ Publication No. 01-E060).

telehealth will remain an unresolved issue – and a leading barrier to innovation, demand and investment.

It has been stated that Medicare reimbursement policies lag behind technology and markets. Although telehomecare is viewed as the next major market for telehealth, for example, CMS does not have the legislative authority to make the home an "originating site." On the other hand, CMS states that "local carriers have the authority to approve all diagnostic tests and interpretations." Store-and-forward technology is becoming increasingly popular with both providers and patients because it increases scheduling flexibility and operating costs are lower. Because the encounter is not "real-time," however, Medicare will not reimburse store-and-forward with the exception of "demonstrations" in Alaska and Hawaii, and for some applications under which the conventional delivery of health care are not delivered face-to-face (e.g. interpretations of an e-ray, ECG, EEG, tissue samples, etc.).

Members of Congress have questioned the variance of CMS and Congressional Budget Office (CBO) costing projections of proposed telehealth provisions, based on econometric models, with actual outlays. For example, CMS projections ranging from $20 million to more than $1 billion[119] as a result of BIPA provisions have, to date, proven to be far greater than actual. CMS reports that, by the end of FY2002, only 1,350 billings for telehealth coverage specified under BIPA have been approved, amounting to less than $50,000 in reimbursement. The Congressional Budget Office substantially lowered its estimates based in part on data provided by OAT and the Center for Telemedicine Law (CTL). "The CTL/OAT estimates of expanding telemedicine payments under BIPA ranged from $50-$100 million over five years."[120]

Historically, Medicare's use of cost models has been justified by a lack of empirical data. The Office for the Advancement of Telehealth (OAT), together with the Center for Telemedicine Law (CTL) and OAT's grantees have, however, developed a series of models to demonstrate the impact of expanding telemedicine coverage on any third party payer's expenditures. Application of these scoring models has the advantage of incorporating actual billing data. Preliminary results suggest that many of the modest telemedicine reimbursement expansions (recommended but rejected as too costly in recent years) would have had a minimal impact on additional Medicare expenditures.

Changes in telehealth coverage were announced in the Physician Fee Schedule, Final Rule for Calendar Year 2003[121] in which CMS proposed (1) to establish a process for adding or deleting services from the list of telehealth services reimbursed, and (2) to add specific services to the list of telehealth services.[122] The most significant change for the telehealth industry is CMS' process for direct stakeholder input. CMS will accept proposals from any interested individuals or organizations, from either the public or the

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[119] Response to a draft of this report from CMS and Puskin, Dena S., Ph.D., (September 30, 2001) "Telemedicine: Follow the Money" *Online Journal of Issues in Nursing*. Vol. 6 No. 3, Manuscript 1. Available: http://www.nursingworld.org/ojin/topic16/tpc16_1.htm

[120] *Ibid.*

[121] We consider the change "significant" because, until now, there was not a formal process for stakeholders seeking changes to codes or coverage. .

[122] CMS rules and procedures were not available at the time this report was published.

private sectors, such as from medical specialty societies, individual physicians or practitioners, hospitals, and State or federal agencies, and, may generate additions or deletions of services internally. Interested parties could also request a change by writing to the Group Director at CMS.[123]

The change should give CMS greater administrative flexibility to accept the requestor's recommendations. Their decision criteria would include whether or not the telehealth service or device alters a diagnosis or treatment plan, includes methods the provider chose to use, or proves satisfactory to patients. The telehealth option must also be similar to the corresponding face-to-face encounter (e.g. real-time).

Such changes in the past have been followed by similar changes by state (Medicaid) and private payers. Expanded reimbursement has historically resulted in increases in telehealth demand by consumers and in technology investments by providers. According to the proposal, CMS would "accept requests for additions to the list on an ongoing basis, and would consider requests submitted by December 31 of each year to be included in the proposed physician fee schedule rule for the following year."[124] CMS expected to have final rules implementing the proposed process by the end of 2003. While this represents a step forward in opening the determination process to the public and offers an alternative to dependence on Congressional leadership, CMS analysis will continue to rely on efficacy and cost-effectiveness studies, and Congress will continue to exercise its authority in legislating coverage.

Another recent change having potential to improve the reimbursement process was announced by HHS Secretary Thompson in March 2003. The HHS Secretary's Advisory Committee on Regulatory Reform recommended streamlining the process by which CMS decides whether to pay for new technologies approved by FDA. The recommendation resulted in establishing a "Medical Technology Council" (MTC). According to the HHS press release, the MTC will work on improving Medicare policy relating to coverage, coding, and payment for emerging technologies. According to the Administrator of CMS, "this new council will reduce the time needed for making and implementing Medicare coverage decisions for new technologies and making CMS' process as seamless as possible for outside stakeholders."[125]

Although data for medically underserved areas is generally unavailable, it seems reasonable to assume that rural provider revenue most often takes the form of Medicare and Medicaid reimbursement, and other federal and state government programs (e.g. the State Children's Health Insurance Program). One of the difficulties facing providers is the "paperwork" required to apply for reimbursement from third party payers. Patients applying for Medicare enrollment must, for example, be personally visited by a health

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[123] Information on applying for a new HCPCS code may be found on the CMS website at http://cms.hhs.gov/paymentsystems/hcpcs/03infopktweb.pdf.

[124] Medicare Proposes 2003 Physician Pay Changes Standards for Physician Data Input Eased," from *Medicare News*, June 27, 2002 from the CMS web site at http://cms.hhs.gov/media/press/release.asp?Counter=465.

[125] As reported by eGov portal "Seniors.gov" on March 24, 2003 http://www.seniors.gov/articles/0303/cms.htm.

care professional in order to complete the multi-page Outcome and Assessment Information Set OASIS form, a 3-4 hour process.

For any provider seeking reimbursement from CMS, the means for electronically submitting cost reports is now or will soon be required. A new CMS proposal would require hospices, organ procurement organizations, health clinics, and other specialized healthcare facilities to electronically submit Medicare cost reports in 2003. Hospitals, skilled nursing facilities, and home health agencies must already submit Medicare cost reports electronically. Electronic submission across all Medicare providers, CMS says, would allow for more accurate preparation and more efficient processing for reimbursement.[126]

Other organizations that would be affected by the proposal for electronic submission of cost reports include federally qualified health centers, community mental health centers, and end-stage renal disease facilities. The first two years of the requirement would be considered a transition period, CMS says, in which submission of "hard or paper copies" of cost reports would still be permitted. Affected facilities would also be able to request a delay or waiver of the electronic cost-reporting requirement, if implementation would cause "financial hardship." Providers with "low or no Medicare utilization" would be exempted.

This policy could have a significant impact on Medicare billings in medically underserved areas. Although the full extent of technical requirements is unknown, one would assume that every participating provider who is not already "on-line" would need to acquire access to a PC, hard drive, modem and phone line, or risk changes to its relationship with Medicare as a payer.

Criteria for Determining Medicare Policy

As the nation's largest third party payer, reimbursement policies often cast Medicare in the role of "industry leader." However, most third party payers apply their own reimbursement criteria, but also claim to follow Medicare's lead.

Even though other criteria have been considered in the past, Medicare criteria includes (by law) both cost and efficacy. Some have argued that Medicare does not have the legal authority to use cost as a criterion for reimbursement. Others have suggested that cost effectiveness rather than cost-benefit should be the determining cost criteria.[127] The Congressional Budget Office applies cost considerations only when quantifying the impact of legislation.

There appears to be either confusion or disagreement over the role of cost-benefit or cost-effectiveness studies in shaping reimbursement policies and legislation. Since 1989,

[126] See Federal Register notice at http://www.access.gpo.gov/su_docs/fedreg/a020726c.html.

[127] For a robust discussion of Medicare criteria, see Dr. Dena Puskin in the *Online Journal of Nursing*, "Telemedicine: Follow the Money" *Online Journal of Issues in Nursing*. Vol. 6 No. 3, Manuscript 1. Available: http://www.nursingworld.org/ojin/topic16/tpc16_1.htm

when Medicare proposed to use cost as a coverage criterion and then reversed its proposal, the medical technology industry has assumed that efficacy (and not cost) is the determining factor for reimbursement decisions. Recent suggestions by CMS that cost-effectiveness may again be included as a criterion may have the effect of further and significantly complicating regulatory and reimbursement policies because of the lack of commonly-accepted models, the difficulty in measuring both cost and effectiveness, and the question of responsibility for conducting such analyses.

Moreover, the availability of federal data that would allow for quantitative analysis in the areas of policy, efficacy, and cost-effectiveness is limited. A researcher looking to the Department of Health and Human Services (HHS) for data relating to the effectiveness of telehealth programs on increasing access to quality healthcare, for example, would find the following:

> HHS programs do not routinely collect service area and outcome data that describes how and precisely where they serve rural people and communities. Sparse populations make the cost of conducting household-based representative surveys expensive and limit HHS' ability to conduct rigorous quantitative research. The diversity of rural areas and rural communities limits the generalizability of research data; service area data is not collected by race, ethnicity and disability, obscuring the diversity of rural communities. [128]

In the case of Medicare or Medicaid, however, the efficacy or effectiveness of the telehealth encounter must also be measured and evaluated as criteria for reimbursement. CMS and private third party payers use clinical studies and demonstration projects as primary tools in applying the efficacy criterion. CMS and the Agency for Healthcare Research and Quality (AHRQ), for example, have undertaken a long term research project which is studying store-and-forward technology, patient self-monitoring, and potential applications for non-surgical services. [129]

The criticism by CMS, AHRQ, and others of the quality of clinical efficacy studies of telehealth has been noted elsewhere in this report. Another third party payer, Aetna, conducted the review of studies for quality funded by AHRQ. Aetna concluded that, with a few exceptions, the efficacy of telehealth has not been clinically established because existing studies do not meet criteria for quality. Not surprisingly, Aetna based its own reimbursement policy, at least in part, on its own conclusions from the results of the AHRQ study. [130] Surprisingly, however, a current industry review found Aetna to be the only major third party private payer that specifically prohibits reimbursement for telehealth (with certain exceptions). [131]

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[128] Taken from "One Department Serving Rural America" report of the Health and Human Services report to the Secretary, July, 2002.

[129] Evidence Report/Technological Assessment No. 24, Telemedicine for the Medicare Population (AHRQ Publication No. 01-E012).

[130] *Ibid.*

[131] Aetna Clinical Policy Bulletin 632 of November 25, 2003.

That AHRQ and CMS continue to base reimbursement policy on the absence of quality clinical and cost-benefit studies would appear to ignore the existence of numerous studies supporting both efficacy and cost-benefit. If providers and payers are so far apart in their understanding of what constitutes "quality studies," there may be reason to expect better communications from CMS and AHRQ on their expectations and/or why meeting those quality expectations is not possible. On the other hand, AHRQ is not, itself, currently funding clinical efficacy studies for telehealth applications.

An informal survey using *clinicaltrials.gov* revealed that of 11 clinical research studies related to telemedicine/telehealth, 10 are underway, completed or planned by the Department of Veterans Affairs and one by the National Cancer Institute. It would seem, then, that VA, AHRQ, and CMS should be meeting to discuss how to include VA's research in reimbursement determinations. Such coordination would be important, for example, to pending CMS determinations concerning telehomecare for which VA has an extensive program and has undertaken peer-reviewed clinical research.

Reimbursement by Medicaid

Medicaid, a joint federal/state funded program for low-income Americans, is another source of reimbursement for telehealth encounters. Medicaid reimbursement is administered by each state and policies regarding coverage vary significantly. According to the latest information from OAT and the Center for Telemedicine Law, 23 states[132] are reimbursing for telehealth services through Medicaid. [133]

> "Generally speaking, payments are provided only under the fee-for-service Medicaid plans, and usually at both ends (hub and spoke) of the telemedicine consultation. A majority of states also require interactive communication between patient and provider as a condition for determining whether Medicaid may reimburse the service. While having the flexibility to pay for additional costs like line-charges, use of equipment, or technical support, a majority of states do not reimburse these expenses."[134]

[132] Arkansas, Arizona, California, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Minnesota, Montana, Nebraska, North Carolina, North Dakota, Oklahoma, South Dakota, South Carolina, Tennessee, Texas, Utah, Virginia, and West Virginia from a CTL report presented to the December 2002 ATA conference. See: http://www.atmeda.org/news/2003_presentations/M3a1.hutcherson_files/frame.htm

[133] The Health Care Financing Administration (CMS) has not formally defined telemedicine for the Medicaid program, and Federal Medicaid law does not recognize telemedicine as a distinct service. Nevertheless, Medicaid reimbursement for services furnished through telemedicine applications is available, at the State's option, as a cost-effective alternative to the more traditional ways of providing medical care (e.g., face-to-face consultations or examinations). As described below, at least eighteen states are allowing reimbursement for services provided via telemedicine for reasons which include improved access to specialists for rural communities and reduced transportation costs. From the CMS Website at http://cms.hhs.gov/states/telemed.asp.

[134] Ibid p. 76.

A recent survey in Virginia reported that "Medicaid is available for telehealth, but providers are not billing" because of such barriers as "motivational" (unaware of polices and procedures) and "operational" (choosing to avoid required paperwork).[135]

Although jointly funded, Medicaid's federal partner (CMS) describes each state's role as:[136]

> "Within broad national guidelines which the Federal government provides, each of the States:
> 1. determines the type, amount, duration, and scope of services;
> 2. establishes its own eligibility standards;
> 3. sets the rate of payment for services; and
> 4. administers its own program."

A significant issue for telehealth providers, then, is the variability of the patchwork of state telehealth policies. According the 2002 CTL survey of Medicaid policies[137], no two states shared the same policies, coverage, and understanding of telehealth. In addition:

- Each state is unaware of coverage policies of other states (although each is interested in knowing what other states are paying for).
- Most of the 23 states that reimburse for telehealth under Medicaid show very low utilization.
- Data research studies showing cost savings would convince most Medicaid programs to reimburse for telemedicine.
- States tend to use the term "telemedicine" because that is the term used by CMS.

Medicaid coverage for telehealth is idiosyncratic,[138] with some states only covering teleradiology, while others cover the full range of services. Restrictive regulatory policies exist. For example, the state of Nebraska covers a wide range of services, but will not reimburse for services if the provider is receiving a grant. However, California, Texas, and Louisiana have passed laws that prohibit insurers from discriminating between regular medical and telemedicine services.[139]

"Montana is a state that enjoys widespread telemedicine reimbursement from Medicaid, from Blue Cross/Blue Shield, and from most private healthcare insurers."[140] One reason given was the long distances that rural Montanans must travel for healthcare which increases the awareness and adoption of telehealth there. On the other hand, Michigan Medicaid and Blue Cross/Blue Shield are not reimbursing for telehealth services. There is

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[135] "Telemedicine in Virginia: 2002 Legislative Report".
[136] "Overview of the Medicaid Program," from the Centers for Medicare and Medicaid Management Services web site at http://cms.hhs.gov/medicaid/mover.asp
[137] *opus cit.*
[138] In determining its own coverage policies, Texas developed a chart of how each state reimburses telehealth that can be viewed at the follo wing Web site: http://www.texasshcc.org/append7a.pdf.
[139] The reason more states are not included as reimbursing for Medicaid is most likely due to outdated data published on the CMS web site.
[140] Stammer, opus cit.

a "Working Group on Telemedicine Policy" for Michigan that has developed recommendations to assist in formulating telehealth policy changes to include payment and reimbursement.

It would appear that one measure to achieve greater or more uniform telehealth coverage by states under Medicaid would be "broad national guidelines" fom CMS. A more effective solution, however, might be simply a matter of providing each state cost-effectiveness data as well as information on coverage policies of other states. The Center for Telemedicine Law (CTL) survey has provided an up-to-date directory of responsible officials in each state. Working with CTL and the Association for State and Territorial Health Officials, the ATA might develop and communicate cost effectiveness and efficacy data, and a matrix of 50 state's coverage policies to each state official.

Reimbursement by Private payers

Until very recently, there has been a serious lack of publicly available data on reimbursement policies of private third party payers. Since 64.4% of American's healthcare is insured through private payers, it is important to understand how telehealth reimbursement policy decisions are made, what is covered, and by whom.

In 2002, AMD Telemedicine, Inc., one of the world's largest firms devoted exclusively to integrating telehealth systems, released results of a landmark survey of telehealth reimbursement policies of private third-party payers telehealth programs within each state.[141] Its findings were significant in that they challenged long held assumptions that private third party payers were resistant to reimbursing for telehealth encounters.

AMD reported that of 72 programs surveyed which offered billable services, 38 programs in 25 states were being reimbursed by private payers. AMD then surveyed the top five payers identified for each state and found that only one specifically prohibited reimbursement for telehealth services[142] (even though that one payer was also reported to be reimbursing programs in three states). In reporting on its findings, AMD emphasized that, in filing claims for reimbursement, telehealth programs emphasized that the procedures were comparable to routine medical services billed using standard CPT codes. AMD went on to suggest that telehealth providers were more likely to get reimbursed by simply making an effort to communicate their intent, notification of future claim submittals, and encouraging payer questions and comments.

AMD also found that 3 private payers were reimbursing for store-and-forward applications, 7 reimburse for facility fees, and most appeared to follow the lead of Blue Cross/Blue Shield which reimburses in 21 states. Moreover, Louisiana (1995), California (1996), Oklahoma (1997), Texas (1997), and Kentucky (2000) have enacted legislation mandating private payer reimbursement for telehealth services.

[141] Results of the AMD survey can be seen at: http://www.amdtelemedicine.com/private_payer/index.cfm
[142] According to AMD's survey, AETNA was the single private payer prohibiting reimbursement for telehealth. Coincidentally, AETNA also conducted an evaluation of telehealth efficacy studies on contract to CMSS, whose results are often quoted as a reason for not reimbursing telehealth.

Another interesting finding of the AMD survey was that Aetna does not cover telemedicine services as a substitute for services that are usually provided via direct provider-patient contact, because telemedicine services have not been demonstrated to be as effective as direct provider-patient contact. According to the AMD, Aetna is the only major third party payer that specifically prohibits reimbursement for telehealth. This finding is significant because it is Aetna's survey of clinical studies for the Agency for Health Research and Quality (AHRQ) that has influenced CMS' position on telehealth reimbursement.

The potential impact of AMD's survey on reimbursement is significant. It would appear from the results of this survey that reimbursement by private payers may be less of an issue than reimbursement by Medicare and Medicaid. It has also been said that Medicare takes it lead on telehealth coverage from private payers. AMD and ATA will be placing information about state private payer policies on the ATA web site at www.americantelemed.org.

Consumer Satisfaction

Consumer satisfaction with telehealth services is also an important consideration of third party payers and consumers alike. Several studies have been published which suggest that consumers are either as satisfied or more satisfied with telehealth encounters that the traditional in-person encounter. In 2002, for example, March Networks recently reported its findings of a Canadian home telehealth pilot that was independently evaluated by researchers from the University of Calgary's Health Telematics Unit. According to March, 95.5 percent of patients who received remote video conferencing homecare visits were satisfied with the home telehealth experience. [143]

Some of the reasons given for patient satisfaction include the independence that comes with scheduling encounters at the consumer's choice of time and place, the comfort and privacy of consultation within the patient's home, and the security of having 24-hour monitoring and access to services. Some critics suggest that remote or asynchronous encounters lacks the "human factor" that is said to exist in the traditional person-to-person relationship with a provider, while others suggest this attitude reflects a romantic but impractical notion of what modern healthcare should be.

The Office for the Advancement of Telehealth recently modified its policy, and will no longer fund studies to measure satisfaction. It has, instead, asked its grantees to analyze performance and value-added of services provided (which includes measures of satisfaction). OAT has also embarked on a major initiative with Abt Associates and its grantees to develop standard performance measures. In addition, OAT, its grantees and Abt are developing outcome measures for a series of specialties/services for use throughout its grantee network.

[143] "March Networks Home Telehealth Pilot Proves Successful," from their Web site at http://www.marchnetworks.com/news/viewnews.asp?newsid=94.

State Licensure

The issue of state licensure continues to play a role in limiting a national market for and in dampening user acceptance of telehealth technologies, with some suggesting it is less restrictive to sell technologies and services into foreign markets than into a neighboring state.

Providers practicing in the field of medicine have traditionally been subject to licensure by state medical and nursing "boards" in the state or other jurisdiction in which the provider's practice is located. Each state, territory, and the District of Columbia independently determines its own requirements for health care providers to practice in their jurisdiction. Executives interviewed for this report suggested that telehealth has been an enigma to the boards because it extends the practice of medicine into a different jurisdiction. State boards have restricted the practice by out-of-state telehealth providers in a variety of ways, from prohibition to permitting reciprocity to declining to take a position at all.

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.

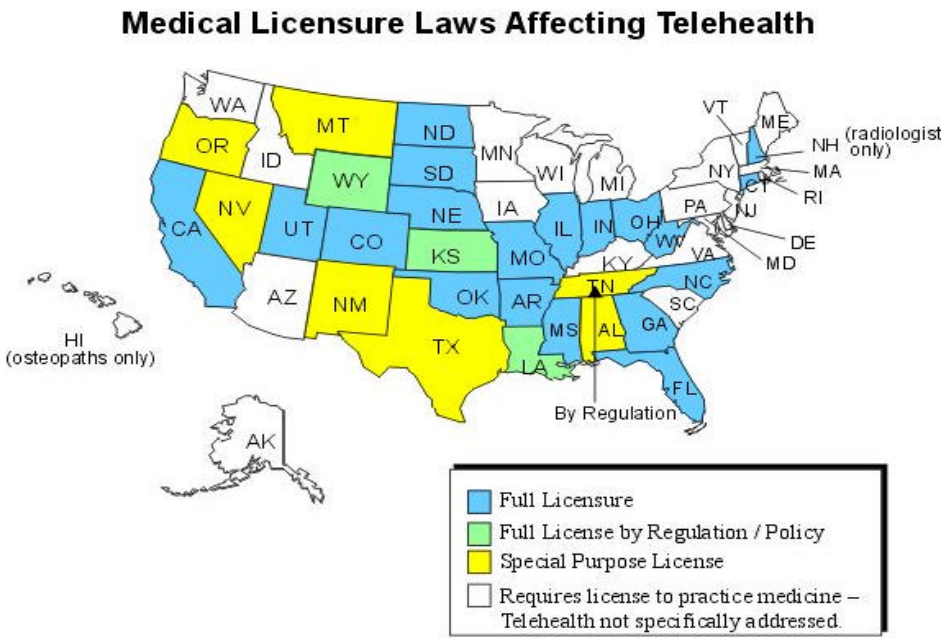
Telehealth providers have countered that the medical boards do not consider the patient's "rights." For example, if the same patient were to travel to another state for consultation or treatment, his "right" to travel and to choose providers would be protected. One argument on behalf of telehealth is essentially the right to "travel" by video or some other form of telecommunications. To deny those patients telehealth effectively forces them to travel physically to another state in order to access the provider of choice, a potential hardship for sick, disabled, or low-income individuals, or for those living in remote areas.

"The issue of state licensure has become even more complex with the growing use of the Internet and other emerging information technologies that cross state lines. For example, state licensing boards find it difficult to police and discipline doctors, in part, because they lack jurisdiction over physicians who virtually cross state boundaries or because of the failure of many doctors who practice online to openly identify themselves."[144]

The Center for Telemedicine Law (CTL) recently surveyed all 50 states to identify laws, policies, and practices relating to licensure. According to CTL, 33 states have enacted laws or regulations requiring licensure for the practice of telehealth, while three others took the rule-making route. Of the 33, 24 require full licensure for out-of-state doctors who practice telemedicine on a regular basis, while 9 make special purpose license provisions for those who consult or offer second opinions on an irregular basis. The following map represents CTL's findings:

[144] Tracy E. Miller and Arthur R. Derse, "Between Strangers: The Practice of Medicine Online", *Health Affairs*, July/August 2002.

Diagram 1



There are several "models" that might prove useful in thinking about solutions to the licensure issue as well as an examination of how some states have addressed the issue.

Table 3.d Models of Interstate Licensure[145]

Consulting Exceptions	A physician who is not licensed in a particular state can practice medicine in that state at the request of and in consultation with a referring physician. Some states permit a specific number of consulting exceptions per year.
Endorsement	State boards can grant licenses to health professionals in other states with equivalent standards. Health professionals must apply for a license by endorsement from each state in which they seek to practice. States may require additional qualifications or documentation.
Reciprocity	Authorities of each state negotiate and enter agreements to recognize licenses issued by the other state without a further review of individual credentials. A license valid in one state would give privileges to practice in all other states with which the home state has agreements.
Mutual Recognition	Mutual recognition is a system in which the licensing authorities voluntarily enter into an agreement to legally accept the policies and processes (licensure) of a licensee's home state. Licensure based on mutual recognition is comprised of three components: a home state, a host state, and a harmonization of standards for licensure and professional conduct. The health professional secures a license in his/her own home state and is not required to obtain additional licenses to practice in other states. The nurse licensure compact is based on this model.
Registration	A health professional licensed in one state would inform the authorities of other states that s/he wished to practice part-time there. By registering, the health professional would agree to operate under the legal authority and jurisdiction of the other state.

[145] Originally presented to Congress in a joint Departments of Commerce/Health and Human Services report in 1997

Limited Licensure	A health professional would have to obtain a license from each state in which s/he practiced but would have the option of obtaining a limited license for the delivery of specific health services under particular circumstances. Alabama, Montana, California, Oregon, Tennessee and Texas have enacted legislation consistent with this model.
National Licensure[146]	A national licensure system could be adopted on the state or national level. A license would be issued based on a universal standard for the practice of health care in the U.S.
Federal Licensure	Under a federal licensure system health professionals would be issued one license, valid through the US, by the federal government.

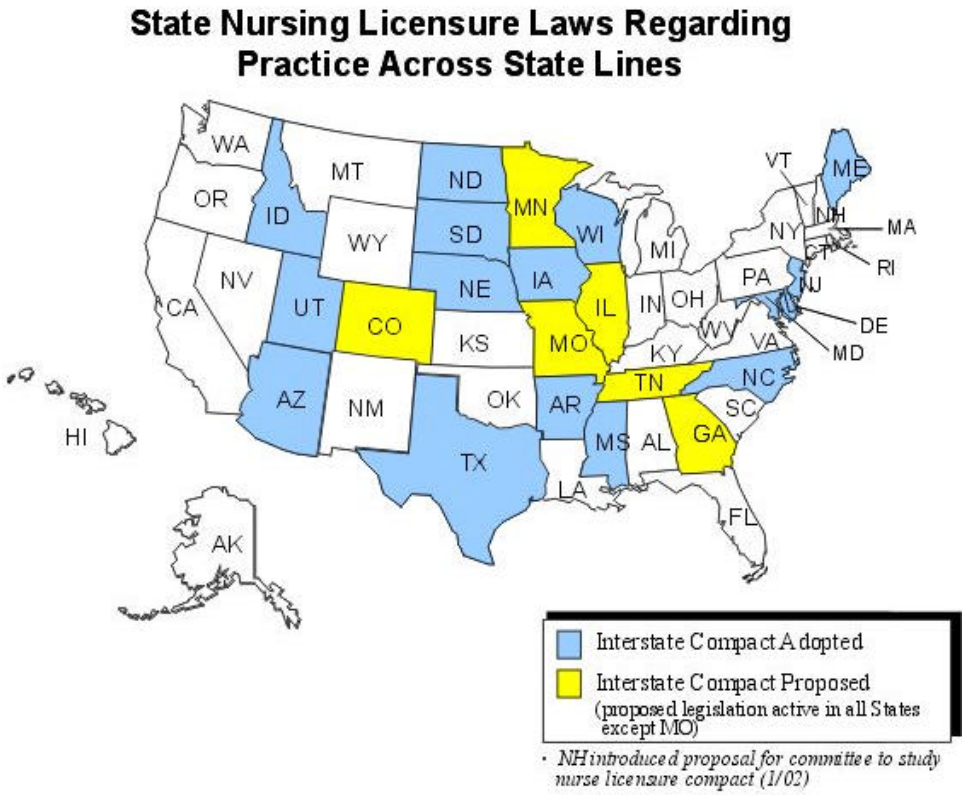
There has been some movement, to date, within the states toward adopting one or more of these models. In 1998, for example, the National Council of State Boards of Nursing proposed an "Interstate Compact," in which participating states voluntarily agree to allow licensed nurses (both RNs and LPNs) from other states to practice in their state without obtaining a separate license.[147] Eighteen states have so far adopted the Compact. A Center for Telemedicine Law map, reproduced below as Diagram 2, shows the distribution of the states as of mid-2002 that have adopted, proposed, or have not yet taken any action on the Interstate Nursing Compact.

The Center for Telemedicine Law (CTL) with support from OAT, convened a workshop of telehealth experts and members of state licensing boards in December 2003 to examine various options for addressing interstate licensure barriers and other restrictions that impact electronic clinical practice. OAT has also contracted with the Federation of State Medical Boards for two regional pilot projects to test and evaluate solutions to address licensure restrictions (to possibly include those developed in the CTL workshop). Participants in the workshop seemed to favor a "compact" approach beginning with a few limited exceptions. Federation participants were also favorable to an updated "model act" for states first vetted in 1997.

Diagram 2

[146] The Center for Telemedicine Law recommends the following: "The Federal Government can provide a carrot to those State licensure boards to convert their systems, because they are taking a risk. They don't know if this new system is going to work or not, and if you give them a modest amount of financial assistance to move in that direction, more of them may move in that area. The medical boards are the same way. They are looking for ways to harmonize between the States data collection that they do for licensing, and so there are carrots that can be offered that are not expensive, but that would help to move this towards more interoperability on the licensing."

[147] using such language as a license to practice registered nursing issued by a home state to a resident in that state will be recognized by each party state as authorizing a multi-state licensure privilege to practice as a registered nurse in such party state



The National Emergency Management Association administers a similar "Emergency Medical Assistance Compact" (EMAC), which provides for cross-state-border emergency management response, is employed by 48 states and 2 territories, and is administered by the association.[148] This Compact most closely parallels the flexibility that would be required by Homeland Security.

In 1996, the Federation of State Medical Boards developed a "Model Act" to regulate the practice of medicine across state lines to respond to telemedicine issues. This Act would have required physicians practicing medicine across state lines, by electronic or other means, to obtain a special license issued by a state medical board. The license would be limited to practicing across state lines in another state and would not allow physicians to physically practice medicine in the other state unless a full and unrestricted license were obtained.

The Federation's proposed special purpose license would only be required if a physician "regularly or frequently" engages in telemedicine. Each state medical board would define what regular or frequent means. A license would not be required if a physician practices across state lines less than once a month, or the practice is less than 1% of the physician's diagnostic or therapeutic practice or less than ten patients annually. The Act would exempt physicians who engage in practicing across state lines in the case of an emergency. Finally, the physician would be subject to licensing and credentialing rules of

[148] Craig Walker Vice President for Policy, Health Care Visions, at the Technology Administration's Roundtable "Innovation, Demand and Investment in Telehealth," June 19, 2002 in Washington D.C.

the issuing state and to the regulatory authority of that state's medical board. To date, no states have adopted the Model Act. [149]

Section 102 of the Health Care Safety Net Amendments of 2002 (S 1533) signed into law in October, 2002 provides for incentive grants to go to State professional licensing boards to cooperate, develop, and implement State policies that will reduce statutory and regulatory barriers to telemedicine. The specific language states:

> It is the sense of Congress that, for purposes of this section, States should develop reciprocity agreements so that a provider of services under this section who is a licensed or otherwise authorized health care provider under the law of 1 or more States, and who, through telehealth technology, consults with a licensed or otherwise authorized health care provider in another State, is exempt, with respect to such consultation, from any State law of the other State that prohibits such consultation on the basis that the first health care provider is not a licensed or authorized health care provider under the law of that State.

It seems that Congress, several states, and even the Federation of State Medical Boards agree in principle to less restrictive rules for interstate telemedicine although most prescribe different models. The needs of Homeland Security for regional and national information networks for bio-defense, health alerts, and expanding emergency medical surge capacities suggest that a "compact" similar to the EMAC might be a practical and appropriate first step.

Liability

Issues such as protection of healthcare and telecommunications entities from undue liability arising out of the use of telehealth have not yet been addressed. One of the nation's foremost authorities on telehealth law has stated "There is a possibility that liability issues may be reduced as this technology matures. Doctor practice issues (the primary area of liability) can be better documented as a track record of their decisions is created." [150]

It is in the interest of telehealth lawyers to assist vendors and providers in understanding issues of legal liability. Although there has not been a great deal of activity in this area, understanding liability is important to providers evaluating risk prior to investing in and/or adopting telehealth. Many healthcare providers claim to be unaware of their legal liabilities under medical and malpractice law in the practice of telehealth, a reason used by some to defer adopting technologies. As such, the potential impact of liability on providers could be considered additional areas where sufficient information and analysis are lacking. Organizations such as the ATA and the Center for Telemedicine Law make information available through their organizational web sites for clients and members.

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[149] Linda Gobis, "An Overview of State Laws and Approaches to Minimize Licensure Barriers," *Telemedicine Today*, Volume 5, August 2002 at http://www.telemedtoday.com/statelawguide/index.html.

[150] Bob Waters, President of the Center for Telemedicine Law at the Technology Administration Roundtable "Innovation, Demand and Investment in Telehealth" on June 19, 2002.

There is no centralized source of such information available to the provider public at large or to policy makers.

It has been said, "Telehealth is not on the cutting edge of technology because of FDA and litigation. Physicians don't want to be first – they are trained to be as cautious is possible – so they will wait until the whole community accepts a new technology. This is due to the definition of malpractice (i.e. the physician did not follow widely-accepted practices)."[151] A closer look, however, would lead to the conclusion that telehealth technology should not be considered "cutting-edge" or even controversial. The experience of telehealth demonstration projects with respect to the issue of liability could provide that closer look, and compilation of empirical data would provide a useful insight to insurers as well as providers.

Provider Acceptance

There are some who suggest that provider acceptance is a barrier to increasing demand for telehealth because healthcare providers are typically slow or reluctant to adopt new technologies. Healthcare marketing information and services firm Manhattan Research notes seven key trends related to physicians and technologies indicate otherwise - that physicians are adopting technology broadly and rapidly. [152]

It would appear that the most important factors affecting user acceptance are the comparative and competitive advantages providers associate with telehealth technologies. That both regulators and payers should apply the same decision factors for approval and reimbursement should come as no surprise in that providers, payers, and investors are looking for significantly greater value added as a condition of acceptance, procurement and deployment.

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[151] *Ibid.*

[152] **Robust Practice Websites Emerge:** In 2002, 34% of practicing physicians had practice websites; over two-thirds reported an interest in having a website in the future. Consumer interest in practice websites has also increased.
PDA and Handheld Computers Come of Age: About one-third (35%) of practicing physicians actively use PDAs. About two-thirds of physicians using a PDA are actively using a pharmaceutical database application. Improvements in form, technology, and price are expected to drive growth and value.
Integrated Electronic Pharmaceutical Detailing Becomes a Reality: 36% of primary care physicians have participated in electronic detailing programs offered by pharmaceutical companies, and more than 80% of current users expect to participate in the next year.
Some Specialists Become Very Dependent on the Web: Information intensive groups of practicing physicians, such as oncologists, neurologists, and rheumatologists become dependent on the Internet for clincial news and pharmaceutical information.
Patient Connectivity Still on Hold: Despite consumer demand, online consultations will remain in a holding pattern until physicians see a strong economic argument to participate. Pilot programs are beginning to justify the value.
Health Plan Portals Become a Viable Customer Service Option: The majority of health plans are finally offering value-added online solutions. Early adopters are also introducing e-care solutions.
E-Prescribing Resurfaces, Under New Management: Electronic prescribing is making a comeback with new backers, such as PBMs and insurers.

Telehealth demand may benefit from an "image improvement" through greater effort in describing, quantifying, and proving the benefits of telehealth applications. It has been said, "If you're going to get doctors to change their behavior, you have to have clinical value, financial value and usability." [153] A former President of the American Telemedicine Association and chief consultant to the Army Surgeon General recently suggested that telehealth's greatest need is the ability to prove value by means of high quality efficacy, cost-effectiveness and cost-benefit studies. Medical professionals do not themselves usually have the training, skills, and resources necessary for efficacy and cost-benefit analysis, so the responsibility for providing such evidence falls to others.

The Office for the Advancement of Telehealth (OAT) adds an additional factor - awareness of and familiarity with the technologies - as another critical issue affecting provider acceptance. OAT's grant programs are viewed as many of the nation's leaders or "champions" for innovation diffusion. According to OAT's Director, the primary purpose of OAT programs is to "help communities build the human, technical, and financial capacity to develop sustainable telehealth programs and networks." Given OAT's record for program expansion (currently supporting 100 programs in 43 states and 3 jurisdictions), this strategy has worked well and the awareness of and familiarity with telehealth nationwide is significantly greater as a result.

Medical professionals also tend to be less familiar with electronic or telecommunications technologies, having focused their training and experience on medical science. This characteristic, coupled with difficulties that technical professionals may have in understanding medical jargon and requirements may make communications more difficult. More recent medical graduates, however, appear to be much more technical and accepting of technology. As a result, providers will be less accepting of telecommunications and IT-related technology for its own sake, and more demanding of viable, efficient and efficacious technical solutions to clinical care from device, applications, and services vendors.

In a recent report titled "Diffusion of Telemedicine: A Knowledge Barrier Perspective," [154] observed business models demonstrated differing degrees of success and failure, and offered an insight into the complex nature of risk, user acceptance, and profitability of telehealth programs. One key ingredient was the organizational and technical leadership provided by a "champion." The success of most programs is directly attributable to the champions' ability to lower the following barriers:

1 Technical barriers: Unlike business computing and software process innovations, telehealth applications require technical knowledge and technical problem-solving skills.

2 Economic barriers: Whereas most practitioners as well as studies point to other issues such as third party reimbursement as a major impediment to the adoption of telehealth technologies, the lack of viable business models is also important.

[153] Lloyd Hey, M.D., founder and chairman of MDeverywhere as quoted in Versel, opus cit.
[154] Tanriverdi, Huseyin and C. Suzanne Iacono. "Diffusion of Telemedicine: A Knowledge Barrier Perspective." *Telemedicine Journal* Vol. 5, No. 3, 1999. pp. 223-244.

3 Organizational barriers: Using telehealth applications on a consistent and regular basis requires creation of new workflow routines and organizational support.

4 Behavioral barriers: Physicians resist applications which may be resisted by others in the organization

Two decision points for electing to use or prescribe telehealth products and services – the clinical decision based on the technology's contribution to meeting the healthcare needs of patients, and the business decision based on prospective return on investment. It would seem to be in the best interest of the telehealth community to focus its attention and resources on influencing these two decisions with reliable study data.

Telehealth has also been frequently discussed as a means for improving the quality of health care through both technology and competition. Telehealth technology may allow individuals to exercise greater choice in their healthcare providers and provide access to the very best providers in the nation – or even internationally. The resulting competition could pressure healthcare providers at every level to improve quality or see declines in their business.

Primary influences on clinician preferences are awareness, proof of efficacy and proof of increased productivity. Their level of awareness relates most closely with their experience and their exposure.

In 1998, HHS' Agency for Healthcare Policy and Research included the following as information needed by providers considering adoption of healthcare technologies within their practices:[155]

- Optimal resource mix
- Legal liability
- Malpractice responsibility
- Privacy regulations
- Licensing regulations
- Clinical efficacy
- Medical and cost effectiveness

Telehealth community leadership should make sure this data is developed, collected, and diffused as widely as possible.

Cost Considerations

There are two dimensions to consideration of cost -- return on investment (ROI) and reducing or containing the cost of healthcare. Whereas ROI will be discussed further in Chapter 4, reducing or containing the cost of healthcare is one of the more important

[155] J. Michael Fitzmaurice, "Telehealth Research and Evaluation: Implications for Decision Makers, AHRQ, August 1998.

justifications given for funding and adoption of telehealth technologies. Reducing or containing healthcare costs continues to be a top social, economic and political priority It was reported that overall U.S. healthcare spending rose 9.3 in 2002, "the largest increase in 11 years and the fourth year in a row that the rate of increase surpassed growth in the rest of the economy."[156] The debate over rising healthcare costs seems to be most lively over Medicaid and Medicare, where 2002 costs increased 11.7% and 8.4%, respectively.[157]

A growing body of empirical data, cost-benefit studies and case studies is gradually replacing any remaining speculation on the impact of telehealth on healthcare cost. Although there remains a great deal of debate over the *quality* of these studies, evidence points to the likelihood that telehealth applications can reduce, contain, or avoid costs when compared with the same services using traditional approaches. Further, while awareness in the provider community of the need for rigorous business case analyses to support telehealth implementation is not widespread, there is a growing "cadre" of technical and business-savvy physicians, nurses, physician assistants and allied healthcare providers is forming with respect to telehealth.

Consider the thoughts of this telehealth "champion:" [158]

> **"One of the cost models for telemedicine or where we demonstrate savings is in the prison population, because transportation and security costs are very expensive, not to mention the difficulties in getting medical professionals to treat prison populations."**
>
> **"If we consider the "convenience" model where the parent has to take their child out of school for a doctor's consultation, he or she may need take off from work, drive several hours, and basically miss the whole day for what, to the economy, is unproductive time (and possibly unpaid). I have seen estimates that for every dollar in health care that a company spends for employees, between $2 and $4 are spent on lost productivity. If the school nurse had telehealth capability (such as in Texas), think of the productivity increases and cost savings."**
>
> **"Then, let's consider another model. If I can stay in my office and go down and see my physician through televideoconferencing and the doctor's office already has all of my insurance information and medical history, just think of all time and cost savings."**

It would be very difficult, however, to suggest that telehealth technology will reduce costs in every case. Certain applications or protocols may never be justified based on cost reduction or avoidance alone. Cost avoidance may not be a satisfactory justification if those costs are shifted elsewhere. High-quality peer-reviewed cost-benefit analyses are necessary to driving demand as well as innovation and investment, and for convincing such payers as Medicare that telehealth will reduce (and not increase) costs. Conversely,

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[156] Daily Health Policy Report, kaisernetwork.org, January 9,2004
[157] *Ibid.*
[158] Scott Simmons, Chief Technology Officer, East Carolina Telemedicine Center, at the June 19 Roundtable.

benefits should include some quantifiable measure of increased access, improved quality, and contribution to homeland security.

DEMAND AGGREGATION

Demand aggregation is the coordination by a group having some common interest (e.g. geography, mission, funding sources, population served, etc.) that identifies, procures, and manages its collective telehealth needs similar to a cooperative. [159]

Because of its common need for technologies, healthcare is well positioned to apply demand aggregation to the purchase of telecommunications.

Because of its common need for networking and equipment, telehealth is well positioned to apply demand aggregation to the purchase of technology

The collective purchasing power of telehealth providers (possibly coupled with other telecommunications consumers) offers the potential to reduce costs, upgrade and expand capacity, and increase accessibility. Because telecommunications is one of the primary and recurring costs of telehealth, any savings resulting from lower rates and costs would increase the return on any investment.

Moreover, diffusion of information on the "benefits of" and "how to start up" a demand aggregation project or program may trigger further demand for telehealth and especially in rural and medically underserved areas.

Examples:

The Alaska Federal Healthcare Access Network (AFHCAN) provides a unique example of demand aggregation. Although AFHCAN is dominated by such federal agencies as the Indian Health Service, Department of Defense, and Coast Guard, the coordination of health needs among 37 federal, state and local government and private partner agencies to build a statewide telehealth network resulted from a process based on organizational and individual relationships.

The demand aggregation process[160] is managed by the AFHCAN Project Office and engineering services are provided by a consultant. The Project Office sets minimum

[159] Berkshire Connect, a non-profit community-based "affinity group" organized to collectively purchase telecommunications services in western Massachusetts, is a currently popular model of demand aggregation. For more information, visit their web site at: www.bconnect.org.

[160] Each member organization, prior to initial deployment, is required to fill out an assessment and participation survey designed to determine their organization's level of clinical needs and readiness, administrative support and desire, installation interests and technical infrastructure. During their needs assessment process, member organizations are encouraged to develop a telehealth team to assess their organizational needs, answer technical questions on the participation survey, and select equipment for each of their sites. If a member organization requests technical assistance to determine their organizational

hardware requirements for participation. AFHCAN finances network connection infrastructure, but operating costs for each site are that site's responsibility. Provisioning of dial-up, satellite, wireless, and fiber optic links is negotiated with the carriers as a single customer. Consequently, AFHCAN has made telehealth a household word in Alaska (even promoted in the annual Iditarod Sled Dog Race).

Another example of local demand aggregation is the Mountain Area Health Education Center (MAHEC) program in North Carolina. Established initially as a network for providing health education to rural and mountainous Western North Carolina health care professionals, MAHEC added its "Center for e-Learning and Telehealth" to offer and support videoconferencing technologies and streaming video to 15 sites. MAHEC's vision was described as "access to continuing education for health care professionals as well as to health services for patients."[161] Discussions with Buncombe County (NC) Health Department and MAHEC revealed interest in applying the demand aggregation model to link their respective organizations in purchasing telecommunications services as a single and much larger customer.

Opportunities:

The most recent data on telemedicine activity in the Veterans Health Administration (VHA) of the Department of Veterans Affairs (VA) show that the VHA is performing over 243,000 teleconsultations annually.[162] These data rank the VHA as the worlds' leading provider of telemedicine and telecare services. VA's telehealth networks or "VISNs" offer a unique opportunity to surrounding networks of providers to link and aggregate demand. Individual VISNs and VA's Community Based Operations Centers are currently reaching out to their communities and regions with an offer to collaborate on utilization of telehealth technology and telecommunications.

The initiative being undertaken by the Southern Governor's Association has many of the elements of "vertical" demand aggregation[163] based on a single common goal – bio-

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needs, the AFHCAN Project Office (APO) is notified and follows up by scheduling a site visit to facilitate the process. Once the needs assessment is complete, technical design staff of the APO and Alaska Clinical Engineering Services (ACES) work with each organization to review local area network (LAN) and wide area network (WAN) connectivity, the technical design, and, if required, refine the equipment selections. ACES is responsible for maintaining an inventory of equipment and will order any additional equipment to fulfill the design. ACES then works with the organization to schedule dates for equipment deployment. Organizations have three options for deployment installation: (1) the organization installs all equipment, (2) ACES installs all equipment, or (3) shared installation. If ACES is responsible for the installation, then ACES staff will pull all required equipment from stock, configure and burn-in the equipment, re-package the equipment for shipping, track the shipments, and finally follow up with on-site installation and testing. ACES provides warranty and technical support for one year to the sites deployed by them.
If an organization elects to install the equipment themselves, rather than use ACES, then the organization will schedule trips to Anchorage for their staff to be trained on all aspects of the deployment. Staff members receive training on all aspects of the hardware and installation and configuration of the software. The staff members configure and burn-in their own equipment at the ACES facility with oversight by ACES, then assume full responsibility for the equipment once the equipment is re-packed and shipped from the ACES facility to the site. In this case, ACES does not provide any ongoing support to the sites.

[161] In an August, 2002 interview with David Rue-Blanchard, Director of MAHEC

[162] Adam Dawkins, M.D., Chief Consultant for Telemedicine, Department of Veteran Affairs

[163] Vertical aggregation occurs when the demand occurs with a single industry sector, such as healthcare.

defense. Other approaches to demand aggregation would include "horizontal" markets[164] where healthcare is one of several major customers/sectors in a locality for broadband telecommunications. Horizontal aggregation diversifies uses and users and, as such, spreads the risk more broadly.

Demand aggregation is not an exact science nor is there a great deal of data available other than a few examples. The DoC's OTP is working with the Appalachian Regional Commission, the Economic Development Administration, and states' organizations in encouraging local and regional demand aggregation initiatives. In addition, HHS' OAT reports it is moving toward community-based programs that could act as a major incentive for demand aggregation among healthcare providers and telecommunications users.

[164] A horizontal market would include, for example, a locality where demand is made up of diverse consumers outside a single industry sector, such as healthcare, education, and industry.

Chapter 4 – Investment in Telehealth

Current telehealth investment[165] opportunities are often too risky and/or expensive for the private sector to pursue alone. The issue of reimbursement poses the greatest risk for without revenue there is no return on investment. The prospect of competition from government or not-for-profit telehealth programs might also limit significant private investment except for large organizations having established markets, such as private payers, or geographic areas or populations where healthcare needs are not being met.

This chapter provides a quantitative and narrative assessment of how public and private entities are investing in telehealth programs and adoption, and a qualitative assessment of what investment and financial issues should be resolved in order to meet the primary public priorities of improved access, quality, and homeland security, as well as reduced or contained cost.

CURRENT INVESTMENT

Although quantitative data is not readily available, public and private investment in telehealth technologies is estimated to be $380 million or more annually, or less than one per cent of the total domestic healthcare technologies market of around $80 billion (see the section on Estimated Demand in Chapter 3). Over 35 federal organizations within 10 federal departments and independent agencies (see Chapter 2, Table 2.b), 49 state governments, numerous universities, private payers, and private not-for-profit organizations fund at least some part of hundreds of telehealth programs in all 50 states and territories.

Provider investment in telehealth devices and applications has been essentially driven by program subsidies and contracts (e.g. prisons) with the exception of teleradiology and VA/DOD healthcare systems for which reimbursement policy is well-established. Significant additional private investment in innovation (research and development) of telehealth technologies, on the other hand, is linked to reimbursement policy. An October 2002 CMS report entitled" Health Care Industry Update - Medical Devices and Supplies" comments that "Investors scrutinize FDA approval process and Medicare coverage and payment decisions that can affect the speed of technology adoption."[166] The report also quotes a Wall Street analyst as saying that "public equity investors are concerned about

[165] Public or private, investment in telehealth takes the form of capital and operations. In healthcare, capital (i.e. usually comprised of assets having a life of more than one year) is invested in devices, application software, and telecommunications infrastructure (such as telecommunications, furnishings, real property and other technologies). Investment in "human capital" includes the acquisition of know-how through education and training. "Operations" generally refer to the more routine costs of doing business such as rent, salaries, administration, transportation, and marketing, costs that may not be completely covered by third party reimbursement.

[166] "Health Care Industry Market Update - Medical Devices and Supplies," published by CMS, October 10, 2002 Page 30.

the lag time between a new device's commercial launch and obtaining Medicare coverage."[167]

Federal government

The primary investment vehicles for telehealth at the federal level include:

1. **direct procurement** for technology products, supporting technologies and infrastructure (most common in "closed" systems such as DOD and VA).

2. **demonstration projects** are the most common means of funding capital investment in technology in non-DOD/VA programs. Demonstration projects can include all the federal Departments and agencies shown in Table 2.a and more (e.g. other NIH Institutes and Centers). Grants are usually awarded on a competitive basis but are also included as legislative "earmarks" or monies appropriated for specific projects in states and Congressional districts in annual appropriations or in individual legislation not tied to the appropriations process. Congressional oversight of or interest in an agency's grants may, therefore, be associated with more than one House and Senate committee.

3. **direct investment** in federal telehealth provider operations. Direct investments primarily involve such organizations as the Department of Defense, Department of Veterans Affairs, Department of Health and Human Services, Indian Health Service, and Department of Justice's Bureau of Prisons, but may also include smaller clinics for such agencies as NASA.

Telehealth infrastructure, which may be acquired through any one of these vehicles, is funded through a few federal grants programs. The "Distance Learning and Telemedicine Grant/Loan Program" of USDA's Rural Utilities Service (RUS), for example, funded North Carolina's Mountain Area Health Education Center "Healthlink," which was later expanded with grants from the private Reynolds and Duke endowments. RUS programs require matching contributions. In 2002, RUS lowered its match requirement to 15%, which doubled the number of projects (46 distance learning and 25 telemedicine) in 33 states, at an amount of $27 million in grants.

Telecommunications infrastructure is essentially comprised of telecommunications and facilities and may range from a "Plain Old Telephone Service" (POTS) phone line with low transmission speeds and capacity to ultra high speed broadband (such as Internet 2) to cable to various forms of wireless and satellite. Telecommunications infrastructure investment decisions may be made solely on the basis of cost or may include such other factors as availability, functionality of the application, the need for higher quality and more reliable transmission.

USDA's Rural Utilities Service and Commerce's National Telecommunications Information Administration provide grants for purchasing and installing telecommunications infrastructure, which may or may not be linked to a federally funded

[167] *Ibid*, Page 6.

project or program. Universal Services Access Corporation (USAC) provides non-appropriated operating capital in the form of buy-downs of telecommunications service charges in order to eliminate differences between rates among different classes of users. In 2002, for example, 746 rural health providers were able to provide healthcare using long distance telecommunications at rates comparable to their urban counterparts. This number, however, represents a very small proportion of the nearly 4000 rural clinics[168] recognized by the federal government, suggesting that the potential for expanding infrastructure is significant.

State governments

States follow a similar pattern by funding procurement for state clinics and institutions, projects and direct investment. Illinois, for example, granted $450,000 among 10 hospitals in 2001 to establish capabilities (i.e. computers, videoconferencing equipment, infrastructure and initial telecommunications charges as well as training for hospital workers). The hospitals will be linked by the "Illinois Century Network," a statewide, high-speed telecommunications system created in 1999 to integrate and expand data, voice and video communications among schools and libraries.

Texas has one of the most comprehensive state telehealth programs to fund infrastructure investment. In 2001, the Legislature enacted sweeping legislation to reflect the high priority given telehealth. The Texas Telecommunications Infrastructure Fund Board (TIFB) has since awarded grants to 87 telehealth programs. An interesting example of "demand aggregation" is the Texas Rural Hospital Telecommunications Alliance (TRHTA), characterized as a "statewide telehealth utility". The Alliance's objective is to become a telehealth application service provider to assist rural and public healthcare providers. The Alliance used the State's Telecommunications Infrastructure Fund Board (TIFB) Internet Connectivity Grant Program as the scalable foundation on which to build services. In 2002, TRHTA was awarded nearly $14 million in grants with an additional $1.56 million in matching funds for 255 sites for local network, workstations and software; secure Intranet over statewide backbone; broadband internet access with email; supporting services.

Private sector

There has also been some attention recently to venture capital as a source of investment dollars. For example, Guidant Corporation has recently partnered with Bay Area venture capital firms Vanguard Ventures and Fremont Ventures to establish Vesalius Ventures,[169] a telemedicine venture accelerator focusing on identifying and funding early stage opportunities in telemedicine, medical informatics and technology.

Private sector investment focuses on telehealth programs and technologies in response to specific markets. Although data is not readily available, discussions with telehealth

[168] U.S. Census Bureau 2001

[169] "Guidant Partners with Prominent Venture Capital Firms to Form Vesalius Ventures," Guidant Corporation press release of August 2, 2002. For entire article, see: http://www.guidant.com/news/200/web_release/nr_000264.shtml.

providers and suppliers suggest that private payers such as Partners Healthcare represent the primary investment within the private sector.

National Health Technology and Information Infrastructure

Over the past several years, there has been a great deal of discussion in healthcare, policy and technology circles about the merits of a national network of healthcare information. Much of the discussion is centered on the pros and cons of an "individual electronic medical record" (i.e. a digital personal medical history). The events of 9/11 and since have elevated this discussion of a national medical network or "grid" to a higher level due to perceived needs for an integrated emergency response, bio-detection and bio-defense, interoperability of data and equipment, and the communication needs of first responders.

A comprehensive and timely response to bioterrorism attacks requires investment in data acquisition, threat detection, and a response infrastructure. Various national organizations have called for federal leadership in this area. For example:

1. "To protect public health and national safety, the American Medical Informatics Association (AMIA) recommends that the federal government dedicate technological resources and medical informatics expertise to create a national health information infrastructure (NHII)."[170]
2. A recent report issued by the National Committee on Vital and Health Statistics noted, "Based on public hearings about the NHII vision, NCVHS has determined that the most important missing ingredient, which could accelerate and coordinate progress on the NHII, is leadership, specifically, Federal leadership."[171]
3. A 2002 proposal by the Rand Corporation to develop a National Information Technology Infrastructure included healthcare applications.
4. A 2002 initiative of HHS, DOD and VA to jointly develop data standards leading to a common electronic medical record.
5. In October 2002, the Healthcare Information and Management Systems Society (HIMSS) launched a "National Health Information Infrastructure Task Force." According to HIMSS,[172] the task force will focus on activities to help the healthcare industry create and adopt a national health information infrastructure (NHII). Initial projects for the HIMSS task force will include creation of an inventory of existing technologies/practices in healthcare, identification of areas that need to be addressed, and development of a HIMSS "version" of the NHII.

Current visions of a NHII lack a central authority that would oversee development and address such issues as standards development, reimbursement, physician licensure,

[170] Tang, Paul C. "AMIA Advocates National Health Information System in Fight Against National Health Threats." *JAMIA* vol. 9 No. 2 March/April 2002, pp. 123.
[171] National Committee on Vital and Health Statistics. "Information for Health: A Strategy for Building the National Health Information Infrastructure." U.S. Department of Health and Human Services, November 15, 2001. p. 3.
[172] For more information on HIMSS, visit their web site at http://www.himss.org/ASP/index.asp.

quality control, etc. The National Committee on Vital and Health Statistics (NCVHS) reflects this sentiment in a recent report:

> "Although many of the basic components for the NHII already exist and are operating in their own spheres, they lack the interconnections that could make them more useful in concert than they are as isolated pieces. Many non health-specific communication technologies are already available, affordable, and widely used in multiple sectors of U.S. society. For the most part, however, their full potential is not realized because they are proprietary, incomplete, or uncoordinated. Also, many existing programs and activities in the public and private sectors provide a foundation for the NHII, but they are fragmented and dispersed throughout agencies and organizations that lack a mechanism for coordination. Their impact would be enhanced if they were part of a comprehensive NHII framework."[173]

Telehealth has been discussed as one of the key NHII technologies for several reasons:

1. Hundreds of telehealth networks are currently operational throughout the nation.
2. Telehealth applications can use any (or all) of the existing telecommunications infrastructure (e.g. Internet, telephony [any composition or speed], wireless, satellite, and cable).
3. Telehealth networks can be readily converted to apply other data and devices.

Integrating even the most diverse information system and telecommunications network into a NHII is technically feasible. The challenge has been met, for example, by the many information systems conversions resulting from corporate mergers and acquisitions (i.e. banks).

One of the first steps must be the development of a national systems architecture featuring a common data structure to include commonly understood elements and definitions. The Consolidated Health Informatics (CHI) project being pursued by DOD, VA and HHS represents a substantial federal effort to build a single information infrastructure by linking existing databases.

National health information systems already exist such as Medicare's OASIS and CDC's Health Alert Network. Several federal agencies are currently developing national or regional health infrastructure for homeland security purposes, such as the Centers for Disease Control and Prevention (CDC) which is working with state and local health departments to design a nationwide "national epidemiological detection and surveillance system" (NEDSS).

The military has begun to integrate its medical records across its service branches via the Composite Health Care System (CHCS) II. This is the largest automated information systems project in DoD and is based on a client-server architecture with a centralized patient record data repository accessible from PC workstations in clinicians' offices. Providers utilizing CHCS-II have a desktop application that grants access not only to the

[173] Ibid., p. 3.

patient's electronic health record, but ancillary services such as laboratory and radiology reports, and pharmaceutical drugs ordering. Further, based on the detail provided in the encounter documentation, levels of diagnostic complexity can automatically be calculated for accounting purposes. At of the release of this report, CHCS-II has been deployed to seven military medical treatment facilities (MTFs) and worldwide deployment of the first major "block" of functionality is expected within a year. Tri-Care On-Line, also being developed for DoD, is working with the VA to provide a "portal" for patients and providers to help increase their access to care (e.g. appointment scheduling, education, patient-provider e-mail)

As noted in Chapter 3, the Southern Governors Association is also planning a "networks of networks" using existing telehealth infrastructure and programs as a building block or "backbone" for integrated bio-defense. To the extent that the several independent discussions of a national health information infrastructure can be coordinated (good) or integrated (better), the Southern Governors' initiative may provide a "proof of concept" test bed. Funding for this initiative was proposed in the 107th Congress; a similar proposal is expected in the 108th.[174]

A national systems architecture should begin with a coordinated, interagency, intergovernmental and public/private process to define requirements and select one or more of these systems to anchor a NHII. The next step would be development of a common data structure among stakeholders at all levels, to include common data elements, common data element definitions, and common data interfaces. Important stakeholders in the discussion of a NHII include the Federal Chief Information Officers Council which has been charged with coordinating the cost effective development and integration of information systems.

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The Markle Foundation's *"Connecting for Health…A Public-Private Collaborative"* established an initiative to "catalyze specific actions on a national basis that will rapidly clear the way for an interconnected, electronic national health information infrastructure". The Foundation proposed that this be accomplished through the eHealth Initiative and other avenues by focusing on three key areas:

1. Accelerating the rate of adoption of national clinical data standards throughout the nation's health care system in order to facilitate interoperability.
2. Identifying practical strategies and solutions for developing an interconnected electronic infrastructure that will ensure the secure and private transmission of medical information and support the continuity of personal health information across plans and providers.
3. Actively working to understand what consumers will need and expect from an interconnected health information system and identifying key steps for meeting their needs.

Lastly, the Institute of Medicine published a report on patient safety in November, 2003 which "addressed key areas related to the establishment of a national health information infrastructure, including: a process for the ongoing promulgation of data standards; the

[174] Per Jon Linkous, Executive Director, American Telemedicine Association

status of current standards-setting activities in health data interchange, terminologies, and medical knowledge representation."[175] This report is viewed by some as the most important of a series of institutional endorsements of an NHII.

Although there has been a great deal of discussion of the "need" for a NHII, very little attention has been paid to its cost and attendant policy barriers to its development. If the need is justified by homeland security requirements, characteristics of a resulting NHII may be quite different from one justified by considerations of healthcare-related access, quality or cost. It is important that there be robust public discussion on the issue of a NHII in which its goals, merits, requirements, costs and benefits are examined closely. Meanwhile, any further federal investments in telehealth applications and telecommunications infrastructure should be considered in the context of integration and/or interoperability with existing systems and networks.

LEVERAGING CAPITAL RESOURCES

Blended Funding

Most of the nation's older and larger telehealth programs have blended funding from a variety of sources. The sustainability of many telehealth programs depends on how creative and effective their managers are in leveraging funding and other revenue sources. The Telemedicine Information Exchange's database of programs and the annual report published by Bloch Consulting group are two good sources of information on how programs are leveraging capital resources creatively.

For example, North Carolina's Mountain Area Health Education Center (MAHEC) blends funding from OAT, eRate and private foundations with fees from users to manage the Western North Carolina "Healthlink" network. MAHEC supplements its mission-related revenue by providing technical support to rural hospitals in designing telehealth infrastructure and in obtaining telecommunication cost discounts under the Universal Service Program for Rural Health Care Providers (USAC). In their funding year ending June 30, 2001, these combined discounts amounted to over $117,000.

Not-for-profit organizations have also become attractive alternative sources of telehealth and infrastructure funding. MAHEC's network build-out has been funded in large part by North Carolina's Duke and Reynolds Foundations, and, the "e-NC Initiative," a statewide effort to connect North Carolina to the Internet recently awarded nearly $4 million in incentive funds to support connectivity efforts in western North Carolina for last mile solutions. 80 private organizations support "eNC" through cash and in-kind contributions.[176]

[175] "Patient Safety: Achieving a New Standard for Care," Institute of Medicine, Washington DC, November 2003

[176] Source: *Federal Telemedicine News*, 1/6/03. For additional information, visit the eNC web site at www.enc.org.

The objective of blended funding and creative financing is program sustainability. The patchwork of third party reimbursement policies coupled with an uncertain outlook for federal and state capital investment make this approach necessary for many programs, but distractive for program managers.

Universal Services Access Corporation (USAC)

USAC reimburses not-for-profit rural telecommunications users the difference between rural and urban rates. "Such a program can make a world of difference to rural healthcare projects," reported the former telemedicine director for the Midwest Rural Telemedicine Consortium.[177] There are issues related to USAC, however, such as difficulty users have in complying with administrative and paperwork requirements, suggestions that the program does not meet the needs of rural providers, unawareness of the programs among rural providers, and restrictions placed on use of USAC (or "rural health care provider discount") funds. [178]

There is also a great deal of debate over the use of USAC's annual and cumulative collections. For example, the discount program for rural health clinics is authorized to disburse up to $400 million per year, although actual disbursements in FY2002 amounted to less than $20 million. Some have viewed USAC's collections in excess of its disbursements as a means of funding investment in telehealth infrastructure. Others caution that these "surpluses" are not real. It would appear that confusion about the USAC program may also be an underlying cause of its lower than expected utilization. [179]

Public-Private Partnerships

Private telehealth companies have entered into "partnerships" with providers for such reasons as research, development, testing and promotion of products.

As discussed in the second chapter, TATRC conducts much of its research with private sector "partners." This arrangement not only increases the probability that the Army's investment is actually commercialized, but also assures the private partner the use of TATRC's know-how and resources for research, development, testing and evaluation. The arrangement is also important to the private partner for providing an instant market and distribution channel for its product.

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[177] Lisa Stammer, "Telemedicine: Getting Ready to Take Off," *Healthcare Informatics*, January 2002.

[178] For example, funds used for healthcare must be separated from libraries and schools thereby discouraging demand aggregation.

[179] The FCC ruled recently that any leftover funds allocated to help schools and libraries provide Internet access will be returned to the telecommunications companies that levy a surcharge to fund the program. *Government Technology* reports that by next April, some of the unused money in the e-rate program will be distributed as additional funding to schools and libraries next year. But a sizable portion of these funds -- estimated at $970 million by the FCC -- will be returned to telecommunications carriers to reduce consumer telephone bills, the agency said. The e-rate is paid by contributions from telecom carriers to the universal-service fund, which ensures that customers in rural areas get rates that are comparable to those paid by city customers. Most carriers pass on the extra charges to their customer in the form of line-item fees on telephone bills.

The Department of Veterans Affairs also partners frequently with private sector technology firms. The advantage to VA is an opportunity to test new technologies, while the private partner takes advantage of VA's know-how and patient population to demonstrate its products, establish a customer base, and to strengthen marketing content through "official" efficacy and cost effectiveness studies.

In 2001, the National Institute for Standards and Technology (NIST) partnered with Computer Motion to advance the state of the art of surgical robotics and telehealth. By developing a unique robot control architecture and system, Computer Motion will allow a mentoring surgeon and a student surgeon – located in different places – to simultaneously control a surgical robot performing minimally-invasive surgical procedures on a patient. If successfully developed, the technology will enable substantial cost savings for hospitals and health-care organizations by maximizing the training effectiveness of their top surgical staff and training opportunities for others. It should also significantly advance the field of minimally-invasive surgery and the number of practitioners, with corresponding benefits to patients and society, since these procedures dramatically lower costs through shorter hospitalization and recovery periods.

Telehealth projects also benefit from partnerships between universities or governments and the private sector. Drew University's partnership with Nortel Networks for remote eye examinations in the Watts section of Los Angeles is one such example. Telehealth "champion," Dr. Charles Flowers, leveraged a $50,000 grant from the Los Angeles County Commission and the investment of telecommunications infrastructure by Nortel to create a $120,000 point-to-point turnkey system for remote eye care. Nortel has benefited from the partnership through product testing and public relations, while Dr. Flowers has leveraged his project's success to add additional telehealth services to his practice.

Homeland Security Funding

Telehealth is one of 18 applications approved for use in the first significant disbursement of homeland security funding. Federal and state governments and healthcare communities are still in the very early stages of identifying strategies and planning for homeland security investments. A scenario where funding is made available to upgrade or expand communications and information technologies in healthcare institutions and public health departments seems most likely, at least for the foreseeable future. The extent to which telehealth is being included in state level security planning is unknown. State homeland security funding will most likely be blended with existing program funding to add capacity and capabilities. It is likely, however, that homeland security funding will not provide a continuing revenue stream but will be earmarked primarily for capital investment.

Not enough is yet known about the Department of Homeland Security's priorities/goals related to national health and safety to begin to estimate what levels of investment should be allocated. It is assumed that as the new Department becomes more established, a systematic approach to healthcare technology needs assessment will evolve.

PRIVATE INVESTMENT

In order to discuss investment required to meet the nation's healthcare priorities of access, quality, cost and homeland security, four assumptions are critical.

1. Government funding for current and/or expanded telehealth programs is limited and levels of future funding are uncertain.
2. The vast majority of healthcare providers practice in the private sector.
3. Any significant growth in telehealth innovation and adoption would likely result from private sector investment.
4. Anomalies in the healthcare market suggest that economic, policy or other incentives may be needed to motivate private investment.

Investment in telehealth technologies is an extremely complex subject. Healthcare affects every American. Therefore, the size of the market, the large federal presence in the market as investor, payer and provider, and the multitude of stakeholder interests complicate the interface of private sector firms who would be investors. If greater innovation and adoption of telehealth technologies is linked to increased private investment, the question of what would motivate private individuals and firms to invest is important.

Private investors (institutions and individuals) expect a financial return on their investments. Public investors (i.e. taxpayers) have other expectations such as providing for the public good, cost-effective access to the best possible quality of healthcare for all Americans, and protecting the nation from threats to its health.

The array of public, private and not-for-profit third party payers includes major health management organizations and insurance companies. In addition to reimbursing providers, many third party payers finance and manage their own telehealth programs and networks. Because private payers are primarily interested in profitability or shareholder value, they are most concerned with achieving the best possible return on their telehealth investments.

This section analyzes possible strategies that may increase investment in telehealth and contribute to the intersection of national priorities with private investment goals.

Increase Demand by Increasing Access

In order to achieve a satisfactory return on private investment in telehealth technologies and infrastructure, the number of reimbursable encounters must achieve a minimum level.[180] Because fee-for-service providers earn income from the volume and type of

[180] For example, it has been estimated by one telehealth provider interviewed that $1500 per month would be required of a rural clinic for recurring basic broadband charges. If referring physicians are reimbursed at a rate of $20/referral, at least 75 referrals would be required per month.

healthcare services provided, they may only invest in devices, applications and infrastructure that will help achieve the highest volumes of and highest rates for reimbursable services. Volumes can be increased by expanding patient access and/or expanding the range of clinical services. Greater productivity of the clinician and the clinical staff may also lead to higher volumes of reimbursable services (e.g. more patients or services per hour). Providers may, however, encounter difficulties in achieving even minimum volumes needed to justify technology investments due to both demographics (e.g. sparse populations) and economic conditions (e.g. ability to pay) within their practice areas (i.e. markets).

However, many healthcare providers may not have much more than a "Plain Old Telephone Service" (POTS) network connection. It would be reasonable, then, to expect such providers to limit their investment to devices and applications that would be compatible with POTS. The additional telecommunications cost of increasing access to patients (e.g. building the volume of encounters over long distances) and to other providers (e.g. expanding services) may be a "disincentive" for private sector providers to invest in upgrading their capabilities unless those technologies contribute value (i.e. increased revenues, improved quality, increased productivity, and/or reduced delivery cost) greater than the additional investment required.

Without economic, policy or commercial incentives for the private sector to invest in medically-underserved areas, either the public or not-for-profit sector must take responsibility for increasing access. The (U.S.) Department of Health and Human Services (HHS) and States having medically-underserved populations have funded extensive programs for many years to increase access. As discussed earlier, not a great deal is known about the impact these programs have had on increasing access and improving health because of the lack of data. One need that has been addressed through educational grants and immigration programs is the recruitment of physicians for underserved areas.[181] Another initiative was the 1989 Medicare program to provide a premium of 10% for reimbursement to providers in medically-underserved areas, a program rescinded in 2001 because it wasn't working.

Another counterincentive to investment (because it has a significant affect on demand) are differences in Medicare reimbursement for providers in different areas of the country. "The disparity in payment stems from geographic adjusters in each of the three elements of the physician fee schedule -- practice expense, work expense and liability insurance costs. Those adjustments can mean differences of thousands of dollars in reimbursement between high-cost and low-cost areas. Fee-for-service Medicare payments for the average patient in Miami in 1996 was $8,414, while the average patient in Minnesota cost the program only $3,431."[182] While resolution of this issue will most likely await serious

[181] For example, a special J-1 visa is currently offered to attract foreign physicians to shortage locations in exchange for service commitments.

[182] To achieve access to quality healthcare for all Americans, a significant program to build and connect infrastructure would be required. Estimates to build out the nation's broadband to provide access to most locations range from $100 to $200 billion. Because of distances and terrain, fiber optic technology may not be an economical option, as is true of wireless in many locations. Satellite links may prove more economical through services which may offer monthly lines for as little as $35.00, as well as reception "kits" that may cost from $1000-$10,000. Satellite broadband offers scaleable broadband connectivity up

Medicare reform, its impact on telehealth adoption and investment (as well as other innovative medical technologies) is significant because, although revenues (e.g. reimbursements and out-of-pocket payments) are generally lower in less urban areas, technology expenses may be as high or higher.[183]

The following Table 4.a discusses incentives that individuals interviewed during the course of this research and report suggested might be effective in motivating investment to increase access:

TABLE 4.a INCREASE ACCESS IN MEDICALLY-UNDERSERVED AREAS

GOALS	METHODS	INVESTMENTS	POSSIBLE INCENTIVES
Increase connectivity	Basic infrastructure[184] Additional functionality	Needs assessment Expanded service	Database of technology usage and resources of rural and remote providers; Eliminate regional and local disparities in reimbursement rates/amounts; Develop a healthcare-related ISP; Address economic impact of Medicare requirement for submitting billings
	Provider participation	Expand reimbursement for services	Higher or comparable third party payment schedules for providers in medically-underserved areas; Increase third party payer payment schedules for technology applications; Faster depreciation for technology expenses
	Public awareness	Multimedia campaign	Campaign sponsorship (e.g. public service announcements); AMA endorsement
Expand applications	Multi-use functionality and horizontal integration (e.g. health, education, security, communications)	Local and regional collaboration; Technical guidelines; Integration services	Medicare, Medicaid and other third party payer coverage of additional services; USAC incentives for extending collaboration by offering additional coverage
	Low bandwidth applications	Technical guidelines; Integration	
Expand networks	Expand current TH networks Add spokes to hubs	Technical assistance	Technical assistance to grantees
	Link networks	Federal grant programs	Technical assistance for IT and telecommunications standards and Interoperability

Improve Quality and Flexibility

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to 2 Mbps. Stratos' fixed satellite services, for example, claims multiple voice/fax connections and high-speed WAN/LAN connectivity at $1.00 per minute.

[183] For example, due to demographics and greater competition, telecommunications costs in urban areas tend to be lower than in rural or remote areas. The AFCHAN program in Alaska, for example, reports healthcare costs that are 300% greater than in the lower 48 states due to such unique as isolated villages, long distances and generally higher costs of living.

[184] Cost estimates to equip an estimated 58,000 physicians in non-metropolitan areas with a basic infrastructure of a personal computer, telephone, Internet access and eMail are estimated at around $300 million (based on start-up investment of $5,500 per site). Linking rural providers to nearby telehealth networks may be simply a matter of dialing up access numbers, and adding sites may incur costs at the "hub" (although interoperability may be an issue). Theoretically, a concentrated effort to link and train even the most rural or remote providers with telehealth networks could be accomplished efficiently and economically within a short period of time.

The role of technology in improving healthcare quality and patient safety has been a focus of attention since the 1998 Institute of Medicine report "Crossing the Quality Chasm" identified the intuitive role that automation of clinical procedures and recordkeeping can reduce human error is somewhat intuitive. For telehealth, quality of healthcare can be defined in other ways as well. For example, expanded access to primary and secondary healthcare through the AFHCAN program improves the quality of care (and quality of life) of remote Alaskan villagers. Teleradiology services provide faster turnaround times between specialists and clinicians for everything from broken bones to mammograms, thus contributing to improvements in quality of care. Telemonitoring allows patients to recover or rehabilitate at home where, some studies suggest, the healing process is more effective. Other studies suggest that mental health counseling is, in some cases, more effective when televideoconferenced, allowing the patient the security of privacy and the flexibility of connecting with a counselor on his or her schedule. The flexibility afforded by telehealth technology also offers the provider and patients more options than a face-to-face encounter.

It is in the areas of quality and flexibility where investment in telehealth technology can have the most impact. While government can design and invest in research and demonstration projects for improving quality, [185] providers make sure those programs benefit the patients. Technologies that improve the quality of healthcare must, by definition, be designed for and distributed to providers, caregivers, or patients.

There is, of course, the potential that improvements to quality of care innovated by providers would benefit the telehealth community in general, and should be encouraged. One incentive to develop and diffuse innovative improvements would be "fast track" protection of intellectual property in the form of patents and copyrights, a change that the Patent and Trademark Office has incorporated into its rules of practice for medical submissions with certain conditions.

Table 4.b below identifies methods, investments and possible incentives that individuals interviewed during the course of this research suggested might lead to improvements in the quality of healthcare delivery. For the most part, these incentives are directed at the provider. It is important to note that, currently, the payer benefits most from reduced healthcare costs as a result of quality improvement.[186] It was suggested by interviewees that these possible incentives have the potential to motivate the provider and could, in turn, benefit both payer and patient.

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185 The Quality Interagency Coordination Task Force (QuIC) was established in 1998 to "ensure that all Federal agencies involved in purchasing, providing, studying, or regulating health care services are working in a coordinated manner toward the common goal of improving quality care." Discussions with the Federal agencies indicate that organization is no longer meeting or functioning on a regular basis.

186 In 2002, CMS announced a demonstration project that would offer bonuses to providers that improve the quality of care provided to Medicare beneficiaries. The project aims to encourage practices to coordinate care of chronically ill beneficiaries; it tests incentives to provide efficient patient services; and promotes the utilization of clinical data to improve efficiency and outcomes. Bonuses will be funded from cost savings the project is expected to produce.

TABLE 4.b IMPROVE HEALTHCARE QUALITY			
GOALS	**METHODS**	**INVESTMENTS**	**POSSIBLE INCENTIVES**
Reduce illness	Disease management	Payer incentives for disease management	Bonus payments or investment credits to providers for applying quality improvement technologies
		Preventive medicine programs	Individual tax credits or subsidies for enrolling patients in preventive maintenance programs
		Information technology	Accelerated depreciation on disease management devices and applications
	Professional and patient education	eLearning infrastructure and applications	Individual or business tax credits for program enrollment/development
Reduce hospitalization	Telehomecare	Adoption of: Devices and applications Information technology	Accelerated depreciation on telehomecare devices and applications; Expanded Medicare/Medicaid reimbursement for monitoring services
	Remote monitoring	Adoption of: Devices and applications Information technology	Accelerated depreciation on remote monitoring devices and applications; Expanded Medicare/Medicaid reimbursement for monitoring services; Bonus payments or tax credits for reduced hospitalization rates and reduced outpatient visits
Reduce medical errors	Automate clinical protocols Application of information technology	Applications such as automated drug prescription and distribution systems	Expanded investment credits for drug decision support and distribution systems; Expanded investment credits for use of Informatics and evidence-based medicine; Expanded investment credits for automating medical records; Bonus payments to or lower malpractice premiums for providers based on quality or patient safety metrics
		Education and training	Double tax deductions for education and training expenses

Improving Productivity and Reducing Cost

It is widely recognized that investments in information technology contributed to a reduction in operating costs and improvement in productivity that accompanied an upsurge in competitiveness and success of the U.S. financial services industry over the last twenty years. The Internet's contributions of eCommerce, eGovernment, and eMail have reduced the cost and increased the productivity of most sectors of the nation's economy. As discussed elsewhere in the report, the healthcare sector has yet to fully benefit from the same level of investment in and adoption of technologies. Where that investment has taken place, however, there are numerous examples of reduced cost and increased productivity. [187]

[187] For example, in a recent presentation to the President's Information Technology Advisory Council, the CIO of Harvard Medical Caregroup, John Halamka, M.D., stated that administrative costs for processing a reimbursement transaction dropped from $5.00 to ten cents with automation.

Reduced cost and improved productivity through the adoption of telehealth and other healthcare technologies will initially benefit the provider through higher profitability (additional revenues through higher volumes and lower costs), more efficient administration, reduced human errors, higher patient satisfaction and the ability to increase patient volumes. The provider's reduced costs and improved productivity could be directed in ways that eventually benefit the payer through the automation of billing and reimbursement, as well as improved data collection and the introduction of innovative applications such as electronic medical records and computerized pharmaceutical order entry. Ultimately, the widespread adoption of telehealth and other healthcare technologies holds the promise of benefitting the nation through improved health and lower costs. Table 4.c below identifies suggested methods, investments and possible incentives that might assist in reducing the nation's healthcare costs.

TABLE 4.c REDUCE HEALTHCARE COSTS

GOALS	METHODS	INVESTMENTS	PERFORMANCE MEASURES and POSSIBLE INCENTIVES
Automate administration	Adopt information technology	Rationalization of reimbursement policies; Automation of administrative operations	Awards, recognition and other incentives for effective cost reduction programs; Expanded investment tax credits or accelerated depreciation for automation expenses; Low-interest loans for automation
Integrate applications	Integration software, systems integration	Systems integration	Metrics related to cost reduction such as change in costs per encounter; Tax policy which incentivizes cost reduction and use of metrics
	Education and training	Professional training programs	Certification programs for healthcare technology integrators/professionals
Increase productivity	Adopt information technology	Automate healthcare financial data systems and applications; Develop and adopt applications for measuring productivity	Metrics related to productivity such as number of total staff hours per encounter or total costs per encounter; Design and implement tax policies which incentivize productivity measurement
	Education and training	Needs assessment Curricula development eLearning programs	Formal recognition for productivity gains resulting from telehealth investments
Share resources	Technology cooperatives	Awareness campaign to include "best practices;" Establish buyer "co-ops;" Practice demand aggregation	Favorable tax treatment for buyer cooperatives or for sharing technology resources
Reduce telecom costs for providers	USAC	Awareness campaign	Revised USAC policy allowing blend of eRate with other applications
Increase return on investment		Create business and return on investment models; Undertake data collection/surveys; Undertake cost-benefit analyses	Industry indices/benchmarks

In attempting to identify investment required, it would be useful to understand under what circumstances private and/or rural providers would invest in technologies, and to what degree access, quality and cost are important criteria.

Responding to National Emergencies and Increasing Homeland Security

Healthcare providers will need to be connected electronically in order to effectively participate in the Centers for Disease Control and Prevention's (CDC) Health Alert Network (HAN) and National Epidemiological Detection and Surveillance System (NEDSS) bio-defense networks and other regional or national information systems relating to homeland security and national emergencies. Investments in technology must meet the primary requirements of multi-use and interoperability. To accomplish this most effectively and efficiently, homeland security and clinical healthcare needs must be integrated locally, regionally and nationally.

It has been suggested that, to assure access to homeland security information systems, all healthcare providers possess a minimum of a computer, electronic interface with the Internet (i.e. an Internet Service Provider), broadband telecommunications (if available), and eMail. Training costs must be included in the baseline because some portion of the users will not have the technical know-how necessary to operate the equipment or utilize the applications effectively. Another widely-accepted notion is that any homeland security applications should be multi-use (i.e., so integrated with day-to-day, routine clinical protocols and business processes that transition to homeland security uses becomes second nature).

The elevation of homeland security as a national priority and the substantial funding being made available introduced the potential for widespread direct government procurement or subsidization of healthcare technologies. Participants in the June 19 Roundtable heard "The money is available for any telemedicine initiatives that address issues of bioterrorism and first responders." [188] More precisely, states have proposed action plans for responding to conventional emergencies and bio-terrorism, and the Federal government, through FEMA and HHS, has disbursed initial funding for first responders and public health bio-defense programs respectively. These initial "tranches" will funtion as a stopgap measure until the Department of Homeland Security is fully functional and can apply a systematic methodology to needs assessment and funding.

Until comprehensive assessment of homeland security's healthcare technology needs is undertaken, research and development of "multi-use" functionality will be speculative.

[188] Dr. George Alexander, Medical Advisor, Office of Homeland Security at the Technology Administration/OTP "Innovation, Demand and Investment in Telehealth" Roundtable on June 19, 2002.

Telehealth programs and networks already in place or being undertaken can provide real-time information and examples to help speed an integrated national response to homeland security needs such as the diffusion of healthcare information, syndromic surveillance, surge capacity and mobile response teams. For example, the Southern Governors Association is undertaking a project to connect existing telehealth networks across eleven states into a single bio-defense network. Another example may be a newly-organized Northern Command that has its own telehealth capabilities. Awareness of these and other current projects might lead investors to consider network linkages or other collaborative strategies.

BUSINESS MODELS

Through the use of some common models describing what works in telehealth programs, what they cost, and what is required, potential investors can begin to simulate costs and cash flow, and to evaluate risk, as in a cost-benefit analysis. As one authority suggested, "We need an integrated cost model across the board to account for the true cost of care so that we can really understand the benefits of these new technologies."[189] Entrepreneurs and institutions contemplating investment will be interested in models that work (and why some don't).

There are several different types of applicable business models. One type that may instructive are models designed to facilitate provider acceptance. If, for example, the provider is unable to finance the capital investment or is unsure of the acceptance or integration of the technology by patients or staff, a leasing or outsourcing model may be most appropriate. Leasing has been effectively applied to telepathology, for example, where the provider may network a device to a remote laboratory for analysis or diagnosis. The services or outsourcing model has been widely practiced in teleradiology, where a provider's investment may be limited to a scanner. (Teleradiology has become so routine in some radiology departments that the term telehealth is not even applied.) Both models should be considered for investment in medically-underserved areas where patient volumes are low, and where pathology and radiology specialists may not be available.

Others models might include:

- Telehomecare. Private profit or not-for-profit agencies employing visiting nurses appear to be the most popular business model (although reimbursement policies impact this field). Technologies used for this model include automatic drug monitoring, cardiac or pacemaker monitoring, disease management, and videoconferencing. The agency may purchase and hold title to the devices and applications, or require that the patient do so.

- Mental health which would employ video-conferencing, informatics, or wireless devices for consultations or monitoring. One telementalhealthcare provider reports that patients are both more satisfied and more easily treatable because videoconferencing allows greater scheduling flexibility and greater privacy than

[189] Comments by Steve Brown, CEO of Home Health Hero, Inc. at the TA/OTP June 19 Roundtable.

group counseling. Recent coverage of mental health by Medicare has made this model more attractive.

- A combined telehealth network and health education network that should increase utilization and add revenue streams. This model has the added advantage of being able to tap distance and lifelong learning resources as well as healthcare. An example of this model is the Mountain Area Health Education Center program described earlier in this report.

- Use of eMail and/or the Internet as the telecommunications platform. While only 13% of doctors use e-mail to communicate with patients, a growing number say they would use it more if email usage is reimbursed. To address these issues, companies such as Blue Shield of California and a group of Silicon Valley employers are testing a program called "webVisit" from Healinx Corporation that reimburses doctors $20.00 for certain online consultations.[190] Medem Inc., the for-profit Internet company backed by the American Medical Association and other physician groups, has recently launched a service that will enable doctors to charge patients for online "visits."[191] As the Internet and the use of eMail become ubiquitous, this model becomes more significant for addressing the priorities of access and cost.

There are many other models. It is important, however, that service delivery and cost models integrate the clinic's routine workflows and protocols, and be able to link all specialties across the enterprise (e.g. clinic, hospital or network).

Telehealth has a long enough track record that empirical models can be coupled with "best practices" and "lessons learned." What is often missing are the development and application of financial "benchmarks" and industry indices which underscores the need for additional research and data collection of investment and cost-benefit indices.

In a traditional business model, capital for start-up and investment in equipment and facilities would be managed separately from capital required to maintain a company's operations. Because an average of 84% of a typical healthcare provider's revenue is received as "reimbursement" from third party payers (see Table 3b.), such measures of financial performance as "return on investment" and "profit and loss" depend almost entirely on how much of the business' revenue is generated by reimbursements. Given this, telehealth providers will invest in services and equipment that are covered by applicable third-party reimbursement policies – and are unlikely to invest in technologies that will not be reimbursed.

Business Models - Lessons Learned

Successful telehealth programs have relied on the multi-use aspect of their technologies. Multi-use means that a hospital may use a videoconferencing network for distance

[190] Landro, Laura. "New Guidelines to Make Doctor-Patient E-Mails Profitable, Less Risky." *The Wall Street Journal* (Technology & Health) Jan. 25, 2002.
[191] Carrns, Ann. "Medem to Enable Physicians To Charge for Online 'Visits'." *The Wall Street Journal* (Technology & Health) June 6, 2002.

learning for clinicians, administrative conferencing, public health education, community development and/or patient care. Such networks as the Midwest Rural Telemedicine Consortium depend on "secondary uses" to keep them up and running. The primary use of their network is educational programming and administrative conferencing. Another cost-saving measure comes from partnering with other organizations to help build and pay for the network. [192]

Issues of privacy, security, reimbursement, and liability still restrict the development of telehealth business models that, in the past, have been created with "cost savings" in mind. Recognizing that poor information flow in healthcare settings contributes to gross inefficiencies, inequities, and quality variations, business models that focus on telehealth as an enabler of better, faster, cheaper information flow will present better cases for profitability. More recent business models have incorporated these considerations and have emphasized how telehealth programs "make" money. [193]

As previously discussed, business models of telehealth applications also contend with estimating revenue streams from a patchwork of public and private reimbursement policies. Although payers publish reimbursement policies, their ever-changing nature coupled with complicated language and exclusions suggests that only those investments having some administrative capacity are best able to manage the research and paperwork associated with claims. In both public and private payer systems, administrative paperwork requirements act as a significant barrier to investment in and implementation of telemedicine programs and especially for smaller clinics (see Chapter 3 for discussion of the impact of "paperwork" on demand and operating costs).

Sustainability

There are only a few types of economic models – teleradiology services, mental health services, telepathology, teledermatology and home healthcare agencies - that project sustainability (i.e. positive cash flow) for telehealth investments without an infusion of external funding. All models demonstrating sustainability include routine reimbursement by third party payers in some fashion. The more rural, uninsured and/or less affluent the market segment or geographic area, the less likely the telehealth program will be sustainable without external assistance directed toward capital investment and operating expenses. At the same time, budgetary pressures on federal and state grant making agencies and third party payers have required that telehealth programs become self-sustaining.

If the goals of access, quality, cost and even homeland security are going to be met, however, a requirement for self-sustainability may not always be a priority. In rural areas, for example, it is unlikely that telehealth providers will experience the volume of encounters and revenue that would cover operating costs or recover capital invested in

[192] Stammer, Lisa. "Getting Ready to Take Off." *Healthcare Informatics* January 2002. p. 4. http://www.healthcare-informatics.com/issues/2002/01_02/take_off.htm.

[193] Kirsch, Gorm. "The Business of eHealth." *International Journal of Medical Marketing*. Jan 2(2): 106-110. p. 106.

technology. The Medical Director of the University of Virginia's Office of Telemedicine has said:

> "In the absence of federal or grant funding, small clinics and hospitals are least likely to afford the capital expenditures and the ongoing telecommunications costs inherent in the establishment and maintenance of a telemedicine facility." [194]

Sustainability is important in another sense because, without it, there is limited incentive for competition, and even less incentive to innovate, improve quality and expand services.

A program's likelihood of self-sustainability can be increased by engaging in partnerships and by applying general business principles. There are examples of telehealth programs serving rural, uninsured and/or less affluent markets that have achieved profitability and sustainability by expanding their services to non-traditional customers. For example, the Telemedicine Center at East Carolina University contracted with the Bureau of Prisons to provide telehealth services at corrections facilities in Eastern North Carolina. Teleradiology firms are contracting with corporations to provide pre-employment X-rays, EKGs, etc. Home healthcare agencies are contracting with Veterans Affairs to provide telemonitoring services to veterans.

The free exchange of such business case information and lessons learned is a favorite subject whenever telehealth professionals gather. A mechanism for continuing and extending this exchange is needed as well as the development of sustainability or profitability benchmarks (e.g. comparative return on investment rations).

Reimbursement Policy

Any discussion of investment will assume that that the "investor" is interested in monitoring the value and effectiveness (i.e. "return") of his or her investment, and will expect that the "return on investment" will achieve certain results. Return on investment (ROI) in a typical private (healthcare) business takes the form of:

1 Revenue for services performed
2 Reimbursement for services performed
3 Increased value of assets
4 Increased value of labor (e.g. skilled workforce)
5 Secondary markets created

From a national perspective, estimating ROI in healthcare is difficult because of economic externalities and the difficulty in quantifying and measuring national social and non-economic priorities such as increased access to quality health care and homeland security. From a private perspective, reimbursement decisions need to be timely,

[194] In testimony given by Karen S. Rheuban MD, Medical Director, Office of Telemedicine, University of Virginia Health System to the U.S. House of Representatives' Commerce Committee on September 7, 2000.

consistent, and "innovation-friendly" so that new or expanded uses of technology are not penalized vis-à-vis established methods of care. Timelier adjustments to reimbursement policy, which are necessary to balance coverage and cost, must be considered by policy-makers, in part, to minimize risk to investors.

"Scoring models" developed jointly by the Office for the Advancement of Telehealth (OAT) and the Center for Telemedicine Law (CTL) offer a series of cost models that use actually data from OAT grantees to provide a more accurate estimate of the impact of expanded coverage on third party payers. For example, the CTL/OAT estimates of expanding telemedicine payments under the Benefits Improvement Act of 2000 (BIPA) ranged from $50 to $100 million over five years, compared to a Congressional Budget Office estimate of over a billion dollars. [195]

While contributing more accurate estimates, scoring models such as CTL/OAT's consider neither productivity increases nor the impact of reimbursement policies on access, quality, and homeland security. As of December 2002 (two years into BIPA), CMS reported actual utilization of only 1,350 approved billings totaling less than $500 thousand.[196] Better scoring models and other technology evaluation process improvements may be considered when public policymakers turn their attention to Medicare reform, and as legislation relating to Medicare reimbursement of telehealth is considered in the 108th Congress.

Telecommunications infrastructure costs and availability

As the need for providers to transmit data increases, the need for higher speed and higher capacity telecommunications such as broadband becomes more important. The advantages of broadband for Internet and voice-over-internet applications include the "always on" feature needed for store and forward applications. Higher capacity bandwidth is also important for accuracy and clarity in digital imaging applications such as teleradiology, teledermatology and pathology. A central question for telehealth providers is the availability of broadband capacity in their locality.

The next consideration is the cost of broadband service and associated technologies such as modems and audio-visual equipment. The potential for significant increases in the telecommunications-related costs are another risk for investors, especially if those cost increases cannot be absorbed within existing fee structures or payer reimbursement rates, or, cannot be offset by improved quality or productivity. In an informal assessment of 26 telehealth programs conduced by the University of Missouri in 2002, 12 programs considered the cost of telecommunications services to be the single biggest barrier to sustaining their telehealth programs. An additional four programs placed telecommunications cost near the top of their list of barriers. These concerns are even more significant for the rural and medically-underserved areas most often identified as the primary beneficiaries of telehealth investment.

[195] Puskin, Dena S. (September 30, 2001) "Telemedicine: Follow the Money" *Online Journal of Issues in Nursing*, Vol. 6, No. 3.
[196] From a presentation by Craig Dobyski, CMS at the ATA's December 2002 Conference.

As previously discussed, programs such as USAC were intended to offset higher telecommunications costs associated with rural and medically-underserved areas. USAC has, however, been criticized for failing to fully disburse USAC funding due to a low level of utilization. Prospective applicants complain that an excessive paperwork burden associated with USAC application requirements falls hardest on those small, rural providers that need to offset higher telecommunications costs the most. North Carolina's Mountain Area Health Education Center reports a very high utilization of USAC because it has aggregated demand. (MAHEC also offers assistance to rural providers in completing and submitting USAC paperwork on a reimbursable basis).

Techniques such as demand aggregation and an "eCommerce approach" may assist in reducing the burden of paperwork. However, a significant and sustained effort will be required to educate investors and extend business models and sustainability "best practices" to providers throughout the nation's continuum of care.