Policy

Research Recommendations for the American Telemedicine Association

ELIZABETH KRUPINSKI, Ph.D.,¹ SUSAN DIMMICK, Ph.D.,² JIM GRIGSBY, Ph.D.,³ GREG MOGEL, M.D.,⁴ DENA PUSKIN, Sc.D.,⁵ STUART SPEEDIE, Ph.D.,⁶ BETH STAMM, Ph.D.,⁷ BONNIE WAKEFIELD, Ph.D.,⁸ JOHN WHITED, M.D.,⁹ PAMELA WHITTEN, Ph.D.,¹⁰ and PETER YELLOWLEES, M.D.¹¹

ABSTRACT

The American Telemedicine Association (ATA) convened a panel of experts to generate a research agenda for the telemedicine community to further support and promote the long-term acceptance and use of telehealth. Three principles to guide research and four key areas within which research is greatly needed were identified. These four areas are technical, clinical, human factors and ergonomics, and economic analyses. It is the hope of the panel that the research recommendations put forth in this document will give investigators the inspiration, tools and goals to make this happen.

INTRODUCTION

TELEHEALTH TECHNOLOGIES, which embrace telemedicine, are being used in an everwidening array of applications and environments, and there is a substantial body of literature advocating their use and general utility. The existing body of literature, however, ranges from purely anecdotal accounts of telehealth applications through well-controlled

⁵Office for the Advancement of Telehealth, USDHHS, Rockville, Maryland.

¹Department of Radiology, University of Arizona, Tucson, Arizona.

²Oak Ridge Institute for Science and Education, University of Tennessee Health Science Center, Memphis, Tennessee.

³Division of Healthcare Policy and Research, University of Colorado Health Sciences Center, Denver, Colorado. ⁴Department of Radiology, University of Southern California, Los Angeles, California.

⁶Division of Health Informatics, Department of Laboratory Medicine and Pathology, University of Minnesota Medical School, Minneapolis, Minnesota.

⁷Institute of Rural Health, Idaho State University, Pocatello, Idaho.

⁸Harry S Truman Memorial Veterans Hospital and Sinclair School of Nursing, University of Missouri-Columbia, Columbia, Missouri.

⁹Center for Health Services Research in Primary Care, VA Medical Center, Department of Medicine, Duke University, Durham, North Carolina.

¹⁰Department of Telecommunication, Michigan State University, East Lansing, Michigan.

¹¹Department of Psychiatry & Behavioral Sciences and Center for Health & Technology, University of California, Davis, Medical Center, Sacramento, California.

randomized clinical trials.^{1–6} Because in part to the inconsistent nature of the literature, there have been questions raised about the quality of telehealth that may be dramatically slowing its integration into the healthcare continuum. In response to this problem, Thelma McClosky Armstrong, immediate past president of the American Telemedicine Association (ATA) convened a panel to formulate a research agenda for the ATA. The panel members, which comprised the authors of this paper, are regarded as experts in the area of telehealth research.

The recommendations were generated via group consensus via phone and e-mail communications, based on individual reviews of the literature and expertise each member brought to the panel. The intent of this agenda is to provide research guidance to the telehealth community in order to further support and promote the long-term acceptance and use of telehealth. It should be noted that in the context of this paper we are using the general term telehealth, and other nomenclatures such as telemedicine and e-health are presumed to fall under this general heading.

PROGRAM ASSESSMENT VERSUS RESEARCH

At the outset, a distinction is made between telehealth (or program) assessment and telehealth research. Assessment or program evaluation refers to a process applied to an individual program for quality assessment/quality control (QA/QC), tracking of cases, and other related activities designed to characterize what a program is doing. For example, a common method to assess the success of a program is to "measure against the mission." Mission statements or yearly plans typically have clearly identifiable goals, and stakeholders can, on a periodic basis, review these goals and determine if they have been met and to what degree. Broadly stated goals such as "we will promote the use of telehealth" are usually assessed subjectively; while more concrete goals such as "in the coming year we will serve 20% more patients via telehealth" can be assessed objectively by comparing hard data. Assessment results are typically used to guide and manage a program in both the short and long term. Although assessment methods can be generalized and used by other programs, the results from one program rarely apply directly to another. This document does not address this type of assessment given its program specific and idiosyncratic nature.

Research on the other hand refers to investigations that are generally hypothesis driven and generate results that can be generalized to the broader telehealth community. Although many research strategies are hypothesis driven and collect what it considered quantitative data, there are a number of very prominent and acceptable qualitative research designs that can be used as well. For example, Grounded Theory falls into the qualitative research design area and rather than have set hypotheses guide the data collection and analysis, the data (e.g., interview responses) are analyzed for recurring themes and relationships in order to generate an understanding of the phenomenon under study.7,8

UTILIZATION OF EXISTING TOOLS, PARADIGMS, AND MODELS

It is clearly not possible (or desirable) to mandate how research should be done. The panel recommended strongly, however, that whenever possible established research methods and statistical analysis tools be used. For example, it is a very common practice in telehealth research to survey those involved in various aspects of a telehealth encounter (e.g., referring clinician, consulting clinician, patient). Survey data can be extremely useful, but if the survey tools are not developed properly (e.g., analyzed for content, criterion, and construct validity) they often generate data that are not reliable or valid. Although the basics of survey construction and analysis can be found in any number of introductory statistics books,⁹ it is also important to utilize methods developed for a particular focus or field if they exist. For example, if a survey is being developed to determine what factors induce patients to seek out or request telehealth services, it might be beneficial to examine the methods and styles used in the construction of consumer satisfaction surveys.¹⁰ If, however, a survey is being developed to assess how participants feel they interacted with a remote group during a telefacilitated cancer support group session, methods from social psychology and the study of group dynamics would be more appropriate to utilize.¹¹ In some cases, research topics such as quality of life are so well studied in healthcare evaluation in general that the existing survey instruments (e.g., World Health Organization's Quality of Life Instruments) are firmly established and often regarded as the standard tool to use.¹² If such validated and widely used tools exist, it is highly recommended that they be investigated for adaptation to and use in telehealth studies.

It is also recommended that if validated models exist within a particular area of investigation, these models be used and tested for potential appropriate use in a telehealth context. For example, when investigating the impact of telehealth on a particular health behavior (e.g., medication compliance) one could frame the research project in the context of the Health Belief Model (HBM).¹³ These models and their underlying assumptions can be used to generate testable hypotheses and guide experimental design and analysis. For example, the HBM tries to explain and predict health behaviors by examining an individual's attitudes and beliefs. The model has three core assumptions regarding the likelihood that someone will engage in a health-related action (e.g., a patient with diabetes will regularly monitor their blood sugar levels). First the individual must feel that a negative health condition can be avoided (e.g., hypoglycemia). Second, they must have a positive expectation that if they take action the negative condition will be avoided (e.g., better monitoring will reduce hypoglycemic episodes). Finally, the individual must believe that they can successfully carry out the recommended action (e.g., can use blood glucose testing devices with confidence).

The HBM also incorporates six theoretical constructs (perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self-efficacy) that account for an individual's readiness to act.¹⁴ Using the core assumptions, one could hypothesize that

using telehealth technology to automatically prompt patients with diabetes to take a glucose reading, transmit it to a nurse, and receive immediate feedback regarding actions to take if necessary, would yield more monitoring compliance (and hence more stable readings) than in a group receiving no telehealth support. The six theoretical constructs could be used to develop surveys pretelehealth and posttelehealth intervention to assess changes in believe structures and how they correlated with changes in behavior.

SUPPORTING EVIDENCE FOR GUIDELINES AND STANDARDS

Currently there are very few standards or guidelines for telehealth at any level, although recent efforts have been aimed at establishing them.^{15,16} One recent effort that can serve as a model is the "Telehealth Practice Recommendations for Diabetic Retinopathy" document developed by the ATA Ocular Telehealth Special Interest Group (SIG) and the National Institute of Standards and Technology (NIST) Working Group.¹⁶ This comprehensive document was developed based on careful review of evidence from the literature and examination of clinical practice models. One of the major goals in producing the document was to improve clinical outcomes. It provides extensive recommendations on such topics as qualifications of personnel, equipment specifications, legal requirements, and quality control measures. The studies supporting the creation of the recommendations serve as excellent examples of the type of research needed to create practice recommendations for other telehealth applications. The recommendation document itself provides a framework around which future studies can be conducted in order to demonstrate improved clinical outcomes with telehealth.

When such documents exist, it is highly recommended that they be used to guide research questions as well as provide some of the tools for designing the research protocol. For example, the diabetic retinopathy document states that "compression may be used if compression algorithms have undergone clinical validation."¹⁶ This statement clearly lends itself to a multitude of research hypotheses. A study could be designed to compare diagnostic accuracy (e.g., detection of microaneurisms) using original uncompressed images with images compression to various levels using the Joint Photographic Experts Group (JPEG) 2000 standard. In order to carry out the study one could then refer to the recommendation document and find that "retinal images used for diagnosis should be displayed on high-quality monitors with a suggested minimum 19-inch diagonal size."¹⁶ To further standardize the display, one could consult the Digital Imaging and Communications in Medicine (DICOM) standard regarding calibration of color displays.¹⁷

One key point that the diabetic retinopathy document serves to illustrate with regard to research and the development of standards or guidelines is focus. The document addressed recommendations for telehealth assessment of diabetic retinopathy. It did not attempt to establish recommendations for the entire practice of teleophthalmology, nor did it attempt to establish recommendations for any other type of telehealth practice or application. It is highly recommended that research studies, especially those with the goal of supporting or establishing standards or guidelines, maintain as much focus as possible on a specific clinical problem and task. If a research study lacks focus or does not concentrate on a specific clinical problem, one often comes up against the problem of having too little data on too many disparate issues. Once the techniques are in place to examine a particular problem and task, they can quite readily be used or adapted to study other problems and tasks.

KEY RESEARCH AREAS

In addition to the overarching research issues discussed above, the panel identified four areas of investigation that it believes will further validate and promote the practice of telehealth. These areas are (1) technical, (2) clinical, (3) human factors and ergonomics, and (4) economic analyses. Connecting these four areas are three overriding research goals. The first reiterates the importance of using existing models and methods whenever possible, as already discussed. The second is the encouragement of multidisciplinary studies (e.g., technology and interpersonal communication), especially in the context of outcome studies. The third is the integration of telehealth research into the body of general healthcare research (e.g., health outcomes in rural/underserved regions). The four areas are not presented in any order of importance since the agenda is meant to be an integrated whole. The ultimate goal, as summarized in the final section on Economic Analyses, is to tie telehealth research questions into the general healthcare context and create a better healthcare system in general.

Technical

Research in the technical area is perhaps the most amenable to the future consideration of standards and guidelines. This is due, at least partially, to the precedents that exist in the most mature telehealth application, that of teleradiology. For example, the DICOM standard contains information regarding numerous aspects of image acquisition, transfer, storage and display that were originally developed for digital radiology and Picture Archiving and Communications Systems (PACS), but are is now being adapted to a number of other medical imaging applications such as ophthalmology, pathology and dermatology.¹⁸ The "Telehealth Practice Recommendations for Diabetic Retinopathy" (generated by the Teleophthalmology SIG of the ATA) document also contains a number of technical recommendations that can potentially be extended to other telehealth applications.¹⁸

Within the technical area, the panel has identified three priority research topics.

a. Infrastructure definition: Communications technologies will continue to change. Although research should certainly be conducted to characterize new technologies as they emerge and determine their suitability for various telehealth applications, it is more important in the long run to investigate the means to integrate the various infrastructure components in a secure and seamless manner. The ATA Technology SIG has already identified compatibility of videoconferencing systems as a specific priority in this area and panel concurs.¹⁹ Although more and more store-and-forward applications are being approved for reimbursement, real-time videoconferencing remains the preferred communication mode for many telehealth applications. A second priority is the development of new or incorporation of existing technical and telecommunications standards into telehealth to facilitate coordination and cooperation.²⁰

b. Good imaging: We need to examine and characterize the entire imaging chain from acquisition to transmission to display to storage, and minimum standards need to be considered at each point. A good model for this already exists in teleradiology. The American College of Radiology (ACR) has a technical standard for teleradiology that covers everything from the matrix size and bit depth for acquiring various types of images (e.g., computed radiography versus computed tomography) to the minimum display luminance to jurisdictional policies for transmission and storage.²¹ The various technical components outlined in the ACR technical standard should be investigated for adoption by other clinical specialties utilizing telehealth technologies. The one component that is lacking in the ACR standard is real-time imaging, but as noted above that has already been identified as a top priority. To reiterate an important point, research in this area needs to focus on particular problems and specific tasks that relate capabilities and performance of the technological devices back to clinically relevant considerations (e.g., what is the minimum bandwidth required to carry out an initial psychiatric evaluation of a patient suspected of having Alzheimer's disease).

c. Comparisons across platforms: The number and variety of devices available in telehealth expands every year. Many of these devices purport to do the same thing—only better than their competitors. More often than not, however, these claims are not supported by independently conducted research studies that compare directly the perfor-

mance of various devices or platforms on specific tasks. For example, there are a number of remote heart monitors available commercially that will monitor and transmit to a central clinical site patient electrocardiogram (ECG) data. Technical studies need to be done to validate the accuracy and reliability claims of these types of devices using clinically accepted gold standards (e.g., standard 12-lead ECG). Studies that compare multiple devices using the same clinical protocols and a well-defined cohort of patients are highly recommended.

Clinical

There have been a number of studies carried out in recent years to demonstrate the clinical utility of using telehealth in a variety of clinical applications. Many of these studies have been done exceptionally well and in some cases have provided the necessary efficacy data to push forward legislation or institution of reimbursement codes. Other studies, however, have not been carried out with the same level of experimental rigor, reducing their impact on the overall push towards the acceptance and incorporation of telehealth into mainstream healthcare practice.²² Some of the major problems in this area have been methodological limitations. Many of the studies to date have examined the concordance between the traditional and telehealth modes of rendering a diagnosis, often using κ analysis to determine statistical significance.²³ These studies were quite useful and did serve to demonstrate that there often were high levels of agreement between traditional and telehealth diagnostic decisions. It is time, however, to move beyond simple concordance. The κ statistic (and other correlation based methods) are useful but limited because they only deal with agreement. They say nothing about the accuracy of the decisions being rendered. If telehealth is going to move beyond being regarded by many as a tool or a substitute for traditional healthcare delivery, its ability to impact diagnosis, treatment options and patient outcomes must be demonstrated using experimentally rigorous techniques supported by appropriate statistics.

In March 2005, the United States Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare and Medicaid Services (CMS) convened a workshop to assess the evidence for the efficacy of telehealth services. A series of white papers generated from this workshop appears in a supplement of the *Journal of Telehealth and Telecare*. The panel recommends strongly that investigators use this series of papers as an additional source of guidance and reference for methods to conduct clinical research studies in telehealth.²⁴

Experimental design and statistics. The randomized controlled trial (RCT) is often regarded as the paragon of clinical trial methods and should be used when it is feasible or practical. However, other accepted trial design methods exist that can be used if an RCT study design is not possible.²⁵ The AHRQ supplement in the Journal of Telehealth and Telecare contains a comprehensive review of alternatives to the RCT²⁶ as well as descriptions of potential sources of existing data that could be used to assess patient outcomes.^{26,27} It is highly recommended that although some of these experimental designs require more time and effort, telehealth investigators use them in patient studies. In particular, the use of pretest-posttest, interrupted time series, and case-control designs are recommended. Meaningful control/comparison groups must be used, and different populations of patients (e.g., gender, age, ethnicity, race) must be included in the samples to improve the generalizability of the findings.

Sample size is a particularly important issue because many studies in the literature suffer from poor statistical power (i.e., the probability of correctly rejecting the null hypothesis when it is indeed false) that is generally the result of having too few patients or cases in the study. Statistical power is not only affected by the number of patients in the study, but also by such things as the number of readers (i.e., clinicians rendering a diagnosis), the magnitude of the expected difference between conditions or comparison groups, the variability between and within groups, the experimental design (e.g., repeated versus independent measures), and even the type of statistical test (e.g., parametric versus nonparametric). It is recommended that investigators provide an estimate of power in additional to the more traditional results of statistical analysis (e.g., the *p* value) when publishing or presenting experimental results. The basics of experimental design, statistical tests and issues such as power can be found in a host of textbooks,^{28,29} but it is recommended that researchers less familiar with these issues collaborate with investigators already experienced in these matters either from traditional medicine or related fields (e.g., psychology, sociology).

Adequate power calculations are a particularly important consideration in the design of equivalency trials. In some settings, telehealth may be a superior alternative to conventional care, however, superiority over conventional care is not necessarily the bar that must be reached before adopting telehealth. Rather, telehealth interventions that yield at least equivalent diagnostic and clinical outcomes to conventional care insure that telehealth is not delivering inferior care. If equivalency is established, other compelling reasons for adopting telehealth such as economic considerations and human factors may be deciding factors. Power calculations and sample size considerations in equivalency trials are of paramount importance since the goal is to be confident that those trials have a high probability of yielding a valid answer, should equivalency be found.

As already noted, although agreement studies (those that only consider whether the diagnosis is the same when evaluating an alternative technology, not whether either of the doiagnoses are actually correct) have been quite useful is establishing concordance between traditional and telehealth in areas such as teleradiology, telepathology and teledermatology, it is now necessary to move beyond simple concordance. In order to assess diagnostic accuracy (in contrast to diagnostic concordance), the panel strongly recommends some of the traditional models and metrics used in traditional clinical studies.³⁰ Rather than agreement, metrics such as sensitivity, specificity, accuracy, and positive and negative predictive value should be utilized. Key to these types of accuracy studies is the use of an independent gold standard. A gold standard refers to the use of an independent source of information to verify the true diagnosis other than the information being evaluated in the study. For example, in concordance studies a group of dermatologists typically examine patients in-person in the traditional manner and also examine a set of digital photos (displayed on a computer monitor) of the same patients. Diagnoses are compared and percent of cases receiving the same diagnosis or κ as a measure of agreement is calculated. In neither reading mode is it possible to determine if the diagnoses were accurate or correct. In an accuracy study, an independent gold standard (e.g., biopsy results) would serve as the point of comparison. The diagnoses from the traditional and telehealth reading modes would each be compared to the gold and standard and sensitivity (e.g., how often the biopsy-proven cancer cases were diagnosed by the dermatologist as cancer) and specificity (how often the biopsyproven noncancer cases were correctly diagnosed as noncancer by the dermatologist) could be calculated for each reading mode. Those values could then be compared statistically to determine if diagnostic accuracy differs significantly between the two interpretation modes.

Whenever possible, the methods used to collect and analyze decision data should be grounded in theory or based on a specific theoretical model. For example, many diagnostic accuracy studies can be framed using the Signal Detection Theory paradigm and statistically analyzed using receiver operating characteristic (ROC) methods.³¹ Recent advances in ROC methods even incorporate traditional statistical methods such as the analysis of variance (ANOVA) into the methods to allow for robust determination of differences between experimental conditions and accurate estimates of case, reader and condition variances.³²

Clinical outcomes. A good clinical outcomes study starts with a good plan of action and a well-defined set of hypotheses. For many investigators this is often the hardest part and too often it is ignored. AHRQ has developed an Evaluation Toolkit to guide investigators through the early steps of designing a study to examine the impact of Health Information Technology (HIT), and parts it address directly clinical outcome parameters.³³ The document also provides sample measures for six key research domains: (1) clinical outcomes measures (e.g., complication rates, adverse drug reactions), (2) clinical process measures (e.g., medication errors, percent alerts resulting in desired outcome), (3) provider adoption and attitude measures (e.g., staff turnover rates, job satisfaction), (4) patient knowledge and attitude measures (e.g., satisfaction, knowledge of medications), (5) workflow impact measures (e.g., time spent per patient, waiting times), and (6) financial impact measures (e.g., percent claims denied, cost of forms). The panel recommends strongly that well-defined outcomes measures such as those defined in the AHRO toolkit be used in studies to assess the impact of telehealth on patient outcomes.

Once hypotheses are formed and specific outcome measures identified, we can begin to address the question of whether telehealth improves the quality of care received by patients from a number of perspectives including structure and process in additional to strict health outcomes. The issues noted in the above section on Experimental Design and Statistics should all of course be considered in the conduct of clinical outcomes studies. In addition, the panel also has identified a number of other issues that need to be included in outcomes research whenever possible. The accuracy, friendliness and utility of telehealth devices (e.g., electronic stethoscope) can often be assessed in the laboratory setting and the results generalized reliably to most real-life settings and applications. Clinical outcomes studies, even though proper control and comparison factors need to be considered, are more likely to suffer from ecological validity problems if they are only carried out in the laboratory university hospital-based setting. Ecological validity deals with the issue of whether the results from a study done in a closed and controlled environment (typically the laboratory) can be generalized to the real-world environment. Outcomes studies in telehealth can certainly start in the laboratory or university setting, but they must start to extend out to the actual settings and patients that will ultimately benefit the most from telehealth-rural and underserved communities. Community-based outcomes studies must be carried out and the characteristics that are common across communities as well as those cultural factors unique to each community and culture need to be examined as correlative variables.

Finally, there are two other recommendations from the panel regarding outcomes studies that given the relatively short history of telehealth are only now becoming possible. The first is that longitudinal studies need to be conducted in order to assess the long-term impact that telehealth has on healthcare. Outcomes for complex diseases and health conditions often take time and numerous interventions before even moderate changes are seen in the patient's health status. Short-term, single intervention studies are unlikely to demonstrate any significant differences in outcomes between traditional and telehealth processes. Longitudinal studies that follow cohorts of patients over significant yet realistic periods of time should be carried out. In order to facilitate longitudinal studies and address other important issues raised above such as increased sample size and the need to investigate outcomes within the context of cultural influences, the panel also recommends more multi-institution collaborations be formed. For both of these to happen, however, the telehealth community needs to pressure the funding agencies to sponsor these types of investigations.

Human factors and ergonomics

Many of the issues discussed previously clearly have aspects that fall under the rubric of human factors and ergonomics research, but the panel wishes to point out some specific points that have not been discussed in this regard. As with the previous two areas, it is important when doing human factors research to utilize methods and theories that already exist. This is especially true when assessing telehealth technologies from the user's perspective. There are well-known techniques for designing and assessing user interfaces that can be applied to the majority of digital devices being introduced into the telehealth market.34,35 The broader role of human factors research in ehealth applications has also been addressed. A variety of texts exist that detail telehealth specific methods and these should be consulted.³⁶ As with the previous areas, study design and proper statistical analyses need to be considered when conducting human factors research.

Usability studies for specific populations. In addition to simply determining whether a particular telehealth device or technology does what it is supposed to do, it is important to carry out usability studies with different populations of users. With the recent focus on home healthcare and consumer-oriented telehealth applications, it is important to consider the fact that the potential users of these new technologies will be very different from each other. It is recommended strongly that different device designs be considered and tested for different populations. For example, portable monitors that record heart rate information and display the results to the user as well as transmit them to a central site for evaluation and intervention may need to be modified for certain populations. Older users may require larger visuals, bigger input buttons, and fewer process steps (i.e., more automated) than younger users if the device is to be accepted and used appropriately. If the device has an auditory component (e.g., an alarm indicating it is time to take a medication or test blood glucose levels), it may need to have adjustable settings to account for age-related declines in hearing. Testing and tailoring devices to specific user populations (patients and healthcare providers) will contribute significantly to reducing technophobia among potential users. Carefully designed training programs that not only take into account the users' physical and intellectual capabilities but also their culture and language must also be developed.

Process and design factors. It is not only important to consider the usability and ergonomics of specific devices and technologies in telehealth, but the broader issue of how to integrate telehealth and its technologies into the health-care system and public use must also be considered.^{37,38} Understanding the process of telehealth better is a priority. In the clinical setting we should consider the impact that introduction of a telehealth application has on workflow and the number of people incorporation

of the telehealth process would impact. Interruptions in workflow and distraction of people from their regular duties have often been cited as a barrier to implementation of telehealth, not only on the provider side but also on the patient side. Most of these conclusions however are based on anecdotal accounts or subjective impressions of how a telehealth intervention or technology impacts the current way of doing things. Telehealth needs to carry out objective studies using established techniques from other domains where technology and workflow have been studied extensively. For example, the aviation industry has a long history of evaluating the impact that the introduction of new technology has on a pilot's ability to navigate his/her way through a plane's cockpit and fly the plane without incident. Tools exist for such varied aspects of workflow in a technological environment such as time-motion analysis, workload assessment, link analysis, and behaviorally based rating tools.³⁹ To a large extent we need to determine whether healthcare in general should be reengineered with telehealth technologies so that telehealth is no longer viewed as a tool or something separate from mainstream healthcare.

Economic analyses

This is one of the biggest issues we have in the telehealth and healthcare in general today.⁴⁰ There is very little sophistication in the economic analyses of telehealth to date. A lot of the research is "surface" at this point. That is not bad, in that we are really just getting a handle on this field and it is developmentally appropriate. An initial consideration is appropriately framing the question that needs to be studied. For example, the economic perspective that one wishes to study should be stated (i.e., societal, healthcare system, etc.). The study design should parallel the question posed and available data. If one is interested in determining the value consumers place on a telehealth intervention then a willingness to pay study design is appropriate. If equivalent outcomes are proven or assumed then a cost-minimization is appropriate; a cost-effectiveness or cost utility analysis is appropriate if incremental differences in cost and effectiveness are present; and a cost-benefit analysis should be used if the outcomes of competing interventions are monetized.

Economic analyses also require a complete and accurate accounting of cost elements. In telehealth there are a specific cost considerations that bear mention. The direct costs (i.e., market cost) of technology is not the only consideration. Other factors such as depreciation, changing price structures, and cost attribution should be considered. A particular technology may or may not be used solely for the telehealth strategy under study and part of that cost may be offset or borne by other interventions. Additionally, some technology may be part of the overall infrastructure of a healthcare system and may be considered a "sunk" cost (i.e., not directly attributable to the telehealth intervention.) Telehealth typically averts at least a portion of patient and or provider travel that may normally occur in face-to-face visits. The time and opportunity cost considerations should be part of telehealth evaluations. Thus, we need methodologies and statistics that are designed for the type of multi-site, longitudinal, complex, dynamic system that we know telehealth is. Fortunately, as with the other areas addressed in this report, there exist methods and models for the general economic evaluation of healthcare that can be adopted for use in telehealth.^{41,42} For cost-effectiveness analyses, the recommendations of the Panel on Cost-effectiveness in Health and Medicine can also be adopted for use in telehealth research. Aside from incorporating more robust analysis techniques into the field of telehealth, the panel has identified two priority areas.

a. What are the short- and long-term impacts of telehealth on healthcare costs? As with clinical outcomes studies, to date it has been easier to study the short-term impacts of telehealth and long-term effects have rarely been looked at. Again this has more to do with the fact that most telehealth programs have simply not been operational long enough to even consider long-term analyses. However, there are some programs that have been operational for a decade or more and the opportunity now arises to make these analyses possible. We need to shift the focus of economic analyses from infrastructure, communications and technology costs to more complex issues such as will telehealth reduce patient costs to the overall healthcare system. Although this seems incredibly broad, the recommendation made previously regarding focus on a specific problem is appropriate here as well and the flow from technology to ergonomics to clinical outcomes to economic evaluation becomes important.

For example, once we have a piece of technology (e.g., remote blood glucose monitor that transmits readings automatically to a central healthcare center for evaluation and possible intervention) that has been validated and shown to ergonomically optimized, we can conduct a clinical outcomes investigation to determine if patients with the remote monitor and feedback are better able to maintain their blood glucose levels and avoid visits to the emergency room for severe hypoglycemic events (clinical outcomes). Economic analyses could then examine the long-term impact that improved diabetes management via telehealth has on avoiding or delaying patient disability and the cost this has to society (e.g., earlier, hence more, Social Security payments to patients with diabetes who are unable to work because of complications). Economic modeling and decision analytic techniques allow for an analysis of both short-term and long-term economic outcomes.

b. Creation of better healthcare business and management models. How can telehealth and more generally telehealth, when combined with health information technologies be used to create better models of healthcare where better is defined as equivalent or higher quality, improved patient safety and equivalent or lower per unit costs than the current healthcare system? This is a complex and difficult question that may not be easily addressed without more clinical outcomes data regarding the long-term impact that telehealth has on healthcare in general. However, the panel feels that it is important to raise the possibility of addressing this goal because we cannot limit ourselves to demonstrating that telehealth is a viable substitute for or alternative to traditional healthcare methods.

SUMMARY

Telehealth is going to transform healthcare, from the way it is delivered to the way it is paid for. Anyone who interacts with the healthcare system in the coming years will be impacted by telehealth. Those within the telehealth field need to have the foresight to take telehealth beyond its current state and make it an integral part of healthcare practice around the world. It is the hope of the panel that the research recommendations put forth in this document will give investigators the inspiration, tools and goals to make this happen.

REFERENCES

- United States General Accounting Office. *Telehealth: federal strategy is needed to guide investments*. Report to Congressional Requesters. GAO/NSIAD/HEHS-97-67. Washington D.C.: General Accounting Office, 1997 Unites States General Accounting Office, Washington, DC; February 1997.
- Hersh WR, ed. *Telehealth for the Medicare population*. Evidence Report/Technology Assessment No. 24. Rockville, MD: Agency for Healthcare Research and Quality, 2001.
- Hailey D, Roine R, Ohinmaa A. Systematic review of evidence for the benefits of telehealth. J Telemed Telecare 2002;8:1–7.
- 4. Hersh W, Helfand M, Wallace J, Kraemer D, Patterson P, Shapiro S, Greenlick M. A systematic review of the efficacy of telehealth for making diagnostic and management decisions. *J Telemed Telecare* **2002**; 8:197–209.
- Hersh WR, Helfand M, Wallace J, Kraemer D, Patterson P, Shapiro S, Greenlick M. Clinical outcomes resulting from telehealth interventions: A systematic review. *BMC Med Inf Decis Mak* 2001;1:5.
- Demiris G, Tao D. An analysis of the specialized literature in the field of telehealth. *J Telemed Telecare* 2005;11:316–319.
- Strauss A, Corbin J. Basics of qualitative research: techniques and procedures for developing Grounded Theory. Thousand Oaks, CA: Sage Publications, 1998.
- Charmaz K. Grounded Theory: Objectivist and constructivist methods. In: Denzin NK, Lincoln YS, eds.

Strategies of qualitative inquiry. Thousand Oaks, CA: Sage Publications, **2003:**249–291.

- 9. Salkind NJ. *Tests & measurement for people who (think they) hate tests & measurement*. Thousand Oaks, CA: Sage Publications, **2006**.
- Hayes BE. Measuring customer satisfaction: Survey design, use, and statistical analysis methods. Milwaukee, WI: ASQC Quality Press, 1997.
- Crano WD, Brewer MB. *Principles and methods of social research*. Mahwah, NJ: Lawrence Erlbaum Associates, **2002**.
- World Health Organization Quality of Life Instruments: www.who.int/evidence/assessment-instruments/ qol (Last accessed December 20, 2005.
- Rosenstock I. *Historical origins of the Hhealth Belief Model*. Health Education Monographs. Vol. 2, No. 4, 1974.
- 14. Glanz K, Marcus Lewis F, Rimer BK. *Theory at a glance: A guide for health promotion practice*. National Institutes of Health, **1997.**
- www.usms.nist.gov/workshops/MedicalImaging. htm Last accessed January 15, 2006.
- 16. www.atmeda.org/ICOT/diabeticretionpathy. FINAL.pdf Last accessed January 16, 2006.
- www.medical.nema.org/medical/dicom/final/ sup100_ft.pdf Last accessed January 15, 2006.
- www.medical.nema.org/ Last accessed January 5, 2006.
- 19. www.atmeda.org/ICOT/sigtechnology.htm Last accessed December 20, 2005.
- Yellowlees P, Harry D. Standards for data collection and monitoring within a telehealth research network. *J Telemed Telecare* (in press).
- American College of Radiology: www.acr.org/s_acr/ bin.asp?CID=541&DID=12292&DOC=FILE.PDF Last accessed December 6, 2005.
- Hersh WR, Hickam DH, Severance SM, Dana TL, Krages KP, M Helfand M. Diagnosis, access, and outcomes: Update of a systematic review on telehealth services. J Telemed Telecare (in press).
- 23. Cohen J. A coefficient of agreement for nominal scales. *Educ Psychol Measure* **1960**;20:37–46.
- 24. Hersh WR, Hickam DH, Erlichman M. Advancing the Evidence Base of Telehealth: Overview of supplement. *J Telemed Telecare* (in press).
- Harris AD, McGregor JC, Perencevich EN, Furuno JP, Zhu J, Peterson DE, Finkelstein J. The use and interpretation of quasi-experimental studies in medical informatics. *JAMIA* 2006;13:16–23.
- Grigsby J, Bennett RE. Alternatives to randomized controlled trials in telehealth. J Telemed Telecare (in press).
- Whitten P. Will we see data repositories for telehealth activity in the near future? J Telemed Telecare (in press).
- Ingelfinger JA, Mosteller F, Thibodeau LA, Ware JH. Biostatistics in clinical medicine. New York, NY: Mc-Graw Hill, Inc., 1994.

- 29. Mould RF. *Introductory medical statistics*. Philadelphia, PA: Institute of Physics Publishing, 1998.
- Swets JA. Signal detection theory and ROC analysis in psychology and diagnostics: Collected papers. Mahway, NJ: Lawrence Erlbaum Associates, 1996.
- Swets JA, Pickett RM. Evaluation of diagnostic systems: Methods from Signal Detection Theory. New York, NY: Academic Press, 1982.
- Dorfman DD, Berbaum KS, Metz CE. Receiver operating characteristic rating analysis: Generalization to the population of readers and patients with the jackknife method. *Invest Radiol* 1992;27:723–731.
- Agency for Healthcare Research and Quality: www.healthit.ahrq.gov/home/index.html Last accessed January 4, 2006.
- Shneiderman B. Designing the user interface: Strategies for effective human-computer interaction. Reading, MA: Addison-Wesley, 1998.
- 35. Vicente K. *The human factor: Revolutionizing the way people live with technology.* New York, NY: Routledge, **2003.**
- Bangert DC, Doktor R. Human and organizational dynamics in e-health. Seattle, WA: Radcliffe Publishing, 2005.
- 37. Shea S. What health delivery system changes are required when integrating telehealth into existing treatment flows of information and patients." Workflow, productivity, resources. J Telemed Telecare (in press).
- 38. Stronge AJ, Nichols TA, Rasche JD, Sessions RG, Fisk AD, Rogers WA. An application of human factors methods to teledermatology. In: Bangert DC, Doktor R, eds. *Human and organizational dynamics in e-health*. Seattle, WA: Radcliffe Publishing, 2005:13–31.
- Federal Aviation Commission, Human Factors Toolbox: www.hf.faa.gov/Portal/toolsbytypetally.aspx Last accessed January 15, 2006.
- 40. Tunis SR. Economic analysis in healthcare decisions. *Am J Managed Care* **2004**;10:301–304.
- 41. Drummond M, McGuire A. *Economic evaluation in healthcare: Merging theory with practice.* New York, NY: Oxford University Press, **2002.**
- Gold MR, Siegel JE, Russell LB, Weinstein MC, eds. Cost-effectiveness in health and medicine. New York, NY: Oxford University Press, 1996.

Address reprint requests to: Elizabeth Krupinski, Ph.D. Department of Radiology The University of Arizona Health Sciences Center 1609 N. Warren, Building 211, Room 112 P.O. Box 245067 Tucson, AZ 85724

E-mail: krupinski@radiology.arizona.edu

This article has been cited by:

- 1. Pauline A. Mashima, Charles R. Doarn. 2008. Overview of Telehealth Activities in Speech-Language PathologyOverview of Telehealth Activities in Speech-Language Pathology. *Telemedicine and e-Health* 14:10, 1101-1117. [Abstract] [PDF] [PDF Plus]
- 2. Bonnie J. Wakefield, Lindsay J. Orris, John E. Holman, Cynthia L. Russell. 2008. User Perceptions of In-Home Medication Dispensing Devices. *Journal of Gerontological Nursing* 34:7, 15-25. [CrossRef]
- 3. Diane M.F. Mahoney, Phyllis H. Mutschler, Barbara Tarlow, Ellen Liss. 2008. Real World Implementation Lessons and Outcomes from the Worker Interactive Networking (WIN) Project: Workplace-Based Online Caregiver Support and Remote Monitoring of Elders at HomeReal World Implementation Lessons and Outcomes from the Worker Interactive Networking (WIN) Project: Workplace-Based Online Caregiver Support and Remote Monitoring of Elders at Home. *Telemedicine and e-Health* 14:3, 224-234. [Abstract] [PDF] [PDF Plus]
- 4. Elizabeth A. Krupinski, Yulei Jiang. 2008. Anniversary Paper: Evaluation of medical imaging systems. *Medical Physics* 35:2, 645. [CrossRef]