Report of the Workshop on Home Care Technologies for the 21st Century

Organizer: Jack Winters, Dept. of Biomedical Engineering, Catholic University of America

Co-Organizer: William Herman, Office of Science & Technology, CDRH, FDA

Funded by
Bioengineering and Environmental Systems Division, National Science Foundation
and
Center for Devices and Radiological Health, Food and Drug Administration

Published 1999 by CUA (see also http://www.hctr.be.cua.edu/HCTWorkshop)

Table of Contents

EXECUTIVE SUMMARY

THE TOPIC

Large-scale demographic, economic, and technological developments are converging to intensify a gathering momentum toward new home- and self-care technologies and systems. Growing numbers of patients are assuming key roles in major aspects of their own health care. Health care delivered in the home (and in other non-institutional settings) is increasing dramatically – whether provided by the patient or by others.

These observations are pointedly underscored by a recent report from the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health, which analyzed future trends in medical device technologies. That report specifically identified home- and self-care as one of the primary developments projected to dominate the evolving medical-device landscape over the next decade. Similarly, the Whitaker Foundation and the National Institute for Disability and Rehabilitation Research have identified home health care technologies and telerehabilitation as high-priority areas. More specifically, those organizations have provided major grants to the Catholic University of America (CUA) to support leading-edge programs in education and research in these fields.

THE WORKSHOP

The National Science Foundation (NSF) plays a primary stewardship role in advancing the discovery, integration and employment of new scientific knowledge in service to society, including the support of bioengineering and interdisciplinary research contributing to improved health care. In pursuit of that mission NSF's Division of Bioengineering and Environmental Systems recently collaborated with the Food and Drug Administration to support a Workshop on Home Care Technologies for the 21st Century. This report describes the results of that Workshop, which took place April 7-9, 1999.

The Workshop was chaired and organized by CUA and FDA. It brought together an interdisciplinary group of more than 100 leading academicians, engineers, clinicians, program managers, and policy experts to address:

- Major technology developments;
- Significant knowledge gaps in science and technology;
- Primary technical, ethical, and policy barriers; and
- Recommendations

central to the safe and effective delivery of emerging home- and self-care technologies. The group included participants from 20 states and 12 federal agencies. Participants having specialized subject-area expertise and experience contributed background information through 12 white papers (disseminated before the workshop) and 7 keynote presentations describing various aspects of the landscape of emerging home- and self-care technologies and systems. Workshop attendees divided into 8 working groups for detailed analysis and discussion of (A) home telehealth; (B) personal status monitoring; (C) ethical, legal, and policy issues; (D) technologies for chronic conditions; (E) human factors; (F) smart devices; (G) robotics and virtual reality; and (H) international issues. Working groups provided detailed analyses of each of these 8 suptopics (see Section 4 of this report). Every putative technology development, knowledge gap, primary barrier, and recommendation articulated by each working group was subsequently scored during a plenary session comprising all participants.

THE RESULTS

Based on a synthesis of the compiled scores (see Section 3 of this report), a degree of consensus emerged on a range of conclusions, including the following:

TECHNOLOGY DEVELOPMENTS – A prevention-oriented consumer-driven model for health care will emerge. Technology will enable health care consumers to access a broad spectrum of services from the home. Key technology-related areas will include noninvasive sensors; "smart" computerized devices; customized products with flexible configurations; data analysis tools to assist in medical decision-making; electronic patient records; wearable products; and wireless internet-linked systems.

KNOWLEDGE GAPS – Crucial knowledge-based needs remain unmet. These include information-reduction and "sense-making" tools; outcomes-assessment tools; functional-assessment tools; data on clinical- and cost-effectiveness of home health services; and research enabling advances in mobile assist devices and other devices to assist daily living.

BARRIERS – Substantial hindrances to optimal development of home- and self-care products and systems exist. Among the most important of these are the need for enhanced reimbursement for home-care services and products; inadequate technical infrastructure (e.g., technical standards, human-factors norms); and insufficient broad-based education about home- and self-care technologies and their effective utilization.

RECOMMENDATIONS – Overall consensus emerged regarding several recommendations. These called for more support for research to develop practical intelligent tools for processing large amounts of health data; greater use of large-scale demonstration projects for home- and self-care technologies; improved opportunities for participation by consumers and health professionals in the design phase of new products; clearer and better-coordinated cross-agency government policies to encourage optimal development and use of home- and self-care products; and more support for education and training of consumers and health professionals regarding optimal use of home- and self-care technologies.

In conclusion, the workshop provided a unique and valuable forum for synergistic interactions among participants from many diverse backgrounds. The resulting interplay of ideas led to a resounding endorsement of the view that home- and self-care technologies, products, and systems can and will play an increasing role in overall health care delivery systems in the U.S. and elsewhere. The workshop participants' interactions also resulted in a consensus view that (frequently identifiable) new technologies will provide the means for an accelerating shift in basic health care patterns. Ultimately, however, participants concluded that if unfilled knowledge gaps and systemic barriers are allowed to persist, they may pose serious obstacles to the optimal utilization of these new technologies.

1. Introduction [http://www.hctr.be.cua.edu/HCTWorkshop/HCT_intro.htm]

1.1 Background

During the Spring of 1998, the Center for Devices and Radiological Health (CDRH) of the FDA released a report entitled Future Trends in Medical Device Technology: Results of an Expert Survey (Herman et al.) that identified six major anticipated trends in medical device technologies over the next ten years. One of these six major technology trends was an accelerating emergence of **home- and self-care products** (the fastest growing segment of the medical device industry throughout the 1990s).

Also in the Spring of 1998, the Catholic University of America received a Special Opportunity Award from The Whitaker Foundation for $1 million entitled "*Educating Biomedical Engineers in Home Care Technologies for the 21st Century*," specifically to establish expertise and training in this emerging area. This was then complemented by a $4.5 million grant to establish a Rehabilitation Engineering Research Center on Telerehabilitation (National Institute on Disability and Rehabilitation Research, U.S. Dept. of Education).

Working together, CUA and FDA sent a proposal to the Division of Bioengineering and Environmental Systems at the NSF to implement a Workshop entitled *Home Care Technologies for the 21st Century*; this was funded.

A Mini-Workshop, with 18 invited participants, was held December 6-7, 1998. The full Workshop, with over 100 invited participants, occurred on Wednesday-Friday, April 7-9, 1999.

This report disseminates the findings of this Workshop.

1.2 Objectives

The focus of the Workshop is timely: namely, to address the rapidly evolving area of home care technologies, with a special focus on the future. During the Mini-Workshop the issue of what constitutes "home" was addressed, with the consensus being to utilize a broad interpretation that focuses on access, and includes mobile technologies. Early on during the full Workshop, in response to a question, the definition "home is where the heart is" was used by one of the organizers.

The key outcome of the Workshop is a report that uses multidisciplinary expertise to:

- identify **major technology trends**, and areas projected to need development;
- prioritize areas where an **expansion of science and technology knowledge is needed**;
- **identify potential gaps and barriers** in moving from product development/design to delivery of effective and safe technologies;
- **anticipate ethical and policy issues** that relate to the impact/utilization of a greater variety of health-related technologies within the home; and
- help establish a **collaborative infrastructure** to effectively address longer-term needs/problems in this area.

This report will be freely disseminated via a Web site (http://www.hctr.be.cua/HCTworkshop) and by surface mail. It will also be reported through other avenues, such as the 1999 joint BMES/EMBS conference in Atlanta.

2. Methods [http://www.hctr.be.cua.edu/HCTWorkshop/HCT_methods.htm]

2.1 Topics & Groups

Topics:

Through a planning process that included a Mini-Workshop on December 7-8 1999, 8 topic areas were selected:

- **Topic A: Interactive "Home" Telehealth: Future Technologies & Services**
- **Topic B: Personal Status Monitoring: Interactive Solutions, Sensors & Automated Systems**
- **Topic C: Appropriate Design of Home Health Technologies: Ethical, Legal & Policy Considerations**
- **Topic D: Home Therapeutics & Assistive Technologies for Chronic Conditions**
- **Topic E: Human Factors Engineering & User-Driven Device Design**
- **Topic F: Smart Devices & the Home of the Future**
- **Topic G: Therapeutic Applications: Rehab Robotics & Virtual Reality; Future Possibilities**
- **Topic H: International Issues in Health & Rehabilitation**

It was decided that each topic area would be addressed twice (by distinct groups of participants), and that each participant would have the opportunity to address two of the eight topics. It was also decided that there would be a separate summary report for each of the eight topic areas, with each including a synthesis of the distilled findings. Each topical report would be the responsibility of the topical co-chairs, working with their participants and the co-organizers. These reports would then be included in the Workshop report and on the Web site.

Groups:

Group 1:
Topic A: Interactive "Home" Telehealth: Future Technologies & Services [Co-Chair: **Gerald Loeb**, M.D.]
Topic B: Personal Status Monitoring: Interactive Solutions [Co-Chair: **Audrey Kinsella**, M.A., M.L.S.]

Group 2:
Topic B: Personal Status Monitoring: Sensors & Automated Systems [Co-Chair: **Joe Andrade**, Ph.D.]
Topic C: Appropriate Design of Home Health Techn.: Ethical Consid. [Co-Chair: **Jeff Collmann**, Ph.D.]

Group 3:
Topic C: Appropriate Design of Home Health Techn.: Legal & Policy Consid. [Co-Chair: **Janell Duncan**, J.D.]
Topic D: Home Therapeutics & Assistive Techn. for Chronic Conditions [Co-Chair: **David Angaran**, R.Ph.]

Group 4:
Topic D: Home Therapeutics & Assistive Techn. for Chronic Conditions [Co-Chair: **Don Marlowe**, M.M.E.]
Topic E: Human Factors Engineering & User-Driven Device Design [Co-Chair: **Jim Grigsby**, Ph.D.]

Group 5:
Topic E: Human Factors Engineering & User-Driven Device Design [Co-Chair: **John Gosbee**, M.D.]
Topic F: Smart Devices & the Home of the Future [Co-Chair: **Steve Warren**, Ph.D.]

Group 6:
Topic F: Smart Devices & the Home of the Future [Co-Chair: **Atul Dighe**, M.A.]
Topic G: Therapeutic Applications: Rehab Robotics & Virtual Reality [Co-Chair: **Corinna Lathan**, Ph.D.]

Group 7:
Topic G: Therapeutic Applications: Future Possibilities [Co-Chair: **Alexandra Enders**, O.T.R.]
Topic H: International Issues in Health & Rehabilitation [Co-Chair: **Nigel Shapcott, M.S.**]

Group 8:
Topic H: International Issues in Health & Rehabilitation [Co-Chair: **Kate Seelman**, Ph.D.]
Topic A: Interactive "Home" Telehealth: Future Technologies & Services [Co-Chair: **Dena Puskin**, D.Sc.]

2.2 Process

Charge For Each Topic:

The primary charge for all topical groups was to create the following types of deliverables, to be reported to all participants during the morning of last day of the Workshop (Friday, April 9, 1999):

- **Vision** -- Identify a small set (2-5) of **anticipated trends** and of **desirable future scenarios/outcomes**. Think outside the box, and 2-10 years from now.
- **Knowledge Base** -- Provide a **prioritized list** (with brief justification) of up to 5 core areas where expansion of our knowledge base is needed (could be hard or soft science, engineering R&D, policy research). Avoid overly broad categories.
- **Barriers & Issues** -- Provide a **prioritized list** (with brief justification) of up to 5 key barriers/issues that **need to be overcome** (e.g., societal, technological, ethical, legal, regulatory, payor/economic, health or tech policy, quality assurance, resource allocation, addressing disenfranchised/disabled/aged).
- **Overriding Recommendations** -- Make a prioritized list of 2-5 bold recommendations (with justification), and identify specific targets for implementation (e.g., specific federal branch, type of industry, standards area).

Plan for Implementation:

The structure for implementing this plan was to first form eight working groups, each of which would have **3 hours to address each of their two topics**: one on the afternoon of the first day (Wednesday, April 7), the other on the morning of the second day (Thursday). These were to yield a set of preliminary bullets in each of the 4 areas mentioned above. These were assembled, and copied during the lunch period on Thursday.

For Thursday afternoon, roughly 50% of participants from one of the groups covering a given topic converged with 50% from the other group that addressed the topic, with the aim of readdressing the same topic within a new, topic-specific group. During this working meeting, the results of the two previous sessions were merged into a **working set of statement bullets** (vision, knowledge gaps, barriers, and recommendations) that were then presented for assessment to the whole group on Friday morning. Co-organizers, and co-chairs for many of the groups, spent Thursday night working on the statements, and placing them on appropriate forms for scoring on Friday.

Each of the groups had roughly 20 min to present their statements, which were scored by all participants.

2.3 Discussion Papers [available prior to Workshop]

Discussion Papers that were made available to help prepare participants for the Workshop [for summaries see Appendix A.1; full papers are available from http://www.hctr.be.cua.edu/HCTWorkshop/HCTa_disc-pap.htm].

HCT-W1: William A. Herman, "Societally Significant Issues in Home- and Self-Care", 1998.

HCT-W2: Jack M. Winters, "A Framework for (and examples of) HCT's", 1999.

HCT-W3: Audrey Kinsella, "Improved Care for Diabetic Populations: The Need for Telehealthcare and Alternatives to Conventional Care Services", 1999.

HCT-W4: Audrey Kinsella, "Infusion Tele-Therapy in the Home: An Alternative Mode of Service Delivery", 1999.

HCT-W5: Audrey Kinsella, "Home care technologies 1999: Movement toward the home as a one-stop healthcare shop", 1999.

HCT-W6: Steve Warren, Richard Craft, and John Bosma, "Designing Smart Health Care Technologies into the Home of the Future" -- best viewed as Word or PDF file, 1999.

HCT-W7: Joe Andrade, "Chemical Sensors in the Home", 1999.

HCT-W8: Gerald Loeb, "Telecare: Enabling the Virtual Housecall", 1999.

HCT-W9: Jeff Colemann, and Anna-Lisa Silvestre, "Building a Security Capable System," 1999.

HCT-W10: Janell Duncan, "Legal and Policy Issues Relating to the use of Medical Devices in the Home, and the Home as a Health Care Setting", 1999.

HCT-W11: Kate Seelman, "Disability's New Paradigm: Implications for Assistive Technology and Universal Design", 1999.

HCT-W12: Jack Winters, "Two Overriding Criteria for Policymakers: Quality of Life and Sustainable Infrastructure", 1999.

2.4 Keynotes:

The workshop started on Wednesday April 7 with welcoming remarks by Gil Devey of the NSF, William Herman of the FDA, and Jack Winters of CUA. The rest of Wednesday morning consisted of a series of five keynote addresses to the group of roughly 100; the last keynote (by Dr. Asada) took place early Thursday morning. The purpose of these carefully selected keynotes was both to provide a knowledge foundation and to stimulate thinking "outside the box." The following speakers are thanked for their insightful and appropriate addresses:

- William A. Herman (Office of Science and Technology, Center for Devices and Radiological Health, FDA): *Future Trends in Medical Device Technology*
- Joe Andrade, Ph.D. (Department of Biomedical Engineering, University of Utah): *Biochemical Individuality: Personal, Private Chemical Sensing for Health and Well-Being*
- Dena Puskin, D.Sc. (Director, DHHS-HRSA's Office for the Advancement of Telehealth): *Telehealth and the Home*
- Jim Grigsby, Ph.D. (University of Colorado): *Human Factors and the Home*
- Des Cummings, (Florida Hospital Health System; Disney's Celebration project): *Launching the Healthcare Culture of 21st Century*
- Henry Kelly, Ph.D. (Office of Science and Technology Policy, White House): *Administrative Perspective of HCTs for the 21st Century*
- H. Harry Asada, Ph.D. (Dept. of Mechanical Engineering, MIT): *Report of the NSF Workshop on Healthcare Robotics & Home Healthcare Research at MIT*

Each of the speakers had several take-home messages, and collectively they provided a thoughtful framework for the subsequent working groups. Joe Andrade made a strong case for the breadth of the future HCT marketplace, including the vast potential for chemical and biochemical sensors to be used for personal status monitoring and home-based public health. Dena Puskin provided a context and vision for home telehealth challenges, and Jim Grigsby provided a context for why human factors approaches need be considered when designing and evaluating HCT's. Des Cummings provided motivation for the need for profound change within society from a centralized episodic model of health care to a model based on wellness and prevention, using the Disney-sponsored Celebration project (a model city of the future) as an example. Henry Kelly summarized key White House initiatives, especially those tying information technologies to health and aging, and then provided an open invitation to participants to come up with innovative ideas. Harry Asada showed us examples of smart sensor technologies that can be made remarkably small, opening up possibilities for new generations of home health products.

2.5 Schedule

Wednesday, April 7:

8:30-9 AM -- Registration, Badge & Coffee

9:00 - 9:40 -- Welcome to Workshop

- **FDA Perspective, and Future Trends in Medical Device Technology** (Bill Herman, intro by Don Marlowe)
- **NSF Perspective** (Gil Devey)
- **CUA: HomeCare/Telerehab Initiatives - Potential** (Jack Winters, intro by James Mayo)
- **Overview of Logistics** (Jack Winters)

9:40 - 10:00 -- Keynote: Biochemical Individuality: Personal, Private Chemical Sensing for Health and Well-Being (Joe Andrade, Dept. Bioengineering, University of Utah)

10:00 - 10:20 -- Keynote: **Telehealth -- Possible Future Outcomes** (Dena Puskin**,** Office for Adv. of Telehealth)

10:20 - 10:40 -- Keynote: **Human Factors & HCT Design** (Jim Grigsby**,** Univ. of Colorado)

10:40 - 10:50 -- Coffee Break

10:50 - 11:20 -- Keynote: Launching the Healthcare Culture of the 21st Century (Des Cummings, with Disney's Celebration Health project and Florida Hospital)

11:20 - 11:50 -- Keynote: Administration Perspective of Home Care Technologies for the 21st Century (Henry Kelly, Office of Science & Technology Policy, White House)

11:50 - 12:10 -- Overview of the 8 topics, Instructions (Jack Winters, CUA)

12:10 - 1:15 -- Lunch

1:15 - 4:45 -- Working Group, Session 1 (break 3-3:15 PM)

Thursday, April 8:

8:30 -- 8:50 -- Keynote: Report of the NSF Workshop on Healthcare Robotics & Home Healthcare Research at MIT (H. Asada, Dept. Mech. Engng., MIT)

9:00 - 12:00 -- Working Group, Session 2 (break 10:00-10:15 AM)

12:10 - 1:30 -- Lunch

1:30 - 4:45 -- Topic Synthesis Session (break 3-3:15 PM)

Friday, April 9:

8:30 - 12:00 -- Reports of 8 Topic Groups (break 10-10:15)

- Presentations for Topics A-H (20 min each)

3. Results [http://www.hctr.be.cua.edu/HCTWorkshop/HCTs_results.htm]

3.1 Vision: Anticipated and Desirable Future Trends

Motivation. A key desired outcome was the identification of both anticipated and desirable future trends. Anticipated trends serve the purpose of helping agencies (e.g., FDA) and industries (e.g., medical device manufacturers) plan for the future. Desirable future scenarios -- especially those broadly shared -- provide the ideal to be strived for, and in some cases suggest paths or roadmaps to help move toward achieving the desired aim.

Organization of Results. Appendix A.2 provides the 43 vision statements that were presented to all participants for scoring, organized by topic and then ranked based on the collective level of degree of agreement by all participants. Each row consists of the statement, a chart showing ranking (also available as text), and the overall degree of impact (a combination of societal and individual impact). Of note is that only up to seven from any specific group are provided (the respective reports of each group may address additional ones). It should be recognized that each vision statement was put forward by a certain topical group on its merit. The reader is referred to the topical reports for discussion of specific vision statements.

Table 3.1 presents the top 21 vision statements, and also includes the participants' sense of "degree of impact" on society and on individuals (graphs in far right column). Notice that in some cases the ranking would be different if our measure had been the degree of impact (vs. degree of agreement); indeed, a "top 21" was selected in part to include F4, which while ranked 21st in terms of agreement, was felt by participants to have one of the highest impacts on individuals.

Brief Synthesis. In general, it proved easier for most groups to articulate desirable futures than anticipated futures, with the former representing over 60% of the vision statements. An overriding theme was the repeated prediction by participants in the working groups that **home- and self-care technologies would grow in importance and utilization over the next decade**. Expectations for an expanding range of products and systems paralleled predictions of growing populations of patients and users. Several statements pointed toward a general movement away from centralized institutional care toward more home- and self-care.

The working groups noted several motivations for this evolution. The **desirability of independent community-living** was cited by several working groups [see also discussion papers by Loeb (HCT-W8), Kinsella (HCT-W5) and Seelman (HCT-W11)]. Participants also described a facilitative relationship that home-care technologies can have for a growing medical paradigm that emphasizes the importance of **prevention** and **wellness**. Moreover, the working groups projected that new home- and self-care technologies will be driven by both consumer and market interests.

Top Ranked Results. Table 3.1 (below) presents the top 20 ranked vision statements. Four vision statements (those requiring a re-scaling of the y-axis to 50 rather than 40 due to the large number (over 60%) of "1's") stood out as having particularly high degrees of agreement:

> Vision-A1: (anticipated): **In the future, technology will enable the consumer to access a wide range of health care services from the home.**
>
> Vision-D1 (anticipated): **Institutional care functions will continue to migrate from the institution.**
>
> Vision-F1 (desirable and anticipated versions): **We desire/anticipate that health care will migrate to a proactive, preventative model rather than the reactive, episodic model utilized today**:
>
> - Intelligent wearable sensors
> - Trend-data-analysis tools, predictive algorithms
> - HMO's will drive migration to HCT's
>
> Vision-G1 (anticipated): **Technology will facilitate continuum of care and management into the home and community.**

In some cases these lack specific detail but, instead, constitute general expectations for continuing growth of home care. Indeed, while more vision statements could be classified into the "desired" rather than "anticipated" category, 3 of these 4 (all but Vision-F1) represent **anticipated** emerging trends -- and as seen in the Topic F Report, both "anticipated" and "desired" scenarios are played out for Vision-F1. So these are strong statements.

One common theme that underlies all of these -- and many others -- was the concept that as our evolving info/telecom **technology infrastructure** more fully impacts on home life, a more **consumer-driven healthcare system will emerge** [e.g., A1, G1, D2, F2, B1, B2; see also Kinsella (HCT-W5)]. Notice the clear implication that technology can **cause** (or be a driver for) societal change, and also the use of the word "consumer." This predicts profound change at the very foundation of our healthcare infrastructure, while also acknowledging the reality that this will take time to develop, due to the natural tension between this model and how medicine has been practiced for most of this century [emphasized in keynotes by Des Cummings and Dena Puskin; see also discussion papers by Loeb (HCT-W8) and Winters (HCT-W12)]. While Vision-A1 emphasizes the role of technology in helping facilitate consumer access to services, Vision-G1 emphasizes care management, Vision-D1 emphasizes de-institutionalization and Vision-F1 addresses the role of 21st-century technology, the undercurrent of broad-based participant identification with this theme of **consumer-driven healthcare with improved access was truly one of the key findings of the Workshop**.

Of note is that the most explicit of the vision statements associated with this theme was the following:

- D2: Product design should be using a "**consumer model**" rather than a "medical model" to be able to take advantage of improvements in **technology**.

This statement, which challenges current medical practice, received strong support (i.e., a "1" or "2") of 80% of those present (i.e., strongly agreed or agreed), yet was not quite as highly ranked (6th overall) because a significant minority objected to it. Perhaps there were some participants (e.g., impacted stakeholders) who found this statement too confrontational.

It is useful to note that some of the most provocative -- and often controversial -- of the 43 statements didn't make the "top twenty" list. Yet perhaps some of these are truly visionary. One observation was that vision statements that connected several concepts, or were of the form "something versus something else" were nearly always destined not to rise to the top -- perhaps too many possible points of contention.

The above observation makes the very high ranking of Vision-F1 especially intriguing, since in many ways it is even more confrontational and futuristic than Vision-D2, and furthermore ties a model for healthcare with "high-tech" concepts such as intelligent sensors and trend-predicting computer algorithms. Pie in the sky stuff? Apparently not, in the minds of the participants. Indeed, if one synthesizes the degree of agreement with participants' belief in its degree of impact on society and individuals, **F1** clearly emerges as the top-ranked vision statement of the Workshop. A hypothesis for this high degree of agreement is the influence of the keynote talk by Des Cummings (that made the case for the proactive, preventative model for managing care and wellness), combined with the strong discussion paper by Steve Warren et al. in intelligent systems [HCT-W6]. Notice the implicit assumption of a fundamental role for advanced technology, including information technology, sensors, and smart data assessment [see also Visions E1, E2, F2, G2], in helping individuals assume a more active role in their own healthcare [F4].

Another popular theme was that of **universal** access, universal design, universal standards, and configurable systems [e.g., Visions B3, F3, H3, A1]. This reflects an evolving theme that has its roots in the disability community, but makes sense for people of all ages and cultures. It is related to the "new paradigm" of disability that is discussed in Kate Seelman's discussion paper [HCT-W11]. Aspects include **access** to information via the Internet and telecommunications, **standards** that allow transparent **interoperability**, and **configurable systems** that facilitate ease of use. Of note is that F3, with a focus on universal design and standardization, was felt by participants to have one of the greatest impacts on individuals.

Another theme was the desire for a true, **broad-based integration** of the continuum of health care systems and services [G1, D4, B4]. This seems quite a challenge.

Anticipated Technologies. Many institutions involved in home care have special interest in anticipated technologies. In projecting **technology developments**, participants described several major types of systems and products as being likely to play important roles:

- Numerous participants cited the likely development of **computerized smart devices and systems** as major factors in home- and self-care over the next decade. **Intelligent medical devices and personal support technologies** were expected throughout the home and community for data acquisition, assessment, assistance with compliance, and integration of care with remote systems and databases. Participants envisioned the automation of mechanistic processes and expected the implementation of simple low-risk decisions by such intelligent devices and systems. **Wearable, wireless** systems were anticipated as well. Examples included hands-free controllers based on EEG/EMG signals, eye-movement tracking, and speech recognition, and mobile telemonitoring systems.

- Several topical groups projected the development of the **electronic patient record** as a major factor in home- and self-care over the next decade. While uniformly recognized as desirable, this comprehensive computerized record of individual health information was envisioned as a key factor in decision-making by individuals, by smart devices in the home, and by geographically remote clinicians. Not surprisingly, several groups also articulated the **security issues** that attend such computerized records.

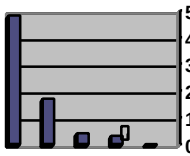
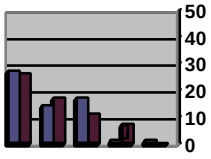
- Working groups noted the likelihood and the importance of vastly improved data analysis in the service of home- and self-care. Participants projected that **data-analysis tools and information-reduction algorithms** would be available not only from geographically remote institutional systems but also in smart devices at home. These systems are expected to provide clinically relevant information to users for technology-assisted **medical decision-making**, as well as recommendations and information about action options.

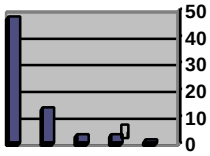
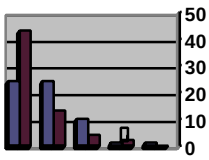
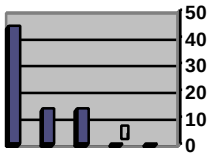
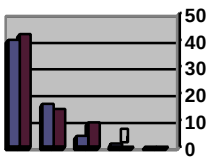
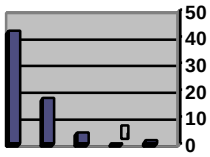
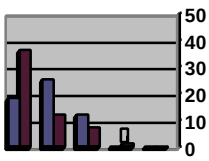
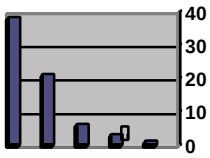
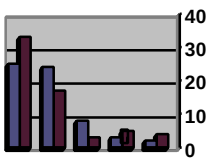
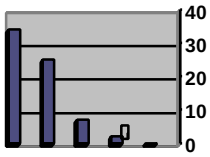
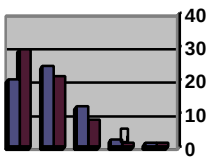
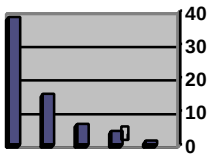
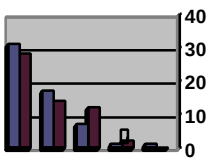
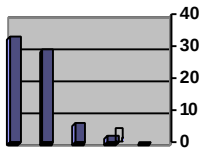
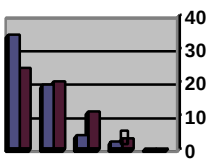
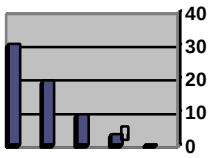
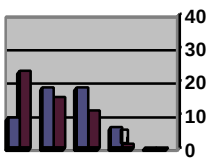
- Multiple working groups projected a critical role for improved **communications systems**. Such high-bandwidth systems were seen as instrumental in connecting patients with electronic records and databases, and with geographically remote clinicians. These systems were expected to be important both for patient follow-up and for independent self-care. Internet and **wireless links** were envisioned.

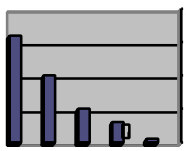
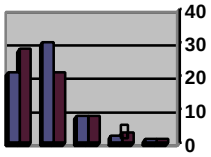
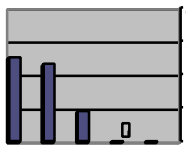
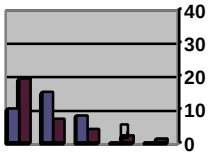
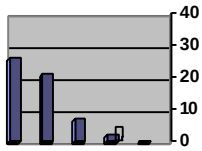
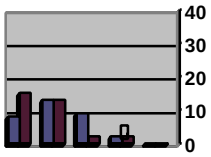
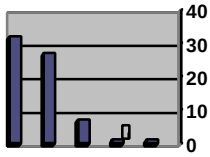
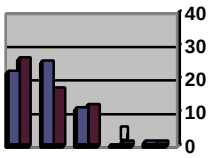
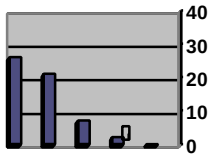
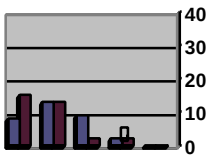
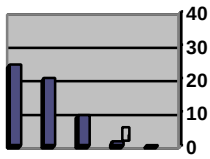
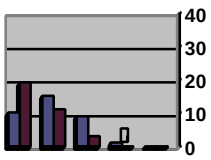
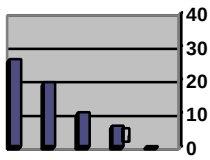
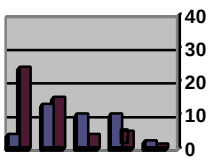
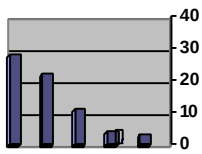
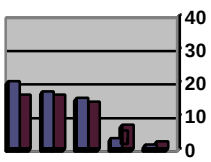
- Participants also noted the expected importance of **non-invasive, intelligent sensors** for continuous monitoring and recording of patient data for input to computerized patient records and to medical data-analysis programs. Some participants projected integrated systems of distributed sensors and monitors inside and outside the home. These may relate to physiological signals, performance measures, biochemical "wellness" sensors [e.g., see the discussion paper by Andrade, HCT-W7], etc.

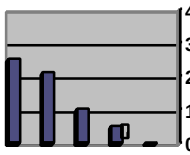
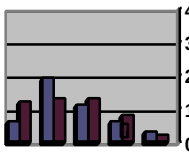
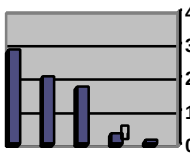
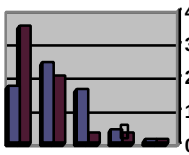
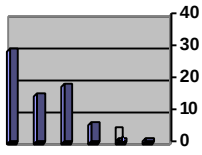
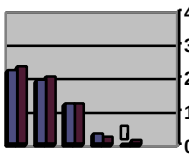
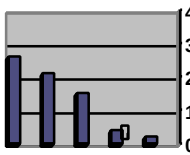
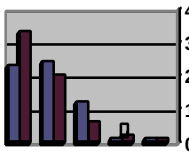
- Several groups pointed toward increasingly **customized products** and systems for home- and self-care. Home care systems were envisioned in flexible configurations comprising "off-the-shelf" components enabled by **standardized universal designs** for interoperability and ease of use.

Table 3.1: The 20 most highly scored **Vision** statements (rank-ordered, underlines added for effect). For all of these the "1" score was most prevalent. [See Appendix A.2 for a full listing, with rankings.] For degree of impact, the left bar is societal impact, the right bar is impact on individuals).

Vision Statement	**Agreement** **agree … disagree** **1 2 3 4 5**	**Impact (S, I)** **hi … low** **1 2 3 4 5**
A1: (i) In the future, **technology** will enable the consumer to **access** a wide range of health care services from the **home**.		

D1: Institutional care **functions will continue to migrate from the institution.**		
F1: We desire that health care will migrate to a **proactive, preventative model** rather than the reactive, episodic model utilized today. • Intelligent wearable sensors • Trend-data-analysis tools, predictive algorithms • HMO's will drive migration to HCT's		
G1: Technology will facilitate continuum of care and management into the **home and community**		
C1: **Reimbursement policies** should not discriminate against home health care, products and services.		
D2: **Product design** should be using a "**consumer model**" rather than a "medical model" to be able to take advantage of improvements in technology.		
D3: There will be an **increase in chronic disease/disability** in all age groups, including children, and populations. Numbers of persons will chronic disabilities leaving institutions and going into productive life will increase.		
H1: … a world in which appropriate and **affordable telecommunication** will be increasingly available globally (data, voice, video, translation,) along with cost reduction, wireless technologies and solar power generation.		
E1: Development of **wearable computer systems**		

F2: We anticipate that a variety of **market-directed** health care and information **technologies** will permeate the home environment: • HC systems designed to meet special needs • Sensors & actuators on person and in their environment, with collective intelligence • Close exchange between devices & Electronic Patient Records		
B1: There will very likely be **consumer demand** for healthcare products and services that will enable patients to stay well and **stay at home**.		
B2: There will be a universal backbone (communications system) through which **healthcare transactions** will take place.		
D4: There should be a systems **integration** across health care and activities of life. No one has responsibility for the integration of the system.		
B3: **Accessible and configurable systems** for health and **wellness** needs. The home-based end of the system should be transparent in the home (i.e., "minimally intrusive").		
B4: There should be an **integrated system** of care, devices, and testing that allows patients to improve their health and to stay in their **chosen environment**.		
E2: Development of **hands-free controllers** (I/O devices/interfaces)		
H2: … a world in which **networking** via the WWW and internet will allow for the formation of health working groups not bounded by geography or nationality, resulting in increasing capability of software collaboration.		

E3: Emphasis on, or requirement of, **human factors** engineering, will be reactive rather than proactive.		
F3: **Universal design and standardization** will facilitate flexible configuration of home technologies for special needs.		
H3: … a world in which industry is committed to **universal design** with the broadest range of ability and function		
F4: We desire that individuals assume a more active role in their own health care in order for a proactive, preventative care model to be effective. ➢ Simple/low-risk care decisions by automated devices ➢ Health maintenance via intelligent algorithms/agents ➢ Individuals will control access to their medical info.		

3.2 Knowledge Gaps

Motivation. The key motivation behind the objective of identifying knowledge gaps is to provide foresight that can be used to help address such gaps in a timely manner. A typical vehicle for addressing such gaps in knowledge or understanding is for agencies to fund targeted scientific research activities. Given the recurring theme of the vision statements in the previous section -- that home healthcare (and HCT's) will continue to grow and evolve -- one might expect that a range of gaps would be identified, and indeed this was the case.

Process. Each of the eight topical groups were asked to identify and prioritize a finite list consisting of at least 3 gaps in knowledge, and were aware that we were especially interested in finding areas that would "rise to the top" of our list. Each list was then re-ranked by all participants, with a "1" assigned to the top choice in the list, etc. While a "global" ranking that spanned all 8 topic areas is not possible since (for time reasons) no attempt was made to have participants synthesize their 8 lists of rankings, by using "3.0" as a threshold, 20 items (the top 2-to-3 from each group) were be identified. Interestingly, a "top 10" also emerged naturally, which consisted of the top ranked item from each of the lists, and 2 others (from topics A and H where there was essentially a near "dead heat" between the top 2 on the topical list).

Top-Ranked Knowledge Gaps. The summary results are provided as Table 3.2. Each of these is addressed more fully within the eight topical reports. The four top-ranked gaps in knowledge, each with more "1" rankings than all others combined, are reproduced here:

1. F1: Information reduction algorithms and sense-making tools.
2. G1: Outcomes and functional assessment tools.
3. C1: Inadequate understanding of the clinical and cost effectiveness of home health services, products and technologies.
4. D1: Need for development of innovative, more effective mobile assist devices to accommodate a greater range of function, and other devices to assist with the other aspects of daily living.

Interesting, these four are relatively independent of each other, and collectively form a remarkably expansive set. The first targets the need for more knowledge in the area of intelligent systems technology, as related to decision-support and automated systems for the future. It opens up many possibilities, and provides strong motivation and support for some of OSTP's and NSF's emerging initiatives on distributed intelligent systems. It also, however, suggests a need for a better understanding of how/when/why health measures are used by medical experts, which is necessary for designing proactive strategies for information extraction.

The second within this list represents a classic gap in knowledge that has been identified in health-related governmental documents, and is often considered to be one of the great challenges of the health profession. The momentum toward home healthcare helps reinforce (and indeed add to) this pressing need to develop, evaluate and utilize such tools. Ironically, the possibility of better access to home-based populations, e.g. through telehealth infrastructure, also provides an inherent mechanism for implementing the types of larger-scale research studies that could help society obtain the quantity of data necessary to refine and validate such assessment tools.

The third gap in understanding relates to the challenge of addressing both clinical and cost effectiveness issues. As is apparent on many fronts, from efforts by National Library of Medicine (NLM), Agency for Health Care Policy and Research (AHPRR) and Health Care Financing Administration (HCFA) to the joint Whitaker-NSF grants program on cost reducing biomedical technologies, this is remarkably important and challenging. Interestingly, while this gap had the largest number of "1's" (43), the response was somewhat bimodal in that it also had the most negative responses (11) of the top four -- perhaps some didn't view this as a gap in knowledge. Yet there is clearly inadequate understanding in this area, for instance of how fluctuating phases of "chronic" diseases impact on delivery, or how much and what type of therapeutic intervention is necessary to balance clinical and cost effectiveness (see especially the reports of Topics B, C and D).

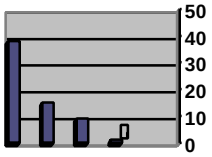
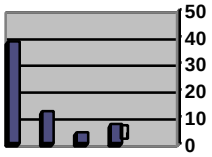
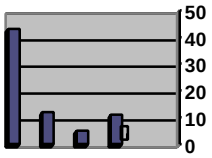
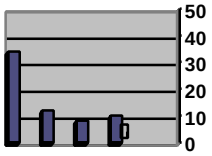
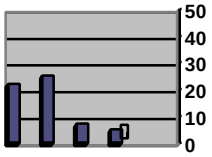
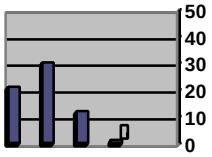
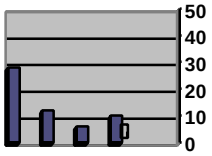
The fourth focuses on the concept that "enabling technology" (that enhances function and independence) remains an important priority. The focus here is on innovation, and there are clearly many fundamental issues related to human-technology interfaces for the future. This ties to the mission of funding agencies such as NSF's Biomedical Engineering and Research to Aid the Disabled and the various research programs of National Institute on Disability and Rehabilitation Research (NIDRR) and the Veteran's Administration Medical R&D (VA).

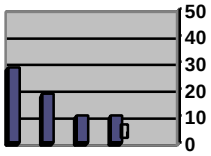
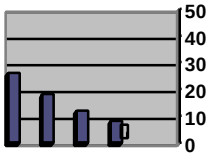
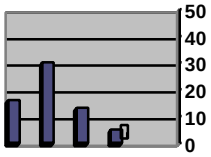
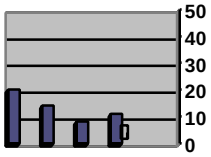
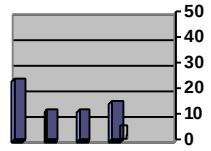
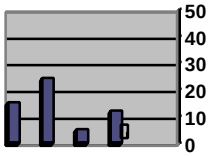
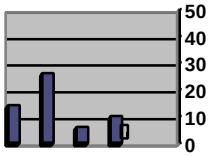
The rest of the "top ten" tend to be consistent with these four, and in particular the second and third. The most recurring theme is the need for ***outcomes knowledge*** that can be used for decision-making and to discern "what works" for home-based healthcare -- this ties G1 and C1 with A1 and H1, and to a lesser extent A2, H2, C1, E1 and H2. The key distinction is that some statements focus more on the service delivery process (B1, A2, H2), others more on populations and databases (E1, H1), and others on monitored data and the clinical decision-making process (A1).

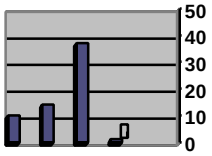
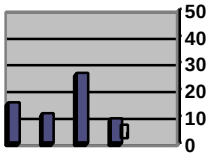
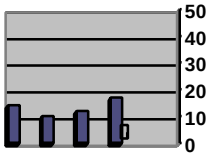
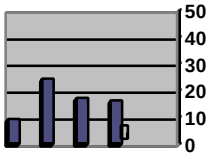
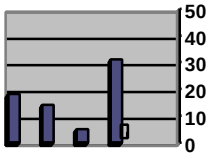
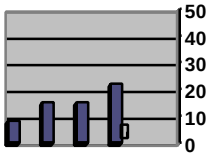
Synthesis. Looking at the full list of knowledge gaps as a collective whole, working groups stressed the general need for information to facilitate the **availability** of home- and self-care technologies, and to assess the **impact** of these technologies. In identifying critical knowledge gaps, several major subjects emerged as having the potential for large-scale importance, here framed as a "needs assessment" list:

- The need for **reliable information on the cost savings and cost-effectiveness associated with home- and self-care**. They also noted the need for development of methods to perform these analyses.
- The need for clear **identification of the patient groups** that are appropriate for home- and self-care. They emphasized the importance of developing well-grounded characterization of the real needs and circumstances of home- and self-care patients for the benefit of equipment designers and health care professionals.
- The need for **research into improved techniques to train and prepare** users, family members, and health care professionals about appropriate use of home- and self-care products.
- The need for knowledge on when **telehealth** is an effective strategy, and on how to optimally design telehealth systems for targeted end-users and providers.
- The need for information enabling the identification of **relevant parameters for patient monitoring**, as well as the importance of developing appropriate methods for the interpretation and analysis of those parameters for **medical decision-making**.
- The need for improvements in the **knowledge base supporting the design process** for new home- and self-care products. Working groups endorsed the value of technology transfer from the design processes used for consumer products and from other industries. Particular mention was made of the need for databases and modeling tools for designers, as well as reliable methods for evaluating the usability and reliability of new designs.
- The need for significantly improved enabling technologies for device input (e.g., sensors), processing (e.g., low-power data processors), outputs (e.g., actuators), and power sources (e.g., battery technology) for miniaturized and wearable products.
- The need for better understanding of technologies and algorithms for storage, reduction, and analysis of the **large continuous data sets generated by wearable sensors and remote monitors** in the home.
- The need for the **development of methods for presenting information effectively to users**. This entails developing techniques for tailoring the type, amount, and presentation of information to users to enable informed and meaningful decisions.
- The need for **analysis of ethical issues** surrounding the choice to use home- and self-care methods instead of traditional methods, and the impact of such choices. Potential ethical issues were also identified concerning the transmission and communication of patient information.
- The need for relevant information on **human error**, as well as on the errors, adverse events, and unintended consequences of integrating a network of multiple devices, drugs, and technologies in the home.

Table 3.2: Highest Rated Gaps in Knowledge Base (top 20). Graphs to right represent rank-ordered "within-group" results (1, 2, 3, "4 and above"), with average in the lower right.

F1: Information reduction algorithms and sense-making tools. These will include automated analysis of physical signs, objective health data analysis, and tools to support identification of relevant data/interactions (from huge, continuous sets). Human modeling and data fusion will be key to the success of these algorithms. These algorithms and tools must support changes in criteria for diagnoses (e.g., psychiatric disorder diagnosis derived from new behavior monitoring) as well as surrogate diagnoses that have yet to be realized. Leaders: NIH, NSF, NLM, MRMC.	 1.57
G1: Outcomes and functional assessment tools	 1.67
C1: Inadequate understanding of the clinical and cost effectiveness of home health services, products and technologies	 1.77
D1: Need for development of innovative, more effective mobile assist devices to accommodate a greater range of function and other devices to assist with the other aspects of daily living	 1.90
H1: There are gaps in knowledge in the identification of needs for health care by region and population. Need to identify and integrate existing data bases and compile best practices	 1.92
F2: Device usability and reliability, including the broad area of human factors. This includes (1) advances in 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) complete testing and debugging of prototypical systems in simulated and real environments prior to public release.	 1.92
E1: Database and models for home care population are incomplete.	 1.96

A1: We don't know how to use different types of data in terms of their importance in clinical decision-making; which data are worth monitoring?	 2.03
A2: Understanding which clinical services are appropriately and effectively delivered via home health technologies versus in person	 2.03
D2: Information management and assessment -- interpretation of continuous data from sensors	 2.05
B1: Lack of knowledge about "what works" in home technology use and home healthcare delivery.	 2.19
H2. Science/evidence-based best practices in rehabilitation and telehealth and telerehabilitation.	 2.25
G2: Personal preparation and training (clinicians and consumers)	 2.25
E2: Insufficient knowledge, coordination, and communication across medical personnel, organizations, and agencies.	 2.39

F3: Technology for wearable devices and remote monitoring in home care systems. This includes reliable, self-calibrating, long-lasting, and unobtrusive sensors enabled by enhancements in (a) storage algorithms, (b) low-power processing systems, and (c) battery technology	 2.47
D3: There is a lack of system integration between health and life system -- ADLs and IADLs.	 2.47
B2: Patient tasks, perceptions, and motivation toward self care. We need to define what should be done, and how patients perceive what they must do.	 2.63
C2: Inadequate understanding of clinical, social, ethical and economic consequences of home health technology for family life.	 2.69
C3: Lack of knowledge about likely errors, adverse events, and unintended consequences of integrating multiple devices, drugs and technologies in the home environment.	 2.72
H3. NGOs and administrators and health care professions in the developed countries need to improve their understandings of local health care needs and conditions and their understandings of individuals in low income countries about realistic health care program needs.	 2.85

3.3 Barriers

Motivation. The third aim for each topical group was to provide a list of barriers that needed to be overcome to deliver effective and safe homecare technologies.

Process. Each of the eight groups presented 3-8 barriers, which were rank ordered (within the group's list) by all participants. Thus direct comparison between groups is not possible. However, in Table 3.3 the top 20 in terms of average score (i.e., giving the top 2-3 within each of the 8 topics) are presented, and our discussion focuses on collective themes that are seen within these.

Key Barriers. As can be seen from the list of the ten most highly-rated barriers (i.e., the top-ranked for each group, plus 2 others that just missed a top ranking and had very strong support), three themes stood out:

- **Reimbursement challenges for home care services and products** (C1, A1, G1). This was the top-ranked barrier for 3 of the 8 topic groups. Of these, the two highest rated were especially specific: the current reimbursement scheme penalizes home care (C1), and there is a lack of mechanisms to support home telehealth services (A1). The discussion within the Topic C report for barrier C1 provides information on the challenges that home health agencies (HHAs) have had with the current interim payment system (IPS).

- **Lack of appropriate technical infrastructure**, including medical device and telecommunications technical standards (F1, A2), human factors processes/procedures for home health (E1), and societal infrastructure (H1). The highest rated of these, F1, was perhaps the most aggressive: we need infrastructure standards and flexible (component-based) information architectures that promote secure interconnectivity between devices from different manufacturers. We also need a set of communications standards for medical devices that facilitate interoperability, including for wireless exchange of information. Without widely accepted standards and procedures, healthcare will lag behind other 21st century developments, with piecemeal solutions. The development of this type of broad-based infrastructure would seem to require a considerable level of cooperation and partnership between several disparate government (e.g., technical, medical) and industry sectors (e.g., medical device, telecommunications, medical insurance, housing). And the human component -- from interface design to cultural barriers -- cannot be neglected.

- **Need for broad-based education about home care technologies** and their effective utilization (B1, D1, H2). This includes enabling consumers to have access to reliable information and decision-support mechanisms (D1), breaking down bi-directional cultural barriers (H2), and proactive, broad-based education about home care technologies aimed at end-users, professionals, students and other potential stakeholders (B1).

The interconnectivity between these areas is quite apparent; indeed, a case could be made that many of these barriers are best addressed in tandem. Perhaps the most revealing interwoven theme is the collective desire on the part of participants that these barriers be addressed with **home/self health explicitly targeted**. While this is likely a biased sample (given the theme of the workshop), these prioritized barriers do provide a sort of roadmap.

Interestingly, all of the key barriers are ones that can, at least in principle, be addressed. This is not to say that the task would be easy. In practice, it would appear that such efforts must involve a significant governmental role, working in cooperation not only with a variety of industries (homecare products, telecommunications, insurance) but also groups representing consumers and practitioners. Such a cooperative, concerted effort is always a challenge and will take time to develop.

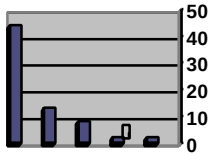
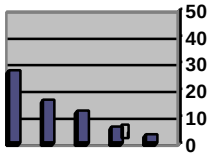
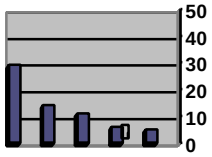
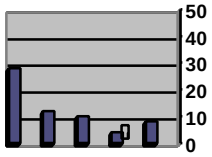
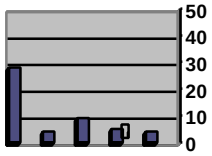
However, it is also clear that a multi-faceted focus on **education/training materials in strategic areas (e.g., telehealth technologies) can proceed at once**; knowledge is empowering, and in this case can only help break down barriers. As an example, while it is true that reimbursement policy can create an environment that

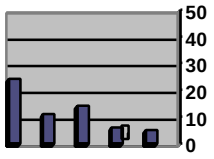
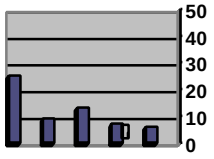
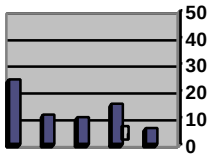
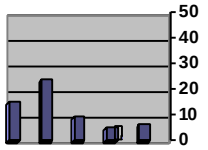
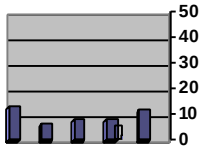
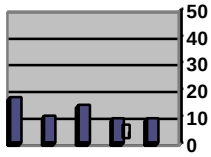
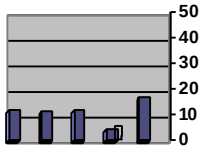
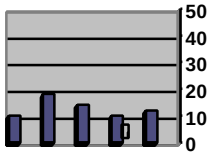
encourages or discourages innovation, it is also likely that a more rational reimbursement scheme requires more **informed end-users and home caregivers**.

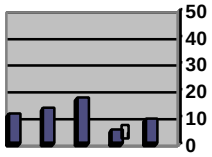
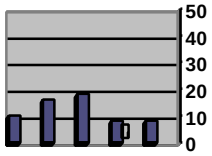
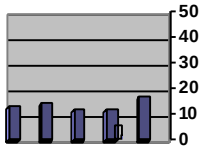
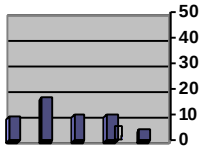
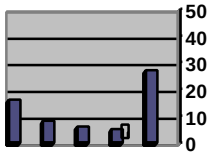
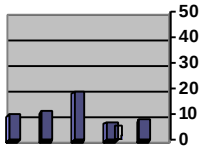
It is also clear that mechanisms are needed to encourage communication between key industry segments (medical devices, telecommunications, computer engineering), with special emphases on key technical issues (e.g., wireless interface standards, mobile devices, lower-cost teleconferencing, usability engineering and universal access, security/safety).

Inspection of other high-ranked barriers affirms the themes already addressed. A recurring theme is the need for cooperation and collaboration among various stakeholders within the new health/technology environment; it seems that such an infrastructure does not currently exist, and will become more needed as we enter the 21st century. Other key barriers are confidentiality/security of patient data, regulatory ambiguity, and the lack of familiarity of practitioners and caregivers with newer technologies.

Table 3.3: Top Barriers (rank-ordered within each group, top 2-3 per group)

C1 Current reimbursement scheme penalizes home health care.	
F1 Infrastructure standards and flexible information architectures do not exist that promote full interconnectivity and secure operation between devices from difference manufacturers. These standards and frameworks are key for smart devices/systems and distributed, "virtual" systems demonstrating collective intelligence	
H1 Lack of infrastructure/systems in the areas of health care, roads, power, education, water, risk management, etc.	
A1 Payment structures and reimbursement mechanisms do not support telehealth services: who pays, for what services, where in the continuum?	
E1 Lack of common set of human factors engineering processes and procedures for home health care.	

D1 The decision of data/information "goodness" has shifted to the consumer without a supporting infrastructure.	
G1 Reimbursement	
H2 Cultural barriers on both sides, primarily language and education, combined with national, provincial and regional perspectives vs. global thinking and planning, e.g., "Americanization" and dominance, cultures and languages.	
D2 Adoption of any new technology with be slowed by the lack of familiarity of the several levels of care-giver community with the technology. The current procedure based payment schedule/process is not an incentive to adopt/use the best available technology.	
B1 Broader education about home care technologies. A number of barriers and issues related to the development of technology for the home and the acceptance of them are associated with educational efforts that need to b e undertaken for helping to make use or technologies in the home seem acceptable and used. There is a need for broader education aimed at users, engineers, students, and various other potential stakeholders about possible applications of home care technologies.	
A2 Nascent communication standards for medical devices (e.g., IEEE 1073) need to be developed, promulgated and accepted widely before system integration can proceed efficiently.	
B2 Confidentiality/security/integration of patient data/other clinical data. A system addressing all of these issues has to be developed before the comfort level among patients and clinicians can reasonably be raised.	
C2 Inconsistency between federal and state laws and regulations creates barriers to rational development of home health care services, products and technologies.	

E2 Lack of cooperation and collaboration among the various stakeholders (e.g., human factors engineers, AMA, FDA, FCC, professional societies, regulators, consumer groups, manufacturers, and funding agencies).	
F2 Few medical information repositories contain data that comprise a useful knowledge base for smart decisions. 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.	
C3 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 ad coding procedures potentially causing cost-prohibitive or innovation stifling delays.	
G2 Business, industry, medical reimbursement and government have to collaborate to bring exemplars forward thereby avoiding "orphan technology" syndrome. There has to be some cost sharing on the development and assumption of safety and liability for the technology.	
F3 Lack of a good reimbursement policy for home-based health care delivery.	
D3 The infrastructure that supports our current lifestyle is old (e.g., housing design, telecommunications, standards of construction, etc.).	

3.4 Recommendations

Process.

Each of the 8 topical groups produced 3-6 recommendations for presentation to all participants, resulting in 31 total. These recommendations were scored from 1-5, with "1" representing a high degree of agreement/impact/role. While three measures were scored (degree of agreement, degree of societal impact, degree of need for government role), here we emphasize degree of agreement. To leave "room at the top," participants were encouraged to keep their average score between 2 and 3. In general, most recommendations were well supported by the participants, and despite the instructions, 23 of these 31 had an average degree of agreement score that was below 2.2, with this being a natural gap; thus we will focus on these 23 (see Table 3.4 below). For 20 of these 23 the score of "1" was the highest category, and for the top 4 there were more "1's" than all other scores combined. Some had a greater spread than others, and it seemed worthwhile to rank order based both on the average score and the percentage of "1" scores; these two were averaged.

Because of the high degree of representation by federal agencies (12 represented, nearly 30 participants), interpretation of these recommendations will include comments on the possible role of specific agencies in implementing recommendations.

Top Recommendations.

The top recommendation (F1), with nearly 90% agreeing to the level of "1" or "2", was the need to fund research to develop effective tools for **intelligent processing of large amounts of healthcare data**. This was previously identified as the top knowledge gap of the Workshop (Gap F1), and clearly participants felt this to be of critical importance -- a priority to be addressed (see also Topic F report). This included the development of knowledge dissemination and information reduction tools, with a special focus on data "flags" using sensor fusion and automated diagnosis. It addresses, head-on, the reality that as the number of new sensor technologies grows and the transfer of information becomes more and more routine, the bottleneck may be figuring out what to do with the information. Since one of the applications would be clinical decision-support, clinicians would clearly need to be involved in the development and evaluation process, as would other stakeholders. This theme often goes under the title of "**telematics**" (more commonly used in Europe) or "bio/medical informatics," only here with the target toward homecare.

Closely tied in concept is the 5th-ranked recommendation, D1, which provides the insightful addition of a specific need to focus on the wealth of information that can come from **continuous data from sensors**. This reflects the anticipated reality of **wearable sensors** with intrinsic **mobile telecommunications** capabilities (Vision statements E1 and F2), and suggests the need for initiatives that specifically address tools for intelligent proactive interpretation and management of such information. Technical approaches range from expert systems to neurofuzzy systems to novel database structures for healthcare applications. Clinical applications range from alerting systems for at-risk persons to therapeutic interventions with telesupport.

The second top-ranked (A1) recommends the need for **large-scale demonstration** projects aimed specifically at **telehealth interfaces**. This was the top-ranked one of a collection of recommendations for large-scale demonstration/partnerships/consortia (e.g., Recommendations A2, C2, G2, B1, F3), and reflects the general sense that while telehealth approaches are relatively novel and have great potential, they are relatively untested. As seen in the Topic A report, the primary motivation rests in the reality that current piecemeal approaches to home telecare that purport to demonstrate cost-effectiveness and enhanced care don't provide the type of data (of larger scope) that is desired by third-party payer decision-makers. This suggests a **coordinated** (tele-managed!) effort involving multiple institutions, with partnerships that include universities, government and industry. It would seem that action in this area will require a strong governmental role, with the most appropriate body for coordinating the implementation of this recommendation being the U.S. Office for the Advancement of Telehealth; it is noteworthy that one of the co-chairs of Topical Group A directs this agency. The remarkably high level of support (editorial note: statements including the word "government" generally didn't fare as well) that this received suggests that there is a real opportunity to mount a cooperative effort to make this happen.

The third top-ranked recommendation has its focus on **participation of consumers** (end users) and **providers** (key stakeholders/users) in new, 21st-century HCT designs. This concept is not the norm, though it is more common in the disability research community (e.g., see the discussion paper by Seelman (HCT-W11)). Yet it is consistent with one of the key visions of the Workshop: that as a society we will move toward a "consumer model" (vs. pathology/episode-driven "medical model") for healthcare and wellness (see especially Section 4.1; discussion papers by Kinsella and by Loeb; Topic Report B). Forming "**integral teams**" is a challenge, and perhaps the high degree of agreement reflects support of the principle more that a specific tangible objective. How could this be implemented? Whatever the mechanism, it would seem that NIDRR could play a key role, perhaps in cooperation with other agencies such as the VA, NIH (National Center for Medical Rehabilitation Research) and NSF.

The fourth (C1) suggests investigating **reform in the regulatory process**, especially as related to technology for home healthcare. While it is difficult to interpret a recommendation with 4 sub-recommendations, and no single action presents itself, the strong support suggests that this could be an area for interagency focus.

The sixth (A2) recommends the promotion of partnerships/consortia that encourage R&D and integration among the **healthcare and electronics/software industries**. In most cases, these industries are not neighbors that know each other well. Yet they'll need to. For instance, a number of technically-inclined participants suggested that within about 10 years, most medical devices within the home will communicate by wireless means. That's a big change. Standards for home wireless technologies (radio frequency; infrared) are currently of enormous financial importance, involving many large international information and telecommunications companies. 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. This recommendation suggests 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. From a "quality of life" perspective, this could emerge as a national priority for infrastructure development [e.g., see discussion paper by Winters (HCT-W12)]. There would also seem to be a role for government-industry partnerships to coordinate such activity; for example, consider the new paradigm of telecommunications-ready medical devices, and integrated home/Internet wireless networks in which a subset of the interfaces are "medical." As noted by many participants, when it comes to health, the interwoven nature of the 21st-century home will certainly bring its share of regulatory challenges.

The 7th and 8th ranked recommendations (H1, A2) both focus on **education and training** of **consumers and professionals**. Notice the inclusion of both consumers (bringing in self-care) and practitioners (who provide healthcare services). This is insightful, in that practitioners are often: **i)** not used to (or trained in) employing technology in their practice, and **ii)** unaware of home-based technological solutions that could enhance caregiving and independence. Additionally, many health professions -- including those in applied health (e.g., physical therapy, occupational therapy, speech/language) -- are encouraging a greater emphasis on education in self-care techniques (motivated in part by shorter hospital stays). Agencies such as NIDRR and NIH could encourage training of health professionals in the use of modern technologies, and in providing quality services that utilize such technologies outside of the traditional hospital environment. Also, agencies that provide educational infrastructure and Internet-based resource materials, such as NLM, could consider funding activities that specifically target resource materials related to the role of HCTs in self-care and caregiving, building on web resources such as www.healthfinder.gov. While a wealth of new health-related materials are entering the Web (especially disease-based), many participants noted the lack of "quality control" in Web-based information, and the need to provide consumers information on reliable and trustworthy sites. Also, there is a need for proactive, coordinated education on the role and appropriate use of HCTs, including the compiling of best practices of telehealth and telerehabilitation (Recommendation H3). A difficulty in certain areas is that research is still needed to determine best practices and outcomes; this ties back to the need for large demonstration projects (e.g., see B1).

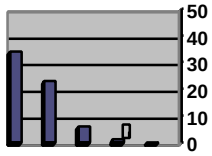
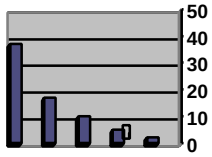
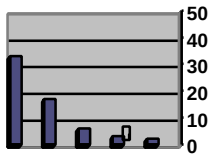
Highlights of Other Recommendations.

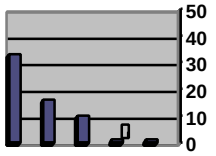
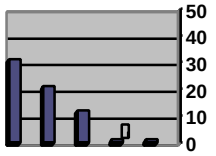
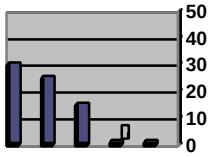
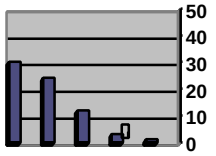
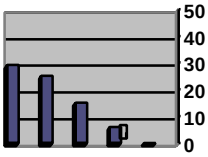
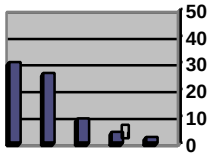
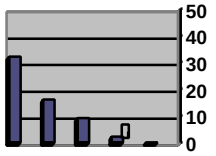
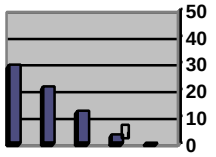
In surveying the rest of the recommendations, many insights and possible action items emerge. Here are a few; the reader, upon reviewing Table 3.4, will likely see others.

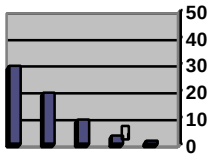
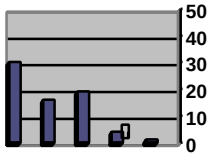
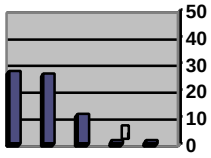
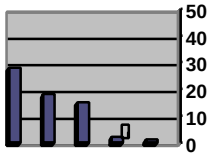
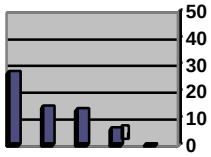
Of note is that there were four other recommendations from groups F (smart homes) and D (technology and chronic conditions) that were synergistic with the top and fifth-ranked recommendations that were mentioned previously: **noninvasive mobile/wearable devices** (F2), **mobile-assist devices** (D2), **tele-remote sensors** (D3), and **information architecture and interoperability standards** (F3). This acknowledges the reality that technological changes will profoundly impact on how we communicate with each other, and that concurrent R&D activities are needed to help determine appropriate healthcare solutions. In addition to the Topical Reports for D and F, the discussion papers by Loeb (HCT-W8) and Warren et al. (HCT-W6) provide an excellent motivation for this future need and possible approaches. These recommendations would seem to fit well the OSTP's initiatives on roles for information technologies in the 21st century, and especially NSF's initiatives on information technologies and intelligent systems.

It is interesting that of the three recommendations that made the top 22 from the Topic E (human factors) group, two recommended the development of **human factors databases** for use in design and for understanding the tasks and operating requirements of HCTs; perhaps these recommendations will help motivate more activity in human factors R&D that targets the home and mobile environments.

There appears to be an implicit recommendation for **cooperation on a large-scale**, to be accomplished through infrastructure such as multi-site demonstration projects, "virtual" centers, partnerships, consortia and working groups (A1, A2, H1, B1, H3, F3). Strategic areas include telehealth and HCT use/outcomes studies. The take-home message would seem to be that for there to be substantial progress in many of the strategic areas, there will need to be **well-coordinated, multi-faceted approaches by teams with a range of expertise, talent, and access to strategic user populations**. This suggests a key governmental role in conceptualizing priorities and anticipating societal needs, and then providing larger-scale mechanisms for addressing such needs.

Table 3.4 Top Recommendations (rank-ordered within each group, top 2-3 per group)	Agreement **agree…disagree** **1 2 3 4 5**
F1: 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 information overload, and 3) data mining tools for acquiring relevant data from distributed repositories. ... sensor data fusion, automated diagnosis ... data "flags" ...	
A1: Support **large-scale demonstration projects** that seek creatively to incorporate and evaluate **tele-homecare interfaces** into home care practice and information into existing health care practice and health information systems.	
G1: **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.	

C1: 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 innovation and adaptive technology, 2) FDA should provide specific guidelines ..., 3) promote ... professional licensure; and 4) HCFA should clearly define coverage and coding ... HCTs.	
D1: **Information management** and assessment -- develop assessment tools for interpretation of **continuous data from sensors.**	
A2: 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.	
H1: Government & 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 sources of information; security; confidentiality, accessibility, consumer rights, privacy, accessibility for literacy and function.	
A3: Support **consumer and professional education**, training and retraining in the use of information and care technologies.	
C2: Launch **demonstration projects** of fully **integrated home health** care systems including ethical, societal, economic and technological evaluation of communities based on both locality and disease groups.	
E1: Development of **human factors databases**, **metrics and standards** for use in design, and with which to assess the adequacy of design.	
F2: **Non-invasive** wearable devices and remote sensors.	

E2: Encourage development & application of **human factors techniques** in the health care technology context (e.g., adaptive, appropriate automated devices that are designed for a specific user population).	
H2: **International** discussion on **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.	
D2: Develop improved, more effective **mobile assist** devices and other devices to **support daily living**.	
D3: Develop **sensor technology**, particularly sensors which will enable caregivers at locations **remote** from patients to interact with the patient.	
G2: **Government consortium** professional care.	
E3: Development of databases including the **tasks and operating requirements** of present and future home care technologies, devices, and processes (e.g., hands-free controllers as present devices).	
B1: Need for a **large demonstration project** to analyze home care technology **use and outcomes**.	
H3 Geographical and virtual **centers** to address identified knowledge gaps as part of the creation of instruments for sharing information and compiling the best practices of **telehealth and telerehabilitation**.	

D4: Assign responsibility and **design integrated systems** which encompass both living and health care.	
G3: Substantial **government support** to develop exemplars of enabling technologies such as **robotics and virtual reality** applications.	
A4: Develop and promote **standards** for exchanging and archiving information that addresses the fluid environment created by **telehomecare**.	
F3: Fund **working groups** that focus on **information architecture issues**, gaps in i**nteroperability standards**, and areas that the government should promote that are not being properly addressed by industry.	