Frameworks for Identifying Universal Standards and Recommended Practices to Enable Effective Access to 21st-Century Telehealth by All Americans

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Draft

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Abstract

This discussion paper takes a broad perspective on the topic of technical standards and recommended practices for telehealth, going beyond conventional videoconferencing approaches to consider the challenging issues of universal access, medical devices, and product evaluation resources for consumers. We start be developing a context for the technical standards process, in particular pointing out some of the distinctions between standards related to medical devices and those for telecommunications/information technologies. Next, we address five areas that this author proposes as governing principles for identifying appropriate frameworks: universal access; consumer choice; interoperability and reliability; facilitating a vibrant marketplace (including open architectures), and access to objective evaluation resources. Finally, we propose a classification scheme consisting of 5 areas for telehealth evaluation: conventional teleconferencing (including teleradiology), data and application sharing (including medical records), medical device assessment for "value-added" sensing of health/wellness status (e.g., vital signs), human performance (including teletherapy), security and confidentiality.

I. Introduction

The purpose of this white paper is threefold: i) to serve as a web-based resource for information on standards in both telehealth and medical devices; ii) to provide a (hopefully thought-provoking) rationale for why government should be involved (and also suggest areas of focus); and iii) to suggest a framework for achieving the stated aim of Telehealth for All.

It is assumed that the reader has access to 4 other sources: position papers by Joanne Kumekawa entitled <u>Telehealth Technical Standards of the Future</u>. The Phantom Menace? and by Alan

Branigan and David Balch entitled <u>What Technical Standards are Used by OAT Grantees and What Works?</u> that are also related to this Workshop, the 1998 <u>Report of the Interdisciplinary Telehealth Standards Working Group</u> [created for the Joint Working Group on Telehealth (JWGT), which is complementary to this report in that it emphasizes legal and clinical "standards"], and the report of the NSF- and FDA- sponsored <u>Workshop on Home Care Technologies for the 21st Century</u>, organized by this author.

II. Background: Process and Motivation for Official and Defacto Technical Standards

Since They're Voluntary, Why Bother? Voluntary standards play a key role in our economic engine and technological infrastructure. To the **design engineer**, existing standards provide pragmatic design constraints (e.g. allowing "nuts and bolts" to interface, devices to communicate, safety frameworks), and in many cases provide explicit performance measures that specify minimum requirements or help define "best practice" approaches. This pragmatic need helps place in context the historic motivation behind the development of standards bodies (see <u>Table 1</u>) that help manage the process of creating, disseminating and maintaining voluntary consensus standards.

While consensus standards have a long history of importance within engineering, it's a relatively new concept for the health service delivery field. Indeed, within the health field the historical drivers have been the certification/credentialing of professionals (who can then be reimbursed for services), and the codes that can be used to attain reimbursement; in healthcare "standards" are usually textbook "best practice" (or "preferred practice patterns") guidelines [e.g., see various practice guidelines for <u>physical therapy</u>, <u>occupational therapy</u>, the American Nurses Association resource on <u>Healthcare Informatics Standards</u>, American Accreditation HealthCare Commission/URAC's <u>24-Hour Telephone Triage and Health Information Standards</u> (standards for the managed care industry)].

Technical standards also, however, fulfill a **societal need**. At the level of macroeconomics and governmental policy, global standards help break down international **trade barriers**. From the perspective of consumers who need to procure technologies, the existence of specified standards can provide guidance and some level of quality assurance; an effective standard both **empowers the consumer** and functions as a sort of security blanket to the purchaser.

It's proposed that successful home telehealth products of the future will meet mass-market **open-architecture standards** for information transfer and conferencing, and be inherently **interoperable** with other products (both medical and non-medical). It's critical to know the operative standards rather relate to a certain type of product or service, and to identify the extent to which a certain company is committed to this new playing field (and if not, why)!

Observations on the Process. The basic process for developing a conventional standard is rather simple: once a need (and a coordinating body) is identified, bring together representatives of the key stakeholder groups [e.g., companies (often both large and small, since their aims may differ); government agencies such as NIST, FDA or FCC, professional societies (e.g., engineering; health), consumer groups (e.g., representing possible end-users and/or a community impacted by

a standard)]. Then evolve to a consensus solution that all can live with. Then publish it, and review/update it periodically.

The **conventional process takes time**, usually on the order of years. This is both a strength and a weakness. In areas such as medical devices, it adds stability and quality assurance to the field. The ANSI-accredited Association for the Advancement of Medical Instrumentation (AAMI) strives to review/update its standards (requiring 6 large reference volumes to document) on a 5-year cycle. Some of these standards can be extensive; for example, in AAMI's Volume 2.1, Biomedical Equipment, Part 2, there are 5 standards spanning over 150 pages just on blood pressure transducers and various sphygmanometers. For medical devices, where issues such as safety and the regulatory process are central, this slower timeline may make sense. Indeed, given that a device needs to go through an extensive review process through the FDA anyway, this slower process can help protect a company's investment.

However, in certain fast-moving areas such as wireless telecommunications or software protocols, the conventional process is too long; new generations of products may have a "lifecycle" on the scale of months, rather than years. Consequently, ad-hoc "consortia standards" often emerge out of mutual agreement by strategic private partners; these can make or break companies (even large ones) nearly overnight. There are also cases where the marketplace, rather than a standards body, serves as the testbed for "**de-facto standards**" creation. Examples include some of the most important "standards" in the modern world: operating systems such as UNIX and Microsoft's Windows, the TCP/IP protocol for information transfer by packets (e.g., the communications backbone of the Internet), and modern "router" technology from companies such as Cisco or Lucent.

A classic example of this market-oriented approach is the flurry of standards activities in the area of communications protocols for **wireless technologies** [e.g., industry-driven consortia: <u>HomeRF</u> working group for the SWAP (Shared Wireless Access Protocol) for low-power, unlicensed (2.4 GHz) home wireless data/voice with TCP/IP connectivity of consumer devices; <u>Bluetooth</u> consortium for open data/voice specifications for global connectivity; <u>Wireless Application</u> <u>Protocol</u> group for internet and telephony wireless applications in the regulated bandwidth (e.g., for cell phones); and ITU's <u>global wireless standards initiative</u> (including the third-generation IMT-2000 to provide universal assess for wireless communications)]. What about wireless technologies and accessibility? See the RERC on Universal Telecommunications Access' report entitled "<u>Technological Trends in Wireless Telecommunications</u>" for a broad treatment wireless technologies of relevance to persons with disabilities.

Finally, the President's Information Technology Advisory Committee's recent <u>Report to the</u> <u>President</u> is aggressively pushing through a research agenda to enable intelligent 3rd-generation (3G) and 4G wireless mobile communications systems (e.g., see an existing <u>NSF initiative</u>).

Federal Role? Do federal agencies have an obligation to address the issue of standards in procurement and grants management? Must accessibility by individuals with disabilities also be addressed? Yes, and yes. Consider two U.S. laws signed in February of 1996. The stated purpose of the National Technology Transfer and Advancement Act of 1995, section 12(d) is to direct "federal agencies to focus upon increasing their use of standards whenever possible," thus reducing federal procurement and operating costs, with NIST serving as the "federal coordinator for government entities responsible for the development of technical standards and conformity

assessment activities" (see Congr. Rec. H1262, February 27, 1996 statements by Rep. Morella).

Section 255 of the Telecommunications Act of 1996 provides that a manufacturer of telecommunications or customer premises equipment, and providers of telemunications services, shall ensure that the equipment is designed, developed, and fabricated to be accessible to and usable by individuals with disabilities, if readily achievable. And if not readily achievable, the equipment or service should be compatible with existing peripheral devices or special customer premises equipment commonly used by individuals with disabilities to achieve access. The Access Board is responsible for developing (and updating) accessibility guidelines (e.g., see Part 1193), in conjunction with the FCC. Ironically, the functions of the Access Board are set in the Rehabilitation Act of 1973 (Section 502), with Section 508 of the same act requiring that electronic and information technology purchased by the Federal government be accessible to individuals with disabilities. Section 508(a)(2)(A) of the Rehabilitation Act Amendments of 1998 requires the Access Board to publish standards (by February 7, 2000) setting forth a definition of electronic and information technology and the technical and functional performance criteria necessary for accessibility for such technology. The Electronic and Information Technology Access Advisory Committee is assisting the Access Board in this process, which clearly impacts on future telehealth solutions.

One final note: During the 1990s the FDA's Center for Devices and Radiological Health's (CDRH's) <u>Standards Program</u> has had the aim of moving toward a greater reliance on voluntary standards and the industry use of "declaration of conformity," as well as having its technical personnel play a more proactive role in this process at both the national and international levels (see lists under the Standards Program page). Furthermore, the FDA has established a considerable number (roughly 300) of device-specific guidelines, as well as (still evolving) policies for telemedicine and computer software.

Of note is that standards bodies – especially in Europe – are recognizing that there is a need for speeding up the process, and are considering procedures that can transform defacto standards to official standards, in cases where there is broad consensus.

Global Trend? Is there a global push toward universal standards and guidelines, and toward other means of breaking down trade barriers? Yes. In general, European society seems to care even more about standards than American, with telecommunication and medical devices high on their priority list. Within the European Union (EU), there is a strong push not only toward getting European standards in line with ISO and ITU standards, but also toward develop procedures for recognizing de-facto standards (more on this later in this paper).

In 1997, the EU signed a <u>Mutual Recognition Agreement</u> with the US that covers over \$40 billion worth of transatlantic trade, with special emphasis on telecommunications equipment, medical devices, pharmaceuticals, electromagnetic compatibility and electrical safety, and recreational watercraft. The first 4 of these 5 target areas impact on telehealth (perhaps Workshop participants can tie in the fifth, e.g., telehealth from my windsurfer?). Conformity Assessment Bodies (CAB's) are set up for each of these categories; from the US side, the FDA, FCC and Department of Commerce appear to be the most impacted agencies. The MRA for medical devices establishes procedures to simplify/streamline product and system approvals; for example, the EU CAB could review a product and make a recommendation to the FDA. Roughly 140 Class I and II (i.e., non life-sustaining or life-supporting) are currently on the list during the

present "confidence-building" period; for the FDA in particular, this is a major change in culture, and progress appears to be gradual.

In a recent EU study entitled *The Role of Telecommunications Systems for Elderly and Those with Special Needs - Ensuring Access for All* (Buhler and Schmitz, EC Contract No. 48442), considerable attention is paid to the US laws mentioned previously, with the underlying message being that the US's more forward-thinking requirements for universal access and universal design (i.e., "design for all" principle), versus a more fragmented European approach, will give European companies a competitive disadvantage in the telecommunications marketplace.

Finally, through their Telematics Applications Programme, the EU has more of an explicit research effort that targets both <u>health telematics</u> and <u>telematics for disabled and elderly people</u>. Interestingly, within the US the allocation of funds for telehealth has been more for infrastructure and demonstration projects, while in Europe it seems more directed towards research; it will be interesting to see which approach is more effective.

Advantages and Disadvantages of Standards. Whether through a conventional process or by other means, an effective standard provides/facilitates the following positive features: interoperability (e.g., communication across platforms and networks), compatibility of components and applications of varying sophistication, quality control and management (depending on whether performance measures are involved), and improved reliability and customer confidence.

There can be negatives. For instance, the existence of a standard may discourage innovation. Also, it's not easy to remove "obsolete" standards, and thus there is potential for misinformation. Perhaps of more relevance here is that due to the need for consensus, the "common ground" of the standard is typically a set of minimal specifications. Thus it is common for companies – from wheelchair manufacturers to telecommunications software developers -- to try to add value to their product that is over-and-above the standard. This helps explain why video and sound quality is often worse when products for different manufacturers connect during a teleconference.

Classic Telehealth Examples. Under the ATA's web page on <u>telemedicine guidelines and</u> <u>technical standards</u>, only three technical standards are listed: <u>DICOM</u> for teleradiology (recognized by the American College of Radiology as a standard), <u>HL7</u> for electronic interchange of healthcare records, and <u>H.320</u> for ISDN (and T1) exchange of information. The OAT standards background paper by Branigan and Balch found that for teleradiology, the primary modes for transmission of images were DICOM and JPEG/MPEG, and that the three classic H.3xx teleconferencing standards from the International Telecommunication Union (ITU) were all in common use: H.320 (primary target -- ISDN, but see the <u>full standard</u>), H.324 (primary target -- POTS-based videophones), H.323 (primary target -- LAN/Internet). Details on these standards can be found many places, and they will not be reviewed in depth here (although some of our evolving efforts at systematic evaluation of H.323- and H.324-compliant technologies will be presented later the tables and figures attached to this report, and full technical reports are becoming available).

Here we back up, and briefly focus on the impact of the ITU's H.3xx standards. Much of the existing federal investment in hub-spoke rural telemedicine networks was put in place before

H.320; often this has not been a major impediment because most networks were designed with 10-25 sites within a state, due to the pragmatic barrier of not practicing medicine across state lines. However, the reality is that, in the roughly two years since H.320 emerged as a recognized presence, the price of higher-end videoconference systems has dropped by nearly an order of magnitude! Even more importantly, the marketplace now demands interoperability; the expensive "legacy" systems of just a few years ago, while fine systems, now seem outdated. Naturally, companies have needed to upgrade their older products to be H.320-compliant, while selling newer (and improved) products at considerably lower prices; often these new systems support the H.323/T.120 standard.

Of even greater importance for the future is the H.323 standard, which while ignored on the ATA's home page, was covered in a report on Recommendations to the ATA from the ATA Technology Task Force (David Balch and Dave Warner, co-chairs, 1997 document). This standard appears very strong, in part because it builds on so many others as an "integrative" collection: a core of several audio codecs (speech compression-decompression algorithms, by default G.711), complemented by the option "if you want to do this, use one of these protocols" philosophy for video (e.g., minimum of H.261 QCIF 176x144 pixels) and data-sharing (via the impressive T.120), and considerations for gatekeepers, gateways, and multipoint control. It can be employed wherever IP (and the RTP/RTCP protocol) is supported, and whether the physical network topology is Ethernet, ATM, T1, etc. Intel provides a nice checklist table for the various features. The combination of "free" Voice-over-IP (VoIP) with selected data-sharing (e.g., files, chat, applications) is broadly considered to dramatically evolve into a major market during the rest of 1999 and 2000. Here is a case where a very good standard has had its importance increased due to a freely available implementation of the standard by a major player: Microsoft's NetMeeting package. As of the Spring of 1999, there had been 16 million downloads of NetMeeting, and since NetMeeting 3.0 is now part of both Microsoft's Office 2000 suite (within Microsoft Outlook) and Internet Explorer, its access will undoubtedly increase manifold. Other manufacturers of H.323 and H.320 products advertise NetMeeting compliance. In our own research on nine H.323/VoIP (H.323 / Voice over IP) products (by Donal Lauderdale, Tables 2 & 3 to be discussed later), we've come to regard NetMeeting as our "gold standard" for determining H.323 compliance (at least for non-multipoint applications). Even the platformindependent, open-architecture developer world (e.g., see OpenH323) uses NetMeeting as its barometer for H.323 connectivity.

2. Proposed Governing Principles for Identifying Appropriate Frameworks

An a-priori assumption of this discussion paper is that the information/telecommunication marketplace will continue the trend toward being **global in scope**. Issues related to access, interoperability, and performance requirements need to be addressed within the context of this presupposition. One of the key predictions of the recent Workshop on Home Care Technologies for the 21st Century was a dramatic move toward a consumer-driven healthcare system, including greater access to services through technology. But barriers were also identified. For purposes of discussion, five governing principles are proposed for helping guide government thought on technical standards and guidelines for telehealth.

2.1 Universal Access

Here we utilize, as the foundation, the following definition of Universal Access: access to products and services by **all persons**, including older adults and those with disabilities. This builds on the concept of Universal Design -- proactively design to be usable by all, including older adults and persons with disabilities [see the <u>RERC on Universal Design</u>'s set of <u>7 core principles</u> (equitable use, flexibility in use, simple and intuitive use, perceptible information, tolerance for error, low physical effort, size and space for approach and use)]. Universal design started with an architectural focus, moved to everyday home products, and more recently to telecomunications/information technologies (see the RERC on Information Access' <u>Designing a More Usable World for All</u> Web page, and human-computer interaction guidelines for <u>Designing More Usable Computers and Software</u>), <u>Microsoft, SUN</u>, and the <u>Usability</u> <u>Professionals' Association</u>; recently W3C, the key body for web protocols, has established the <u>Web Accessibility Initiative</u> and published the <u>web content accessibility guidelines</u> for web page design.

The ITU also uses the term "<u>universal access</u>," but with a different context: technological communications access, where the focus is on the **equipment** rather than on the person using the technology. This is useful as well, and can be considered a subset of what is being addressed here.

At the HCT Workshop, the topical group on international issues provided the follow vision statements: "... a world in which industry is committed to universal design with the broadest range of ability and function ... a world of unlimited access, a world which promotes compatibility, interoperability and reliability." There is nothing particularly innovative about this concept, especially since it is really just insisting on compliance with Section 255 of the Telecom Act of 1996 (not to mention for Americans With Disability Act of 1990). Universal Access should be a given. Companies and procurers just need some guidance on how to do it!

Example of practical aspects:

- Persons with **visual-impairment** can benefit from an interactive "zoom" (and pan) feature, including for the remote site. Most products meeting H.320 and H.323 standards already have this capability, as do some H.324 products; there is little reason it couldn't be an expected norm! Another issue of critical importance is guidance on **lighting** for conferencing. Clearly, guidelines on lighting that meet the needs of persons with visual impairment are likely to benefit everyone.
- Persons who are hard-of-hearing can benefit for volume and tone control; volume control is already a norm, though it can be harder to find than necessary for some systems. For persons who are deaf, TTY-enabled implementations are possible, as can be seen via the TTY version of 8x8's ViaTV (with wireless keyboard, captions on screen). Additionally, given recent advances in speech-recognition systems that have reached the mass market, caption-enabled technologies that accept standard text streams could be expected.
- Persons with limitations in **mobility and/or coordination (or tremor)** can benefit from access to a wireless remote unit, in particular one ergonomically designed with the needs

of persons with disability in mind. Buttons should be able to be sensed by touch. For systems with a mouse pointer, there should be access to platform-specific options related to accessibility (e.g., see Windows 95/98 features under the Control Panel, under Accessibility Options and Mouse), and to third-party software developed for persons with disabilities.

- This discussion paper views the <u>T.120</u>-based collection of data-sharing standards as a "killer" application for H.323 (and VoIP) and H.320 implementations. With the NetMeeting additions for application-sharing, it also has the potential to be a Godsend to many persons with disabilities who use third-party Windows-based programs -- these now can be shared, allowing interactive training and troubling-shooting at a distance (not even to mention telemonitoring or teletherapy!) T.120 provides a classic example of an enabling technology that helps break down the barrier of distance. Embrace T.120, and proactively encourage its use (for situations where security/confidentiality are less of an issue). Value-added conference servers for T.120 are also available for purchase. Finally, the ITU's T-series standards ("terminals for telmatic services") go well beyond just conferencing, providing open-architecture standards ranging from fax transmission to multimedia exchange.
- Assess to information, in accessible forms, should be a priority; this includes **manuals** for all telehealth products. There should be a mechanism for evaluating manuals, and providing feedback to manufacturers.
- Wireless technologies can be enabling to many persons with mobility or functional impairment. While the wireless world is currently involved in high-stakes de-facto standards developments that still need to shake out (as discussed previously), there is one wireless standard that is stable: the <u>IRDa protocol</u> for infrared communication, used for over 50 million devices on the market. With it, devices such as laptops, printers and TVs can communicate, and with IRDA 2.0, do so at rates ranging from that for a common "serial port" speed (115 KB/s) to very high speed (4 MB/s). Another reason for supporting infrared-enabled communication is that it is more intuitive (less mysterious) to users (e.g., they quickly realize that they may have to experiment with the pointing direction), and generally reliable and serviceable (e.g., most common problem is a new battery).

In closure, all would seem to benefit if the above suggestions were to become the norm for telehealth products in the new millenium; there is not really a down side to federal policy that helps make it so. Indeed, it is consistent with current federal laws, and with the mission of the Access Board.

2.2 Consumer Choice

One of the key findings of the recent HCT Workshop was the expectation that our society will move toward a consumer-driven healthcare system. One of the driving factors will be the aging of the "baby boomer" generation -- they'll view a doctor as a resource rather than the ultimate authority. Fundamental to "enabling" consumer choice is access to information. Here are

several observations and consequent recommendations that relate to telehealth:

- Consumer choice suggests an enabling end-user environment, which in turn suggests putting forward incentives for creating systems that are designed around the **abilities and choices of the end-user**. This suggests that issues such as usability, optional features, and component compatibility need to be part of future design guidelines.
- Consumer choice suggests that alternatives should be available on the marketplace, that products be interoperable, and that the design should be compatible with "add-on" features used by persons with disabilities. This suggests technical standards related to **open-architecture**.
- Consumer choice suggests access to dependable (and frequently updated) **information resources for consumers** on the features, specifications and performance of telehealth products.
- Consumer choice suggests that the telehealth field should encourage the use of low-cost mass-market products of the present and near future -- including VoIP "Internet phones" with chat/file transfer capabilities and the H.323/NetMeeting standard.
- Consumer choice suggests that information on the Internet be made available in **alternative formats that follow W3C accessibility guidelines**, and furthermore be cognizant of emerging (cheaper) means for obtaining access to the Web, such as through VoIP, WebTV, through a special cable TV channel, through lap/palm top computers, and (soon to more fully emerge) via cell phone technology. (Of note is that at present, while about 50% of US homes have computer access to the Internet, about 70% of homes with children have access. For greater penetration, means for Internet access that don't require a PC computer need to be encouraged.)
- Consumer choice suggests that teleconsults will often be **initiated by the consumer** rather than the provider, and that health service delivery infrastructure should be available to meet this expectation. This suggests thinking out the "what professional is going to be on the other side of the line and what can they do" challenge, i.e. broad-based clinical guidelines for home telehealth that consider a new (consumer-oriented) paradigm.
- Consumer choice suggests that there should not be a distinction between the "haves" and "have-nots," which in turn implies that considerable attention needs to continue to be directed toward **rural and inner-city urban** populations.
- Consumer choice suggests that **medical devices** be able to hook up to telehealth systems, integrated together as appropriate, with possible regulatory barriers to such access being proactively addressed by appropriate federal bodies such as the FDA.
- Consumer choice suggests that **reimbursement** be available for telehealth consults when it can enhance the provision of healthcare or wellness. (If not for services, at least for the core telehealth technology.)

2.3 Interoperability and Reliability

These two features should be addressed in all efforts related to the development of telehealth standards and guidelines. Based on this author's conversations with rural nurses during the annual OAT grantees meeting in early 1999, lack of H.324 interoperability has been a real frustration. In our own evaluation of H.323/VoIP and H.324 products, it is our experience that often products do not initially appear to interoperate, but with perseverance and/or trial-and-error (e.g., by Donal Lauderdale and Dan Krainak, CUA students), interoperability can often be attained. Sometimes a very refined connection protocol is required (e.g., it may matter which product initiates the call). Sometimes, once connected, the quality is poor, or certain features are lost. Thus, when it comes to interoperability, there are shades of gray. <u>Table 2</u> summarizes some of our results for 9 different H.323/VoIP systems.

We suggest the following:

- **Marginally interoperable** means that it is possible for products to interoperate, but it takes significant expertise to achieve connection, and/or quality (e.g., of sound, video) diminishes significantly below standard expectations once connected.
- **Truly interoperable** means that the products readily connect or communicate, and that there is little (if any) degradation in performance in measures related to the standard.
- For interoperability to be a useful measure, evaluation schemes have to be proposed that **define relevant performance measures**.

It is often said that **reliability** is the single most important factor is determining whether telehealth technology is used or abandoned (and thus the growth rate of the field of telehealth). There are also shades of gray that relate to reliability. Indeed, for our H.323 and H.324 product evaluation studies, the experienced researcher can "say" which products have been found to be reliable; yet it is difficult to come up with objective measures. Sometimes the connection is lost, other times the quality temporarily degrades. For H.323/VoIP products in particular, reliability can be a function of peripherals, such as what other drivers are loaded onto the computer, the capabilities of the computer, the "status" of Internet traffic, and the personality of the user (an aggressive, impatient user can virtually always find a way to eventually break or corrupt a T.120 communication). There is a need to determine and prioritize "reliability" indices.

2.4 Vibrant Marketplace

Manufacturers of videoconferencing systems love to see telehealth applications for their products; yet they do not want their product to be classified as a medical device.

Intelligent systems developers have, for a long time, been involved in designed medical decisionsupport systems; yet to date, few "intelligent" products are on the marketplace, in part because of concerns about product liability and what constitutes a medical device.

There is a reality that is so obvious that it is often difficult to back up and see it: with rare (generally very expensive) exceptions, **medical devices and telecommunications technologies**

don't mix well within the current marketplace. If hardware or software simply moves around information without significantly changing it (e.g., the <u>HL7 Standards</u> page for electronic interchange of clinical, financial and administrative information among independent health care oriented computers), it is not a medical device. It probably is, however, if designed to be intimately integrated with a medical device, or to proactively extract information that plays a role in computer-assisted diagnosis (CADx). In principle, any change in a medical product requires interaction with the FDA -- but what if it's just a line of code (e.g., bug fix)? The FDA has long been aware of the reality that software is often an integral part of modern medical devices, and has (to date) taken a fairly "hands off" approach, including the concept of a "software quality audit" (e.g., see Arent Fox' FDA Regulation of Telemedicine Devices).

While there are no guarantees, consensus standards can buy security. Furthermore, welldesigned standards can streamline the regulatory process, for example by enabling the manufacturer to establish a **declaration of conformity**. When used for interfaces (e.g., communications buses, software objects being passed), the added modularity of structure can be useful. Some of the classic motivations for the shift for open-architecture standards and interoperability are: communication across platforms and networks, compatibility of applications of varying sophistication, competitive pricing, improved customer confidence (and perhaps quality), and product upgrades, and quality control.

A good example is the <u>IEEE 1073</u> family of standards for open-systems medical device communications, often called the Medical Information Bus. It identifies a 7-layer communication stack structure, has security features, has network choices (e.g., TCP/IP, Intranet, Internet) and physical/media access choices. It's stated purpose is "to allow hospitals and other health care providers to interface medical instrumentation to host computer systems in a manner that is compatible with the patient care environment." The EU is incorporating parts of IEEE 1073 into its important CEN TC251 set of standards; many other countries are also participating. While targeted for the hospital environment, there seems to be no reason why the "patient" couldn't be at home, and the "office" be anywhere.

This could be a big deal. Why? Because a remarkable number of technically sophisticated medical devices have moved from the hospital to the home; yet to date, most are not telecommunications-ready. While information could be sent in many ways, including quite simply (and cheaply) using the T.120 data-sharing standard, the possible added value of IEEE 1073 would be its existing compatibility with other healthcare software (including electronic patient records), its built-in support infrastructure for major classes of applications (e.g., infusion devices, ECG), and its embedded security/confidentiality mechanisms. Furthermore, there are synergies: software using the IEEE1073 standard could be running as a shared T.120 application during a H.323 televisit! Another reason for pushing this envelope is that much is happening in health telematics standards, especially in Europe.

One final point is that <u>electronic conferencing standards</u> go well beyond the H.3xx series, and the future may bring new approaches that synthesize information even better.

The bottom line is that there is significant cost -- both time and money -- with integrating systems that include a medical component. This is a barrier that needs to be broken down, and should be a priority.

2.5 Product Evaluation Resource, Using of Stated Performance Criteria

The last governing principle is purely pragmatic: there is a need for a telehealth-specific product evaluation resource that works in support of government efforts in telehealth standards and guidelines. Key reasons include:

- In making informed decisions, consumers need access to information on telehealth products, especially as related to access, interoperability, reliability, and serviceability. Here "consumers" include both end-users and procurers of telehealth technology.
- The telehealth field lacks in-house research/evaluation labs, which can serve as a resource for governmental decision-making (e.g., the role of the Office of Science and Technology for the FDA's CDRH). (Since in principle distance should not be a barrier, this need could be attained through a multi-site "virtual center," but funds are necessary to provide the infrastructure and adequate staffing.)
- A well-conceived evaluation resource will get the attention of industry, and provide information/guidelines to help design and evaluate their products.

3. Technical Evaluation Tools and Resources: Needed!

As a background, in evaluating health/medical technology and assistive devices, the following approaches find common use:

- **Technical Specifications and Promised Engineering Benchmarks**. Products generally have a set of "specs" that are available from the manufacturer. These are primarily benchmark measures that the manufacturer promises for a product, and normally come in three forms -- binary "yes-no" measures common for the class of product (e.g., whether the product has a certain performance or safety feature, or supports a certain standard interface), minimal performance benchmarks (usually in the form of a single threshold number with units); and input/output measures (e.g., required input voltage, range of output signal, communication interface bandwidth).
- Engineering Evaluation. Often there is a desire to document/extend manufacturer benchmarks, to determine information not provided by the manufacturer, to evaluate a system that integrates various products, or to examine interoperability issues. This could also involve use of modeling and computer simulation tools to assist with analysis.
- User Evaulation. As would be expected, evaluation of a technology with actual users is quite important. While in the early stages these may involve "normals" (e.g., health young adult college students), the optimum "subjects" are members of the intended end-user population (e.g., older adults with diabetes). Normally data of some type is collected, and volunteers sign a human subjects consent form. Criteria include, at minimum, considerations of user performance and safety. Analysis often includes the use of human factors / usability engineering tools, and a focus on the human-technology

interface(s). For research within rehabilitation, the PAR (participatory action research) model suggests involving the intended end user, e.g. a person with disability, in all stages of the design/evaluation process.

- **Clinical Trials.** In some cases, especially for expensive new technologies that need to document their effectiveness or utility, controlled clinical trials are performed. These normally consist of a "control" group and "experimental" group(s). The aim for such trials is typically to statically evaluate the effectiveness in a form respected by the research community. Normally a reasonably large sample size is necessary, and clinical trials can be quite expensive to perform (most commonly funded by a governmental agency). Typically the results will be published.
- Other Evaluation Considerations. Many other criteria and approaches can enter into the evaluation process, including economic factors, reimbursement considerations, regulatory considerations, market niches, aesthetics, and legal issues. Some of these are addressed in the 1998 <u>Report of the Interdisciplinary Telehealth Standards Working Group</u>.

3.1 Conventional Teleconferencing (including teleradiology)

The two classic approaches, "store-and-forward" and interactive, have been discussed many other places. Also discussed elsewhere are issues related to bandwidth. The classic standards -- H.320, H.323 and H.324 -- are also well developed elsewhere. Here we simply focus on some issues related to the process of product evaluation.

- Interoperability. During the Summer of 1999 we have been systematically evaluating four H.324 products (student: Daniel Krainak; supervisor: Dr. Binh Tran) and nine H.323/VoIP products (student: Donal Lauderdale; supervisor: Jack Winters).
 - The 4 H.324 systems were: 3 versions of 8x8's ViaTV; 2 versions of the C-Phone; Panasonic's videophone; and Innomedia's Infoview. All easily interacted with a partner of their own kind. Interoperability proved to be a challenge, despite all products claiming to be H.324-compliant. With some effort, we have been able to establish connections for 10 of the 12 possibilities -- all but for Infoview calling the C-Phone, and C-Phone calling Infoview. Since some the connections required "tricks" in settings. Thus, a "cookbook" manual is being written that will be placed on our web site in time for this Workshop -- this is an example of the type of resource information that is needed for consumers. For detailed information see the technical report by Tran, Krainak and Winters.
 - For the 9 H.323/VoIP systems that we (Donal Lauderdale) have systematically evaluated [Conference 4.0 (part of Netscape Communicator 4.61), CU-SeeMe Pro 4.0.1, Internet Phone 3 (Intel), Internet Phone 5 (VocalTec), Java Phone, NetMeeting 3.01, Talk99, VDOPhone, WebPhone 4.02], the number of possible permutations is quite a bit larger. Furthermore, we quickly found "driver incompatibilities" -- certain drivers cannot simultaneously reside on the same computer. We also found occasional false advertising; for instance, only 6 of the 9 could interoperate with

products other than themselves. <u>Table 2</u> displays some of our basic interoperability findings, using a simple partition of the H.323 standard into audio, video and datasharing features. We considered products to be interoperable only if a usable, twoway connection could be established. <u>Table 3</u> addresses various practical features (this table is still being updated). Obviously there is a history and various insights behind many of these tabulated items, and the reader is urged to read the technical report (Lauderdale and Winters). We also found that the most interoperable product was NetMeeting.

- Audio. Virtually all interactive teleconferencing applications include audio, which usually has the highest priority for bandwidth allocation. Audio requires only a small amount of bandwidth (e.g., about 6K, which is roughly 10% of the capacity of a POTS line or 18% of a typical H.324 modem connection), and audio codecs are part of all of the classic standards. Perhaps the key observation is that in our own testing of H.323 systems (including LAN-LAN, LAN-POTS, POTS-POTS), we have found significant time delays. For LAN-Internet-LAN connections, packages such as NetMeeting have a built-in time delay of about one quarter of a second, in part to address the reality that packets may not arrive at the destination in the order in which they were sent. With POTS connections, the delay can be several seconds. The other observation is that voice is considerably improved when video is paused (we will come back to this later). We are currently evaluating approaches for systematically assessing time delays and sound quality performance measures, and will build on a number of published approaches in the industry (e.g., see *Delivering Voice over IP Networks*, D. Minoli and E. Minoli, John Wiley, New York, 1998).
- Video. Video is an integral part of the H.320 standard, and the "rule of thumb" is that about 384K (3-line ISDN) is necessary for reasonably sharp images that handle movement artifacts. With the emergence of ADSL and cable modem technologies into suburbia, bandwidths within this range will be easier to attain, for a moderate cost. However, H.323 and H.324 through Internet and POTS will remain important. During the summer of 1999, we (Dan Kraniak, Binh Tran) have been systematically testing video quality for H.324 systems, including: video timing (frame rate, linearity, number of dropped frames), regional distortion (spatial linearity), color, horizontal and vertical resolution, and visual acuity Our procedure was based on a use of still images produced in Adobe PhotoShop which were viewed by the camera and sent from one videophone to the other, then to a TV/VCR for recording. Figure 1 shows some of the results, here for frame rate as a function of sharp/fast setting scale. One point is that curves such as this need to be placed in context through explanatory text: on first observation, the 8x8 would appear superior and the C-Phone (high-resolution version) the worst, but note the higher standard deviation (rate fluctuation) with the 8x8 and the rock-solid consistent rate of the C-phone. But one can see that this type of information can illuminate the differences between the units (which to our shock appears to be information that is not available elsewhere).
- **Ease of Use.** While we have state-of-the-art usability lab equipment, to date we haven't had time to systematically assess usability. However, 4 nursing faculty have been directly involved in our ad hoc assessment of the H.324 systems, and well as a good

number of engineering and nursing students. One quick observation is that the approach between the systems really does differ. For instance, 8x8's ViaTV and the Panasonic both feel like an **extension of a touch-tone phone** (e.g., the one enters information using the touch-tone phone numbers), while the C-Phone feels like an **extension of a wireless "remote" for a TV**. Different users have had difference preferences, and there is a good deal of varying opinions among our staff. For the H.323 systems, the move appears to be toward mass-market simplicity -- for instance, NetMeeting 3.0 has a smaller and simpler interface than did version 2.1, and several options were eliminated; yet in retrospect it is probably an improved product. Defining explicit human factors measures in this area may prove difficult. Another observation is that T.120 data/application sharing can become unwieldy if the users don't agree on their own protocol for sharing the mouse, etc. This may be a good area for developing guidelines on protocols/etiquette for effective data-sharing.

• **Performance Measures.** In our own research/evaluation work of this summer, we have come to the conclusion that objective performance measures are useful for H.320 and H.324 implementations, but (unfortunately) not for H.323. There are two reasons. First, the peripherals matter. NetMeeting performance, for instance, depends not only on the connection line but also on the speed and capacity of the computer and the implementation of audio and video (e.g., enhanced performance with videocards, or the new H.323 hardware implementation of codecs, such as with LineJACK). Equally importantly, new versions of products typically appear every year, often with significant enhancements. Thus detailed quantitative information may become obsolete quickly.

3.2 Data/Application Sharing

The T.120 standard is, in my opinion, extremely well thought out. The key mass-market application of the near future will be VoIP (i.e., an "Internet phone" that can make free long-distance calls) complemented with data-sharing that includes chat, file transfer and shared applications (including shared mouse/keyboard). This is essentially the H.323/T.120 standard, run in the Windows environment, without a shared whiteboard or running video. Recently, AOL and Microsoft staged a well-publicized battle over compatibility of chat/buddies programs, and Yahoo was added to the list of major players (e.g., Microsoft, Netscape, Intel) that are providing, for free, programs that provide VoIP and selected data-sharing over the Web. Whole generations will soon grow up being used to data-sharing for applications ranging from interpersonal communication to cooperative/distance learning to interactive game-playing. They will be fundamentally comfortable with passing information from place to place, whether via wireless units in the home or data-sharing on the computer.

My key point, related to technical evaluation in telehealth: the major focus should be on ways for passing information, including physiological signals. For applications ranging from infusion therapy to teletherapeutic games, first and foremost is data-sharing for telemonitoring. Audio, sometime complemented by video, play a **support** role. This is a paradigm shift, and the telehealth community could establish leadership in enabling this mode of assisted self-care.

3.3 Medical Devices Assessment for "Value-Added" Sensing of Health/Wellness Status (e.g., Vital Signs)

Let's start with a comment, followed by a prediction:

Videoconferencing is only one mode of operation for telehealth!

Successful home telehealth products of the future will meet mass-market openarchitecture standards for information transfer and conferencing. They will thus be inherently interoperable with other products (both medical and nonmedical).

It is for this reason that this author must respectfully object to certain wording within ATA's Telehomecare Clinical Guidelines -- for instance, in 50% of their 22 criteria employ the term "video visit." While there are times when "a picture is worth a thousand words," this "picture" can often be a still image (e.g., jpeg file) rather than interactive video. It could also be health information, or telemonitoring during therapies ranging from physical exercise to drug infusion. Currently we are evaluating, for Instrumedix, a telehealth system in which cardiac "events" are captured and stored via a portable system the person feels them happening, with subsequently records (ECG, blood pressure, SpO2) transmitted by an easy-to-use interface in which data is sent by audio. They have added a videophone (Panasonic) to their product, and we are accessing its "value added." The addition of video is clearly ancillary (e.g., to see if electrodes or the blood pressure cuff are placed appropriately, and to help trouble-shooting).

With this motivation, it is suggested that Technology Criteria 1 (the 16th criteria) be changed from the present patient-centered definition (which also seems to emphasize one company's current product):

The technology used should be based on the patient's clinical and functional needs. Based upon the clinical needs of the patient, many components may be included such as: a) two way interactive video, b) telephonic stethoscope, c) blood pressure and pulse. Other optional equipment may include oximetry, EKG, glucose meter, other medical devises, Internet capabilities, etc.

to, for instance:

The technology used should be based on the client's clinical and functional needs. Examples of **process** include interactive audio, audio/video, chat, audio/data-sharing, audio/video/data-sharing, store-and-forward data with interactive audio/data as support, regular store-and-forward, and Internet access. Examples of **measures to be transmitted** include vital signs (e.g., blood pressure, SpO2, pulse), telephonic stethoscope, optical scopes, ECG, glucose meter, infusion device measures, measures of exercise performance (e.g., motion, forces), psychophysical/neurocognitive performance measures, and skin/pressure ulcer status.

3.4 Human Performance Assessment Measures.

This third category may be the "sleeping giant" of telehealth. Under a "consumer" model of telehealth, the concepts of "wellness" and "independence" relate to the ability to manage one's own care, within a supportive infrastructure. Human performance assessment is an integral part of the job description of allied health professionals such as physical, occupational, and speech/language therapists. It is well documented that during the 1990s there has been a considerable reduction in the inpatient time within comprehensive rehabilitation hospitals. It is

also well accepted that compliance with home exercise programs is low among all age groups. There would seem to be tremendous (as yet unrealized) potential for remote human performance evaluation, and this represents a critical part of most of the projects of the new <u>RERC on</u> <u>Telerehabilitation</u>.

Here we focus on interactive human performance tools that can be used for evaluation. Since few telerehabilitation products currently exist, our focus is a bit more on system design/evaluation than in previous sections. In contrast to vital sign measurement, the **goals of the task to be performed must typically be given**, and the resulting response (e.g., movements of the body) can take many forms (e.g., from an arm tracking movement to standing on one foot). Thus the telehealth process is inherently more **interactive**. Framing the task may be achieved by many means, for example by some combination of:

- verbal command,
- demonstration (by the expert evaluator),
- interactive telecoaching,
- tracking a pre-planned target on a screen,
- playing a video game (which typically evolves in a less structured, exploratory way),
- exercising on equipment.

A further challenge, from the eyes of a systems developer/evaluator, is that each type of rehab health provider (e.g., PT, OT, speech/language, rehab psychologist, rehab nurse) has their own types of protocols for assessing health status and performance; not only the "patient" but also the provider may need to be "coached" through a protocol. There must also be some level of interactive "developer tools" or "developer menu" to help a user/developer customize a plan, then set so it can't be changed. On the flip side, the concept of (and need for) objective measures of health status and outcomes is a huge issue within the rehab field (e.g., NIH reports). **Telehealth solutions could not only eliminate the barrier of distance, but actually add value to the delivery of services, and even define "best practice"!**

A key technical point, from a telemonitoring perspective, is that sensor readings for telerehabilitation can often be collected at either low (e.g., 10 Hz) or moderate (e.g., 100 Hz) rates. The reason for this is biomechanics: due to body inertia and muscle properties, voluntary human movements rarely possess frequency content above 10 Hz, except during impacts with an external object. Indeed, normal tremor of the hand is 8-12 Hz, and most pathological tremors are in the range of 3-5 Hz. Thus, transferring such information through as data via a POTS connection is readily achievable!

Here are some examples of modes for sensors that would make barely a dent in the POTS bandwidth, and are relative routine to collect:

• Standard computer mouse (with driver): captures planar human movement 2 channels (x and y directions), via serial port.

- VR mouse: captures spatial (3-D) human movement, with 3 channels of information.
- Simple joint angle goniometers (e.g., elbow, knee), e.g. for exercising. One could also send a force or torque signal, without making much of a dent in the POTS bandwidth.
- Body tilt sensors (e.g., head, for monitoring balance or controlling an interface).
- Accelerometers (e.g., for tremor or balance monitoring).
- Movement switches of many types, typically optical but could be other modes (e.g., electrical contact).
- Other force (e.g., tension in a cable during exercise) or torque sensors.
- Contact sensor switches (e.g., simple pressure sensor film, or electrical contact shortcircuit).
- EMG, if only smoothed envelope is needed and preprocessing is done carefully.

Currently, some of these are being collected using Dave Warner's <u>NeatTools</u> package with various simple interface hardware. Notice the large number of possibilities where POTS-based transmission in near-real-time is a real possibility. Indeed, even palmtop or hand-held computers (e.g. running Windows CE) communicating by wireless IR could easily handle the load. At some stage in the future, such devices could be an integral part of medical and health-related equipment. Why not sooner rather than later.

Here are examples that might need to be dedicated, preferably in a "store-and-forward" mode, but where POTS communication should not be a limiting factor:

- High end electromagnetic-based telemetered 3-D motion analysis systems (Flock of Birds, Pohemus). This requires 6 channels per body segment (i.e., 300 Hz per segment if each channel is sampled at 50 Hz).
- ECG (the international protocol followed by most companies is to sample each channel at 500 Hz, with 3 or 12 leads the most common), and EMG or EEG for most applications.
- High end 6-axis force transducers, normally sampled at 50 or 100 Hz per channel.
- Thin pressure mats with sensor grids, e.g. 12x12=144 sensors (or more). Typical sampling rates are only about 1-10 samples/sec -- but for the whole grid, i.e. lots of sensors!

Currently, between the <u>HomeCare & Telerehab Technology Center</u> and our nearby RERC partners at the National Rehabilitation Hospital, we are using all of these technologies, but only with interfaces to the local computer near the technology. All the collection programs, however, are Windows-based, and in theory all could run as a shared application; no one has had a reason to try it yet.

Often the human interface will be wireless, especially as home wireless standards strengthen. Many interface boards and bus protocols are available. A colleague, Dr. Mark Mirotznik, has recently back-engineered the mouse port, so that it can function as a 2-channel interface board that could take many of the above signals. But remembering that any Windows application can be shared through the T.120 protocol (if running NetMeeting), one sees that transmitting a few channels of human performance data could be accomplished as quite low cost, with modular components. Thus one sees that there are many approaches -- data could even go directly into an electronic patient record that happens to be open. For a more customized and streamlined approach, one could use NetMeeting's Developer Kit to write a small transmission module.

A resource that could set guidelines and simple standards in this area of human performance would be valuable.

3.5. Security and Confidentiality

This is clearly an area where a telehealth evaluation resource would be useful, especially within the US. This was raised often during the <u>HCT Workshop</u>.

This author has no technical expertise in this area, so this is a good place to stop.

Table 1: Key bodies involved in creating technical standards and clinical best practices: International (general bodies):

- ISO (International Standards Organization),
- <u>ITU</u> (International Telecommunication Union).
- International Multimedia Teleconferencing Consortium standards page

National:

- <u>ANSI</u> (American National Standards Institute)
- <u>ASTM</u> (American Society of Testing and Materials)
- <u>AAMI</u> (Association for the Advancement of Medical Instrumentation)
- <u>IEEE</u> (Institute of Electrical and Electronics Engineers)

Web Resources with expanded lists:

1. Telecom:

- Telecommunications Industry Association standards/technologies resource
- <u>Telecom standards bodies</u> list from University of Michigan
- <u>List</u> of information tech and telecom standards [e.g., see information packet transfer (ADSL, ATM, ISDN), the object-oriented info transfer protocol CORBA, the internet protocol (IP, etc), the USB (Universal Serial Bus)]

2. Medical Device / Telematics Standards

- FDA's <u>Standards Program for Medical Devices</u>, include FAQ on consensus standards, a list of FDA-recognized medical device standards (e.g., wheelchairs), and a list of standards organizations and their specific committees and task groups.
- A good European standards page on telematics <u>standardization organizations</u>, and on <u>CEN/TC 251</u> and <u>IMIA Working Group 16</u> that relate to healthcare informatics and telematics.
- A good set of links to <u>health informatics standards</u> developers. (From Duke, includes the <u>HL7 Standards</u> page for electronic interchange of clinical, financial and administrative health information, the <u>DICOM</u> standards (Digital Imaging and Communication sin Medicine), medical devices standards coordinated through <u>ASTM Series E</u> (computer message exchanges, the Arden Syntax for medical logic modules) and IEEE (medical device info transfer).
- <u>American Nurses Association</u> healthcare informatics standards.

Product	works with						
Product	audio	video	data				
Conference 4.0 (Netscape Communicator)	Conference 4.0 (Netscape Communicator)	N/A	Conference 4.0 (Netscape Communicator)				
CU-SeeMe Pro 4.0.1	• CU-SeeMe Pro 4.0.1	• CU-SeeMe Pro 4.0.1	• CU-SeeMe Pro 4.0.1				
	• NetMeeting 3.01	• NetMeeting 3.01	• NetMeeting 3.01				

Table 2: Interoperability of H.323/VoIP Products [prepared by Donal Lauderdale]

	 Internet Phone 3 (Intel) WebPhone 4.02 	• WebPhone 4.02		
Internet Phone 3 (Intel)*	 CU-SeeMe Pro 4.0.1 NetMeeting 3.01 Internet Phone 3 (Intel) WebPhone 4.02 	 CU-SeeMe Pro 4.0.1 NetMeeting 3.01 Internet Phone 3(Intel) WebPhone 4.02 	not verified	
Internet Phone 5 (VocalTec)	• InternetPhone 5 (VocalTec)	• Internet Phone 5 (VocalTec)	• Internet Phone 5 (VocalTec)	
Java Phone 1.2	 Java Phone 1.2 NetMeeting 3.01 (NetMeeting must initiate call) 	N/A	N/A	
NetMeeting 3.01	 CU-SeeMe Pro 4.0.1 Java Phone 1.2 (NetMeeting must initiate call) Internet Phone 3 (Intel) NetMeeting 3.01 WebPhone 4.02 	 CU-SeeMe Pro 4.0.1 Internet Phone 3 (Intel) NetMeeting 3.01 WebPhone 4.02 	 CU-SeeMe Pro 4.0.1 NetMeeting 3.01 	
Talk99 (MediaRing)	• Talk 99 (MediaRing)	N/A	• Talk99 (MediaRing)	
VDOPhone*	VDOPhone	VDOPhone	VDOPhone	
WebPhone 4.02	 CU-SeeMe Pro 4.0.1 Internet Phone 3 (Intel) NetMeeting 3.01 WebPhone 4.02 	 CU-SeeMe Pro 4.0.1 Internet Phone 3 (Intel) NetMeeting 3.01 WebPhone 4.02 	• WebPhone 4.02	

		Internet	Phone	Phone	NetMeeting	Talk99 MediaRing	VDOPhone	Webphone4	
4.0.527	Pro 4.0.1.018	3.1.0.45	5.01 build 171	1.2	3.01 build 3385	6.5.005	3.5 Professional Internet/ITU324	4.02	
yes	yes	yes	yes	yes	yes	yes	yes	yes	
no	yes	yes	yes	no	yes	no	yes	yes	
yes	yes	yes	yes	no	yes	yes	yes	yes	
yes	yes	yes	yes	no	yes	no	via nm(nv)	no	
no	yes	yes	no	no	yes	no	via nm(nv)	no	
no	yes	no	no	no	yes	no	via nm(nv)	no	
yes	yes	yes	yes	no	yes	no	via nm(nv)	no	
yes	no	no	yes	no	no	yes	no	yes	
no	yes	yes (nv)	no	no	yes	no	no	no	
yes (Qwest)	no	no	yes (ITSP)		yes gateway	yes (Valuphone)	yes	yes (nv)	
no	yes	no	yes	no	no		yes	yes	
no	yes thru "cafe"	no	yes	no	no	no	clubs	no	
no	no	no	no	no	yes	no	no	no	
4 now 8 soon	yes (nv)	no	audio only	yes (nv)	yes, data only	no?	via NM	yes (nv)	
	Netscape4.0.527yesnoyesyesnonoyesnoyesyesyesyesyesyesnoyesnoyesnoyesnoyesnoyesno </td <td>NetscapeSeevice Pro4.0.527Pro 4.0.1.018yesyesnoyesyesyesyesyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesyesnoyesnoyesnonoyes</td> <td>Conference NetscapeCU- SeeMe ProInternet Phone S.1 Intel4.0.527Pro 4.0.1.0183.1.0.45yesyesyesnoyesyesyesyesyesyesyesyesyesyesyesnoyesyesnoyesyesnoyesyesnoyesyesyesyesyesyesyesyesyesyesyesnoyesyesnoyesyesyes (Qwest)nononoyesnonoyesnonoyesnonoyesnonoyesnonoyesnonoyesnonoyesno</td> <td>Conference NetscapeCO- SeeMe ProPhone S.1 IntelPhone S.01 VocalTec4.0.527Pro 4.0.1.0183.1.0.455.01 build 171yesyesyesyesnoyesyesyesnoyesyesyesyesyesyesyesyesyesyesyesyesyesyesyesnoyesyesyesnoyesyesyesnoyesyesyesyesyesnoyesyesnonoyesyesnoyesyesyesyesyes (nv)yesyes (Qwest)nonoyesnononoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyes</td> <td>Conference NetscapeCU- SeeMe Pro Si linetPhone Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft</td> <td>Conference NetscapeCU- SeeMe Pro S.1 Inter Note S.1 Inter S.01 NocalledPhone S.01 Note NetMeeting4.0.527Pro 4.0.1.0183.1.0.455.01 build 1711.23.01 build 3.385yesyesyesyesyesyesyesyesyesyesyesyesyesyesnoyesyesyesyesyesyesyesyesyesyesyesnoyesyesyesyesyesnoyesyesnoyesyesyesnoyesyesnoyesyesyesnoyesyesnoyesyesyesnoyesyesnoyesyesyesyesnoyesnoyesyesyesyesnoyesyesyesyesyesyesnoyesnoyesyesyesyesyesyesnoyesnoyes</td> <td>Conference NetscapeCu-brence Phone Sol NotalianPhone Sol NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone SolPhone Phone NotalianPhone Sol<td>Conference NetScape CU-ber Phone N. Lifered No. Phone No. Phone Phone No. Phone NetMeeting Talle99 MediaRung vulbenesing 4.0.527 pro 4.0.108 3.10.40 5/1 vill 3.2 38.5 vill 5.005 3.5 Professional Internet/TU324 yes yes</td></td>	NetscapeSeevice Pro4.0.527Pro 4.0.1.018yesyesnoyesyesyesyesyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesyesnoyesnoyesnonoyes	Conference NetscapeCU- SeeMe ProInternet Phone S.1 Intel4.0.527Pro 4.0.1.0183.1.0.45yesyesyesnoyesyesyesyesyesyesyesyesyesyesyesnoyesyesnoyesyesnoyesyesnoyesyesyesyesyesyesyesyesyesyesyesnoyesyesnoyesyesyes (Qwest)nononoyesnonoyesnonoyesnonoyesnonoyesnonoyesnonoyesnonoyesno	Conference NetscapeCO- SeeMe ProPhone S.1 IntelPhone S.01 VocalTec4.0.527Pro 4.0.1.0183.1.0.455.01 build 171yesyesyesyesnoyesyesyesnoyesyesyesyesyesyesyesyesyesyesyesyesyesyesyesnoyesyesyesnoyesyesyesnoyesyesyesyesyesnoyesyesnonoyesyesnoyesyesyesyesyes (nv)yesyes (Qwest)nonoyesnononoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyesnoyes	Conference NetscapeCU- SeeMe Pro Si linetPhone Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft Soft	Conference NetscapeCU- SeeMe Pro S.1 Inter Note S.1 Inter S.01 NocalledPhone S.01 Note NetMeeting4.0.527Pro 4.0.1.0183.1.0.455.01 build 1711.23.01 build 3.385yesyesyesyesyesyesyesyesyesyesyesyesyesyesnoyesyesyesyesyesyesyesyesyesyesyesnoyesyesyesyesyesnoyesyesnoyesyesyesnoyesyesnoyesyesyesnoyesyesnoyesyesyesnoyesyesnoyesyesyesyesnoyesnoyesyesyesyesnoyesyesyesyesyesyesnoyesnoyesyesyesyesyesyesnoyesnoyes	Conference NetscapeCu-brence Phone Sol NotalianPhone Sol NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone Phone NotalianPhone SolPhone Phone NotalianPhone Sol <td>Conference NetScape CU-ber Phone N. Lifered No. Phone No. Phone Phone No. Phone NetMeeting Talle99 MediaRung vulbenesing 4.0.527 pro 4.0.108 3.10.40 5/1 vill 3.2 38.5 vill 5.005 3.5 Professional Internet/TU324 yes yes</td>	Conference NetScape CU-ber Phone N. Lifered No. Phone No. Phone Phone No. Phone NetMeeting Talle99 MediaRung vulbenesing 4.0.527 pro 4.0.108 3.10.40 5/1 vill 3.2 38.5 vill 5.005 3.5 Professional Internet/TU324 yes yes	

Table 3: Features for Various H.323/VoIP Products [prepared by Donal Lauderdale; nv = not verified]

snap shot	add not take	no	yes	no	no	no	no	yes	yes
photo album	no	no	yes	no	no	no	no	yes	no
WebBoard	no	no	no	no	no	no	no	clubs	no
security			no			yes			h235
password/parental control		no	no	yes	no	yes certif	no	yes	pin for acct
price	free	\$69.00	Packaged with camera \$69-\$154	\$49.95	free	free	free	\$69.00	\$49.95
comments	browsing, news group, message	Uses NetMeeting 2.1 or later for T-120 operations			Shel Cad Hi Phone plug into serial pt. Java		POTS to LAN does not seem to work	mode, e-mail,	May require Creative camera

Figure 1: Average Frame Rate as a Function of Sharp/Fast Settings (Scaled) [prepared by Binh Tran and Dan Kraniak]



Appendix A: Proposed Process-Oriented Terminology for Telehealth

We will use the operative term "conferencing" to represent technologies use for direct interactive communication between two or more persons at a distance (modes can be audio, video and/or data sharing); teleconferencing, video conferencing, data sharing, videophony, etc., are then subsets of this term. "Multimedia" describes the use of these three core media, but multimedia needn't involve conferencing (e.g., it could just involve a person interacting with their computer).

- **Teleconsultation** -- A nice medical/legal term that suggests communication across distance in which there is an expert consultant who provides some sort of service.
- **Teleconferencing** -- The process of 2 or more people interacting across a distance, supported via telecommunications.
- **Telematics**: the study of intelligent, effective strategies for transporting and utilizing health-related information and/or healthcare services for Tele-education -- The process of education/training at a distance. (Education represents one of the key professional activities of a visiting home health nurse.)
- **Telemonitoring** (interactive) -- The process of monitoring health status at a distance. Involves interactive conferencing, and perhaps the transmission of data (e.g., vital sign recordings).
- **Telemonitoring** (unobtrusive) -- The process of unobtrusive sensing of personal health status, or of the environment.
- **Telesupport** -- Interactive support, e.g. via a tele-nurse. Depending on the protocol, the "patient" and/or the provider of support may initiate the call.
- **Tele-evaluation** -- Systematic professional evaluation at a distance, e.g. by a physician, therapist, nurse, rehabilitation engineer, or other health professional.
- **Teleassessment** -- Systematic assessment of health status by a healthcare professional, often more broad-based that an evaluation. Normally would need to be interactive.
- **Telediagnosis** -- The process of performing diagnosis at a distance. This has legal implications, and thus for instance, the FDA might have concerns if there is a "lossy" nature to data transfer (e.g., via a data compression-then-decompression process).
- **Telecompliance** -- The process of providing support, encouragement and education at a distance (like a personal coach), so as to enhance compliance with health maintenance (e.g., taking medication) or home self-therapy (e.g., a prescribed exercise program); perhaps one of the best uses of telehealth infrastructure.
- **Teletherapy** -- The process of actual therapeutic intervention at a distance. For instance, physical/occupational or psychological/psychiatric therapy. Ideally, there would be built-in objective telemonitoring that related to performance and outcomes measures.

• **Teleplay** -- Interactive, exploratory "games" that can have built-in therapeutic and/or monitoring capabilities. Interface device parameters (e.g., for alternative mouse) could be adjusted (remotely) by therapist depending on the patient's progress.