SANDIA REPORT

The Role of Technology in Reducing Health Care Costs - Phase II and Phase III

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The Role of Technology in Reducing Health Care Costs - Phase II and Phase III

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Abstract
In Phase I of this project, reported in SAND97-1922, Sandia National Laboratories applied a systems approach to identifying innovative biomedical technologies with the potential to reduce U.S. health care delivery costs while maintaining care quality. The effort provided roadmaps for the development and integration of technology to meet perceived care delivery requirements and an economic analysis model for development of care pathway costs for two conditions: coronary artery disease (CAD) and benign prostatic hypertrophy (BPH).

Phases II and III of this project, which are presented in this report, were directed at detailing the parameters of telemedicine that influence care delivery costs and quality. These results were used to identify and field test the communication, interoperability, and security capabilities needed for cost-effective, secure, and reliable health care via telemedicine.

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The successful completion of this project was possible because of the excellent clinical support provided to Sandia by the clinicians and medical research staff of Ochsner.

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1 Executive Summary - Discussion of Phase I, II and III Results

In Phase I work of this project, Sandia National Laboratories (Sandia) and 40 other contributing organizations created a medical technology roadmap identifying development strategies for eight major health care areas, each with the potential to dramatically reduce health care costs in the military and civilian sectors. This work was accompanied by the rank ordering of high-cost medical procedures in the United States. Economic modeling methods were developed to quantitatively assess the cost effectiveness of technology-intensive medical interventions applied to various medical conditions, such as coronary artery disease and benign prostatic hyerplasia. The Phase I work was summarized in two reports: *Strategies for the Future: The Role of Technology in Reducing Health Care Costs,* (Sandia, November 1996), and *Final Project Report: The Role of Technology in Reducing Health Care Costs,* (Sandia, August 1997). These reports provide a broad overview of medical technology innovation and its potential role in reducing health care costs while maintaining or improving the quality of health care.

The roadmapping efforts in Phase I identified advanced telemedicine, health care and health care informatics, and information and network surety as three technology areas with immense potential to reduce health care costs while maintaining or improving care quality. These three areas became the focus of activities in Phase II of this project. Three major tasks were identified for Phase II:
- evaluate a typical telemedicine system in a medical environment to assess impacts on health costs and diagnosis quality;
- develop a system design for a high surety information system for telemedicine-based remote health care; and
- apply technology roadmapping techniques to identify technology improvements to enhance U.S. infrastructure protection. These three activities were conducted in parallel and were completed in October 2000.

Physician visits were identified in Phase I of this project as a major driver of health care costs so this clinical activity was selected for evaluation in Phase II. With the assistance of a clinical partner, the Alton Ochsner Medical Foundation of New Orleans (Oschner), we clinically assessed the cost-effectiveness and diagnostic quality of a state-of-the-art telemedicine technology applied to physician's visits for hypertension monitoring. The work resulted in a parametric economic model to assess the cost-effectiveness of telemedicine applied to this care scenario. The results of this task were presented in a report by Ochsner (Ochsner, December 1999).

The system evaluated was equipped with video, audio, blood pressure cuff, pulse oximetry capabilities, weight scale, temperature probe, and a stethoscope. In the evaluation of over 150 patients, about 19% of the encounters could not be adequately assessed because of telemedicine system deficiencies, indicating significant opportunities for enhancement of telemedicine systems. Even with these deficiencies, the Ochsner study showed that clinical diagnoses and patient satisfaction with telemedicine equipment for hypertension monitoring is comparable to regular office visits and that patients were still managed appropriately in the study. The study also revealed that more highly educated patients were more likely to use telemedicine systems

and pay the approximately $22 more per visit for a telemedicine diagnosis. If travel and patient time costs are included, system costs reduced, and utilization and reliability improved, the study showed that dramatic increases in the relative cost-effectiveness and cost-benefit of telemedicine over in-person visits could be realized.

After a detailed study of technology utilization in the telemedicine industry, Sandia initiated the design of a plug-and-play architecture based on interoperability standards, which would allow the development of low-cost, high-performance telemedicine systems that can be assembled from off-the-shelf components to meet the needs of a specific patient. Sandia expected this approach would help promote telemedicine acceptance by reducing overall telemedicine system costs and improving reliability and utilization through standardization and system flexibility and by maintaining patient data and information safety and confidentiality. This type of system was needed to address the existing telemedicine system deficiencies noted in the Phase II Ochsner telemedicine clinical trials and address a limiting concern for the future expansion of telemedicine applications. The architecture developed by Sandia was described in various conference papers and presentations. The response from industry and medical organizations about this design architecture prompted Sandia and the Department of Defense (DoD) to investigate follow-on Phase III activities to focus on implementing and clinically evaluating the reliability and effectiveness of this architectural framework in a plug-and-play telemedicine system.

Also, as part of the Phase II efforts, Sandia conducted a roadmapping activity to outline how the United States can protect its critical infrastructures. Sandia applied the process and information gathered from the initial Phase I roadmapping activities to assist in the preparation of roadmaps for protection of six critical infrastructures, including emergency services. The Emergency Services infrastructure includes law enforcement, civil defense, fire and rescue, as well as health agencies and medical providers such as hospitals, nurses, and doctors. The roadmapping effort insured that medical technology innovation is accurately integrated into the broader context of infrastructure protection needs and roles, and to help identify DoD and civilian medical issues important to the US infrastructure. This effort brought together over 200 participants and stakeholders with expertise in technologies and policies pertaining to the six critical infrastructures. For the emergency services infrastructure, the roadmap outlined the technology and policy objectives over the next fifteen years to improve overall response and protection. The results of this effort were published in a report, *US Infrastructure Assurance Strategic Roadmaps: Strategies for Preserving Our National Security* (Sandia National Labs Document, SAND98-1496, August, 1998).

Based on the results of Phase II, five major tasks were originally identified for Phase III of this project. Unfortunately, only half the expected funding was received and Sandia, therefore, concentrated on completing three major tasks, including: 1) collaborate with government, academia, and industry to enhance architecture service areas, 2) demonstrate a telemedicine technology that incorporates plug-and-play and information surety capabilities, and 3) clinically evaluate the cost-effectiveness and diagnostic feasibility of this type of telemedicine technology. These three activities were completed in December 2001.

While developing the Telemedicine Reference Architecture, Sandia actively participated in standards meetings and telemedicine conferences to gain acceptance of these ideas and concepts in the telemedicine community. These efforts drew attention to our activities and allowed the team to help contribute to the future industry and international vision for telemedicine and remote health care.

The Telemedicine Reference Architecture was used as the basis for the development of a plug-and-play telemedicine system for clinical evaluation by Ochsner. The system was designed for home health visits and included six different medical devices from different manufacturers. The Telemedicine Reference Architecture and system configuration enabled all six medical devices to be linked as needed into a laptop with the associated patient records. The system design and applications were initially presented to the telemedicine community at the American Telemedicine Association Conference in June 2000 in Phoenix. The system was tested and evaluated by Sandia through October 2000 before being delivered to Ochsner for clinical testing in November 2000.

The purpose of the remote patient care demonstration task was to illustrate how plug-and-play diagnostic devices, advanced information systems, and remote patient care can benefit health care costs for both the US and the DoD. The system was used on about 150 chronic heart failure patients in a store-and-forward application by Ochsner. The results of the clinical trials with the Sandia provided system were summarized by Ochsner (Ochsner, December 2001). Overall, the system architecture and medical device integration worked relatively well. Major issues were identified with the unsatisfactory performance of a few of the individual medical devices. Also, the weight and bulkiness of the system made it difficult for the clinical staff to use. This needs to be considerably improved to improve overall patient and home health care provider acceptance. Even with these limitations, over 78% of the patients identified that they would consider being cared for by a telemedicine system. Therefore, the overall utility and cost-effectiveness of the plug-and-play architecture concept were validated by the Phase III clinical trials.

The results of the Phase II and III activities for this project indicate that the use of telemedicine technology or systems are being accepted by patients and can provide quality diagnoses and health care to a wide range of medical conditions. As the medical device technology and communications capabilities continue to expand, the cost-effectiveness and reliability of telemedicine will continue to improve. The clinical trials showed that low-cost, plug-and-play, based telemedicine systems can provide the flexibility needed to improve the cost and utilization of telemedicine medical devices in many settings. Our efforts showed that improvements in telemedicine related technologies such as medical devices, communications, patient record standardization, and patient record security, may be able to significantly reduce future health care costs and enable the expansion of high quality health care to much wider and more diverse segments of the population.

2 Phase II - Telemedicine System Surety Research and Development

The roadmapping efforts in Phase I identified advanced telemedicine, health care and health care informatics, and information and network surety as three technology areas with immense potential to reduce health care costs while maintaining or improving care quality. These three areas became the focus of activities in Phases II of this project. Three major tasks were identified for Phase II:

- evaluate a typical telemedicine system in a medical environment to assess impacts on health costs and diagnosis quality;
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2.1 Evaluation of Telemedicine System Effectiveness

2.1.1 Ochsner Clinical Study Background and Design

Telemedicine has been under development in the United States for almost 40 years. Its promise of expanding access to quality health care has been well appreciated in many quarters. However, in large measure this promise has been unrealized. As we enter the 21st century, telemedicine is employed only in niche applications and its prospects for long term development remain unclear. The reasons for the failure of this technology to live up to its promise as of this time are multiple. Students of the subject have pointed to deficiencies in communication technology and the absence of adequate reimbursement to make telemedicine feasible, legal and licensing constraints on physicians who wish to use telemedicine in the care of patients, and a general perception that telemedicine is in many instances uneconomical.

Telemedicine is currently practiced in a variety of modes. While such disciplines as teledermatology, teleradiology, and telepsychiatry are all encompassed under the definition of telemedicine, the practicality and economics of each differs from the others and from telemedicine in general. Similarly the provision of telemedicine consultation in hematology/ oncology, neurology, general surgery, rheumatology, hypertension, gastroenterology have been studied. The use of telemedicine in nursing homes and in other long care studies represents another aspect of the technology. It is, therefore, a challenge for the policy maker to analyze telemedicine as an entity when it can be considered a collection of relatively independent disciplines with different needs sharing a common communications technology. The study of telemedicine is also complicated by the many venues in which this technology is employed. Units are currently being used in prisons, nursing homes, schools, clinics, military facilities, and remote hospitals. Another complicating factor is the multiplicity of transmission methodologies currently employed for the practice of telemedicine. These include regular telephone lines (POTS), ISDN lines, T1 lines, cable, and store-and-forward technologies, among others.

Thus, while examples of successful telemedicine applications exist, these are generally either applications centering on a specific population with special needs (such as providing care to remote populations, providing care to prisoners in a state penal system, or providing care to military personnel and their dependants around the world), or involve the subsidization of the telemedicine initiative either for the purposes of providing care to a special population or for the purpose of studying the delivery of health care by telemedicine.

Given the many faces of telemedicine and its variable application, it is perhaps not surprising that the cost-efficacy is difficult to access. Indeed, the estimated average cost of a telemedicine consultation has ranged from as high as $1,184.00 (a cost calculated by dividing the cost for equipment and network use by the number of consultations reported over one year) to an estimated cost of telemedicine consultation for oncology services of $812.00 and finally to $15.94 for a radiology consultation conducted in Norway. These cost estimates clearly are influenced by the perspective from which cost is determined (provider cost, insurer cost, patient cost, societal cost), the sophistication and cost of the equipment employed, the population served and the frequency of use of the technology, the diagnostic and therapeutic accuracy of the modality in a given specialty as well as the off-setting cost of travel in a local environment. (Moore, 1998).

It appears that most studies of the economics of telemedicine are qualitative or semiquantitative and are generally conducted from the point of view of one particular segment of the stakeholder universe – in most cases that of the provider. There have been relatively few controlled trials of telemedicine because these are difficult and expensive to implement. However, it would be expected that a controlled trial of this technology would provide more robust information regarding its cost-benefit profile than would uncontrolled studies such as many of those conducted to date.

Sandia and Ochsner aimed at defining the interrelationship of medical technology and health care costs. In Phase I of this project the study team conducted an inventory of cost and volume drivers of health care in the United States. Physician visits clearly were identified as a major driver of health care costs. Because of the expertise of Sandia in telecommunications and information surety and the identification of physician visits as a potential target for cost reduction, we elected to study telemedicine in an effort to define those characteristics (figures of merit) which, if developed and implemented, could render telemedicine a cost-effective means of providing physician care to patients.

Therefore, as part of Phase II of the project, Ochsner conducted an in-depth clinical study comparing the cost and quality of telemedicine diagnoses for hypertension as compared to an in-person physician visit. In order to maximize the potential value of the study, the study design was defined by three essential goals. First, it was decided to study a common, high-volume chronic condition as well as any associated conditions which might develop in a study population over a one-year time period. This was done so that the study would reveal the general characteristics of telemedicine as applied to what amounts to the care of a general medical population. From these parameters, estimates could be made of how the technology would or would not operate in more specified environments. Also by choosing a common disorder the study team was guaranteed that any data generated would be relevant to a large patient

population and its care by telemedicine. For this reason the telemedicine care of hypertensive patients was selected, recognizing that these patients would in many cases carry with them co-morbidities of diabetes, congestive heart failure and renal insufficiency. Thus the study design centered on a test of a real life disorder, its complications, and associated illness, as well as any related illness which might occur in the study population.

Second, the study team elected to utilize a telemedicine system capable of operating over ordinary telephone lines. It was recognized that this would not provide an optimal telemedicine encounter for clinical care. However, this decision permitted potential positive results of the study in terms of cost-effective uses of telemedicine to be widely applied in the future and assured that uses would be even more cost-effective as band width increases throughout the nation over time.

Third, the study team elected to conduct a controlled laboratory trial in which each patient subject would be seen both in person and via telemedicine in the same facility on the same day. Although, the order of in person and telemedicine visits would be randomly altered, this decision complicated the study in terms of demands on patients and physicians and it also complicated the interpretation of the study data in that the effects of the first visit type on physician and patient could conceivably alter the outcome of the second visit type. For this latter reason the order of the visit types was randomly determined. In spite of these complexities added by the study design, the study team preferred this methodology since it provided the possibility of a head to head comparison of in person and telemedicine care in the same patient population. This is a fundamentally different approach than has been used commonly in the past.

As was the case in Phase I of the project, the successful completion of Phase II required the coordinated activities of a multidisciplinary team including clinicians, health service research personnel, economists and statisticians. Ochsner team participants included Richard Re, M.D., Marie A. Krousel-Wood, M.D., MSPH, David Bradford, Ph.D., Andrew Kleit, Ph.D., Ahmed Abdoh, Ph.D., MBBCH, MSPH, MPH, Richard Chambers, MSPH, Natalie Gomez, R.N., Carolyn Altobello, R.N., and Barbara Ginther, R.N. In addition, Michael Morrisey, Ph.D. of the University of Alabama, Birmingham served as a consultant to the project. The clinical results and statistical analysis for this clinical study are reported in Ochsner,1999 and are summarized in the following subsections.

Before proceeding with the telemedicine study, the selected telemedicine equipment was calibrated to experimentally compare measurements taken with the Telemedicine (TM) equipment to measurements taken with the instruments used for the in-person (IP) visit. The paired measures were taken on patient volunteers. The physiological parameters compared were blood pressure, pulse, body weight, and body temperature. The systolic pressure compared well between both technologies by all tests. The diastolic had small observed differences that were not clinically important, and the technologies were well correlated. Both pulse and weight compared well between both technologies. The small observed differences were not clinically important. The observed difference in temperature was also small, however, neither patient with fever nor disagreement in detecting fever was tested. Overall, the medical devices for the study were either well correlated or were not clinically important.

2.1.2 Patient Willingness to Use Telemedicine Technology

There has been an increased interest by providers and policymakers in telemedicine as a means of delivering healthcare and as a means of improving access to care for patients in underserved areas. Information regarding patient interest in and willingness to use telemedicine is lacking. This study examined the association between patient characteristics including functional status and patient willingness to participate in a one-year telemedicine study. A Cross-sectional study design was employed. Patients arriving for appointments in the hypertension section of the Ochsner clinic were given a pre-survey to complete and were subsequently asked if they would be willing to participate in a one-year telemedicine study. The pre-survey included questions regarding patient demographics, co-morbidities, functional status (using the Short Form 36-SF36), and willingness to pay for telemedicine. Bivariate analysis was performed comparing patient characteristics and responses for study participants versus non-participants. Logistic regression analysis was performed to determine which variables predict participation status.

Of the 259 patients approached for the study, 224 (86%) completed the pre-survey and 150 (58%) agreed to participate. A logistic regression analysis to predict non-participation was performed using the following independent variables: age, race, education, impairment preventing work, blindness, myocardial infarction, physical role functioning, and perception of health. Although several differences between participants and non-participants for the telemedicine study were identified with bivariate analysis, multivariate analysis revealed that educational status was the only significant variable predicting participation in the study. Those patients reporting higher education (i.e. college or more) were more likely to participate.

These results indicate that educational status be carefully considered when designing and analyzing studies of telemedicine. Also of interest is that several studies are underway to define the capabilities and figures of merit of telemedicine as a technology. One goal of this technology use is to provide better access to underserved populations (which may not have access to higher education). Because it may be an important variable in determining who participates in such studies, educational status may be a key factor in implementation of telemedicine technologies.

2.1.3 Performance Evaluation of the Telemedicine System

Of the 224 patients approached to participate in the study who also completed the pre-survey questionnaire, 162 patients (72.3%) agreed to participate. Out of those who agreed, 62 patients (38.3%) actually participated in the study generating107 paired visits based on the data collected. Those who refused to participate were more likely to have a high school education or less, more likely to have impairment keeping from work, and were more likely to report blindness. The mean age of the study participants (N=62) was 67.1±11.4 years; 56.6% males, 80.6% white, 78% married, 27% employed, and 35% with annual income $\geq$ $50,000.

For each type of visit, TM and IP, clinical data on diagnoses (morbidity and co-morbidity), medications (both currently taken or newly prescribed medications), physical findings including blood pressure and pulse measurements, and clinical orders were independently evaluated and recorded on a clinical data sheet. The data was entered in a specially designed program permitting standardized coding of the conditions and medications (on-line) to allow for pair-wise comparisons between the two visits in terms of clinical data.

Regarding the pre-diagnosis of essential hypertension, 91% of participants had this diagnosis recorded in both the IP and TM encounters. The post-visit record of the diagnosis of essential hypertension differed by encounter: TM visits had it recorded in 85% of visits as compared to 88% in IP visits. Both types of visits had similarly evaluated co-morbidity, as measured by the Charlson Comorbidity Index (CCI). 37% of the patients had a CCI of one or more. The mean systolic blood pressure (SBP) as measured by the left/right arm in a sitting position was 149±19 and 158±23 mmHg for the IP and TM visits, respectively. The mean diastolic blood pressure (DBP) as measured by the left/right arm in a sitting position was 84±9 and 82±12 mmHg for the IP and TM visits, respectively. The diagnosis of high blood pressure (defined as SBP ≥ 140 mmHg or DBP ≥ 90 mmHg in the sitting position) was made in 69% and 82% of the IP and TM visits, respectively. The mean pulse rate was 69±10 and 72±14 beat/minute for the IP and TM visits, respectively. Medications (both current and newly prescribed) were divided into six categories: diuretics, calcium channel blockers, ACE inhibitors, adrenergic agents, anti-hypercholesterolemic drugs, and others. The ACE inhibitor group was the most frequent single group prescribed. It was prescribed in 65% of the cases in both IP and TM encounters. For the most frequently recorded clinical orders, the following comparisons were made: return to clinic: 100% and 97% in IP and TM visits, respectively; SMAC7: 51% and 49% in IP and TM visits, respectively; and medication changes: 48% and 45% for IP and TM visits, respectively.

A specially designed program allowing for timing of all tasks in the TM visits, from the patient arrival until departure, was used. In a dashboard-like setting, each task was timed as start and end by clicking on a specific icon by the attending research nurse, allowing for automated calculation of the duration of the task. The program captured the number of trials for a given task. In addition, whether the patient needed assistance in a particular task was captured. In case of failure of the TM machine, the program added a record to capture data for the new attempt. The mean overall duration of the TM session was 21.7±10.4 minutes. The mean duration of assistance was 4.5±5.1 minutes. In 86% of the TM visits one attempt was successful; two attempts were successful in 12% of these visits and three attempts were successful in 2%. Even though the duration of the TM session increased by the number of attempts and whether there was partial or total failure, the difference in visit time for the telemedicine sessions grouped by number of attempts and system failure was not statistically significant. However, in many of the cases of equipment failure, an additional in-person visit would be required to make a correct diagnosis (>16% of all telemedicine visits).

Non-parametric tests were used to measure pair-wise associations for different variables by visit type (TM versus IP). For the assessment of accuracy of the TM visit as compared to the current gold standard (i.e. the IP visit), this required calculation of sensitivity, specificity, positive and negative predictive values for dichotomous outcomes (e.g. +/-). Diagnoses (morbid and co-morbid conditions) by TM visits showed very good agreement and correlation with the IP visits and lack of statistically significant discordant differences with the IP visits. Evaluation of validity also showed high validity assessment (close to 100% in most cases). Medications (current and newly prescribed) by TM visits showed very good agreement and correlation with the IP visits and lack of statistically significant discordant differences with the IP visits. Evaluation of validity also showed high validity assessment (close to 100% in most cases). In addition, clinical orders by TM visits showed less than good agreement and correlation for some of the orders (EKG, chest X-ray and therapy) with the IP visits. However, there was no

statistically significant discordant difference with the IP visits. Evaluation of validity also showed low sensitivity (<70%) for some of the orders (Renin, PSA, TSH, EKG, chest x-ray and mammogram). The remaining orders showed reasonable validity assessment. Thus, overall resource use and therapy was not significantly different between the two types of visits.

Patients' satisfaction and attitude towards medical care in general was measured for both visits (TM and IP). Overall, visit satisfaction ranked favorably high for both types of visits. However, the in-person visit ranked consistently higher in all items of the evaluation. For the "attitude towards medical care", "assessment of own health care", and "technical quality" the same pattern was observed. However, for "communication" and most of the interpersonal care items, there were not statistically significant differences. Regarding physician satisfaction with telemedicine visit in terms of the "overall work load", "mental effort", "technical skills", "risk/psychological stress", and "estimated visit duration", all ranked in favor of the in-person visit. Thus some differences in diagnostic sensitivity for high blood pressure and in patient and physician satisfaction were noted. These, however, were small differences and parameters related to diagnosis and treatment did not differ statistically between in-person and Telemedicine visits.

The telemedicine system used for this study was designed to facilitate the doctor-patient visit for the care of patients with a common chronic disease, hypertension. The system was equipped with video, audio, blood pressure cuff, pulse oximetry capabilities, scale, temperature probe and a stethoscope. However, in the medical care of patients with chronic disease, other events and/or diseases occur which require diagnoses and treatment. In this study, 18 patients could not be fully evaluated. Of the 107 encounters, 19 (18%) could not be adequately assessed due to patient complaints and concerns. There were three primary categories of inadequacies: palpation, auscultation and visualization with palpation, or anxiety, a problem in 68% of the cases (13/19).

Based on the clinical information collected and discussed above, patient care, diagnoses, medication changes, and follow on observation were not clinically different between telemedicine and in-person visits for this condition. The study showed that the existing telemedicine system and associated medical devices have some problems with reliability and patient anxiety with their use. Despite these identified system inadequacies, patients were able to be managed appropriately using telemedicine. Several opportunities for enhancement of the telemedicine system were identified and technology improvements to increase system reliability and robustness have the potential to significantly expand the acceptance and utility of telemedicine based health care.

2.1.4 Estimated Telemedicine Costs and Demand

The ultimate goal of the economic component of the demonstration project is to assess the costs, cost-effectiveness, and cost-benefit for both telemedicine and in-person visits for the treatment of hypertension. This component of the research brought together results from all of the other economics sub-sections in order to generate these economic evaluations. We first addressed estimating the raw costs of the two technologies, and then moved into comparisons based on cost-effectiveness and cost-benefit.

With these estimates in hand, and additional information from preliminary studies generated by the economics' component of the project, we can present estimates of the opportunity cost,

estimated cost-effectiveness, and estimated cost-benefit from each visit type. We constructed cost-effectiveness ratios in terms of costs per case of hypertension detected. Detections of hypertension were taken from the study presenting the detection-controlled estimation models of effectiveness. Cost-benefit for telemedicine was expressed in terms of the difference between total willingness to pay for access to the technology minus the incremental cost of the technology for 1000 patient encounters/ visits per telemedicine unit are shown in Table 1.

	In-Person Visit	Telemedicine Visit
Opportunity Cost	$42.71	$65.70
Cost-Effectiveness	$57.83	$88.99
Cost-Benefit	NA	Break-even with 2625 patient visits per year

Table 1. Cost, Cost-Effectiveness, and Cost-Benefit of Each Visit Type

Based on these figures, we see that telemedicine is $22.99 more costly than the in-person visit type. That telemedicine is more costly is not the issue, however. The real question is whether telemedicine is cost-effective, or whether it could ever generate benefits (in terms of patient willingness to pay) in excess of the costs. If either of those two conditions are met, then the technology would be economically beneficial and likely to prosper in the market. We see that the cost-effectiveness ratio for telemedicine is a bit higher than for in-person visits, though still favorable. In terms of cost benefit, 38% of the study patient population were be willing to pay the differential cost for access to telemedicine (after having gone through the trial). Therefore if patients who were willing to pay for TM were also willing to utilize the system for every chronic encounter required, 2625 encounters would be required to generate the 1000 patient visits necessary to achieve the break even point (assuming a 38% participation rate).

In general, these results indicate that the telemedicine unit evaluated for this study is a relatively strong new technology, and is very promising with respect to its economic characteristics. Any improvements that could be made to increase the number of visits provided with a single unit (above the 1000 per year assumed for this study), reduce the number of times the technology proves inadequate, or reduce the actual purchase price of the unit itself will dramatically increase the relative cost-effectiveness and cost-benefit status of telemedicine over in-person visits for the treatment of chronic hypertension.

Traditionally, estimating the demand for a product is conducted by reviewing how much of a product consumers bought at particular prices. This methodology, however, assumes that the market for a particular product already exists. Presently however, telemedicine services are not generally traded in the marketplace. Thus, traditional methods cannot be used to conduct an analysis of the costs and benefits of telemedicine. Therefore, to estimate the demand for telemedicine we will use a relatively new methodology, the contingent valuation method (CVM). CVM measures the value of goods not traded in the marketplace. It is often used to value such resources as environmental amenities and wildlife animals. The basic methodology is to survey people and ask how much they would be willing to pay for a particular good in question. Unfortunately, one of the difficulties with CVM is that the survey respondents often have no direct experience with the question at hand. In a classic case, a respondent may be very familiar

with how much he or she is willing to pay for a head of lettuce, but very unfamiliar with how much he would pay to protect, for example, seals in Newfoundland.

Participants in a CVM study are often presented a range of choices; i.e., "would you pay $100, $200, $300, or $400 to protect one seal in Newfoundland." It appears that answers to this question are systematically different than if the participants were asked, "would you pay $200, $300, $400, or $500 to protect one seal in Newfoundland." This "framing" problem can be avoided by using the dichotomous choice, or "Yes or No," approach. For example, sample participants are simply asked whether or not they would pay a certain amount to protect a seal in Newfoundland. The amount asked varies across participants.

Patients were given a survey that included a question regarding their willingness to pay a certain amount for telemedicine. Then patients were asked if they would be willing to participate in a telemedicine study. Willing patients subsequently underwent evaluation of their condition with paired in-person and telemedicine visits. After going through a year-long program, patients were again asked whether they would be willing to pay a given amount for access to telemedicine services. This provided us the opportunity to estimate the demand for telemedicine after it had been used – yielding perhaps a better long-term estimate than an estimate based on asking people who have no experience with the technology. We applied these results to varying prices and created a demand curve for telemedicine. In particular, at a price of $23.00, (the estimated cost of supplying telemedicine –see report "Calculating the Cost of Telemedicine"), 30.4 patients (52.4%) would demand telemedicine according to the pre-survey results, and 22.1 patients (38.1%) would demand it according to the post-survey results.

2.1.5 Summary of Clinical Evaluation of Telemedicine Performance and Cost

Based on the clinical study, several conclusions regarding the potential cost-efficacy of telemedicine on either a small or national scale were reached. These include:

- Patient educational level may play a big role in the acceptance and use of telemedicine systems and technology.
- When costs and benefits are estimated from the point of view of society at large, the value ascribed to patient time and the magnitude of travel costs can significantly affect the analysis. As the value of patient time increases and as travel costs increase, telemedicine becomes increasingly more cost effective.
- The cost effectiveness of telemedicine clearly increases as the number of users per system increases. Substantial reductions in the cost of telemedicine hardware would be required if telemedicine is to become cost effective on the basis of one unit per household.
- System failure represents a potentially significant cost to the provisions for telemedicine services. Efforts to improve system reliability can substantially affect the cost-benefit of telemedicine.
- The cost of missed diagnoses, whether those diagnoses are missed because of a known deficiency in the system or are missed inadvertently, can be substantial. In the test system used in this study for the treatment of hypertension, inadvertently missed diagnoses had relatively little impact on total system cost. The inability of the system to perform certain examinations, however, did impact costs in important ways. The trade

off clearly is between the purchasing/developing of more expensive equipment capable of performing additional diagnostic tasks versus the cost of missing specific diagnoses and requiring inpatient visits to offset this deficiency. There appears to be an opportunity to judiciously expand the capabilities of telemedicine as applied to common medical conditions so as to reduce the cost of diagnostic inadequacy.

- When used for the treatment of common medical conditions even a low cost POTS based system exhibits few unanticipated diagnostic failures and is generally well received by patients and physicians.
- Patients expressed general satisfaction with telemedicine care for a chronic condition (hypertension) and expressed a willingness to pay a modest surcharge for some forms of telemedicine care.
- The overall quality of patient care for this application of telemedicine was essentially the same as an in-person visit.

The observations made during this clinical study suggest that there is an opportunity to judiciously expand telemedicine services in a cost-effective manner in the care of general medical conditions. This can be accomplished provided that certain technology improvements to telemedicine capabilities and reliability are achieved and units can be placed in such a fashion as to be utilized by a relatively large number of patients.

2.2 Development of High Surety Telemedicine Reference Architecture

At the onset of the phase II clinical study in Fall 1997, Sandia performed a technology survey of the telemedicine market with a goal of identifying telemedicine systems that could meet a predefined set of clinical requirements for the hypertension study. From an initial list of 25 vendors, Sandia identified eight systems that provided some, but not all, of the required functionality. Sandia contacted these vendors and in some cases met with them directly in an effort to quantitatively assess their ability to meet the clinical requirements. The TelAssist TLC 2000 received the highest comparative score in a quantitative rating that included 51 categories in an Excel spreadsheet. Ochsner Clinic then placed a purchase order with TelAssist for one TLC 2000 system, with the agreement that the system would be enhanced to meet Ochsner's clinical requirements. This is the same system used in the clinical study described above. Sandia also purchased a system to identify other enhancements valuable for the clinical study and to use for concept demonstrations.

During this time, Sandia continued to learn about telemedicine and medical informatics technology in order to define where information surety principles could have the highest impact on future systems. For the purposes of the phase II and III efforts, the original focus was on the control of access of patient data and system services via user identification and authentication and on preservation of privacy while the data is being moved between remotely located users. As originally planned, Sandia would augment the TelAssist unit to include these features and Ochsner would evaluate the modified systems with a view to determining how the security overhead introduced by these changes impacted the cost and ease of using the telemedicine system.

As Sandia studied the way in which the telemedicine industry was building its telemedicine systems, it became clear that the architectural approaches being employed did not reflect emerging trends in computing. In particular, while the rest of computing was moving to open, plug-and-play, network-based designs, telemedicine vendors were delivering closed systems with fixed capabilities that operated over point-to-point communication links. In light of this conclusion, the proposal to retrofit the TLC 2000 to address a subset of the security needs facing the telemedicine industry seemed of limited value. In a fairly short time, the nature of telemedicine systems would change and the work done by Sandia would be meaningless.

To address this concern, Sandia created the "Telemedicine Reference Architecture" (TRA) as a representative view of what telemedicine systems would look like once emerging trends in information technology had played out. Beyond this, the TRA was meant to address a number of technology-based deficiencies that Sandia believed to be present in telemedicine designs existing at that time. For example, most telemedicine systems available at the time that the TRA was conceived were designed for a specific purpose and, as such, hosted a limited set of instruments that were not readily replaced with other instruments if local operational needs required this. Second, most telemedicine systems were regarding as too expensive to achieve the widespread penetration needed if the community's vision of "anywhere, anytime" provision of healthcare were to become a reality. Driving down system costs would require reduction in materials costs and reduction in the man-hours needed to deliver systems. Third, telemedicine systems were not capable of general purpose communications – any person with a telemedicine station could not simply "dial-up" anyone else who owned a station. Proprietary protocols used by each vendor ensured that interoperation could not occur. More a result of the fact that no interoperability specifications existed for this industry than a tactic for excluding competition, this state of affairs nonetheless reduced the overall value of telemedicine systems to potential end users of these systems.

Given this architecture, Sandia's plan was to identify the security issues in this future system design and to then develop an assurance architecture that would address the needs identified in this assessment. The TLC 2000 could then be retrofitted in a way that was consistent with this effort's findings, the experiments could be run, and a report on the notional architecture and its security issues and assurance approaches released. When these plans were briefed at a national conference and attendees showed greater interest in the architecture than the security issues, Sandia realized that it had stumbled onto something of value to the telemedicine community and modified its plans to allow for the development and demonstration of the architecture along with the proposed initial work in security.

2.2.1 The Telemedicine Reference Architecture

2.2.1.1 The State of Telemedicine Technology

Figure 1 illustrates the typical telemedicine system architecture in use when the TRA was being developed. In this two-station design, the patient station consists of a number of devices for person-to-person communication, medical devices for monitoring or treating the patient, user interface elements for monitoring and controlling station operation, a platform (typically computing hardware and software) for knitting all of these things together, and communications for enabling the station to interact with a remotely located caregiver's station. Very often, all of

these components are housed in a vendor-developed chassis and delivered as a monolithic box. By contrast, the caregiver's station, while containing all of the same capabilities (with the exception of the medical devices) plus a means of storing, processing, and retrieving patient records is typically delivered as a personal computer, application software, and some number of peripherals. The communications link between the two stations will typically be a phone line (traditional analog or ISDN) but, in some cases, might be something more exotic like a satellite link or the Internet.
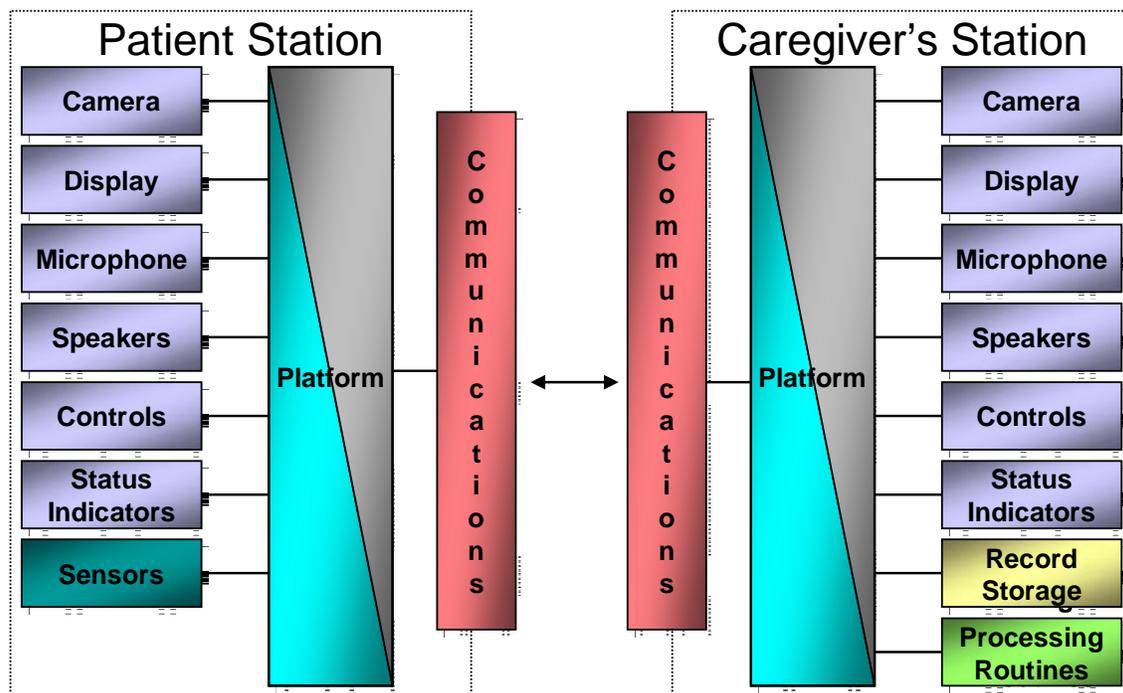
Figure 1. Typical Telemedicine System Architecture

Given that many telemedicine system's employ a turnkey or "drop in place" approach to system deployment, this kind of system architecture makes a lot of sense. Both the caregiver and patient stations can be self-contained and require nothing more than a power outlet and phone jack in order to operate.

At the same time, this approach introduces a number of problems that, if not addressed, threaten telemedicine's ability to achieve widespread deployment and utilization. First, inasmuch as the medical devices that are included in most of these systems are tightly integrated into the system's stations, changing the mix of devices to meet the unique operational requirements of a given site can be difficult. Even if components can be disconnected from the station (which is often the case), the connectors to which they attached are usually highly specialized, being dedicated to the exclusive use of those devices. Adding new components that the station was not originally designed to support can involve adding new physical connectors, writing new software to handle the devices, or both.

Second, turnkey operation means that everything that the stations need to operate (save for the phone system) is bundled into the stations themselves. While this ensures ease of use, it drives

up the material costs of the systems. For example, it is not uncommon to see systems that contain integral computers, hard drives, and displays. Dropping the material cost means either finding cheaper components (not a very promising prospect as most companies building systems of this sort have already pursued this avenue with a vengeance) or eliminating components from the stations (not a viable option in today's environment if turnkey operation is the driving philosophy).

Third, when the full range of things that can be done via telemedicine-based approaches is compared with the full range of things that can be done clinically, it becomes obvious that telemedicine's overall value is still relatively limited. As noted in the Ochsner study, the inability to do certain things over the wire can significantly impact in certain settings the value of attempting to employ telemedicine-based approaches to care delivery. Addressing this shortcoming requires the development of more devices and supporting software for telemedicine stations but vendors of these devices are reluctant to enter the market. To be sure, issues related to reimbursement factor into this reluctance but so does the turnkey architectural approach. Most vendors in the telemedicine world are system integrators who make their living turning disparate components into cohesive systems. Device manufacturers wanting to introduce their capabilities into the device market place are faced with the prospect of marketing to the system integrators or of developing their own turnkey capabilities. This latter approach requires not only that they know how to build their devices but that they also develop expertise in user interface design, database implementation, application software development, data communications, and possibly person-to-person communications. These requirements can raise the cost of entry into the telemedicine market to a level higher than these device vendors are willing to jump.

Finally, because the industry lacks a defined approach to station-to-station interoperability, vendors create stations that employ their own proprietary application-level communication protocols. As a consequence, stations from one vendor cannot exchange information with those of another and cannot monitor and control devices on remote platforms. The result of all of this is that today's telemedicine networks are islands – collections of stations able to talk with one another because they were all procured from one vendor but not able to talk to stations on other islands (unless they too happen to be made by the same vendor).

2.2.1.2 A Modular, Distributed, Plug-and-Play Approach

Figure 2 presents a notional view of the Telemedicine Reference Architecture. Each of the outer six cells represents a class of service offered by a telemedicine system. The user interface class includes all of the mechanisms required for an operator to control and monitor operation of station components and to engage in the "surface" aspects of person-to-person communications. The medical devices are all of the instruments required for assessing and treating a patient. The patient records include both the record structures and the media on which these structures are stored. Communications addresses all of the station external interactions. Processing includes all of the data transformation capabilities resident on a station (e.g., statistical analysis, anomaly detection, etc.). Protocols embody all of high-level logic that governs station operation. The backplane consists of all of the mechanisms required to stitch components from each of the other six areas into an integrated set of components.

Central to this architectural approach was the standardization of the interfaces that components in each service class presented to the rest of the components within a station (and even across stations). If these and the Backplane elements were properly executed, then it would become
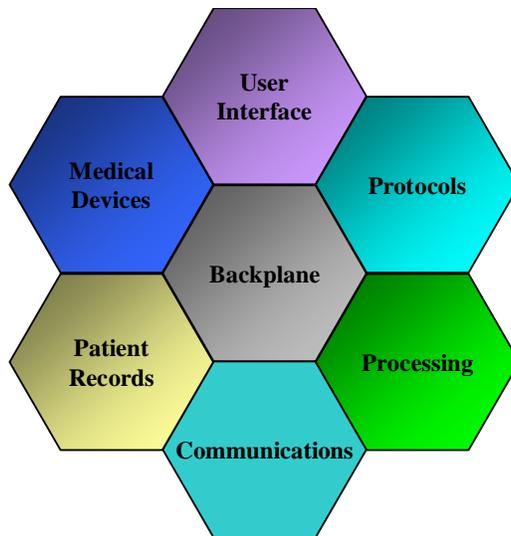
Figure 2. The "Honeycomb" Architecture

possible for components to be assembled in mix and match fashion to create "new" telemedicine capabilities (Figure 3).

This modular approach to telemedicine system design was seen as helping the problems cited above in several key ways. First, the move towards standardized interfaces would lift the

Stand-alone Monitoring Unit   Personal Status Monitor
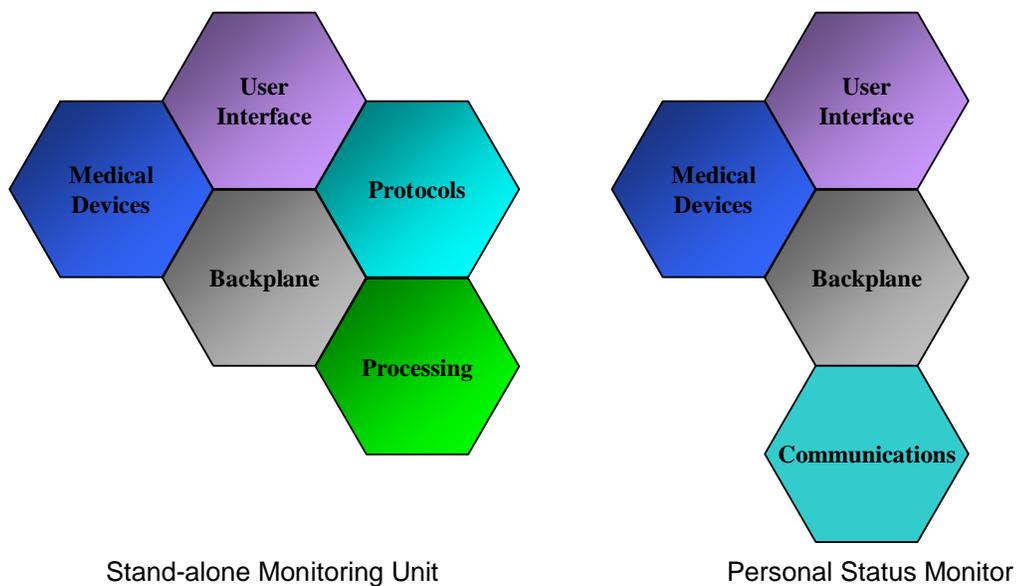
Figure 3. Mixing and Matching Building Blocks

problem of integration from the shoulders of individual vendors making it very easy to rapidly assemble systems in Lego© fashion. Second, because component interfaces are well-defined, vendors of specific kinds of components could focus their resources on creating best-of-breed components or components that address certain price-performance points or certain market niches without having to worry about developing "the rest of the system" just to sell their products. This fact could encourage the formation of a third-party add-ons market and, thereby, expand the range of things that can be done over the wire. Third, if properly rendered, this interoperability approach would allow for the creation of systems that incorporate non-standard components, such as digital televisions capable of running applets or network-based storage devices shared with other applications in a home or office environment. This combined with the fact that the engineering time required to field systems would be greatly reduced would drive the cost of systems down and, hopefully, lead to greater market penetration.

To the Sandia engineers, it was clear that changes in technology would lead to a world in which computing systems were made up of services running "out there somewhere" on the Net and knitted together as needed to deliver a required capability (Figure 4). In this world, today's turnkey telemedicine system designs would be replaced by interface devices, medical "peripherals", and application-specific software accessing record storage, processing, other services vended by Net-based providers. In this world, costs of systems would be so low as to all but demand their use as a standard means of accessing care.
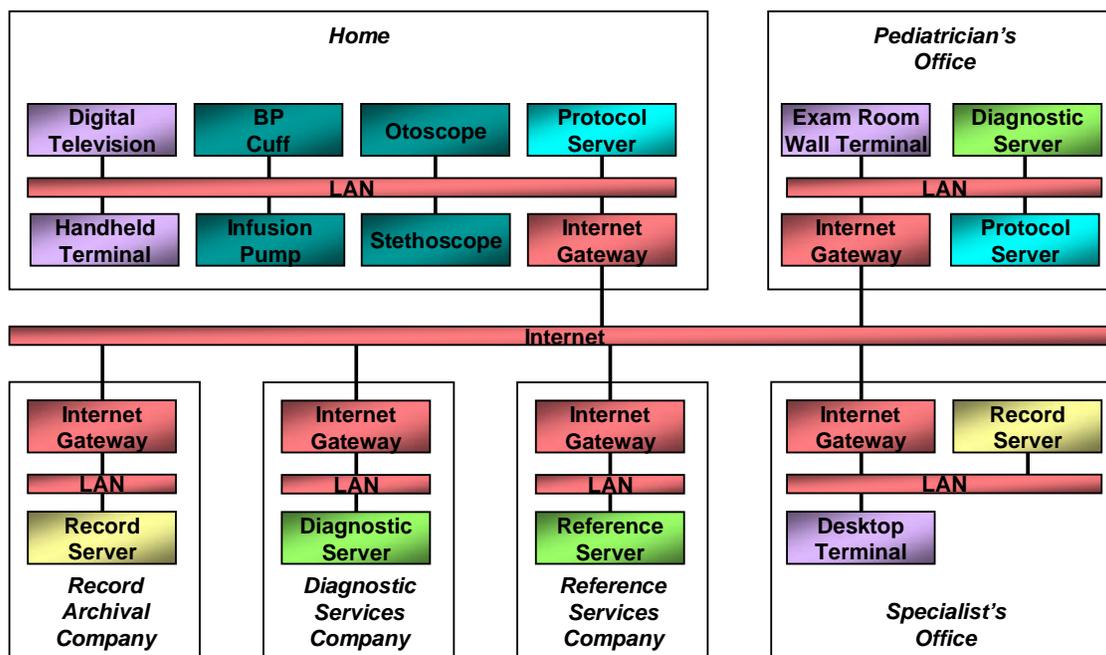
Figure 4. A Distributed Telemedicine System Architecture

2.2.1.3 Pursuing the Architecture

In considering how to create a first implementation of the TRA, Sandia researched existing standards and technologies of potential use. Several on-going efforts stood out as candidates for consideration. Among these were the IEEE 1073 Medical Information Bus approach to plug-

and-play device interaction, HL7's approach to patient record communication, and the OMG's CorbaMed specifications related to record storage and retrieval and information security.

Building on this foundation, the team developed the first detailed architectural concepts and began development work on a first prototype that would address some of the capabilities included in the Backplane and the User Interface, Devices, and Patient Records service areas.

2.2.2 Surety Issues with Existing Technology

As expected, looking at telemedicine system architectures in this alternate way pointed out a number of security issues that would need to be addressed that were not central issues in current system designs. As telemedicine systems moved from closed systems based on proprietary designs and running over dedicated circuits or phone lines to open systems based on accepted standards and running over public networks, it was expected that the security threats associated with telemedicine would increase. While healthcare security's emphasis on the confidentiality and integrity of patient data would continue to be important, future telemedicine systems would bring with them a whole range of new security issues. In part, this is due to the fact that the components of future telemedicine systems would be Internet devices. As such, they would inherit many of the security concerns associated with the Internet. In addition to this, these systems represent a new generation of information technology. Whereas the current generation is characterized by the merging of large numbers of formerly independent, static networks of computers into a global Internet, the next generation will be characterized by pervasive computing, high performance communications, mobile devices, and ultra-distributed processing. In this new world, many of the fundamental assumptions underlying current approaches to security would no longer hold true. In fact, how to address many of the security problems of this new generation of systems were seen to be the subject of on-going leading edge security research. Among these were things like security policy negotiation, certification of remote services, and safe federation of independently developed components.

Assuring telemedicine system operations requires addressing a number of security and safety issues. Among other things, these include:
- ensuring that patient data privacy requirements are enforced, that all such data is accurate, and that it is available for use whenever needed,
- controlling who has access to what system services and under what conditions,
- making sure that all users of these systems can rely on the system to do exactly what they are supposed to do whenever they are used irrespective of who is using them and of the settings in which they are being used, and
- guaranteeing that all system operations can be audited when required.

2.2.2.1 Privacy, Accuracy, and Availability of Patient Data

Control of patient data falls into three broad categories: enforcing privacy requirements, guaranteeing its accuracy, and ensuring its availability when needed. Privacy concerns manifest themselves in several ways. First, data stored in repositories on telemedicine systems might be read directly from the records if no access controls are in place. Similarly, the files in which the repository data is stored might be copied. Media on which these files reside might also be taken and read directly if not somehow protected.

Communications within a telemedicine system are also vulnerable to unintended disclosure. Eavesdroppers can intercept communications between stations. When RF links are used to connect medical instruments or interface devices to a station, communications can be tapped.

In some settings, "inferencing" can be used to learn things about a person that are otherwise safeguarded against disclosure. One example of this would be tracking who is talking to whom. While the observer may not be able to directly read any of the traffic between a patient and his caregiver, mapping calls or network connections might be enough to infer what kinds of health issues the patient is facing.

Just as patient data must be protected against unauthorized disclosure, it must also be guarded against corruption. This includes protecting against both accidental corruption, as might occur in noisy communications or in data entry, and intentional corruption, as when an attacker attempts to alter records or impersonate a given entity in a network. As with privacy, the integrity of data in storage and in transit are both issues that need to be addressed.

Finally, patient data implies must be available for use when required. This means that it must be easy to locate and rapidly retrieve relevant information and must be difficult to lose the data in a single-point failure (e.g., a disk crash). This will also mean mechanisms for allowing certain users of the data to override default access control mechanisms when the timeliness of access is exceptionally critical and normal access controls cannot be supported operationally.

2.2.2.2 Controlling Access to System Services

The ability to control how and when system and station services are accessed and by whom has implications for both security and safety. As a starting point, it is necessary to control how "authorized" users employ a system's resources. Not all functions are appropriate for all users. Certain clinical functions (especially those that are safety critical) may need to be off-limits to patients being treated with the devices that deliver these functions. Likewise, certain maintenance functions, such as device calibration, may need to be restricted to personnel trained in these functions.

In telemedicine systems, it is entirely possible that a device's functions may be accessible both remotely (i.e., controllable by some remote device) and locally (e.g., through a front panel on the device). In these cases, it may be desirable –even necessary – to allow the device to be configured to preclude the use of one method of control or the other. In these sorts of cases, care needs to be taken to ensure that access control cannot be subverted simply through replacing one component with another (e.g., by replacing one interface device that has been configured to enforce interface function access controls on a station with another like device that has not been configured in this way).

Even when remotely generated commands are encrypted or simply cryptographically signed, steps must be taken to guard against "replay attacks". In these attacks, valid commands are recorded by a "man in the middle" and then replayed to and acted upon by the target device that sees the commands as valid.

2.2.2.3 System Reliability

If clinicians and patients are to use telemedicine systems to carry out healthcare transactions, they must be able to trust that these systems will act faithfully and predictably on their behalf. This will mean that systems will need to run the first time every time, where possible. Where not possible, the systems must not fail in ways that can harm patients. Also, caregivers must understand what they can trust the systems to do and the degree to which they can trust them (e.g., they will want to know that remote devices are functioning correctly and are being employed correctly if they are to trust their use)

Because telemedicine systems are often employed in less than ideal settings, communications reliability can be a significant issue. Consequently, systems intended for use in these environments must ensure fail-safe operation in the face of communication system interruptions. In addition, in performance critical operations, it must be possible for the stations involved to gain a sense of whether or not the associated infrastructure can guarantee certain responses before the stations commit to a given course of action.

2.2.2.4 Auditing System Operations

In remote operations, caregivers must know who is on the other end of a link. They must have a sense that any data generated by a remote system during a session or actions taken by that system are associated with the person that they believe to be on the other end of the link. Likewise, when patients "visit" a remote caregiver, they want to be able to identify the individuals with whom they are dealing.

In many cases there will be a need to log what operations were done with a given system, when these operations occurred, who performed the operations, and on whom they were performed. In addition to the obvious connection to patient records, this audit log feature may be required for, among other things, tracking down erroneous data generated by a faulty component or for identifying operator problems that need to be remediated in some way.

2.2.3 Other Items of Note

Sandia decided early on that the Telemedicine Reference Architecture had potential to influence the telemedicine community and decided to elect title from DOE on it. An initial description of the Telemedicine Reference Architecture that was filed at this point and followed up within the year by a full patent application. Sandia has yet to hear back from the USPTO.

Sandia also participated in several workshops and conferences during this period and produced papers and presentations describing its concepts. These are available as SAND reports from Sandia's Technical Library and can be accessed on-line at http://www.sandia.gov.

2.3 Infrastructure Roadmapping Activities

2.3.1 Application of Medical Roadmapping Strategies to U.S. Infrastructure Protection

In Phase I, an interactive gaming approach was used to build a consensus and to develop roadmaps establishing technology's role in meeting health care delivery needs. The Biomedical

Prosperity Game© and associated roadmapping activities were conducted from November 1995 through April 1996 with representatives from over 40 organizations with expertise in a broad spectrum of health care. The Game was an interactive simulation, which explored complex health care issues in a variety of economic, political, and social areas. The simulations were high-level exercises of judgment, planning, discretion, and negotiating skills. The Game provided participants with an understanding of some of the obstacles and opportunities associated with current and proposed health care technologies and technology-related policies. The objective of the Game and this task was to identify those technologies and technology related policies with the potential for significantly reducing future health care costs while maintaining or improving quality.

The principal products of the Game were technology and policy roadmap outlines for eight prioritized health care areas. The results of the effort were compiled by Sandia in the report *The Role of Technology in Reducing Health Care Costs* (Sandia, August 1997). The technology and policy areas discussed include: Advanced Telemedicine; Health and Health Care Informatics; Information and Network Surety; Integrated Predictive Diagnostics; Minimally Invasive Therapy, Imaging, and Energy Delivery Systems; Performance Measurement and Outcomes Research; Preventative Medicine and Incentive Programs, and Rehabilitative Science and Assistive Technologies. The outlines in the report provide the guidance and identify the needs for the proper development and introduction of promising technologies and policies to improve the US health care infrastructure and delivery system. The results presented have direct application to the DoD's range of medical needs for monitoring patient health, be it at home or on the battlefield.

The Game proved to be a valuable tool and provided a general consensus that the future health care and health care information infrastructure must support systems capable of handling all measures of care complexity while maintaining flexibility, responsiveness, and quality. Our medical care infrastructure of doctors, nurses, emergency medical technicians, hospitals, clinics, etc. are dependent on infrastructures such as electric power, oil and gas, water, transportation, and telecommunications to fulfill their missions during routine and emergency situations. Therefore, it was apparent that future health and health care will be reliant on safe, secure, and reliable infrastructure elements to support economic prosperity, national defense, and quality of life. Therefore, for Phase II of this project, a task was identified to use the Biomedical Prosperity Game© format discussed above to assess vulnerabilities of the critical infrastructures and their influence or affect on medical care for the nation and national defense.

2.3.2 US Infrastructure Assurance Prosperity Games™

For this task of Phase II of the project, Sandia facilitated two US Infrastructure Assurance Prosperity Games™ to validate strategic options for policy and supporting technology applications that substantially increase the safety, security, and reliability of US infrastructures. The results are reported in *US Infrastructure Assurance Strategic Roadmaps: Strategies for Preserving Our National Security* (Sandia National Labs Document, SAND98-1496, August, 1998) and can be obtained from Sandia's Technical Library or accessed on-line at http://www.sandia.gov.

3 Phase III - High Surety Telemedicine System Design, Testing and Evaluation

In Phase II, a commercially available telemedicine unit was obtained and studied in a hypertension clinic. The figures of merit including receiver operating curves for the technology were developed in Phase II and in general the technology performed at an acceptable level for the care of recurrent outpatients with this chronic disease. This led to Phase III that had, as its goals, the application of the methodologies developed in Phases I and II to telemedicine and, in particular, to a new telemedicine system developed by Sandia National Laboratories.

Based on the results of Phase II, five major tasks were originally identified for Phase III of this project. Unfortunately, only half the expected funding was received and Sandia, therefore, concentrated on completing three major tasks, including: 1) collaborate with government, academia, and industry to enhance architecture service areas, 2) demonstrate a telemedicine technology that incorporates plug-and-play and information surety capabilities, and 3) clinically evaluate the cost-effectiveness and diagnostic feasibility of this type of telemedicine technology. These three activities were completed in December 2001.

Since General Devices (GD), the developer of the TLC 2000 (the telemedicine system used in the Phase II study) was targeting development of new systems around the core technology from the original TLC 2000 system, Sandia and General Devices decided in November 1998 to form a cooperative research and development agreement. For this joint effort, Sandia would supply the fundamental architecture definition, information surety capabilities, and plug-and-play mechanisms. General Devices would build its new systems around this architectural definition. Initially, both parties would work to incorporate general modular telemedicine functionality into a base system. GD would then upgrade the base system to include functionality for the new platforms, while Sandia would upgrade the base system to include the functionality needed for the phase III clinical study with Ochsner Clinic in New Orleans. However, due to GD's fundamental change in direction (i.e. away from telemedicine systems and toward emergency response systems) and the perceived difficulty of retrofitting the TLC 2000 software to accommodate the modular concepts central to the Telemedicine Reference Architecture, the Sandia project team decided to pursue the introduction of this technology through a concrete demonstration in a clean-sheet proof-of-concept design. As a result of this, the Sandia / General Devices CRADA was never birthed.

As originally planned, this proof-of-concept work would be pursued in three phases. The first phase (Figure 5) would focus on the design of a single node in a telemedicine and would be used to develop the infrastructure needed for distributed, modular system designs. The second phase (Figure 6) would address the issues in distributed system design and would deliver a traditional two-station design but one that was readily extensible to large networks of stations. The final phase (Figure 7) would address the form factor of the stations themselves with a view to breaking the stations up into a number of components that could federate as required to deliver a given capability. While security issues would be considered to some degree in the first phase, they would be addressed more fully in the latter two phases.

Figure 5. Build 1 - The Traveling Medic Unit

Figure 6. Build 2 - The Remote Care System

Figure 7. Build 3 - Advanced Medic Instrumentation Suite

3.1 Design and Development of a High Surety Telemedicine System

In this three-phased development, this first application of the TRA was a "Traveling Nurse's Station" (TNS). The TNS was designed as a store and forward system. It was to be taken into the field by a nurse and used to collect health data such as weight, body temperature, blood pressure, etc., and to record observations of the patient. The system would be returned to the clinic where the data could be uploaded to a "Doctor's Station" for additional study.

The system was created and delivered to Ochsner where it was used in a clinical trial starting in October 2000. The system, built in a flexible manner, integrates commercially available medical devices from several different manufactures were integrated into a single system. All of the devices except for stethoscope supported an RS232 interface for remote control and status. The stethoscope provided only an analog signal out.

The system was designed to be a "plug-and-play" system in hardware and software. Medical devices plugged into the computer using Universal Serial Bus (USB). USB allowed the devices to be added and removed while the system is running. The software was designed so that a new device could be easily incorporated. The software was written in Java to promote portability between different computers and operating system.

3.1.1 Hardware

3.1.1.1 Medical Devices

The types and the specific medical devices included in the system were recommended by Oschner and several devices had been used in the Phase II telemedicine study.

3.1.1.1.1 Weight Scale

The weight scale is an A&D Engineering, Inc., UC-300. The weight scale required a custom built interface to convert the output serial data to RS232. The user engages a button on the side of the scale to initiate the measurement and then steps on the scale. The result of the measurement is displayed on the unit as well as being transferred to the computer.

3.1.1.1.2 Blood Pressure Monitor

The blood pressure monitor is an A&D Engineering, Inc. UA-767PC. The unit provides an arm cuff for taking the blood pressure measurements. Results of measurements are displayed on the unit as well as being transferred to the computer.

3.1.1.1.3 Pulse Oximeter (SPO2)/Temperature Monitor

The SPO2/Temperature monitor is a BCI International, BCI 3301T. This unit provides a finger unit to take SPO2 and pulse rate measurements and provides an ear probe to take body temperature. Results of measurements are displayed on the unit as well as being transferred to the computer.

3.1.1.1.4 Electronic Stethoscope

Welch Allyn produces the electronic stethoscope. The unit provides a headset as well as output of the electronic signal to the computer. The computer stores the same sounds that the user hears through the headset in a file on the computer. The file can be played back later through headphones attached to the computer.

3.1.1.1.5 ECG Heart Monitor

The ECG Heart Monitor is a Perigon Medical Distribution Corp., CM4000 PAM Cardiac Monitor. It has built in probes for a three-lead measurement, as well as a connector to attach the probes for a twelve-lead measurement. Results are stored on the unit where they can be reviewed as well as transferred to the computer.

3.1.1.2 Laptop

To allow portability of the TNS, a laptop computer is used as the computer for the system. The laptop is a Dell Inspiron 7000, however any similar computer could be used. The laptop runs the Windows 98 operating system. Windows 98 was used due to the limited support at the time for USB, however newer versions of Windows now support USB.

3.1.1.3 USB

All RS232 interfaces are connected to USB serial converters. The serial converters are connected to the computer via a USB hub. The USB serial convertors and hubs used are manufactured by Belkin Components.

Figure 8. TNS Package

3.1.1.4 TNS Case

For portability, all of the TNS hardware is packaged in a hard-sided rolling case. The laptop is contained in its own carrying case, which can be strapped to the main case. All devices are interconnected as much as possible to simplify setup. Because of the USB architecture, the devices could have packaged in several different units however we felt it would be easiest for the non-technical user if the system were assembled as much as possible.

Figure 8 shows the TNS case. The weight scale is attached to the lid of the case and the other medical devices are contained in individual compartments at the top of the case. The lower part of the case contains the USB equipment, power strip, and power converters. The pouch in the lid holds other accessories. The laptop computer is not shown.

3.1.1.5 Doctor's Station

The Doctor's Station is simply a laptop with the necessary software to transfer data from the Traveling Nurse's Station and to view the data. This software is a subset of the software that is on the TNS.

3.1.2 Software

Figure 9 illustrates the general architecture of the TNS software system. Key components of this are physical devices that can be added and removed from the system, user interface components that provide a user with access to the system's services and to the information that it generates, a repository (not shown) for storing data generated by the devices or entered by the user interface, and a software infrastructure that allows these components of interact with one another.

Virtual Device
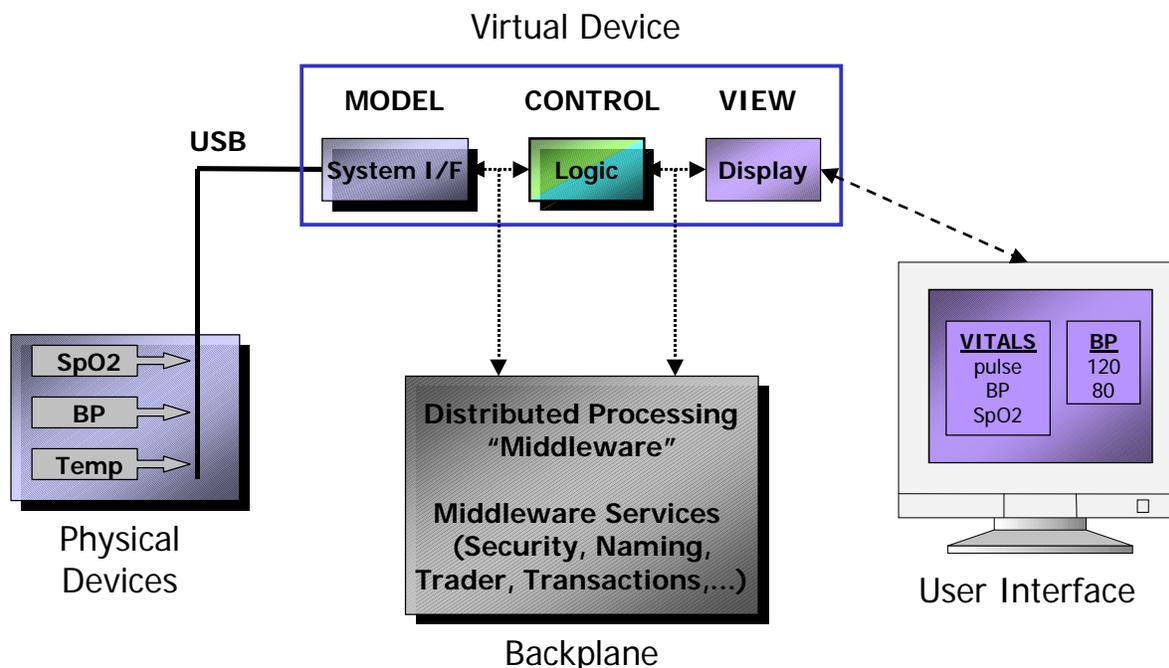
Figure 9. Notional Architecture

3.1.2.1 Software Backplane

The common software services necessary to integrate the independent software components are implemented as a CORBA backplane. Implemented in this way, the physical location of a device is transparent. A device on one host is accessible, via the network, from another host. The medical devices, in the software, ultimately appear as CORBA servers. The CORBA servers are created when a device is plugged into the system. The CORBA servers register their existence in the Naming Service. The Naming Service publishes events to registered applications to indicate when the CORBA server is added or taken away from the system.

Operating system events are intercepted that indicate a USB node has been plugged in, which in turn implies that a device has been plugged in. The operating system events are processed by a Control Program application. This application causes the appropriate CORBA server to be created. The CORBA Servers are designed such that when multiple devices of the same type are plugged in, a single CORBA server handles them.

3.1.2.2 Devices

The software representing the hardware medical device consists of a Device Model and a Device Interface.

3.1.2.2.1 Device Model

A Device Model represents the software interface provided by the CORBA server. The interface is designed using a few fundamental rules, which are applied independent of the type of device. The data available from the device is described as properties. There are methods to get and set properties as appropriate. The methods are named in a predictable manner using a naming

pattern. The Device Model sends events to indicate a change of data. The Device Model typically provides the *state* of the device so that application displaying the device information can show the operation of the device. The display application accesses the Device Model via CORBA.

3.1.2.2.2 Device Interface

The Device Interface is a separate software module that represents the device independently of the CORBA server. In this way the Device Interface can be used with other software systems. The Device Interface handles the low-level serial interface to the hardware device. It interprets the data and presents it in an interface using properties, property methods, and events, the same manner as described above for the Device Model. The Device Model accesses the Device Interface directly as the two are linked together in the same software application.

3.1.2.2.3 Standardized Data

The data that is available from the different medical devices is standardized to provide a common interface. A combination of ideas from the OMG Clinical Observation Access Service (COAS), HL7, and MIB were used to do this. Data provided by a device is wrapped in a software object that also provides information about the type of measurement. The type of measurement then is specified by standardized codes from HL7 and MIB. For example, when a blood pressure measurement is taken, the value of the measurement is saved, but also other data is saved such as the unit of the measurement and how it was taken, i.e. the position of the patient and which arm was used for the measurement. All of this data is preserved together and stored together as part of a single measurement in the database.

3.1.2.3 Data Storage

The data storage used in the system is an implementation of the OMG's Clinical Observation Access Service database. The version used by Sandia was implemented by Dave Forslund, et. al., of Los Alamos National Laboratories under a separate TATRC program. The interface to the database is via a CORBA server. The backend database behind the CORBA server is a POET Software object-oriented database. Storage and display of data is accomplished through the Desktop.

Batch files are provided to automate the process of copying the database from the TNS to the Doctor's Station. A batch file is executed on the TNS to copy the database to a zip disk. The zip disk is removed and inserted in the Doctor's Station computer. A batch file is executed on the Doctor's Station to copy the database file to the appropriate location on the computer.

A separate application is provided that exports data from the POET database into a set of text files. The text files are suitable for inclusion by other data applications such as spreadsheet or a relational database.

3.1.2.4 Desktop

The Desktop (developed with guidance from Dr. Larry Clevenger and his staff in Sandia's medical department) shows the medical devices that are available as icons in the toolbar. When a device is plugged in, the icon is enabled; when the device is removed, the icon is disabled.

Clicking on the icon brings up a new window, called the Device View, which shows the controls available for the device and readings taken with the device.

This functionality is possible because the Desktop registers as a listener for the CORBA Naming Service events. When a new CORBA Server appears, representing a device that is plugged in, the Desktop receives the event and makes the icon enabled. When the user clicks on the icon, the Desktop establishes a network connection with the corresponding CORBA Server. It uses the CORBA Server interface to retrieve the data that is displayed in the window. In this was the Desktop is very generic and serves primarily as a *container* to show the Device Views.

The Desktop also allows the nurse to create patient records that includes personal information about the patient as well as the measurements taken for the patient. Measurements and other data are organized as an *Encounter* with the patient.

Figure 10 shows one of many views of the Desktop. In this figure a patient record is open and a weight measurement has been taken. The weight measurement is saved in the database for this patient by clicking on the Record button in the Weight window.
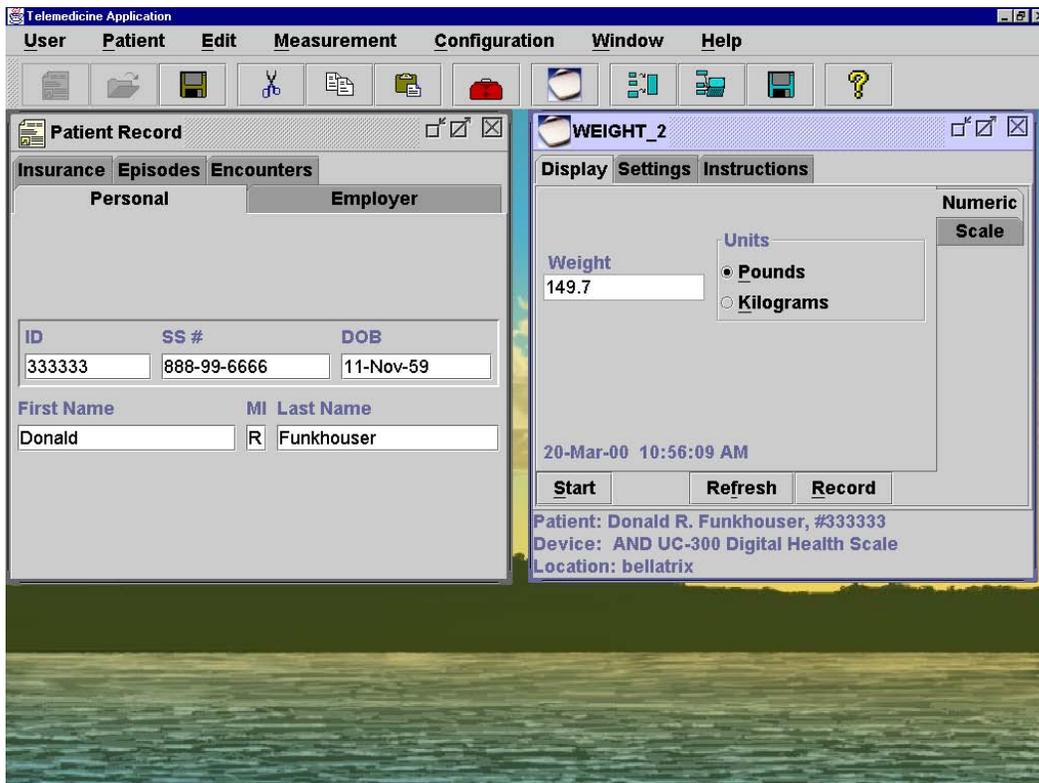
Figure 10 The Desktop

3.1.2.4.1 Device View

Devices are accessed via the corresponding icon on the toolbar. When the user clicks the icon a new window is opened showing the interface to the device. When a measurement is requested,

the window instructs the user on the steps necessary to take the measurement. When a patient record is open, the device measurement is saved to the patient's record by clicking on a button to record the measurement.

3.1.2.4.2 Patient Record

To add a new patient to the system, a new Patient Record is created through the Patient Menu Item on the Main window of the Desktop. The Patient Menu can also provide a list of existing Patient Records. Selecting one of the existing Patient Records opens a Patient Record. The Patient Record includes Personal Information, the list of Encounters for a patient, and Trend information from measurements.

3.1.2.4.2.1 Personal Information

The Personal Information window allows the nurse to enter identifying personal information about a patient.

3.1.2.4.2.2 Encounters

The Encounters window lists all of the Encounters with a patient. A Date and Time identify an Encounter. Encounters may also be grouped by an Episode. An Episode relates to a continuing medical condition that may take several Encounters to address. When an Encounter is selected or a new one is created, the Encounter window is shown. The Encounter window has two options, either display of the SOAP notes, or display of the Measurements.

3.1.2.4.2.2.1 Subjective, Objective, Assessment, Plan of Action (SOAP) Notes

SOAP is a common way for a clinician to record an encounter with a patient. A summary of measurements taken is listed in the Objective part of the Notes. The Subjective, Assessment, and Plan portions allow the clinician to record notes as he sees fit.

3.1.2.4.2.2.2 Measurements

The Measurements window shows a scrolling list of measurements. Textual tables are shown for blood pressure, weight, temperature, and blood oxygen measurements. A graphical plot is shown for ECG results. Digital stethoscope sounds are recorded as a *.wav* file and can be played back by clicking a button.

3.1.2.4.2.2.3 Trends

The other window for a Patient Record is the Trends display. The Trend window shows a graphical plot, where applicable, for each type of measurement. The plot shows the value of the measurement across a number of Encounters. For example there is a plot of the Blood Pressure History which shows the Systolic and Diastolic measurements for each day that there was an encounter. A line connects the data plots, which easily identify a trend in the measurement values.

3.1.3 Additional Work

Experiments were tried using commercial video conferencing devices towards the goal of making the system a remotely accessible telemedicine system. Problems were encountered using this equipment due to lack of prioritization of data packets on the network. Much work is currently being done in the commercial network world to incorporate prioritization of voice and

video packets on a network and this will soon become much more feasible and may be so already.

3.1.4 Lessons Learned

The primary motivation behind pursuing each of the three proposed development phases was to gain hands-on engineering experience in the each area identified in the Telemedicine Reference Architecture with a view to publishing the results of the work in these areas in the form of an interoperability specification. The focus of TNS activities was on the development of the infrastructure on which all other work would be based and on the development of plug-and-play device capabilities.

Figure 11 shows the TNS system as it looked before being loaded into the roll-away chassis. The picture is intentionally "ugly" and is meant to illustrate many of the challenges involved today in creating a telemedicine system. For example, the weight scale (the pentagonal box at the upper left of the picture) used in this system was the one found most often in telemedicine systems that were available at the time that the system was being built. The scale was not designed for continuous connection to anything outside itself but did offer a "test" port that just happened to allow an external device to read out weight values. All operations involved in using the scale (e.g., turning it on, "zeroing" it, etc.) had to be done manually by a human operator. To make the signal coming from the test port usable by the computer, a converter circuit was added (this is the rectangular box located at 2 o'clock relative to the scale) that turned the scale into a serial device. The output of this serial converter was then fed into a serial-to-USB converter to make the scale operate as a plug-and-play device.

The electronic stethoscope (lower left corner of the picture) was designed for use with audio equipment (e.g., it could be plugged into the sound card of a PC much like a microphone or the output of an audio deck could). To make it usable by the PC as part of the patient record, the stethoscope's output was fed into a Roland converter that digitized the signal and streamed it out a USB connection.

The blood pressure monitor was "easy". It came equipped with a serial connector and was capable of being monitored and controlled directly by a PC. As with the other serial devices, to make it plug-and-play it was connected to the PC via a serial-to-USB converter. The experience with the EKG was similar.

The pulse-oximeter / thermometer (center of the picture) provided Sandia with an interesting experience. While a serial device and designed for use with a computer, when software was written to interact with the device, it failed to work. A call to the manufacturer found that there was an additional byte of information in the device's data stream that needed to be read but that was not accounted for in the programming documentation. When this was addressed in the software, everything worked as it should. In the course of developing a copy of the TNS for Ochsner's use, a second device was bought and, when tested, failed to operate. When all else had failed to expose a reason why an identical device should not work, a call to the manufacturer found that the manufacturer had changed the protocol for interacting with the device since the time that the original device had been purchased – same make and model but now a new set of commands for using it.

Figure 11. The Bare TNS

For evaluation purposes, web cameras and videoconferencing software were added to the TNS and Doctor's Station. The web camera was the one native USB device included in the system. During tests of the station operating in various modes, problems with the USB network emerged. Although this technology had been hailed in the press as a breakthrough and the devices that Sandia procured had been in standard use for a significant period of time, the TNS application pushed the USB bus hard and exposed problems that had not yet been discovered in other uses of the hardware. Given that three of the devices on the bus all streamed data, saturating the bus became quite easy.

Simple material costs for the system (including the PC) were around $10,000 with about half of this coming from the PC and USB equipment and the rest from medical equipment. While volume pricing would drive down the cost of components and a cheaper PC might be used, the overall cost of the system would probably still be too high to support widespread deployment. In telemedicine system designs common at the time that the TNS was being developed, most telemedicine systems on the market incorporated single board computers and integral storage, display devices, and controls. For the purposes of cost containment, these systems typically used less capable components – less powerful processors, lower resolution displays, etc. – than those used in the TNS.

Understanding these experiences is important because they point to what must happen technically if telemedicine is to advance. First, every device that Sandia handled had its own ways of interfacing with a computer (and some had to be forced to interface with a PC). The kinds of integration activities that Sandia undertook are typical of the experiences of many

vendors in the telemedicine community who spend many man-hours stitching devices into systems. This is one of the factors that drive up the cost of telemedicine systems.

An interoperability architecture that standardizes the way in which specific kinds of devices interact with the computers that host them will help this situation. This standardization must occur at two levels: at the physical interconnection level and at the device communication level. In the latter case, interoperability might be achieved by defining logical interfaces to specific kinds of devices and rendering the software that manages these interfaces inside the telemedicine system (as is done today with printers, scanners, etc. that connect to PCs). In this case, each vendor is free to implement its own device-unique protocol just as long as it delivers the software capable of encapsulating this protocol behind the standard interface. Alternatively, devices themselves could be made to implement standard protocols. In this way, a device from one manufacturer could be readily swapped out for devices from other manufacturers. While some devices might incorporate vendor-unique features, all compliant devices would be guaranteed of operating a common subset of all features available from all vendors.

Regarding the question of how devices physically attach to the PC, as discussed above, none of the devices used in the TNS came ready for plug-and-play operation. Their designs all assumed that, if they were being used, the knowledge of this fact would have been built into the systems hosting them. While this works for designs that are meant to host a fixed suite of devices, it becomes unmanageable when the goal is to allow telemedicine systems to be customized at will with whatever devices are required for the operational problem at hand (which was the prime motivation for pursuing plug-and-play operation of devices).   Because these devices assumed that the knowledge regarding what they were and how to use them was built into the station's hosting them, none provided any means for allowing the telemedicine to query them for this information. Consequently, while the very nature of USB allowed the PC to detect when devices were added or removed from the bus, nothing told the PC exactly what had been added. To handle this, special software had to be written that performed certain "tricks" to figure out which device had been attached. For these reasons, to address the physical interconnectivity issues, two needs should be addressed. First, devices should incorporate interfaces that are designed for plug-and-play. Example technologies that provide this today are USB, FireWire, IrDA, or BlueTooth (note that network/IP-based interfaces, as are used in things like printers or storage devices, are also possible candidates). Second, at a minimum, devices should be able uniquely identify themselves to devices that host them. This identification could include a manufacturer's ID, a model number, and a serial number. This information should be enough to permit devices of a given type made by different manufacturers to be simultaneously hosted by a system. It would also allow multiple devices of the type and from the same manufacturer to be hosted at the same time on the computer. This becomes important if each such device is independently configured and can be swapped out at will by the system users. Beyond this simple identification, devices become more powerful if they can describe themselves to the platforms to which they are attached (e.g., "I am a thermometer. I am compliant with protocol X. I implement commands A, B, C.").

Finally, one look at the picture shows that wiring has the potential to become problematic. The TNS hosted a half-dozen devices and it is easy to envision systems that might host more. Given this, using wireless wherever possible would be prudent. At the same time, some devices in the

system are high-bandwidth and demand wired connectivity. For whatever interoperability architecture is put in place, it is likely that provisions will need to be made to accommodate both. More importantly, technology evolves, so creating a layered architecture, as was done in the TNS, which makes it possible to change media without impacting system components that use devices connected to this media is important.

In addition to these device-oriented recommendations, the TNS effort pointed out the value of a number of architectural features that could be carried forward in developing an industry-wide approach to the design of telemedicine systems. Among others, these include:
- communication through standardized virtual devices that proxy real-world components
- the use of a publish and subscribe model for dynamic federation of system components
- an object brokering infrastructure that allows for the ready distribution of components around a network, and
- the use of programming approaches, such as Java-based coding, that allows software components to be hosted on a broad range of platforms.

3.2 Industry and Medical Interest in the Architecture

3.2.1 Collaborations

In order for Sandia's ideas regarding interoperability to make any difference, a constituency for these ideas must be developed. One avenue for doing this was presentations at conferences, workshops and meetings with interested groups; however, the most effective activity pursued was a collaboration established between Sandia and Texas A&M, a relationship that was initiated at the encouragement of TATRC. The fruit of this partnership was an interoperability summit co-hosted by SNL and TAMU, which ultimately led to the formation of an interoperability task force within the American Telemedicine Association.

3.2.2 The Summit

The Workshop on Healthcare Interoperability Standards, held April 25-26, 2000, in San Antonio, Texas, focused on next-generation approaches to healthcare delivery and on the steps that the healthcare community needs to pursue in order to realize the full potential of these next generation approaches. The goals of the workshop were to:
- consider how technology may help radically improve the way health care is delivered.
- identify barriers that must be overcome in fully exploiting these technologies
- develop suggestions for overcoming these barriers, and
- recommend mechanism(s) for implementing these suggestions.

Attendees were drawn from various parts of the government and private healthcare communities and included:

Dean Bidgood   SR Data Solutions, Key Contributor to development of DICOM

Wes Burnett   TATRC

Dave Chizmadia   CSC/Information Assurance Solutions, Former NSA security specialist, Distributed software security expert

KC Christensen	Medical Research & Material Command
Rick Craft	Sandia National Labs, Project Lead for Telemedicine Reference Architecture Project
Michael Freckleton	Texas A&M, IPA Radiologist to Wilford Hall Medical Center
Jim George	Los Alamos National Labs, Active in CORBAMed, Co-developer for LANL's TeleMed Electronic Patient Record
Gary Gilbert	University of Pittsburgh IPA to TATRC, Former commander of MATMO
Doug Hamilton	Wyle Life Sciences, MD/PhD (in electrical engineering)
Kurt Henry	Program Manager, DARPA/DSO, Internist at Pensacola Naval Hospital ER
Michael Hightower	Sandia National Labs, Program Manager for Sandia's telemedicine efforts
Mark Janczewski	Director of Air Force Telemedicine, Air Combat Command
Charles Jones	Director-Telemedicine, Southwestern Bell
John Linkous	Executive Director of the American Telemedicine Association
Pat Lichter	Director of Corporate Technology, QRS Diagnostic
Steve Liu	Associate Professor, Computer Science Department, Texas A&M, Lead developer of the TAMU PORDITS telemedicine system
Randall Maschek	Director, Total AMEDD Systems Management
Patrick McGinnis	Flight Surgeon, NASA, JSC
James Mendes	Medical Defense Partnership for Reinvention
Dave Parker	Family Physician, Design Lead for CHCS II
Dave Riley	Independent Consultant, Health Care Informatics
Dave Roberts	Microsoft, MBA, System Engineer
Mathew Sailors	UTHSC Houston, Digital EMS Project Director
Jose Salinas	Texas A&M, Development Lead for DR&EMS
Jay Sanders	President, The Global Telemedicine Group
Scott Simmons	Wyle Life Sciences (NASA/Johnson), Former project lead for NASA's Telemedicine Instrumentation Pack

Following opening talks, workshop participants were divided into four groups, representing major technical components of future healthcare delivery systems. These were Medical Devices, Decision Support and Medical Reference, Electronic Patient Records, and Telecommunications and Computing Infrastructure. Each group was then given the task of:

- describing what they envisioned for the "ideal" healthcare delivery system(s) of the future,
- characterizing the benefits that would be gained by realizing this "ideal" future,
- cataloging deficiencies (in existing standards), and
- identifying the necessary conditions to create the ideal healthcare delivery system.

While their answers were much more detailed than what is described in this report, the heart of what participants described was a predictive, rather than reactive, system that was patient-centric

in its focus and whole-life oriented in its implementation (much like what the IOM recommended subsequently in its Crossing the Quality Chasm report (Institute of Medicine, 2001).

Following this, the four groups once again broke into individual discussion groups to address the question "What are the barriers to getting us where we need to be?" Specific aspects the groups were asked to address included:

- infrastructure barriers,
- technology barriers,
- security/privacy barriers,
- cost effectiveness/quality/safety barriers,
- regulation/policy barriers, and
- market entrance barriers.

Among other issues, their answers focused on cost issues, lack of standards for interoperability, security concerns, bureaucratically induced "drag", old guard resistance, and the lack of a clear vision regarding the nature of future healthcare delivery approaches.

On the second day, the attendees met as one group to discuss the best forum for working toward achieving the goals discussed during the first day. In these discussions it was noted that, while a number of roadmaps had been created for the telemedicine arena, progress toward the objectives outlined in these roadmaps had been slow. The workshop steering committee suggested that a group, whose purpose would be to actively seek to remove the barriers to telemedicine's success, might be formed under the auspices of the American Telemedicine Association. Acting as the agent of the ATA, this organization would form alliances with other bodies, such as HL7 or RSNA for the purpose of producing interoperability specifications and other products necessary for the elimination of the barriers. After some discussion, this recommendation was accepted and it was agreed that the workshop steering committee would approach the ATA Board of Directors and Industry Advisory Board with this proposal.

Given that the ATA accepted the notion of such an organization, the next question for the attendees to answer was "What tasks should this organization seek to accomplish first?" It was generally agreed that telemedicine interoperability standards should be the primary focus. After some discussion, the vehicle proposed for working through these standards was the development of a comprehensive system for a specific disease state. Of various diseases nominated, diabetes percolated to the top of the list because of its crosscutting nature in terms of demographics and attendant pathologies. It was felt that a telemedicine system meant to care for the diabetic would incorporate a broad range of medical disciplines and would involve care in a diverse collection of care delivery settings.

As envisioned by the workshop participants, this effort would result in a series of demonstrations of increasingly sophisticated system capabilities. One approach suggested was to conduct this demonstration as part of a larger "plugfest", like RSNA's Integrating the Healthcare Enterprise. An alternative (and complementary) approach was to demonstrate and evaluate these capabilities in a series of clinical trials.

3.2.3 The American Telemedicine Association

At ATA 2000, the workshop steering committee addressed both the ATA's Board of Directors and its Industry Advisory Board (the ATA's vendor association) on the need for the telemedicine community to begin pursuing the development of interoperability standards. Both groups accepted this recommendation and a core committee was formed to begin planning how this effort will play out in the context of the ATA.

3.3 Testing and Evaluation of High Surety Telemedicine System

3.3.1 Clinical Study Background and Design

Based on the previous phases of this work, it was clear that many proprietary telemedicine systems were operative in the United States, that inter-compatibility between these systems was virtually nil, and that no one system appeared economically viable when applied to general populations. That is not to say that some systems could be economically successful caring for remote populations, prison populations and other selected groups. However, economic viability of the wide spread application of telemedicine had not been demonstrated. Because of Sandia's expertise in computer architecture, surety, and telecommunications, they elected to develop standards for telemedicine that could be widely applied with the goal of providing inter-compatibility and cost efficacy. It was felt that the achievement a standard architecture could help in the maturation of the telemedicine industry and help achieve economic viability. Thus it was determined that Sandia would design such a universal architecture and produce two units for clinical study by the Ochsner team.

The telemedicine equipment Sandia developed was a PC-based low-cost, plug-and-play system designed to collect clinical data relevant to the monitoring and care of patients suffering from CHF. The equipment is intended to be carried with a visiting home health nurse to assure a more accurate and more comprehensive set of clinical indicators that can be recorded. The system contains integrated: weight scale, blood pressure monitor, pulse oximeter, hand-held EKG (electrocardiogram) heart monitor, an electronic stethoscope, and base PC platform. In a clinical setting, the home health nurse uses the system to conduct an examination; all data is electronically captured, stored, and the reviewed at a later time by the supervising physician.

The research team selected chronic heart failure (CHF) as the condition to study for several reasons. First, it is an extremely common condition – approximately 4.7 million American live with CHF at any given time (American Heart Association, 2001). Further, the disease carries significant mortality risk – with a 5-year mortality rate of 50% (American Heart Association, 2001). Second, it is a chronic disease, where medical management generally requires relatively frequent, but low-intensity, visits at a physician office. Third, it is a disease largely of the elderly, which is the most rapidly growing segment of the U.S. population.

The Phase III clinical study consisted of three parts. In the major experimental effort, the Sandia units were to be employed in the treatment of patients with chronic heart failure, a serious medically intensive chronic condition. Receiver operator curves for the diagnosis of inter-current diseases as well as for the application of diagnostic tests and other resources were to be

determined. It was decided that it would only be feasible to achieve this goal if the units were to be used in a chronic heart failure clinic on the Ochsner campus. A second activity was to use the Sandia units in randomized outpatients cared for by Home Health nurses. The units were to be used in parallel nurse visits with information stored for later forwarding to a physician. The concordance between the real time nurse visits and the store-and-forward visits was to be determined. To the extent there would be adequate follow-up time, patient satisfaction and functional status was to be monitored. A third sub-project involved observational study of a commercially available home health alert type monitoring system (HomMed).

The development of the computer architecture and the construction of workable telemedicine units proved more difficult than originally anticipated. Because of this and a reduction in funding for the Phase III efforts, only one Sandia developed telemedicine unit was provided at a later date than expected. Nonetheless, the first part of this activity was completed in a timely fashion. It became necessary to eliminate the randomization and six month follow-up of Phase II patients because time did not permit such a follow-up. However, this shortcoming was considered minor in that the duration of follow-up originally planned and the nature of the interventions were not expected to provide meaningful data over so short a period. Nonetheless, the project was changed in this regard. The HomMed observational study continued as planned. The results of all activities are presented in detail in Ochsner, 2001 and are summarized in the following section.

3.3.2 Observed System Operational Performance

Time motion studies were conducted in the chronic heart failure clinic substudy and the home health substudy. The purpose was to quantify the overall and task-specific times required to operate the telemedicine equipment. Such information could be useful in the development of future prototype systems.

The laptop computer is as reliable as any top-of-the-line laptop. There were no malfunctions as the fault of the laptop. The disk drives are easy to swap. The batteries are easy to charge and gave very good service-time per charge.

While the selection of clinical measurement devices provided with the telemedicine system enabled collection of relevant clinical data (blood pressure, scale, stethoscope, etc), the box was too big and heavy to be practical. If any further use were planned with the device, as it exists, then additional handles in different locations would make it easier to maneuver. In the home health application, the nurses found the prototype cumbersome and unwieldy.

Overall, the devices worked reliably (missing measurements were very rare). Each component is discussed separately below.
- The stethoscope was cumbersome to hold in place while, simultaneously, operating the controls and the software interface. The auto-shut-off feature is set too short for practical application. An additional 30 to 60 seconds would still protect the battery; yet allow for setting and re-setting the patient and equipment for a good recording without starting all over again after the stethoscope automatically shut off.
- The blood pressure monitor comes with a standard sized cuff with tubing that is too short. The device often had to hang in the air in order to reach the patient. After a reading, the

- time until the system is ready to take another reading is too long. It is not clear whether this reset time is in the unit or the computer.
- The thermometer appears to the operators to read low. The spectrum of temperatures in the patient populations studied was too narrow to determine whether this is a simple calibration problem or some other error. The trigger is positioned so that it is too easy to hit it in error and get an erroneous reading (of the room, table, etc.); then the erroneous reading is recorded with no way to delete or edit and remeasure.

The scale is unsteady, especially on carpet where it is so unsteady that it is unusable. The platform is too small for big feet (less accommodating than corresponding clinical scale platforms). For clinical work, the capacity should exceed the existing 300 pounds (as high as 500 pounds would be helpful).

The EKG (electrocardiogram) was viewed to perform well within the limited scope of use. The nurses liked it, but the clinicians did have complaints about the limited use of the recorded reading. The output cable is positioned to poke patients' faces when the device was used with the dry electrodes (as designed) and positioned on the patient's chest beneath the chin. Adequate contact cannot be made on patients who are petite or barrel-chested.

The operating system (OS) run on the TNS was MS Win 98, and the Doctor's Stations ran MS Win 2000. Overall the operating systems provided good service. There were some instances where ominous error messages appeared warning that data might be lost. These were cases where the OS sensed that Sandia software was being closed externally rather than internally. No data was lost due to OS problems. Win2000 security features worked too well once when administrative passwords were changed during service by ISD, and we were not informed. This was the hectic first day of setup with the Sandia engineers. In order to do simple tasks we had to have the OS reinstalled and set with the passwords that we wanted and had recorded. No data was lost.

The telemedicine application (TM) written by Sandia accomplished the goal of harmonizing the operation and data collection from components that were not designed to work together. Overall the application did control the devices and centrally collected the data. Loss of data was relatively rare and can be attributed to instances where the TM software crashed or froze during a reading. Even so, a number of issues with the TM software were identified, including:
- The user interface reconfigured itself to unwanted formats. Sandia support was needed to return the fonts, graphics, and sound back to the desired settings.
- The TNS laptop could not be used, even for data transfer, without being connected to the complete unit of peripheral clinical measurement hardware.
- Many device control screens were not formatted well (buttons out of view, data off of screen), or gave error messages when activated (grids too small for EKG upload).
- The architecture forced an inherent dependence on the laptop, making the many parts cumbersome to use.
- The proprietary database structure was not practical. It did not use memory efficiently and slowed performance noticeably with each added case.
- Internal system settings allowed the application to run out of storage space. This required a patch and changes to internal settings to fix.

A utility written to allow uploading and downloading of the TNS' database required that the Telemed application be running in order to work, and because this is exactly opposite of the upload of data from the TNS unit to the CSS units, this was an easy step to forget. This led to some problems that would have been avoided if a user prompt had been added to the top of the program to reminds the user of the correct with to use the utility.

During the system's use, an installation of AOL by a home health nurse's 13-year-old son disabled the entire system. The Sandia engineers were able to work around the problem on their first try. Additional data was collected after this, and the system worked fine.

Overall, the prototype telemedicine system developed by the Sandia engineers accomplished what it intended: integration of different clinical data collection tools from various vendors into one system for use in outpatient settings. A number of opportunities to improve the system for the next phase of operation were identified and are described in the conclusions of this report.

3.3.3 System Performance Evaluation in the Clinical Setting

Ochsner employed a cross-sectional survey design study to evaluate a plug-and-play based telemedicine system designed and built by engineers from Sandia. They conducted the study in the established chronic heart failure clinic at Ochsner Clinic Foundation in New Orleans, Louisiana. After patients were seen in the heart failure clinic for their scheduled appointment, their treating physician(s) asked the patients if they would be willing to participate in the telemedicine study. Patients agreeing to participate accompanied the telemedicine study nurses to a near by office. The study nurses provided a description of the project to the patients, and those willing to participate signed a written informed consent document. All patients sent to the study nurses, whether or not they were willing to participate in the telemedicine portion of the project, were given an opportunity to complete the study questionnaires: the short form 36 (SF36 Functional Status Survey), the Kansas City Functional Status Survey, and Demographic and Economic questions. The study was conducted from January 8, 2001 to May 10, 2001.

Of the patients attending the CHF clinic during the study period, 142 patients completed the study questionnaires. One hundred (70.4%) of the patients agreed to participate in the paired visit assessment, which included an in-person visit and a telemedicine visit. Of the 142 patients who completed the surveys, only 42 (29.6%) of the patients did not interact with the telemedicine machine and were classified as non-participants. The demographics of the participant population were as follows: mean age of 58.7 years of age ±14.3 years), 66% male, 72% married, and 56% with a high school education or more. There were no significant differences with regards to these demographic variables between the participants and the non-participants.

Data were entered into a specially designed database program (TeleQuest) running under Windows platform computers (Win 95/98/NT/2000). The TeleQuest program provided separate data entry screens for the questionnaires, in-person clinical data and telemedicine clinical data. In addition, a backup facility to backup all the necessary data to a removable disk was provided. The questionnaires screen had tabs for the pre-survey, functional health status and provider's workload surveys. The in-person clinical data screen included tabs for vital signs measurements, local and general examination, laboratory findings, EKG, diagnoses, clinical orders and co-

morbidities. The telemedicine screen included similar tabs and the capability to import data recorded by the telemedicine system. The program allowed for the calculation of the functional health status scales after entering each patient's responses. A random sample quality check (on 10%) was done after each phase of data entry and prior to analysis.

For the participants, the telemedicine portion of the study always followed the clinical visit. The study nurses asked the participants questions relating to their heart failure disease such as whether or not they had difficulty breathing, how many pillows they slept on, any pedal edema, change in abdominal girth, and increase fatigue. After responding to the questions, participants were then engaged in collection of the clinical data with the telemedicine machine: blood pressure, oxygen in the blood (pulse oximetry), weight, temperature (with ear probe) heart and lung sounds (with the stethoscope), and heart rhythm (with a three lead EKG). Clinical data collected was automatically stored in the telemedicine machine and was later extracted for analysis. The questionnaire information was entered into a specially designed program, which was used to manage the data entry and the processing (TeleQuest). The clinical data captured with the telemedicine system was eventually integrated into the TeleQuest program for analysis.

In assessing the recording of morbidity and comorbidity for both the in-person and the telemedicine visit, the sensitivity, specificity, positive and negative predictive values, were evaluated. Sensitivity was low for the laboratory orders and sensitivity and specificity were relatively low for the return to clinic classification. Possible explanations for this could be poor recording on the part of the participating physicians, inability to properly record due to insufficient information available from the telemedicine equipment, or real differences in recording practices based on the information presented at the two different visits. The workload perceived by the physicians who participated in this portion of the telemedicine project indicated an increased workload associated with the use of the telemedicine system data. The estimated duration of the use of the telemedicine system data was 8.4 minutes. The level of comfort with the telemedicine system data was a mean of 3.5 (range 0.5 to 7.5). General comments from the physicians who participated in this project indicated that additional information could be collected with the telemedicine equipment and that improvements need to be made with regards to the quality of the provided medical devices and associated recordings for the heart and lung sounds.

Detection controlled estimation (DCE) is a powerful new econometric estimator in the family of missing data estimators. By collecting measures from a variety of inspectors or inspection technologies, DCE is able to make inferences about the entire population, even when that population is not directly observed. In the context of technology assessment, this permits DCE to establish a "gold standard" that does not have to assume that existing technology is perfect. Consequently, DCE can ask whether innovative approaches do a better job at assessing conditions than existing technologies. This represents a significant methodological advance for much effectiveness analysis. Using this innovative method, we were able to assess whether telemedicine technology could be substituted for in-person visits when providing maintenance care for patients with chronic heart failure. This helps remove any bias associated in subjectively evaluating a new technology relative to a standard technology or subjectively assuming that a standard technology provides the correct answer.

Overall, using the data collected and assessing the measured differences through the application of DCE indicates that there is no support for the proposition that telemedicine is less effective than in-person visits for determining whether CHF patients require new medication. The results though do indicate that telemedicine visits may be less effective when male patients require new laboratory tests. The results also imply African-American patients were referred for fewer resources (lower quality care) when it came to the need for both new medicines and laboratory tests with in-person visits. This was not the case and for telemedicine applications and the results are suggestive of the possibility that the difference in treatment toward black patients may be ameliorated in a telemedicine setting.

3.3.4 Performance Evaluation of Home Health Application

Home Health professionals provide state of the art medical care at home. This provides the benefits of being at home in a private relaxed environment, while at the same time allowing the medical services needed for recovery. For this study, we asked a Home Health nurse to utilize the Sandia telemedicine system in the routine evaluation of a small group of established Home Health patients.

A convenience sample of twenty-five patients enrolled in Ochsner Home Health who had the diagnosis of chronic heart failure (CHF) or were discharged from the hospital following a myocardial infarction (MI) or other illness with CHF or MI as comorbidities were eligible to participate in this study. The mean age was 73.1 +/- 9.8 years, 80% were Caucasian, and 76% managed care patients.

Training of the Home Health Nurse and assistant began at the end of May 2001 and the first patient in the study was seen on June 14, 2001. The Home Health Nurse confirmed prior consent of participation by calling the patient's physician and by contacting the patient. Written informed consent was obtained from all patients who agreed to participate. Both an in-person and telemedicine visit was conducted on each patient with the order of the telemedicine visit alternated with the in-person visit. The twenty-five patients completed surveys at the beginning of the visit that included the following questions: demographic, economic, and functional status. Satisfaction surveys were completed following the in-person portion and the telemedicine portion of the visit. The Home Health Nurse completed two clinical data forms (one for each visit) and provider satisfaction survey (also for each visit). An assistant collected time motion data on all twenty-five patients during the in-person and telemedicine visits with the following variables: set-up of the machine, blood pressure measurement, weight on a floor scale, temperature by ear probe, blood oxygenation (SpO2) and heart rate by finger probe, heart rhythm and rate by a three lead EKG (electrocardiogram), and breakdown of the machine. The Home Health Nurse conducted collection of the informed consent, administration of the surveys, set-up of the telemedicine machine, the in-person visit, the telemedicine visit, and the closedown of the telemedicine machine. The Home Health Assistant provided support with transport of the telemedicine machine and conducted the time motion portion of the project.

The patient and provider survey data and the data from the patient clinical forms were entered into a specially designed database program called HomeHealth which works on Windows platform computers (Win 95/98/NT/2000). The HomeHealth program provided separate data entry screens for the questionnaires, in-person clinical data and telemedicine clinical data. In

addition, a backup facility to backup all the necessary data to a removable disk was provided. The questionnaires screen had tabs for the pre-survey, functional health status, provider's work load surveys, and patients satisfaction surveys. The in-person clinical data screen included tabs for vital signs measurements, local and general examination, laboratory findings, EKG, diagnoses, clinical orders and comorbidities. The telemedicine screen included similar tabs and the capability to import data recorded by the telemedicine machine. A random sample quality check (on 10%) was done after each phase of data entry and prior to analysis.

The telemedicine reading were on average higher than the in-person for blood pressure and pulse rate, the difference was, however, only statistically significant in the case of blood pressure measures. These measures showed high and significant correlation between the two visit types. The temperature measures were taken orally in the in-person visit versus by ear probe in the telemedicine visit. This prevented any direct statistical comparisons between the two methods.

The telemedicine visit showed on average higher workload compared to the in-person visit. The level of comfort with the telemedicine machine was moderate (mean=4.9 points) and the sense of contribution of the machine data to the clinical assessment was high (84%). The telemedicine machine worked well in the Nurse's view in 58% of cases.

Patient satisfaction ranged from moderate to good in most of the domains measured for both the in-person and the telemedicine visits. The small sample size did not permit any further statistical comparisons due to the low magnitude of differences between the two visits in terms of patient satisfaction. Overall, 76% would consider being cared for by the telemedicine system.

3.3.5 System Cost Effectiveness Evaluation

The standard method for assessing the demand for non-market goods is the contingent value method (CVM). The usual approach for CVM is to present individuals with a description of a good, and then ask if they would be willing to buy it at some set price. This is known as a single-bound dichotomous choice. However, more information can be obtained if one asks follow-up questions about willingness to pay. These methods (when one follow-up is asked) are known as double-bounded dichotomous choice (DBDC) models. We employed this recent methodological innovation to produce estimates of willingness to pay for access to telemedicine services.

The target patient population is CHF patients who attend the CHF clinic for evaluation and treatment. Currently, these patients must travel to the clinic frequently to be assessed. With this equipment, the hope is that they could be assessed in their homes by a visiting nurse, without the need for the (still relatively ill) patients to leave their homes. The question we wish to address in this study is whether patients would be willing to pay any amount out of their own pocket to access health care in this fashion.

A second important point to note is the level of the out-of-pocket prices that can be supported for telemedicine. At a $20 offer price, around 32% of the HTN population would be willing to pay that out of pocket for access to telemedicine. At that same price, over 45% of the CHF population would be willing to pay out of pocket for access to this equipment. This suggests that there is a significant potential to support telemedicine clinics by charging some form of balance

billing for access to telemedicine (rather than having a patient go to a physician's office). While such balance billing is currently prohibited under Medicare, these results suggest that this prohibition should be reconsidered, if there is a public interest in creating a basic infrastructure of telemedicine capacity.

Other results are also of interest. Age has a significant and negative effect, suggesting that the willingness to pay for telemedicine is lower among older patients compared to younger. This might be the result of a greater level of discomfort with technology in general among older people. Women are marginally more likely to be willing to pay for telemedicine out of pocket than men, but only at the 10% level of significance. Travel time is significant with the expected positive sign, suggesting that patient willingness to pay for telemedicine rises with the inconvenience of travel to the physician's office.

Overall, we used the contingent valuation methodology to determine the demand for telemedicine services to patients with hypertension or chronic heart failure. We find that the demand for telemedicine is relatively high, with between 30% and 50% of the overall population willing to pay at least $20 out of pocket for access to telemedicine. Patients with the more debilitating disease, CHF, not surprisingly, have a greater willingness to pay for telemedicine, since the technology allows them to access medical care from their home. These results extend recent studies which indicate that there may be a feasible market for some telemedicine systems that are supported from clinical revenues, when balance billing is permitted.

3.3.6 Evaluation of HomMed Based Telemedicine Technique

HomMed Monitoring System is a commercially available in-home monitoring system with a national network of more than 50 home health agencies, health systems and teaching institutions utilizing this system in their outpatient care programs (www.hommed.com). The HomMed Monitoring System has two components: the HomMed Monitor, which is placed in the patient's home, and the HomMed Central Station, which receives, tracks and trends the collected data. Ochsner Cardiomyopathy & Transplantation Center currently provides this service to those CHF patients covered only by the Ochsner Health Plan or those who choose to pay privately. Authorization for this service is based on a specific list of diagnoses. The qualifying criteria for HomMed are:

- New York Heart Association class III or IV symptoms (except hospice/terminal care patients)
- Have had greater than one Emergency Room or Urgent Care visit for heart failure as the primary diagnosis
- Currently undergoing diuretic or inotropic IV therapy (Home Care)
- Have had one or more hospital admissions for chronic heart failure (primary or secondary diagnosis)

After approval is received from the Health Plan, the physician completes an order form. The HomMed machine assists in the monitoring of congestive heart failure at the patient's convenience by capturing daily weights on a scale, blood pressure with a one piece blood pressure cuff, blood oxygenation with a finger clip-on, and a subjective assessment of dyspnea and fatigue with the patient responding to two questions, "Are you experiencing more difficulty breathing?" and "Are you experiencing more fatigue today?" Fifty-two patients with the

diagnosis of Chronic Heart Failure were available for this study. The mean age was 73 years, 62% males, 60% white, 92% were Managed Care, and 65% were married.

A Research Nurse spent five days in the HomMed Base facility unit (8/16/01, 8/23/01, 9/18/01, 9/19/01, 9/20/01) observing and documenting the HomMed Nurse actions with the HomMed Base computer. The HomMed Monitor prompts the patient daily at a predetermined time selected by the patient to begin taking the measurements. The patient takes his/her weight, blood pressure, SpO2, and answers the questions. Meanwhile, each day the HomMed Nurse at the Base facility unit receives the transmitted vital signs at the assigned time for each patient. If the patient's vital signs fall outside of the set parameters determined by the physician's orders, or if the patient answers 'yes' to either question, the vital signs then fall into an alert/outlier category.

These categories are color coded on the computer screen and include notation of incomplete data and elevated or decreased parameters. The nurse must choose from several options in order to address the outliers. She may choose to notify the patient by phone to verify the problem, or notify the physician (or his nurse) by phone. Another option is to FAX a seven-day trend report to the physician. Lastly, the nurse may opt for no action to be taken and simply continue to monitor the patient. All of the actions the nurse implements are recorded in the HomMed Base computer. The HomMed Nurse follows the patients throughout the working day. In addition to checking patients for outliers, the HomMed Nurse completes administrative duties and recruitment of patients. The HomMed Monitoring System has a field nurse who conducts the set-up of the monitor in the patient home, checks the monitors for problems, conducts maintenance on the monitors, and retrieves unused monitors. When the HomMed Nurse finds a problem with a monitor she contacts the HomMed Field Nurse to go to the patient's home to solve the monitor or, connection problem.

A flow sheet indicating the date, time spent in the HomMed Base facility, as well as, the number and type of patient outliers, and actions taken by the nurse was utilized during observation in the base facility. Medical Record review was undertaken to record the 52 HomMed patients' healthcare utilization two weeks after the observation in the HomMed Base facility. Outcomes were tracked from 8/16/01 to 10/04/01. All clinic visits, inpatient and outpatient hospital stays, and ER visits were reviewed.

This is a descriptive study conducted over 5 days of observation. 30 of the 52 HomMed observational study patients were found to have telemedicine readings outside acceptable limits. These patients consumed more health care resources (Emergency room visit, laboratory tests, and clinic visits) than patients whose parameters remained within acceptable ranges. The telemedicine care of patients with chronic heart failure identified important abnormalities (as defined by the responsible clinicians) in 30/52 patients over 5 days of observation. Thus, the potential for telemedicine to make significant impact in the care of these patients with chronic disease appears to be real.

3.3.7 Summary of Clinical Evaluation of System Performance and Cost

Based on the clinical and home health evaluations of the Sandia developed plug-and-play, telemedicine architecture, several conclusions regarding the potential cost-effectiveness and

overall performance relative to standard clinical in-person or home health visits were reached. These include:

- Participants and non-participants in this study of telemedicine in chronic heart failure were shown to possess similar demographic attributes. Thus, conclusions based on the results of the study are unlikely to be affected by information bias (i.e. missing data). This is an important point since the possibility that study participants drop out of studies based on their attitudes towards the technology or based on other factors is an important consideration, which must be taken into account when technology is being assessed.
- Automated blood pressure recordings by the telemedicine unit were consistently higher than in-person readings. This phenomenon was also noted in Phase II of the current project dealing with the telemedicine care of hypertensive patients.
- The telemedicine equipment tested was associated with less than optimal performance/utility of its peripherals.
- Auscultation was found to be particularly difficult given the stethoscope available. Although the pulse oximeter appeared to function well, the results were of limited value in the clinical care of the chronic heart failure study patients according to the participating physicians. This did not result from a failure of the equipment, but rather from a lack of relevance of the generated data in the eyes of study physicians. Thus, auscultation was unacceptable for technical reasons and this modality must be improved if this system is to be useful clinically.
- Pulse oximetry was of less than significant value for clinical reasons. That is, as was the case in the previous study of hypertensive patients, much of the diagnostic and therapeutic activities directed towards the care of patient suffering from chronic heart failure of moderate severity is based on history, visualization of the patient, and simple tests such as weight measurement. Other modalities such as pulse oximetry are confirmatory. Thus, depending on the medical condition being treated, condition-specific peripherals must function optimally, whereas others need not, and probably only need be used in the case of extreme abnormalities or emergencies.
- However, based on the present studies of hypertensive and chronic heart failure patients and the opinions of the participating physicians, it appears that the ability to visualize the patient with good resolution, to clearly communicate with the patient, and to have real time access to patient historical and laboratory data are the most uniformly important factors in the care of medical conditions.
- The sensitivity, specificity and other defining perimeters of the telemedicine encounter compared to an in-person encounter were lower than expected concordance (based on the Phase II study of hypertensive patients) of some outcomes between the telemedicine and in-person visits (i.e., the surrogate outcomes test ordering and the ordering of return clinic appointments). This could be due to a failure of the technology leading to inaccurate assessment of a patient's condition or to a tendency on the part of study physicians to be less complete when using the telemedicine equipment because of an assumption that the in-person visit would be the final determinant of patient care. It is possible that the level of ordering concordance, which was in fact lower than that seen in the case of hypertension care, was due to frustration with the equipment on the part of the physicians leading to incomplete ordering patterns. Alternatively, the more complex nature of chronic heart failure as compared to hypertension could have revealed previously unappreciated operating characteristics/deficiencies of the telemedicine system.

- Finally the telemedicine system was studied in a store-and-forward mode as opposed to the interactment mode used in the hypertension component (Phase II) of this study. Given the importance of patient history on the follow-up of chronic heart failure patients (per study physicians), the absence of real time patient-physician interaction places telemedicine at a disadvantage when compared to in-person care.
- The Home Health nurses found the prototype unit to be unwieldy in many respects. It was bulky and heavy, making it difficult to transport and use. Clearly this is an artifact of the prototype, but it could have in fact lead to less than optimal results. Thus, the results of the study must be considered a minimum baseline regarding the capabilities of this technology. Blood pressure as determined by telemedicine was again found to be higher than in-person readings. Health care provider reported in 84% of visits that the availability of the telemedicine system contributed to therapy and in 58.3% of visits reported that the unit functioned well. Patient satisfaction with the telemedicine encounter was good (patients agreed with "satisfied with medical care" with a score of 1.96, 1.0 implying strongly agree, 5.0 implying strongly disagree).
- Time motion studies were conducted for the chronic heart failure study and the Home Health Study. Time consumed for individual tasks were in general greater for the Home Health visits than the clinic telemedicine visits, consistent with the uncontrolled field environment in which home health visits were conducted. The large size and weight of the unit also probably contributed to this result.
- A listing of issues related to the function of the telemedicine unit was compiled for use in directing future system development. None of these involved the novel systems architecture developed by Sandia National Laboratories. In general issues center on the size/weight of the prototype and the functioning of peripherals.
- Economic analysis revealed that approximately half the population (48.8%) would be willing to pay $20 and 23.3% would be willing to pay $40 over the cost of an in-person office visit (double-bounded dichotomous choice methodology). These figures are higher than the amount hypertensive patients were found to be willing to pay (Phase II of the project). This likely results from the fact that the chronic heart failure patients are more symptomatic and feel themselves to be sicker than those with hypertension. Therefore, medical care is likely of more value to them and concomitantly telemedicine is of more value to them. The $40 figure implies that the telemedicine care of chronic heart failure patients could be close to being economically feasible in the open market based on Phase II cost results.
- Detection controlled estimation (DCE) was employed in the evaluation of telemedicine. DCE showed that telemedicine care is comparable to in-person care except in the case of the ordering of new tests. DCE analysis also raised the possibility that African American patients were referred for fewer resources in-person settings. This conclusion must be confirmed in larger studies and, if confirmed, the reasons for this finding, and the possibility that telemedicine could offset this effect, explored.
- The results indicate that more work need be done in the following areas before telemedicine can be optimally applied to the care of chronic heart failure patients:
  - Improved quality stethoscopes to provide better auscultatory support for patient care;
  - The telemedicine device must be made more compact and lighter;
  - Improved online access to patient records in real time is required;

- Real time interactivity is important to physicians in the care of chronic heart failure patients and is an important tool in rapidly assessing a patient's status and in determining future care. While store and forward modalities such as HomMed can help alert physicians to changes in patient status, any effort to use telemedicine in place of the clinic visit will likely require real time interactivity.

In summary, the telemedicine system functioned well in a technical sense. It was reliable, and all components functioned according to specification. Thus, the utility and practicality of the novel computer and systems architecture developed by Sandia for this project has been validated. Moreover, measurements of vital signs (blood pressure and pulse) were well correlated between telemedicine and in-person visits. However, agreement between outcome measurements (orders for tests, return visits) was not as high as seen in the hypertension portion of this project (Phase II). The reasons for this cannot be traced to the computer architecture or to the hardware, but rather to the requirement for better auscultatory capability and the other potential contributing factors considered above. Clearly, improved auscultatory capability is demanded by the nature of the care required by chronic heart failure patients. Limited EKG (electrocardiogram) capability also was noted. These deficiencies are properly ascribed to the level of function of currently available peripherals and the need for appropriate auscultatory and other support demanded by this patient population. This in no way reflects on the telemedicine unit *per se.*

Further, units targeted to specific indications likely can be developed at lower costs and yet serve patients adequately. Thus, for example, in the care of hypertensive patients, high quality auscultatory devices are not required as shown in Phase II of the study. Reasonable quality stethoscopes will suffice for most indications, whereas accurate blood pressure measurements are important for outcomes. In the case of chronic heart failure, auscultatory devices become more important. In other conditions, other peripherals potentially become critical determinants of outcome. For example, in dermatology visualization of the skin is obviously of paramount importance. Pulse oximetry could assume much greater importance in the care of asthmatic or chronic obstructive pulmonary disease patients than in the current study.

Thus, although a slate of basic peripherals will be required for the care of any chronic patient suffering from a medical disease, in some instances more attention must be paid to the performance of specific peripherals based on the specific needs of the condition being treated. This kind of analysis could lead to cost savings by targeting units for specific purposes and thereby reducing the cost. It may well be that the one-size-fits-all telemedicine unit is not the most efficient way to introduce the technology. This is clearly seen in the case of the HomMed device, which while not rich in peripherals or imaging equipment, does appear to detect clinically meaningful events in the population for which it is designed.

3.4 Advancing the Vision

Sandia's long-term goal was to deliver three sets of products out of this effort. The first product was a collection of telemedicine devices that demonstrated the secure, distributed, plug-and-play concepts described in the TRA. These devices were to be the product of the three "builds" described above.

The second product of this engineering effort was to be a set of interoperability specifications that document the interfaces between the Backplane and each of the other six service areas. While not addressed within the scope of this effort, a follow-on effort funded by TATRC has delivered an architectural framework that extends the concepts developed in the TRA work and addresses a number of features that were to have been explored in Phases II and III of the TRA effort. This framework is documented in "Telemedicine System Interoperability Architecture: Concept Description and Architecture Overview" (see http://telemedicine.sandia.gov or the Sandia National Labs SAND report archive at http://www.sandia.gov).

The final product of this effort was to be a technology roadmap that identifies barriers to telemedicine's success and suggests work that can be done to remove these barriers. A number of the key issues to be address in this roadmap are addressed in the next chapter of this paper.

3.4.1 Socializing the Concept

Over the course of the last two phases of the project Sandia sought opportunities to share its work with others. Among other things, this activity included presenting at conferences and workshops and meeting with individual companies and organizations.

3.4.1.1 Conferences and Workshops

Home Care Technologies Workshop (March 1999, Washington, D.C.) – This meeting, organized by Catholic University of America and funded by NSF, focused on establishing an agenda that NSF could pursue in the area of telemedicine-based care. Sandia prepared a position paper for this meeting and participated in the home care and advance devices breakout sessions of this workshop.

Friends of the National Library of Medicine 1999 (Washington, D.C.) – This meeting was the Telemedicine Reference Architecture's first public exposure. It addressed the architecture as a context for work in telemedicine security. It was favorable comments at this meeting that first helped Sandia understand the possible external interest in the issue of interoperable telemedicine systems.

The Electronic Patient Record Conference (TEPR) 1999 (Orlando) – At this meeting, Sandia gave two presentations – one on the architecture and one on security issues in the architecture. We were the last two presentations in our track before lunch and, maybe because we didn't really fit in our track, the session attendance had dwindled to less than 10 people before we even began to talk.

Spring 1999 IEEE 1073 Meeting (Toronto) – This was a normal IEEE 1073 working group meeting held in conjunction with HL7. Sandia took part in discussions and had an opportunity on the last day of the meeting to introduce the work that it was doing in the reference architecture and to note the intent to engage this group as the TRA effort matured.

ATA 1999 (Salt Lake City) – This is the first time that Sandia presented its concepts to the telemedicine community. The content of the talk focused on the "honeycomb architecture", an approach for encapsulating current devices behind standardized wrappers, and initial thoughts on security for plug-and-play interoperability.

IEEE BMES-EMBS Conference 1999 (Atlanta) – As his last activity before transitioning to Kansas State, Steve Warren presented the TRA work to the IEEE biomedical community.

Distributed Medical Intelligence 2000 (Steamboat Springs) – Traditionally, this is the meeting for the "out of the box" types in the telemedicine community. Sandia presented its progress on the TRA at this meeting and received a generally positive reception.

ATA 2000 (Phoenix) – Sandia had an entire session of the program dedicated to its plug-and-play architecture. In this standing room only session, SNL discussed the motivation for this work and the design of its system. Sandia also demonstrated the system's operation. In the same meeting, Rick Craft, serving as co-chair of the ATA's Technology Special Interest Group, led a session on the future of technology and its implications for telemedicine. Everything flowered at this meeting with SNL's concepts generating a lot of interest.

3.4.1.2 Companies and Other Organizations

NASA Johnson Space Center – Following the Friends of the NLM briefing, Sandia was invited to come share our work at NASA JSC. The meeting, hosted by Scott Simmons from Wyle Labs, included members of Wyle's staff as well as regular NASA employees. The work was well received by this group.

Wyle Labs – Three months later, Sandia was invited back to a review of NASA JSC's plans for work the telemedicine arena. Rick Craft represented Sandia in this meeting. Other reviewers include Ron Poropatich (TATRC), Cori Lathan (CUA), and Jack Smith and Kim Dunn (UT Houston).

Rio Grande Medical Technologies – RGMT is an Albuquerque-based manufacturer of non-invasive blood chemistry monitoring devices. Sandia was invited by RGMT to talk about what was happening in the telemedicine world and used this as an opportunity to talk about the architecture and its implications for next-generation medical devices.

Joint Working Group on Telemedicine – Sandia presented its TRA work to the JWGT along with its views on where the telemedicine industry needs to be heading next in terms of technological issues. Key groups represented in the audience included OAT, FDA, NIST, and CTL.

USRA Workshop – In 1999, NASA was trying to establish a roadmap for telemedicine research that spanned all of its facilities. Sandia was invited to participate in this meeting and helped shape the recommendations that were forwarded to NASA HQ.

DoD/NASA Summit – In December 1999, NASA and TATRC met to discuss formal collaboration in the area of telemedicine. Sandia attended this meeting in support of TATRC.

NLM/NCI – In July 2000, Sandia met with representatives of the National Library of Medicine and with representatives at the National Cancer Institute and shared the work that had been done in the TRA effort and where the Labs hoped to take the effort in the future.

Stanford – Early in 2000, Sandia was invited to take part in a TATRC meeting with Stanford's medical informatics group. As his first introduction to this part of the healthcare community, Rudy Garcia, Sandia's representative, found this to be something of a baptism by fire.

US Geological Survey – During a visit to Sandia, a team from the USGS working on water issues in China was briefed on the TRA work.

Vector Research – At the urging of TATRC, Sandia met with staff from Vector Research to discuss their work in healthcare complex modeling. These meetings led to the development of the Care Delivery Architect concept discussed in the Conclusions section of this report.

4 Conclusions

4.1 Overview of Results of Clinical Research

The purpose of the remote patient care demonstration task was to illustrate how plug-and-play diagnostic devices, advanced information systems, and remote patient care can benefit health care costs for both the US and the DoD. The system was used on about 150 chronic heart failure patients in a store-and-forward application by Ochsner. The results of the clinical trials with the Sandia provided system were summarized by Ochsner (Ochsner, December 2001). Overall, the system architecture and medical device integration worked relatively well. Issues were identified regarding the unsatisfactory performance of a few of the individual medical devices. Also, the weight and bulkiness of the system made it difficult for the clinical staff to use. These matters must be addressed to improve overall patient and home health care provider acceptance. Even with these limitations, over 78% of the patients identified that they would consider being cared for by a telemedicine system. Therefore, the overall utility and cost-effectiveness of the plug-and-play architecture concept were validated by the Phase III clinical trials.

The results of the Phase II and III activities for this project indicate that the use of telemedicine technology is being accepted by patients and can provide quality diagnoses and health care for a wide range of medical conditions. As the medical device technology and communications capabilities continue to expand, the cost-effectiveness and reliability of telemedicine will continue to improve. The clinical trials showed that low-cost, plug-and-play, based telemedicine systems can provide the flexibility needed to improve the cost and utilization of telemedicine medical devices in many settings. Our efforts showed that improvements in telemedicine related technologies such as medical devices, communications, patient record standardization, and patient record security, may be able to significantly reduce future health care costs and enable the expansion of high quality health care to much wider and more diverse segments of the population.

4.2 Overview of Results of Engineering Research and Development

The chief focus of the engineering activities in this effort was on exploring what is required to develop a secure, distributed, plug-and-play architecture for use in the design of the next generation of telemedicine systems. To this end, Sandia formulated and socialized the Telemedicine Reference Architecture concept and identified a number of the issues that would need to be addressed in order to ensure safe and secure operation of systems built using this approach. The issues addressed by this work are central to the resolution of a number of the needs identified in the clinical portion of this effort.

A prototype system that focused on the infrastructure aspects of this architecture as well as an approach for achieving plug-and-play operation of the medical devices hooked to the system was developed and evaluated. Plans for a second "build" which would develop the communications capabilities needed for station-to-station interactions and a third build which would address distributed, federated operation of station components were laid but anticipated funding needed to execute these builds was not forthcoming.

Even so, the fundamental issues explored in this Build 1 effort yielded a number of critical lessons. These lessons and the architectural approach used in the design of the prototype system were the springboard into follow-on work funded by TATRC that proposed an architectural approach for addressing the issues belonging to all three of the proposed TRA builds.

4.3 Future Directions

Telemedicine's promise is the ability to provide healthcare to anyone at anytime wherever that person may be and in a way that uses the appropriate resources for the task at hand. To date, the lion's share of research in the field has focused on the clinical dimensions of telemedicine, with most of this work addressing the clinical efficacy and financial viability of delivering care "over the wire". In addition, much of the technical work that has been done has focused on the person-to-person and data communication aspects of telemedicine system design and on the integration of various off-the-shelf components into turnkey telemedicine stations. In order to realize telemedicine's full potential, there is much that remains to be done technically. Among other things, this includes the establishment of community-accepted interoperability standards, the creation of a broad range of "medical peripherals" designed for wide deployment, the development of methods for diffusing clinical expertise, and a wholesale rethinking of healthcare delivery structures in light of what will be made possible by coming changes in computing and communications.

4.3.1 Research and Development Needs

As this report has described, achieving interoperability is fundamental to securing telemedicine's role in the future of healthcare. Because it allows end users to assemble their own systems, interoperability drives the engineering integration costs out of telemedicine systems. Because it defines standardized interfaces and plug-and-play mechanisms, interoperability allows end users to customize stations to meet their own unique operational needs. Because it defines how different components within a telemedicine station are to interact with each other, it promotes entry of vendors into the market (thereby promoting development of a broader base of hardware and software components) because it is now possible to compete in component niches rather than having to deliver entire turnkey systems.

As valuable as this is, interoperability alone is not sufficient to realize telemedicine's potential. Today, the range of components available for use in telemedicine-based care delivery is relatively limited. To achieve the vision of anywhere, anytime deliver of care, a new generation of devices suited for use in non-traditional care delivery settings is required. Just as the new lunch-boxed sized ultrasound systems now allow this capability to be carried to the patient rather than having the patient come to the ultrasound, a rich suite of devices that are smaller, cheaper, more rugged, easier to use, and compliant with the agreed upon interoperability specifications will be foundational to the creation of new care delivery structures.

Just as new devices are needed to support the delivery of care in non-traditional settings, mechanisms that allow for the effective diffusion of clinical knowledge are also required. Without this, telemedicine is just as ineffectual as if it lacked the devices needed to deliver care remotely. It should be noted that this clinical knowledge takes two forms: that knowledge which relates to the clinical state of an individual (physiology, anatomy, etc.) and that which relates to

the operation of clinical devices used in the diagnosis and treatment of individuals. Just as training EMT's in a limited suite of diagnostic and therapeutic procedures resulted in lives saved through the delivery of care in locations other than the hospital, figuring out how to further distribute clinical expertise will result in other gains. Some of those things done today by specialists might be done tomorrow by primary care doctors; those things done by primary care doctors might be done by their nurses; and those things done by nurses might be done by patients themselves.

Finally (and, maybe, most importantly), the telemedicine community should be actively involved in examining how care delivery is done today and how it might be done tomorrow. At its heart, telemedicine is really about the reengineering of care delivery structures. By changing where care is delivered and by whom, telemedicine practitioners have been able to demonstrate improvements in care delivery that would not have been possible with traditional approaches to care. Even so, the telemedicine community may be suffering from an incrementalist mentality that limits its ability to see what could be.

As illustrated in Figure 12, change can proceed in either of two directions and, to some degree, it is occurring in both today. In the first direction, existing structures are rearranged with little or no introduction of new technology. When viewed simplistically, this is part of what outcomes-based medicine is all about – figuring out which of the things we do today works best and how to do those things we do today better. In the second direction, existing processes are automated – paper records are replaced with digital records, face-to-face communications with electronic, etc. Again, being overly simplistic, this is the goal of many of the technology-driven activities in areas such as informatics. While both thrusts are beneficial in isolation, combined they have the
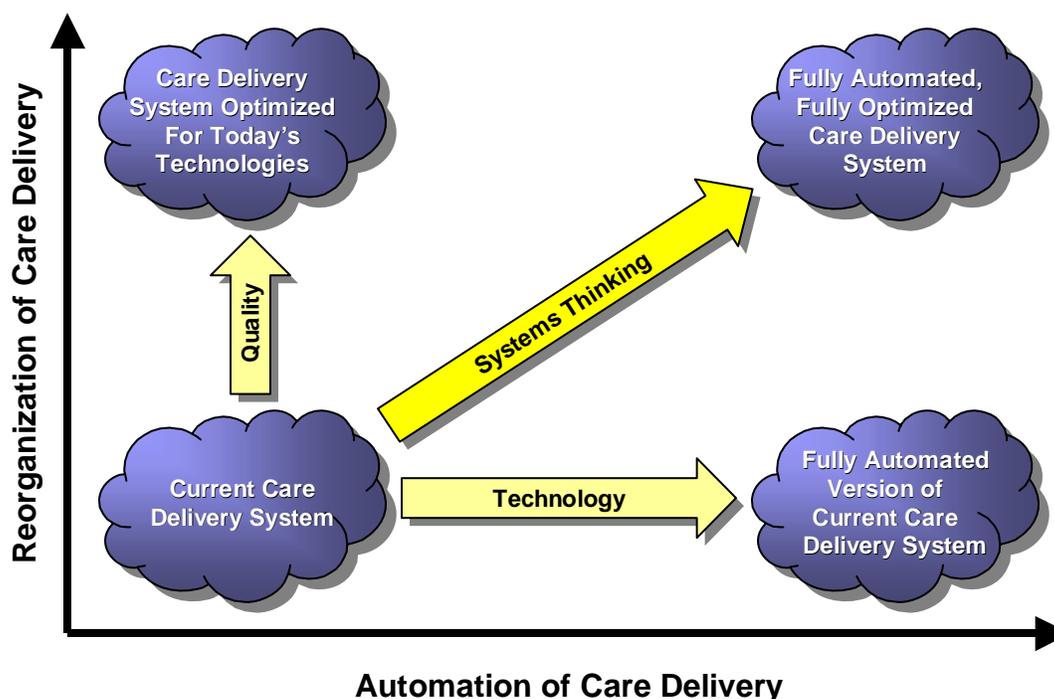

Figure 12. Reengineering Care Delivery

potential to revolutionize healthcare; however, unleashing this potential will require that the healthcare community step back for a moment and systematically question each and every aspect of healthcare delivery. "Why do we do this thing in this way and with these resources?" "How could this be done differently and what would it take for this to be so?" "What will emerging technologies allows us to do tomorrow that we cannot do today?" "What benefits would we realize from these alternative approaches?" Although it is clear that much effort has been expended on the first two thrusts, it is not clear that any significant amount of work has been poured into the third.

4.3.2 Four Projects

To address these four needs, four projects are suggested, one of which is already underway. These are:

- The Telemedicine System Interoperability Architecture
- The Observable Human
- Primary Care 2010
- The Care Delivery Architect

4.3.2.1 The Telemedicine Reference Architecture

Telemedicine Interoperability Alliance

The Telemedicine System Interoperability Architecture Project, a follow-on effort to the work described in this report, seeks to move both the commercial and NATO telemedicine communities toward an agreed upon set of interoperability specifications for the design of interoperable telemedicine stations. Based on the concepts developed in the original interoperability work done by Sandia, this effort is producing a strawman interoperability architecture that addresses all of the issues covered by the original work plus work that was to be addressed by "Build 2" and "Build 3" of this R&D effort. Once complete, this strawman will be circulated in both of the communities identified, the goal being to foster debate about which approach should be taken to achieving interoperability and, hopefully, developing a constituency (the "Telemedicine Interoperability Alliance") for an agreed-upon approach.

As currently envisioned, the TSIA proposes three sets of interfaces that can be implemented completely, in part, or not at all, as the needs of each vendor dictate. The first set of interfaces addresses the way in which stations interact with one another. Capabilities covered in this set of interfaces include the ability to locate a given station or stations of a given type, the ability to explore the services that a remote station offers, the ability for two or more stations to negotiate how they are going to operate together (e.g., whether a session will be encrypted, what protocols will be used, etc.), the ability for stations to lease and make use of each other's resources, and the ability for stations to dynamically locate, retrieve, and install software needed to support station operations. The second set of interfaces addresses the mechanisms used to allow peripheral devices (e.g., PDAs, medical devices, patient record cards) to be added to and removed from a telemedicine station in plug-and-play fashion. The third set of interfaces addresses how stations might be composed from distributed components and exists to address the not too distant future in which telemedicine systems might be based on existing computing infrastructure (e.g., home

networks and digital televisions), "medical peripherals", application software that glues it all together.

In moving forward with this effort, significant traction could be gained through a simple demonstration of a subset of the capabilities addressed by the station-to-station interfaces. In particular, by focusing on the device discovery interfaces for stations from several manufacturers and, ideally, working with the device interoperability community, we could demonstrate the ability for independently developed stations to explore each other's capabilities and to remotely monitor and control a limited set of each other's devices. While admittedly short of the goal, it would still be a significant first step.

4.3.2.2 The Observable Human
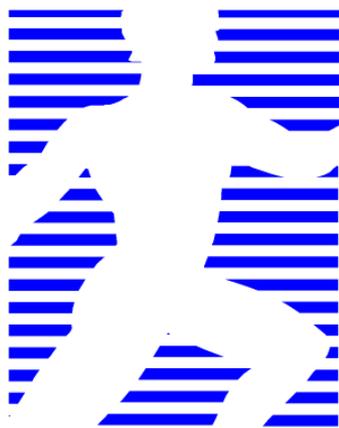
It is one thing to say that a new suite of devices suitable to the telemedicine environment is required; it is another thing altogether to identify what those devices should be. For example, while a glucometer-style, home-based blood chemistry analyzer might be of use, a do-it-yourself home appendectomy kit probably wouldn't be. Also, even though reengineering a given clinical device so that it can be used in non-traditional care delivery settings might be desirable, it may not be possible from a technical perspective. Given this, what is needed is some way of identifying those things that are both clinically important and amenable to reengineering (Figure 13). Note that, while the discussion here focuses on devices, the principle being articulated could be extended to include software-based capabilities (e.g., making an appointment, or taking a comprehensive history).

	Easier To Reengineer	More Difficult To Reengineer
Higher Clinical Value	• Target this group in the first "wave" • Encourage private sector R&D	• Target this group in the second "wave" • Encourage pure government R&D or private sector development based on government-funded research
Lower Clinical Value	• Target this group in the second "wave" • Encourage private sector R&D or private sector development based on joint funding from industry and government	• Wait for conditions to change clinically or technologically before addressing this group

Figure 13. Prioritizing Telemedicine Technology R&D Investments

To this end, a three-part project should be initiated with the ultimate goals of developing a "wish list" that identifies those capabilities falling in the shaded quadrant and of encouraging their development. The first phase of the project of this project would draw on medical and technology experts to define a framework to be used in assessing both the clinical value (e.g., in terms of dollars spent on the procedure or total volume of the procedure) and clinical viability of distributing a given capability and the technical feasibility of reengineering a given device in ways that make it smaller, cheaper, more rugged, and easier to use or of casting a manually-implemented capability as one that is suitable for telemedicine-style automation. A key element in this effort would be the establishment of ranking mechanisms in both the clinical and engineering dimensions that promoted consistency across many independent reviewers. This framework would then be captured as a web site that allowed a user to identify a clinical capability and the mechanisms used to deliver the capability and that would lead the user through the process of assessing the capability and supporting devices per the established framework.

In the second phase of the project, the web site would be opened up to a larger body of experts (potentially universities and similar medical and engineering organizations) for population of the capabilities/devices database. Work done in this way might be allocated by clinical specialty, disease state, etc. into different workgroups. Periodic reviews by expert panels would be used to review the growth of the database and to encourage "normalization" of findings across different workgroups.

The final phase of the project would focus on disseminating the results of this study – especially a ranked list of top candidates – and on promoting the development of these new capabilities. Depending on the nature of the capabilities being discussed, this may be through purely private mechanisms (e.g., encouraged through demonstrated market potential), purely government means (e.g., as was done by DARPA in the funding of a portable ultrasound capability), or some combination of the two (as is done in NIST's ATP programs).

As an interim step to start meeting the need addressed by this project, an effort lead by a group like the American Telemedicine Association to establish a "Top 25" list of devices that they would like to see added to the telemedicine instrumentation portfolio would be tremendously useful.

4.3.2.3 Primary Care 2010

As a test bed for the feasibility of disseminating clinical knowledge, a project focused on the primary care setting of tomorrow should be initiated. More than just a "thought piece", this effort should identify and clinically evaluate, for a range of acute and chronic conditions, various approaches to moving knowledge and responsibility to new places in the care delivery process. This should include means of delivering (in just-in-time fashion) to primary caregivers knowledge and capabilities that would normally reside with specialists. It should address the question of what knowledge and functions

normally assigned to the doctor in primary care settings might be assigned to other staff in the office. Finally, it should also consider which knowledge elements normally possessed only by the professional caregivers could be placed in the hands of patients or lay caregivers.

More than simply examining what knowledge and capabilities could be reallocated, this project would examine methods for allowing this reallocation to take place. As such, it would look to educational researchers to help lay a theoretical framework for identifying how particular individuals learn, for delivering customized training to these individuals, and for assessing the efficacy of this training. Ideally, the effort would also produce technical building blocks that could be incorporated into other systems to support the theory developed in the course of this effort.

4.3.2.4 The Care Delivery Architect
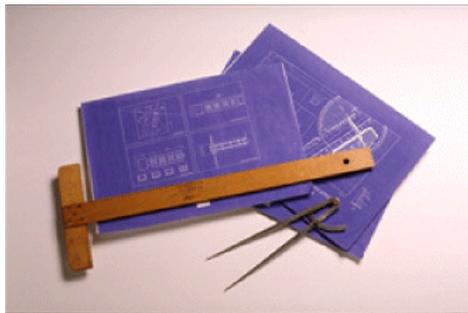
In engineering, computer-aided design tools that automate many of the engineer's tasks are commonplace. These tools give the engineer the ability to capture his designs in electronic form, provide the engineer with best practice knowledge and libraries of standard solutions, and allow the engineer to analyze his designs for compliance with various objectives and constraints. In recent years, "intelligent agents" added to some of these tools have given humans the ability to think through many more design options than would be have been possible in past times.

In examining how care delivery is done today and how it might be done tomorrow, one approach that the telemedicine community might pursue is the development of a suite of Internet-based modeling and analysis tools similar in philosophy to the computer-aided system engineering (CASE) tools used by engineers. This public suite of tools would allow people from around the healthcare community to explore novel care delivery system design concepts using models of actual and yet to be designed system components (e.g., devices, people, facilities, computing and communications infrastructure). Through the use of simulation and analytic tools, users of the CASE environment could evaluate the performance of their system designs, as well as extract a range of additional facts about these systems. With the help of software agents that deliver genetic programming and related techniques, users could work with the tool suite to automatically discover improved variations on their original design concepts. Using these same capabilities and an "editor" for describing healthcare policy that is to govern a system being evaluated, users could watch entities within the healthcare system try to adapt in response to changes in policy and thereby evaluate how a proposed policy might impact various elements in a care delivery system, as well as identify "winning" strategies in any given environment. Finally, at a much lower level, this "self-programming" approach to design would allow for the automatic generation of conceptual design of novel telemedicine system components and for evaluation of the impact that the availability of these components would have on the performance of a care delivery system.

One concept for delivering such a tool suite would be to build on the Healthcare Complex Model (HCM) that TATRC funded Vector Research to implement. The strength of this modeling and simulation system is its ability to analyze the behavior of a given healthcare delivery system
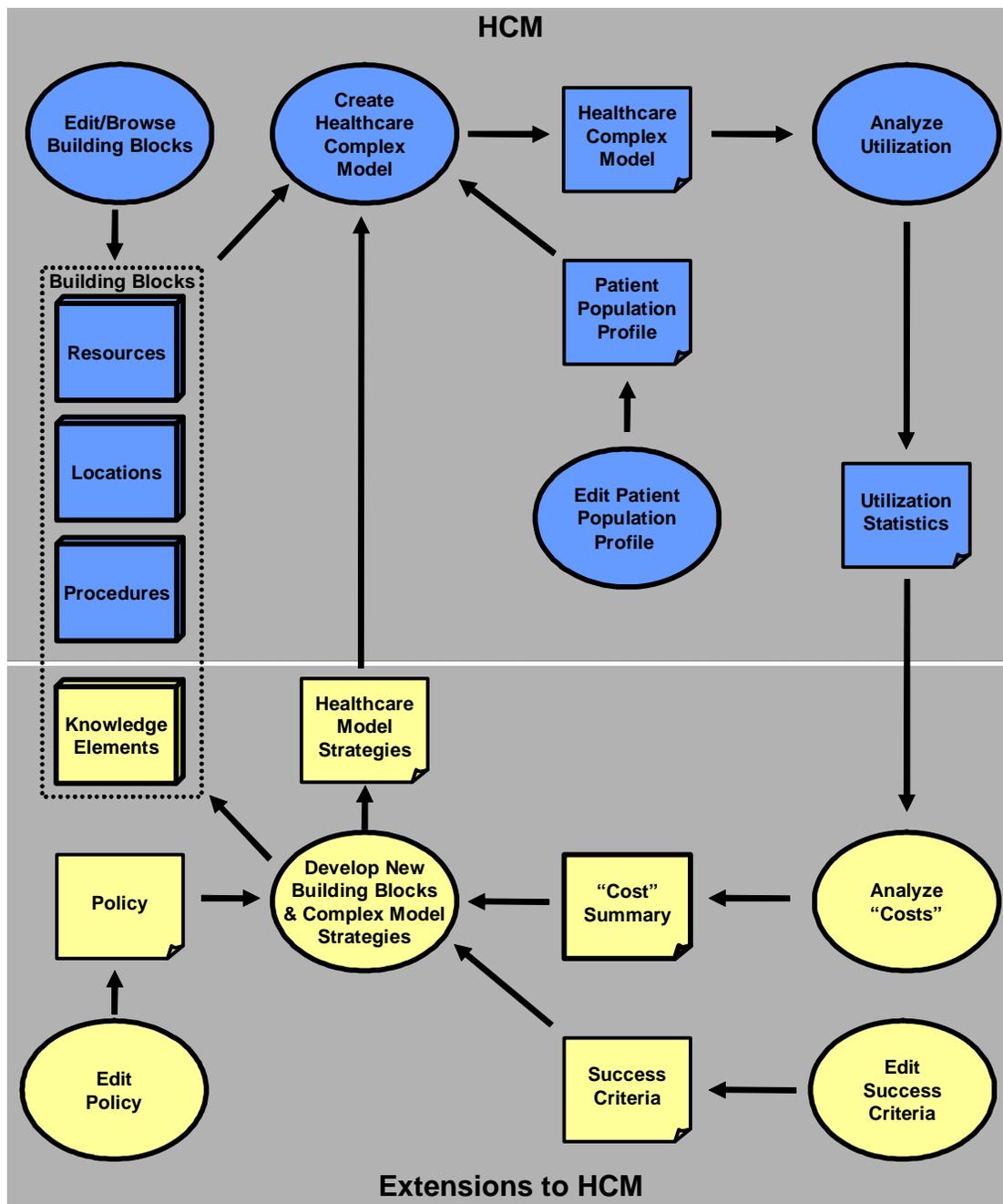
Figure 14. Extending the HCM to Identify Telemedicine Opportunities

design. Using the approach shown in the following figure, this tool can be extended to support the kinds of capabilities described above. By enabling automatic assessment of the "fitness" of a given model relative to success criteria established by the user and automatic generation and analysis of new models, the HCM tool enables a user to examine many more system designs than are possible with the current manual approach provided by HCM.

As different users employ these Web-based tools, the toolkit could provide them with the opportunity to publish their system and component designs to public portions of the web site for others to review or to use as starting points in their own designs

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