

4. Topical Reports

During the months following the Workshop, each of the 8 topical groups completed a report. Authored by the co-chairs (with feedback from key members of their group), its purpose was to capture the sense and insights of the working group. The length and substance of the reports was left to the discretion of the co-chairs, with the following core instruction: capture the motivation and insights behind the statements/bullets, using a structured narrative that could be 3-10 pages in length (the majority ended up 6 pages).

Since the purpose was to capture the 9 hours of time spent on the given topical area by a diverse team of experts, in preparing their report, the co-chairs were not given access to the summary results (which were evolving during the same time period).

All reports were lightly edited, in two ways: to create a level of uniformity in organization and style, and to reorder the presentation (and numbering scheme) of the statements/bullets based on the rank-ordering by all participants (but without changing the actual discussion). Of note is that often only a prioritized subset of the bullets within a certain category (e.g., barriers) could be presented to the assembled group on the last day (Friday); in such cases the only documentation of the bullet is then within the respective report.

Each report stands on its own as a useful document, and these reports represent one of the key contributions of this Workshop.

4-A. [Interactive "Home" Telehealth: Future Technologies & Services](#)

4-B. [Personal Status Monitoring: Interactive Approaches, Sensors & Automation Systems](#)

4-C. [Appropriate Design of Home Health Technologies: Ethical, Legal & Policy Considerations](#)

4-D. [Home Therapeutics & Assistive Technologies for Chronic Conditions](#)

4-E. [Human Factors Engineering & User-Driven Device Design](#)

4-F. [Smart Health Devices & the Home of the Future](#)

4-G. [Therapeutic Applications: Rehab Robotics, Virtual Reality, Future Possibilities](#)

4-H. [International Issues in Health and Rehabilitation \(Developing Countries\)](#)

Topic A:
**INTERACTIVE “HOME” TELEHEALTH –
 FUTURE TECHNOLOGIES AND SERVICES**

Prepared by Co-Chairs:

Jerry Loeb, M.D., Dept. Biomed. Engng., Queens University, loeb@biomed.queensu.ca

**Dena Puskin, D.Sc., Office for the Advancement of Telehealth,
dpuskin@HRSA.dhhs.gov**

Participants:

Deborah Burton, M.A., Univ. Kentucky Medical Center; **Kathryn Dansky, Ph.D,** Penn State Univ.;

Kathy Bowles, RN, Ph.D., University of Pennsylvania; **Cynthia Howar Trutanic, J.D.;**

Des Cummings, Vice President, Florida Hospital; **Adil Alaoui, M.S.,** Georgetown University;

Sal Sheredos, Engineer, VA Rehab R& D; **Pam Whitton,** Michigan State University;

Richard Craft, Ph.D., Sandia Labs; **Mary Ann Urka, R.N., M.L.S.**

Co-participatory members from Group 1 (also Topic B - Personal Status Monitoring): Audrey Kinsella, MA, MLS (Co-Chair), Binh Tran, Ph.D., Ilene Warner, M.N.S., M.A., M.L.S.P., Kimber Richer, M.D., Jim Hutchinson, M.S., Marjorie Bauman, R.N., Susan Vesmarovich, R.N.

Co-participatory members from Group 8 (also Topic H - International Issues in Health and Rehabilitation in Developed Countries): Kate Seelman, Ph.D. (Co-chair), Chris Kirtley, M.D., Ph.D., Dudley Childress, Ph.D., Joanne Kumekawa, M.B.A., Paul Acherman, Ph.D., Elizabeth Saindonm J.D., Guy Hammer.

Special thanks to Kathryn Dansky, who patiently kept detailed notes throughout our discussions.

VISION

ANTICIPATED DEVELOPMENTS/TRENDS:

A-1: In the future, technology will enable the consumer to access a wide range of health care services from the home. The home will be the entry point into much of the health care system. With the evolution of increasingly low cost, interactive technologies in the home, consumers will interact with their health care providers from the comfort and privacy of the home in much the same way that they currently do in their providers' offices. Miniaturization of technology will provide the consumer with unobtrusive health monitoring devices that enable effective monitoring of health status from the home. Greater availability of affordable, wider bandwidth telecommunications services in the home will facilitate the deployment of more sophisticated home care and self-monitoring devices.

A-4: Technology applications for health care will emerge from consumer driven lifestyle medicine. Maintaining and improving health status is consistently listed as one of the highest priorities of consumers on surveys of consumer values. The private sector has seized on this emerging market to develop a variety of products to meet consumer-driven demand. At the same time, government and traditional third-party payers for health care have been slow to recognize and pay for emerging consumer-driven products. This has left a vacuum for private industry to create and exploit health care product niches. These niches can be so engaging that more affluent and/or trend setting consumers are willing to pay for them out-of-pocket, even if there is no 3rd party reimbursement. Health care products are sold

much as any other consumer product, with increasing availability of over-the-counter medications, alternative therapies, herbal remedies, and marketing over the web and on television. Life-style medicine programming on television receives prominent, prime-time spots on commercial and public television. The demand for health-related information is evident by the growing use of consumer/health oriented sites on the web for obtaining information and products.

To be successful in these privatized markets, products are likely to possess some or all of the following characteristics:

- Provide information and services that patients want or could be persuaded to want;
- Provide a sense of privacy and control over health information;
- Provide a sense of connection with caregivers, family, and community;
- Provide access to the health care system at the point of need, thereby bypassing traditional gatekeepers;
- Low cost for information and services; and
- Ease of use through familiar interfaces and procedures.

A-5: The government will take an active role through education, regulation, and provision of services that become accepted privately as the standard of care. Consumer-driven demand will lead to products targeted to specific types of consumers. This demand is likely to lead to increasing pressure on government and health care insurers to provide reimbursement for these products. A decision to pay for a product or service will require payers to set standards for what they will pay for and what they won't. Following historic trends, there will be a convergence among payers as to what is an acceptable service or product for payment, especially if Medicare has decided to cover them. This will result in de facto standards that are likely to be accepted by the private market, for as it is said, "He who pays the piper, calls the tune." In addition, there is likely to be growing concern about the safety or validity of the claims for such products, especially if such products are directed at the elderly, disabled, or infirm. As in the past, this concern could be galvanized into pressure on federal and state agencies to take a more active role in educating the public about, and regulating the sale of such products.

FUTURE SCENARIOS:

A-2: Home care technologies will enable integration of the environment and the community to support independent living. Maintaining the highest level of independent living is a key goal for most older and disabled individuals. Environmental barriers in and outside the home (access to banking, shopping, transportation) are often critical deterrents to maintaining independence. Technology can bring services to individuals, rather than the individual to services. Thus, home shopping and banking are already services that assist individuals in obtaining the services they need. In the future, such services are likely to mushroom. But perhaps even more important is the social connections provided to individuals by the Internet, through e-mail, chat rooms and listservs. Via-TV and other low cost home video-conferencing systems are pointing the way to the future where we will be able reduce social isolation by bringing people together virtually in their homes at the flip of a switch.. The long-term health and well-being of disabled or infirm individuals are highly dependent on their remaining connected to their community to avoid the crippling effects of social isolation. At the same time, without adequate precautions, technologies can create isolation, being used as a substitute for human contact.

A-3: Home care services of the future will be supported by an electronic patient record that reflects a comprehensive history and supports continuity of care, while assuring security, privacy, confidentiality, and integrity of the data. The electronic patient record today is increasingly integrating text and images, but still does not capture much of the narrative that is critical in medicine. However, technology is rapidly moving ahead with voice recognition and other software to capture the "patient's story," the free text of medicine. The home care record will be integrated into a seamless information system that supports the integration of the patient's care into the rest of the health care system. Individuals will have access to their comprehensive record, without compromising their right to privacy and confidentiality.

GAPS IN KNOWLEDGE BASE

A-1: Which types of data are important for clinical decision-making; which data are worth monitoring?

Given advances in engineering, computers, and miniaturization, we can monitor a myriad of bodily functions and collect endless patient data. Such monitoring and data collection can create an information overload. The key is to determine what parameters and clinical information is significant to measuring health status and quality of life. The information collected should be clearly integrated into the health care decision-making process for individuals.

A-2: Which clinical services are appropriately and effectively delivered via home health technologies versus in person?

If we fail to answer this question, we run the risk of: (1) substituting technology too often or inappropriately for in-person care, thereby compromising the quality of services received; or (2) substituting technology too little, thereby losing the opportunity to gain efficiencies in our health care system, or missing an opportunity to more effectively monitor patients, thereby compromising the quality of services that might be available to individuals.

We fear the consequences of unregulated health care delivered through the Internet and consumer-oriented computer technology. Yet, we have no data on the relative risks posed by more traditional alternatives, which may entail delayed or restricted access and/or hurried or incompetent practitioners despite conventional licensing and regulation. Moreover, as in most of health care, we need to develop a consensus on quality home care services: what is it, who should measure it and how?

A-3: How do telehealth/telemedicine technologies influence the structure of the health care system

(positive and negative)? Technology has the potential to significantly increase the efficiency and effectiveness of how we deliver health services. To date, however, the introduction of computers and other information intensive technologies have not significantly changed the paradigm of how we organize health care services in western countries.

A-4: What can we learn from the design process for consumer products to enhance the usefulness and acceptance of medical devices, products, etc.?

The design process for consumer products that successfully use similar technologies (computer games, Web-TV) is not well understood or even attempted by most medical device teams, whether located in universities, government or industry. There may be significant lessons for improving the acceptance of new medical devices from the experiences of device teams that develop consumer products.

A-5: How can we assure equitable distribution of technology?

America continues to experience a maldistribution of health resources, with urban and rural poor or geographically isolated populations continuing to be underserved. Much of the adoption of home care technology will be initially driven by private sector market forces. In the absence of public policies, there is no reason to believe that underserved populations will achieve any greater access to tele-home care services than they have for other health services. Without such policies, we will exacerbate our current 2-class medical system. Thus, we might expect those with financial means to be maintained in the comfort of their homes, irrespective of their disabilities, and those without means to be warehoused in largely publicly-funded institutions, at significant monetary and social cost to our nation.

A-6: What are the economic, social, policy, and other barriers?

Although several barriers are listed in the next section, the work group recognized that it is difficult to identify, a priori, the many barriers that can emerge as new technologies are deployed.

BARRIERS AND ISSUES

- A-1: Payment structures and reimbursement mechanisms do not support telehealth services; who pays, for what services, where in the continuum?** The long-term sustainability of any health service depends on the development of a stable revenue stream. Some low cost home health care technologies may thrive simply on private out-of-pocket payments. Nevertheless, integration of these technologies into mainstream home health care services will depend ultimately on coverage by third-party payers. Such coverage is analogous to a “Good Housekeeping Seal of Approval.” Medicare, the largest single third-party payer, provides limited reimbursement for tele-consultation services but no payment for tele-home care services. Given the myriad of services that might be reimbursed, the challenge for third-party payers is to determine what services are cost-effective. Many overall cost reductions can only be realized by “vertically integrated” health care systems in which savings in institutional care are balanced against the added costs of employing telehealth technologies in homes.
- A-2: Nascent communication standards for medical devices (e.g., IEEE 1073) need to be developed, promulgated, and accepted widely before system integration can proceed efficiently.** The lack of standards in the field is a major impediment to telehealth technologies reaching their full potential in terms of market penetration. Health care professionals and administrators are frustrated by health care devices that do not work together or are not easily upgraded. They are reluctant to make large-scale investments in technologies today that will become out-dated legacy systems tomorrow. In the long-run, standards facilitate rather than impede technology development. The challenge is to develop standards and effective procedures for updating these standards without stifling innovation.
- A-3: Lack of protocols for transferring data from consumer-controlled lifestyle management to caregiver-controlled health care and health information systems.** We need generally accepted procedures for determining when consumer-controlled self-care/home care management needs to transition into the caregiver-controlled health care system and how information from both systems should be integrated.
- A-4: Practitioner Resistance.** It is often difficult to get practitioners to accept telehealth technologies, especially those that promote greater self-care, because they are often uncomfortable with new, “unproved” technologies. Moreover, these technologies challenge practitioners’ traditional roles and position of control.
- A-5: Lack of access to telehealth technologies.** The lack of affordable or reliable telecommunications services in some rural and inner city communities limits access to the infrastructure necessary to support certain telehealth technologies. But, in terms of home care, relatively simple telecommunications services (POTS) can support many applications. More often, limitations are related to lack of experience, familiarity, expertise, training, and comfort with home health tele-technologies.
- A-6: Information liability: a health care provider who receives information directly from a home or patient may receive low-quality data and may be liable for failures to detect or anticipate adverse outcomes implied by such data.** Liability has not been a major impediment so far to the telehealth field. However, as the field grows, insurers anticipate increasing concerns in this area. One key issue is who is liable: the practitioner, the telecommunications company?
- A-7: Regulatory/Licensure Barriers.** Within the United States, health practitioners are licensed within the state in which they practice. If they wish to practice in more than one state, they must receive a separate license for each state in which they practice. This process can pose a significant impediment to those that wish to practice in several states. Device regulation, on the other hand, is generally set at a national level. Device regulation issues are similar to general issues surrounding establishment of standards; namely significant challenges to developing quality standards without obstructing innovation in a rapidly evolving field.

RECOMMENDATIONS

- A-1: Support large-scale demonstration projects that seek creatively to incorporate and evaluate tele-homecare interfaces into existing health care practice and health information systems.** Currently there are many small scale demonstrations that purport to demonstrate the cost-effectiveness of the technologies under study. What is needed, however, are large scale test-bed studies that specifically examine how tele-home care technologies can be effectively deployed in a variety of home health settings. Without such studies, it is unlikely that home care agencies and third-party payers will heavily invest in these technologies.
- A-2: Promote the use of partnerships and consortia to encourage R&D and system integration among the health care industry, consumer electronics and software industries, university researchers, and government.** Consortia and partnerships have been instrumental in rapidly moving the computer and electronics field ahead, especially in the area of defense and space exploration. Government agencies could play a similar role in the medical device arena to “jump start” development of low cost devices that may not have a large commercial market or for which the market is unclear.
- A-3: Support consumer and professional education, training, and retraining in the use of information and health care technologies.** Too often we invest in technology without adequately considering the investment required to develop the human interface for supporting the effective use of the technology. “Build it and they will come” does not necessarily apply. The requirement to consider the training process early in the design cycle often motivates technology developers to produce user-friendlier systems in the first place.
- A-4: Develop and promote standards for exchanging and archiving information that address the fluid environment created by tele-homecare.** In an increasingly mobile society, we need standards that promote the exchange of information regarding the care of an individual that cut across sectors of the health care field. Such standards would enable rapid exchange of information regarding individuals, no matter where they received health and health-related services. At the same time, these standards must reflect concerns that the privacy, confidentiality, security, and integrity of data are maintained.
- A-5: Identify and forecast legal, economic, social, and regulatory barriers to effective deployment of telehealth technologies, and explore options for reducing or eliminating them.** Often technology initiatives have been developed without adequate consideration of the unintended consequences and the range of barriers that could hinder implementation. A thorough analysis of the range of barriers and options for addressing them, including “What if” simulations, is invaluable in the successful implementation of such initiatives. It will be important to involve skeptics of telehealth technologies in identifying possible negative scenarios, as well as advocates.
- A-6: Pass legislation that ensures universal, affordable access to the Internet by 2003, including households, health care providers, and social service providers.** Provisions to assure universal, affordable access to basic telecommunications services were included in the Telecommunications Reform Act of 1996. Unfortunately, the implementation of the provisions leaves much to be desired. In today’s world, access to the Internet has become as essential as access to the telephone was 50 years ago. We need a strong national program to ensure that all households, and health care and social service providers have affordable access to this basic service. It is unclear whether this objective can be achieved without additional legislation, explicitly outlining a national program for universal Internet access.

Topic B:

PERSONAL STATUS MONITORING IN THE HOME

Prepared by Co-Chairs:

Joe Andrade, Ph.D., Dept. Biomed. Engng., U. Utah, joe.andrade@m.cc.utah.edu

Audrey Kinsella, MA, MLS, Catholic Univ. America, kinsella@cua.edu

Participants:

Nancy Pressly, Food and Drug Administration; **Binh Tran**, Ph.D., Dep. Biomedical Engng., CUA

Harry Handlesman, D.O., AHCP; Deborah Burton; **Ilene Warner**, M.N.S., C., M.A., M.L.S.P

John Enderle, Ph.D., Dept Elec. & Sys Engng, Univ Conn.; **Kimber Richer**, M.D., FDA,

Ed Clark, M.D. Children's Med Cen, Salt Lake City; **Jim Hutchinson**, M.D., St. Joseph's Hospital, Atlanta

Dr. Howard Weetall, Biosensor Group, NIST, Gaithersburg; **Marjorie Bauman**, RN

Jim Ford, M.A. VA R&D, Baltimore; **Susan Vesmarovich**, RN, Shepherd Center, Atlanta, GA

Co-participatory members from Group 1 (also Topic A, Interactive Home Telehealth): Gerald Loeb, M.D. (co-chair), M.A., Kathy Bowles, R.N., Ph.D., Richard Craft, Ph.D., Des Cummings, Sal Sheredos.

Co-participatory members from Group 3 (also Topic C, Ethical Issues Surrounding Appropriate Design of Home Health Technologies): Jeff Collmann, Ph.D. (co-chair), Keith Bauer, Richard Birkel, Ph.D., Gil Devey, Mary Ann Schroeder, Ph.D.

INTRODUCTION: BASIC PRINCIPLES AND ASSUMPTIONS

Creating effective personal status monitoring systems in the home requires us to first address the key issues involved in their development and use. These concerns include identification of at-home users and their needs, the self-care and wellness demands that are driving today's health and home care markets, and tools that can and should be developed to meet particular at-home needs.

Focus on the Patient and Home Provider

Key among planning efforts for new devices and technologies for home care is a needed emphasis on *enabling* persons living at home to easily access necessary and personally suitable care services. Creating an effective home health care environment is a primary consideration. The environment has to be suitable for persons living with chronic diseases who require regular medical care as well as for other persons living at home who are living at varying levels of wellness.

The home medical/health care environment must first and foremost be a "home." Devices, monitors, and other technological facilities must be designed and manufactured with the home or place of residence in mind. Without question, the patient's room must NOT look, feel, or smell like an intensive care unit (ICU) or an emergency room (ER).

Home medical/healthcare devices and technologies need to be designed and used differently than similar tools used in conventional medical care settings. Ease of use is a key design issue. Particularly for persons requiring medical care, all devices and facilities must serve to empower the patient and to aid and facilitate self-care and care through the aid of family or live-in providers.

A central issue in design of home care technologies is, simply, aiming toward creating easy to use tools that *will* be used regularly by persons in their self management routines. To encourage regular self care, moving beyond the easy of use issue, home care devices and facilities must be customized and tailored to the particular needs and preferences of the patient and family. This means that home care devices will be very different from the present generation of ICU, ER, hospital, or even physicians' office point-of-care devices and equipment. The technologies *have* to be focused on at-home patient needs delivered by laymen (patients themselves and/or their care assisters) in typically very low-tech settings. The technologies must be small and transportable. In addition, as more developments in home care deliverables become more readily available, there will need to be options for patients with certain needs (for instance, chronic conditions such as diabetes) to choose among conventional, higher tech, and implantable devices to receive the care that they need.

The Home Setting as a New Frontier in Healthcare Delivery

Providing care and tools in the home care setting is a new and broad challenge to meet. The biomedical engineering and medical device and hospital products communities have little experience in these areas. In addition, given the new-ness of the technology and absence of track records, the Food and Drug Administration (FDA) has been skeptical of home devices that are long on promise to the consumer. Today, therefore, to begin to meet the challenge of helping at-home patients (and other persons living at varying degrees of wellness) to receive the care and services they need, the FDA must become a close partner with the bioengineering and manufacturing communities in assuring that the next generation of devices and equipment for home care are appropriately designed, tested, manufactured, and implemented.

In the best case future scenario, all devices and equipment created for home care must aim toward being very easy to use, and for the most part require a minimum of only a third grade education and reading level. The operation of such devices must be obvious. Their use and application in the home must be unobtrusive and, preferably "transparent." All of these design and planning emphases will assist in the increasingly necessary enabling-of-self-care process.

Nature of Wellness and Illness

Western medicine deals with pathologies-- that is, abnormalities. It does not deal well with "normality" -- that is, wellness. What is "well" and how do we measure "wellness"?

Important as the concern with wellness is today, there is little understanding of the concept of wellness and thus no consensus about how it can or should be measured. The medical community shows little interest in the value of wellness and wellness education for patients and the general public, operating as it does in the more challenging "repair mode" of "fixing" sick patients. The "well" state is the baseline; deviations from that baseline, depending on their magnitude and severity, represent non-wellness or pathology -- an illness or condition which must be "repaired", returning the patient to normality -- to wellness.

Today, our healthcare system, particularly managed care, continues to operate in the "fixing" mode of disease management. There is little emphases or tangible incentives toward patients' working toward health improvement and relative wellness. At the same time, there are increasing reductions of the kind and extent of services which insurers have typically provided. If nothing else, this trend toward reduced conventional healthcare services has encouraged a boom in the alternative medicine and wellness consumer market.

Clearly, consumers are voting with their feet and pocketbooks -- they are demanding wellness by buying and eating or taking alternative medicines, "medicinal" herbs, vitamins, metabolites, etc. Alternative medicine and wellness is a booming business. We cannot ignore it. Many home health patients and others living at home are now participating in alternative medicine and alternative nutrition activities.

This drive toward alternatives represents a combination of the consumer- oriented thrust toward wellness and industry-directed push toward patient self-care. The drive toward self-management is coming from many fronts, whether consumers are receptive and/or able to follow this trend or not. In these circumstances, we have to direct our development efforts toward helping consumers in their self care routines and staying relatively well, doing so effectively and safely.

To do so, first off, we must learn to parameterize and measure wellness. We need to ask: What parameters most effectively indicate normality and abnormality? How patient specific are these measures? Although we have a set of physical parameters which are generally accepted (temperature, blood pressure, pulse rate, ECG), we rarely consider chemical parameters. If we were to develop tools to measure these parameters, we would need to ask: What is our personal biochemical individuality? What is my personal wellness baseline? Yours? And finally, what magnitude of deviation from that personal baseline constitutes an illness or a pathology?

Currently, except for blood glucose and cholesterol measurements, biochemical measures are not used for wellness assessment. Specific chemical and enzyme activity assays are, however, regularly ordered to "confirm" the diagnosis of various diseases or pathologies. How can we promote wellness and/or encourage patients to aim toward this end if we lack the means to parameterize and measure it? There is, obviously, a need to broaden our range of study of patient health/wellness parameters.

Sensors and Other Measurement Devices: Tools to Enable Self Care

Once a set of wellness parameters are developed, we must be able to measure these parameters. And we must be able to measure them in the home -- easily, simply, and, preferably, non-invasively. Many Science Centers throughout the nation measure the EEG, blood pressure, and temperature of their visitors and participants; so do high school and even junior high classes, with very inexpensive, safe, and easy-to-use equipment. The major constraint is chemistry. We need simple, easy-to-use, inexpensive, quantitative, and reliable means to measure the key metabolites, nutrients, and other chemicals necessary to the assessment of personal wellness.

The diabetes community is leading and driving major research and development activities to further improve the measurement and monitoring of glucose and of other metabolites important to diabetes, with an emphasis on methods which do not involve the trauma and discomfort of blood sampling. There is a move towards the use of interstitial fluid as the analytical sample and even to the development of truly non-invasive methods of analysis. Considerable research and development is now being focused upon minimally invasive approaches for obtaining samples of interstitial fluids for glucose analysis. Such fluid can be collected from the skin epidermal layer, which is devoid of blood vessels or nerves. The process is therefore painless and bloodless. A problem with minimally invasive approaches to sampling is that the volume collected is often one microliter or less and thus considerably smaller than a typical blood glucose sample, generally 30 microliters or more. This presents a considerable challenge for current analytical methods of detection, which in the case of glucose are primarily electrochemical or reflectance colorimetry.

There are many research groups that are developing means for interstitial fluid collection and analysis. (See details on the Web sites developed by the Juvenile Diabetes Foundation [www.jdfcure.com] and by the American Diabetes Association [www.diabetes.org]). It is likely that these efforts will be successful and that truly, minimally invasive, painless means for acquiring samples for biochemical analysis will become available in the very near future. These new methods, together with more specific and sensitive means for chemical analysis, will make home chemical measurement and monitoring practical [see also Andrade, [HCT-W9](#)].

Home Health Technology Systems Integration

A key concern to ensuring the efficacy of a home health devices and technology use is developing effective systems integration among the tools and also among tools in place at a central clinical receiving site. Home health is not, in effect, confined to the home. Home health services and their delivery must be seamlessly and transparently connected to and a part of the overall health care system. In the best case scenario, not merely a monitoring device will be placed at the receiving end, but the patient's physician, nurse, dietitian, physical therapist, psychiatrist, pharmacist, etc. will be virtually available. To enhance any of their services, the patient's data and medical/health/wellness record must be readily available.

Enabling this ready communication of information and service requires a universal backbone (communications system) to be in place and accessible by all homes in the U.S. Through this system's use, data and images obtained in the home care environment would be easily accessible to a broader health care system. The value of this system can be noted in providing:

1. verifiable results of patients' interactions with home care devices and services;

2. opportunities for frequent follow through with patients;
3. assistance to patients in performing their own self care routines regularly and competently;
4. more detail needed to compile comprehensive, computerized patient records.

Issues of importance that must be addressed to enable integration of home health technologies to be acceptable must address issues beyond technological concerns. There must be algorithms and expert systems to assess the voluminous streams of data from home care patients who are being continuously or regularly monitored. However, while these data and images obtained in the home care environment must be easily accessible to the health care system, there need to be appropriate controls placed on privacy and security issues.

In addition to the integrated system providing for the care of the patient, the system must be a source of data for researchers and others whose aims are to more fully understand wellness and illness, in order to better treat all patients. Thus every patient "encounter", every measurement, must be a source of information, again with appropriate concern for anonymity and privacy.

Patient Education

Personal and private health and well-being are very powerful pedagogical tools for education and learning. Patients, and their at-home providers and caregivers, must be empowered to learn, understand, criticize, observe, control, and measure their disease and their degree of wellness. They must be interested and involved in their personal return to wellness and in the treatment of chronic disease. They must be part of the "solution". Clearly, there are many kinds of patients; some are more readily empowered and involved than others, but all must be given the opportunity to become interested, involved, and enabled.

Disparity in learning styles and capabilities or no, there is nevertheless a great deal of effort that must be expended toward discovering how to educate patients and help them to learn the techniques of their own personal self care routine. We need to ask: What motivates patients to become educated, empowered, and involved?

How do we design, produce, and use education materials to facilitate patients' education, understanding, and involvement in their self care routines? How do THEY perceive their disease or condition; their health care providers; the instruments and devices in THEIR home? What is the role of patient support groups, now so readily available on the Internet? Can we use physicians or nurses with the same illness or pathologies, who understand and empathize, to help the patients become more involved? There is obviously a great deal we have to learn about how patients learn.

Interagency Collaboration in the Developing Home Care Service Delivery Arena

There are many stakeholders in home care -- an array of agencies, both state and Federal; foundations and other not for profit institutions; patient support groups; industry; insurance firms; and, of course, clinicians such as physicians, nurses, and other professional care givers. All of these entities must be encouraged to work together much more closely. They must facilitate -- namely, FUND -- demonstration projects. They must provide incentives to encourage the community to meet the needs of effective home care. And, most challenging of all, they must work together toward minimizing the standardly myopic, short-term economic and cost/benefit analyses-oriented view of health care service delivery. This must be done first of all in order to be able to consider the long term potential of effective home health care delivery which includes self care and wellness routines.

SUMMARY

The Home as the Health Care Delivery Setting of Choice

Consumer demand for home health and home health care is not new. When patients have a choice, and if they have a reasonably stable and caring home environment, they choose to go home, almost without exception. If they have a severe, chronic, difficult condition it is difficult to permit them to go home, unless the home is fitted with the appropriate technology and care giver. We have the opportunity today to help enable this choice by

developing technology that is easy to use, suitable for the patients' particular needs, and allows access to trained, off-site professionals who can work with the patient on educational/problem areas of concern.

Modern consumers have grown to accept technological advances -- indeed, they expect such advances in medical and health care technologies. Industry is slowly responding, although payers, and, some believe, the FDA, are not responding efficiently.

Making the Home an Effective Choice for Health Care Service Delivery

Ease of use. It is indeed possible to design, manufacture, install, and implement medical and health care technologies which are simpler, easier to use, and do not require an advanced college degrees to operate. Consumers today can operate highly sophisticated devices and equipment, assuming such devices are appropriately designed and engineered. That is a challenge. The home must remain a home, and not look like an ICU or ER. And secondly: The home health care system must be transparent, and it must be integrated -- seamlessly -- with the total health care system.

The communications infrastructure. Appropriate communication technologies and networks are already in place and rapidly becoming more effective and more affordable. The need and challenge is to seamlessly connect home health care monitors, sensors, and assistive devices to these communication systems and thus to the various professional care providers. Challenges include reliability, security, privacy, quality, and related issues, most already being addressed by the existing informatics and telehealth communities.

Creating a feasible view of home healthcare service delivery. The health care economics and payer communities rarely consider the integrated lifetime costs, from conception to burial, yet that is indeed the most relevant societal health economics metric. Can we develop more long range economic models and analyses? If we think we can, there are many questions that must be addressed, including: How do we collect data to facilitate such analyses? How do we define and analyze the "cost effectiveness" of a particular technology or device? How do we deal with "orphan diseases" and the "orphan" technologies or devices needed by those patients? How do we incentivize researchers to study, and companies to develop and produce, information and devices for which there is no conventional "market"?

Providing universal access to home care services. Apart from a universal communications network, we need to consider how products and devices can be readily available in American homes. In large part, we have to ponder: How can we develop high volume, adaptable manufacturing?

First, we need to fund the development of highly adaptable, high volume manufacturing processes. The best current example is the microprocessor or the charge coupled device (CCD) light detection/imaging chip. These are manufactured in such high volumes that they are very inexpensive, even though sophisticated manufacturing processes are used. The low costs are a direct result of the high volume, which is due to the flexibility and adaptability of the product.

Using this example, we can apply scenarios in home health care service. What about physical and chemical sensor "chips" that can measure almost anything of possible interest? They can be wired, programmed, or otherwise implemented in a manner to provide true custom sensors and devices, perhaps disease or condition specific.

Effective education and training. Patient education and training for self care are critical for effective delivery of home healthcare services; however, a look at the broader audience of players in the home healthcare arena emphasizes how key the involvement of multiple other entities can be. We have to educate and encourage a new generation of design and manufacturing engineers, bioengineers, and physicians and other health providers, for instance, to study how to provide needed services in the home.

Among the many challenges: getting biomedical engineers involved with home care patients -- not just after the fact (the design and manufacture of the home care tool), but before the fact -- in the design, development, and testing of appropriate devices and technologies. Another critical challenge among many: Educating the academic health policy and health economics communities to develop means and methods with which to take a long term, integrated view of healthcare delivery? We then also need to educate and incentivize payers, including Medicaid, Medicare, HCFA, among other insurers to do the same.

Summary Recommendations for Research

Research and fund the development of a Personal Health Profile. What are the parameters of patient's health and wellness? How should these parameters be measured? How should the data be assessed and analyzed? How should the data be presented to the patient? to the professional providers?

1. Research and fund the development of Personal Health Education programs and materials. There is a need for both patient and clinician and other teacher modules to help patients (and the general public) in their new, self management routines.
2. Fund the design and development of adaptable manufacturing processes.
3. Encourage (through sponsorship and other funding) the study and development of innovative health economics tools and models. These tools would measure and define chronic and long-term care needs and costs, and provide a basis for policymaking on healthcare and societal needs and issues.
4. Fund large scale demonstration projects, preferably interagency, which address the issues and needs discussed above.

Topic C:
APPROPRIATE DESIGN OF HOME HEALTH TECHNOLOGIES:
ETHICAL, LEGAL AND POLICY CONSIDERATIONS

Prepared by Co-Chairs:

Janell Duncan, J.D., Arent Fox, duncanj@arentfox.com

Jeff Collmann, Ph.D., Georgetown University, collmann@isis.imac.georgetown.edu

Participants:

Michael Morris, J.D., Sr Community Options; Wendy Nelson, Ph.D., R.N., NIH,
Larri A. Short, J.D., Arent Fox; Keith Bauer, MSW, MA
Gideon Kantor, Ph.D., CUA; Gil Devey, NSF,
Sheryl Giardiniere, Technological Specialist; Richard Birkel, Ph.D., Kennedy Institute,
Marcia Nusgart, R.Ph., Washington; Mary Ann Schroeder, Ph.D., School of Nursing, CUA

Co-participatory members from Group 2 (also Topic B, Personal Status Monitoring): Joe Andrade (co-chair), Ed Clark, John Enderle, Jim Ford, Harry Handlesman, Nancy Pressly, Howard Weetall

Co-participatory members from Group 3 (also Topic D, Chronic Conditions): David Angaran (co-chair), Jack Buchanan, Margaret Cushman, Jeannette O'Neill-Gonzalez, Donald Monkhouse, Stuart Speedie, Frances Richmond

INTRODUCTION

The title “Appropriate Design of Home Health Technologies: Ethical and Legal Issues” implies that good processes of technological design incorporate key moral, social, and legal values as well as satisfy good engineering practices. In addition to compliance with federal regulations designed to assure safe and effective operation, designs for home health care devices, for example, should help patients and families adapt a technology to the demands of their homes, not just force homes to adapt to technology. This has readily apparent implications for disabled individuals, but should also underlie how we think about home technologies for all patients and families.

Developing such a framework requires changes in how we educate engineers, train users, design and manufacture products, and process new technologies through the regulatory system. Supporting families in home health care also requires changes in policies and funding of community infrastructure. Social planners should evaluate methods for providing access to the “information superhighway” from the homes of all people without regard to their ability to purchase “the last mile” of connectivity. For home care to function as a true choice, patients and families should have access to and understand various alternatives for care of chronic illness.

Important legal issues impacting upon future innovations relate to the identification and reduction or elimination of regulations that serve as barriers to new product development and use. The provision of home care by home health agencies, as well as use of medical device technologies is strongly affected by Federal regulations and policies governing reimbursement for services provided by home care agencies, and reimbursement for use of durable medical equipment.

Maximizing the benefit of new home care devices therefore requires forging new types of relationships between designers and customers, new types of community organizations and new methods for flexibly managing social and technical innovations in support of decentralized health care.

VISION

C-1: Reimbursement policies should not discriminate against home health care, products and services.

Reimbursement for patient care should be provided for on a site neutral basis. If reimbursement for such care is provided for in a setting such as a hospital, a long-term care facility or a hospice, reimbursement for the same care should not simply be denied because the care took place in the patient's home.

C-2: Develop system of “mass customization” that encourages personalized design, adaptable

manufacturing and flexible regulation of home care devices. The NSF program for senior design projects in rehabilitation technology constitutes a new model of device development for the future. In contrast to traditional techniques of mass design and production, the NSF program partners senior engineering students with patients in a process incorporating the context of use into individualized device development. Context-sensitive design requires methods of adaptable manufacturing to permit “mass customization” of home care technology. As design and manufacturing processes respond to the demand for customized technology, regulatory agencies should adapt procedures to facilitate responsible evaluation of an intrinsically dynamic product stream.

C-3: Federal policy and funding should support linking the home to the “information superhighway” to support home health care, including regulations to embed relevant technology in housing design.

The metaphor of the “information superhighway” suggests that the U.S. government has assumed the obligation of connecting everyone to the communication infrastructure of the future, much as it subsidized travel on an enhanced national system of highways. In addition to investigating ways to connect remote and low-income families to the Internet, federal agencies including Housing and Urban Development (HUD) and the OSTP should develop standards and codes to encourage construction of “information-ready” homes. Embedding advanced information technology in housing design would complement the context-sensitive design of devices and adaptable manufacturing in yielding living spaces engineered for maximum support of home health care.

C-4: Promote public debate and understanding about clinical and ethical conditions for appropriate home health care.

As Arras and Dubler² make clear, home health care does not meet the needs of all patients or their families. As the pressures grow to move patients earlier from the hospital to other locations of care, families face momentous decisions with few options and little understanding. On the one hand, few affordable alternatives to home care exist for the population as a whole. Innovative assisted-living or graduated care communities frequently cost more than many families can afford. Depending on the clinical and family situation, even practical and skilled nursing for home care may be unaffordable. The question of long-term care has been part of the debate about health care reform for many years, particularly in the days of the Pepper Commission and the Medicare catastrophic care debate. No consideration of home care technology can avoid the broader policy discussion about developing viable alternatives to both the hospital and the home for care of the chronically ill. On the other hand, families do not always understand or assess in advance the burdens as well as the benefits of the home care choice. Social policy should promote an open discussion of the complexities, costs and potential satisfactions of home care out into the open. Arras and Dubler² correctly draw the parallel with the process of informed consent. Discussions of the complexities of home care should certainly constitute central components of “discharge planning” for individual patients. Because managing this issue will face so many American families over the next twenty years, social planners should also consider it a public health issue worthy of the kind of wide exposure granted such campaigns as anti-smoking and AIDS prevention. Use of electronic technologies such as the World Wide Web and other Internet-based tools for public education and debate in this area should complement their use in “telemedicine” applications. Pushing chronically ill patients into unprepared homes should not result from the failure to engage in wide public debate about the complexities and alternatives to home health care for the chronically ill.

KNOWLEDGE GAPS

C-1: Inadequate understanding of the clinical and cost effectiveness of home health services, products and technologies. The National Library of Medicine (NLM)¹⁶ has supported comprehensive studies of the clinical and cost effectiveness of telemedicine, including some home health projects. These studies constitute a foundation for extending inquiry into the conditions under which home health care may or may not be clinically and financially appropriate. The NLM studies also constitute models for how future studies should be designed in that they require examination of the entire system of home health care, not just the individual impact of a range of devices. Even if processes of customized design and adaptable manufacturing yield improved devices, their relative impact will vary with the clinical and financial circumstances. Corbin and Strauss⁹ emphasize how stable and unstable phases of a chronic illness affect everyday life in the home. Stable phases yield differing burdens and outcomes than unstable or declining phases. Managed care and fee-for-service systems of reimbursement differently condition the financial evaluation of home care by focusing attention on avoiding and/or promoting delivery of services. Central questions for home health care also remain of who bears what kinds of costs as care migrates from the hospital to the home in varying circumstances. It is likely that costs saved for the hospital will migrate to the home in new unanticipated forms. Additionally, creating acceptable systems of home health care will undoubtedly create new costs in technology and staff for providers as well as families. Defining what constitutes a “cost” or a “cost savings” poses major conceptual challenges to the assessment of the benefits of home health care technology.

C-2: Inadequate understanding of clinical, social, ethical and economic consequences of home health technology for family life. The growth of home care technology (HCT) is an ethically and socially complex phenomenon.^{14,16} As the site of healthcare delivery continues to move from hospitals to private homes, a better understanding of the ethical and social dimensions of HCT is required. This process of understanding is twofold: first, the ethical and social consequences of HCT should be considered; second, ethical guidelines should be established for assessing the choice of HCT in individual cases.

Future HCT demonstration projects and policies need to anticipate the probable ethical and social consequences of home care technologies for family life. We need to know whether HCT succeeds or fails in promoting the moral values of *autonomy, well being, dignity, privacy, confidentiality,* and *justice* for patients and their families.^{4, 11,12, 22}

As a necessary condition for promoting the aforementioned moral values, a number of socio-ethical issues associated with the use of HCT need to be examined.^{2,20}:

- Although future HCT may prove to be cost effective and technologically efficient, it may *medicalize the home environment* by turning the private domain of the home into an ICU. This may lead to about home, family, and the human body.¹⁷ As a society, we should ask ourselves whether we want our private living environments, our families, and our bodies to be transformed in this way.
- HCT will require patients and families to manage more of their own healthcare. Is this an excessive burden or the promotion of patient and family autonomy and responsibility? In addition, conflicts of interests normally not found in traditional medical settings, in which healthcare is governed by a *patient-centered moral framework*, will arise in the home. Hence, a *family-centered moral framework* will be necessary as more patients receive their care at home. What this future framework will look like is less than clear.
- HCT research and policy ought to consider whether home care technologies impede the development of *empathy* and *compassion* between patients and healthcare providers.^{3,19} Good character and *virtue* are central to the moral practice of medicine and the lack of appropriate

emotional ties between patients and providers can be construed as an unacceptable *moral vice* in clinical medicine.²¹

C-3: Insufficient methods for tailoring the type, amount and manner of presenting information to patients and families to enable them to make informed decisions about home health care services, products and technologies. Retooling homes to support complex home health care will require extensive (re)training of families. Although such training will have to meet minimum standards of and will encounter current problems with conventional informed consent (Faden and Beauchamp 1986; Arras 1996), complex home care poses new problems for informed consent itself. New research should address the following questions, among others:

- 1) To what do patients/families give consent when deciding about a system of care rather than an isolated event or device?
- 2) When evaluating a system of care before and during use, what constitutes denial/withdrawal of consent? For example, when does rejecting a portion of a proposed treatment plan constitute rejecting the whole? How can patients/families negotiate with providers about the components as well as the whole of a treatment plan?
- 3) Given the responsibility of patients/families for multiple clinical and technical tasks in home care, who should be responsible for obtaining and reaffirming informed consent?
- 4) Given the long-term implications of home care for chronic illness, how should the process of training and informing patients/families occur, including what new technologies might support extended, on-going education?
- 5) Given the possibility of collapse in systems of home care, what obligations do providers have in proactively initiating reconsideration of the decision to proceed with home care.

C-4: Lack of clear ethical and clinical guidelines for assessing the choice of home health care in individual cases. In 1998, the American Telemedicine Association (ATA) formulated *clinical guidelines* for tele-homecare that set criteria for patients, providers and technologies.¹ These guidelines are currently under review by the Health Care Financing Administration (HCFA) and the National Association of Home Care (NAHC). Although the ATA clinical guidelines are a step in the right direction, explicit *ethical guidelines* for assessing the choice of home health care in individual cases still need to be formulated.

- Ethical guidelines for HCT should identify the *benefits* and *burdens* of HCT in a way that advances the moral values of *autonomy, well being, dignity, privacy, and confidentiality*.⁴ Of course, our understanding of the benefits and burdens of future HCT will be improved once we gain more knowledge about the likely implications of HCT discussed above. Furthermore, HCT should meet the requirements for *a minimum conception of healthcare justice* that allow us to determine whether various home care technologies promote *fairness, availability, access, and quality* in home healthcare.^{11, 22}
- An adequate *on-going informed consent process* for patients and their families will be necessary.² If families and patients are technically, medically, and emotionally naïve about HCT, it is highly unlikely that they will be able to make informed decisions about HCT.
- Related to the issue of informed consent, there is the need for *viable options to home care*.² Will home care become a replacement or a supplement *vis-à-vis* healthcare services? Informed consent to HCT requires that patients and their families have real alternatives to home care. If no options to home care services are present, then consent to home care is an empty formality for patients and their families no matter how informed they are. Moreover, talk about patient and family autonomy and well being is meaningless.

In summary, the ethical and social consequences of HCT should be thoroughly considered, and clear ethical guidelines should be established for assessing the choice of HCT in individual cases. This is easier said than done, but, we must remember that knowledge, whether scientific, technical, or clinical ultimately serves values. As our society increasingly adopts home care technologies, it is important that we identify our common moral values to guide us in the creation of a more ethical, just, and humane healthcare system.

C-5: Lack of knowledge about likely errors, adverse events, and unintended consequences of integrating multiple devices, drugs and technologies in the home environment. Clinical pharmacologists increasingly appreciate the importance of assessing drug-drug interactions as well as a drug's specific action in a patient's care. When considering home health care, one may generalize the point to highlight how drugs, devices and supporting technologies interact to create complex, emergent circumstances with potentially harmful and/or beneficial consequences for the patient and family. Corbin and Strauss⁹ emphasize how families articulate different tasks to accomplish the work necessary for home care. The possibility for errors, adverse events and unintended harmful consequences increases with the complexity of the tasks and the difficulty of integrating them into a manageable work process. As they stress, disruptions in illness-related work holds the potential for destabilizing the rest of life and thus negatively affecting the overall illness trajectory itself. Rochlin (1998) adds to this analysis that introducing computers into skilled labor such as hospital or home-based health care potentially generates new, unanticipated kinds of errors as users depend upon computer output to inform them about and control the phenomenal world under consideration. Computerized monitors, telecommunications devices and other home care devices might thus potentially reduce instead of improving effectiveness of communication between patients, families and care providers. Most studies of telemedicine affirm its positive impact on patient-provider interaction. Indeed, preliminary data suggests videoconferencing and other communication devices enhance patients' overall ability to manage their illnesses (Warisse etc.). The question still remains how a comprehensive treatment network that includes diagnostic, therapeutic and communication devices (such as a telemedicine-supported peritoneal dialysis network) might alter their individual performance and the ability of families and providers successfully to use them.

BARRIERS & ISSUES

C-1: Current reimbursement scheme penalizes home health care. The provision of home health services has been greatly affected by the passage of the Balance Budget Act of 1997 ("BBA"). According to the Congressional Budget Office ("CBO"), the percentage of Medicare spending on home health care had nearly doubled between 1987 and 1994.³² In addition, the CBO had estimated that Medicare home health expenditures would grow at an annual rate of nine percent through the year 2000.³³ In an effort to slow the growth in spending of Medicare's home health benefit, provisions of the BBA created changes in reimbursement for home health services. Whereas previous reimbursement policies had been on a cost-basis, the BBA established two systems for payment: (i) an interim payment system ("IPS"); and (ii) a prospective payment system ("PPS"). The IPS was to operate in Fiscal Year ("FY") 1998, while the PPS was to be developed by the Secretary for the Department of Health and Human Services ("DHHS"), and begin in FY 1999, but was extended to October 1, 2000, due to concerns with Year 2000 problems.³⁴

By all accounts, IPS has had a devastating effect on the provision of home health benefits to the elderly. Generally, IPS allows for reimbursement of home health agencies ("HHAs") in the amount of the lowest of: (1) their actual, allowable costs; (2) the aggregate reduced per visit cost limits; or (3) a new aggregate per beneficiary limit (based on cost per patient including non-routine medical supplies during federal FY 1994). The combined effect of the provisions required many agencies to significantly reduce their average cost per visit and average cost per patient. In an effort to force home care agencies to reduce costs, become more efficient, and reduce utilization, the IPS reimbursement system restricted agencies to reimbursement at levels established for FY 1994. The restriction on reimbursements were

enforced regardless of any change in the patient population served by an individual home health agency.

This change in reimbursement created an incentive for firms either to stop serving higher cost patients, or to restrict care so as not to exceed cost caps. The reported result of these cuts was a significant increase in home health agency closings. A recent General Accounting Office (“GAO”) Report indicates that 318 HHAs had closed from October 1, 1997 to July 1998.³⁵ The National Association for Home Care (“NAHC”) conducted its own survey, and estimates that the actual number of closures from October 1997 through March 1999 to be around 1,067.³⁶ In addition, because these numbers reflect main offices, NAHC surmises that the actual number of locations closed is higher. Finally, figures released on March 12, 1999 by the Congressional Budget Office (“CBO”) show that the figures used to justify the cuts made in the BBA of 1997 were grossly inaccurate. In developing the 1997 budget, the CBO had estimated that Medicare home health outlays between fiscal years 1998 and 2002 would be \$127 billion. In March 1999, the CBO revised this estimate to be only \$79 billion.³⁷

In response to the concerted efforts of home health providers seeking relief from the IPS, Congress and the Administration provided some relief, and agreed to changes as part of the October 1998 omnibus appropriations legislation. These changes included an increase in the per visit cost limits from 105% to 106% of the median cost per visit. They also raised the per beneficiary limit for providers. These changes were effective for cost reporting periods beginning on or after October 1, 1998. In addition, the IPS reforms delayed the scheduled 15% reduction in cost limits from October 1, 1999 to October 1, 2000 and delayed implementation of a home health PPS until October 1, 2000.

C-2: Inconsistency between federal and state laws and regulations creates barriers to rational development of home health care services, products and technologies. Inconsistent state laws and regulations, particularly those governing professional licensure and medical records confidentiality, create barriers to the rational development of home health services, products and technologies. In the area of licensure, inconsistent state laws relating to licensure create barriers to the provision of telemedicine services. In addition, in the area of privacy and confidentiality, many states have differing, and sometimes conflicting privacy requirements for the gathering and maintenance of medical records. On the Federal level, the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”),³⁰ mandates stringent security protection for electronic health information both while *maintained and while in transmission*. A proposed Security Standard called for by HIPAA was published in the Federal Register on August 12, 1998, and proposes standards for the security of individual health information and electronic signatures use by health plans, health care clearing houses, and health care providers.³¹ Such entities would use the security standards to develop and maintain the security of all electronic individual health information. As the Federal government becomes more active in regulating this area, some state laws may be in conflict with these Federal laws and regulations. The current debate seems to center around whether any enacted Federal legislation should serve as a floor (*i.e.*, minimum requirements where states could enact more stringent guidelines), or as a ceiling in this area. Regardless, any existing inconsistencies will need to be reconciled in order that home health services that choose to transmit information electronically have a clear mandate of their responsibilities in this area.

C-3: Regulatory ambiguity: (a) FDA has not provided specific guidelines for the definition, classification and regulation of drugs, devices (e.g., software, exempt telemedicine services), and drug-device combinations; (b) HCFA does not have clearly defined coverage and coding procedures potentially causing cost-prohibitive or innovation-stifling delays. See discussion in Recommendations section below.

C-4: Lack of public confidence in the security and confidentiality of computer-based patient health records undermines trust in using automated information systems to support home health care. The debate about medical information security tends to polarize into two broad perspectives. The media and privacy advocates argue that easy trafficking in medical information poses grave risks to patients’ privacy, a situation that the computerized patient record (CPR) only promises to exacerbate [1-7]. CPR advocates argue to the contrary that the entire progress of health reform including

improvements in maintaining patients' privacy depends upon adopting electronic record keeping systems and their associated technologies such as universal health identifiers [8-12]. Congress and the Department of Health and Human Services will provide guidelines within the next two years thanks to a variety of medical record reform efforts underway. As with all such guidelines, nonetheless, health care providers will have to interpret and possibly go well beyond the legal requirements in order to meet their obligations to both their patients and themselves. How should a contemporary health care provider responsibly act in the face of such diverse and uneasily mediated positions? Moreover, what should patients understand about how health care providers protect their information in order to make a rational decision to trust or not trust them? Providers' actions and patients' trust are linked. Although surveys reaffirm that Americans doubt that large organizations adequately protect sensitive, individually-identifiable information, they do trust particular organizations under certain organizations. When Americans observe an organization diligently seeking to protect sensitive information, they provide necessary information about themselves and trust the organization will adequately guard it. Implementing home health care using computer-based information systems will require, therefore, good security practices on behalf of providers coupled with comprehensive, accessible materials informing patients about the security efforts underway.

C-5: Restrictions on interstate professional licensure of health care providers inhibit development of telemedicine support of home health care. All states regulate the health professions, including doctors and nurses. Although some states recognize that medical consultation by a physician who is licensed in another state not only should be permitted, but also can be beneficial, more than 20 states have modified their laws in the last five years to require those engaging in the practice of medicine within their borders to have a state license. The potential penalties for practicing without a license may include civil fines and even criminal prosecution.

Similar licensure issues face nurses that seek to provide care across state lines. Telenursing normally involves a nurse having contact with a patient in his or her home. These issues especially arise for nurses staffing cross-state phone help lines, home health nurses, and others practicing in border areas. Finally, licensure issues arise relating to HHAs because many states require home health care agencies to have a state license. Therefore, if an HHA has multiple facilities located across several states, each may be required to comply with state licensure laws in the state where it is located.

RECOMMENDATIONS

C-1: Investigate reforms in the regulatory process (federal and state) to encourage delivery of home health care services and development of innovative products. Specifically: 1) HCFA Prospective Payment System should allow for innovative and adaptive technology; 2) FDA should provide specific guidelines for the definition, classification and regulation of drugs, devices (e.g., software, exempt telemedicine services), and drug-device combinations; and 3) federal guidelines should be promoted for medical professional licensure; and 4) HCFA should clearly defined coverage and coding procedures with respect to home care technologies. HCFA regulations revising the Medicare Conditions of Participation for home health agencies and implementing the Medicare home health prospective payment system mandated by the Balanced Budget Act of 1997 should be flexible enough to permit the use of innovative and adaptive technologies in home care even if those technologies obviate the need for face-to-face contact between the patient and the agency care giver.

Manufacturers are less likely to innovate when faced with ambiguous regulations of products and/or services. In order to give device manufacturers a clear framework in which to operate, FDA should provide clear guidance on when a product is a medical device, when it will be considered to be a drug, and where it is a drug-device combination -- how will it be regulated. In addition, the regulation of software must be clarified so that manufacturers can easily understand the requirements for software driven devices. Finally, manufacturers need clear guidance as to when upgrades or minor revisions to software require additional clearance from FDA.

Under the premise that patients deserve access to site-neutral care, patients should also have access to the provider of their choice regardless of their or the provider's geographic location. In order to encourage the use of telemedicine services, federal guidelines should be promoted to allow qualified practitioners to legally administer medical care or advice over distance, without respect to state boundaries.

HCFA should establish open, understandable procedures for establishing Medicare coverage policy and setting reimbursement rates for durable medical equipment and other new diagnostic and treatment methodologies. These procedures should recognize the fast pace of technological developments and should not contribute to undue delays in the introduction of new and innovative products into the Medicare marketplace.

C-2: Launch demonstration projects of fully integrated home health care systems including ethical, social, economic and technological evaluation of communities based on both locality and disease groups.

The Department of House and Urban Development in conjunction with the White House Office of Science and Technology Policy sponsors neighborhood construction projects showcasing house design and construction of the future. HUD and OSTP should require that such demonstration projects include demonstration of homes fully equipped with an information system capable of supporting home health care. The projects should require ethical, social and economic as well as technological evaluation of the information system. Although the demonstration projects may occur in model neighborhoods based on locality, they should also support evaluation of "virtual communities" whose members share clinical circumstances but may live remotely from one another (such as cystic fibrosis or hospice patients). Chronically ill people potentially benefit from support from both types of community, local and virtual.

C-3: Launch demonstration projects of customized design and adaptable manufacturing of home health care devices.

NSF's senior design project in rehabilitation medicine successfully demonstrates how patients and engineers may benefit from a process of customized device design. In order to operationalize such customized design on a large scale to yield "mass customization" the mass manufacturing process must be redesigned. The federal regulatory process for new devices should also be reviewed in light of prospects for producing devices that share some but not other critical features. Perhaps as part of HUD's new housing design program, a demonstration modeling new processes of customized design, adaptable manufacturing and flexible regulation should be developed.

ETHICS REFERENCES

1. American Telemedicine Association, ATA adopts tele-homecare clinical guidelines, *ATA News Update*, Fall, 1998.
2. Arras, J.D., and Dubler, N.N., Bringing the hospital home: Ethical and social implications of high-tech home care, *Hastings Center Report* 24, no. 5 (1994): S19-S28.
3. Balas, E.A., Jaffrey, F., Kuperman, G.J., Boren, S.A., Brown, G.D., Pinciroli, F., and Mitchell, J.A., Electronic communications with patients: evaluation of distance medicine technology, *JAMA*, 278(2), 152-159, 1997.
4. Beauchamp, T.L. and Childress, J.F., *Principles of Biomedical Ethics*. Fourth Edition. New York, Oxford University Press, 1994.
5. Cohen JD. HIV/AIDS Confidentiality: Are Computerized Medical Records Making Confidentiality Impossible?. *Software Law Journal*. 1990;4(1):93-115.
6. Collmann J. Reflecting on the Ethical Administration of Computerized Medical Records. in *Proceedings, Medical Imaging '95, PACS Design and Evaluation: Engineering and Clinical Issues*. R. Gilbert Jost and Samuel J. Dwyer III (eds.). 1995;2435:547-552.
7. Collmann, J. M. Meissner, W. Tohme, J. Winchester and S.K. Mun. Comparing the security risks of paper-based and computerized patient record systems. *Proceedings, Medical Imaging '97, PACS Design and Evaluation: Engineering and Clinical Issues* SPIE, Newport Beach, CA, Vol 3035:172-182.

8. Collmann, J. et al, The CPRI Toolkit: Managing Information Security in HealthCare, Bethesda, MD: Computer-based Patient Record Institute, 1999.
9. Committee on Maintaining Privacy and Security in Healthcare Applications of the National Information Infrastructure, For the Record, National Research Council, National Academy Press. Washington, DC, 1997.
10. Corbin, J.M. and Strauss, A.L., Unending Work and Care: Managing Chronic Illness at Home, San Francisco: Joseey-Bass, 1988.
11. Curry T, McCarroll T, and Wyss D. Nowhere to Hide. *Time*. November 14, 1991;138(19).
12. Daniels, N., *Just Health Care*. New York, NY: Cambridge University Press, 1993.
13. Edwards, R.B. and Graber, G.C., *Bioethics*, Harcourt Brace Jovanovich, Inc., Washington, D.C., 699-703, 1988.
14. Freudenheim, M. Privacy a Concern as Medical Industry Turns to Internet. *The New York Times*. August 12, 1998.
15. Goldberg, M., Home health care via telemedicine. *Telemedicine Today* 3(3): 16-23, September, 1995.
16. Gostin LO, Health Information Privacy. *Cornell Law Review*. 1995;80(101):451-528.
17. Institute of Medicine, *Telemedicine: A guide to assessing telecommunications in health care*. Marilyn J. Field, ed., National Academy Press, Washington, D.C., 1996.
18. Kohrman, A.F., Chimeras and odysseys: Toward understanding the technology-dependent child, Special Supplement, *Hastings Center Report* 24, no.5 (1994): S4-S6.
19. Meissner MC, Collmann J, Tohme WG , et al. Protecting Clinical Data in PACS, Teleradiology Systems and Research Environments. *Proc. Soc. Photo-Opt. Instrum. Eng., PACS Design & Evaluation: Medical Imaging*, vol. 3035, 1997 .
20. Nichols, L.O., and D.M. Mirvis, Physician-patient communication: Does it matter? *Tennessee Medicine*, 94-96, March 1998.
21. Østbye, T. and Hurlen, P., The electronic housecall: consequences for physicians, patients, and society. *Archives of Family Medicine*, 6: 266-271, 1997.
22. Pellegrino, E.D., and D.C Thomasma, *The Virtues in Medical Practice*, Oxford University Press, New York, 1993.
23. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Securing Access to Health Care*, vol. II,
24. Appendices: Sociocultural and Philosophical Studies. Washington, D.C., U.S. Government Printing Office, 1983.
25. Rochlin, Gene, Trapped in the Net: the unintended consequence of computerization, Princeton, NJ: Princeton University Ppress 1998.
26. Rothfeder J. What Happened to Privacy. *The New York Times*. OP-ED, April 13, 1993.
27. Schiederemayer DL. Guarding Secrets and Keeping Counsel in the Computer Age. *The Journal of Clinical Ethics*. 1991;2(1):33-34.
28. Siegler M. Confidentiality in Medicine - A Decrepit Concept. *New England Journal of Medicine*. 1982;307:1518-21.
29. Woodward B. The Computer-based Patient Record and Confidentiality. *The New England Journal of Medicine*. 1995;333 (21):1419-22.

LEGAL REFERENCES

30. Pub. L. No. 104-191, 110 Stat. 1936 (1996).
31. 63 Fed. Reg. 43241 (1998).
32. Smith, B. M., et al., Medical Home Services: An analysis of the Implications of the Balanced Budget Act of 1997 for Access and Quality, The George Washington University Medical Center, Center for Health Policy Research, at 1.
33. Id.
34. Id. at iii

35. "Medicare Home Health Benefit: Impact of Interim Payment System and Agency Closures on Access to Services," September 1998.
36. "National Association for Home Care, Survey of state licensing agencies," March 1999.
37. National Association for Home Care: http://www.nahc.org.NAHC/CaringComm/TopNews/Mbrs_only/cbofig.html.

Topic D:
HOME THERAPEUTICS & ASSISTIVE TECHNOLOGY
FOR CHRONIC CONDITIONS

Prepared by Co-Chairs:

Don Marlowe, M.M.E., Office of Science and Technology, FDA, dem@cdrh.fda.gov

David Angaran, R.Ph., Angaran Associates, LTD, dangaran@aol.com,

Participants:

Nell Armstrong, Ph.D., R.N., Nat Inst. Nursing Research, NIH;

Jack Buchanan, M.D., Ph.D., Memphis VA Med Cen Univ. of Tenn.

Earllaine Croarkin, P.T., Dept. Rehab. Medicine, NIH;

Margaret (Peg) Cushman, M.S.N., Home Care University

Carol Haberman, MS, MPA, National Library of Medicine;

Donald Monkhouse, Ph.D., VP R&D, Therics Inc

Joe Lane, RERC on Technology Transfer, Univ. Buffalo;

Jeannette O'Neill-Gonzalez, Health Care Financing Administration (HCFA)

Stuart Speedie, University of Minnesota; **Mark Pettinato**, M.M.E., WRAMC

Co-participatory members from Group 3 (also Topic C, Legal and Policy Issues surrounding Appropriate Design of Home Health Technologies): Janell Duncan, J.D. (Co-Chair), Michael Morris, J.D., Larri Short, J.D., Gideon Kantor, Ph.D., Sheryl Giardinere, Frances Richmond, Ph.D.

Co-participatory members from Group 4 (also Topic E, Human Factors Engineering and User-Driven Device Design): Jim Grigsby, Ph.D. (Co-Chair), Thomas Armstrong, Ph.D., Chris Parmentier, Barry Beith, Ph.D., Sunday Mezurashi, Kathy Ladipo, J.D.

WORKING GROUP TOPIC

Home Therapeutics & Assistive Technologies For Chronic Conditions – Home therapeutics and assistive devices include any item, piece of equipment, or product system, whether acquired commercially off-the-shelf, modified or customized, that is used to increase, maintain, or improve the functional capabilities of an individual with a disability. For the purposes of this report, pharmaceuticals used for the maintenance and care of persons requiring chronic care in all environments outside health care institutions are also included.

INTRODUCTION

The hospitalization of persons with chronic conditions is a relatively recent phenomenon in health care. Prior to the revolutionary ability to medically prolong life that followed the discovery of the “miracle” drugs and the rapid advances in life sustaining medical equipment in World War II, their families, in their homes, treated these individuals. Thus, the recent history of care of individuals who have been diagnosed with chronic diseases or conditions requiring continuous care is merely a return to the type of care offered to like individuals before the “age of hospital care” (e.g., see also [HCT-W2](#), Winters, 1999). With the aging of the “baby boomer” population, the cost of institutional care has become simply overwhelming for the system. To control the costs, the push to treat chronic-care individuals or monitor their condition outside the institution, in the home, was inexorable. More recently, the desirability of extending chronic care and monitoring to the workplace and the recreation environments has emerged. The purpose of this report is to outline a vision of the future developments in therapeutics and devices for use outside health care institutions, identify knowledge gaps and societal barriers for the accomplishment of this vision and make recommendations regarding the bridging of these gaps.

PROBABLE FUTURES

The participants in this Workshop identified several trends in the evolution of these technologies that they feel certain are likely to occur within the next three to five years.

Following the recent trends, particularly with partially and totally paralyzed individuals following spinal cord injuries, ***institutional care functions will continue to migrate from the institution*** into the non-institutional environment. We believe that every product used to monitor or maintain persons in critical care situations today will appear in the home environment tomorrow. These products will operate in a “closed loop” mode, i.e. they will sense the changing status of the individual and modify their outputs to maximize the benefit to the patient. These devices will also be interactive, i.e., the operation of each will be in consort with others operating on the same patient, independent of the health care provider.

Also, ***products not designed or intended for patient care will be important in home care*** : old products for new purposes and new products for old purposes. This is already apparent in the use of toys designed for pre-school children in the rehabilitation of accident or stroke victims.

We believe ***there will be an increase in the absolute numbers of chronic disease and disability in all age groups, including children, and populations***, e.g., premature children who are expected to survive with disability into adulthood; drug compromised persons; aging persons. This is not a negative finding of this study. Logically, as chronic care improves and enables persons to leave institutional care, the numbers of persons with chronic disabilities leaving institutions and going into productive life will increase. We also noted that approximately 40 percent of individuals seeking health care are seeking it outside traditional sources. Health care consumers are less trusting and expect the system to require they solve their own problems. This will pose a challenge in the area of therapeutics and assist devices as consumers find alternative sources of supply not only for care but for technology. If they hold true to form about 30-50 percent will not confide those purchases or use with their traditional providers.

In another area related to information exchange between patient and caregiver, ***communication bandwidth is increasing and costs are decreasing. This is expected to enable information exchange and, as prices come down, encourage small suppliers to enter the market.***

IDEAL VISION

The discussion group also explored the “ideal” home care environment. First, we determined that the design process for many products designed for maintenance and monitoring as well as treatment of persons in the home care environment never included the types of people for whom their use was intended, i.e. a “consumer model”. Instead, products were designed by “healthy” people, i.e., persons without any experience in their use but who felt they knew what was “best” for the user, the “medical model”. Product design should use a “consumer model” rather than a “medical model”. The consumer model of product development includes end-user involvement in product design and testing, an assumption that customers have multiple purchase options within a free market structure, and that reimbursement sources permit selection options.

Second, as we noted above, an increasing number of persons with disabilities will be moving from institutionalized care into the workplace and home. However, the community infrastructure that would enable them to function in the outside world does not support this migration. ***There should be a “systems” integration across health care and activities of life*** in the design of conventional products for the use by this group of citizens. For example, nutrition is a significant piece of home care. Proper nutrition requires the storage and preparation of food. We were unaware of any appliance manufacturer who has food preparation and storage equipment easily useable by many in this population. We noted that, at this time, no one has responsibility for the integration of the system.

Mass customization, the tailoring of mass-produced devices and therapeutics to a single individual’s needs through programming and interaction of products – universal design – should be the norm.

Third, ***appropriate financial and regulatory initiatives for all stakeholders should be increased and disincentives decreased.*** For example, R&D funding for new products should be increased; the definition of “home care” should be expanded to include non-institutional care/management; tax incentives for new product development should be established; and, applicability of the Orphan Drug Act should be expanded to include products useful to this group of users. The tax incentives should encompass both tax credits for manufacturers engaged in the development and production of such products and tax deductions for people who acquire such products. The marketplace will not benefit from these incentives unless they address both the buyers and sellers. Fourth, the “Ideal Vision” includes the concept that persons with chronic diseases will be continuously monitored for exacerbation of their conditions to provide a medical response that minimizes the impact of the problem on their health. This, in turn, implies the development and refinement of appropriate sensors and monitoring devices that can detect physiologic evidence of these problems as soon as they occur. Ideally, the sensors will detect the precursors of the exacerbation that could be used to entirely avoid the problem.

Finally, the ***education of health care providers in HCT needs to be expanded, and extended to include family members.*** We are aware that if medical practitioners receive any formal training in home care problems, it may be as little as a single lecture while in medical school. We also are aware that women, either the wife or daughter of the patient, provide 80 percent of home care. The training given to the relatives of the home care patient is very minimal and not adequate to enable them to care properly. Taking care of the caregivers is going to become a major issue. Recent evidence indicates caregivers contribute approximately \$192 Billion in “free” care and, because of the related stress, perform poorly at their jobs. New information tools, such as search engines and intelligent agents, could be organized to provide a new form of education such as “just-in-time” information. In this new model, the person posts the query at the time they need to make a decision, and, at that time, receives only the most current, accurate information about the options available. Such decision support systems are critical to the future management of coming information glut.

Pharmacological intervention will be greatly facilitated as the more invasive and technology requiring forms of drug administrations, e.g. Intravenous, will be replaced by non-parenteral forms of therapy such as inhalation or topical application. Compliance with medication regimens will be enhanced by devices that dispense at the correct times, with reminders and prompts, and collect monitoring data to assess the effectiveness and safety of the regimens. Remote dosage adjustment will be possible for not only intravenous but solid dosage forms, as well. Sophisticated real time remote monitoring capabilities will allow medications, requiring close supervision for therapeutic response or adverse reactions, to be used outside the usual health care environment.

KNOWLEDGE GAPS

The participants described several specific technological gaps. These included: development of innovative, more effective mobile assist devices, such as exoskeleton systems and functional electrical stimulation (FES), to accommodate a greater range of function; applications of science and technology for persons with cognitive limitations, e.g. Alzheimer's and developmental disabilities, including cognitive prostheses, neural networks and decision support systems. We also propose development of remote and closed loop sensors, bowel and bladder incontinence aids and a language interpreter for persons with speech disabilities, including dysarthric speech. While they were not specified, devices to assist with the other aspects of daily living are needed. Here again, the problems of a lack of system integration between health and life systems were apparent.

Finally, information management and assessment, particularly interpretation of continuous data from sensors which might be imbedded in the home to monitor the patient's condition, is lacking. Algorithms to sort signals, which indicate a change in the state or condition of the client from the continuous stream of a monitor's output signal, are needed. Integration of all the forms of electronic monitoring, sensors and telecommunications devices with face-to-face care in the endless variations of the "home" will be the challenge to creating a system that is efficient, effective, safe and economically viable.

The interaction of people, machines, devices, medications and sensors outside the controlled environment of the health care institution will be the major challenge. These elements may interact mechanically, electrically or physiologically, possibly potentiating or antagonizing one another, but almost certainly producing unexpected and possible adverse effects. We lack a systematic approach to testing, in the field, and improving our Phase 4 surveillance system.

OTHER BARRIERS

Several policy or non-technology barriers to accomplishment of the "ideal model" were identified. With the Internet, the decision of data/information validity or "goodness" has shifted to the consumer without a supporting infrastructure. We noted that persons with access to information today have no means by which to evaluate the credibility of the source. As we noted above, the amount of training and level of comfort of health practitioners with the new concepts of home care is severely constrained. History has shown us that adoption of any new technology will be slowed by the lack of familiarity of the several levels of the caregiver community with the technology. This will require the establishment of extensive awareness programs and remedial training. As we noted above, the traditional education/training models will not be able to maintain knowledge at the current/accurate level required for optimum decision-making. Also, the current "procedure based" payment schedule/process is not an incentive to adopt/use the best available technology. In fact, it encourages "make-do" solutions rather than optimal solutions in the mediation of a disability. Above, we noted that an ideal model would integrate the patient monitoring with patient maintenance and that maintenance included the functions of daily living. Another shortfall of the current "procedure based" payment process is the emphasis on treatment as opposed to prevention. We strongly suggest studies of the cost/benefit to preventive payment policies as opposed to a reactive policy, e.g. the cost of preventing decubitus ulcers as compared to treatment.

Unfortunately, the infrastructure that supports our current lifestyles is old, e.g. housing design, telecommunications, standards of construction, etc. Most of our infrastructure was not designed to interface at all, much less easily, with care of partially or totally incapacitated persons. We noted the constant tension that exists between privacy concerns, particularly of persons with care needs that are not always apparent to the casual observer, and access to and control of technology. Finally, telemedicine has often been proposed as a way of multiplying the productivity of a caregiver by enabling the professional to interact with the client at long range. We detected a tension between the desirability of communication and treatment at-a-distance to improve productivity and reduce costs and the known benefits of "high-touch" care giving. A large percentage of these patients will be Medicare beneficiaries. Medicare does not pay for medications or home care focused telemedicine. Medicare serves as the payment policy standard for other third party payers. While the new sensors may be cheap, the newer medication dosage forms will be expensive and, even though cost effective, the return-on-investment will be hard to measure and a long time in being recovered. This will greatly inhibit the market development.

RECOMMENDATIONS

- a. In response to identified **knowledge gaps** –
 1. Develop improved, more effective, mobile assist devices such as exoskeleton-based systems and FES.
 2. Develop devices for the treatment of bladder and bowel incontinence.
 3. Develop devices to enable persons with cognitive limitations.
 4. Develop speech recognition systems to assist persons with dysarthric speech
 5. Information management and assessment – develop assessment tools for interpretation of continuous data from sensors. Data filters and selective combination will be an essential to using this flood of information.
 6. Assign responsibility and design integrated systems that encompass both living and health care. The separation of health care, housing, transportation, work environment and recreation from one another is an artificial distinction from the days of the hospital. This lack of cross talk is detrimental and must be overcome.
 7. Develop sensor technology (preferably non-invasive) that can validly and accurately measure the appropriate physiologic and behavioral status indicators for patients with chronic disease and disabilities. Such sensors should minimize the demands on the patient to perform monitoring specific tasks and should integrate completely with the patient's living environment. They should also conform to data generation and telecommunications standards that would promote inter-device communication and integration of data from diverse devices.
- b. In response to identified **barriers** –
 1. Survey consumers re their sources of information and determine how they would prefer to qualify the quality of the source.
 2. Develop qualified Internet portals for the information and consumer education in how to evaluate health care information.
 3. Educate professionals early in the process of technology development – CEU programs, Just-in-time information. All health care professionals should receive didactic and clinical experience in the delivery of care outside the health care institutions. Academic accreditation agencies should make this a required performance standard.
 4. Perform a “needs assessment” to evaluate the old infrastructure of daily living and determine the best means and costs of updating the infrastructure to meet the current and projected capabilities of technology.
 5. Open the discussion on the issue of privacy vs. access. Apply human factors technology to evaluate and understand the relative benefits and costs of “hands-on” vs. “at-a-distance” treatment.
 6. Restructure Medicare to support these therapeutic interventions. Broaden the “therapeutic environment” beyond the health care facility to include the home, the neighborhood and the entire community.

Topic E:
HUMAN FACTORS ENGINEERING
& USER-DRIVEN DEVICE DESIGN

Prepared by Co-Chairs:

John Gosbee, M.D., gosbee@ksms.msu.edu

Jim Grigsby, Ph.D., Univ. Colorado, Jim.Grigsby@uchsc.edu,

Participants:

Barrett Caldwell, Ph.D., Univ. Wisconsin, **Thomas Armstrong, Ph.D.**, , Univ. Michigan,

Jim Mueller; Chris Parmentier, CDRH, FDA

Ron Kaye, CDRH, FDA; Barry Beith, Ph.D., Vice Pres., Monterey Techn. Inc.,

Gerald Miller, Ph.D., Virginia Comm. Univ.; **Sunday Mezurashi**, Admin on Aging, HHS,

Elizabeth Hughes, R.N., Ph.D., School of Nursing, CUA; **Kathy Ladipo, J.D.**, NAMES

Co-participatory members from Group 4 (also Topic D, Chronic Conditions): Donald Marlowe (co-chair), Nell Armstrong, Earllaine Croarkin, Carol Haberman, Kelly Kirkpatrick, Joe Lane, Mark Pettinato

Co-participatory members from Group 5 (also Topic F, Smart Homes): Steve Warren (co-chair), Steve Bauer, John Bosma, Paula Josey, Cheryl Trepanier

INTRODUCTION

The discipline of human factors (HF) and ergonomics is best described by the mission statement of the Human Factors and Ergonomics Society:

The Society's mission is to promote the discovery and exchange of knowledge concerning the characteristics of human beings that are applicable to the design of systems and devices of all kinds.

The Society furthers serious consideration of knowledge about the assignment of appropriate functions for humans and machines, whether people serve as operators, maintainers, or users in the system. And, it advocates systematic use of such knowledge to achieve compatibility in the design of interactive systems of people, machines, and environments to ensure their effectiveness, safety, and ease of performance.

HF evolved as a discipline in the United States out of recognition of the need to maximize its safe and effective operation of military equipment. In the civilian sector, the design of aircraft has been the industry most influenced by HFE. This concern has expanded to consumer and industrial of equipment, including computer hardware and software. Unfortunately, the influence of HFE has been less noticeable in the design of medical devices.

This state of affairs has recently drawn the attention of the U.S. Food and Drug Administration (FDA) and the National Science Foundation (NSF). Failure to consider usability in the design and construction of medical devices has at times led to patient morbidity and mortality because the equipment was inadvertently used improperly. Such incidents are too often attributed to “human error,” and receive little attention beyond this. Yet there are significant constraints on human abilities to use medical equipment safely and effectively. This includes limits on cognitive capacities such as information processing, memory, reaction speed, behavioral control, perceptual, and motor abilities.

It is not sufficient simply to follow standard operating procedures; users also must be able to recognize and respond to irregularities and equipment failures. These are not trained professionals that normally perform these procedures. Instead, they represent a broad range of intellectual abilities and skill levels. Moreover, even the most efficient and capable human beings make mistakes regularly. Therefore, it is important that medical devices be designed in such a way that they are simple to use, thereby reducing the incidence of preventable errors, and that they are tolerant of the kinds of errors their users are likely to make.

The Working Group on Human Factors Engineering focused on the application of HF principles in the design of home health care technology. Because HFE is primarily a set of *processes*, our emphasis was on the procedures involved in design, rather than on specific equipment that might be useful for home health patients. The following is a summary of the discussion of the two subgroups assigned to this topic.

PROBABLE FUTURES

If history is a guide to future events, it seems likely that a structure for coordinating and regulating human factors engineering in the development of home health care technology *will not* develop spontaneously. The use of HFE in this area has been infrequent and inconsistent, and it is probable that some kind of direction will need to be provided by such agencies as the FDA if device manufacturers are to be expected to successfully incorporate human factors considerations, including specific techniques such as usability testing into the design process. Without some regulatory intervention, the application of HFE is liable to be sporadic, and primarily reactive to serious problems that arise in the routine use of specific medical devices, rather than proactively preventing these problems from occurring.

While advancing technologies such as wearable computers offer great potential, it may be more cost effective to manual technologies in many cases. Theoretically, cars can be operated by computers, but human drivers probably will be most cost-effective for the foreseeable future. Advancing technologies often can facilitate a task thus reducing the skill and training required to perform the task effectively. Human factors is of critical importance to the safe utilization of these technologies.

The development of wearable or implantable computer systems is already underway, and while few wearable systems are ready for clinical use, the feasibility of some such devices has been demonstrated. Examples of wearable systems applicable to clinical use include sensors for physiologic monitoring, such as the “smart T-shirt” developed by the Defense Advanced Research Projects Agency (DARPA) and used on a recent expedition to Mt. Everest, or wearable/implantable blood glucose monitors for individuals with diabetes. Mechanisms for the analysis and transmission of the data obtained from these systems can be incorporated with wearable sensors, allowing home health patients’ health status to be monitored remotely. Devices of this sort must be durable, reliable, easy to maintain, and simple enough to be used routinely by patients with a wide range of functional capacities, without generating such problems with their use as overreliance, or inadvertent misuse that would adversely affect patients’ health.

Another type of device that needs attention from HF engineers is the hands-free control device. These human-machine interfaces will permit persons with a wide range of disabilities to operate machines and perform a variety of tasks that are necessary to everyday functioning. Some preliminary research already has been done on input devices that are controlled by electromyographic (EMG) and electroencephalographic (EEG) means. Other input devices controlled by tracking eye movements, or by speech recognition technology, are also under development. Devices that offer this kind of assistance show considerable promise for individuals with spinal cord injuries or other nervous system disorders resulting in paralysis, but must be carefully designed in order to maximize their utility.

IDEAL VISION

In addition to these current and anticipated trends, the working group was interested in a number of possible future scenarios. Some of these will be discussed below in the Recommendations section of this report. Among these desirable outcomes were the following:

- The development and application of HFE methods in the context of health care technology should be encouraged. To date, HFE has made minimal contribution to health care equipment in general, and many of the devices now used in the home were designed for use by health care providers rather than patients and their families.
- The development of HF databases, metrics, and standards to be used in the design of home health equipment, and that could be useful in assessing the adequacy of its design, should be undertaken. These databases, metrics, and standards should focus on the cognitive, physiologic, physical, and perceptual issues that pertain to use of advanced home health care devices.
- The FDA and other appropriate agencies should promulgate policies, guidelines, and regulations that promote the consideration of HFE issues in the development of home health care equipment, to ensure the safety and effectiveness of these devices.
- Manufacturers should develop adaptive and appropriate automated systems that are designed with the needs of specific user populations in mind. This involves attention to the *process* of carefully defining and studying precise user needs (both patients and providers), of understanding the specific home health context in which the systems will be used, and testing the safety and effectiveness of devices as needed prior to seeking to make them available to the general public.
- Manufacturers should be encouraged to develop devices that support the functioning of individual patients in the home setting, and the use of which will be consistent with patient needs and lifestyles.
- If persons who receive home health care services are viewed by device manufacturers as *customers* rather than simply patients (i.e., as the ultimate purchasers who will make decisions about buying the manufacturers' products), manufacturers are more likely to incorporate an emphasis on usefulness and usability into the entire design and development process.

GAPS IN THE REQUISITE KNOWLEDGE BASE

Successful user-centered design of home health care equipment is dependent upon the acquisition of accurate information on the characteristics and capacities of the users (both providers and patients), the nature and processes involved in the tasks that are performed, and the different contexts in which these tasks must be accomplished. Such information is a *sine qua non* for appropriate design. While there is some general information of this kind available, it is not sufficient in quality or quantity to permit a careful analysis and specification of design parameters for most purposes.

Specifically, the knowledge base should be expanded in several areas. First, more information on the home care population, must be obtained. This currently is limited to demographics, diagnoses, type of service (e.g., skilled nursing, physical therapy), and frequency of services (although somewhat more detailed information may be available in association with an outcome-based quality improvement demonstration project currently underway and funded by the Health Care Financing Administration).

Members of different groups potentially having an interest in home health technology—including home health care providers, employees of federal agencies (e.g., FDA, NSF), designers of medical devices, and HF engineers—share too little common knowledge and perspective on these issues. Consequently, there is no shared set of concepts and terminology that would promote communication, and very little cooperation among them in the design and implementation of the equipment used in home care.

Most human factors engineers have little knowledge of home health care. The same holds true for most equipment designers. Many of the human factors problems we see are thus the result of failure to consider precisely how and where equipment will be used.

This is especially problematic because there are no systematic data available to HF engineers regarding the kinds of tasks performed in home health care by nurses, therapists, and patients themselves. The wide range of clinical conditions treated in the home, and the different processes of care for those conditions make it unlikely that an exhaustive database could be developed. Such a database might be developed, however, for more commonly treated chronic disorders (e.g., congestive heart failure, diabetes, arthritis), and for certain commonly occurring nursing and therapy tasks.

Finally, many different diagnostic instruments, monitors, and other devices are used in home health care. They are manufactured for specific purposes, by different companies, with little thought given to interoperability. This situation creates confusion and delays for users who must rely on these devices for assistance, treatment, or information. Moreover, most devices are not intended for use in conjunction with telecommunications technology. Telemedicine equipment developed for use in the home is liable to be incompatible with other such equipment, and with non-telemedicine devices.

OTHER BARRIERS

Members of the human factors work group identified several aspects of the status quo that represent barriers to the development of effective new home care technologies. The most important of these was thought to be the absence of a common set of HFE processes and procedures for use in the development of home care equipment. Consequently, developers and manufacturers lack a standardized set of processes to ensure that their equipment is safe, effective, and easy to use. In addition, manufacturers currently too often do not acknowledge a responsibility to ensure that their product is safe and effective when used by the intended users. Opportunities for unsafe or ineffective use of medical equipment may be the result.

Another major obstacle to the delivery of safe and effective technologies is the current lack of collaboration and cooperation among the various stakeholders associated with this kind of equipment. These parties include HF engineers; federal agencies such as the FDA and FCC; professional societies, such as the American Medical Association, American Telemedicine Association, or Association of Telemedicine Service Providers; consumer groups, manufacturers, and funding agencies such as NSF or the National Institutes of Health. These groups may in fact view themselves as adversaries. The same holds true for scientists, product designers, and manufacturers involved in the development of medical devices for home care. Even within a single device manufacturer, there may be conflicts over professional turf among engineers, marketers, human factors professionals (if present), and researchers that compromise the effectiveness of the equipment produced.

Finally, it frequently is the case that the process of design is conducted without adequately considering what will be required in the supply, maintenance, and repair of these devices. An otherwise useful piece of equipment thus may be impossible for a patient to maintain in the home without a good deal of assistance.

RECOMMENDATIONS

Although the working group discussed a number of recommendations that follow logically from the barriers and gaps in knowledge addressed above, a general consensus was reached concerning the following three strategic approaches to the problem.

- Of greatest importance is the development of reasonably comprehensive human factors databases, metrics, techniques, and standards that are applicable to home care devices. These would be used in the early stages of device design, and also would serve as benchmarks with which to assess the adequacy of equipment throughout the development process. Such databases could be placed on a server where they could be interrogated and updated as necessary. Techniques such as usability testing also could ensure that devices are safe and effective for users.
- It would likewise be beneficial to develop databases that contain information regarding the tasks and operating requirements of both present and anticipated home care technologies, equipment, and processes. For example, hands-free controllers are already available, at least on an experimental basis, but it is not entirely clear how they can be used to yield useful, effective, easy to use and mistake-proof home health care equipment. An important and unanswered question is whether the technology creates the needs, or the needs drive the technology. The answer is probably that causality operates in both directions, and such a

database (ideally web-based) will make it easier for the “technologist” to find applications for new technologies, as well as helping with the human factors. This should be web based as well.

- Finally, policy makers should explicitly encourage the development and application of human factors methods to the development of home health care equipment. The objective is to produce adaptive, appropriately automated devices that are designed for use in the home by specific user populations. For any given technology or piece of equipment, the needs of one subgroup of users (e.g., diabetics) may differ significantly from those of another (e.g., hemiparetic stroke patients).

Topic F:

Smart Health Care Systems and the Home of the Future

Prepared by Co-Chairs:

Atul Dighe, M.S., Inst. Alternative Futures, futurist@altfutures.com

Steve Warren, Ph.D., Sandia National Labs (now at Kansas State University)

Participants:

Michael Rosen, Ph.D., National Rehabilitation Hospital;

Paula Josey, R.N., M.S.N., Eastern AHEC, East Carolina University

Doug Hamilton, M.D., KRUG Life Sciences;

Kelly Kirkpatrick, Ph.D., White House OSTP, Technology Division

Eric Viirre, M.D., Ph.D. Univ. of Washington;

Cheryl Trepanier, Ph.D., National Rehabilitation Hospital

Deborah Birkmive-Peters, TAMC, U.S. Army, Hawaii;

Steve Bauer, Ph.D., RERC on Technology Transfer, Univ. of Buffalo

Joe Cleetus, Ph.D., Concurrent Engng Res. Cen., U. West Virginia;

John Bosma, Potomac Inst. For Policy Study

Co-participatory members from Group 5 (Human Factors): John Gosbee, M.D., Steve Bauer, Ph.D., John Bosma, Barrett Caldwell, Ph.D., Elizabeth Hughes, R.N., Ph.D., Ron Kaye, Gerald Miller, Ph.D., Jim Mueller

Co-participatory members from Group 6 (Therapeutic Applications): Corinna Lathan, Ph.D. (co-chair), Harry Asada, Ph.D., [Krista Coleman, PT, Ph.D.](#), [Mary Cupo](#), Neville Hogan, Ph.D., [Cathy Wassem, RN](#)

WORKING GROUP TOPIC

These thoughts, which relate to the implementation of smart health care devices in the home of the future, were generated through synergistic discussions in three workshop topic areas: human factors, smart devices (twice), and therapeutic applications in rehabilitation and virtual reality.

INTRODUCTION

Smart home care systems, by definition, would be capable of making contextual decisions regarding the state-of-health of individuals in the home. These intelligent systems could range anywhere from simple fall-detection alarms to full-blown systems that continuously monitor an individual's vital sign data, attempting to predict future health based on past and present health data. During the Smart Devices working group discussions, a distinction was made between "capable" devices and "smart" devices. Many leading-edge devices and systems (e.g., glucose monitors, chemical sensors, and desktop telehealth systems) are capable in that they provide health

information previously difficult to obtain, but they are not necessarily smart. The technology mechanisms for utilizing health information in truly automated, intelligent systems differentiate this workgroup topic from the other topics in the Future Home Care Technologies Workshop.

The two discussion sub-groups (Groups 5 and 6) approached this topic in slightly different ways. The first sub-group began their discussion with a general vision for how health care might be delivered in the home of the future. The role of smart health care technology was then rolled into this vision. The second sub-group focused their initial discussion on smart homes of the future, including services that would be provided and the technologies that would deliver those services. When the results of the individual discussion groups were merged into an overall summary listing, four primary vision statements emerged. These vision statements comprise the core of this group report. Note that the discussion groups did not initially break every vision statement into categories of “probable” versus “ideal.” Rather, emphasis was primarily placed on the desired vision, with the knowledge that some capabilities were less probable than others.

The following editorial sections compare the probable future with the proposed ideal future. These thoughts assume that the probable future will take place given current telehealth technology trends, while the ideal future will only occur if the telehealth research and development community addresses specific gaps in knowledge and other barriers. Therefore, the overriding recommendations at the end of this report focus on areas that should be addressed in order to attain the ideal vision.

PROBABLE AND DESIRED FUTURES

The four primary vision statements for home health care identified by the Smart Devices working group were similar for both the probable (anticipated) and ideal (desired) future. The probable and ideal futures for the next ten years differ in scope, or the degree to which these visions will be realized.

Several current market trends will drive this future:

- the realization of high-performance computer networks in the home through industry initiatives targeting distributed computing,
- increasingly capable desktop telehealth systems,
- greater internet access to health information,
- the health care industry’s migration to electronic patient records,
- emerging standards for medical information exchange and device interconnectivity, and
- a growing number of enabling technologies, including novel biosensors, wearable devices, and intelligent software agents.

The impact of these market trends will vary depending on which classes of technology are targeted for substantial government/industry funding over the next ten years. In the following vision statements, the *anticipated* future for home health care based on a conservative interpretation of present technology trends. The *ideal* visions are worded more strongly and are indicative of a high-payoff home care environment enabled by overcoming the knowledge gaps and barriers stated in this report. The four vision statements for the ideal future are the following:

F1: Proactive, Preventative Health Care Delivery

We anticipate that health care will migrate to a more proactive, preventative care delivery model compared with the reactive, episodic care delivery model utilized today. Desktop telehealth units and limited numbers of wearable sensors (e.g., heart rate monitors, fall detectors) will enable semi-continuous state-of-health monitoring. Some intelligence will be built into these systems, such as software/hardware modules that can detect an emergency event and send an alert to a care provider or emergency call center.

While utilization of home care technology will increase over the next ten years, health care professionals will continue to make most of the care decisions based on analysis of these data: automated care decisions will be limited in number. This preventative health care model will rely on

- lifestyle management tools, including medication compliance products,
- internet access to health information,
- public education regarding healthy living, and
- tools that identify early indicators of upcoming health problems.

In this scenario, health maintenance organizations will drive the development and acceptance of home health care technology that has been shown to demonstrate superior cost-benefit ratios.

We desire that health care will migrate to a highly proactive, preventative model that is vastly different from the reactive, episodic care delivery model utilized today. In this scenario, non-invasive, intelligent wearable and remote sensors will continuously record individuals' physiological data, and home care systems will predict their future state of health based on past and present data. These predictive algorithms will utilize geographically distributed medical knowledge repositories, and alarm mechanisms will denote adverse events detected by these systems. Because of the huge volume of data generated by these continuous acquisition systems, trend data analysis tools and information reduction algorithms for avoiding patient/provider information overload will proliferate.

F-2: Information Technology and Customized Care Delivery Systems

We anticipate that a variety of market-directed health care and information technologies will permeate the home environment. Home care systems will be assembled/configured to meet individuals' needs, but direct interaction of these systems with electronic patient records (EPR's) will be hampered by the need for role-based information security tools that adequately protect patient confidentiality and the integrity of the associated electronic medical information. As security tools proliferate, hackers will develop methods for counter-acting those protections. Device design standards for interoperability, security, plug-and-play, and information exchange will continue to emerge, but their adoption will be slow due to the competing business priorities of telehealth equipment manufacturers.

We anticipate that most home-based telehealth systems will be similar in nature to the monolithic, single-vendor solutions provided today because of (1) a lack of information frameworks and standards that promote plug-and-play device interoperability and (2) the current way in which the Food and Drug Administration approves medical devices. Mechanisms do not yet exist to approve generic devices / peripherals (medical or otherwise) based on the roles they assume in a system. For example, an LCD display intended for use by palm pilot computers may not be certified for use in a vital sign acquisition device. If this display, designed with current technology, is purchased off-the-shelf as a commodity item, the display will not know enough about itself to approve/disapprove its use in a given scenario. Until on-board, role-based device approvals can be realized, "virtual care devices" (possibly distributed) composed of commodity components will not integrate themselves into the home.

We desire that a variety of highly advanced, market-directed health care and information technologies will permeate the home environment. Home care systems will be assembled on-the-fly and configured to meet the special needs of every individual in the home. These devices and systems will interact directly with electronic patient records (EPR's) inside and outside the home through high-bandwidth communication mechanisms, where EPR data will provide context for decisions made by smart home care devices and systems. This will be facilitated by robust standards for interoperability, security, information storage/exchange, and device interconnectivity. These intelligent systems will be inexpensive and rely on commodity, commercial-off-the-shelf technology purchased at discount stores. Health care devices and systems will use home-based information infrastructures also utilized by smart appliances and other home automation technologies.

In this future environment, sensors and actuators will be distributed on a person as well as in the person's environment: both inside and outside the home. These sensors, health-related and otherwise, will exhibit a collective intelligence, with each sensor aware of its own role in the integrated system. Information surety (security, integrity, reliability, safety, and availability) mechanisms such as novel biometrics and role-based access controls will be key to this active interchange between devices and EPR's. In order to ensure safe and reliable operation of the myriad configurations of home health equipment created from plug-and-play components, each component device will be self-aware to the extent that it knows, prior to its addition to the system

- what it can do,
- how it may be used, and
- what care scenarios it can support.

Devices that are not approved by the FDA for certain contexts will not allow themselves to be used in these home care systems.

F-3: Universal Design and Standardization

We anticipate that universal design and standardization will begin to facilitate flexible configuration of home technologies for special needs. While these custom environments will be expensive relative to the environments that serve the needs of the general population, standards for device/system interoperability and information exchange will drive costs down. An emphasis on human factors will help to guide development of truly useful assistive technology that promotes cost-effective independent living. Based upon the growing understanding that the home environment can actually contribute to patient wellness, the elder care market will investigate technology that promotes independent living as an alternative to the resource-intensive assisted living arrangements commonly utilized today.

We desire that universal design and standardization will facilitate cost-effective, flexible configuration of home technologies for special needs. Independent living will be fully realized by special needs groups that can benefit from assistive technologies and resources. The cost of these systems will be reasonable, since they will be constructed with commodity technologies that adhere to universal design standards.

F-4: The More Active Care Role of Individuals

We anticipate that individuals will assume a more active role in their health care. This personal care role will rely on the same technologies that enable preventative care and lifestyle management today: internet access to health information and public education regarding healthy living. Building on trends started in the late 1990s, individuals will continue to download relevant health information and enter into informed dialogue with health care providers regarding diagnosis and treatment options. Legislation will empower individuals to control access to their medical information by caregivers and other entities.

We desire that individuals will assume a much more active role in their own health care, essentially becoming a member of their own primary care provider team. To support this role, mechanistic processes such as vital sign acquisition will be automated in home care systems, and simple/low-risk care decisions will be made by devices and systems that complement the limited medical knowledge of the average person in the home. Intelligent agents will assist individuals in this care delivery process. Collective intelligence algorithms will proliferate in this environment, accessing geographically dispersed medical information. Individuals will be ultimately empowered to control access to their medical information by caregivers, automated health maintenance systems, and other entities.

KNOWLEDGE GAPS

In order to realize the ideal vision stated in the previous section, government and industry must address certain gaps in knowledge: core subject areas where research and development is needed either in hard science, soft science, or policy. This section lists the gaps in knowledge identified by the Smart Devices working group, beginning with the areas identified as the most important and continuing in decreasing order of priority. The general technology areas that encapsulate these gaps in knowledge include the following:

F-1: Information Reduction Algorithms and Sense-Making Tools. Information reduction algorithms and sense-making tools are needed that can digest the huge quantities of information generated by continuous state-of-health monitoring equipment in the home. These tools will enable (1) automated, objective analysis of health data and (2) identification of data/interactions relevant to the physiological state of the individuals in the home. Human modeling and data fusion will be key to the success of these algorithms. These algorithms and tools must support changes in diagnosis criteria (e.g., psychiatric disorder diagnoses derived from new behavior monitoring) as well as surrogate diagnoses that have yet to be realized.

F-2: Device Usability and Reliability. Device usability and reliability, including the broad area of human factors, is a substantial area of need that must be addressed before the ideal vision of home health care can be realized. Knowledge gaps that must be overcome include

1. behavioral science for automation and semi-automation,
2. established levels of technology dependency and the effects of that dependency (e.g. during loss of function),
3. device-user interaction, and
4. methods for complete testing and debugging of prototypical systems in simulated and real environments prior to public release.

F-3: Wearable Devices and Remote Monitoring Technology. Before continuous data acquisition in the home can be realized, equipment designers must understand (1) the data generated by wearable devices and remote monitors and (2) the hardware and software necessary to realize these devices, including data processing algorithms for reduction of motion artifact and extraction of new state-of-health indicators. This environment will require the development of reliable, self-calibrating, long-lasting, and unobtrusive sensors enabled by enhancements in (a) storage algorithms, (b) low-power processing, and (c) battery technology.

Other Barriers

The Smart Devices working group identified additional hindrances to the optimal realization of smart, automated health care delivery in the home. These include the following, listed in order from highest to lowest priority:

F-1: Infrastructure. “Infrastructure” is a broad term that encapsulates all underlying information exchange functionality necessary to enable a mass networked, fully distributed healthcare information enterprise. This includes computation and communication mechanisms available to smart devices in the home: the fundamental connectivity to make contextual decision making feasible. It is not clear that current communication modalities (phone lines, cable TV lines, etc), home automation tools, and internet capabilities will be adequate for the needs of future home health information systems. First, these capabilities do not fully address the need for distributed computing and access to resources from anywhere in the home. Second, the rates at which these communication mechanisms transfer information may not be adequate for fully-automated, smart devices; especially those devices that require real-time access to image-intensive, external information repositories and knowledge databases.

For truly automated, smart health care delivery in the home to succeed, high-surety, component-based information frameworks (similar to an operating system in a personal computer) must exist in order for components to interact with one another in a meaningful way. Development of all-encompassing,

component-based information architectures is difficult with current technology because of the specific implementation needs of individual devices operating in myriad care scenarios. Interoperability standards do not exist that promote full interconnectivity and secure operation between devices from different manufacturers. These standards and frameworks are prerequisites for realizing smart devices/systems and distributed, “virtual” systems demonstrating collective intelligence.

- F-2: Information Repositories and Their Utilization.** Few medical information repositories exist that contain data comprising a useful knowledge base for smart decision-making. Knowledge assimilation algorithms and processing techniques that utilize these data are immature. In addition, protocols and algorithms that reproduce or emulate a physician’s decision-making process have not reached acceptable levels of clinical effectiveness to be considered useful in an automated home care environment.
- F-3: Reimbursement.** An acceptable reimbursement policy for smart home-based health care delivery does not exist. However, home health technology will not be reimbursed until it is proven to be reliable, safe, effective, low-cost, and secure. Because (a) reimbursement depends on technology development and (b) one financial driver for technology development is reimbursement itself, government can help to mitigate this barrier by providing reimbursement resources for a limited time until the market stabilizes under normal supply and demand forces.
- F-4: Information Overload.** Humans have inherent limitations regarding the amount of information they can process. With the advent of continuous state-of-health monitoring and potentially life-long electronic patient records, quantities of electronic medical information relevant to care decisions will be unprecedented. Present medical information reduction tools are inadequate for the home care setting because the information is not suitable for all stakeholders.
- F-5: Dialogue** -- Lack of effective dialogue between care providers, scientists/engineers, manufacturers, and end users leads to poorly defined requirements for medical systems, making these systems ineffective in many care scenarios.

RECOMMENDATIONS

In order to achieve the ideal vision for smart home care systems, the Smart Devices working group put forth recommendations in three categories:

F-1: Utilization of Large Amounts of Data

Fund research for intelligent processing of large amounts of data, including (1) knowledge assimilation techniques required to optimize the effectiveness of care decisions, (2) information reduction tools for avoiding patient/provider information overload, and (3) data mining tools for acquiring relevant data from distributed repositories. In a proactive/preventative care model, continuous data acquisition will generate unprecedented amounts of electronic medical information. These data must be effectively reduced to support clinically appropriate decisions. This focus area includes algorithms for sensor data fusion, automated diagnoses based on those data, and data “flags” for noting health conditions that merit follow-up. Work of a similar nature is being successfully addressed in other arenas, such as the manufacturing automation and automobile industries.

F-2: Working Groups

Fund working groups that focus on information architecture issues, gaps in interoperability standards, and other areas that the government should promote that are not being fully addressed by industry. Current standards do not adequately promote plug-and-play interconnectivity between devices from different manufacturers that will ultimately be available off-the-shelf, limiting both the functionality and the ultimate cost-effectiveness of these home care systems. In addition, practical standards (e.g., role-based security standards) do not exist that promote wide adoption of intelligent home care technologies. This lowers the probability of reimbursement for these home care procedures and limits the economy of scale that would drive down the cost of automated, smart home care devices and systems.

F-3: Wearable Devices and Remote Sensors

Focus funding on advanced non-invasive wearable devices and remote sensors. These devices must incorporate high-reliability components, possibly utilize multiple capabilities on single hybrid platforms, be self-aware, and know the identity of the individuals from whom they acquire data. Wearable devices must be lightweight, unobtrusive, and low-power. Once these devices are in place, continuous data acquisition in the home and the accompanying trend analyses will be feasible.

Topic G

Therapeutic Applications

Prepared by Co-Chairs:

Alexandra Enders, O.T.R., University of Montana enders@selway.umt.edu

Corinna Lathan, Ph.D., Catholic University of America, lathan@cua.edu

Participants:

Bill Peterson, M.S.E., Program Officer, NIDRR;

Neville Hogan, Ph.D., Dept. Mechanical Engng., MIT

Jim Barry, NY/Bell Atlantic; **Mary Cupo**, VA R&D, Baltimore

Alfred Gilman, Washington; **Cathy Wassem**, RN, Office Advancement of Telehealth, Rockville

Linda Botten, O.T., Montana; **Harry Asada**, Ph.D., Mech Engng, MIT

Lou Quatrano, Ph.D., National Center for Medical Rehab. Research, NIH;

Krista Coleman, PT, Ph.D., Enhanced Mobility Techn., Minnesota

Helen Bozzo, R.N., Washington; **Scott Selbie**, Ph.D, Rockville

Co-participatory from Group 6: (also Topic F, Smart Health Devices and Home of the Future): Atul Dighe, MA (co-chair), Deborah Birkmire-Peters, Ph.D., Doug Hamilton, MD, Michael Rosen, Ph.D., Michael Tracy, M.B.E., Eric Viirre, MD, Ph.D.

Co-participatory from Group 7 (also Topic H, International Rehab: Developing Countries): Nigel Shapcott; (co-chair), Roxanne Hauber; Robert Jaeger; Brian Kon; Scott Selbie; William K. Smith.

INTRODUCTION

Home care environments of the future will be increasingly driven by available technologies, especially when home is defined as “anything outside a health care facility”. Trends evident since the 1980’s already show that the use of technology in home care is increasing. Longino reports that

“.... the use of assistive devices and housing modifications is rising sharply, while the long-term use of personal assistants alone is declining significantly. Greater residential independence, combined with the development and use of personal-assistance technologies, seem to be part of a modern elderly person’s long term adaptive process. Unless there is some kind of interdependence that preserves self-respect and self-determination, dependency on family members or others will be a far less attractive alternative than technically supported self-care for those who can afford it.” (p.41) (“Myths of an Aging America”, Charles F. Longino, Jr. , *American Demographics*, August 1994, pp 36-43)

In order to reap potential societal benefits of emerging technology in “home care”, all of the stakeholders must be involved early in the identification and development of technology. The health system will continue to shift, as it gets ready for the increase in demand by aging baby boomers. Both the individuals who are going to actually use the new technology (consumers, health care professionals, and informal caregivers, etc) as well as the gatekeepers and reimbursement decision-makers (consumers, private and public health care financing

systems, etc) will drive the system components and configurations more than the actual availability of technology. Technology advances are more likely to come from mass market demand, and their health care applicability and potential may need to be creatively enhanced. Targeted and focused applications for more specialized HCT category sub-groups may need to be subsidized, especially in the early stages of R&D.

The orientation toward future potential and therapeutic applications resulted in this group being able to take a longer range view about both the health services environment and the technology itself. The technological emphasis on the more futuristic applications of Virtual Reality and Robotics also had input from the Smart Health Devices and Home of the Future group. The Future Potential for Therapeutic Applications group, strongly oriented to practitioners, especially to rehabilitation practitioners, also had input from the experts involved with Developing Countries: International Rehabilitation and Health. Self-management was included as one aspect of the technology-driven home care environment of the future. All participants, whether acknowledging it or not, also represented the self-managed home care consumer of the future. The subgroup which focused on the health services environment spent scant attention to specific technologies, assuming that the technology needed would be available if the service systems issues were appropriately addressed. Their primary technological concern was focused on software, expert systems, and other information oriented technologies.

Therapeutic applications are generally thought of as being discrete interventions that prevent or remediate the effects of a disease or pathology; address an impairment that results in a limitation of one or more activities of daily living; prevent a secondary condition; and/or facilitate wellness and health. Therapeutic applications can be focused on the body at the structural level, at the level of an individual's ability to perform daily activities, or on the person's participation in their environment. Self-management, including self-monitoring, plays an essential role in therapeutic roles, whether the interventions are self-directed, performed by unpaid caregivers, or administered by paid professionals, in person or at a distance. Therapeutic applications involve not just the physical and sensory aspects of an individual, but also developmental, cognitive and psychosocial functioning.

Virtual Reality generally refers to a simulated visual environment. However, a virtual environment can also simulate other modalities such as smell, touch, and sound. The development of relatively low-cost virtual reality technology has been driven by the entertainment industry. VR has potential as an effective interface for care and self-management since it provides a 3-D, multisensory, interactive environment that can be customized and manipulated to meet an individual's needs, interests, and preferred learning modes. **Robotics** refers to devices that can take input, process it, and do something with it. **Actuators** (e.g. motors) enable interaction with objects. Robotic enhancement of living includes both physical interaction with a patient as well as service oriented robots. Robotics can let therapists shape various degrees of freedom (axes of motion) simultaneously and provide mobility while working in an appropriate range of motion.

Exemplars refers to applications of cutting edge technology that are put into the community as examples of how the technology could be used. For example, computer technology was driven by the fact that people saw the technology and thought of great things to do with it!

The same concept can be applied to professional development, in which case it would be: a practice settings which serve as a demonstration sites where practitioners and students can get hands-on practical experience working in technologically-enhanced environments which will become routine in the future, but are exceptional today.

In both cases, the medium is the message: familiarity with using technology increases acceptability of technology as a useful, desirable, non-threatening tool. (And it can identify undesirable or inefficient features which can then be redesigned early in a product lifecycle)

PROBABLE FUTURES

Person-Environment Fit

The traditional perspective has been to use technology to either fix people, or to fix environments. Better joints and implant glue, better drugs, better pumps and pacemakers. Remove the steps, make buses kneel, install an elevator, take out a few movie seats and add a level platform. (Note that these more accessible environments will also enhance robotic mobility.)

In the medical model, we have traditionally viewed the purpose of technology as fixing the individual. Rehabilitation systems have had difficulty pushing the entrenched “fix it” concept to include the improvement of function, within the mechanistic bias of today’s reimbursement models. For example, Medicare will pay for a cochlear implant, which replaces a defective body part, but will not pay for a hearing aid which does not replace a part, but does improve the function of hearing. Most of the exciting advances in “fixing people” will probably come from molecular medicine and the other 5 areas included in the Future Trends in Medical Devices Technology paper. (FDA, 4/98) Functional restoration and maintenance will be a mainstay of what is being called “home care technologies”, and much of the audience will be individuals of all ages with chronic conditions. The health/wellness market will also drive the system. However the majority of these technologies will most likely fall outside the purview of the traditional medical community, and are likely to be outside the regulatory oversight of agencies like the FDA, since claims are not being made for medical efficacy.

Traditional strategies of fixing people and fixing environments, both overlook the essential issue of the person-environment interaction. HCT device designers and therapy systems change agents will be forced to look more closely at this interaction level for two basic reasons: [1] to meet the demand for outcomes based reimbursement in a health care environment, and [2] to address the realities of converging mass market technologies. Distribution in the new information-telecommunications-entertainment technologies convergence is active, not passive, and will have interactivity built into its basic infrastructure. Mass market technology portability will also be a force for understanding that “home care” is not just something done at home. And will have a significant impact both on the environments the devices/systems will be designed for, as well as on the types of personnel trained to use HCT as effective therapeutic tools.

Further, the applications we are discussing through the euphemism “home care technologies” are not going to stay in the traditional categories. Technology will bring us smart houses, which will incorporate features that allow non-health products to perform health related functions. Integrated control of lights, multi-media, appliances, lends itself well to interfaces for monitoring and sensing health related issues. If today, you can voluntarily put your house onto a web camera, and let the world view your every move throughout the day, the same technology can be used for surveillance, monitoring, compliance, etc. (The ethical issues of whether surveillance is voluntary or not, are addressed in another report.) A family member might prefer to monitor an elderly relative, live and online video, rather than just getting reports of toilet flush counts, and refrigerator door closures. Video surveillance is possible today! And will be even easier in the future. Choice and control will become critical issues in the development, deployment and reimbursement of new technologies. Who is “watching” will be a powerful driver of what and how the monitoring is done, who pays for it, and how the data is used.

Some Specific Technology Trends:

- In the next five to ten years, we can expect technological advances in instrumentation and sensing, simple actuation, and data-basing. For example, our beds, chairs, shoes, etc. will actively monitor our behaviors, smart bathrooms will analyze aspects of our health, service robots and smart ambulation aids will become readily available.
- Virtual reality will go beyond vision to include high fidelity sound and olfactory sensing. Home self-therapy will use low dimensional actuators such as joysticks with force feedback. We will add actuation to home assessment.
- Telecommunications devices and customer premise equipment will be manufactured with built in, integrated accessibility designed into the products (sec 255 of the Telecom Act mandates this) Universal design will become a part of good manufacturing practice in telecom, and information technologies. (IT, for federal purchasers, is covered by sec 508 of the Rehabilitation Act)
- The next stage, ten year and beyond will include higher dimensional actuation, integrated databases, and smarter aids. High tech haptic (sense of touch) interfaces will evolve. Multi-axis (many degrees of freedom, eg. extension and supination) therapy will be available.

Services/System Trends

Professionals and health care consumers will become both more and less receptive to using transparent (unobtrusive) technology tools that are automated and easy to use. The smart toilet which can monitor chemical balances and make diagnoses may be years away, but raises serious ethical questions about confidentiality and access to data.

In “Improved Care for Diabetic Populations: The Need for Telehealthcare and Alternatives to Conventional Care Services” Kinsella raises the issue of the redefinition of team membership, when she asserts that as easy to use technologies are developed to assist diabetics in the mundane but necessary daily tasks of self care and self management, “the home care “team” may very well be the diabetic, his or her glucometers and educational technologies, engineers, and offsite clinicians who have worked together to customize the technical and educational tools to make self care a successful undertaking.” Needless to say, including the technology as a team member, and not just as a tool like the stethoscope, will raise the level of concern in the therapy community! This brings up the larger fear that certain technologies (e.g. expert systems) will be used to replace clinicians (or at least cut them off from reimbursement), rather than augment and enhance therapeutic activities. And that the mechanization of routine tasks will mean the end of person-to person interaction. *Acknowledging and actively working to reduce the perceived threat posed by technology is an essential aspect of integrating technology efficiencies into home care.*

Professional Development

The roles of therapists are changing, largely driven by reimbursement patterns and practices. Role re-definition will be greatly impacted by the development and availability of technology which can perform many of the routine tasks currently being done by skilled therapists. Incentives will be needed for “re-tooling” therapists to take a pro-active and positive role in the development of new technology driven systems, as their roles change from the professionals during the routine tasks, to the professionals doing the assessment, therapy design and monitoring, and case management activities. If positive and engaging strategies are not developed to include therapists in all phases from technology design and development to system implementation, there is likely to be considerable resistance to early adoption and use of technology enhanced home care systems. Just as pharmacists will be moving beyond the role of pill dispensers, therapists must move beyond routine tasks which could be more efficiently performed either with technology, or by supervising someone less skilled coupled with technology assistance, e.g. monitoring.

There are incentives for patients and payers which could be developed during the transition period to technology enhanced therapy. For example, the patient could receive a cash payment of a designated percentage of what would have otherwise been spent on conventional therapy sessions. The scenario could be: in the current model, therapy is prescribed to achieve a measurable goal (e.g. increase in strength, range of motion, dexterity) therapist makes assessment, designs therapeutic intervention, works one-to-one in repeated therapy sessions over time. Therapist is paid for professional services whether goal is achieved or not. Patient receives benefit of outcome being achieved. In a new technology driven model: the system would be similar through the stage of the design of therapeutic intervention. In the foreseeable future, it will be possible to use an individualized computerized therapy program, which includes sensing and monitoring technology. Patient performs therapy in the environment of his/her choice (home, gym, clinic, etc) as guided and monitored by computer driven system. Therapist reviews progress on a regular basis, and performs post-therapy documentation. Therapist is paid for professional services (assessment, therapy design and monitoring) whether goal is achieved or not. Patient receives benefit of outcome achieved, plus a designated percentage of cost savings.

IDEAL VISION

It seems most obvious to focus “vision” on specific technology applications, especially those which piggyback with mass market products, reducing costs, increasing efficiency, improving efficacy. However, the underlying driving forces primarily lie outside the technology – in market forces, profitability factors, and information flow. And consideration must be included for the emerging paradigm which moves from a “care” based model to one of a continuum of independence and personal choice, which takes person-environment interactivity into account, and re-draws the boundaries of health and wellness.

Technology

- Technology will help achieve therapeutic goals by enhancing the continuum of care and patient management, including self-management, and by facilitating the extension of care strategies and effective management into the community.
- Smart appliances and personal support technologies will permeate society providing a distributed means of supporting all persons. For example, a virtual reality or robot based system could go home (school, work, etc) with an individual and do data acquisition, assessment, integrate with a database, and assist in self-management and self-monitoring. Particular systems we see developing are automated data acquisition analysis and reporting and platforms for instrumentation/actuation.
- In-home smart devices and enabling technologies will automatically acquire, analyze and report back to the user as well as to other individuals or devices/systems. The *distributed technologies* will provide *local medical decision making* and will alert the user to present and potential medical needs prompting the user with various options and recommendations designed to optimize health and wellness. Distributed personal support and enabling technologies will be able to automatically provide information back to a *central medical site* for more detailed monitoring of the user and to provide interventions as needed. Automated information acquisition and analysis coupled with the reporting capability of the distributed technologies

will facilitate and support continuing studies of the impact of HCTs on the user (*outcomes studies*)

- Personal robots may become our eyes and ears extending "mobility" and interaction with the environment, possibly even changing what are thought of as robotics by becoming more like "pets." Smart canes may help with navigation and smart chairs or beds may adjust to prevent pressure sores.
- All home therapeutic devices at all stages of development (design, prototype, manufacture) have POTS (plain old telephone services) interrogatable use monitors. The devices should be able to objectively tell you if it is being used, how when, where, over traditional telecommunications transmissions lines

Market Forces: Consumers and Professionals

- Professionals and consumers will be receptive to and prepared for the transparent use of HCT tools. Transparent means that the technology will be unobtrusive, and fade into the background. It will not interfere with person-to-person relationships, allowing the focus to be on the therapeutic, caring process.
- There will be systematic efforts to put exemplar technologies in place so that appropriate tasks and uses for emerging technologies enhanced HVT can develop (a technology "pull"); consumers can develop a comfort level with technology as an element of their health care team; and professionals can be adequately prepared (at both pre-service and inservice levels) to practice in more technology enhanced environments. (Deploying exemplar technologies in a range of settings will allow students to be able to do internships in technology enriched practice settings -- without these settings, their exposure, experience, and acceptance will be negligible)
- There will be increased communication and collaboration to increase the information flow among engineers/designers, clinicians, consumers, and policymakers. Clinicians will be involved in the R&D process from the initial stages, to both shape the technologies, and to become familiar and comfortable with technological potential for innovation.
- Expertise will be decentralized and customized rather than concentrated in resource rich urban area to create better equity and individualized access to care.

Information

- Information production and access will be a bi-directional process. Health care consumers and providers/suppliers will both be involved in the creation of knowledge. Mass market technology convergence will support interactive information sharing, and move society away from the traditional top-down, one way flow of information that has existed in the formal health care field.
- Health care consumers and providers will both have access to timely, accurate, affordable information, from multiple sources and in appropriate formats (cultural, language, alternative format, etc)
- The role of the health professional as the gatekeeper of health information will diminish, but their roles as interpreters, synthesizers will increase. Value-added will be redefined.
- Confidentiality issues will be appropriately addressed, although focus may need to be redirected toward patient protections (along the lines of the Americans with Disabilities Act), since a totally secure system for patient records seems unlikely. If we cannot safeguard the data, then safeguard people from being harmed by inappropriate use of the information.

KNOWLEDGE GAPS

The knowledge base for HCT tools and the personnel using it need to be developed in parallel. The following are some of the major knowledge gaps which need to be addressed in order to develop a system which promotes technology-enhanced home health care.

Technology Knowledge Gaps

- G-1. ***Quantification of functional activities*** is required to provide framework for the development of "smart" devices and serve assistance technologies. Current tools are too crude. Technical issues in developing good quantification tools revolve around research needed to identify measures and tools that reflect human performance. We need to understand how functional performance is derived from basic motor and sensory capabilities. Unfortunately, we need good measurement tools, but we don't know what we need to measure. (eg. How do you convince someone there are microbes without a microscope? Then how do you evaluate a microscopes ability to detect microbes?)
- G-2. ***Actuator Development***. Actuators are physical (hardware) component that can act on the user of the environment. Current actuator technology is inadequate to meet the enabling (assisting) home and self-care needs and desires of clinicians and consumers. To accommodate the integration of health care into home and community, novel actuator technology will have to be created. There is a tremendous gap between actuator technology and sensor technology. Improved actuator technology is required to facilitate development of enabling technology beyond the single axis type movements.
- G-3. ***Development of structured models of human processing and performance***. These models need to include methods of characterizing input to the human from the environment, how the human processes the data, and how the information is acted upon. Some of the challenges include characterizing virtual reality stimulus and quantifying human responses. Multi-scale modeling is important, (eg. environmental as well as muscular level models).
- G-4. ***To extend the continuum of care, a system should be developed for automated acquisition and analysis of information from and to the user***. Consumers and clinicians should be able to easily apply the technological devices. The devices must be robust, self-monitoring, self-maintaining. Technology should support the individual without being intrusive or disruptive (transparent). Functional performance assessments must include all aspects of home and community life so that complete integration of technology and health care is achieved.

Systems/Process Knowledge Gaps

Systematic identification of appropriate, efficient, and effective technology enhanced health care practices. Research in this area needs to be geared not only toward development and identification of best practices, but also toward facilitating adoption by reimbursement decision-makers, and legislation where appropriate.

Including users in the development of technologies may provide a greater inherent acceptance of the technology. Interplay between the various parties involved in co-designing new technologies should be facilitated at all stages of work. Professional and societal attitudes need to be changed to support the philosophy that technology will not replace, but will supplement, extend, and enhance the professionals' interaction with their patients.

Personnel Preparation and Training

Professionals and consumers need to be prepared and receptive to using HCT tools that function as an integral part of the health care team. Knowledge is needed in order to redefining core competencies, practice models, curricula. Many therapists have not made the conceptual shift away from doing the routine tasks, and instead functioning as managers or coordinators. Nursing education has begun to make this shift. Other professionals need to make a similar shift, as well as how to effectively practice in a technology enhanced environment.

OTHER BARRIERS

Barriers related to low-volume market problems (orphan technologies), societal acceptance, lack of communication and collaboration between consumers, clinicians and engineers, and lack of process outcomes measures–efficacy/standards (treatment, education) have been elaborated on elsewhere in this report. Profitability has to be factored into the equation, whether the barriers are related to low-volume domestic market problems (orphan technologies) or to the international harmonization of standards in order to sell a standard product in a worldwide market.

G-1: Reimbursement. Many of the issues in HCT are similar to those which also pose barriers in telemedicine reimbursement, telehome care and telerehab issues should be brought into the telemedicine debates. For example, currently therapists are not included in discussions for telemedicine reimbursement because therapists do not have consultative procedure codes (i.e. therapists cannot currently bill Medicare for consultation). Changing procedure codes and controlled vocabularies in reimbursement/terminology- is a lengthy process which makes it very slow for introducing new treatments approaches.

G-2: Product Standards. Standardization among the technologies especially in the area of functional requirements (e.g., convergence of telecommunications, entertainment, and information technologies).

Uncertainties about regulation. Who has authority and responsibility? FDA? FCC? What is the scope and coverage? Mass market companies are unlikely to incorporate standard features into product, if they believe the FDA may require oversight of that component, system, or the entire product. This will make piggybacking HCT onto mass market products difficult. Without piggybacked device applications, HCT will be exponentially more expensive. Regulatory uncertainties are disincentives. FDA has jurisdiction over medical software and hardware. Does this provide a safeguard or does it significantly limit changes? Where does the line get drawn for fail safe systems and built in redundancy, when a product, designed and sold as a game, is used for a more critical role in monitoring or measuring?. Science fiction stories abound that are founded on a fear of technology run amok. The question of sentient technology – the so-called “smart devices”, especially smart devices that have robotic mobility, has figured prominently in science fiction’s dark utopias.

The blending of alternative medicine with smart houses brings images of aromatherapy being automated into house functions, programming release of relaxing scents in certain spaces at preprogrammed times, and invigorating scents in other spaces and time intervals. So, what will keep aerosol drugs being administered the same way? And where are the safe guards, fail safe systems, etc for release of more powerful substances being applied as medical treatment, when the technology fails (as it always does, and usually the day before a holiday, when it is impossible to get a repair service or new part). It seems the FDA would want to have something to say about this. And magnets, that are appearing everywhere: shoes, braces, beds, necklaces – what happens when they appear in the floor and the furniture, or when the house programs the electromagnetic current for therapeutic purposes (e.g., in the bidet, for hemorrhoid treatments) This kind of pseudo-health care technology will reach a new level of possibility when combined with smart house functions, and the baby boomers insatiable appetite for things that keep us young and healthy. Does the FDA have oversight responsibility for home exercise equipment? Do they have to comply with any type of safety standard when used outside the clinic, or in the gym? How about the gym in the workplace?

Having already brought the gym home (and sometimes to the office), now we are bringing the hospital and the clinic home too. And how will we know these things are safe? Will there be a UL type label? Where does a medical claim begin, one that would cause the FDA to take notice? Where will the lines be drawn about what is “medical”? If we follow health care reimbursement patterns and practices, it could easily be drawn at literally fixing the person. Then most of the stuff outside the “hospital at home” scenario, has no oversight.

There is a huge market for technology that promises youth and continued function – and it usually isn’t covered by health insurance. But it will be there, because baby boomers generation will demand it and pay for it. Where is the assurance it will be safe and sturdy? How do we incorporate these technologies into the systems that may be more traditionally “health and health care” related. When people have vacuum cleaners with HEPA filters, beds with magnets, and supplement (vitamin, etc) dispensers built into their cupboards, online access to medical information via TV – shouldn’t we be trying to incorporate these products into “home care”. Should biomedical engineers be working with mainstream product developers to insure a measure of quality, effectiveness, and

safety are included in universally designed technologies? Where is the balance between consumer protection and market incentives/profitability.

There is a word in pharmaceuticals for drugs that are used for something that they were not approved for. There are other types of technology that will also be used this way – how does the FDA handle this? How do R&D funds look at targeted investigations for additional applications of the technology? Isn't this the "swords into plowshares" idea of military & space program tech transfer to the civilian population?. So how do we build on it, and not turn it into a regulatory barrier? First, probably by acknowledging that it is happening, and second, by encouraging and nurturing it. Where can the linkages be built; what would inhibit new development (probably even the idea of FDA oversight in their universe will terrify the home automation industry).

Software Issue. Presently the FDA regulates software for medical devices. Because of the current state of software safety, they place strict restrictions on the environment in which certified software is run, such as disallowing the installation of uncertified other applications. This probably is a disincentive for piggybacking HCT onto non-medical software and systems. The burden on industry of the present process for FDA certification of software as fit for use in a medical device is a significant barrier to commercial development of service on the margin between classical health care and education and entertainment, as envisioned in the desirable future. Affordable, trustworthy software is a key gap in knowledge

RECOMMENDATIONS

[G-1] Consumers and providers who need to use the HCT of the future must become integral team members, from the early stages of design and development. Unless both "retool" their expectations and assumptions about the benefits and utility of technology to home care applications, neither will reap potential benefits .

This is both a marketing and an educational effort. Information exchange is vital to its implementation. Specific activities, like mandating participatory action research into federal grant related to HCT development is one mechanism which could be used. Useful products, and people ready and able to use them must reach market at the same time. New methodologies for applying future HCTs must be developed in tandem with product development, and incorporated into training strategies, both formal and informal.

[G-2] Substantial government support is needed to develop exemplars of enabling technologies such as robotics and virtual reality applications . Business, industry, medical reimbursement and government have to collaborate to bring exemplars forward thereby avoiding "orphan technology" syndrome. Good demonstration projects will inspire people to come up with tasks/applications.

[G-3] Substantial government influence could be used to establish a consortium which would facilitate development of technology enhanced home care in the professional care system . Government agencies need to work to create a forum where consumers, industry, and providers can meet and formulate agendas and identify issues relative to regulation, research, and introduction of new therapeutic techniques, technologies and development strategies, and to ensure that technology enhanced services are equitably available regardless of income level, geographic location, etc.

[G-4] Changes must be incorporated into professional development (both pre service and continuing education). Government and private foundation support should be targeted to the development of re-oriented professional development (e.g., the Whitaker Foundation Special Opportunities Award to CUA for "Educating biomedical engineers in home care technologies for the 21st century.")

[G-5] Appropriate guidelines are needed for decision-making and choice of technology , info is needed by both providers and consumers . Research is needed to facilitate understanding of functional requirements and the development of appropriate functional measurement tools to support outcomes studies, modeling and the research utilizing HCT.

[G-6] Currently agencies responsible for health care technology assessment are not focusing evaluation efforts on these types of emerging technologies. AHCPR (Agency for Health Care Policy Research in the HHS Public Health Service, and other related or responsible government agencies, need to investigate and document the relative efficacy of HCT.

[G-7] Software: Link basic research in software science to trusted-software applications in health

maintenance and medical care, and to ongoing reform of the regulatory process. Software science investment should include an objective that unregulated software and health-critical applications can be run on the same commodity computer without concern for the continuity of operation of the health-critical functions.

[G-8] *There must be continued development of an affordable, ubiquitous, high capacity telecommunication network so that all segments of our population have access to technology .*

Topic H

HEALTH CARE TECHNOLOGIES - DEVELOPING AND DEVELOPED COUNTRIES

Prepared by Co-Chairs:

Kate Seelman, Ph.D., Kate.Seelman@ed.gov

Nigil Shapcott, M.Sc. Shapcott@pitt.edu

Participants:

Chris Kirtley, M.D., Ph.D.; Hong Kong University (now at Catholic University);

Robert Jaeger, Ph.D., National Inst. for Disability & Rehabilitation Research;

Dudley Childress, Ph.D., Northwestern University; **Roxanne Heuber**, Shephard Center, Atlanta;

Joanne Kumekawa, M.B.A., Office Advancement of Telehealth;

Martin Ferguson-Pell, Ph.D., Helen Hayes Hospital;

Paul Ackermann, Ph.D., National Inst. Disability & Rehabilitation Research;

Brian Kon, AZTEC/T2RERC; **Elizabeth Saindon**, J.D., Arent Fox;

William K. Smith, M.D., Physicians Against Land Mines & Northwestern Univ.;

Cille Kennedy, M.D., NIMH

Co-participatory from Group 7: (also Topic G, Therapeutic Applications): Alexandra Enders, O.T.R., (co-chair), Jim Barry, Linda Botten, O.T., Helen Bozzo, Alfred Gilman, Bill Peterson, M.S., Lou Quatrano, Ph.D., Scott Selbie, Ph.D.

Co-participatory from Group 8 (also Topic A, Home Telehealth: Dena Puskin, D.Sc. (co-chair), Adil Alaoui, M.S., Kathryn Dansky, Ph.D., Cynthia Howar Trutanic, J.D., Pam Whitton, Mary Ann Urka, R.N., M.L.S.

INTRODUCTION

Approximately 80% of the world's population (about 2.4 billion people) live in Developing Countries. One implication of the lack of infrastructure in developing countries and this enormous population is that the true scale of need in the health care area is not well defined. However through ongoing International and National efforts some improving trends in basic health care are being detected. These improving trends are periodically reversed in certain localities due to natural disasters of various types (disease, famine, weather, earthquakes etc.) and the man made disaster of war.

Our working groups focused on HCT issues which are of relevance to the stable majority of the 80% who were not under natural or man made threat, but who may be in need of Medical and Rehabilitation resources, and on the issues of the remaining 20% of the world's population residing in Developed countries who have similar needs.

Our topics were addressed in three major stages:

- i) Developing Countries- in interaction with the Therapeutic Applications Group Session I

- ii) Developed Countries- in interaction with the Interactive "Home" Telehealth -- Future Technologies & Services
- iii) Developing Countries then joined in with the Developed Countries group and looked for common themes between the groups. To the surprise of both groups there were strong common themes, which came together smoothly and are reflected in the following document.

PROBABLE FUTURES

- **A world in which appropriate and affordable telecommunications will be increasingly available globally (data, voice, video, translation) along with cost reduction using wireless technologies and solar power generation**
- **A world in which networking via the Internet will allow for the formation of health working groups not bounded by geography, nationality or language, resulting in increased capability AND software laboratories**
- **A world of unlimited access, a world which promotes compatibility, inter-operability and reliability**

Discussion:

Whether we like it or not, the fact is that commercial forces are driving the world, its engine has vast resources available once started. In the areas of telecommunications we are likely to see leapfrogging of complete infrastructures by less developed countries, in order to gain markets. An example of this is the prediction that most of Africa will be served by wireless communication systems rather than the hard wired Plain Old Telephone Systems (POTS) which the developed world have used for decades. Another trend is the reduction in cost of sophisticated telecommunications and computer equipment, currently many cell phones are "free" and there are recent examples of "free" computers in the US. Additionally we are seeing new and emerging technologies: -

- Real time translation of e-mail communications (Babblefish by Alta Vista is one example).
- Continuous speech recognition has started to penetrate the US market (costs range from less than \$100 for home use versions to \$600 for specialized commercial versions- a decade ago these systems were 10's of thousands of dollars. Eg Naturally Speaking by Dragon Dictate).
- The advent of 64 bit chips with greater speed and processing power in the near future (the Intel Merced chip is expected to be available late 1999 or early 2000).
- New high bandwidth standards for wireless communications in Europe are in discussion (these standards will enable Megabit level communication, one result of this will be the widespread availability of video conferencing).
- Video conferencing technologies are becoming better and cheaper (ViaTV make a POTS based system including camera costing \$350, ISDN and LAN based systems are available from Intel starting at less than \$800).
- Low Earth Orbit Satellite Systems are already in service and being planned which give bandwidth availability with short time delays anywhere on the earth (Iridium has recently established a service).
- There are laptop computers available now, which have built in digital/video cameras (Sony and NEC).

- All these developments point to a ubiquitous availability of telecommunications in the next decade or two, which we will consider to be as “natural“ to use as the telephone or television.

IDEAL VISION

- **A world in which we are able to effectively share information about deployment of home health care services for a variety of populations. To the extent feasible, we should be able to share in the development of Home Health Care across Nations.**
- **A world in which industry is committed to universal design enabling technologies to be within reach of those with the broadest range of ability and function**
- **A world committed to a “bottom-up” understanding of the applications environment and population**
- **A world in which federal and private support for collaborative efforts in both America and World-Wide will address global health problems**
- **A world in which increasing efforts and resources will be dedicated to the engineering and design of products and services which are appropriate to cultures, economies, climates and geographies of low-income and under-served populations**

Discussion:

The “ideal vision” implies the application of universal standards, protocols and principles in the field of HCT. This will not happen on its own and will require leadership at the International and Federal level to influence the “mighty” commercial forces to adopt and develop these universal standards, protocols and principles, in a manner which is INCLUSIVE and will allow the emerging technologies and techniques associated with HCT to thrive.

As well as standards there will need to be sensitivity to the needs of different populations with different backgrounds, levels of education and abilities. In particular the disabled population could be adversely affected by the failure to adopt the principle of “Universal Design”.

We must hope that the commercial sector realize that most of us reading this report struggle to program our VCRs and that they are thoughtful when designing systems by including the end user in the process.

KNOWLEDGE GAPS

- **There are gaps on knowledge of in the identification of needs for health care by region and population. There is a need to identify and integrate data from existing databases in order to provide a readily accessible knowledge base. There is a need for the compilation of best practices to be incorporated as a fundamental component of these databases.**
- **NGO’s, Administrators and Health Care Professions in the Developed Countries need to improve their understandings of local health care needs AND local conditions. The understanding of individuals in low-income countries needs to reflect economic and pragmatic issues of modern health care program needs.**
- **At the level of the individual there are gaps in the knowledge of NGO’s such as RESNA, WHO, AAATE, ISO, RI etc. where there is a need to improve their understanding of local health care needs, conditions, and individuals in low income countries. Through formal and informal for a, to improve and coordinate their services and advocacy for individuals with disabilities.**

- **There are gaps in standards by which professionals are trained, demonstrate competence, and receive licensure and certification.**
- **Science and evidence based best practices in rehabilitation generally and in Telehealth and Telerehabilitation.**

Discussion

We have some information on what the needs are for HCT on various databases throughout the world and within various international agencies. A well-led integration of these resources would be of huge benefit in the planning of systems to meet the needs.

Many aid projects are imposed by individuals and organizations that have little real understanding of what local needs are. The intelligent and planned use of exchange visits combined with POTS based low cost teleconferencing technologies might bring more understanding of the needs to both organizations and individuals who are developing HCT Systems for a wide variety of needs and geographical areas.

The academic community should begin to focus in on the needs for training and licensure as well as researching best practices for HCT; this is potentially a huge area of expansion.

OTHER BARRIERS

- **Cultural barriers on both sides, primarily language and education, combined with National, Provincial and Regional perspectives versus global thinking and planning. For example, the dominance of “Americanization” cultures and language.**
- **Real pragmatic issues of planning, logistic, management, geography, time zones, financing, and funding; by individual countries and global organizations.**
- **Disincentives to innovation and marketing: The perception of small markets and orphan technologies; technology incompatibilities between countries and between technologies, particularly in speed of transmission, infrastructure compatibility, device certification and reciprocity, universal standards and quality information assurance.**
- **Lack of infrastructure and systems in the areas of health care; roads; power; education; water ; risk management etc.**

Discussion:

There were strong voices in our groups regarding the potential “imperial” nature of US based activities, which disclosed sensitivity to the dominance of the US in many fields. These cultural sensitivities are important to understand and by approaching International systems developments as true “partnerships” may lead to more fruitful relationships answering real needs on the ground.

Also within our groups was a sense of “fear” that the FDA and other standards agencies might impose regulations, which would restrict the availability and development of the technologies. As an example the \$350.00 ViaTV POTS based videoconferencing system is being used on a demonstration basis to provide Assistive Technology and Rehabilitation Services in several areas within the US. The need for FDA approval as a medical device would probably mean that such a system would not be available for this purpose either because of cost increases or the manufacturer may decide that such certification did not warrant the investment required. Each country has its own maze like this each creating the uncertainty, which results in a perception of major disincentives.

RECOMMENDATIONS

Our group strongly recommends that the following policies should be implemented.

- **Development of Government and NGO partnerships which plan and coordinate bi-National and bi-directional exchanges of persons as well as coordinated training and education for researchers, consumers and providers. Involved in this training would be the creation of models of:**
- **Authentication of information sources**
- **Security**
- **Confidentiality**
- **Accessibility**
- **Consumer rights**
- **Privacy**
- **Accessibility for literacy and function**
- **Development of International fora to design and promote discussions of universal design, uniform standards and guidelines, strategies to ameliorate the impact of instant obsolescence, and the development of human factors which result in user-friendly technology.**
- **Development of integrated National and International policy and funding strategies for geographical and virtual center(s) in Telehealth. These should be designed to enable the knowledge gaps, identified within this report, to be addressed by the creation of instruments for obtaining and sharing information and compelling the best practices of Telehealth and Telerehabilitation research and service delivery.**

Discussion:

Bodies such as the FDA might consider approaching the problem of certification, which as has been stated earlier may create disincentives to innovate, from the perspective of system certification. In other words an individual who has a certain level of training which includes understandings of failure modes would be one component of a system which includes low cost sensor and telecommunications technologies which individually are not certified. Thus following the example of the simplest and most common form of Telehealth, the phone call to the Doctor or Nurse; in this case we are using ubiquitous systems prone to failure (the \$10 phone) to elicit medical advice or intervention. Of course, there are areas where the FDA and other approvals are required by the nature of the technology and the related medical circumstances. A “light and careful tread” by National and International regulating bodies would be of benefit to all by encouraging the use these exciting HCT technologies by removing the disincentives of perceived or real uncertainty.

5. Discussion [see also http://www.hctr.be.cua.edu/HCTWorkshop/HCT_disc.htm]

5.1 Placing the Results in Context

In interpreting the results of Sections 3 and 4, it is useful to first establish a context. The participants constitute, to some extent, a biased sample. For instance, attendees presumably chose to be present because of a fundamental interest, or stake, in the theme of the Workshop; thus they may have been biased toward the importance of home care technologies.

Minimal Representation from Industry. Also, there was minimal participation by representatives from industry. This was for a very pragmatic reason: it became clear that due to the high level of interest, it would be difficult to keep the number of Workshop participants down to a reasonable level (first planned to be 80, later modified to 100). No fair selection criteria emerged for inviting representatives from the large number of industry

stakeholders, and consequently a decision was made to invite several key industry trade associations, but not companies with a direct stake in the topic of the Workshop.

Diversity of Backgrounds and Talents. Nonetheless, in terms of background and experiences, there was considerable diversity among the participants in terms of backgrounds and talents. Nearly half of participants had academic appointments, though their fields varied from engineering to health sciences to policy. Over one quarter were government employees, although coming in with a rich variety of types of job descriptions. Nearly half of the participants had an engineering degree, and nearly half a clinical degree. However, in both of these categories, many of these were not actively "practicing" -- their primary job description could be described as "management." One of the key comments that participants expressed to the organizers was the feeling of being in a minority during the discussions, with their opinions not given as much weight that they wished during the synthesis process. This appeared to span different classifications, from academic engineers to clinicians to government policy specialists. Nonetheless, comments on the evaluation forms suggested that most found the process to be agreeable, and considered the Workshop to provide a learning experience.

Strong Consensus on Many of the Presented Topical Group Statements. Placed within this context, the high level of consensus that was often reached for certain anticipated trends, knowledge gaps, barriers and recommendations seems surprising. This suggests that key overriding themes are worth careful inspection.

5.2 Overriding Themes

No attempt will be made here to summarize the results, since Sections 3 and 4 stand on their own merit. However, key trends are:

Top **anticipated trends**, of 43 that were presented, included an expectation that technology will enable consumers to access a wide range of health care services from the home; and that health care will migrate to a proactive, preventative consumer-driven model rather than the reactive, episodic model utilized today (with advanced technology and intelligent systems serving as important tools for helping facilitate continuum of care and management into the home and community).

The top **knowledge gaps** were the need for information reduction and sense-making tools; the need for outcomes and functional assessment tools; the need for better understanding of the clinical and cost effectiveness of home health services; and the need for research on innovative mobile assist devices and other devices to assist with aspects of daily living.

Key **barriers** included reimbursement challenges for home care services and products; lack of appropriate technical infrastructure (e.g., medical device and telecommunications infrastructure standards, human factors processes/procedures for home health); and the need for broad-based education about HCTs and their effective utilization.

Top **recommendations** of the Workshop were the need to fund research to develop effective tools for intelligent processing of large amounts of healthcare data; the need for large-scale demonstration projects aimed at areas such as telehealth interfaces; the need to set up infrastructure to enable the participation of consumers and providers in new HCT designs; the need to investigate reform in the regulatory process as related to future HCTs; and the need for education and training of consumers and health professionals.

There was a sense among participants that this Workshop was appropriate and timely. Two overriding themes were the move toward a more consumer-driven, technology-assisted healthcare infrastructure that focused more on prevention and wellness, and the need for research on intelligent processing of large amounts of data so as to optimize effectiveness of care decisions and avoid information overload.

Yet perhaps the primary impact of this workshop relates to the sense that to solve problems in healthcare and move toward a desired future where individuals have optimal access to health services and appropriate technologies from their home, coordinated multidisciplinary efforts are needed. These include targeted large-

scale demonstration projects, and the forming of partnerships and consortia to address key knowledge gaps and barriers.

5.3 Healthcare Paradigm Shifts?

In his keynote, Henry Kelly of the White House's Office for Science and Technology Policy (OSTP) presented a number of White House initiatives that tied together several key themes: information technologies, healthcare, housing, and aging. He also encouraged Workshop participants to put forward ideas to his office. His office coordinates inter-agency partnerships, and tries to involve industry in cooperative initiatives. So there is an opportunity for Workshop participants to serve as a resource to OSTP.

The comments to follow represent the observations of one participant (and organizer), Jack Winters, related to two possible fundamental paradigm shifts that seemed to be suggested by the results of the Workshop. Each would require a concerted effort to reach fruition, one that could be coordinated by OSTP.

Paradigm Shift -- Consumer-Driven Healthcare with Telesupport? Many participants used the fact that billions of dollars are spent on alternative medicine as an example of the reality that there is a consumer market that goes beyond third-party reimbursement. But these needn't be mutually exclusive. There was shocking agreement that the current systems of healthcare reimbursement -- whether fee for service or managed care -- needed fixing. There was also the sense that: with the aging of baby boomers, healthcare clinicians will start to be viewed more as a resource than the source of all knowledge; and longer-term cost-effective solutions were missing with the current focus on episodic healthcare delivery. Given that information and telecommunications technologies are starting to permeate the American home, it makes sense to "piggyback" on this massive societal investment in these areas. Consider the new paradigm of telecommunications-ready medical devices, and integrated home/Internet wireless networks in which a subset of the interfaces are "medical." The concept of universal access, and of enabling health/self-care across distance (with telesupport), would represent a radical shift in how healthcare is delivered in this country. It would be a noble, worthy aim that will require large-scale, multidisciplinary partnerships that include government, industry and academia. It also ties in all of the OSTP priorities listed above.

Paradigm Shift -- Research into the Science of Wellness? In January of 2000, the conference on Health in the New Millennium will launch [Healthy People 2010](#), an extension of a key federal health initiative of the 1990's entitled [Health People 2000](#). But the reality seems to be that the continued focus of health research is to keep people from become unhealthy; there is no Institute of Wellness at NIH. The theme of wellness (and prevention) emerged from several of the keynotes and topical groups, most notably Topic B. When combined with the insightful findings of Topical Groups F, D and G on advanced sensors and intelligent support infrastructure, one wonders if perhaps the time has come to focus on the **science** of wellness. Science? While "wellness" may be difficult to define, one can identify attributes and grades of wellness, and the determination of objective (sensor-based) measures of the state of wellness could be of value. For instance, biological/physiological measures could be correlated with human performance or function measures to establish wellness indices. Assuming that sensors that are unobtrusive and/or wearable become more viable, such measures could form the foundations of a new process for evaluating health trends and predicting possible health risks. OSTP is encouraged to seriously consider an initiative that directly addresses the ties between healthcare and information technology in which the "home" (here also including anywhere were mobile wireless communication is possible) is a target, with the focus on understanding and developing reliable measures of the state of wellness. From a "quality of life" perspective, this could emerge as a national priority for infrastructure development.