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13. ABSTRACT *(Maximum 200 words)* The expansion applications of telemedicine are being effectively employed in numerous disciplines from acute care to care of the chronically ill. Critical technological, security and clinical issues must be addressed according to each application's requirements. A pilot study has been underway to examine the impact of home telemedicine for insulin-dependant diabetic patients. Our initial results are very positive, and we plan to increase the number of patients on-line to approximately 30. Needs assessments for telemedicine is an essential incipient step, and such a methodology has been applied to the telemedicine project for the State Department and a hospice center. We continue to lead the teleradiology applications for deployed environments. Security, a serious concern in the transfer of any electronic data, is being addressed through technological and organizational approaches. Simulation of medical procedures will have a profound impact in the future, especially if controlled remotely. We have initiated prostate biopsy, spine surgery and palpation simulation capabilities that can be remotely controlled for eventual applications of invasive telemedicine. The following manuscripts provide in depth accounts of our progress in telemedicine in 1998.

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Executive Summary

The expansive applications of telemedicine are being effectively employed in numerous disciplines from acute care to care of the chronically ill. Critical technological, security, and clinical issues must be addressed according to each application's requirements. A pilot study has been underway to examine the impact of home telemedicine for insulin-dependant diabetic patients. Our initial results are very positive, and we plan to increase the number of patients on-line to approximately 30. For acute care we have established peri-operative management of neurosurgical patients between Washington, DC and New York City. Our application of telemedicine to renal dialysis patients has been making excellent progress. One key technology for telemedicine is the multimedia database, a schema for which has been developed. Needs assessment for telemedicine is an essential incipient step, and such a methodology has been applied to the telemedicine project for the State Department and a hospice center. As it appears that more telemedicine applications will depend on the use of web technology, we have developed web-based telemedicine software. We continue to lead the teleradiology applications for deployed environments. Security, a serious concern in the transfer of any electronic data, is being addressed through technological and organizational approaches. Simulation of medical procedures will have a profound impact in the future, especially if controlled remotely. We have initiated prostate biopsy, spine surgery and palpation simulation capabilities that can be remotely controlled for eventual applications of invasive telemedicine. The following manuscripts provide in depth accounts of our progress in telemedicine in 1998.

Diabetes Home Monitoring Project

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Abstract

Objective: To study the feasibility of remotely monitoring people with diabetes using low-cost technology.
Methods: Using a personal computer, randomly chosen people with type I diabetes transmit their diabetes related data to their physician at Georgetown University Medical Center on a weekly basis where he analyzes it and contacts the patient every week to make safe adjustments to diet, exercise plan and insulin dose to prevent different kinds of diseases.
Findings: Based on the data received the physician at the Endocrinology Department was able to early correct blood glucose levels for many patients enrolled in the program and prevent many possible clinical complications.
Conclusion: This preliminary study indicates that tight monitoring people with diabetes and frequent patient-physician communication and feed-back utilizing a low-cost technology can significantly lower the risk of getting diseases and avoid costly short and long term hospitalizations and ER visits thus increase the quality of life and life expectancy.

Introduction

Successful management of diabetes depends on maintaining blood glucose values within acceptable ranges. The Diabetes Home Monitoring Project enables the patient to better understand the disease and the physician, such as conducted in the Endocrinology Department at Georgetown University Medical Center, to follow his/her patients' blood glucose level variation on a weekly basis to determine the patient's health conditions and changes over time. This study to remotely monitor patients who were previously diagnosed with type I diabetes using an electronic device to gather blood glucose levels and transmit them electronically to their physician in the Endocrinology Department of GUMC.
Each patient is supplied with a One touch Profile glucose meter by Johnson and Johnson and an IBM compatible personal computer with "in Touch" Diabetes Management Software by Lifescan Johnson and Johnson.

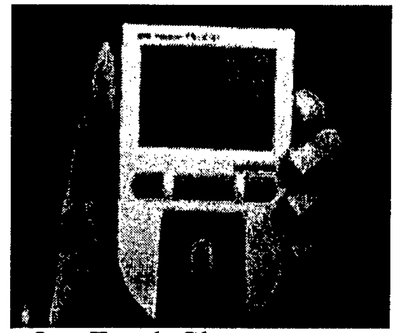
Technical Description

The One Touch Profile meter is a diabetes tracking system that has the ability to store up to 250 readings and associate each reading with an event label to help both the patient and the physician analyze the blood glucose level changes. The patient is able to link the Insulin dosage and type to each reading. To establish communications the One Touch Profile has a data port that connects to a serial port of the computer.
Each patient has a personal computer running Windows 95 and a 33.6-Kb modem. Data transferred to the physician's computer is via a standard telephone line.
The user interface between the One Touch meter and the database is "in Touch" Software which consists of two parts:

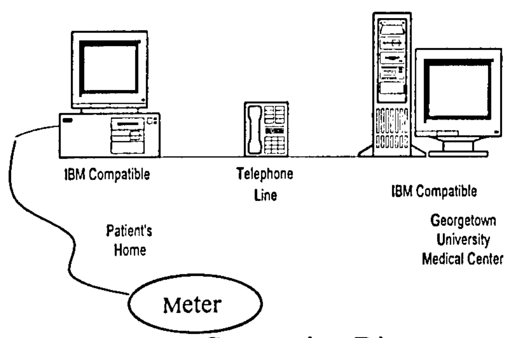
1. Diabetes Management: This part enables the patient to transfer blood glucose readings stored in the Meter to the Diabetes Management Program, analyze current and past data stored in the IN TOUCH database, and view and print reports that describe it. Set targets (high and low glucose levels), see an average glucose level for a specified time frame, and perform different file controls such as saving data, importing/ exporting, or archiving/restoring data. It also allows the patient to analyze meter settings, retrieve, view, and reset the meter's option settings, meter clear and delete readings stored in the meter's memory.
2. Education: This part is meant to educate a diabetic patient or a member of his/her family. It contains a large variety of educational tools, informations on Diabetes and how to manage it. Self-monitoring, control sugar level, how to avoid the disease, diet and exercise. It also answers frequently asked questions.

Operational Protocol

For this preliminary study we randomly selected 10 patients with type I diabetes (Insulin dependents) they all are being treated at Georgetown University Medical Center and all from the Washington DC metropolitan area, their age varies from 13 to 65 years old. Each patient owns and uses a One-touch profile meter. It is a small device (approximately 4.5"x2.6"x1") that can be carried anywhere.
The patient is supposed to test his/her blood three times a day, and up to 250 readings is automatically stored in the meter's memory.
Once a week patient connects the meter's data port to the serial port of the computer, turns on both the meter and the computer, and runs the "in Touch" Diabetes management software. With one click all the readings are downloaded to the computer. The software reminds the user to ensure that a connection exists between the meter and the computer, and notifies when


One Touch Glucose meter

communication is established. Once the data is downloaded the user is informed of the total number of readings in the database and the number of the new readings. The new readings are added to the existing ones each time the data is read.



Connection Diagram

By selecting the Data List report option the patient is able to list the meter readings. It is a raw report that shows the readings in a format very close to the format in which they were retrieved from the meter.
At the bottom of the data list report there is a window to associate comments with each reading. To do so the patient has to select the reading he or she wants to add any comments to, and type the corresponding comments that could have affected the blood glucose at that time, such as food, exercise, stress or any other

activity the patient believes it had an impact on his or her blood glucose level and if he/she wants to share the information with his /her physician. At this point the patient has to archive (store) the data to the computer's hard drive. We instructed the patients to use their names as filenames to be archived. The purpose was to avoid using different file names and getting the patient confused.
The program also offers more features and information to the patient and the physician such as:

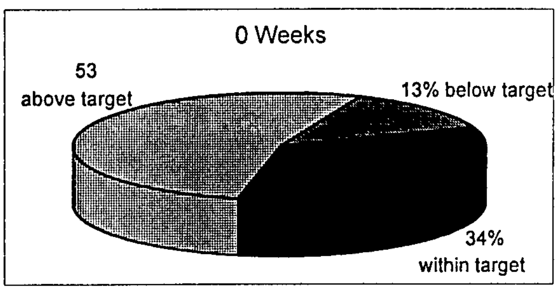
- The Logbook report which displays blood glucose readings and insulin dosages. Each entry summarizes one day. The Daily Details screen shows more detailed data about a single day. It also lets the patient edit the data.
- The Data Statistics report displays statistics on blood glucose levels throughout the day, computed from all readings in the date range. The Average Readings report displays charts of blood glucose levels throughout the day and week, computed from all readings in the date range
- The Readings Within Target report presents statistical charts of within-target and out-of-target readings computed from all readings in the date range. The report uses the overall target range to determine which readings are within target in all time slots. Blood glucose levels above 600 mg/dL (33.3 mmol/L) are treated as if they were equal to 601 mg/dL (33.4 mmol/L), no matter how high they actually were. The 14 Day Summary report displays tables and charts that summarize blood glucose levels and related information over a period of up to 14 days, ending at the end of the reporting date range. The Glucose and Insulin Graph report presents two graphs: one of blood glucose readings and one of insulin use. Both graphs cover a period of 14 days.
- The Histogram report presents a histogram of the patient's blood glucose levels. Each bar's height shows the number of readings that fall in a specified range of levels.

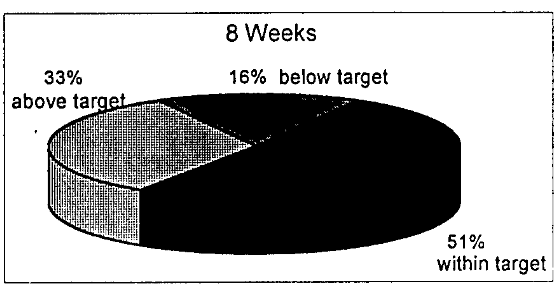
Our goal in designing the system was to minimize the patient's input in the procedure of transferring data to the physician's side. After testing many possibilities the patient's and the physician's input in the data transfer part was eliminated. A fully automated dial-up procedure was implemented to transfer the data from the patient's side to the physician's side.
A Macro was designed to run at a scheduled time each week and automatically initiates the dial-up and performs the connection to the physician's office where a unique account was created for each patient and the database is updated.
To retrieve a patient's data the physician runs the "in Touch Software" chooses a patient from the list, and restores his/her data. This allows the physician to view the latest data downloaded and identify patterns of glucose levels, select a specific reading and view the associated comment, if one exists.
After reviewing data the physician gets his feed back to the patient and establishes personal diabetes targets and changes in insulin doses exercise or diet in order to optimize blood glucose level. Also the physician can answer any concerns or comments the patients may have sent him along with their readings.

Findings

Patients showed a great interest in getting enrolled in the program. Some of the patients enrolled never used a glucose meter to monitor their blood sugar level found the program very motivating and started getting their blood glucose readings on a regular basis.
Outcome measures are overall glucose control as measured by Hemoglobin levels, frequency

of Hypoglycemia, Emergency Room visits and hospitalizations.
Preliminary data received by the physician shows that the average number of readings per patient per day increased from 1.6 to 2.5 readings per patient per day that were automatically sent to the physician' s computer.
After analyzing data and looking into all patterns the physician contacted patients and made suggestions to optimize blood glucose levels.
Data shows big improvement was achieved with patients who were not monitoring their blood glucose level prior to their enrollment.
Also the physician was able to bring within range blood glucose levels by changing insulin dose diet and exercise.
The pie- charts below show the percentage of patients' blood glucose levels within range and out of the recommended range before and after enrolment in the study:





These pie charts show that after getting enrolled in the program for 8 weeks the average patients' glucose readings within range increased from 34% to 51%.

During this study none of the enrolled patients has had Hypoglycemia or Emergency Room visit.

Discussion

Diabetes is a chronic disease that affects more than 16 million Americans and is characterized by serious, costly and potentially fatal complications. Untreated diabetes can lead to many preventable diseases such as blindness, amputation, heart disease, and kidney disease. 15% of U.S. health care dollars are spent on diabetes, $100 billion in direct costs (more than any other disease) and $140 billion with indirect costs.
Annually, 12,000-24,000 people with diabetes go blind. Diabetes is the leading cause of blindness, impacting 25% of patients.
Annually, 54,000 people with diabetes require an amputation due to nerve damage. 20-40% of all patients experience nerve disease.
Annually, 20,000 people develop kidney disease requiring daily dialysis or transplant. Diabetes leads to kidney disease within 15 years of disease onset in 34% of all cases. The risk of heart disease and stroke is 2-4 times higher for people with diabetes, 65% of people with diabetes also have high blood pressure.
A ten-year trial study sponsored by the National Institutes of Diabetes and Digestive and Kidney Diseases included 1,400 people with insulin dependent diabetes showed that the patients in the "tight diabetes" <control> group, who kept their blood sugar levels close to normal by frequent blood sugar testing, and lifestyle changes including exercise, and healthier eating lowered
Blindness cases by 76%, kidney failure cases by 56%, and amputations due to nerve damage by 61%.

Conclusion

Treating diabetes early can improve health outcomes for people with diabetes. Therefore,

routine screening and correct diagnoses are essential.
This is a cost-effective solution to bring health home to patients. As we mentioned earlier in this paper the requirements are basics that a big majority of citizens can afford and that are necessities nowadays Phone line and a personal Computer estimated at $ 500 or less, a glucose meter estimated at $ 75
Diabetes telemonitoring offers the possibility of eliminating distance and time as a barrier to a good blood glucose management, disease prevention and thus a better quality of life and a significant cost reduction in the short and long term hospitalizations, treatment and ER visits.

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Telemedicine in Neurosurgery: Peri-operative Management

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Telemedicine in Neurosurgery: Peri-operative Management

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Abstract

Despite the growing interest and use of telemedicine, few studies have examined the clinical efficacy and reliability of telemedicine, and none have looked specifically at the role of telemedicine in Neurosurgery. This prospective, observational study evaluates the effectiveness of telemedicine in the management of perioperative neurosurgical patients. A PC based compressed video media-conferencing system with high-resolution image transmission and retrieval is used. All transmissions are via point-to-point integrated services data network (ISDN 3) at 384kbps. Patients are examined by an on-site physician and remotely by a second physician using telemedicine. Examination data, assessment and recommendations are recorded on a standardized data collection form. The results of a pilot study of ten patients are presented. Correlation between the on-site and remote examiner was 100% for the following parameters: mental status, cranial nerves, sensory examination and wound evaluation. Correlation between observers was 89% for reflexes and 80% for speech, motor, and gait abnormalities. Sensitivity for detection of neurological abnormalities using telemedicine was 86%. Assessment and management decisions were identical for the on-site and remote physicians. Telemedicine provides an effective means to evaluate and manage neurosurgical patients in the peri-operative period.

1. Introduction

Advances in telecommunications technology have sparked renewed interest in telemedicine. As in the past, however, many obstacles continue to hinder the widespread acceptance and deployment of telemedicine as a standard part of the healthcare delivery system. Liability and licensing issues increasingly have been addressed by legislation. Costs of technology have dropped dramatically but remain significant both in up front acquisition costs and ongoing transmission expenses. While technical standards have been addressed in teleradiology, optimal system requirements in various clinical situations have not been defined. Recent Health Care Financing Administration (HCFA) reimbursement policies, although an important first step, are so restrictive as to discourage expanded application and innovation in telemedicine.

Fundamental to telemedicine's failure to become more pervasive is the lack of scientifically validated effectiveness in a broad spectrum of clinical situations. A number of studies in the 1970s showed promising initial clinical data in dermatology and other medical specialty consultations for underserved areas. During the current resurgence of interest in telemedicine, however, many studies describe technical advances and clinical projects while only a handful of studies compare the accuracy and reliability of telemedicine with the gold standard of face to face care. Indeed some authors have specifically argued against evaluating the technology in this way, maintaining that telemedicine is merely an extension of current practice and should not face the burden of clinical trials.

Lacking this type of data, however, many clinicians will not accept telemedicine and HCFA has emphasized that its reluctance to reimburse telemedicine reflects its long- standing policy not to pay for experimental care. Without such studies, clinical standards cannot be developed. Nor does this type of evaluation represent a formality that will not impact how telemedicine is used. The recent experience with endoscopic surgery in a number of surgical disciplines demonstrates the importance of clinical trials in defining the role of new "extension" technologies. Finally, the existing clinical data already demonstrates specific strengths and weaknesses of telemedicine which reveal that it is not merely an extension of standard care.

In this study, we examine the effectiveness of telemedicine in the management of patients who are about to undergo or recently underwent neurosurgical procedures. The accuracy of evaluation, based predominantly on the clinical examination and supporting images, and its impact on management decisions, between an on-site and remote physician are compared.

2. Materials and Methods

This study is part of a larger clinical study of telemedicine in neurosurgical patients. A prospective, observational design is used. In this pilot, ten patients were randomly selected from the neurosurgical in-patient service at the New York Presbyterian Hospital. All patients age 18 and over were eligible. There was no exclusion based upon sex or race. Patients were excluded, however, if they required intensive care unit monitoring which prevented them from being transported to the telemedicine unit, if they were too ill or uncomfortable to participate in the examination or if they were unable to give informed consent.

Each patient underwent a complete neurological examination by a physician on- site and also by a remote physician whose exam was assisted by a clinical nurse on-site. The remote physician conducted his examination via a PC based interactive video teleconferencing system with a CODEC supported by the Zydachron H.320 system. Transmission was point-to-point via integrated services data network (ISDN 3) lines at 384kbps. Each observer completed a standardized data collection form which included recording of a clinical assessment and both diagnostic and therapeutic management recommendations. Acceptance by the patients being examined was also assessed.

After all patient evaluations had been completed, the responses of the two physician observers were compared and analyzed.

3. Results

Six male and four female patients participated. The mean age was 49 years with a range of 27 to 77 years. Eight patients underwent spinal surgery and two patients underwent cranial surgery.

Each examination evaluated seven neurological parameters; the eighth parameter was wound assessment. The neurological parameters were mental status, speech and language, cranial nerves, motor, sensory, reflexes, and gait. Seventy- seven of a possible 80 parameters were completely scored by both examiners and available for analysis. Among these 77 parameters there were 22 neurological or wound abnormalities- a rate of 28.5%.

The remote observer detected 19 of the 22 abnormalities found by the on-site observer for a sensitivity of 86%.

Congruence between the remote and on- site observer was 100% for four parameters: mental status, cranial nerves, sensory examination and wound evaluation. The reliability for reflex evaluation was 89%. For speech, motor, and gait abnormalities, observer agreement was 80%.

Evaluation of the neurological examination was further broken down into minor and major differences. Differences in the interpretation of physical findings were considered minor if they were unlikely to have an impact on the clinical assessment and management of the patient. Major differences were those that could potentially alter clinical decision making. Three observation differences were considered minor: two patients who had undergone anterior cervical discectomy and fusion had changes in their voice appreciated by the on- site physician that were not heard by the remote examiner. A third patient had a unilateral Babinski response that was missed by the remote examiner.

Three parameter observations were considered major. All findings were in a patient who had undergone an anterior release for kyphoscoliosis. The examiners differed in their assessment of her strength, reflexes and gait.

The final assessments and recommendations of both the on-site and remote physicians, however, was 100% with no difference in the diagnostic and treatment plans for any patient.

Patient acceptance was 100% with no patient uncomfortable with the videoconference format.

4. Discussion

This pilot study demonstrates that interactive telemedicine may be useful in the management of neurosurgical patients in the perioperative period. The correlation between the on-site physician and remote physician was perfect in half of the parameters evaluated and in no parameter was agreement less than 80%. Moreover, even in those patients where there were differences in physical findings, these did not impact the overall assessment and management recommendations. Patient satisfaction in the test setting was high as well.

Telemedicine performed surprisingly well in certain areas where we had anticipated difficulties. Foremost among these was wound evaluation. The telemedicine system employed in this study not only reproduced subtle tissue colors accurately but also allowed for non- intrusive high magnification viewing of the wound that is not routinely performed at the bedside. Despite a number of complex wound findings, none were misinterpreted. Magnification also made testing of the cranial nerves simple and accurate. In addition a photographic record of an abnormality can be rendered as the exam is conducted without interference.

The sensory examination was also more successfully accomplished than we had foreseen. With the assistance of an on-site nurse and a cooperative patient, fine details of sensation were readily assessed remotely.

Certain limitations in telemedicine for neurological evaluation became apparent. Minor technical difficulties in room configuration and camera tracking resulted in errors in gait assessment which otherwise would not likely have occurred. The motor exam, however, relies upon the interpretation of the on-site assistant for gradations of strength that are less than full but greater than antigravity strength. Highly accurate assessment of strength could be carried out with sophisticated equipment but would be too cumbersome and is unlikely to affect decision- making enough to justify the additional time and expense.

More interesting, and unanticipated, was the failure of the remote examiner to detect subtle changes in voice characteristic and output in two patients who had undergone anterior approaches to the cervical spine. In these operations there is a small risk to the function of the external branch of the superior laryngeal nerve and to the recurrent laryngeal nerve. Injury to the former can result in difficulty in producing higher tones and in shouting. Recurrent laryngeal nerve palsy results in hoarseness. In both of these patients changes in speech were likely due to retraction and peri- operative edema; neither had injuries to either branch and the changes in their voices resolved in several days. Why these findings were missed is not clear. Telemedicine has been shown to be highly sensitive in the evaluation of speech and language disorders. One possibility is technical- namely that our system does not reproduce audio information of sufficient quality to ascertain the mild abnormalities encountered. Also, without other evidence of dysfunction no more detailed testing was performed. Certainly telelaryngoscopy has been performed and could diagnose vocal cord paralysis.

There are many limitations in this pilot study. First is the small number of patients. This limits the spectrum of neurological abnormalities encountered. Also, in some parameters the number of abnormalities was small which could overstate the accuracy of telemedicine. Because of the location of our telemedicine unit and lack of monitoring capabilities, sicker patients were excluded. Less ill patients are able to cooperate well. How effective telemedicine would be in evaluating the more critically ill neurosurgical patient population is not known. The overall sensitivity and accuracy of telemedicine in the neurosurgical setting studies is remarkably similar to that found in dermatology, fetal medicine and psychiatry.

As with most clinical studies in telemedicine our study design is prospective and observational. This may not reflect the true accuracy and capabilities of telemedicine as well as a randomized, prospective controlled trial in which patients would actually be managed by telemedicine and the compared with a comparable group managed by on-site care. Certainly patient satisfaction and acceptance may be considerably different under these circumstances.

The efficacy of telemedicine as demonstrated in clinical studies will determine the role of this technology in the future. Scientifically valid clinical studies will allow meaningful evaluation of cost-effectiveness, expanding the use of telemedicine where patients will benefit and defining its weaknesses prior to widespread application.

Telemedicine and Dialysis: Project Phoenix

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ABSTRACT

Greater than 280,000 patients are treated by hemodialysis in the US. The first year annual adjusted mortality is very high and in part relates to the dose of delivered dialysis (Kt/V). Using multimedia telemedicine we have been following dialysis patients for over one year with a weekly "telemedicine visit" in addition to weekly physician visits, in an attempt to maintain compliance with the dialysis schedule, in addition to comprehensive medical consultation. Transmission is achieved with T1 lines from the clinic to the physician's office or home. The telemedicine session uses electronic patient folders containing relevant medical details, digitized X-rays, lab values, etc.. We are able to achieve high quality videoconferencing, capture still or video images, record remote stethoscope sounds; capture local or remote data (laboratory values, dialysis machine parameters), and modify the medical record. Our goal is to increase the quantity of delivered dialysis, and thereby improve quality of life, patient satisfaction, and reduce costs of medical care, at the same time maintaining patient confidentiality. Appropriate measures to ensure data integrity and patient confidentiality have been integrated into the study. Questionnaires are also utilized to measure on an ongoing basis (quarterly), quality of life, patient satisfaction, while a weekly questionnaire captures any medical event taking place. The project will near completion this year, with subsequent data analysis in the following 6 months. The system and procedures we have employed are accepted enthusiastically by patients and staff alike and have aided in patient management.

Introduction:

Hemodialysis (HD) is the mainstay of treatment for end-stage renal disease - the point at which substitutive therapy for renal function sustains life, followed by peritoneal dialysis (PD). Concerns about adequacy of treatment, specifically the amount of dialysis delivered, prompted our application of telemedicine for patient management and review. Our requirements were based on the ability to access, not only medical records, but also, the patient, consulting physician, and other members of the health care team, and the dialysis procedure itself. Teleradiology already has attained a certain level of maturity, with established technical design parameters, specified guide lines,[1,2,3,4] and evaluation methodology.[5,6] We have published our views on the technical requirements and clinical application of personal computer based telemedicine for hemodialysis.[7,8] Our hemodialysis study[9] addresses the requirements for rigorous evaluation, assessment of technical capabilities, cost-effectiveness, and security of medical records, suggested by the Institute of Medicine.[10] This paper discusses the technical and clinical application of telemedicine in HD and outlines our plans to bring this technology into the home for management of PD patients.

Methods:

The technical capabilities of the telemedicine system are given in Table 1. The hemodialysis study compares two sites on the impact of telemedicine on patient outcomes. One site is the test site where telemedicine is used, and the other where telemedicine is not used. Instruments for measuring patient satisfaction, quality of life, cost data acquisition, and security have been used during the study. To ensure patient privacy in the open dialysis unit, we have used a patient microphone/earphone headset, which is interchangeable with standard microphone/speakers or stethoscope into the telemedicine system. The software used allows integration of all devices necessary for audio-visual communication between sites, construction of paperless medical records, which include multimedia files, and supports interactive sessions between sites.

Hemodialysis data (automated blood pressure, venous pressure, arterial pressure; transmembrane pressure, blood flow rates; dialysate flow rates, conductivity, and temperature, ultrafiltration rates, and sodium delivery) is downloaded from the machines (Fresenius, Irvine, CA), using an interface program, via a buffer PC. We are in the process of integrating our system with a clinical information system[11] containing demographics, patient history, clinical laboratory results, over the dialysis life of the patient. Fully integrated in the clinical operations protocol is an explanation of the security and patient confidentiality risks in the study and measures taken to prevent or reduce these risks.[12] In addition we have developed a web-site based teaching program for patients regarding the security issues in our telemedicine protocol.[13] We plan to expand this as a general teaching tool about kidney disease, dialysis, and telemedicine, with links to relevant web-sites for patient education.

Table 1: Telemedicine work-station components

Component Description	*Capabilities*
Pentium PC	2GB hard drive, 32 MB RAM
Video card	1MB
SVGA monitor	High resolution picture
CODEC	Audio/Video Coder/decoder
CSU/DSU	Channel services unit/data service unit
T1 board	Supports T1 lines (1.5 mbps)
VCR	Video recording
Zip drive	100MB storage
Housecall software	Integrated multimedia program
Electronic stethoscope	Diagnostic quality
RS232 port	Dialysis parameters

For the peritoneal dialysis project we have tested the potential for modem based and CODEC based videoconferencing, using two different types of camera (Canon VC-C1, MK II®, and Connectix®). Using low speed modem telephone lines (28.8 kbps) we have found that for diagnostic quality of the Connectix® is poor, and have plans to use the CODEC based system and ISDN lines (128 kbps). This study is at a very early stage.

Results:

The formal data analysis is planned to take place in the next six months, but some preliminary results have been assessed. To date, 40 patients have been enrolled in each site and about 1500 individual patient contacts by telemedicine have been made. The use of telemedicine has become routine and patient satisfaction (measured by instrument) has been high. Demographically the two sites differ in educational level (the telemedicine site has a lower educational level), and race (more African-Americans at the telemedicine site). Quantity of dialysis delivered (Kt/V) appears to be no different between the 2 sites.

Discussion

Hemodialysis in the US carries a 22% first-year gross unadjusted mortality, a figure which greatly exceeds that in Europe (14%) or Japan (12%-14%).[14] The higher annual mortality rate for hemodialysis patients in the United States is attributable in part to prescribed shorter dialysis time,[15,16] or sessions missed or sessions deliberately shortened by the patient.[17] Telemedicine, by virtue of increased and visual patient contact and interaction with the physician, on a regular basis, or during times that the patient may wish to terminate dialysis early, or during emergencies, is likely to maintain the amount of dialysis delivered

Most dialysis facilities, staffed by nurses and technicians, are situated at a distance from the physician. Physicians see patients at the dialysis center, weekly to monthly, depending on the local practice. It is our practice that the hemodialysis patient is seen once weekly. The test hemodialysis center, which is off-campus in Washington, DC, is now linked to the physician's campus office or physician's home.

Often, long distances between dialysis patients and nephrologists in some states and countries exists[18,19,20,21] stimulating the need for telemedicine. The multimedia database system we have designed and used, integrates diagnostic capabilities (e.g. stethoscope) for detection of pulmonary edema, cardiac abnormalities, and vascular access dysfunction (also by inspection). Physicians may be able to prevent some medical emergencies with adequate longitudinal information monitored during patient rounds. Currently, information necessary to manage

some of these conditions (such as imaging, laboratory reports, prior dialysis parameters) is stored in various places throughout the medical center, not at the dialysis clinic. When emergencies or acute problems occur when the attending physician is off-site, it is now possible to provide real-time access to the patient or patient information needed to manage the situation. The physician can now intervene to provide immediate reassurance or encouragement to complete dialysis, when the patients threaten to shorten their dialysis session. Additionally, a multimedia database for diagnostic audio, radiology images, and clinical still images, stored in the patient folder, fosters an improvement (over conventional) in monitoring patient status over time. T1 lines offer point-to-point, and therefore secure, data transmission, but we will also explore entry into the NII for easier and less costly data access from any computer connected to a local area network, and to the internet throughout the world. A firewall will be necessary to protect patient confidentiality.

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A Multimedia Medical Database for a Telemedicine Application in Renal Dialysis Service

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Abstract

In aims to increase the efficiency of distributed multimedia medical databases in terms of clinical consulting process, we propose a multimedia medical database component for a dialysis telemedicine application to manage external data access using distributed middleware standardizations. External data access to distributed multimedia medical databases consists of a collection of software components that interact with each other using a common set of system-level interfaces defined by DCOM and CORBA. External data access interfaces consist of individual DCOM and CORBA interfaces, a DCOM-CORBA connection interface, and DCOM/CORBA interfaces to legacy data. With our current focus on the seamless integration of component and non-component programs in medical databases, we support a telemedicine system, which allows the distribution of multimedia medical data.

1. Introduction

As telemedicine consultations enter routine clinical practice there is an important clinical need to find data contained within previous diagnostic discussions, waveform patterns such as electrocardiograms and phono-cardiograms, diagnostic audio for cardiac/pulmonary status using stethoscope, still pictures such as skin lesions, gray scale images, still video from video camera, and motion video from real-time ultrasound. The large variety, the massive volume, and the need for easy and fast access to these multimedia medical data underscore the importance and complexity of the MMDB (Multimedia Medical DataBase). A key to the success of telemedicine is the acceptability of multimedia electronic data to patients, physicians, nurses, and technicians.

A new challenge posed by the advent of multimedia electronic data is to meet the demand for better access to clinical, administrative and research information while maintaining the confidentiality of individual patient records [7]. Multimedia medical databases are just now starting to be developed for health care applications and there exist only a few multimedia medical database systems such as KMeD [2], TeleMed [3], and MIDB [1].

The multimedia medical database is a dynamic and active database that is continually updated, and the multimedia medical data must be stored in this for long periods. These characteristics raise many and important issues such as

o efficient integration models of each multimedia medical database,

o information representation related to a user-independent view and semantic heterogeneity,

o query of multimedia data based on a description,

o content-oriented search,

o place efficiency and scalability requirements on the multimedia medical database.

Also, the multimedia medical database needs many technologies such as multi-indexing, storage management, and multimedia processing of browsing, compression, decompression, and visualization, communication of PACS and internet-based applications.

Although the multimedia medical database management system is the most important system to integrate video-conference tools and many kinds of multimedia devices, the integration with these systems often shows excessive dependency on expensive hardware or specific platforms. Therefore, if the goal or requirements of these systems are altered, all the systems may or should be modified according to the alterations, making some hardware useless. To cope with these problems, standardization of technology and a systemic design from the initial step become more important. The fact that various portions of the data may exist locally or remotely or at combination of local and multiple remote sites is made invisible to the user. The development of a multimedia medical database component system should use the implementation technologies of distributed systems' standardizations. This system makes multimedia medical objects accessible to DCOM/CORBA (Distributed Component Object Module/Common Object Request Broker Architecture) clients without exposing the database schema to their clients.

A dialysis telemedicine application needs a multimedia medical database since it should have the following capabilities: direct downloading of dialysis parameters, storage and transmission of patient charts, EKGs and lab results through a document camera, storage in electronic patient records for future consultation, storage and retrieval of x-rays previously digitized at tertiary care centers, storage and transmission of digitized audio from an electronic stethoscope, and live patient-physician interaction.

This dialysis telemedicine component based on multimedia medical databases can be used in the regular patient consultation. We expect increased patient satisfaction and education since the physician always explains causes to patients by comparison data with other rational data. But to operate this component regularly, we need to integrate many modules with multimedia medical databases. This research proposes development methodologies of the dialysis telemedicine component based on DCOM/CORBA [5,6] to be integrated with a video-conference component and a device data storage component.

2. Modeling of Clinical Background and Requirements

Patients with uremia or end-stage renal disease (ESRD) undergo hemodialysis, a mechanical process whereby blood is removed, cleansed of unwanted impurities, and returned via vascular access, usually a fistula in the forearm. Dialysis patients commonly experience a variety of acute, chronic, and emergency conditions requiring physician attention. Physicians may avert some types of emergencies with adequate longitudinal information monitored during patient rounds by instructing the dialysis personnel to alter the dialysis parameters. But the information necessary to manage some of these conditions such as imaging, laboratory reports, and previous dialysis parameters is currently stored in various places throughout the medical center, not at the dialysis clinic [14]. To provide this information anytime, we need a dialysis telemedicine system based on the multimedia medical database component. This dialysis telemedicine system allows for remote patient consultation of renal patients from a physician's site to off-site dialysis clinics or a patient's site.

The dialysis telemedicine system needs to have the following capabilities:

o Direct downloading of dialysis parameters via the telemedicine system to a remote site.
o Digitization, storage and transmission to a remote site of patient charts, EKGs and lab results through a document camera.
o Storage in electronic patient folders for future consultation.
o Storage and retrieval of x-rays previously digitized at GUMC.
o Capture, storage and transmission of digitized audio from an electronic stethoscope.
o Live patient-physician interaction.

The design of a dialysis telemedicine system is all about seeing the key issues in its development. The dialysis telemedicine system should allow simultaneous updates of databases to provide the same data to all users such as physicians, nurses, and patients.

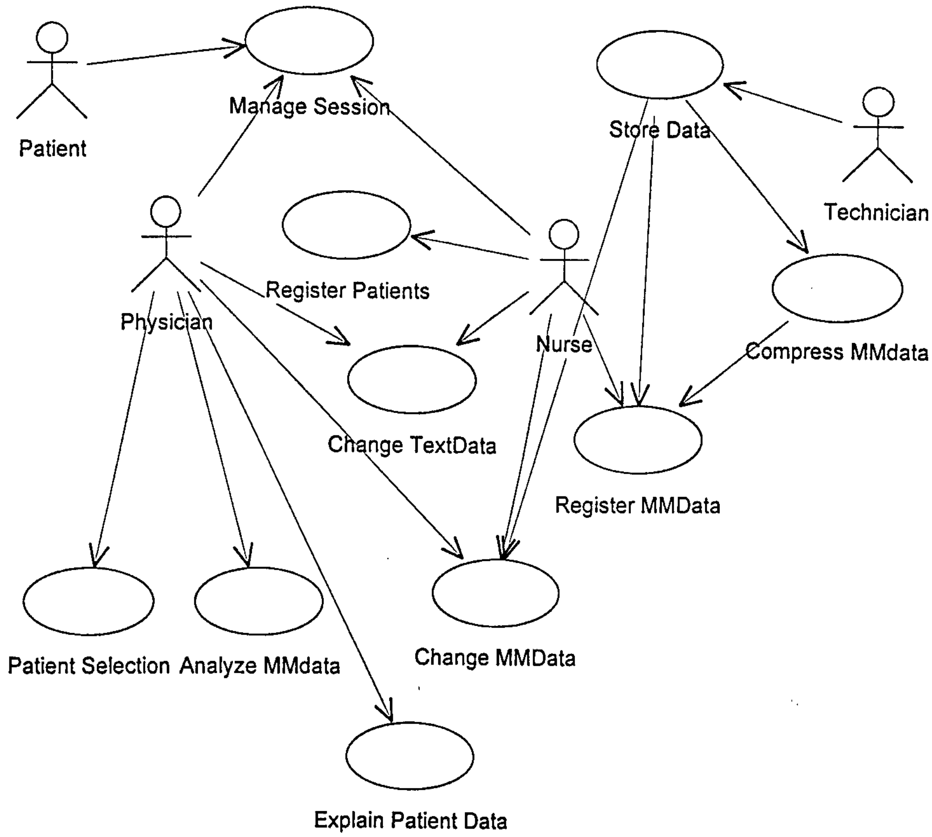

Figure1. Use cases diagram of a dialysis telemedicine.

To allow advantages of object languages and achieve good communication, we need to understand the users' world well. The good understanding of the users' world is the key to developing good software. Since Jacobson [8] raised the visibility of the use case to the extent that it became a primary element in project development and planning, the object community has adopted use cases to a remarkable degree. A use case is a snapshot of one aspect of our system. The sum of all use cases is the external picture of our system [4].

When we represent the above clinical requirements as use cases, we get a use cases diagram as shown in Figure 1. This figure has been drawn by Rose/C++ version 4.0 [12]. Figure 1 includes ten use cases and four actors who are roles that users play with respect to the system. This diagram shows actors only when they are the ones who need the use case. Ten use cases are all about externally-required functionality of the dialysis telemedicine and identify external events from the dialysis telemedicine world to which we want to react. Ten use cases capture user-visible functions to be related with three kinds of components: video-conference, multimedia medical databases, and digital device data storage.

3. Architecture

To provide support for clinical requirements, the dialysis telemedicine system requires many modules such as a video conference subsystem, a storage subsystem of digital device or dialysis machine data and a multimedia database subsystem.

Our dialysis telemedicine system's architecture has one server system through which physician, patient and nurse clients are connected. This system should be ready to begin the telemedicine session at any time. Before each session, the nephrologist will ask the nurse to send him the most recent folders of that day's patients. Once a week, the nephrologist decides which portion of the auscultatory findings for cardiac and pulmonary assessment, fistula still images and dialysis parameters to keep in the patient folder and which to discard. The data that is kept is then transferred to a zip or jazz drive belonging to that patient and is held for up to three months. This data also includes all other patient information available in the patient chart such as EKG and x-ray reports, lab values, etc.

To incorporate regular dialysis information system seamlessly into this system, we need the telemedicine middle-ware following up the standardization of distributed objects systems. To clients such as patients, physicians, nurses and technicians, all access to the multimedia medical databases is through objects. This means that a local object represents the database, and although objects could be used in remote objects, they are invisible to clients. To do this, the object server has to make the object public, so that any remote clients can access it. Now the client developer can create an object and use it without worrying about any network programming issues. The developer just creates the object and calls its methods. The object is more than just remote, distributed.

To incorporate telemedicine systems seamlessly into regular multimedia clinic medical databases systems, we need the database access middle-ware to follow the standardization of distributed objects systems. To clients such as physicians and nurses, all access to the multimedia medical databases is done through objects. This means that a local object represents the database, and although objects can be used in remote locations, they are invisible to clients. To do this, the object server must be made public, so that any remote client can access it. Now the client developer can create an object and use it without worrying about any network programming issues. Instead the developer must simply define its methods. Therefor the object must be more than just remote it must also be easily distributed.

Telemedicine systems must fulfill two requirements for distributing clinic databases. One requirement is the efficient and cost effective access to databases. Along with this comes the integration of these databases using tools, which have already been established, such as those based on Windows. DCOM supports such standardization through the creation of universal objects in Windows, which allows the client flexibility in integrating objects on machines across the network. DCOM contains both a binary and network standard that allows any two components to communicate regardless of what machine they're running on, in which operating system the machine is running, or in what language the components are written [10]. This DCOM architecture helps simplify the process of development for the proposed telemedicine application. The other requirement for clinical data distribution is the opportunity to access large amounts of clinical data such as image databases or Picture Archiving and Communications System (PACS) databases. Although most clinic databases run on UNIX, we need yet another standardization which contains interfaces for clinic databases. COBRA is the technology which supports these functions, because it provides a channel for the distribution of medical applications over a network and allows for the utilization of various medical applications and information.

The clinic table also contains a blob field for the storage and retrieval of multimedia clinical data. This data must be acquired through the use of specific medical devices during a direct consultation or taken by a camera through indirect consultation. In regards to the management of clinical data, it is better for it to be stored into a table of a medical database for use in telemedicine. In some cases, proprietary databases, installed in the equipment, are used to acquire and manage clinical data independently and efficiently. These proprietary databases are a necessity in telemedicine. In telemedicine, for an efficient, urgent care service, we must have access to scanned image files. Since the size of these image files is quite large these images are stored into a separated database or file systems. If these systems do not support component services, we should provide interfaces to be able to access wrapping objects for use in non-component programs. We support two different types of data access: one to access component programs or databases based on CORBA and DCOM, and the other for non-component programs such as proprietary databases. The former is easier than the latter because these databases or component programs already provide necessary interfaces. Wrapper objects of non-component programs provide interfaces using some of the existing functions. In DCOM and CORBA based systems, one highlight of the wrapping of an existing code, is the ability to implement an IDL interface using these existing classes. If the existing class has accurate member functions and each function has the correct parameter type, then the call has met the appropriate function. It is more likely that the existing code will not have exactly the correct member functions, than it is for the code to have the incorrect parameters. The code for wrapper objects can manipulate any call that it receives before passing it on to the code for existing classes. This manipulation can compensate for differences in function names and parameters, and differences in function semantics.

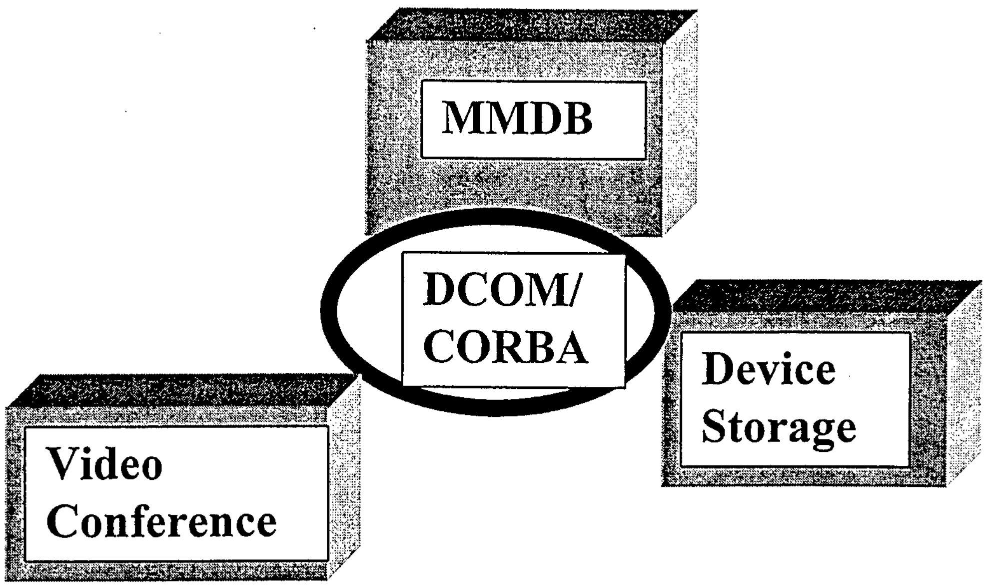

Figure 2. A dialysis telemedicine architecture.

4. Multimedia Medical Database Component

With the current pace of change in the software industry, applications cannot afford to be static after they have been shipped. Developers must find a way to breathe new life into applications that have already shipped. The solution is to break the monolithic application into separate pieces or components [13]. A component is like a mini-application and it comes packaged as a binary bundle of code that is compiled, linked, and ready to use. Multimedia application development has focused on solutions for stand-alone computers before going distributed [11]. Distributed multimedia medical application development has to harmonize multimedia programming, multimedia authoring, distributed programming, and distributed authoring. Currently most telemedicine systems are operated with a stand-alone type, but they should be integrated with regular clinical activities or health information systems. Since a dialysis telemedicine system uses a lot of multimedia data such as EKGs, laboratory reports, x-ray reports, Kardex, fistula still images, these data are distributed in the physician site and the patient site.

Each patient in the Master table has several items of clinic data, which are also contained in the Detail table. Each item of clinic data can access component programs or non-component programs with DCOM and CORBA interfaces or Wrapper object interfaces. In order to join interfaces flawlessly from a clinic data table to application programs such as component programs or non-component programs, we add IDL to wrap objects in accordance with DCOM and CORBA specification. Wrapper object interfaces are changed into DCOM and CORBA interfaces so that we can consistently access components and non-component programs.

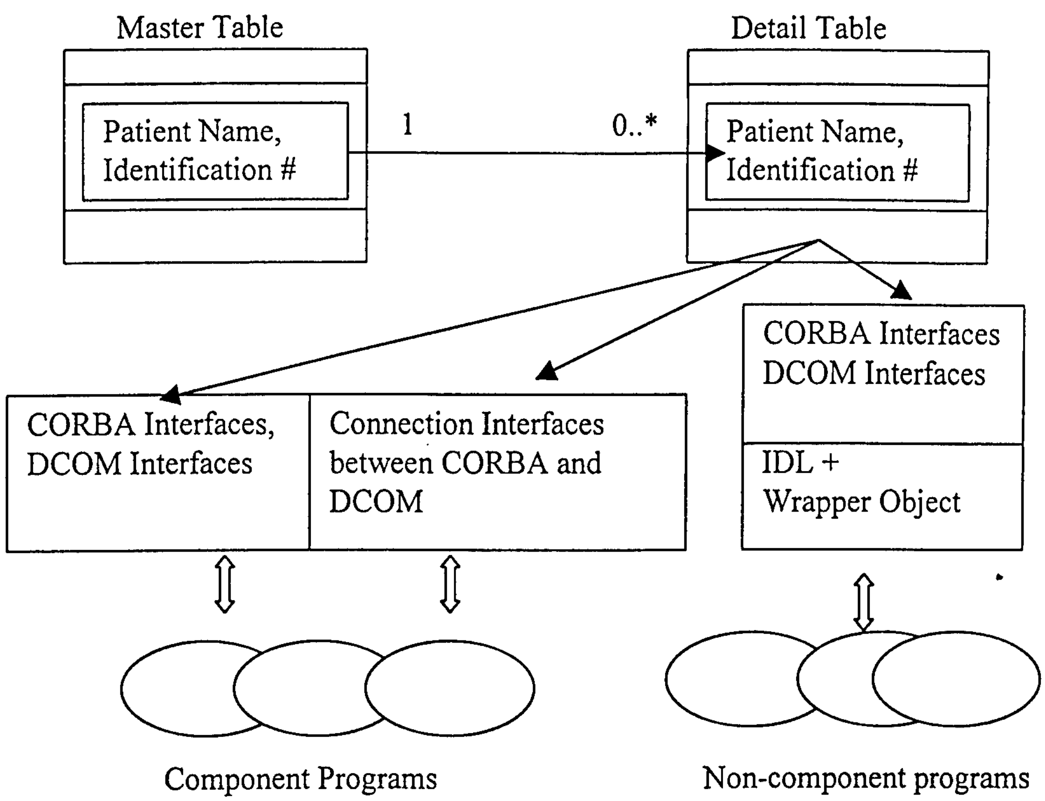

Figure 3. Data Model for seamless connection of component and non-component databases programs

For CORBA interfaces of non-component databases we develop a methodology to connect CORBA IDL interfaces to non-component databases. This provides a connection library for clients that are composed of six classes: a Connection, Statement, Prepared Statement and CallableStatement for SQL, and Results. The class diagram of their relationship is shown as figure 4.

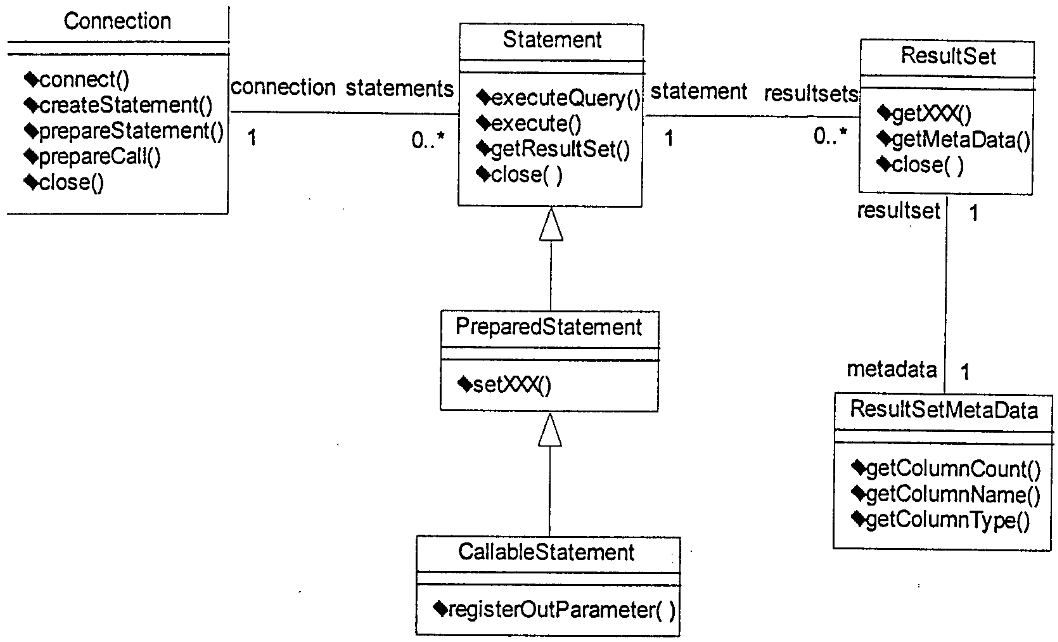

Figure 4. Connection classes diagram.

For DCOM interfaces of non-component databases we follows Object Linking and Embedding DataBase (OLE DB) specification. Because OLE DB specifies a set of Microsoft Component Object Model (COM) interfaces that encapsulate, or hide, various database management system services, these interfaces enable us to use many kinds of data sources software components such as Spread Sheet, ODBC/SQL, ISAM, SPATIAL, and File [9].

To use data to be stored in data sources wrapped with CORBA on UNIX, we need another connection specification between COM and CORBA [6]. This connection spec,ification should enable transparent integration between COM on Windows development environments and CORBA on UNIX. It also allows developers of telemedicine applications to build applications using data sources located across the network on diverse hardware and software platforms

5. Conclusion

The dialysis telemedicine component approach provides a component-based management of multimedia medical data that has been seamlessly coupled to a video conference component and a device monitoring component. The multimedia medical database component is connected to the video conference component and the device monitoring component by the DCOM/CORBA interface. This approach also uses an object-oriented programming technology to manage the distributed multimedia medical data.

With our current focus on the seamless integration of component and non-component programs in medical databases, we will provide a telemedicine system which allows the distribution of multimedia medical data. It could include the newly added capability of telecollaboration between multiple physicians while viewing the identical data and commenting and documenting their observations.

Acknowledgement

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Approaches to Needs Assessment in Telemedicine: Planning A Pilot Project for the Department Of State

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Introduction

A comprehensive approach to health care needs assessment attempts to evaluate the relationships among technical, clinical, organizational and strategic conditions in the situation under review. When the Medical Services Organization (MSO), US Department of State approached the ISIS Center, Georgetown University Medical Center and the Telemedicine and Advanced Technology Research Center (TATRC), US Army Medical Research and Materiel Command, Ft. Detrick to plan, develop and deploy a pilot telemedicine program, the needs assessment produced two possible alternative approaches. The first approach adopts the strategic assumption that the telemedicine system should be able to support the Regional Medical Officers (RMO) during routine visits to foreign medical posts in the regions under their responsibility. The second approach adopts the strategic assumption that the telemedicine system should support the foreign medical posts in their daily operations. The first approach produces a single model for deployment in the four medical posts chosen for the pilot project. The second approach produces four models modularly linked from basic to specialized technical capabilities with one of the four pilot sites functioning as an example of each model. In both approaches, the MSO headquarters in Washington, DC functions as a clinical and communications hub. The MSO selected the first approach for the purposes of the pilot project. The second approach remains an option for later development if relevant.

Supporting the RMO in the Field

Regional Medical Officers routinely make rounds to all medical posts under their responsibility. During their visits, they function as physicians as well as review the operations of the medical post. Although local capabilities vary enormously among the various medical posts, the arrival of the RMO immediately augments any post's clinical capabilities. The RMO handles cases that otherwise might be transported to larger regional centers or the United States. Because the RMO functions as a general practitioner and few foreign medical posts have access to highly specialized clinical services, managing some cases would benefit from consultation between the RMO and subspecialists at American medical centers. The communications infrastructure of few foreign medical posts can support videoconferencing; but many can support store-and-forward types of telemedicine including teleradiology. The telemedicine model for RMO support therefore includes basic Internet access with email and a telemedicine unit with digital camera, peripheral diagnostic scopes and x-ray film scanner. The planning matrix below outlines this model.

Technical Functionality	Telemedicine Toolkit	Suggested Equipment	Suggested Retail Price ($)
• **Email to Referral Ctr**	• Email Client • PC/Modem	• Gateway, Intel 300MHz Pentium II processor (Includes 56 Kbps Modem & SCSI)	3,943
		• Microsoft Office 97	600
		• Microsoft Exchange	
• **Doc Scanning**	• Doc scanner	• Color PageWiz	160
• **Hi Res Still Image & Transmission**	• Digital Camera	• Sony Digital Camera DKC-1D1	1,800
	• SCSI Interface	• Adaptec	
	• Image Manipulation S/W	• Adobe Photoshop 4.0	250
	• Web Browser	• Internet Explorer 4.0	
• **Xray Transmission**	• Film Digitizer	• Vidar VXR-8 plus	11,000
• **Low-end VTC**[2]	• Internet VTC S/W	• Microsoft NetMeeting	
• **Whiteboard**[1]	• VTC Camera	• Color QuickCam	200
• **Web Database Server**[2]	• Server PC	• Gateway, Intel 333MHz Pentium II (Includes Modem & NT Server 4.0)	5,602
	• Web Server	• Internet Information Server (IIS)	
	• Database Server	• SQL Server 6.5 (5 clients)	1,400
	• Database Connector	• Active Server Pages	
	• Development tools	• Visual InterDev 1.0	500
		• ActiveFile 1.0	200
		• Windows NT4.0	
		• Internet Explorer 4.0	
	• Email Server	• Microsoft Exchange Server 5.5 (25 clients)	2,200

[1] Only in China post
[2] Only in Server location

Supporting Daily Operations in the Field

Foreign medical posts vary in the size of their patient population, the sophistication of medical practice in the local community and the types of medical practitioners stationed in each location. The MSO identifies four general combinations in which these conditions may occur listed as Post Situation A-D below.

Post Situation A: posts with fewer than 60 beneficiaries or posts with more than 60 located in an area with adequate medical facilities.

Post Situation B: posts with more than 60 beneficiaries located in medically underserved area.

Post Situation C: posts with adequate medical facilities for medevacs, excellent communications and travel capabilities

Post Situation D: exceptions, isolated posts with fewer than 60 beneficiaries located in medically underserved areas

The MSO staffs each post according to the conditions of its situation type.

Post Situation A: Because the demand for care in this situation is typically small or may be met through local medical facilities, a locally hired nurse or licensed practical nurse staffs the medical clinic.

Post Situation B: Because the demand for care in this situation is typically large but the local medical facilities are meager, an American-trained nurse practitioner or locally trained physician with nursing support staffs the medical clinic.

Post Situation C: Type C post situations often function as regional medical offices with responsibilities for large patient populations at their own embassies and other medical clinics in their regions. An American physician and nursing staff typically provide care.

Post Situation D: Because the demand for care in this situation is small but local medical facilities are meager, an American-trained registered nurse typically staffs the medical clinic.

When evaluating the requirements for telemedicine in each post situation, we developed an approach based on enhancing the role performance of the types of medical practitioner typically stationed in each location. Using the telemedicine system to consult with remote higher level medical facilities, individual post medical staff should be able to offer care characteristic of provider roles one grade more advanced in the provider schema. For example, the telemedicine system should enable a registered nurse in Post Situation D to offer diagnostic and treatment care typically provided by a nurse practitioner. General practitioners in Post Situation C should be able to use the telemedicine system to help deliver subspecialty level care in their local clinics. Although this approach would not enable an RMO to obtain subspecialty consultation during rounds to regional clinics of types A, B or D, it would cost less to deploy. This approach to telemedicine might also permit the MSO to enhance care in foreign medical clinics without increasing the level of deployed staff or to assist in the process of reengineering their deployed staffing requirements. A matrix with key outlining each level of this approach appears below. Please note: each technical level of the telemedicine system builds incrementally upon the level just below it in the planning matrix. A series of four increasingly sophisticated but linked modules thus emerges.

Post Category[3]	Example	Role Enhancement	Clinical Enhancement	Technical Functionality	Telemedicine Toolkit	Communications Requirements	Suggested Equipment (off-the-shelf)
A	CUBA	LPN to RN	Screening for Referral and Evacuation	• Voice • Fax • Email to Referral Ctr	• Telephone • Fax • PC/Modem	• Analog Lines • Commercial Internet Access	• Pentium 233/ 64MB/2GB HD/ 56Kmodem/ Office 97
D	NIGER	RN to NP	Screening, Basic Dx/Tx, ref/evac, follow-up	In addition to above: • FTP • Doc Scanning • Hi Res Still Image & Transmission	In addition to above: • FTP S/W • Doc scanner • Digital Camera • SCSI Interface • Image Manip S/W • Web Browser	Same as above	In addition to above: • Cuteftp • PageWiz • Kodak DCS420 • Adaptec • Adobe Photoshop • Netscape
B	HAITI	NP to MD	Primary Dx/Tx, ref/evac, follow-up	In addition to above: • Xray Transmission	In addition to above: • Film Digitizer	In addition to above: • >56Kbps	In addition to above: • Vidar VXR-12
C	CHINA	MD to Specialist	Specialty Dx & Tx, ref/evac, follow-up	In addition to above: • Low-end VTC • Whiteboard	In addition to above: • Internet VTC S/W • VTC Camera	Same as above	In addition to above: • Cu-SeeMe • Color QuickCam
HQ	DC			• Web Server	In addition to Category A: • Internet Information Server (IIS)	• LAN with Internet Access	In addition to Category A: • Windows NT4.0 • Netscape

[3] Post Category:
A: posts with less than 60 beneficiaries or posts with more than 60 but with adequate medical facilities
B: posts with more than 60 and medically under-served
C: posts with adequate medical facilities for medevacs, excellent communications and travel capabilities
D: exceptions, isolated posts with less than 60 and medically under-served

KEY TO PLANNING MATRIX

DEFINITIONS

Post Situation: in his review of the medical requirements for all foreign posts of the Department of State, Dr. Dumont identifies four sets of circumstances (A, D, B, C) according to the size of the post and the adequacy of local health care services.

Example: this pilot project will install and evaluate telemedicine capabilities at one site exemplifying each type of post situation.

Role Enhancement: Telemedicine will enable a health care worker (for example, a licensed practical nurse) to perform at the level of the next highest role (for example, a registered nurse) in a typical clinical situation when necessary.

Clinical enhancement: Telemedicine will enable a health care worker (for example, a licensed practical nurse) to provide clinical tasks of the next highest role (for example, a registered nurse) in a typical clinical situation when necessary.

Technical functionality: enabling technologies necessary to achieve the clinical enhancements specified for each level of post.

Telemedicine toolkit: the type of telemedicine equipment necessary to provide technical functionality specified for each post.

Communications requirements: type of communication service and bandwidth necessary for adequate performance of the telemedicine toolkit at each level of post.

Suggested Equipment: Off-the-shelf products recommended to complete the telemedicine toolkit for each level of post.

POST SITUATION A

Post Situation A: posts with fewer than 60 beneficiaries or posts with more than 60 located in an area with adequate medical facilities.

Example: Havana, Cuba

Role Enhancement: with the aid of telemedicine, a licensed practical nurse or locally hired nurse should be able to perform when necessary at the level of an American-trained registered nurse.

Clinical enhancement: with the aid of telemedicine, a licensed practical nurse should be able accurately to screen patients for referral to local practitioners or for evacuation.

Technical Functionality: The technical functionality will consist of telephone, fax and email communication with the referral or evacuation center.

Telemedicine Toolkit: The toolkit will consist of a telephone, a fax and a PC equipped with modem capability.

Communication Requirement: At least two telephone lines will be required for telephone and fax (analog). An additional line is required for Commercial internet access.

Suggested Equipment: 233 MHz Pentium PC with 64 Mbyte of memory, 2 Gbyte hard drive and an internal 56 Kbps modem. Software requirements include the Office'97 package.

POST SITUATION D

Post Situation D: exceptions, isolated posts with fewer than 60 beneficiaries located in medically underserved areas

Example: Niamey, Niger

Role Enhancement: with the aid of telemedicine, a registered nurse should be able to perform when necessary at the level of an American trained nurse practitioner.

Clinical enhancement: with the aid of telemedicine, a registered nurse should be able accurately to screen patients for referral to local practitioners or for evacuation, to provide basic diagnostic and treatment services, and to follow-up cases upon return to post.

Technical Functionality: In addition to the POST CATEGORY A configuration, the nurse will use File Transfer Protocol (FTP) to transmit files, document scanning for EKGs, lab or x-ray reports and high resolution still color images such as dermatology cases. The nurse will post cases on the Web server in Washington.

Telemedicine Toolkit: In addition to POST CATEGORY A toolkit, the toolkit will include FTP Software, a document scanner, a digital camera, a SCSI interface for the digital camera, image manipulation software to capture, view, manipulate and save images on the hard drive and a web browser to create web pages.

Communication Requirement: The system configuration is equivalent to Post Category A.

Suggested Equipment: In addition to the POST CATEGORY A equipment, CuteFtp, PageWiz scanner, Kodak DCS 420 digital camera, Adaptec SCSI, Adobe Photoshop, and Netscape.

POST SITUATION B

Post Situation B: posts with more than 60 beneficiaries located in medically underserved area.

Example: Port-Au-Prince, Haiti

Role Enhancement: with the aid of telemedicine, an American-trained nurse practitioner or locally trained primary care physician should be able to perform when necessary at the level of an American trained primary care physician.

Clinical enhancement: with the aid of telemedicine, an American-trained nurse practitioner or locally trained primary care physician should be able accurately to screen patients for referral to local practitioners or for evacuation, to provide primary diagnostic and treatment services, and to follow-up cases upon return to post.

Technical Functionality: In addition to the POST CATEGORY D configuration, the nurse in this post will use an X-ray film digitizer to scan X-ray films.

Telemedicine Toolkit: In addition to the POST CATEGORY D toolkit, the toolkit will include a Film Digitizer.

Communication Requirement: The system configuration is equivalent to Post Category D

Suggested Equipment: Vidar VXR-12.

POST SITUATION C

Post Situation C: posts with adequate medical facilities for medevacs, excellent communications and travel capabilities.

Example: Beijing, China

Role Enhancement: with the aid of telemedicine, an American-trained physician should be able to perform when necessary at the level of an American trained specialist physician.

Clinical enhancement: with the aid of telemedicine, an American-trained primary care physician should be able accurately to screen patients for evacuation, to provide specialist diagnostic services and non-surgical specialist treatment services, and to follow-up cases upon return to post.

Technical Functionality: In addition to the POST CATEGORY B configuration, the physician in this post will use low-end videoconferencing (VTC) with a whiteboard to share images during consultations with the referral center.

Telemedicine Toolkit: In addition to the POST CATEGORY B toolkit, the toolkit will include internet VTC and VTC camera.

Communication Requirement: The system configuration is equivalent to Post Category B

Suggested Equipment: Cu-SeeMe and Color QuickCam

POST SITUATION HQ

Post Situation HQ: headquarters for the Department of State

Example: Washington, DC

Role Enhancement: TBD

Clinical enhancement: TBD

Technical Functionality: web server

Telemedicine Toolkit: In addition to POST CATEGORY A toolkit , the toolkit will include an Internet Information Server (IIS)

Communication Requirement: Secure direct connection to the Internet.

Suggested Equipment: Windows NT Server 4.0

Development of Web-based Telemedicine System

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Development of Web-based Telemedicine System

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Georgetown University Medical Center

1. Introduction

Telemedicine requires good access to high speed communication network. The poor communication infrastructure in remote locations makes telemedicine more difficult and costly. Medically relevant telemedicine requires technology, personnel, new management approaches and new clinical protocol.

A Web-based telemedicine system is designed to provide clinical staff in remote areas with state-of-the-art telemedicine capabilities to transmit electronic information such as patient demographics, x-ray images, lab reports, ECG graphs, dermatology images, and others to a referral facility for a second opinion over a secure Internet connection.

2. Objective of this "Proof of Concept" Initiative

The primary objective of this phase of the project is to validate technical approach and operational scenario of Web-base Telemedicine System.

3. Project Team

Georgetown University Medical Center has been actively engaged in multiple telemedicine programs spanning the globe and in multiple medical applications over the past 10 years. The Imaging Science and Information System Center and the Office of Medical Informatics under the leadership of Seong K. Mun, Ph.D. and Chief Engineer, Betty Levine, MS will assume the responsibility of this phase of the project. Nassib Khanafer, MS will be responsible for the system testing, training and installation. Jeff Collmann, Ph.D. will be responsible for establishing the operational scenario. Dr. Collmann will also assist in addressing the question of data security and patient confidentiality as a following activity.

4. Technical Approach

The proposed system is designed using commercially available state-of-the-art off-the-shelf components. It follows existing open standards and it is built in a modular configuration. As more advanced technologies become commercially available we will be able to keep the system state-of-the-art performance.

Because of poor communication access in most of the isolated areas we have adopted to use telephone line, either conventional telephone or a satellite links. Communication protocol is based on Internet.

The prototype telemedicine system is an Internet-based application that links three major sites: *Post*, *Server*, and *Referral*. A patient folder will be created at the *Post Site* utilizing state-of-the-art equipment and sent it to the *Server Site* over a secure Internet connection using an Internet browser where the folder will be saved in a central database. The referral physician at the *Referral Site* will be notified by automatic email and will be able to retrieve the patient folder from the central database via a secure Internet connection using an Internet browser.

5. Operational Scenario

The clinical staff at the Post Site will no longer feel be isolated since the telemedicine system will provide them access to more experienced practitioners for a second opinion. When the clinical staff at Post Site needs a second opinion, he/she prepares a patient folder, which may consist of scanned x-ray films, digital images, scanned reports or even scanned EKG graph. The telemedicine system is equipped with state-of-the-art technology to convert paper-based information into electronic format. Once the electronic patient folder is prepared a Web Database Application is used at the Post Site to submit the case to a central database on the Server Site over a secure Internet connection. The Web Database Application saves the case in the central database and notifies the Referral Site by sending an automatic e-mail.

After the Referral Site gets the notification email, which includes the Patient ID and Study ID, the referral physician accesses the central database via an Internet browser over a secure connection to retrieve the case. The Web Database Application sends the patient folder from the central database to the Referral Site. The referral physician examines the case and replies to the Post Site by phone, fax, or email.

6. Technical Description

6.1 Telemedicine System Configuration

6.1.1 Overall System Configuration

Figure 1 illustrates the general set up. The Post Site will have image acquisition devices such as x-ray digitizer, digital camera, and document scanner, which will be connected to standard ports. Once files are scanned, an Internet-based application which runs via an Internet browser will transfer the data over a secure connection to a central database server in the Server Site. The Referral Site will be automatically notified by e-mail about the new study and will be able to access the central database using an Internet browser.

6.1.2 Post Telemedicine System

Figure 2 illustrates in detail the system configuration for the telemedicine workstations at Post Site. Image acquisition devises will be connected to the computer via standard ports. A Web application will be used to send the data from the Post Site to the central database at the Server Site.

6.1.3 Server Telemedicine System

Figure 3 illustrates in detail the system configuration for the telemedicine workstations at the Server Site. The NT Server is running a Database package, Web server, and Active Server Pages as a database connector (i.e. to connected the Internet with a database). The Database package could be installed on the same machine as the Web Server or another machine on the local area network (LAN).

6.1.4 Referral Telemedicine System

The Referral Site can access the database via the Internet using an Internet browser. An x-ray viewer will be use to manipulate the images.

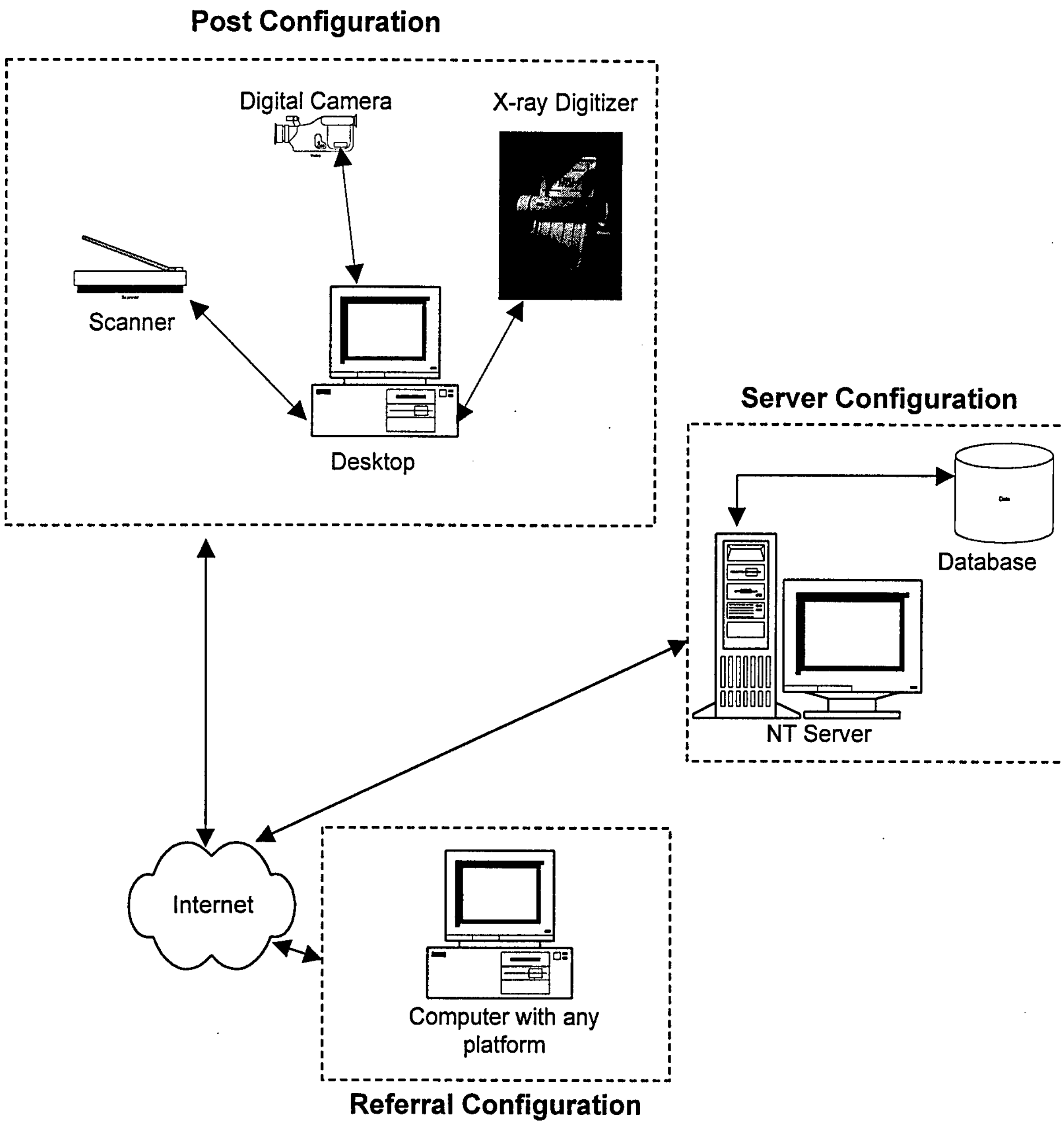


Figure 1 Overall System configuration

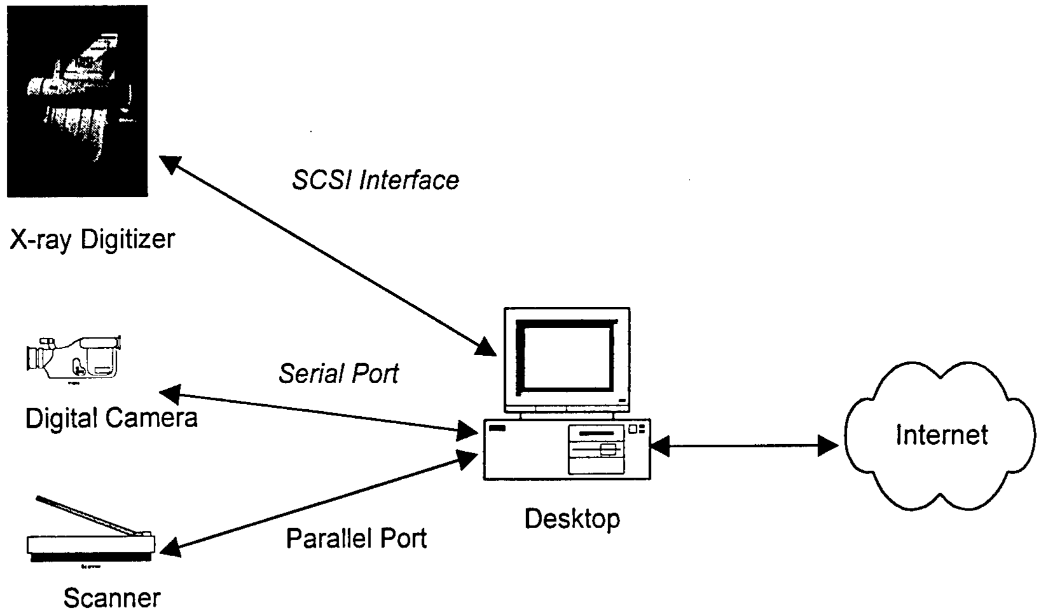


Figure 2 Post Configuration

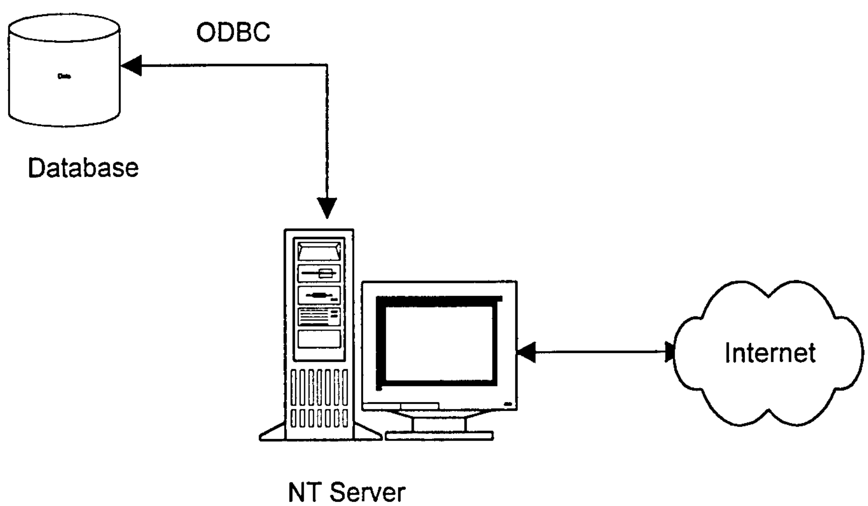


Figure 3 Server Configuration

6.2 Telemedicine Requirement

These are lists of software and hardware that should be acquired. If not specified, any commercial product should be able to deliver the desired output.

6.2.1 Post Technical Requirement

- *Personal Computer*
  Recommendation:
  Windows 95 platform because of application availability,
  Built-in 56K modem, Ethernet card and SCSI card to reduce the technical problems, SCSI hard disk to improve performance.
- *Internet Access*
- *Email Client*
- *Internet Browser*
  Recommendation:
  Intern browser that support VBScript such at Internet Explorer 4.0 or later
- *X-ray digitizer*
  Recommendation:
  Vidar 12 plus VXR, *see appendix A*
- *Digital Camera*
  Recommendation:
  Olympus D-600L, *see appendix B*
- *Document Scanner*
  Recommendation:
  PageWiz
- *X-ray Viewer*
  Recommendation:
  Osiris, *see appendix C*
- *Photoshop Application*
  Recommendation:
  Adobe Photoshope 4.0

6.2.2 Server Technical Requirement

- *Personal Computer*
  Recommendation:
  Windows NT 4.0
- *Internet Access*
- *Internet Browser*
  Recommendation:
  Internet browser that support VBScript such as Internet Explorer 4.0 or later
- *Web Server*
  Recommendation:
  Internet Information Server 4.0
- *SQL Database*
  Recommendation:
  Microsoft SQL Server 6.5
- *Web Development Tools and components*
  Recommendation:
  Visual InterDev 1.0

- *File Transfer Application*
  Recommendation:
  Web Database Application, *see Software Architecture 6.3*

6.2.3 Referral Technical Requirement

- *Personal Computer (any platform)*
- *Internet Access*
- *Internet Browser*
  Recommendation:
  Internet browser that support VBScript such as Internet Explorer 4.0 or later
- *X-ray Viewer*
  Recommendation:
  Osiris, depending on the platform Unix or PC.

6.3 Software Architecture

6.3.1 Design Specifications

Because the Web Database Application will be fulfilling a critical role, these critical specifications were considered in developing the application:

1. *Scalable*

Technologies that support standard protocols only have been utilized which makes the application scalable without a lot of effort to reengineer the application.

2. *Reliable*

Due to it's critical role, the application has to be reliable. Robust component which support open standard has been utilized to build the application.

3. *Easy to support*

The client side (i.e. the Post and the Referral) dose not require special configuration. The required software are off-the-shelf products that have been proven to be stable. The server side (i.e. Server Site), however, has special application to handle data transmission and database connection (i.e. Web Database Application). The application runs on the Web Server which makes very efficient to support since there is no need to travel or send patches once deployed.

4. *Easy to enhance and add new capabilities*

Component Object Model (COM) is the infrastructure technology for the Web Database Application. It is a component-based technology, which allows the developer to add new capabilities by integrating off-the-self component, figure 4.

5. Evolves with the technology

Since the application uses standard protocols, as the protocol enhance, the application will enhance.

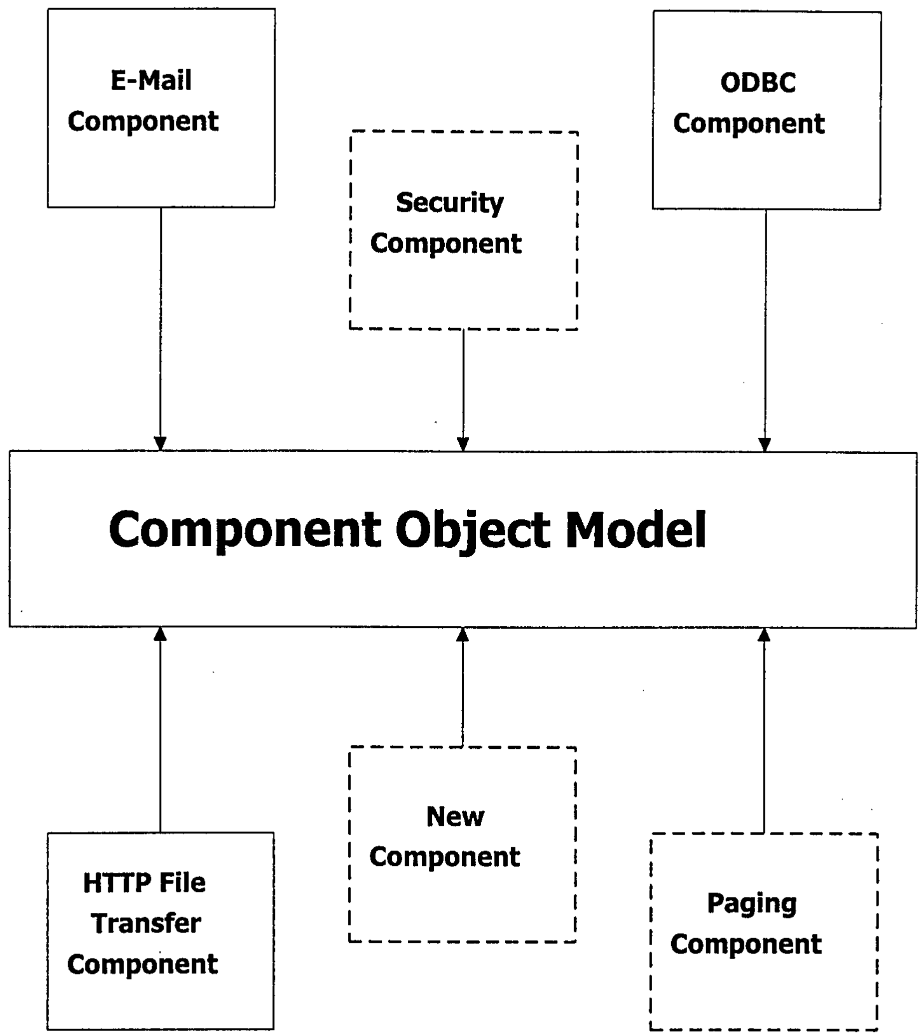


Figure 4 COM is the foundation of the application any component can be easily integrated (solid box means it is currently available, dashes means it could be integrated)

6.3.2 Overall Software Architecture

Figure 5 describes the overall software architecture. The client-side requires an Internet browser only to access the application. The Internet browser accesses the Web Server via secure connection (i.e. http protocol that support secure socket layer or https). The Web Database Application which uses the Web Server (i.e. Internet Information Server), Database Connector (i.e. Active Server Pages), and Database package (i.e. SQL Server) handles all the transaction between the different component in the server.

6.3.3 Security Model

Figure 6 illustrates the security model of the application. access control and encryption of the application. When the Internet browser tries to connect to the server via the standard Internet protocol (i.e. http) the server establishes a secure connection using secure socket layer (SSL), https, where the server and the client exchange digital IDs. Once the exchange happens and each party acceptance the digital ID the connection establishes and the user is asked to enter his/her password

6.3.4 Application Flow Chart

Figure 7 describes how the application works. Application always takes the user to the login page even if the user tries to skip it, the application will not allow that. Once the user enters a valid username and password, the user could add a new case or review one.

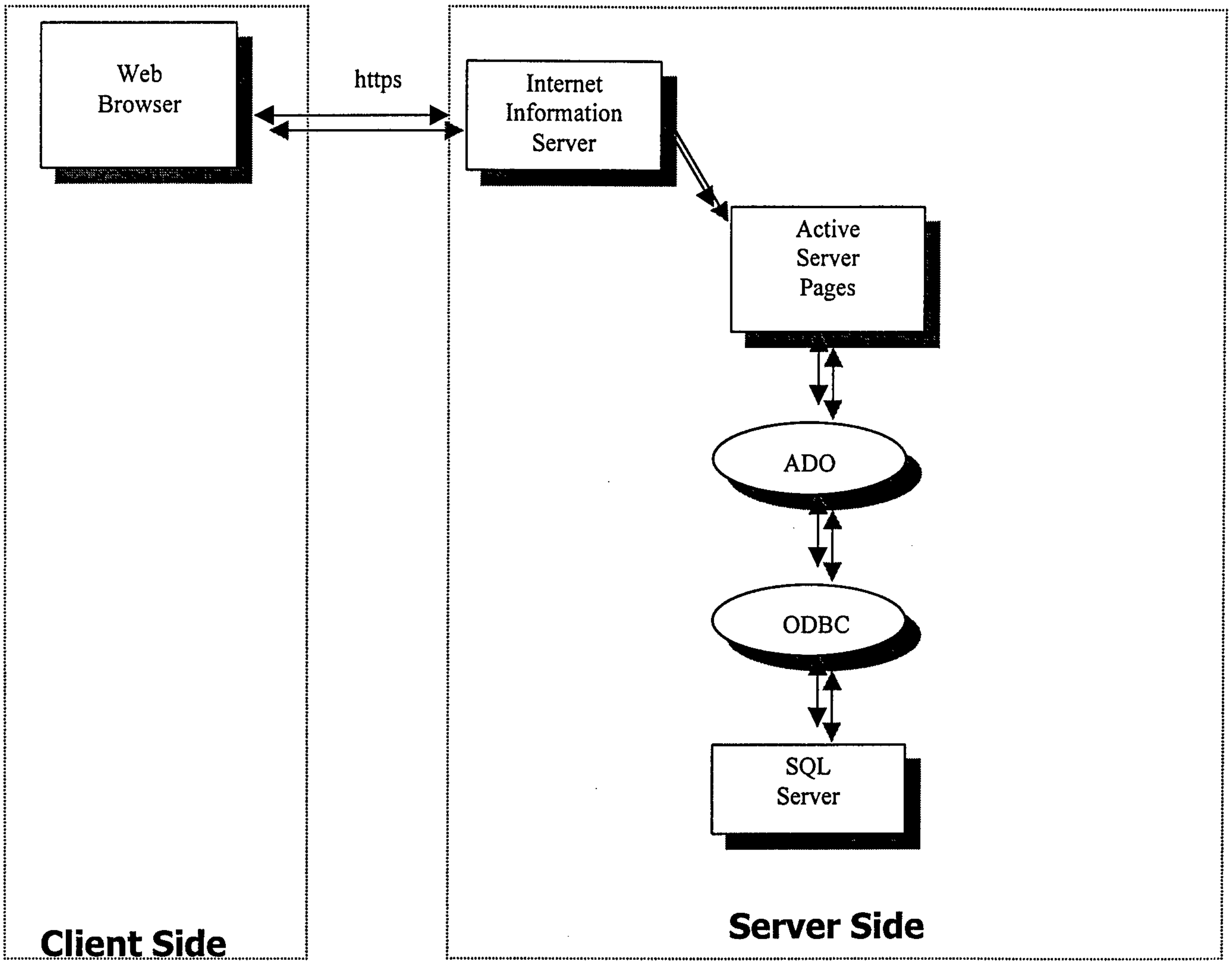


Figure 5 Overall Software Architecture

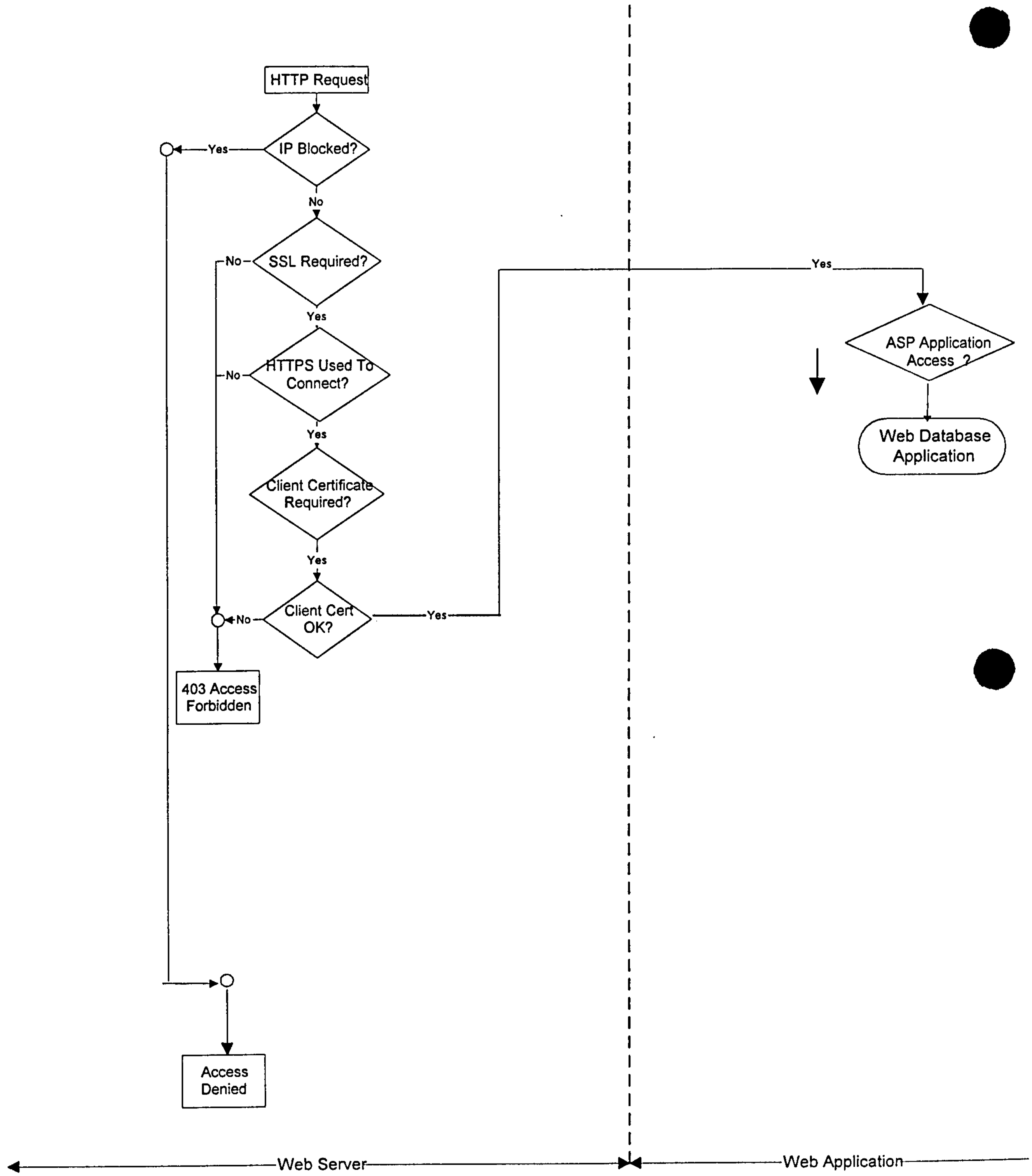


Figure 6 Security Flow Chart

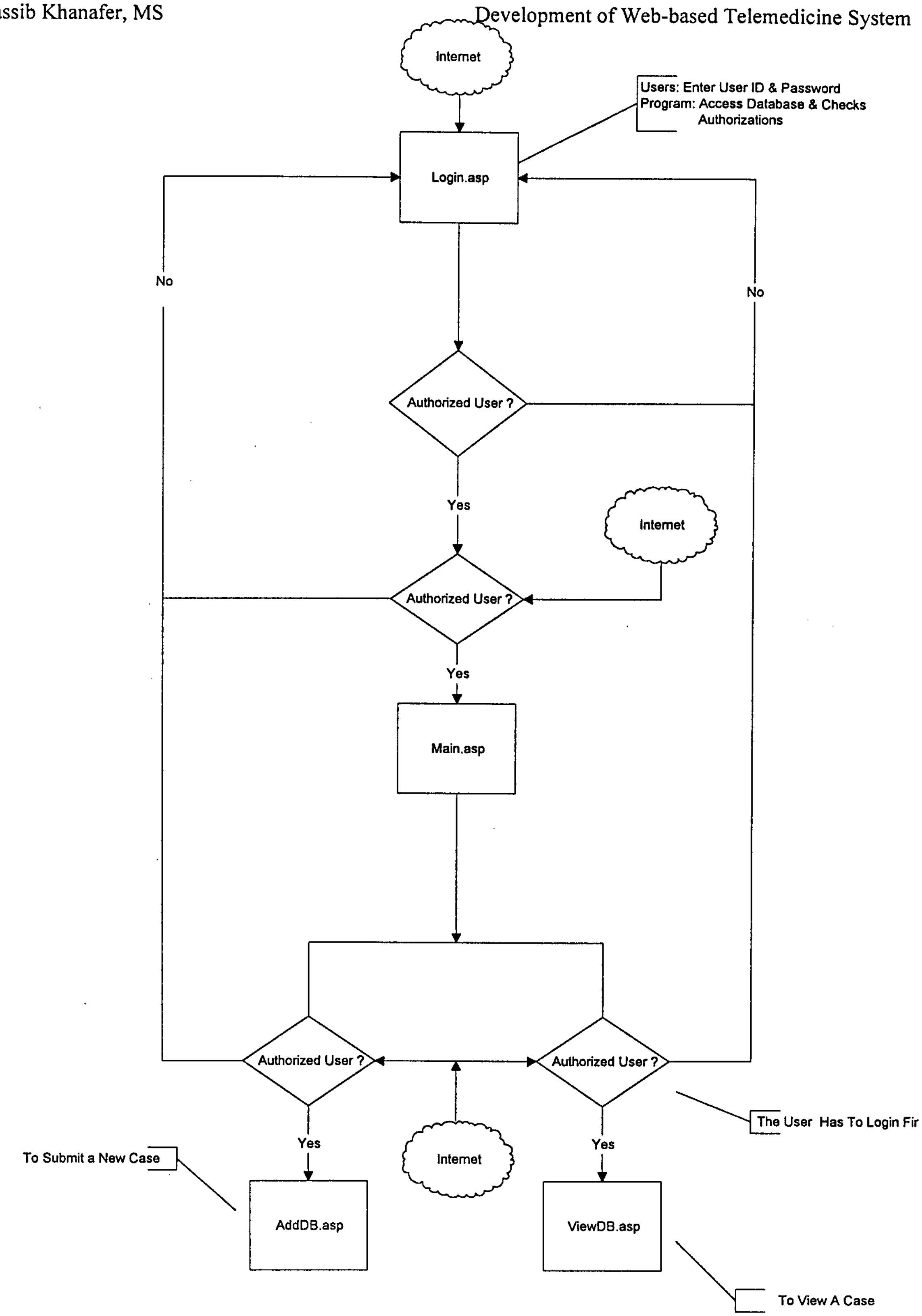


Figure 4 Web Database Application Flow Chart

7. Open Issues

Telemedicine raises number of challenges. Although this project addresses the technical challenges only, others challenges have to be addressed:

1. Security Policy. The prototype has a security component to ensure privacy and confidentiality, however it should be compliant with the acquiring institution.
2. Database Design. The prototype is based on a central database, however the database design is should complaint with existing legacy database.
3. Post and Referral coordination. The communication between the Post site and the Referral site has to be further defined.
4. Technical Support. Engineering support to ensure stability of the project, periodic upgrades to the system and enhances, and periodic training have to be addressed.

A comprehensive list of telemedicine issues can be found in appendix E

8. User Manual

8.1 X-ray Scanner

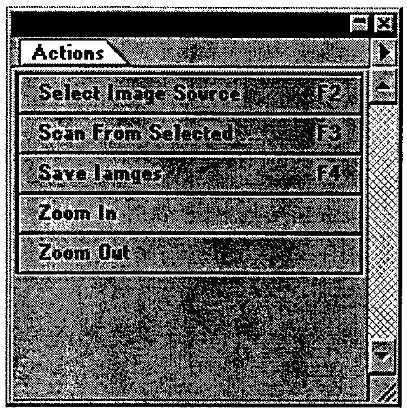
8.1.1 Scanning an x-ray

To scan an x-ray:

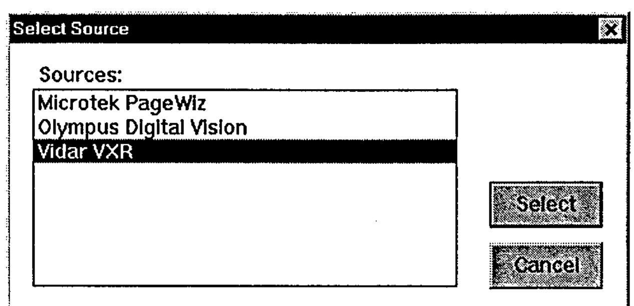
1. Run **Adobe Photoshop** (double click on the Adobe Photoshop icon

Adobe Photoshop

2. On the right there are predefined keys, press **Select Image Source** or press **F2**

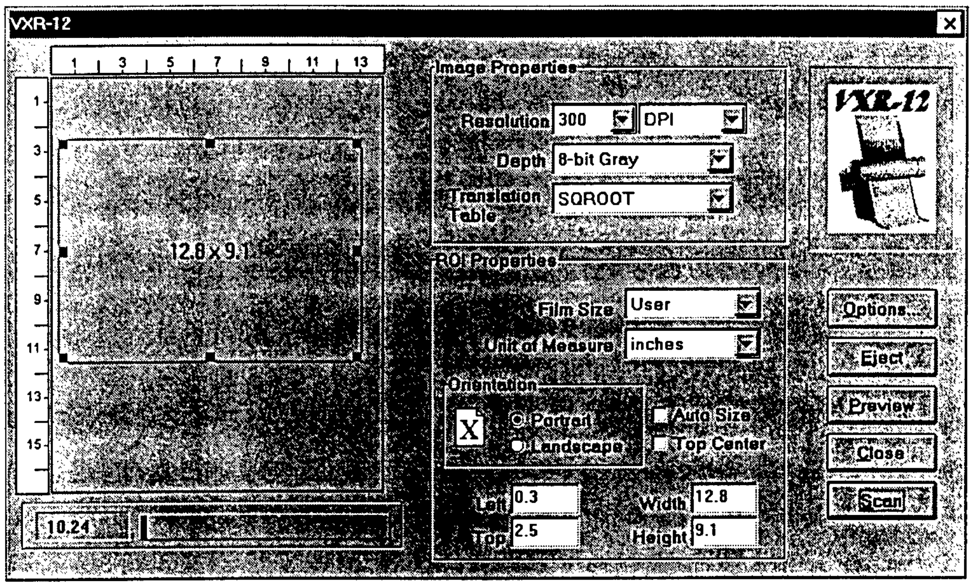


3. Choose **VIDAR VXR**

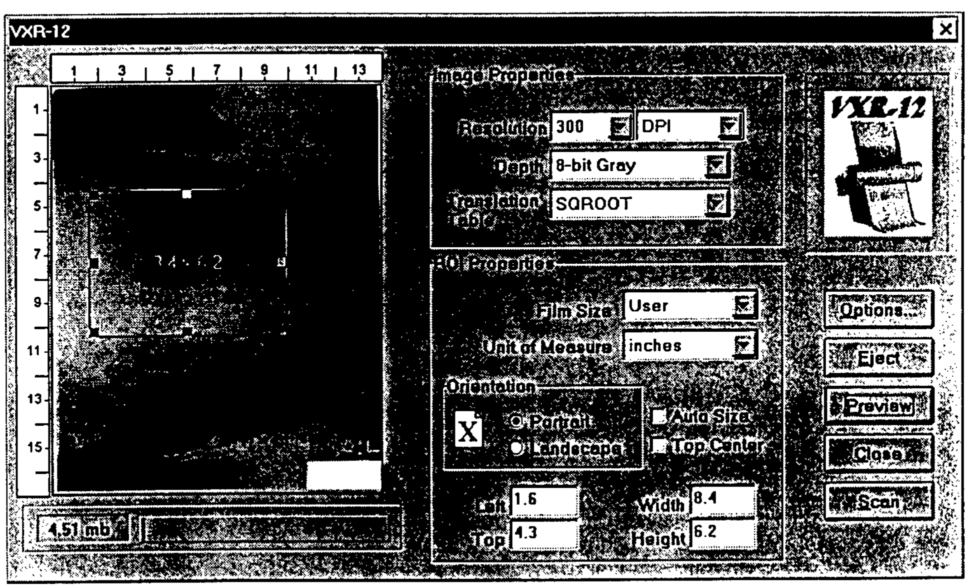


6. Press **Select**

5. Then, again from the keys on your right, Press **Scan From Selected** or press **F3**



6. Press **Preview**



7. Position the box around the part of the image that you want scanned, then press **Scan**
8. **Save** the scanned document

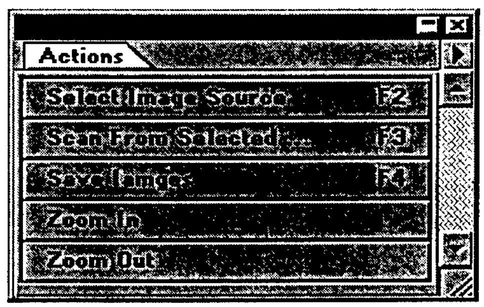
8.2 Digital Camera

8.2.1 Downloading images from the digital camera

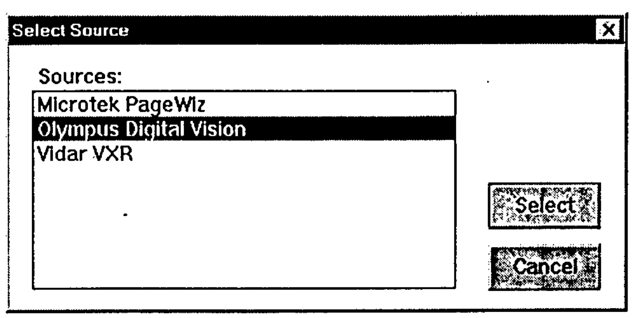
To download images from the digital camera:

1. Run **Adobe Photoshop** (double click on Adobe Photoshop icon)

2. From the predefined keys on the right, press **Select Image Source** or press **F2**

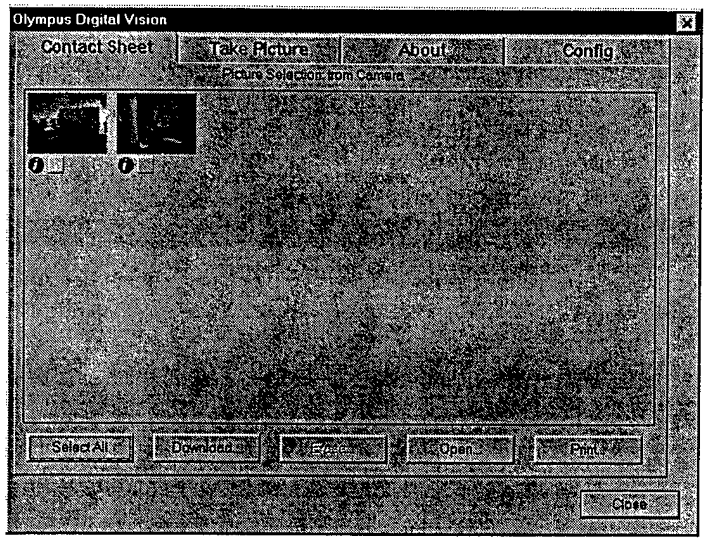


3. Choose **Olympus Digital Vision**

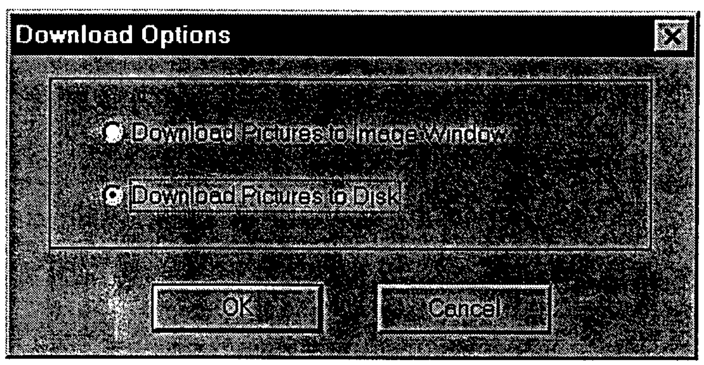


4. Press **Select**

5. Then, again from the keys on your right, Press **Scan From Selected**
6. Olympus will open. **(Depending on the number of images on your camera, this may take a little while.)**



7. In the **Contact Sheet,** press **Select All,** and then press **Download.**
8. Choose **Download Picture To Disk**



9. Choose where to download the image. This will download the image, which may take awhile.

10. The image is now saved to a file.

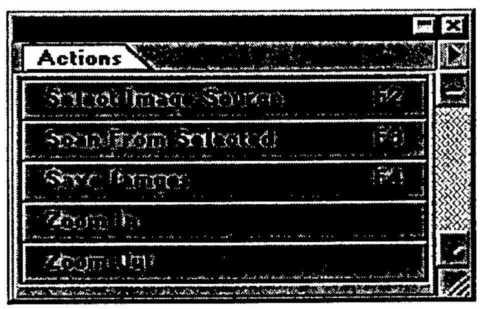
8.3 Document Scanner

8.3.1 Scanning a document

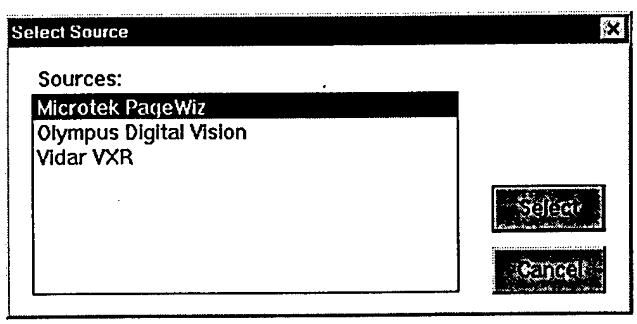
To scan a document"

1. Run **Adobe Photoshop** (double on Adobe Photoshop icon)

2. From the predefined keys on the right, press **Select Image Source** or press **F2**

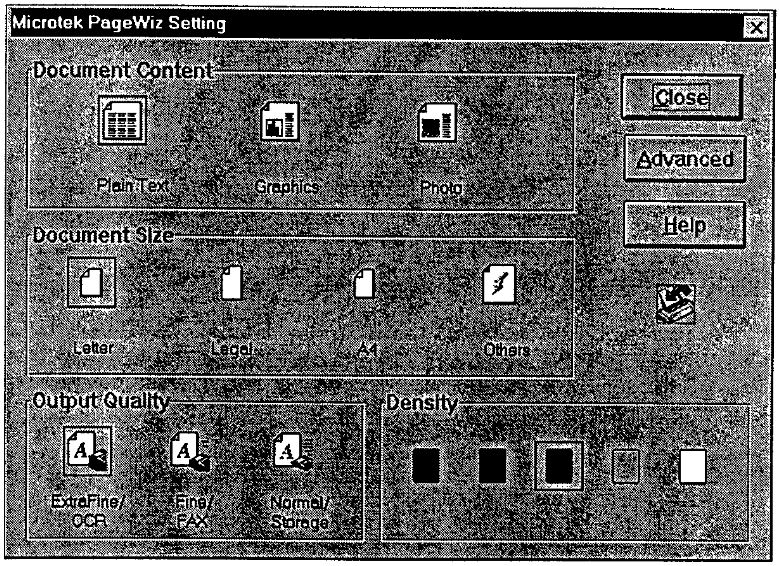


3. Choose **Micotek PageWiz**

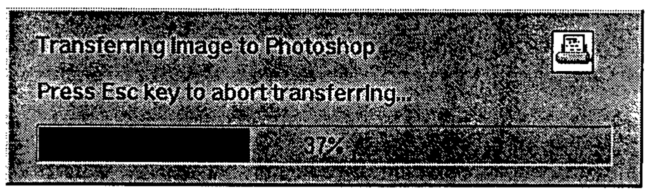


4. Then press **Select**

5. Then, again from the keys on your right, Press **Scan From Selected**
6. PageWiz will open new Window



6. Put the paper in the scanner, and the scanner will start to scan.



6. Save the file.

8.4 Web Database Application

8.4.1 Submitting a case

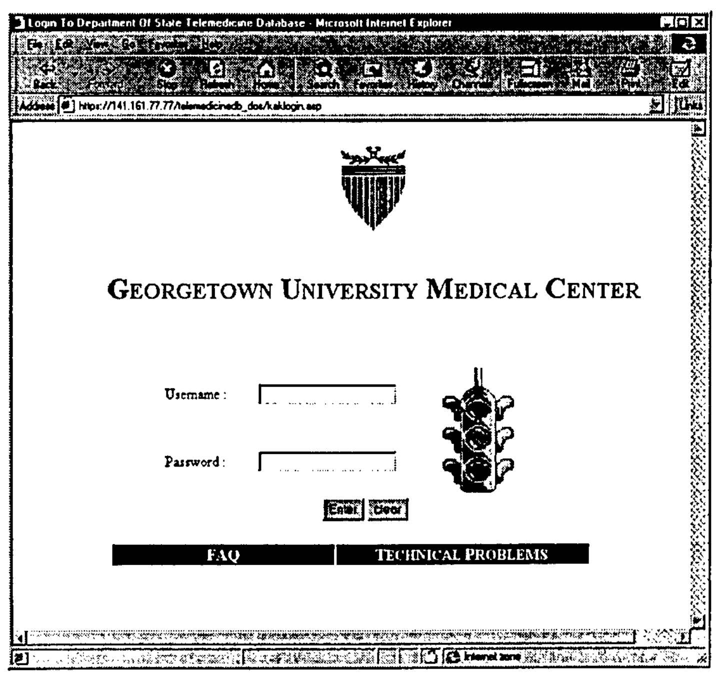
To submit a new case:

1. Run **Internet Explorer (IE)** (double click on the icon)

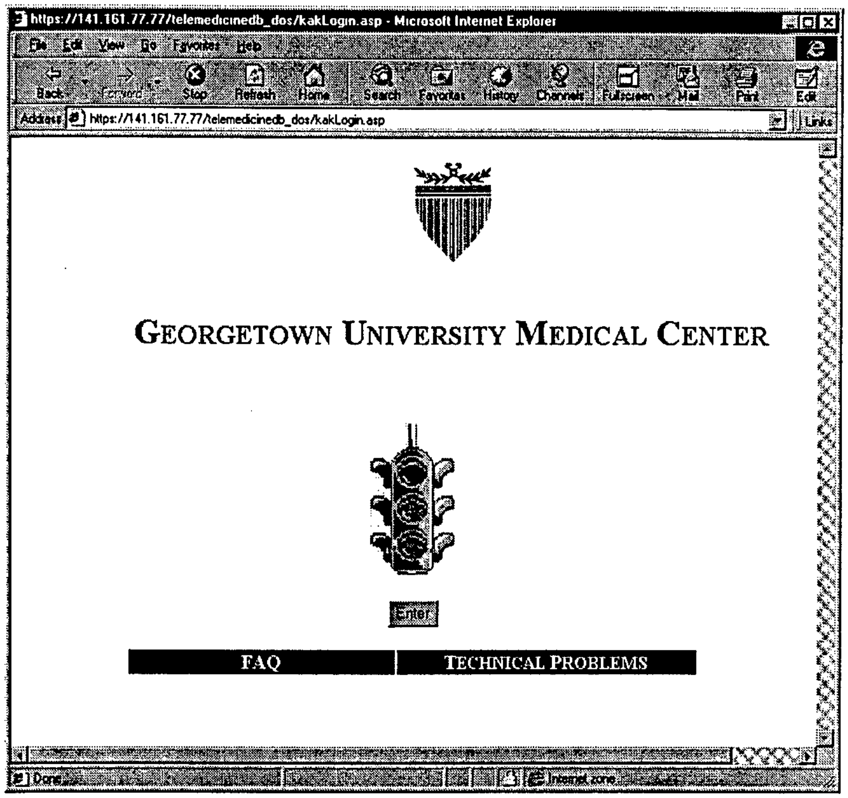
2. IE has been programmed to go to the **Web Database Application** once it is opened. However, if it does not, type in the address:

https:<<Web Site>>

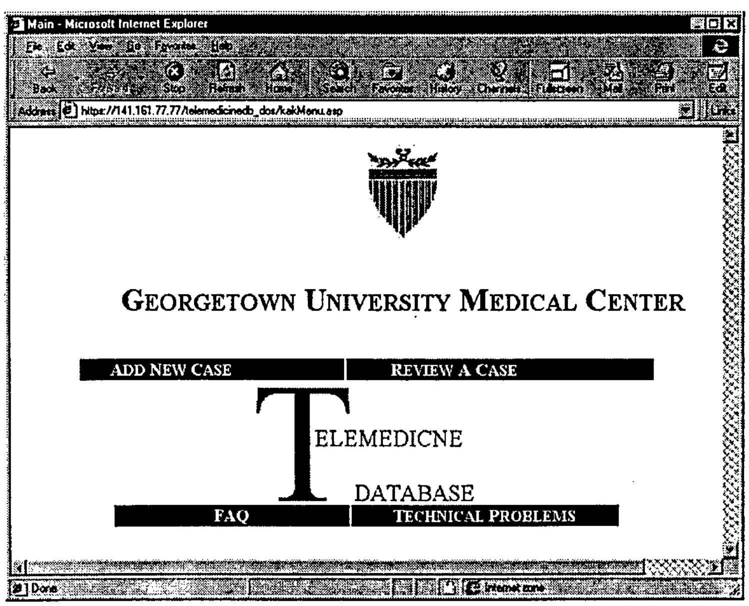
3. The application establishes a secure connection to ensure confidentiality and privacy. Then the application asks for the user log in and password, and press **Enter.**



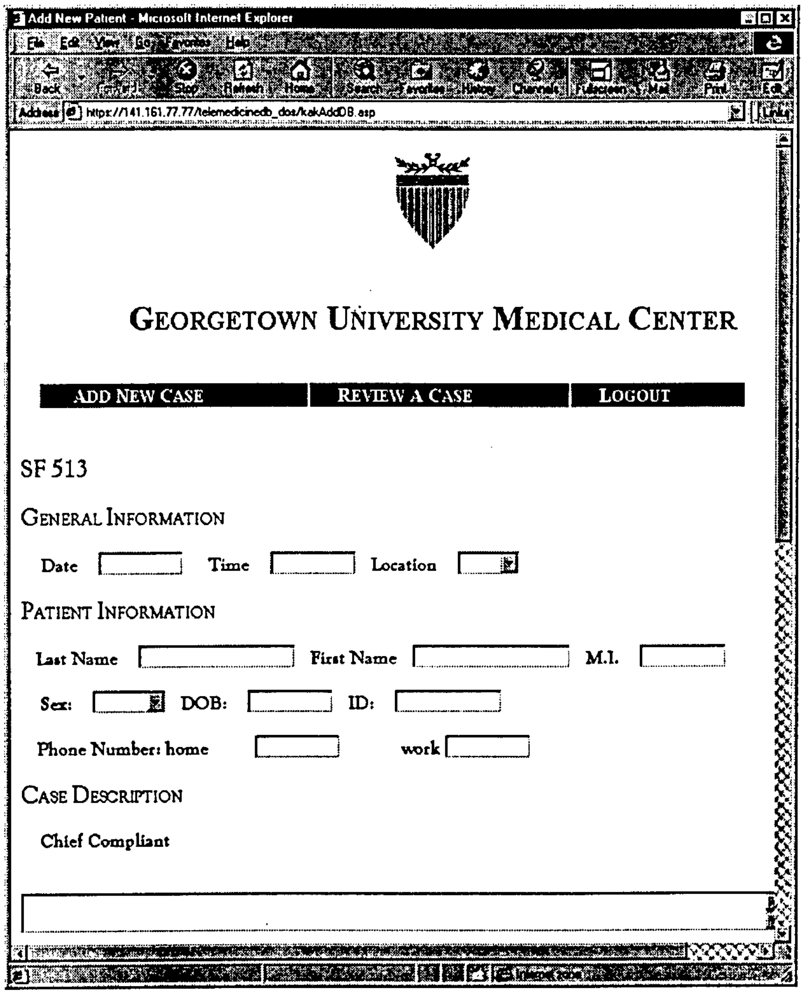
4. If authorized, press **Enter**



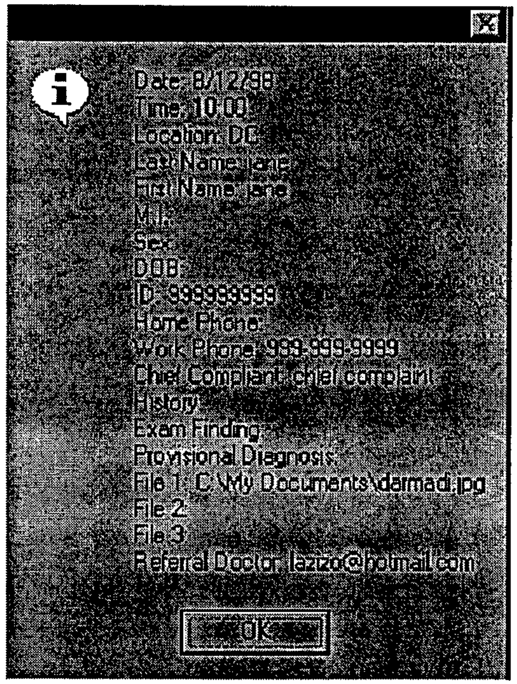
5. From the main menu, press **Add New Case**



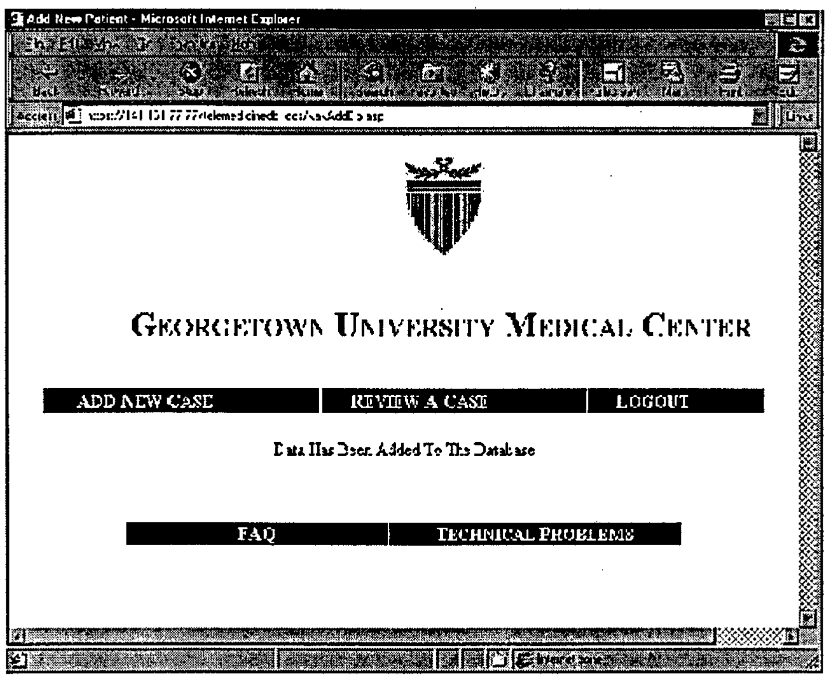
6. Fill all the necessary information in the **SF 513**. For the files, either enter the path or try to find one by selecting **Browse**.



7. Once done, press **Submit Form.**
8. The application will prompt you to verify the data entered. It is very important to verify all the data otherwise attempting to submit wrong formatted will fail the whole process.



9. If it succeeds, the application will confirm, and send an email to the referral physician.



8.4.2 Reviewing a case

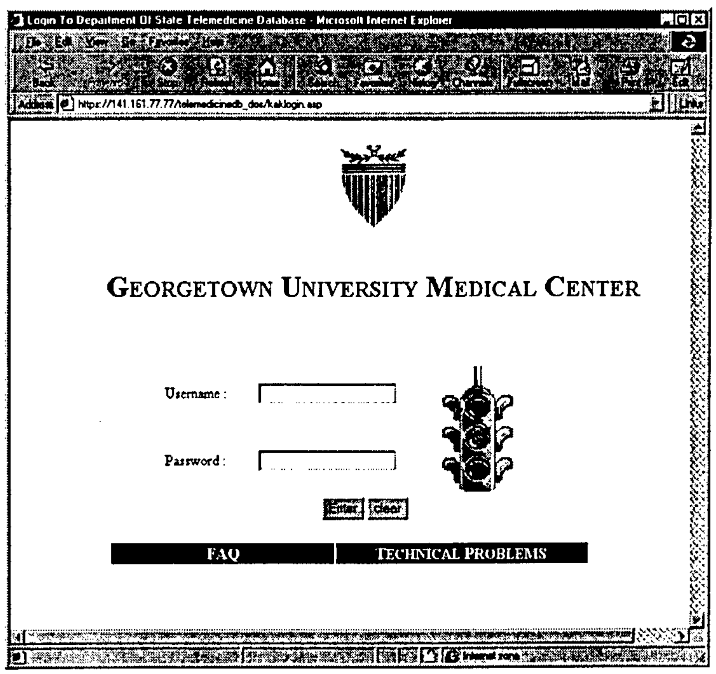
To review a new case

1. Run **Internet Explorer (IE)** (double click on the icon)

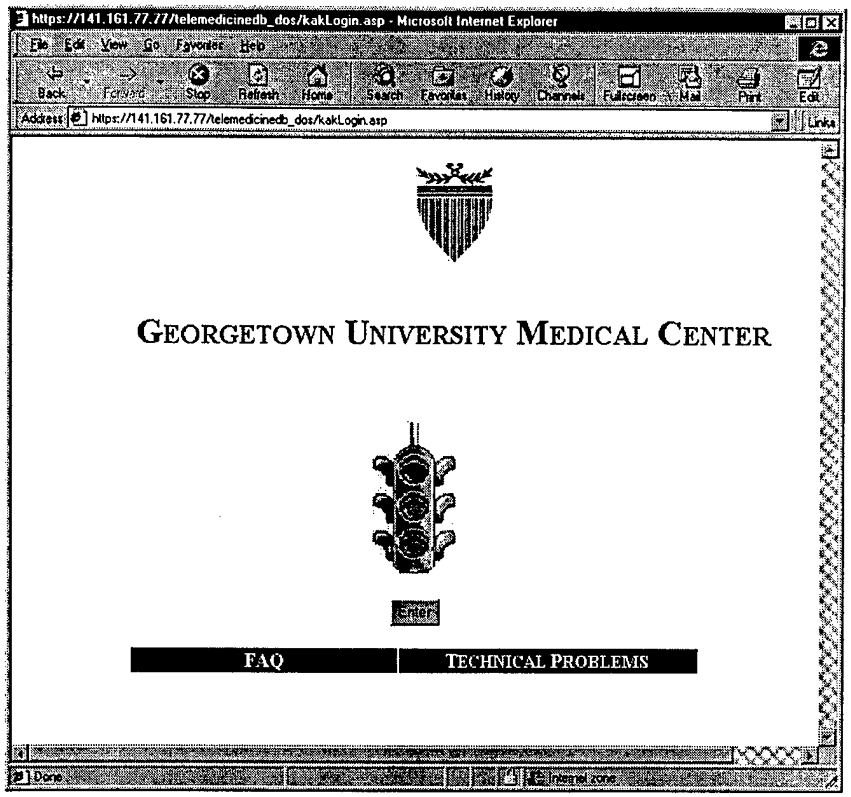
2. IE has been programmed to go to the **Web Database Application** once it is running. However, if it does not, type in the address:

https:<<Web Site>>

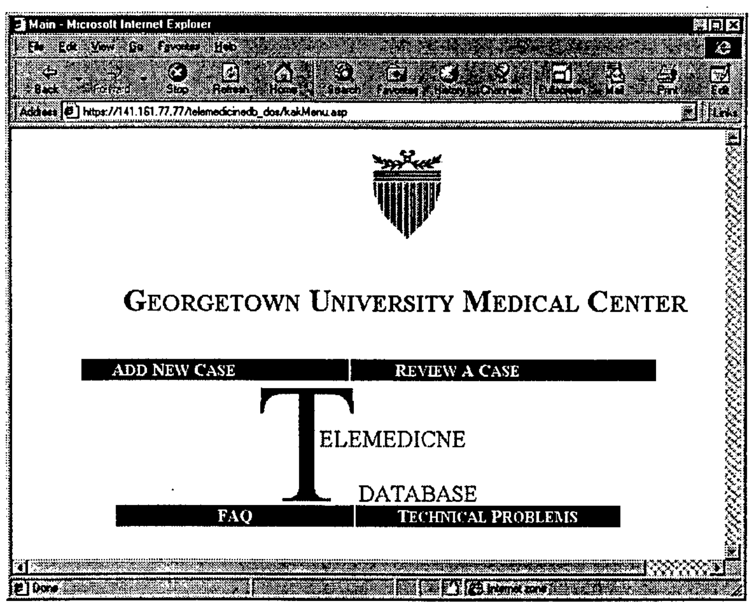
3. The application establishes a secure connection to ensure confidentiality and privacy. Then the application asks for the user log in and password, and press **Enter.**



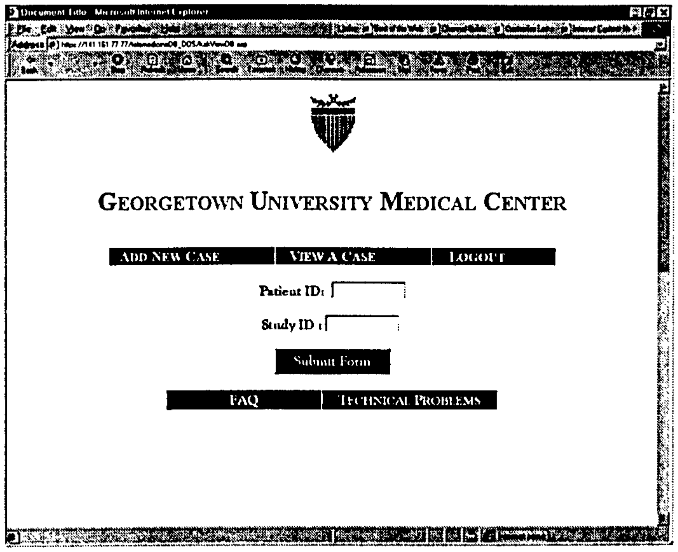
4. If authorized, press **Enter**



5. From the main menu, press **Review A Case**



6. Enter **Patient ID & StudyID**



7. Press on **Submit**
8. The application will retrieve the patient folder.

8.5 X-ray Viewer

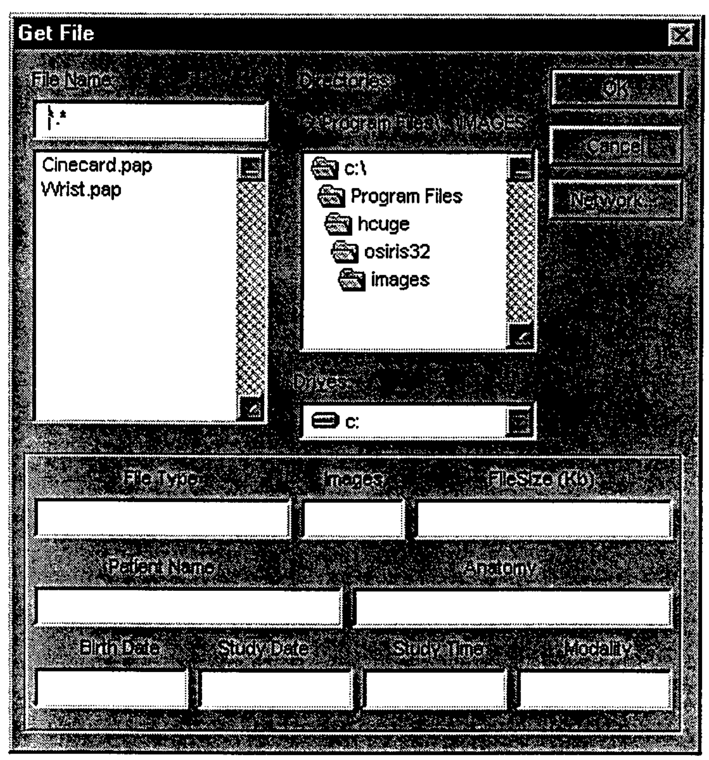
8.5.1 Opening an image

To open an image file :
1. Once the patient folder has been retrieved from the central database (see Web Database Application- Retrieve A case), the user can either:
Double click on the image and an application will run automatically
Or

Right click on the image->save image as

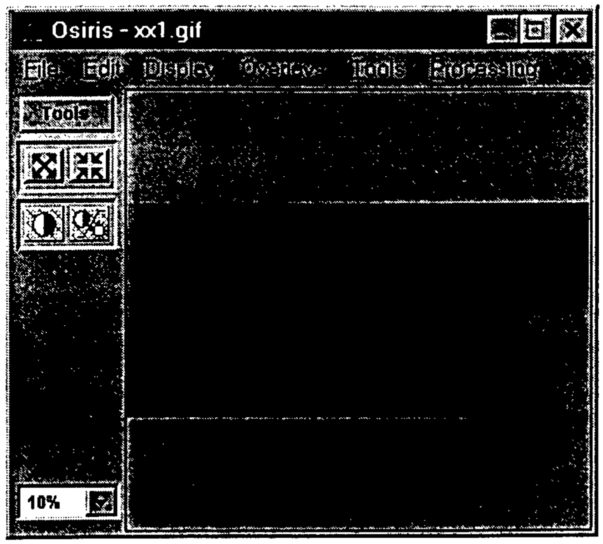
1. Run **Osiris** (Double click on Osiris icon)

2. To select the correct file, locate the folder by looking under the heading for **Directories,** and find the correct folder by looking under the heading **File Name.**



4. Highlight the file name and Press **OK**

7. The file is now open in Osiris.



Strategic Telemedicine: A Guide for Planning

Telemedicine Working Group
Georgetown University Medical Center

Seong K. Mun, Ph.D, Chairman
Jeff Collmann, Ph.D., Executive Secretary

Thinking Strategically about Telemedicine

Georgetown University Medical Center believes that planning, installing and evaluating major technological systems should support the institution's strategic thrust. With this in mind, the medical center administration commissioned a group of faculty and administrators (named the Telemedicine Working Group or "TWG") to study potential uses of telemedicine in the medical center's future. After several meetings, the TWG realized that many people were interested in telemedicine but few had much technical knowledge about its potential utility. The TWG also realized that the term "telemedicine" means different things to different people. The TWG decided therefore to develop a method for evaluating the potential feasibility of telemedicine projects as an aid to strategic medical center planning as well as individual faculty efforts. The "Georgetown Telemedicine Guide" explains this method. Upon completing the "Georgetown Telemedicine Guide", the TWG realized that it explains an approach that any health care provider potentially could use to assist in developing its own telemedicine projects and offer the Georgetown Telemedicine Guide as a general resource for the health care community.

Georgetown University Medical Center will perform its classic functions of patient care, medical education and biomedical research in new ways during the 21st century. National changes in the system of health care financing, medical practice organization and patient demographics require Georgetown to reach out beyond its own walls into the surrounding community. Advanced computer networks linking distributed centers of activity and expertise could become the foundation of Georgetown as a new type of academic medical center, a medical center without walls.

Telemedicine shall be incorporated as a strategic capability in the clinical, educational, research and administrative infrastructure of Georgetown University Medical Center. Applications of telemedicine should function to increase direct and indirect sources of revenue, reduce direct and indirect costs, and improve the quality of organizational and customer service. Experience with telemedicine will help GUMC evaluate the relative utility and potential importance of developing a computerized clinical record to supplement its emerging information system. By contributing to its infrastructural development, telemedicine will give GUMC a strategic advantage in regional, national and international competition in all areas of its work.

The Telemedicine Working Group (TWG) was formed to investigate ways to foster the growth and development of GUMC through the use of telemedicine by performing the following functions:

1. Identify, evaluate the feasibility of, and when authorized sponsor telemedicine projects of strategic importance to GUMC. The medical center's computerized information and telecommunications system should eventually offer telemedicine as part of its general services. Until the information system supports such functions, however, GUMC may sponsor individual telemedicine projects to address specific clinical, educational or administrative needs. This Georgetown Telemedicine Guide (Telemedicine Guide) explains how to identify, assess and select telemedicine projects for potential GUMC implementation. The TWG shall proactively evaluate the potential role of specific telemedicine projects for the medical center's strategic development using the Telemedicine Guide as a planning tool.

2. Function as a resource center for all GUMC faculty and staff working on telemedicine projects.As GUMC faculty and staff develop telemedicine projects to serve specific needs in their own programs, they may consult the TWG for information and support. The TWG will maintain information about telemedicine projects that are completed, underway and being planned. This information will enable the TWG to refer project developers to colleagues with relevant experience and knowledge. The TWG will make the Telemedicine Guide available for all GUMC project developers to use in planning their work. The TWG will function as a resource center designed to help project leaders develop the best projects possible not as a regulatory panel on the model of the Institutional Review Board.

3. Provide advice to GUMC faculty and staff on specific telemedicine projects when requested. In addition to functioning as a general resource center, the TWG will respond to requests for advice and assistance on specific projects. Depending on the needs and desires of the project developers, such assistance may range from providing comments on project proposals to becoming a functioning member of the project team. The Telemedicine Guide includes a list of TWG members, contact information and brief summaries of their telemedicine experience.

4. Advise GUMC regulatory committees such as the Institutional Review Board about issues and, when requested, specific projects in telemedicine. From time to time, GUMC administrative and regulatory bodies may require information about issues and projects in telemedicine. Although not functioning as a regulatory body, the TWG will respond to requests for information or guidance as required.

Selecting Telemedicine Applications

When considering particular telemedicine projects, Georgetown conducts a formal process of project identification, planning, implementation and evaluation.

Evaluating the organizational feasibility of telemedicine projects

Various groups at GUMC have explored, started and, in some cases, completed clinical and educational telemedicine programs. To aid in developing future projects, the TWG maintains a list of completed projects, summary of lessons learned, and implications for the future of current and past telemedicine projects. TWG actively solicits information on new projects as they are developed. Appendix A summarizes the information about current and past projects gathered by the TWG to date.

The TWG examines the GUMC strategic plan with an eye to identifying clinical, educational, research and administrative areas where telemedicine could significantly amplify the value of planned investment. After identifying potential telemedicine projects, the TWG takes the following steps formally to evaluate their individual feasibility:

Identify conditions promoting or inhibiting likely achievement of project goals.

Many conditions potentially affect the likely success or failure of a specific telemedicine project. Although these conditions vary, the TWG has learned to ask certain important questions, including:

a. Does the telemedicine project address a critical need or problem?

Fascination with the capabilities of modern telecommunications has sometimes encouraged investigators to launch telemedicine projects with more glitter than substance. Such projects often end as soon as the media departs and the news story grows old thus contributing to telemedicine's reputation as useless technowizardry. When selecting projects for development, the TWG focuses on possibilities where telemedicine will make a positive contribution to difficult problems. For example, hemodialysis patients frequently depart early from their dialysis sessions thus reducing the effectiveness of the treatment. By giving them greater access to their nephrologist through weekly videoconsultations, telemedicine encourages patients to complete their prescribed dialysis time. Clinical, educational and administrative needs assessment constitutes the foundation of any successful telemedicine project.

b. Does the problem matter to the practitioner who owns it?

Precisely because few clinicians, educators or administrators love technical capabilities for their own sake, telemedicine projects that do not solve problems that matter to the relevant practitioner risk failure. A telemedicine expert may see the potential relevance of a telemedicine solution; but telemedicine offers no solution to problems about which practitioners do not care. Beware of the Champion Syndrome! Every project needs a clinical champion to succeed. Champions come in several forms. Visionaries may offer guidance to their colleagues whose eyes focus on the daily problems at hand. Some champions promote whatever gizmo glitters brightest on the contemporary scene. True champions must perceive a connection between telemedicine and an important clinical problem in their discipline that warrants the work.

c. Will the problem require continuous solving using telemedicine?

Telemedicine has witnessed many experiments that worked telemedicine right out of a job. For example, primary practitioners often benefit from telemedicine consultations with remote subspecialists. It commonly occurs, however, that consulting with subspecialists increases the primary practitioner's understanding of a problem thus eliminating the need for more telemedicine consults. This phenomenon seems most common with acute illnesses in which immediate intervention resolves the clinical problem. When managing chronic illnesses such as end stage renal disease, however, telemedicine functions as part of the infrastructure of routine care. Telemedicine may make a sustainable difference when it affects acute decisions with major treatment effects such as whether to evacuate a patient from a remote location.

d. Can the impact of telemedicine be measured?

When designing a telemedicine project, investigators should identify measures of their relative success. Some problems offer quantitative measures enabling precise evaluation of relative impact (such as Kt/V in hemodialysis). Measuring other effects may require more indirect, qualitative indicators such as patient satisfaction. No project should begin without identifying measures of success or failure. When choosing measures, investigators should remember that a single project has several objectives and find measures for each project objective.

e. Does improved telecommunications offer the best solution to the problem? Telemedicine may offer a solution to an important problem, but other, less demanding solutions may exist. Given its expense and typical complexity, telemedicine should be deployed only where it offers the best of alternative solutions. This consideration helps guard against conducting a telemedicine project just for the sake of seeing the technology perform.

Evaluate organizational risks to project success

Telemedicine projects face identifiable organizational risks. Some organizational risks characterize any large project. Others are specific to systems of telecommunication. Dr. Turner, a member of the TWG, has developed the concept of "telecompetence" to help interpret the process of managing these risks. By telecompetence Turner means the variable ability of organizations or individuals to integrate a new communication technology within everyday work practices. Turner identifies six conditions of telecompetence that promote or hinder a telemedicine project's success, including

a. Rationale: Each partner must feel some incentive to collaborate and participate in the telemedicine project. Developing indicators of shared commitment is an important project management task. In the early phases of project development, one should monitor measures of collaborators' mutual interest and good will such as a willingness to attend project meetings or meet proposal deadlines. A Memorandum of Understanding can formally state expectations and responsibilities once a firm project plan exists.

b. Access: Collaborators must have opportunities to participate in the design, implementation and use of reliable telemedicine systems. From a project management perspective, this is an organizational as well as technical consideration. Having access to the design process helps build commitment.

c. Expertise: Successful telemedicine projects require technical and managerial expertise. In addition to having appropriately skilled principal investigators, projects benefit from having a team of people who have worked together on pilot studies. Pilot studies represent a good method for acquiring preliminary data for funding proposals, developing technical expertise, and building a project team. This is particularly important for complex projects including several investigators, departments or organizations.

d. Co-Creation of a Communicative Environment: Project members must mutually develop understanding of how to accomplish tasks, implement protocols, and communicate effectively using the telemedicine system. When this process occurs, projects develop the organizational resilience necessary to manage contingencies and setbacks as well as successes.

e. Norms, Rules, and Expectations: Project leaders must establish some ground rules for system use. On the other hand, some norms of behavior will emerge as the project develops. These processes enable projects to progress.

f. Communication Protocols: As established and emergent norms become more engrained within the project, they may become formalized in specific protocols. Such protocols serve as blueprints for understanding the social contracts, relationships, and interactions occurring within a project.

Estimate clinical, educational and/or administrative benefits measured in terms of increased revenues, reduced costs, and/or improvements in quality

The TWG should focus its attention on developing telemedicine projects that produce important organizational benefits. In the contemporary situation, telemedicine projects should either produce new revenues or reduce operating costs while maintaining or improving quality of services. Project evaluation requires careful analysis of the source, magnitude and impact of prospective revenues or cost savings. Project developers should include measures of quality of service as part of all evaluation instruments.

Evaluate medico-legal risks

Telemedicine poses some special legal problems because of the potential for offering services across state lines. During the last year, federal efforts to facilitate interstate telemedicine services failed in the face of local opposition. This means that telemedicine projects including collaborators from several states must pay close attention to licensing and liability jurisdiction issues as part of their initial planning. Because the situation is so contentious and dynamic, telemedicine project developers should consult closely with GUMC legal counsel for advice on potential medico-legal problems.

Rank projects on a scale of feasibility from low to high

The TWG should use the information gathered while taking steps 1-4 to form a picture of a project's organizational feasibility. This analysis should enable the TWG to rank acceptable projects in terms of their relative feasibility. The TWG may eliminate some projects at this stage. The TWG may recommend subjecting highly feasible projects to technical analysis.

Determine the technical requirements of telemedicine projects

Many technical approaches exist for providing "telemedicine" services. Although videoconferencing and telemedicine are often mentioned in the same breath, the telephone, Internet, ISDN, T1 lines and satellite platforms offer many alternatives whose suitability for particular situations varies. New telemedicine products emerge daily. Telemedicine may also be done using equipment originally designed for use in non-medical situations. Choosing the appropriate equipment for a telemedicine project requires careful analysis. The following questions help guide the technical analysis.

1. What technical functionality does the project require?

The needs assessment drives the answers to this question. Not all telemedicine projects require videoconferencing. Most technical services come in a variety of flavors. The demand for Internet based services with its telephone-based technology has produced new products. Choices increase daily but are constrained by the services a project proposes to deliver. Although the current Internet supports low cost videoconferencing, for example, the image quality required of most clinical applications precludes using existing technology. Internet videoconferencing may nonetheless function well in some projects depending on its use.

2. What telecommunications bandwidth does the project require?

Making a selection of equipment to meet a project's needs usually establishes a minimum requirement for bandwidth, or rate of data transmission. Internet videoconferencing does not meet most clinical needs because Internet bandwidth is too low. Although image data moves across the Internet, the slow rate of transmission yields choppy, poor resolution images unsuitable for clinical diagnosis.

3. May equipment be purchased off the shelf or does it require custom development?

As the market for telemedicine products has developed, conventional, off the shelf products have become increasingly available for many telemedicine applications. Moreover, standard products such as videoconferencing equipment or personal computers compose segments of "telemedicine" networks even though not specifically designed for medical use. If a project requires developing custom applications, it becomes riskier and often more costly.

4. Is the technology known or must it be learned?

As Turner emphasizes, telemedicine users must develop expertise in using the equipment and services. All projects should include training for prospective users but should also evaluate the relative complexity of proposed technology as a factor in the likelihood of successful use. Moreover, if a project addresses populations with special needs, project leaders should incorporate meeting their access and training requirements into the project design.

5. Does the project require new infrastructure or technical capability?

Many telemedicine projects begin as freestanding efforts that require installing dedicated or specialized communications infrastructure. As the GUMC information system develops and Internet based applications emerge, telemedicine projects will use common infrastructure at different levels of the global communications network.

6. Is technical support available in-house or must it be purchased?

Few telemedicine applications are "plug-and-play" thus requiring technical support at some level. Projects vary in their support requirements and in the availability of suitable personnel on GUMC's staff.

By combining the results of the organizational and technical analyses, the TWG should be able to rank prospective telemedicine projects in terms of their relative organizational and technical feasibility.

Develop business plans for telemedicine projects

The TWG will sponsor preparation of a business plan for each project selected as organizationally and technically feasible. A business plan should include a project budget, a project management plan, and a project evaluation plan.

1. The budget will include estimated costs, revenues and cost savings. The TWG should consult with GUMC administration on criteria for evaluating the financial feasibility and success of telemedicine projects.

2. The project management plan will identify the principle investigator(s), management committee, statement of project accountability, an administrative operating plan and plans for project documentation. The TWG will not directly manage any telemedicine projects. The TWG shall seek principal investigators from the specific clinical, educational or administrative domain of the project if none emerges as part of the evaluation process. Unless otherwise determined, each project shall be accountable to the administration of its specific domain. A plan detailing project phases, milestones for each phase, membership and schedule of management committee meetings, and job description for key participants shall be prepared. A plan for documenting and routinely reporting on each project's progress will be prepared. Copies of the report should be forwarded to TWG for inclusion in its data bank about telemedicine projects at GUMC.

3. The project evaluation plan will assess the relative success and/or failure of each project in light of its goals and consequences for GUMC. The plan will outline measurable quantitative and/or qualitative indices of the intended effects of the

telemedicine project. Project leaders will report on any beneficial or harmful consequences of the project not foreseen in the original project plan.

Management Of Data Security In Telemedicine

The emergence of computer-based patient records, including telemedicine systems, has added to public concern about the security and confidentiality of patient medical information. The TWG must address this concern by promoting development of institutional policies, procedures and methods for secure data management in telemedicine. In its capacity as an advisory and resource group, the TWG should perform the following functions:

1. follow developments in federal and relevant state laws affecting patient record management;
2. advise the GUMC Information Technology group on data security issues when appropriate;
3. assist telemedicine project teams in developing and evaluating the effectiveness of plans for managing risks to patient data security, and;
4. function as a clearinghouse for information about methods for maintaining data security in GUMC telemedicine projects.

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Telemedicine and Virtual Hospice Community

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When terminally ill patients and their families solicit hospice care, they initiate two potentially conflicting processes. On the one hand, they bring the dying process into their homes thus distancing themselves from the organizational and technological control of a hospital. On the other hand, they invite health care professionals into their homes to assist in managing the tasks of caring for the dying. Hospice providers officially support and encourage their clients' desire to retain control of the end of their lives. Because hospice care usually occurs in patients' homes, the setting also helps control the imposition of potentially unwanted medical influences and priorities. What happens when hospice patients, families and providers interact in virtual space and time? Will the potentially improved ability for hospice providers to manage the physical symptoms of terminal illness undermine the goal of enhancing patient autonomy in dying? Or, will improving hospice clinicians' ability to manage pain and other distressing end-of-life symptoms actually better enable families to attend to the psychosocial dimensions as the patient's life draws to a close? With respect to peer relations, will advanced computing and telecommunications systems enable hospice patients and families to reach out to other people thus transcending the often isolating conditions of dying? We will investigate these questions by creating a "Virtual Hospice Community" (VHC) using advanced computing and telecommunications systems will enable hospice patients, families and providers better to manage symptoms of terminal illness at the end of life.

Investigators from Georgetown University, Washington, D.C. and Hospice of Northern Virginia, Falls Church, Virginia, have formed a partnership to plan, implement and evaluate this project. Our project has four objectives, including:

1. To evaluate and compare the consequences of three levels of participation (none, Internet only, and Internet with interactive video) in the VHC for communication among hospice patients, family members, physicians, the hospice team, and other hospice patients;
2. To ascertain how hospice patients, families and providers use the VHC to help manage everyday hospice work in the home, particularly balancing analgesia with side effects in managing pain with medications;
3. To describe how hospice patients and their families exploit the VHC in confronting issues of individual and family identity at the end of life, and;
4. To measure the impact of the VHC on the quality of hospice care and the prevalence, characteristics and distress of patient symptoms at the end of life.

By using systems of advanced computing and telecommunications to create VHC, hospice patients, families and providers will

1. Redesign communication in managing the end of life;
2. Improve symptom management in the home;
3. Enhance achievement of individual and family closure at the end of life, and
4. Better monitor symptoms and assess the quality of care at the end of life.

The VHC will provide certain hospice patients, families and providers of the Hospice of Northern Virginia with Internet access and, in some cases, videoconferencing. The VHC will support a variety of activities in virtual space and time using this infrastructure including chat rooms, newsgroups, a project webpage, and patient education materials. Videoconferences between patients and hospice staff will occur regularly including events such as weekly interdisciplinary team meetings, nurse consultations, and family therapy groups. The triage center will have access to the Internet and Videoconferencing for use during emergencies.

The theoretical foundations, actual implementation and potential consequences of this project are intrinsically interdisciplinary. We draw our ideas about virtual communities from the literature of communication theory (Fulk, Schmitz, and Steinfeld 1990; Fulk, Steinfeld, Schmitz and Power 1987; Fleming 1990; Scheerhorn, Warisse, and McNeilis 1995, Warisse 1996). Medical sociology grounds our approach to the potential impact of the VHC on hospice works in the home, particularly the writings of Corbin and Strauss on chronic illness (Corbin and Strauss 1988). We approach the process of "closure" in hospice from the perspective of the anthropology of experience, particularly of life review (Atkinson 1995; Myerhoff and Simic 1982; Weintraub 1988). Studying how the VHC affects negotiations about pain management unifies these disciplines in the context of a fundamental clinical problem in end-of-life care because it articulates the ambiguities for hospice patients of withdrawing from but maintaining access to medical expertise (McCabe 1997; Fagerhaugh and Strauss 1977; Collmann 1988). Our goal is to help improve clinical management of the symptoms of terminal illnesses at the end of life by enhancing hospice patients' access to necessary medical and social services without sacrificing control over their own care and creating new opportunities for communication with the community outside the home. This project will lay a groundwork for future studies of the role of advanced telecommunications technology in the remote management of chronically-ill, homebound patients, particularly as new technologies such as the Next Generation Internet become widely available.

Assessing the Impact of the VHC

The VHC will permit the investigators to evaluate and compare the consequences of three levels of participation (none, Internet only, and Internet with interactive video) in the VHC for communicative exchange among hospice patients, family members, physicians, the hospice team, and other hospice patients. Knowledge and distributed information systems permit communication once bound by space and time to emerge in new, apparently boundless interactive environments and, thereby, enable "virtual" communities to develop with unexplored characteristics. Cerulo notes, "the developing technologies are creating an expanded social environment that requires amendments and alterations to the ways in which we conceptualize various social processes" (1997:49). Past definitions of community have centered "around the unproblematized notion of place, a 'where' social scientists can observe, visit, stay, and go" (Jones 1995:19). Community observations have taken place within geographic boundaries. The emergence of virtual communities creates new opportunities to study organizational change as boundaries move, collapse, and become redefined (Warisse 1996; Jones 1995).

The term "virtual communities" initially emerged from research within computer-mediated communication among groups organized for work, social support, entertainment, and information-sharing (see Walther 1996 for review). Definitions of "virtual community" emphasize people interacting using a variety of online modalities from distant locations outside constraints of time. Stone suggests that virtual communities are "passage points for collections of common beliefs and practices that united people who were physically separated" (Stone 1991:85). Individuals meet face-to-face in virtual communities but "under new definitions of 'meet' and 'face'" (Stone 1991:85).

Because organizations have introduced multiple media options to accomplish work, research on virtual communities must shift from studying contexts within the confines of a specific communication technology to examining how organizations and individuals utilize multiple technologies to reframe interaction and work practices. Turner, co-principal investigator of this project and formerly writing under the name Warisse (Warisse 1996), began this exploration by investigating implementation of an interactive video telemedicine network among an academic medical center, a prison hospital, and a maximum security prison to provide telemedicine services to prison inmates. Before creation of the telemedicine network, each organization operated with its own specific and often different rules, cultures, constraints, missions and physical boundaries. Linking them together with new communication technology created a virtual organization requiring the development and creation of new missions and rules to govern it. Through the study of this virtual organization Turner developed the construct of "telecompetence".

By telecompetence (Warisse 1996) Turner means the variable ability of organizations or individuals to integrate a new communication technology within everyday work practices. Achieving telecompetence in support of a virtual community requires organizations to renegotiate the conditions of their interaction in certain defined ways. According to Turner, a communication infrastructure consists of three dimensions: technological, organizational, and individual. The technological dimension refers to the hardware and wiring used to facilitate communication using a variety of technologies. The organizational dimension refers to the goals, structures, norms, and rules that govern communication within the specific organization. And the individual dimension refers to the specific incentives, norms and rules that govern the way people communicate within the organization. When organizations join using new communication technology, a virtual organization emerges requiring co-development of its communication infrastructure along the same three dimensions. Co-creation and co-development necessitate collaboration among each organization to promote integration and the virtual organization's growth.

Turner's experience with virtual communities among several bureaucratic agencies provides important lessons relevant to understanding the VHC. Within the hospice setting, very distinct organizational contexts exist with distinct missions and goals. The hospice organization, individual physician offices, and patient homes each provide distinct contexts for interaction and work. The use of new communication technologies within these contexts to span geographic boundaries and create a new virtual organization comprised of these different contexts provides a rich environment to study interaction and organizational practices. This project will establish a technological infrastructure using multiple technologies, including videoconferencing, computer-mediated online communication, and World Wide Web (WWW) information sources. It will therefore enable a study of high-end (videoconferencing) and lower end communication (online) technologies, as well as asynchronous and synchronous communication contexts. The VHC will establish opportunities for interaction in virtual space and time among the following roles: terminally ill patients; family members; hospice providers (physicians, nurses, social workers, chaplains, administrators and volunteers), and non-hospice general and specialty physicians. Telecompetence within the creation of this virtual community will require a recognition and understanding of the individual goals of the participants as well as the development of common goals of the virtual community.

Turner identifies six conditions enabling the three dimensions of the communication infrastructure. These dimensions and conditions help interpret how a new communication technology may facilitate interaction within a virtual community. The six enabling conditions include: rationale for implementation; access to the system; expertise in use; co-creation of a communication environment; development of norms, rules, and expectations; and creation of communication protocols. Each organization must renegotiate the significance of these conditions for itself as well as for the virtual organization.

A system of advanced computing and telecommunications will connect at least five distinct settings, including regional hospice offices, a hospice triage or emergency center, the hospice medical director's home, the office of an oncology physician group, and patients' homes. There will be multiple combinations of these locations, and some combinations may not develop. However, the communication technology deployed will create the potential for virtual organizations to form. In addition to the distinct locations, distinct individuals that work within those geographic locations may form virtual teams and partnerships. In doing so, the conditions of telecompetence need to be recognized.

Rationale: Each organization or individual must feel some incentive to collaborate and participate. The VHC offers many potential benefits, including enhanced contact with hospice staff and access to online patient educational materials thus improving symptom management. The VHC will offer new opportunities for contact with other patients and families. It will be important to identify potential risks or disincentives for participation by hospice patients, family and providers such as felt loss of autonomy.

Access: Several conditions affect a potential user's ability to participate in a virtual community. They must have ready access and time to use services that routinely function well. Appropriate interfaces must enable individuals with varying backgrounds, computer literacy, and physical capabilities to use the technology. Voice and keyboard interfaces will give patients and family members access to the VHC in the home. Georgetown student volunteers and hospice staff will provide training and support

Expertise: Users must have time to learn and understand how the technology works. Undergraduate students from the Georgetown University service learning program will instruct patients and families in equipment use. All hospice staff will receive initial and follow up training as needed. The training program will include easy-to-follow instruction materials developed during Phase 1. Hospice staff will routinely support patients in using the equipment. Technical staff will assist patients and family with equipment problems as they arise. We will evaluate whether or not patients and families can learn to use the system effectively enough to affect their care in the time available in hospice.

Co-Creation of a Communicative Environment: The VHC will create a new, virtual environment for interaction. We will study how hospice patients, family and providers mutually develop understanding of how to accomplish tasks, implement protocols, and communicate effectively in the virtual space.

Norms, Rules, and Expectations: When we create the VHC, we will establish some rules for use. For example, we may decide only nurses may initiate a videoconference between patient homes and the triage center. On the other hand, some norms of behavior will emerge as the VHC develops. Users may decide that certain topics are suitable for spouse discussion groups but not for patient discussion groups. These are implicit understandings of the way that communication occurs within the virtual community. The implicit understandings of communication within the VHC will be important guides to evaluating the new virtual contexts and how they relate to traditional environments.

Communication Protocols: As established and emergent norms become more engrained within the system, they may become formalized in specific protocols. The specific communication protocols created by the VHC will serve as a blueprint for understanding the social contracts, relationships, and interactions occurring within the new context. They will also reveal how the VHC change patient homes and the hospice organization.

The VHC and Articulating Work among the Chronically Ill

Juliet Corbin and Anselm Strauss have developed a sociological model of conditions facing people trying to manage chronic illness at home that is highly relevant to understanding the characteristics, enabling conditions and consequences of the VHC on hospice patients, families and providers. (Corbin and Strauss 1988). Corbin and Strauss argue that managing chronic illness at home depends on integrating three "lines of work", illness-related work, biographical work, and the work of everyday life. Illness work is all work focused directly on managing the illness itself. Biographical work refers to activities involved in defining and maintaining an identity, particularly a patient's evaluation of the impact of chronic illness on her/his identity. Apart from illness and biographical work, people must take care of their everyday affairs such as keeping up a home, managing an occupation, and attending to the needs of others in their family. Each line of work singly and together potentially affects and conditions the others. Corbin and Strauss emphasize the difficult "balancing act" chronically ill patients and their families must perform to keep lines of work well enough articulated so that life can go on, particularly patients who live alone.

Hospice enters the lives of terminally ill patients and their families during the final phases of the illness trajectory (Corbin and Strauss 1988). After periods of greater or lesser deterioration in the patient's condition and more or less negotiation about its meaning, the patient, family and health care providers have concluded that death is imminent. The estimated life expectancy varies from days to months. To receive reimbursement for hospice care under the Medicare Conditions of Participation, the estimated life expectancy must be six months or fewer as certified by a physician (PL 97-248, 122). Hospice bears on the sociological problems of the end of life because it affects the location and style of dying. Specific questions in the management of the end of life include the following: Where will the patient die? Who shall attend the dying patient? Will managing the symptoms of illness at the end of life consume all the effort of patient and family? Or, will each have the opportunity to address important emotional, domestic and biographical issues? Hospice enables patients and their families to manage the end of life at home with assistance from health care providers. Hospice philosophy stresses that by strenuously controlling symptoms and offering emotional and spiritual support, hospice helps patients and families achieve autonomy without foregoing the benefits of medical expertise. Hospice thus hopes to help terminally ill patients and their families to make the most of their time left together accomplishing whatever important tasks remain.

What are the organizational conditions that bear on how hospice performs its work? Patients, family and hospice providers organize hospice work through scheduled and unscheduled encounters in the home and in the hospice office (Goffman 1961, 1974). Various kinds of people perform hospice work through different types of encounters in multiple settings. Multiple combinations of patient, family and professional hospice providers perform hospice work depending on the situation. Encounters may be scheduled or unscheduled (including but not limited to emergencies). Because the VHC will change these conditions, they are described in analytic terms below.

Scheduled encounters in the home setting: Hospice supports patients in managing the end of life in their own homes as much as possible. Hospice providers assist the patient and family in managing pain and other symptoms, the activities of everyday living (patient personal care and household chores) and psychosocial work (coming to emotional and spiritual terms with the patient's death, resolving disputes in the family and saying goodbye). Certified nurse assistants (CNA) assist in personal care of patients. Specially trained volunteers assist in household chores, provide companionship, and offer respite and bereavement support for family members. Social workers, art therapists and chaplains focus on promoting psychosocial growth at the end of life. Each of these hospice professionals visits patients' homes on a scheduled basis. The most frequent visits come from the CNA who tend to the patient's personal needs several times a week. Nurses visit regularly depending on the patient's clinical needs. Social workers, chaplains and other specialists such as art therapists schedule visits as needed. Although each hospice provider focuses on particular tasks, each assists patients and family with all types of work when necessary. The CNA may develop a particularly close relationship with a patient thus extensively involving the CNA in biographical as well as everyday work.

Scheduled encounters in the agency setting: In addition to providing necessary administrative functions such as hiring, training and supervising hospice providers, the hospice agency supports encounters directly related to patient care. Once weekly an interdisciplinary team including the hospice assistant medical director, nurses, social workers, dieticians, chaplain and volunteers meets to review and coordinate planning each patient's care. At the moment, neither patients nor their families attend the interdisciplinary team meetings. During regular business hours, the hospice agency supports scheduled encounters such as art therapy groups and bereavement groups. Patients or their family members must leave home to participate in these groups.

Unscheduled encounters between the home and agency: Hospice patients or their families require unscheduled assistance to help manage emergencies. Being unable to manage or endure difficult pain creates the greatest anxiety of all situations among patients with terminal illness and their families. Managing telephone calls for unscheduled assistance poses perhaps the single greatest clinical challenge and financial risk to the hospice agency. The hospice agency maintains a triage center that functions after business hours, during weekends and on holidays. Nurses receive telephone calls at the triage center and assist patients with their problems. The nurse's inability to see patients poses major problems in accurately assessing their situation. In the case of assisting with equipment problems, nurses also face difficulties in describing possible repairs without being able to illustrate their points. When the triage nurse cannot resolve the problem, a hospice nurse is dispatched for an unscheduled home visit thus increasing the expense of hospice care.

Scheduled or unscheduled encounters in other settings: Hospice and the patient's illness help establish a field of activity that potentially embraces many people including the patients' own physicians, friends and non-resident family. Scheduled and unscheduled encounters among these people occur in many settings.

The incorporation of knowledge and distributed information systems in hospice care potentially changes the organization of hospice-related encounters and settings. On the one hand, the number and types of encounters occurring through mediated modes of communication will increase, including using them for scheduled encounters. On the other hand, advanced computing and telecommunications systems will help create new kinds of setting, the collection of which we identify as the Virtual Hospice Community. The opportunities for new types of encounters in the context of the VHC will reorganize relationships among the patients, family and hospice providers as the home and agency settings systematically and routinely interact using mediated modes of communication. Hospice providers hope better to accomplish certain types of work (for example, clarifying a patient's condition during an emergency call to the triage center). Given the organizational and ideological differences between a home and a bureaucratic agency such as hospice, however, one must expect unanticipated social consequences of the VHC for both families and the agency. As Collmann demonstrates for the provision of health care and other welfare services to Aborigines in Central Australia, this is particularly true for bureaucratic agencies that provide "help" to families (Collmann 1988).

Negotiations about the meaning of pain in the context of the VHC should provide empirical circumstances for studying clinical and sociological dimensions of the VHC.(Fagerhaugh and Strauss 1977; Field and Cassel 1997). From the hospice perspective, pain, particularly pain defined as 5 or greater on the 0-10 Numeric Pain Intensity Scale (Gracely and Wolskee 1983; Houde1982; Sriwatanakul, Kelvie and Lasagna 1982) poses numerous clinical problems. Managing this pain often requires high doses of medication. Higher doses of opiates bring elevated risks of undesirable side effects, particularly for patients' sedation and confusion. Administering drugs in this setting requires experience and careful management. As recently emphasized in a study of ethical issues in hospice care, higher medication doses in palliative care redefine the meaning of physician and nursing experience (Coyle 1997; McCabe 1997). Nurses with extensive experience in acute care pharmacology potentially find palliative care challenges their basic assumptions about dose levels thus providing real concern about unwanted side effects. Because pain in terminally ill patients dynamically changes, patients, family and hospice staff must continually reassess pain and adjust medications accordingly. Under the best of circumstances with fully alert patients, accurate pain assessment requires attention. When patients lose the ability to communicate their own experiences, the task becomes formidable and poses major dilemmas for family and hospice staff (Coyle 1997). Lastly, unresolved cases of distressing and persistant pain pose major financial risks for hospice agencies. Managing pain thus creates a field of negotiation among patients, family and health care professionals even for hospice where palliative care constitutes the goal. Although patients privately and subjectively experience pain, hospice patients, family members and hospice providers must achieve intersubjective agreement about its severity, changing nature and consequences for palliative care to occur.

Confronting Issues Of Individual And Family Identity At The End Of Life

Thirty-five years ago, Robert Butler, former head of the National Institutes on Aging, coined the term "life review" for the process of verbal reflection on life in which people often engage when facing chronic illness, signs of aging, or terminal diagnosis (Butler 1963). More recently, Kleinman (1988; Good, Brodwin, Good, and Kleinman 1992), gives a twist to the concept of life review when he elaborates on "illness narratives," in which chronically ill patients talk about the *experience* of illness. He argues that understanding this process and the contents of people's narratives can teach us about the human condition as well as the everyday reality of individuals confronting suffering, disability, loss and the threat of death. In telling their life experiences people create meaning and define who they are to themselves and others, especially as they approach the end of life. Kleinman highlights that the illness experience affects all those who are a part of a patient's web of relationships, including in this project hospice personnel, caregivers, volunteers, family members, friends and neighbors. Stories emerge as significant because people create them with a sense of purpose rather than citing random memories. Each individual negotiates within him or herself before choosing what to tell. (Weintraub 1988). They sift the contents of stories through time and experience, re-organizing and ultimately expressing them as if for the first time. Through choosing what to tell, individuals state who they are. In the case of dying individuals and their families, this process enables closure.

Closure is most frequently associated with the dying process and death, the study of which has generally been placed within the context of the study of aging. Aging has experienced a period of redefinition as increasing numbers of people live longer. Myerhoff and Simic (1982) introduce the concept of "aging as life's career," a concept which forces attention to the process of living a life, rather than on the category of "old." The assumption of continuity of life experience underlies the concept of "aging as life's career perspective," Terminal illness and involvement in hospice care, however, imply the imminence of abrupt change, a concept well explored by Hazan (1992). He urges exploration of the experience of abrupt change in the construction and understanding of late life or near end of life. One of the most salient features of change is its associated issues of control the accompanying existential experience. It is here that identity formation and identity becomes a critical and fundamental consideration. The VHC may enable individuals to talk through and share their experiences and their search for identity, autonomy, and meaning. Both change and continuity may thus be addressed.

The models proposed by Butler, Kleinman, and Price are all compatible with the underlying principles of hospice care. In this setting, which provides palliative or comfort care, the focus is on quality of life, personal meaning and symptom alleviation.

A biopsychosocial approach forces a view of the chronically ill, dying patient as one that deserves to have all needs addressed including psychosocial and physical. Important time and skill must focus on alleviating symptoms and pain control. Many people including hospice social workers, volunteers, chaplains as well as family and friends provide opportunities to reminisce, review one's life, share memories, elucidate an ethical will, communicate information with those who are at a distance, and maintain contact with professional helpers potentially thus helping meet the patient's psychosocial needs. No other mechanism for achieving such comprehensive care can match those made possible by advanced computing and telecommunications systems. Hospice care humanizes the process of dying by incorporating a holistic view of the patient into its philosophy and everyday plans of action. Creating a VHC is a logical extension this approach. Furthermore, the VHC will make life review and other forms of communication more accessible to hospice patients and their family members thereby facilitating closure.

Storytelling, Life Stories, Life Review and Life History have long concerned anthropologists because they create important possibilities for insight. Life Reviews first provide insight into individuals' lives, usually someone from "another" culture. Second, life reviews often open a "window" into the society under study. Third, anthropologists interested in psychology, cognition and personhood interpret life reviews as crucial to identity formation. The telling and review processes themselves are keys to understanding important issues granting participants the opportunity for evaluation, restructuring, healing, and often closure. Price (1995) reminds us that life review may be therapeutic (resolving problematic life events) and help enhance the autonomy of those (such as hospice patients) who are in a period of dependency. Two perspectives on this form of discourse–meaning-based and therapeutic–follow other research on the "story" and the "life" perspectives taken here. It would seem that a combination of the two is altogether possible and could have positive results for all those who are a part of a VHC. The creation of a VHC brings with it a view of the dying as potentially dynamic and spirited persons, particularly if given the opportunity to focus outside of their bodies and into their minds and hearts. Creating a VHC could potentially increase the presence of dying patients with those who are a part of their lives. They may separately, or together, explore the possibilities of self and shared knowledge.

The VHC and Managing Symptoms at the End of Life

According to the Institute of Medicine (IOM), "the understanding of what it means to live well while dying and how to measure the quality of dying remains at an early stage" (IOM Committee on Care at the End of Life, Field and Cassel 1997). In their recent report the IOM recommended that investigators develop better tools and strategies for measuring symptom distress, quality of life, quality of care and other outcomes for dying patients and those close to them. Innovative approaches are needed to assess these parameters particularly in settings where the very ill are receiving care in their homes. By supplementing the pattern of home visits, the VHC will provide new opportunities for symptom assessment through improved communication between patients, families, hospice and other healthcare professionals. We further expect the VHC to improve the overall quality of life for patients and their families by improving their access to the wider community, including medical and hospice providers.

Through this study, we will be able to assess the impact of the VHC on the quality of patient life and hospice care in two ways, namely by administering formal evaluation instruments and by conducting interviews and participant observation. We have chosen two newly validated instruments for our formal evaluation. We will administer the Memorial Symptom Assessment Scale (MSAS) to assess development of patient symptoms over time. We will administer the Support Team Assessment Tool (STAS) to assess the quality of hospice care (see Research Design and Methods below). We will gather extensive data about the impact of the VHC through interviews with patients, family and providers, observation of hospice work encounters such as the Interdisciplinary Team meetings and Triage management, and text from the chatrooms and newsgroups. These data will help contextualize the data obtained from the formal evaluation instruments as well as provide direct information about the operation of the VHC. We will evaluate how the VHC helps mitigate the effect of the following specific barriers to measurement that have been highlighted by the IOM. (Committee on Care at the End of Life, Field and Cassel 1997:140-47)

The Timing of Assessments: Early, precise intervention for the relief of pain, other symptoms and distress, requires frequent assessment, particularly in the final stages of a terminal illness. As described in previous sections, the VHC may permit patients and/or their families to more readily communicate with hospice staff in both routine and emergency situations thus providing increased opportunities for structured symptom assessment and prompt intervention. The project will create opportunities for more frequent hospice staff assessment of patient and family status during regularly scheduled virtual hospice visits such as the biweekly Interdisciplinary Team meetings and nurse videoconsultations. Indeed this may be among the most important benefits of the videoconsultation arm of the VHC.

The Variable Sources of Information about the Situation: It is known that, in a given situation, patients, families and hospice staff may not assess problems and distress in the same way. The IOM has emphasized the need for exploration of the degree to which these perceptions of distress match or differ, and the need for the development of methods of approaching assessment in situations where a patient cannot communicate. (Committee on Care at the End of Life, Field and Cassel 1997:140-47) The VHC potentially creates opportunities for acquiring data about multiple perspectives on the same situation. Not only will patients and family have access to discussion groups and chatrooms for specific topics on the Webpage, videoconsultations will enable staff settings to visualize and interview patients and their families at the times that problems occur. The VHC will hospice staff new opportunities to evaluate the degree to which patient and family perceptions match and adjust their clinical response accordingly, particularly in triage situations

Creating the VHC

Our long term goal is to investigate the attributes, enabling conditions and consequences of creating virtual hospice communities among hospice patients, families and providers using systems of advanced computing and telecommunications. To achieve this goal, we propose to create an experimental VHC in collaboration with patients, families and staff of Hospice of Northern Virginia, one of the largest and most well established hospice organizations in the United States. To create the VHC we will build a technological infrastructure and establish settings within which hospice participants will interact using the technical infrastructure. Having created the basic conditions for the VHC, we will analyze how and with what consequences for communicative exchange, symptom management and closure hospice participants interact in the VHC. We will gather data using techniques of qualitative research including participant observation of VHC settings and structured interviews with participants. We will selectively employ formal, quantitative survey techniques to address specific questions of the quality of care at the end of life. We will assemble data about the cost of the VHC from the ongoing records of the hospice agency.

The Study Population and Project Design

The project will draw subjects from hospice patients, families, volunteers, consulting physicians and professional staff of the Hospice of Northern Virginia (HNV), Arlington, Virginia. HNV is a non-profit, independent organization governed by a volunteer board of directors of physicians, community leaders, long-time volunteers and clergy. Founded in 1977, HNV has provided hospice care to over 20,000 terminally ill persons and their families. The HNV staff currently includes 897 volunteers and 369 professional providers serving the population of ten counties and nine metropolitan areas in Northern Virginia. In 1997 HNV maintained an average daily census of 322 patients with an average length of stay in the program of 61 days. HNV provides a complete range of hospice care, including home care, social work services, chaplain, inpatient and bereavement care. HNV receives reimbursement for its services from Medicare, Medicaid, CHAMPUS, private insurance and prepaid health plans. HNV also receives extensive support from community donations of financial aid and volunteer services.

The HNV interdisciplinary team responsible for patients living in Fairfax County, Virginia will implement this project. The Fairfax interdisciplinary team includes 1 physician, 1 senior nurse, 20-25 hospice nurses, 15-20 certified nurse assistants, 1 licensed practical nurse, 1 senior social worker, 6 social workers, 1 volunteer coordinator, 1 chaplain and 1 bereavement coordinator. Nurses from the Triage Center will support the project during its hours of operation. Melanie Scofield, Director of Communications, will function as overall coordinator for HNV. Physicians from the Fairfax-Prince William Hematology and Oncology Group, Annandale, VA. Richard Binder, M.D., F.A.C.P., director of this group, serves as Chairman of the HNV Board of Directors.

Patients will be offered the opportunity to participate in the study if they meet three criteria, namely

1. receive hospice care from the Fairfax hospice team;
2. have an estimated life expectancy upon enrollment in hospice of three months or greater;
3. experience or at risk for pain defined as 5 or greater on the 0-10 Numeric Pain Intensity Scale (Gracely and Wolskee 1983; Houde1982; Sriwatanakul, Kelvie and Lasagna 1982)

Family members living with the hospice patient will be invited to join the study. The number of patients enrolled at any one time during the study is estimated at 30, with an estimated life expectancy of three months per each patient. The total estimated patients to be enrolled per year is 120. Over the 2.5 years of the implementation phase of the study, we expect to enroll 300 patients.

Establishing the technical infrastructure

The project proposes to install various technical capabilities and services in patients' homes, the Hospice of Northern Virginia and the ISIS Center, Georgetown University Medical Center in support of the VHC. In order to determine the impact of various technology modalities on the research questions presented, three categories of participants have been designated based on their opportunity for participation in the VHC: no participation, Internet only, and Internet with interactive videoconferencing.

No participation in the VHC (Controls): The participants within the Control group will not have access to the VHC as established by this project. The Control group will receive conventional, standard of care hospice.

Please note: The Hospice of Northern Virginia is designing a Webpage for use by its patients and other interested constituents. Although HNV will provide the Control group and all other clients information about and instructions for using the Website, it will not be formally included in this project. Moreover, some members of the Control group may already have computers and Internet access through which they could potentially use the HNV Webpage. Controls with their own computers nonetheless will not receive passwords necessary to log on to the project homepage, enroll in the chat rooms or participate in newsgroups specific to the project VHC.

Internet participation in the VHC (Internet Only): Subjects within the Internet Only group will receive Internet access to the VHC. The project will provide Internet Only subjects who do not own a personal computer with Web-TV technology, Internet access through subscription to an Internet Service Provider (ISP), installation and monthly operation of a project telephone line. The project will provide Internet Only subjects who own a personal computer with Internet access through subscription to an ISP, and installation and monthly operation of a project telephone line. Internet Only subjects will receive passwords granting them online access to the project specific Webpage, chat rooms, newsgroups and email. Internet Only subjects will have access to all Internet services otherwise available as part of their subscription to the ISP.

Internet with interactive video participation in the VHC (Video): The Video subjects will receive access to the Internet and the ability to perform interactive videoconferencing. The project will provide Video subjects with a personal computer equipped with videoconferencing, Internet access through subscription to an ISP, installation and monthly operation of a project telephone line for Internet access, installation and monthly operation of a project ISDN line for interactive videoconferencing, and word processing software. In addition to receiving passwords for access to the project homepage, chat rooms, newsgroups, and email, video subjects will be able to participate in interactive videoconferences with hospice staff. Their PC will include keyboard and voice recognition interfaces to permit use by patients and families with a range of physical capabilities. Word processing will permit subjects to create text files in support of hospice diaries and other services. Video subjects will have access to all other Internet services otherwise available as part of their subscription to the ISP.

Hospice of Northern Virginia:

Workstations: the project will provide five workstations equipped with Internet access and multipoint videoconferencing to HNV. The units will perform the following:

1) Regional team office: one workstation in the regional office of the Fairfax regional team to support videoconferencing, email, and team contributions to selected chat rooms and newsgroups;
2) Triage center: one workstation in the HNV triage center in Arlington, Virginia to support videoconferencing, email and triage contributions to selected chat rooms and newsgroups.
3) Hospice physicians: one workstation in the home of Dr. Cheryl Arenella and one in the private office of Assistant Medical Director of Fairfax team to support twenty-four hour videoconferencing, email and physicians' contributions to selected chat rooms and newsgroups.
4) Oncology office: one workstation in Fairfax-Prince William Hematology and Oncology Group, Annandale, VA to support videoconferencing, email and contributions to selected chat rooms and newsgroups.

ISIS Center: the project proposes to install a video bridge to support simultaneous videoconferencing among up to four sites (for example, regional team center, patient's home, and oncology office) at the ISIS Center, Georgetown University Medical Center. The bridge should be installed at the ISIS Center in order to guarantee adequate expert equipment support during the life of the project.

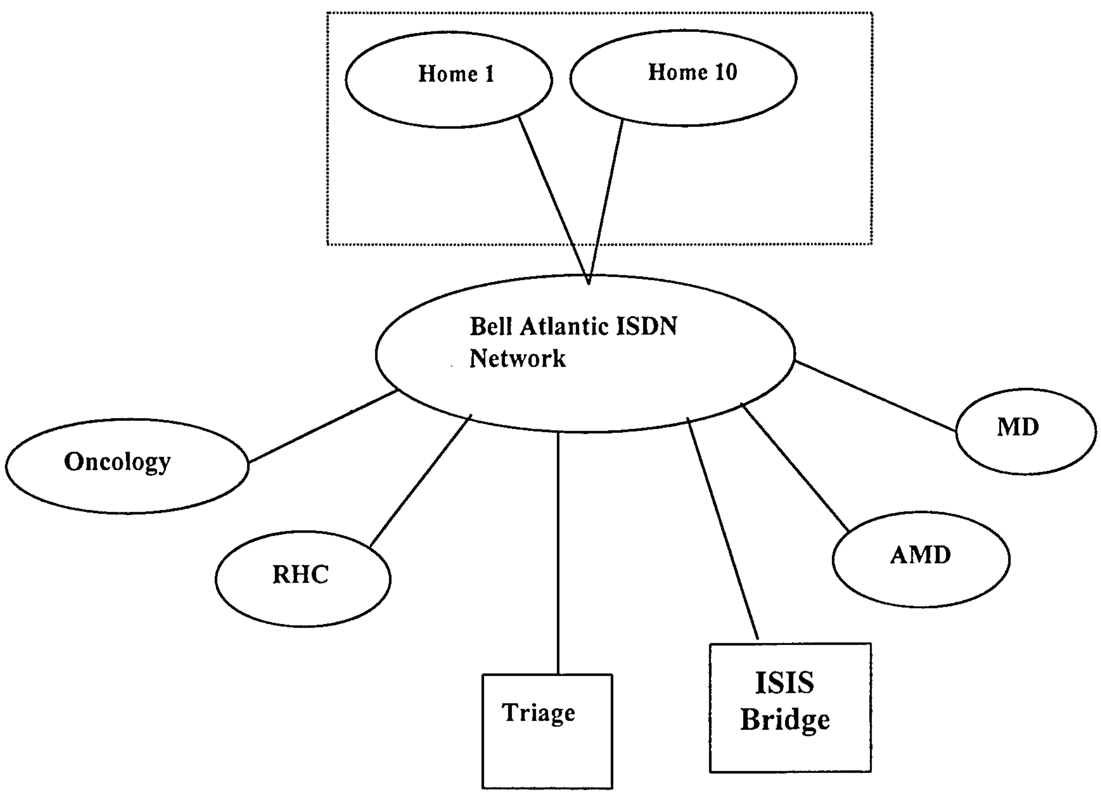

Figure 1: The VHC network

Technical Justification

In deciding on the technical infrastructure for VHC, we considered the availability and cost of telecommunications bandwidth to link patient homes, Hospice of Northern Virginia and the ISIS Center, Georgetown University Medical Center. Bandwidth, or the amount of information that can be transported over communication lines, has been the limiting factor in bringing internet and videoconferencing to the home. It is important to differentiate between broadcast type applications (used in cable television) and bidirectional applications where the home user downloads as well as sends out information. This is what differentiates Internet from videoconferencing applications. While they are both bi-directional, Internet-based applications typically require more downlink than uplink speeds because the user only sends out requests or text-based information but downloads images, video and other bandwidth intensive applications. This is also true for other types of new commercially available (albeit in limited areas) technologies such as Cable Modem or ADSL (Asynchronous Digital Subscriber Line) where download speeds can reach 6 Mbps but the uplink speeds are limited to 28 Kbps, or the equivalent of point-to-point modem speeds. In videoconferencing applications, the minimum acceptable bandwidth is 128 Kbps. Anything below this speed will provide choppy video at about 3 frames a second. Internet-based video provides uplink modem speeds and downlink speeds at the maximum possible for internet connectivity (about 40 Kbps). However this is highly dependent on traffic on the Internet and much lower speeds are usually available to the user. Based on this study and several evaluations and comparisons we performed, we excluded Internet-based videoconferencing for use in this project. The only other technology that was readily available commercially and providing high uplink and downlink speeds was ISDN (Integrated Switched Digital Networks). We have used this technology in several of our telemedicine projects and have determined that 128 Kbps is appropriate for videoconferencing in a switched configuration (Tohme, Winchester, Collmann, et al 1997; Tohme, Winchester, Dai, et al 1997). We have also used 3 BRI (Basic Rate ISDN) lines in other projects providing up to 384 Kbps; but, providing this service to the home is not cost-efficient (Tohme, Hayes, Winchester, et al, 1997).

Encounters in the Virtual Hospice Community

The project will sponsor many types of encounters using the Internet and interactive video.

Internet Encounters: Hospice staff and patients in the Internet Only and Internet with Video groups will have access to email, chat rooms, newsgroups and webpages using commercial Internet Services Providers (ISP).

1. Email will provide patients, families and hospice providers with asynchronous access to each other 24 hours a day, seven days a week.
2. Newsgroups will address specific audiences including spouses, children, and patients. Members of the designated audiences will have access only to their own newsgroup and to an "everyone" newsgroup. For example, spouses may interact in a newsgroup for spouses but not for patients. All registered participants will be given access to the "everyone" discussion group. Registered hospice staff members will have access to "everyone". Investigators will be able to monitor newsgroups for investigative purposes only.

3. The project will sponsor scheduled synchronous chat rooms on topics of general interest to hospice patients and their families. Nurses, social workers, chaplains and other other professionals will develop and participate in chat rooms as deemed clinically relevant but may include issues such as nutrition and hydration, pain control, children's grief, guilt in hospice care, and handling remote family members.
4. The project will design, build and support a webpage including services such as Frequently Asked Questions (FAQ), online patient educational support, and links to useful other sites on the World Wide Web. The online patient education technology already exists and will be developed for topics such as pain control and grief management for specific use in educating hospice patients and their families. The project webpage will reside on the HNV webserver.
5. The project will support and document unexpected, innovative use of the Internet by patients and their families in so far as financially possible.

Interactive Video Encounters: The project will schedule regular interactive videoconferences as part of the clinical hospice protocol and support calls to the triage center and emergency medical equipment calls after regular hours. Scheduled telehospice visits will include the following:

1. Biweekly meetings between a patient and family at home and the interdisciplinary team responsible for the patient's care in the regional center;
2. Consultations between a patient and family at home and the hospice nurse in the regional hospice center;
3. Consultations between hospice nurse in the patient's home and the hospice or oncology physicians in their offices;
4. Consultations between Certified Nurse Aid in the patient's home and supervising hospice nurse at the regional center;
5. Consultations about medical equipment maintenance between patient/family in the home and technical staff at the regional center
6. Consultations between a patient and family at home and social workers, dieticians, clergy and other staff in the regional center as necessary;
7. Support groups meetings including patients' families in their homes and hospice staff at regional center

Assessing Symptoms and the Quality of Hospice Care

In addition to the qualitative measures of VHC impact outlined above, the project will deploy two survey instruments for assessing the impact of the VHC on the prevalence, characteristics and distress of patient symptoms and quality of hospice care.

Symptom Assessment: The project will administer the Memorial Symptom Assessment Scale (MSAS), a new patient self-assessment instrument that has been developed and validated to provide multidimensional information about 32 common symptoms (Portenoy, Thaler, Kornblith et al 1994). The project will also administer a version of the MSAS modified to collect information about the perceptions of the family caregiver about the patient's symptoms. When patients are no longer able to complete the MSAS, data will continue to be collected from the family caregiver. The project will administer the MSAS once upon admission into the study and biweekly thereafter. The project will also administer the MSAS on an unscheduled basis at times of major clinical change. The project research assistant will train the patient and family in use of the MSAS. Data from the initial training session will function as the baseline for each patient. Data extracted from the MSAS will provide information about symptom prevalence and distress in this population from the perspectives of the patient and family caregiver. The project will compare data about the results of MSAS from the control, Internet Only and Internet with Video groups in order to evaluate the impact of the VHC on symptom development and distress. By acquiring MSAS data from the patients and the family caregivers, the project investigators will ask fundamental questions about discrepancies in symptom assessment between patients and caregivers.

Quality of Care Assessment: The project will administer the Support Team Assessment Schedule (STAS) to patients and hospice staff to assess quality of care. This instrument has been widely utilized and validated in hospice settings in the United Kingdom for assessment of the quality of hospice care (Higginson 1993). This instrument provides information on ten patient and family related items, including pain and symptom control, and patient and family insight and anxiety; and seven service items, including professional communication and practical aid. The project will administer the STAS for members of the control, Internet Only and Internet with Video groups. The research assistant will train patients in using the STAS. The research assistant will administer the team assessment as part of the Interdisciplinary Team meeting.

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Experience implementing a DICOM 3.0 multi-vendor teleradiology network

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ABSTRACT

Objective: The ISIS Center at Georgetown University received a grant from the U.S. Army to act as systems integrator for a project to design, develop, and implement a commercial off-the-shelf (COTS) teleradiology system to support the U.S. troops in Bosnia-Herzegovina. The goal of the project was to minimize troop movement while providing primary diagnosis to military personnel. This paper will focus on Digital Imaging Communications in Medicine (DICOM) 3.0 related issues that arose from this type of teleradiology implementation. The objective is to show that using the DICOM standard provides a good starting point for systems integration, but is not a plug and play operation.

Methods: The method used to develop the deployable radiology system was to purchase systems that were based on the DICOM 3.0 standard. The modalities implemented in this effort include computed radiography (CR), computed tomography (CT), film digitization (FD), and ultrasound (US). Dry laser printing and multiple display workstations were critical components of this network. The modalities and output devices were integrated using the DICOM 3.0 standard. All image acquisition from the modalities is directly to a workstation. The workstation distributes the images to other local workstations, to remote workstations, to the dry laser printer, and to other vendors' workstations using the DICOM 3.0 standard. All systems were integrated and tested prior to deployment or purchase. Local and wide area networking were also tested prior to implementation of the deployable radiology network.

Results: The results of the integration of the multi-vendor network were positive. Eventually all vendor's systems did communicate. Software configuration and operational changes were made to many systems in order to facilitate this communications. Often software fixes or patches were provided by a vendor to modify their DICOM 3.0 implementation to allow for better communications with another vendor's system. All systems were commercially available, and any modifications or changes provided became part of the vendor's commercially available package.

Conclusion: Seven DICOM interfaces were implemented for this project, and none was achieved without modification to configuration files, changes or patches in vendor software, or operational changes. Some of the problems encountered include missing or ignored required data elements, padding of data values, unique study identifiers (UID), and the use of

application entity titles. The difficulties with multi-vendor connectivity lie in the understanding and interpretation of standards like DICOM 3.0. The success of this network proves that these issues can be overcome and a clinically successful network implemented utilizing multiple vendors' systems.

1. INTRODUCTION

The U.S. military has been a proponent of digital imaging and teleradiology for over 15 years[1,2,3,4]. In early January 1996, a six-week project was undertaken to design and implement a multi-vendor teleradiology system. This system was designed to support the 20,000 U.S troops deployed as part of the NATO peacekeeping forces in Bosnia-Herzegovina[5]. Imaging modalities procured by the U.S. Army for their medical facilities were to be integrated into a digital network and the images were to be disseminated digitally throughout a fixed facility and to remote diagnostic areas. The goal of this project was to design a deployable radiology (DEPRAD) system capable of supporting the operations of a Mobile Army Surgical Hospital (MASH) in a deployed environment, while providing the capability to send radiology images anywhere, anytime[6].

A MASH was setup in Bosnia-Herzegovina that had advanced radiology imaging capabilities (x-ray, CT, US), but no radiologist assigned to the unit. Prior to implementation of the teleradiology network, the radiology films were often sent to a radiologist stationed at the Combat Support Hospital (CSH) in Taszar Hungary, via air or convoy transport, for primary diagnosis. The CSH is the next echelon of medical treatment for troops stationed in Bosnia and is located approximately 100 miles away. Due to the many land mines still in place in Bosnia-Herzegovina and poor access , transport of personnel and films was very difficult.

In this paper a short DICOM tutorial is provided to familiarize the reader with some of the basic concepts of the DICOM 3.0 standard. Next the DICOM project is described, followed by an explanation of some of the DICOM related problems encountered and their solutions.

2. DICOM INTRODUCTION

DICOM 3.0 is the Digital Imaging and Communications in Medicine standard developed by a joint committee of the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA)[7]. Some key features of the DICOM standard are: it's applicable in a networked environment; it specifies how devices must respond to commands and data that are exchanged; and it specifies different levels of conformance.

The purpose of the DICOM 3.0 standard is to address the exchange of digital information between medical imaging equipment. This includes, but is not limited to, imaging modalities, workstations, archives, and output devices such as printers. The standard does not intend to specify details about how applications are developed or implemented.

DICOM message transfers begin with a network connection being made. Once this connection is made, a DICOM association is established or the start of a negotiation between the devices is begun. To establish a DICOM session, three pieces of information are needed from both the requesting and receiving systems: Internet protocol (IP) address, DICOM application entity title (AET), and DICOM port number. The IP address is the unique network address assigned to a device on a network. The AET is a name given to a unique DICOM application on a specific system on a network. The DICOM port number is the logical port that is used to establish a Transport Control Protocol (TCP) connection for the DICOM message exchange. These parameters allow systems to know who is attempting to establish an association with them and decide whether to accept or reject the request.

Besides IP address, AET, and port number the association establishment negotiates which types of service object pair (SOP) classes can be exchanged and how the data will be encoded. In simple terms, a SOP class is a combination of a data object and the operations that can be performed on that object. Examples of SOP classes that are exchanged in a DICOM message include modality image storage (CR, CT, US, etc.) Some of the operations that can be performed are storage or print. There are also SOP classes relating to the query and retrieve of information, patient management, visit management, study management, and others. The data in a DICOM message may be encoded using either big or little endian (related to byte order in 2 byte data) or JPEG compressed.

The DICOM association acceptance or rejection is returned by the receiving system. The receiving side may agree with all aspects of the request or it can return an association acceptance while sending back requests relating to other types of and formats of data to be passed.

In order for a system to be labeled DICOM 3.0 compliant, at a minimum it must accept the defined default transaction syntax. That is, if an approved requesting system sends an association request to a receiving system, at a minimum they must be able to communicate using the default transfer syntax. The DICOM 3.0 default transfer syntax is implicit value representation (VR) little endian, where implicit VR means that each data element of the message will be composed of three fields: the data element tag (group, element), a value length, and a value field. The default transfer syntax is provided as a mechanism for systems to communicate at a basic level.

Once the association has been established, the DICOM message is sent. DICOM messages are sent in packets the length of which is defined in the association negotiation. A DICOM message is composed of a command set and a data set. Both command and data sets have the format of element tags composed of group and element numbers, a length field for the element, and the value of the element. (Explicit VR transfer syntax will contain the value representation field as well immediately following the element tag field.) Standard command elements have a group number equal to 0000H. Standard data elements have an even group number greater than or equal to 0008H. Private data elements have odd group numbers greater than 0007H but not including FFFFH. Manufacturers pass data that is not defined in the DICOM 3.0 standard using private groups.

Each element in a DICOM message has a data element type associated with it that defines whether the element is required, conditional, or optional. Type 1 elements are required and mandatory. They must not have a length of zero. Type 1C elements are required under certain conditions. If the condition is met, then they must be included and not have a length of zero. If the condition is not met, then they shall not be included in the message. Type 2 elements are required, but if the element value is unknown then the length of these elements can be zero. Type 2C elements, like type 1C, are required under certain conditions. If those conditions are met, then they may contain a length of zero if the value for the element is unknown. However, if the conditions are not met, then they shall be omitted from the message. Type 3 elements are optional and may contain a length of zero or may be omitted if a value does not exist for the element.

3. DEPRAD PROJECT

The goal of the DEPRAD project was to design, develop, and implement a commercial off the shelf teleradiology network to support the U.S. troops in Bosnia-Herzegovina. There were three sites to be connected for this project: The 212th MASH located outside Tuzla, Bosnia-Herzegovina; the 67th CSH located in Taszar, Hungary; and the Landstuhl Regional Medical Center (LRMC) located in Landstuhl, Germany. There is a single radiologist located at the CSH who is responsible for primary diagnosis of all images from the MASH and CSH. The radiologists stationed at LRMC are responsible for assisting the CSH radiologist when on leave, if the workload is too great, or if an expert consultation is required. General x-ray imaging via a computed radiography reader, computed tomography, and a film digitizer are in place at both the CSH and MASH for the acquisition of images into the DEPRAD network. There is also an ultrasound unit in place at the MASH. These acquisition devices communicate with the central radiology workstation using DICOM 3.0. Dry film printing is available at all sites through DICOM 3.0 messaging.

There were a total of seven DICOM interfaces that needed to work for the project to come together. There are 11 different systems connected and multiple DICOM interface gateways provided. A DICOM gateway is a system designed to connect non-DICOM devices to DICOM devices. It is usually a computer with special interface software. All equipment, software releases, and interface software products were commercially available.

Figure 1 provides an abstract view of how the equipment was connected throughout the DEPRAD network. It is not meant to represent a specific implementation.

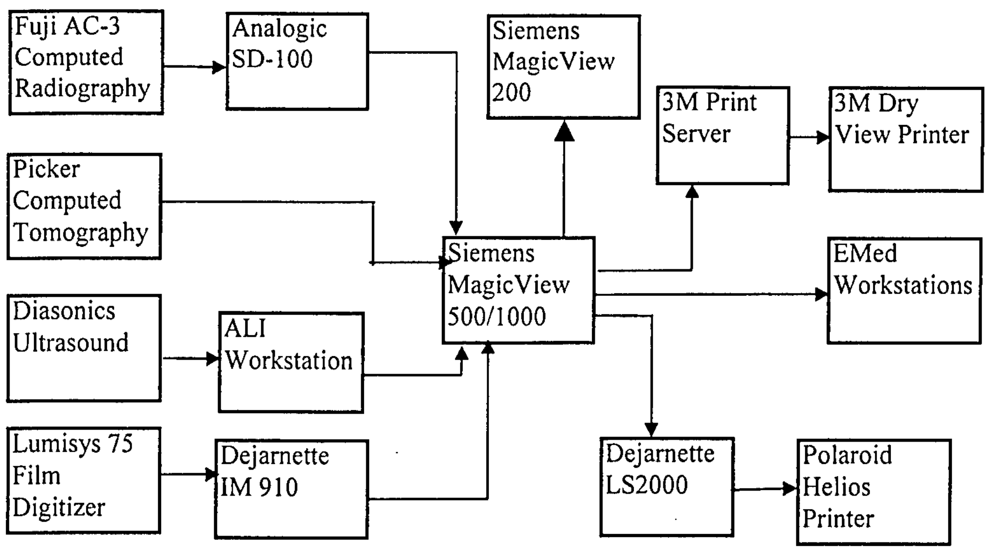

Figure 1 DICOM connections used in DEPRAD project.

The Fuji AC-3 (Fuji Medical Systems, Stamford, Connecticut) is a computed radiography (CR) reader. This device utilizes phosphor plate technology instead of x-ray film to acquire images off a standard x-ray machine and then read the data off the phosphor plate using laser technology. The resulting digital image is transferred to the Analogic SD-100 (Analogic, Peabody, Massachusetts) CR gateway. The SD-100 connects to the Fuji AC-3 over a proprietary interface. Fuji approved image processing algorithms are applied to the image and it is communicated to the Siemens MagicView workstation (Siemens Medical Systems, Iselin New Jersey) using DICOM 3.0 messaging. Three different models of MagicView workstations were utilized for this project. Wherever a Radiologist was stationed, a MagicView 500 and/or 1000 were deployed to provide diagnostic quality display and larger storage space. In areas such as the intensive care units or emergency treatment areas MagicView 200s were deployed. They provide most of the functionality of the 500 and 1000 systems with a much simpler interface and lower monitor resolution. A Picker PQS CT scanner (Picker International, Inc., Cleveland Ohio) was also connected to the network. This device contained software developed by DeJarnette Research Systems, Towson Maryland, which provided a DICOM 3.0 interface to the CT scanner computer. The Diasonics Ultrasound unit (Diasonics Inc., Milpitas, California) connected to an interface gateway from ALI Technologies, Burnaby, BC Canada. This gateway was used to convert the Diasonics data into DICOM messages and thus send the images to the MagicView. A Lumisys 75 film digitizer (Lumisys, Inc., Sunnyvale, California) was deployed to provide access to old films or films coming from other places into the digital network. The DRS IM 910 (DeJarnette Research System, Towson, Maryland) was connected to the digitizer to provide a user-friendly interface for scanning images and transmitting them to the MagicView.

The output devices on this network included 2 separate dry laser film printers: the 8700 Dry View film printer (Imation Enterprises Corp., Oakdale, Minnesota (formerly Minnesota, Mining and Manufacturing - 3M) and the Polaroid Helios printer (Polaroid Medical Imaging Systems, Cambridge, Massachusetts). A DryView was installed at the MASH and CSH while a Helios was installed at LRMC. This provided network printing without the need for chemicals or water.

4. DICOM PROBLEMS AND SOLUTIONS

None of the equipment in the DEPRAD network was connected without problems[8], however the use of the DICOM standard as a basis for connectivity made the integration of these systems easier[9,10,11,12]. This section will detail some of the DICOM implementation issues and problems that were encountered while establishing the DEPRAD network. The following are the DICOM connections established for this project and a brief description of each device:

- Analogic SD-100 CR gateway to the Siemens MagicView
- Picker PQS CT scanner to the Siemens MagicView
- ALI DICOM gateway to the Siemens MagicView
- DeJarnette Image Share 910 to the Siemens MagicView
- Siemens MagicView to the EMed teleradiology system
- Siemens MagicView to the 3M Print Server
- Siemens MagicView to the DeJarnette Laser Share for printing

This section is not intended to criticize any of the vendor's DICOM implementation, but to enlighten the reader to some of the problems that can occur. All vendors worked hard to solve all of the issues that were encountered in a timely fashion. It is to the benefit of all parties involved in an integration project to ensure connectivity among multiple vendors.

4.1 Configurable values

Some configurable default values that are part of the Siemens MagicView DICOM implementation initially caused problems when setting up associations with other devices. Unique Identifiers are defined throughout the DICOM 3.0 standard. Every vendor uses an unique identifier assigned by the National Electrical Manufacturers Association (NEMA) called an application context name. The value of these elements may be of odd or even length. However, the MagicView's DICOM implementation expected all DICOM Identifiers including the application context name to be of even length. Thus a default configuration value was set to pad these Identifiers with trailing blanks if they were not of even length when they were received. When a DICOM association establishment was negotiated, the MagicView's DICOM implementation would send a padded application context name back to the requesting system and thus not what the requesting side was expecting. The requesting side would then terminate the association request. Although this was a simple configuration change, the cause of these types of errors is not always obvious. This problem was seen with many of our DICOM interfaces to the MagicView.

4.2 Data element types

Initially, CR images coming from the AC-3 through the SD-100 CR gateway to the MagicView were displayed with the gray scale inverted on the MagicView. Within the DICOM standard, there is a type 1 data element (a required element) called photometric interpretation (group and element tag: 0028, 0004) which defines whether the pixel values of the image being sent represent the minimum pixel values as white or black. Bone is normally represented by the minimum pixel value corresponding to white. When bone is displayed as black, it is said to be inverted. This data element is an enumerated value, with the acceptable values being Monochrome I or Monochrome II. Monochrome I refers to bone being displayed as white and Monochrome II displays bone as black. This element was being sent as Monochrome II from the SD-100 to the MagicView since the image was inverted coming from the SD-100. The MagicView ignored the photometric interpretation element and therefore all the CR images sent to the MagicView were received and displayed inverted. This problem was quickly rectified by Analogic. They inverted the pixel values of the image sent to the MagicView and changed to a Monochrome I photometric interpretation. Subsequently, Siemens has corrected the problem on their side and now recognizes the photometric interpretation element.

4.3 Private data groups

Private data groups are permitted in the DICOM standard as long as they are an odd value and are between 0007 and FFFF (exclusive). The DICOM standard states that vendors shall ignore these groups if they do not know what to do with the data contained within them. During our installation and implementation of the DEPRAD network we noticed a problem with restoring computed radiography images from the Siemens archive device. After some work with both Siemens and Analogic engineers, it was determined that SD-100 messages contain a private group with an element that is 4K bytes long. The MagicView software ignored the private group during a DICOM message transfer, but maintained the private group with the image data. Once the data was converted to their own internal format, they were not able to read the image back off their archive. They were expecting to see a value within the first 1000 bytes of data when reading from the archive; since they were maintaining the header as sent from the SD-100, they did not see the element expected. Siemens modified their software to ignore the private group and strip it off the image before storing it in the database. This is a good example of where DICOM does not specify how an application should behave, therefore one must be careful in designing applications receiving DICOM messages.

4.4 Pixel data attributes

Computed radiography (CR) pixel data is 10 bits deep. Within group 0028, the image pixel module attributes group, there are three elements that define the number of bits per pixel for the image data. They are bits allocated (0028, 0100), bits stored (0028, 0101), and high bit (0028, 0102). The values passed from the SD-100 to the MagicView are 16 bits allocated, 10 bits stored, and high bit equals 9. A configuration option on the MagicView allows for the conversion of pixel data upon receipt of 8 or 10 bit data to a full 16 bit data. By default, the workstation was configured to convert this data, so that all images received would look fine on the softcopy display, but were lacking contrast when printed. Modifying the MagicView configuration file solved this problem.

It is often critical to perform mensuration on images. However, it was not possible initially to perform measurements on the computed radiography images received from the SD-100 on the MagicView. When a measurement was performed, the MagicView would display a question mark, because it did not have the information required to correctly determine the measured value. There exists an element in the image pixel module attributes group (0028, 0030) that details the pixel spacing for the image. This is the distance, in mm, between the center of each pixel in both the x and y directions. This field, although a type 1 element (i.e., required element), was not being passed from the SD-100 to the MagicView. New DICOM software has been installed to provide for the inclusion of this element in the DICOM message.

4.5 Study acquisition elements

Different elements get passed in a DICOM message based on the modality of the images. There are window/level defaults, as well as other data that affect the way images are displayed on a workstation. There are also often default values that are associated with certain types of images. These defaults often are applied to images when they are received by an imaging workstation. Initially, the PQS CT images were not being displayed properly. The quality of the images was quite poor. After some investigation it was discovered that the DICOM data element for modality (0008, 0060) was being passed with a length of 4 bytes, not 2. Therefore, the modality "CT" was being passed as "CT " with 2 extra spaces after the modality value. This caused confusion on the MagicView and prohibited the workstation from properly identifying the images as being from a CT. Siemens changed their software to recognize "CT " as well as "CT".

4.6 Image versus study

The concept of image versus study can often get confused. Studies often contain multiple images. DICOM allows for this type of hierarchy within the standard. While all vendors were DICOM conformant in their implementations, each CR image was received as a unique study on the MagicView. An operational change at the sites trained the technologists to combine the multiple studies containing individual CR images into a single study with multiple images on the MagicView. However, when the technologists sent this study to the Dry View printer via a DICOM interface, the images were once again separated into unique studies and printed one per sheet, even though the print server was configured for printing of two images per sheet of film (also called 2 up). A fix to the MagicView's DICOM implementation to send a single unique Study Identifier for a study and not send Study Identifiers with each image in the study was implemented. The DryView printer software then could recognize the multiple image study and print the images 2 up.

4.7 Multi-vendor workstation connectivity

One of the requirements of the DEPRAD project was to share images between the DEPRAD network and other military implementations. One of the military sites designated to share images with the DEPRAD network was the U.S. Navy's telemedicine implementation aboard the USS George Washington. An EMed teleradiology system (E-Systems Medical Electronics, Inc. San Antonio, Texas) was deployed aboard the ship. As mentioned in section 2.0 DICOM Introduction, DICOM port number is one of the key pieces of information for establishing a DICOM connection. The EMed system's user interface to configure the DICOM port number did not allow for a port number greater than 9999. The MagicView's port number is 50082. Therefore, the EMed system could not easily be configured to connect to the MagicView on its port number. EMed engineers directly modified the configuration files to set the port number, bypassing the user interface.

4.8 DICOM print management service class

All the DICOM applications discussed up until this point used DICOM storage service class messages to transmit data to a storage class provider (SCP) and have the SCP store the images. DICOM has a fairly extensive set of data set elements to ensure that the SCP has the necessary data to make the stored data useful. However, if the same data set is to be transmitted to a printer, there are additional data elements that need to be defined. The DICOM print service class defines these elements through the use of additional SOP classes[13]. These classes define such things as images with annotation, graphics, or overlays; film layouts or image display formats; basic presentation parameters for the film session; and basic device management. Most of the information required in these SOP classes do not exist in a DICOM storage service class message where the intention is for the receiving system to store the image(s) sent by the requesting system.

The 3M and Polaroid printers are designed to receive DICOM print management service class messages. However, the MagicView is not designed to transmit DICOM print management service class messages; therefore third party software was required to translate the DICOM storage class messages into DICOM print management service class messages. This software controls the printing parameters, image processing parameters, and other items that affect the hard copy output of the film. Many elements required in a DICOM print management service class message are not present in the DICOM storage class request, so defaults were programmed into the store to print converter software. While this worked for our application, it is not an ideal solution. Devices that initiate the print process, such as workstations, need to be print service class users and not rely on third party software or DICOM store to print converter applications.

5. CONCLUSION

DICOM 3.0 is the recognized standard among imaging modality vendors and digital imaging workstations. Without this standard, a project like DEPRAD with a 6-week design and development schedule would not have been possible. DICOM 3.0 has provided the opportunity to mix and match different vendors' hardware to develop a digital imaging network either locally or over a wide area communication network.

The experiences acquired in the DEPRAD project provided a valuable test-bed for testing multi-vendor DICOM implementations and the interactions between them. Pieces of the network are constantly being used to test new DICOM implementations and upgrades to existing implementations to guarantee that the network remains current and can be easily modified as new technologies and applications become available.

The examples of DICOM inconsistencies given here were provided to educate future users of digital imaging networks as to some problems that one might encounter when dealing with multi-vendor networks, even if standards are used to integrate the components. It also shows how even though vendors are adopting the DICOM 3.0 standard, there is not always coordination as to what is required and what is necessary to provide complete functionality.

The issues outlined in this paper are not unique to the DICOM 3.0 standard. It is nearly impossible to specify everything in a standard, while still permitting vendors' freedom in writing their own applications that utilize the standard. Standards will always be interpreted differently based on individual biases and perspectives. The best one can hope for is that vendors continue to cooperate and work towards making the DICOM 3.0 standard a truly useful tool that encourages and promotes inter-operability among multi-vendor networks.

For more information regarding the DICOM 3.0 standard, refer to references 14 and 15. Much information is available on the World Wide Web relating to the DICOM 3.0 standard. The following web address are excellent starting points to learning more about the standard, vendor conformity, and useful tools for debugging DICOM interfaces:

Penn State Department of Radiology DICOM Web Page: http://www.xray.hmc.psu.edu/dicom/dicom_home.html

Otech Imaging DICOM Web Page. http://www.otechimg.com/otech/

DICOM Software Tools. http://idt.net/~dclunie/dicom3tools.html

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DEPLOYABLE TELERADIOLOGY:

BOSNIA & BEYOND

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DEPLOYABLE TELERADIOLOGY: BOSNIA & BEYOND

Abstract

The US military has been an effective proponent of digital imaging and teleradiology for the past 15 years(1). A digital imaging network that eliminates the use of x-ray film makes military medicine requirements simpler. X-ray film requirements include storage of new, unexposed films, storage and use of chemicals and water for processing, and disposal of chemicals. In some deployed situations, the chemical discharge needs to be collected and shipped out of the area. Therefore, the ability to implement electronic imaging, and eliminate or greatly reduce the dependence on film, chemicals, and water are intrinsically important to military medicine.

In December 1995, the US government began deployment of 20,000 US troops to Bosnia-Herzegovina as a part of NATO's peace keeping implementation force (IFOR) operation. A full complement of military medical support facilities was established in Bosnia. An army base in Hungary was the location from which the deployment was staged. The project to deploy telemedicine and teleradiology capabilities to the medical treatment facilities (MTF) in Bosnia & Hungary became known as PrimeTime III(2). This paper deals with the deployable teleradiology (DEPRAD) system that was installed by the ISIS Center at a number of facilities to implement filmless radiology and teleradiology services in support of PrimeTime III.

Combat Casualty Care in Europe

The medical care for the US troops in Bosnia is provided through 4 echelons of medical treatment facilities: forward medical and surgical elements (FME and FSE) located throughout Bosnia; a mobile army surgical hospital (MASH) in Tuzla, Bosnia; a combat support hospital (CSH) in Taszar, Hungary;

and a European based US military tertiary care medical center, the Landstuhl Regional Medical Center (LRMC), in Landstuhl Germany.

The deployment of US troops to Bosnia was seen as an excellent opportunity to take advantage of and verify the use of teleradiology. The existence of more than 2 million land mines and potential hostile elements in the region warranted strict control over the movement of troops in the region. A convoy of at least four vehicles and eight combat soldiers was required to transfer a single casualty. Air evacuation was possible, but again limited by available personnel, potentially hostile environment, and poor weather conditions. Helicopters flying in and out of Bosnia-Herzegovina were required to fly in groups of two or more with an attack helicopter escort having guns in the ready position. The implementation of teleradiology in the region was seen as a mechanism to limit casualty evacuations to life or limb threatening cases, while providing the highest level of medical care.

The forward elements do not usually have x-ray imaging capabilities. X-ray imaging including CT, conventional x-rays, and ultrasound imaging is available at the MASH and CSH. Table 1.0 shows the x-ray imaging service capabilities for the Bosnia deployment.

	MASH	CSH	LRMC
Conventional X-ray	X	X	X
Computed Tomography	X	X	X
Ultrasound Scanner	X		X
X-ray Technologists	X	X	X
Radiologist		X	X

Table 1.0 X-ray Imaging services

In this deployment, a radiologist was deployed at the CSH in Hungary, but not at the MASH in Bosnia. Radiologist's support was provided solely via teleradiology.

DEPRAD was designed to support the following clinical scenarios:

- Acquire radiological images and patient data at each field hospital.
- Provide a filmless radiology service at the MASH and CSH.
- Provide teleradiology support for the MASH from the CSH and LRMC.

The intended benefits of DEPRAD include:

- Provision of a chemical-free image processing environment
- Reduction in troop movement
- Reduction in unnecessary medical evacuations
- Provision of remote expert radiological diagnosis

System Configuration

A number of devices were required to establish the filmless radiology and teleradiology capability that linked the three medical facilities: MASH, CSH and LRMC. In order to connect all the equipment in a clinically useful network, the Digital Imaging and Communication (DICOM) 3.0 medical imaging communications standard was required[3].

While DICOM is fast becoming the standard of choice by most medical imaging vendors, limitations of the standard were realized. A system integration effort of this magnitude could not have been accomplished in the compressed time frame (90 days) had DICOM not been used.

DICOM conformance statements were available from most vendors and they provided a mechanism for determining the level of DICOM compatibility between multiple vendors. While none of the devices were plug and play, the extra work required to make the systems communicate was far less than if proprietary interfaces had been developed([4,5,6]). Among the DICOM implementations encountered, none were connected without modification to configuration files, software changes or patches by vendors, or operational changes.

Computed radiography (CR) was installed at the MASH and the CSH to replace the conventional x-ray systems. CR devices utilize reusable phosphor plates in place of conventional film. A cassette containing a phosphor plate is used in place of an x-ray film cassette in the existing x-ray equipment to expose the image. A laser reads the phosphor plate and the resultant digital data is used to form high fidelity images comparable in quality to conventional x-ray film images. A compact CR system, the AC-3 by Fuji Medical Systems, was selected for its reliability and excellent image quality. A DICOM interface gateway was purchased from Analogic to make the AC-3 compatible with the rest of the network.

Filmless radiology and teleradiology require high-resolution workstations for viewing of radiological images. Two types of display workstations were selected, a 2,000 line monitor system and a 1,000 line monitor system. The Siemens MagicView workstation was selected because it could support both types of display monitors. It was felt that 2K monitors would be necessary for primary diagnosis for all radiological studies and 1K monitor systems could be used outside the radiology service for review purposes. The Siemens MagicView workstations also support DICOM 3.0 for image exchange.

One of the most important additions to the DEPRAD network was the use of dry film printing for generating hard copy images. The Imation 8700 DryView and Polaroid Helios printers were deployed to make occasional hard copy images for non-US troops, Bosnian locals and other special uses like OR cases. These printers print high-fidelity X-ray images on film without the use of chemicals or water. DICOM interface gateways were required for both printers to communicate on the network. This allowed for the transfer of images from the Siemens workstations to the printers as needed.

The Lumisys film digitizers was deployed along with a Dejarnette workstation to allow for the introduction of existing x-ray films into the DEPRAD network. X-ray images generated at other locations can be digitized and transmitted to the radiologist for comparison or review.

The Army provided computed tomography from Picker International and ultrasound imaging by Diasonics for inclusion in the DEPRAD network. While the CT scanner did come equipped with a DICOM 3.0 interface for transmitting images, the Ultrasound unit required the use of an ALI interface computer in order to send image to the Siemens workstations.

Table 2.0 provides a list of equipment included in the DEPRAD network. A network diagram of the MASH is shown in Figure 1.0. The network diagrams for the CSH and LRMC are similar.

Equipment	MASH	CSH	LRMC
Picker PQS CT	1	1	
Diasonics Ultrasound with ALI interface	1		
Fuji AC-3 CR with Analogic SD-100	1	1	
Lumisys Lumiscan 75 with Dejarnette IM910	1	1	
Imation 8700 Printer Imation print server	1	1	
Polaroid Helios Printer Dejarnette print server			1
Siemens workstations	3	6	2

Table 2.0 Equipment Configuration List

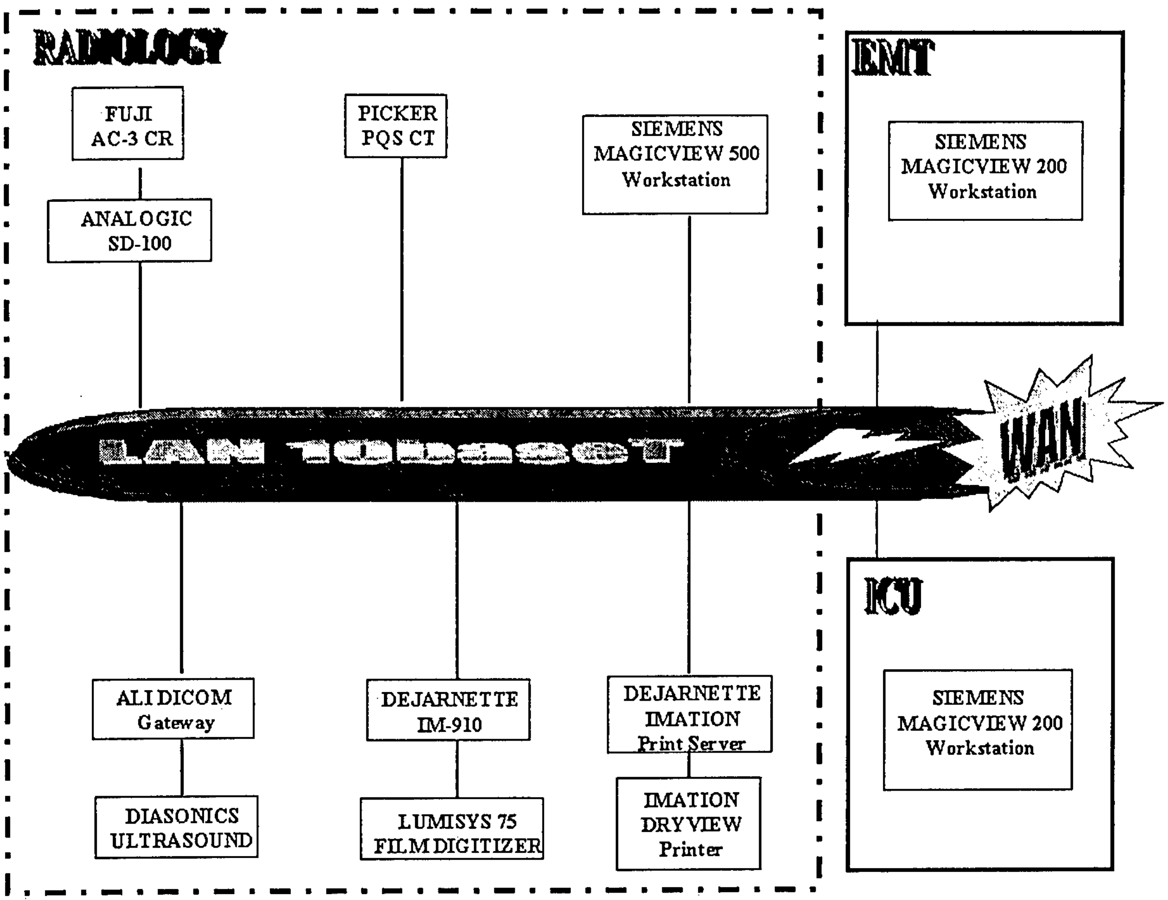

Figure 1.0 Equipment Configuration at MASH

Communications Network

Several types of communication systems were used throughout the DEPRAD network. A 10BaseT local area network (LAN) was implemented to move images within the MASH and CSH. Wide area communications between LRMC and the MASH utilized microwave and satellite links. Images acquired at the MASH were sent via a microwave extension to a US air base. The data was then relayed to Landstuhl via satellite connection.

The communication between Landstuhl and the CSH was over E-1 lines (2.048 Mbps signaling rate) leased from the German and Hungarian telecommunication companies. Internet access was established at all sites. A diagram of the communications network installed for the DEPRAD project is shown in Figure 2.0.

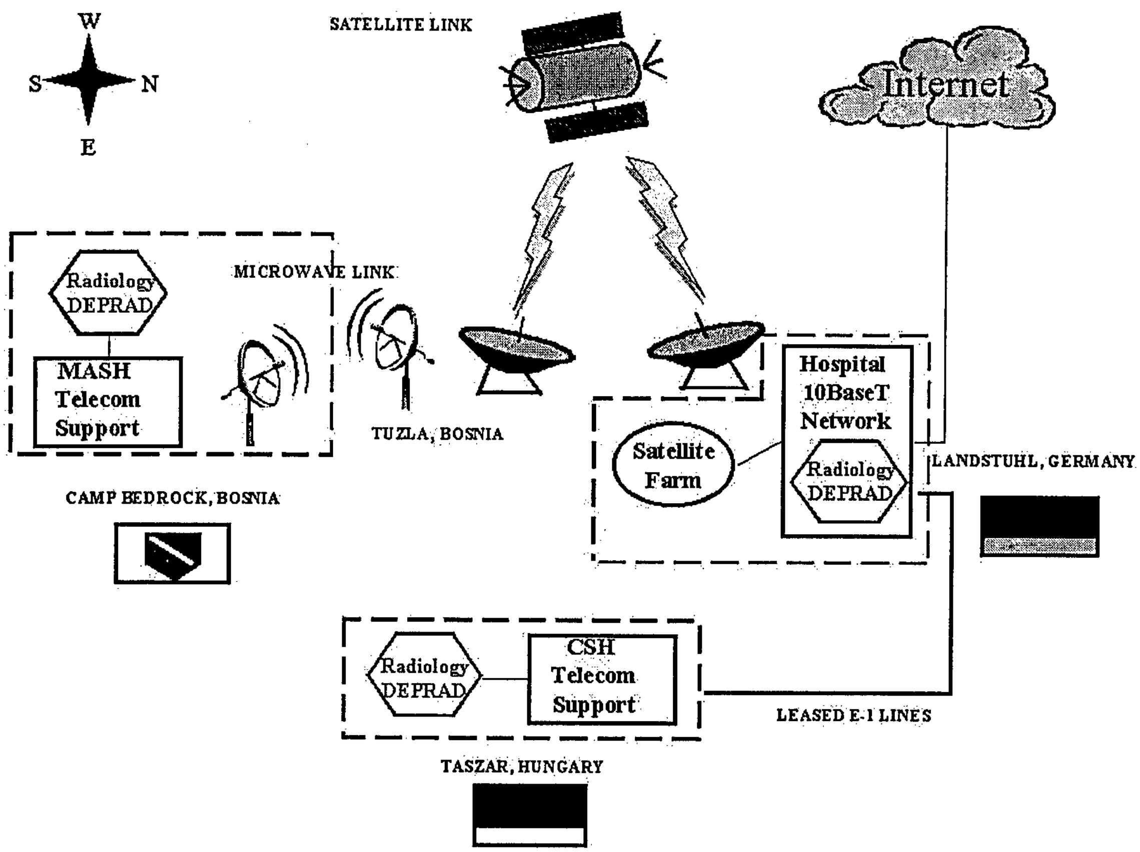

Figure 2.0 Communication Diagram

Clinical Scenario

Images are acquired digitally at the MASH and CSH. Since there is no radiologist stationed at the MASH all images acquired there are sent to the CSH for softcopy primary diagnosis. LRMC is available as a backup unit for reading images from either the MASH or CSH. Simultaneously, images are transferred within the MASH and CSH to local workstations and/or printed as needed. (Printing is done routinely for operating room cases and as needed for follow up care at civilian hospitals for foreign nationals and other peacekeeping partners.) Permanent archival of all studies acquired at the CSH and MASH was maintained at the CSH. Images were transferred to LRMC if a patient was evacuated there, if a radiologist was unavailable at the CSH, or for a second opinion. This process flow is shown in Figure 3.0.

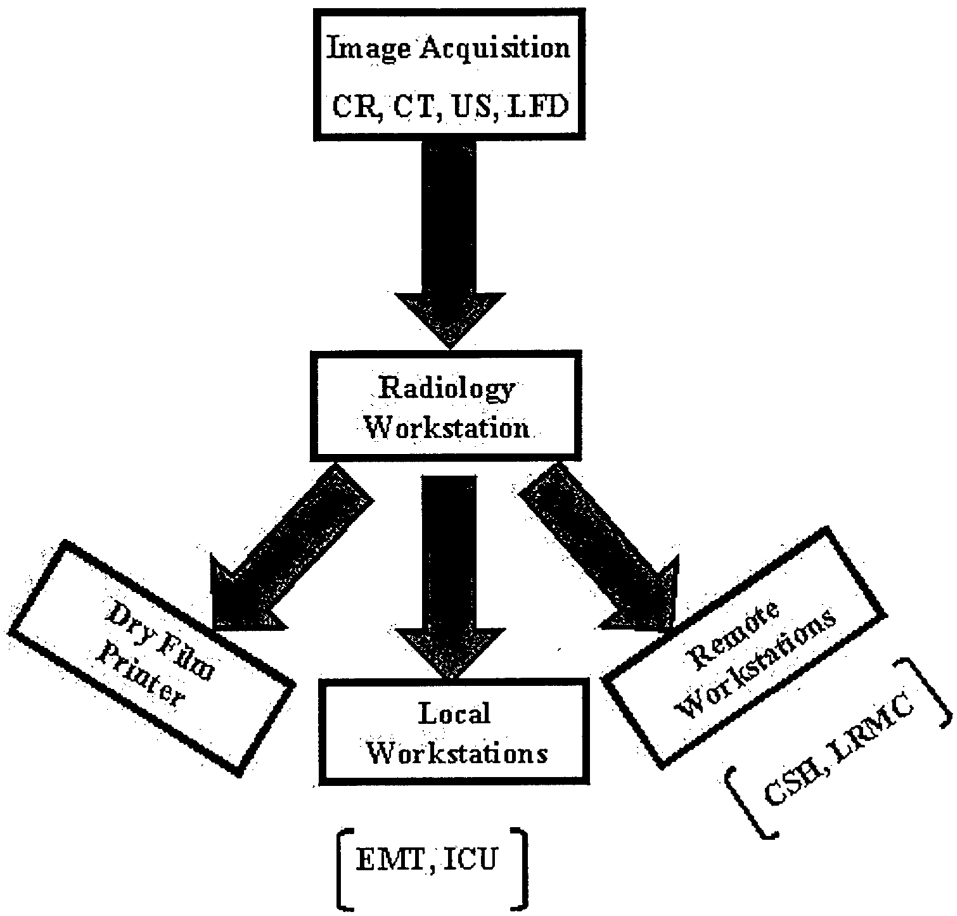

Figure 3.0. Process flow diagram of Project DEPRAD.

All images were sent to the CSH in batch mode at the end of each day except for emergency cases that were transferred immediately. This was found to provide sufficient turn around for the non-emergent cases within this population. Once studies were diagnosed at the CSH, the radiologist either phoned back the report to the MASH or recorded it at once into the Composite Health Care System, the military's world-wide hospital information system.

Throughput

Throughput over the wide area network (WAN) was slower than expected due to a lack of data compression in the DEPRAD network and the use of standard parameters for transport control protocol/internet protocol (TCP/IP) over satellite communications. When the project was designed and implemented, there was not time to include data compression as a means of increasing throughput rates. Similarly, while the WAN utilized provided for T-1 transmission rates, the inherent delay in satellite links and the default settings for TCP/IP communications prohibited full utilization of those rates. TCP/IP parameter optimization to utilize T-1 rates was examined and it was concluded that it would increase throughput times, however, the schedule prohibited its implementation.

Transmission times for a single chest image, 7-10 MB of data, from the CR device to a local workstation were under 2 minutes. The transfer time for an image from one local workstation to another was less than 30 seconds. The transfer time going from Bosnia to Germany or to Hungary was about 7 minutes; from Hungary to Germany, approximately 2 minutes. Over the Internet, image transfer times varied considerably depending on the time of day and utilization of the Internet. It could take between 20 - 60 minutes for a single image. The Internet access was used only for quality control and system diagnostics, not for any clinical support.

Technical Support and Maintenance

The ISIS Center at Georgetown University is responsible for technical support and maintenance of the teleradiology system for the Bosnia deployment. This is done through the Internet and telephone calls. At the beginning of the teleradiology operation, many hours of technical support were necessary. As the staff gained experience, and more bugs were fixed, the amount of required support decreased significantly. A set of documents describing system configuration, operations, and systems administration were very effective in making the system operationally acceptable.

The sites were checked daily from a teleradiology support suite at the ISIS Center in Washington, DC, using Internet access. The disks were checked for fullness and local error logs reviewed. Usage statistics were also monitored. Other continued maintenance and support items included modification to the initial system configuration to meet the increased workload at the MASH. Image quality was checked by having problem images sent to the ISIS Center via the Internet where a physicist, technologist, or radiologist experienced in CR imaging would evaluate them.

Bosnia Update

The DEPRAD network at the MASH and the CSH provided high quality filmless radiology that did not generate any chemical waste. On a typical day, the MASH performs 20 x-ray studies using CR, 3-4 CT studies and 1-2 ultrasound studies. These images were routinely sent to Germany and Hungary for radiology consultation. In November 1997, the CSH was closed down and the network was reconfigured operationally to send images to LRMC for primary diagnosis. Archiving of exams became the responsibility of the MASH. These changes have not negatively impacted operations of the network or the continued use of the local filmless operations. However, due to an interruption in wide area communications, it has become more cumbersome to transmit the images to LRMC and impossible to continue support over the Internet. The technologists, however, have persisted and continue to transmit the images to LRMC routinely.

More than 10,000 radiological examinations have been acquired and diagnosed using the DEPRAD network over the past 18 months.

For the first time in US military medical deployment, the entire radiological workload of the MASH was supported by radiologists hundreds of miles away. The system was serviceable remotely from the ISIS Center in Washington, DC with assistance from deployed military technologists and bioengineers.

The Next Generation T-Med Platform

The success of the DEPRAD network led to other Army telemedicine deployments. They will be discussed briefly below.

Cobra Gold

First, a military joint exercise in Thailand, named Cobra Gold, was planned for spring 1997. The goals of Cobra Gold were to provide corps level health service support, humanitarian care to the indigenous population, and a testbed for an experimental medical detachment telemedicine system. The telemedicine system was designed to augment existing health service support practices by providing telemedicine capabilities to the front line. The primary role of the telemedicine system was to capture, store, and transmit still medical images, including but not limited to radiology images.

The system was deployed at three sites in Thailand: a MASH and to mobile units called Medcap 1 & Medcap 2. The following equipment was deployed at all three sites:

- Medical scopes including otoscopes, opthomaloscopes, dental scopes, etc.
- Picasso phone for capturing, storing, and transmitting images

- MMS Carelink telemedicine station for storing and forwarding patient folders
- Film digitizer for digitizing x-rays
- Inmarsat satellite for communicating with the forward sites.

The still images and patient folders were transmitted from the Medcap sites to the MASH for diagnosis. They were also sent to Tripler Army Medical Center in Hawaii and Madigan Army Medical Center in Washington state.

This deployment was a much smaller scale than Bosnia, however it also proved that teleradiology and telemedicine does play an important role in military medicine.

Saudi Deployment

Again, growing out of the success of the Bosnia deployment, the Army chose to provide teleradiology and telemedicine support to the US troops remaining in Saudi Arabia. This effort resulted in a phased approach.

The first phase was to provide teleradiology support by providing film digitizers and workstations that are compatible with the DEPRAD deployed workstations. A Lumisys film digitizer with Dejarnette workstation was deployed to Saudi Arabia. The images are digitized and sent to LRMC for primary diagnosis using the Siemens review stations provided as part of the Bosnia network.

The next phase was to provide computed radiography and dry film printing to Saudi Arabia. This would be connected to a KLT Telecom telemedicine workstation to provide x-ray image display and transfer along with video conferencing capabilities.

The use of a single workstation for teleradiology and telemedicine support is a great advantage and enhancement to the world of telemedicine.

Conclusion

Teleradiology both in the private and the military sectors has proven to be effective, clinically viable, and affordable. The DEPRAD project was a perfect example of how teleradiology can support deployed troops during peacetime or war. More than 10,000 radiological examinations have been acquired and diagnosed using the DEPRAD network over the past 18 months. The extensions of DEPRAD, Cobra Gold and the Saudi Deployment grew directly out of the DEPRAD project and were undertaken due its success.

By all measurements, Project DEPRAD was a success. Its three design features, the acquisition of radiological exams at the MASH and CSH, the provision of a filmless radiology service at the MASH and CSH, and the provision of teleradiology support for the MASH were all realized. All exams were and still are acquired and viewed digitally. Computed radiography was used exclusively at the MASH and the CSH and all studies were transmitted to the CSH or LRMC for primary diagnosis.

The intended benefits of the project were also realized. For the times when a hard copy film is required, the dry film printers installed as part of project DEPRAD provided water and chemical free diagnostic quality film printing. Troop movement and unnecessary evacuations were greatly reduced due to the teleradiology component of the project. Expert remote diagnosis was provided which led to faster response to trauma and a reduction in evacuations.

One shortcoming of the project is the performance rate with which images are transferred over the wide area network. Since the project was undertaken in a compressed timeframe, the implementation of compression techniques or other mechanisms to speed up transfer times were not implemented. While techniques to improve communication rates over satellites were investigated, the timeframe did not permit for the testing or implementation of the findings. A clinical deficiency of the DEPRAD network is the lack of an automated archive. Archiving of digital studies requires a manual procedure implemented by a technologist to ensure all studies are successfully archived to a magneto-optical disk. While all data has been successfully archived, the implementation of an automated jukebox style archive would provide more security and less frustration for the users of the system.

Any major teleradiology or digital radiology effort is much more viable when standards are used as the basis for connectivity throughout the network. Without the use of DICOM 3.0, this project would not have been completed in the compressed time-frame. Standards provide the ability to develop open systems where multiple vendors' equipment is more easily connected, and the cost and options for such networks are improved.

While DICOM played a major role in the rapid design, development and implementation of the DEPRAD network the vendors' cooperation and willingness to work cohesively to create this network was critical. Without their support and cooperation this project would have been impossible to complete.

ACKNOWLEDGMENTS

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Lessons Learned from the DEPRAD Deployment

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Abstract

In April 1996, a deployable teleradiology system was installed in Bosnia-Herzegovina to support the 20,000 US troops recently deployed to the area. The purpose of the system was to provide Radiology support to an area that had radiology imaging capability but limited access to a radiologist. The development of the system deployed in Bosnia-Herzegovina was a systems integration feat that included equipment from 11 different vendors and the use of the Digital Imaging and COmmunications in Medicine (DICOM) 3.0 standard for connectivity to integrate much of the equipment.

While the development, integration, and implementation were completed in 3 months, the project was not straightforward. Many of the systems did not communicate initially and required much troubleshooting and investigation to create a cohesive, comprehensive network. The project was completed and implemented on time and has been supported remotely for the past two and one-half years.

While the project has been seen as a huge success by many standards, there are still aspects of the implementation that would be done differently if the project were to be repeated today. These areas include hardware decisions, implementation issues, operational considerations, and continued maintenance and support items.

This paper will discuss briefly the details of the Deployable Radiology (DEPRAD) network, the clinical operations, and support mechanisms in place to keep the system operational two and one-half years after implementation. It will then discuss the areas of the implementation that require consideration before undertaking such a project again as well as the lessons learned from such an experience.

1. Introduction

The Deployable Radiology (DEPRAD) network project was to design and implement a teleradiology network that supported remote diagnosis of radiology images generated in Bosnia and Hungary. It was deployed in a non-peacetime situation and provided remote diagnosis anytime between Bosnia, Hungary, and Germany, with potential participation by stateside military hospital.

DEPRAD was designed to support the following clinical scenarios:

- Acquire radiological images and patient data at each field hospital
- Provide a filmless radiology service in Bosnia and Hungary
- Provide teleradiology support for the hospital in Bosnia from Hungary and Germany

The intended benefits of DEPRAD include:

- Provide chemical-free image environment
- Reduce in troop movement
- Reduce unnecessary medical evacuations
- Provide remote expert radiological diagnosis

2. Deployable Radiology

DEPRAD was designed to acquire radiological images and patient data at the hospitals in Bosnia and Hungary. Computed radiography, computed tomography, and ultrasonography imaging were combined with soft copy viewstations and dry film printing to provide a complete digital imaging network to the hospitals in Bosnia and Hungary. Teleradiology capabilities provided access to the images generated in Bosnia in Hungary and Germany for primary diagnosis or secondary review. This reduced the need for unnecessary evacuations of patients and a reduction in troop movement. A diagram of the network installed in Bosnia is shown in Figure 1.0.

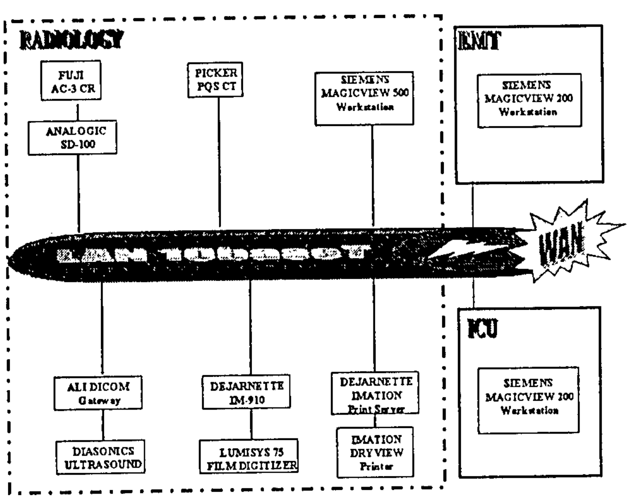

Figure 1.0 Equipment Configuration in Bosnia

Several types of communication systems were used throughout the DEPRAD network. A 10BaseT local area network (LAN) was implemented to move images within the local hospitals in Bosnia and Hungary. Wide area communications between Germany and the Bosnia hospital utilized microwave and satellite links. Images acquired in Bosnia were sent via a microwave extension to a US air base. The data was then relayed to Germany via satellite connection.

The communication between Germany and Hungary was over E-1 lines (2.048 Mbps signaling rate) leased from the German and Hungarian telecommunication companies. Internet access was established at all sites. A diagram of the communications network installed for the DEPRAD project is shown in Figure 2.0.

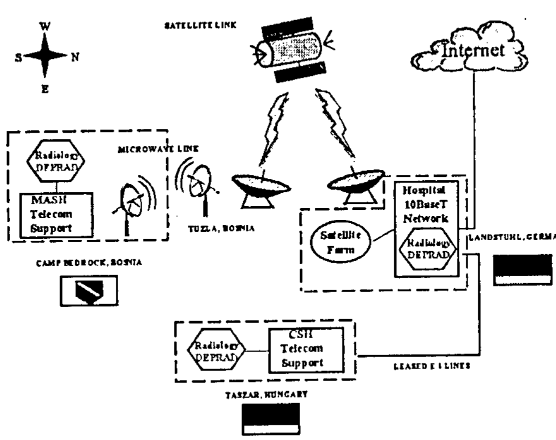

Figure 2.0 Communication Diagram

3. Readiness

Project DEPRAD showed that technology exists today to provide filmless medical imaging to military deployments in non-peacetime situations. This is no longer a research effort and should no longer be treated as such. In order to continue providing filmless medical imaging, and thus receiving the benefits from such a system as outlined above, there must be a commitment from the military to keep the technology current, provide access to training, and upgrade hardware and software systems that are part of such a system. A training site should be setup that allows troops entering areas that contain a DEPRAD network to be trained prior to deployment. This training center needs to have and a full complement of equipment, both hardware and software, that the unit may encounter within their deployment. Full-time personnel must be assigned to the training site to keep the equipment operational and up-to-date. Both clinical usability as well as maintenance and support issues need to be trained at the site.

There also needs to be an inventory of equipment that has been checked out and ready for deployment available so that on short notice this equipment can be deployed whenever and wherever it is required. All equipment needs to be integrated before deployment and tested, although this can occur upon receipt of the equipment. Time needs to be allocated to determine the requirements of the deployment, i.e. what equipment needs to be shipped to support the troops in the deployed area. This includes the types of imaging modalities as well as the number and types of review stations and hardcopy devices. Wide-area and local-area communications links should be tested prior to deployment if a new technology is employed. Also the wide-area connectivity should be in place prior to deployment of the DEPRAD network.

4. Items for Consideration

When a DEPRAD deployment is undertaken, the items that require consideration include:

- Logistics
- Project acceptance
- Communications links
- DOD rules & regulations
- Continued support and maintenance

Logistics

A realistic timeframe must be allowed for the deployment. This includes time to properly analyze the situation and properly design the system (imaging modalities required, number and types of review stations) and time to purchase or coordinate the equipment. The equipment must be installed, tested, and the users trained on the system. Training should be done prior to deployment and a follow-up session immediately after the troops arrive at their deployment. There needs to be a commitment from all the parties involved that this network is necessary to the overall success of the military deployment.

Project Acceptance

The critical element to the success of a DEPRAD deployment is acceptance of the project from multiple levels. The users of the system must be committed to understanding the importance of the project. They must be willing and excited to use the system and guarantee its success. Developing advocates at all levels of the deployment will make this task easier. If there is a commitment to the success of the project from the highest levels of the deployment, the enthusiasm for the project will trickle down to all levels of users. To increase acceptance of the project, training local clinical users and support personnel will increase their comfort level with the system and improve their willingness to use and maintain the system properly.

Communication Links

Communications at each deployment will most likely be limited to the availability of communications at that site. When options do exist for a deployment, a decision should be made based on availability, cost versus performance, and suitability. While the higher speed networks will transmit the images more quickly around the globe, the cost associated with such a network may be prohibitive and the advantages not as great. Understand the expected transfer rates that can be expected with the choice of communications, both in the best-case and worst-case scenarios. The communication links should be installed as early as possible and tested thoroughly with the equipment prior to going live with the system. When possible, testing the communication links prior to deployment, preferably in the States, will reduce problems and interruption encountered during the deployment. It is critical to understand which organizations are responsible for installing, supporting, and maintaining the communication links. Remote troubleshooting procedures should be well understood and a procedure for clearing up problems in place before the end of the installation.

DOD Rules and Regulations

Especially for non-military personnel, it is critical to understand the rules and regulations for the deployment before installing any equipment. That is know how equipment will be moved about, how travel must occur, and how easy it is to get in and out of the deployment area if necessary. A point-of-contact should be identified for each site from the military side as well as the vendors. It is important to know who can help get things done if they need to happen quickly, i.e. getting equipment or furniture moved around. The military schedule often feels like a hurry-up and wait schedule, so be prepared for down-time and delays while equipment is being moved, paperwork filled in, and inventory counted and recounted.

Continued Support & Maintenance

The best way to ensure low maintenance and support issues is to properly train local users to perform daily, weekly, and monthly preventative maintenance measures for all pieces of equipment. To facilitate this, it is critical to provide good documentation for all systems, including but not limited to vendor documentation. Known potential problems, like power outages, should be planned for prior to installation and recovery procedures documented and taught to local users. Remote support procedures should be in-place before leaving the deployment area and wide-area connectivity in place to remotely check systems. Besides a systems communication path, their needs to be a good communications path in place for telephone and e-mail support, especially when military telephone lines are not available to the supporting agencies. A mechanism needs to be clearly identified for shipping equipment in and out of the deployment area. This will facilitate the repair and replacement of equipment as needed.

5. Lessons Learned

The success of project DEPRAD has led to future deployments of DEPRAD equipment in Kuwait and smaller systems in Saudi and forward sites in Bosnia. However, there are many things we learned from this project that are important to consider in future efforts like project DEPRAD. Undertaking any project with a scope as grand as project DEPRAD requires clear, comprehensive, and complete project requirement specifications before beginning. It is critical to understand the goals of the project and how these goals will be reached. These specifications should lead to the development of technical and clinical requirement specifications.

To facilitate a project of this magnitude, commercial off the shelf (COTS) hardware and software should be required. This will guarantee availability of hardware and software, and more importantly ensure vendor support, upgrade paths, and ease of use. Likewise, the use of standards like the Digital Imaging and COmmunications in Medicine (DICOM) 3.0 standard improve the ease and completeness of connectivity. Once these systems are defined and integrated, end-to-end testing should be completed, preferably prior to deployment.

Cooperation and project "buy-in" from all vendors, military personnel, systems integrators, and others involved in the development effort is crucial to the success of the project development. When working under tight deadlines and short timeframes, understanding the importance of the project will propel all individuals involved to work quickly and efficiently to get things done.

Short and long term support and maintenance scenarios need to be in place before the system is deployed. Plans for on-site maintenance and support should be well documented and individuals trained on these procedures before completing the initial system implementation. Remote support procedures also need to be well detailed and communicated to on-site personnel so that the appropriate chain of command is followed for getting fast support when problems arise. Training both prior to deployment and immediately after will improve operability of the system and project success. A testing and training lab in the States should be used for pre-deployment training followed-up by on-site training immediately following deployment. Included in maintenance scenarios, should be upgrade paths to facilitate the upgrading of hardware and especially software involved in the deployment. While this seems straightforward, it is often difficult to do when the equipment is deployed in a non-peacetime environment and in a distant location.

The three areas of the project DEPRAD that require more evaluation and had there been more time for the design and implementation of the system might have been done differently include:

- Automatic archive
- Connectivity to reporting system
- Faster transfer rates/compression

The current DEPRAD system relies on the technologist manually selecting each study to be copied to a magneto-optical disk (MOD) to maintain a long-term archive. Each MOD needs to then be manually labeled and stored in an off-line location and maintained so that studies can be retrieved at a later time if required. Automation of this procedure using MOD jukeboxes or tape archives would reduce the risk of lost studies as well as removing a time-consuming task required of an already busy technologist.

The DEPRAD network is stand-alone in that it is not connected to any hospital or radiology information system. Therefore, when studies are read remotely by radiologists, the reports that they generate are faxed, phoned, or remotely entered into a reporting system. While this does provide for near-immediate results reporting, a more convenient system would be to integrate the results reporting system to the DEPRAD network to provide immediate on-line access to reports with relying on telephone lines which are often difficult to access. The lack of a comprehensive information system between the sites involved in the DEPRAD deployment, and the compressed timeframe prohibited the investigation of this type of interface for this project.

Lastly, the wide-area transfer rates for studies were longer than expected by the upper command. Wide area connectivity was never established in the States while testing the DEPRAD network. The delays inherent to satellite communications increased the transfer times for radiology studies past the expected times of military personnel. While it took 6-7 minutes to transfer a single chest x-ray from Bosnia to Hungary, this time could be halved had lossless compression techniques been implemented. However, the review station selected for the deployment did not support compression techniques and the compressed timeframe prohibited our developing of a compression technique. Investigations of satellite communications techniques provided some other solutions to increase the transfer rates, but again timeframes and distance once the system was deployed prohibited the testing and consequent implementation of these techniques.

6. Conclusion

DEPRAD has proven that filmless radiology and remote diagnosis of radiology studies are viable alternatives within military deployments. Since radiologists are often not deployed to mobile army surgical hospitals, the use of a DEPRAD network can continue to provide first rate radiological support to those situations.

The lessons learned and the experience gained from the DEPRAD deployment are critical to future successful technology deployments within the military. Many of the situations that were encountered during this effort are not unique to project DEPRAD and are good lessons for future work with DOD and military deployments.

In order to guarantee the success of a mission like project DEPRAD, it is important to know the clinical environment for the deployment, the personnel involved, and the void that the project fills. Commitments for the deployment from all parties and all levels of the military will also increase the project's acceptance and thus the success of the project.

Building a Security Capable Organization: A Workshop for PacMed Net 98

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Abstract

This paper presents general principles and case examples of how health care providers might prepare themselves to become data security capable organizations; that is, organizations in which ensuring the security and confidentiality of medical information becomes incorporated into the every day working routines of all staff. Building a security capable organization requires institutionalizing a security surveillance process, not just implementing security measures.

Implementing a security surveillance process requires several steps, including:

1. Monitoring the changing legal and regulatory environment;
2. Enhancing patient understanding of the organization's data security efforts, and;
3. Continuously updating data security policies, procedures and practices in light of changing mission.

Case examples from KP Online, an interactional patient tool from Kaiser Permanente Health Care and Project Phoenix, a telemedicine project from Georgetown University Medical Center illustrate the general points.

Introduction

The debate about medical information security tends to polarize into two broad perspectives. The media and privacy advocates argue that easy trafficking in medical information poses grave risks to patients' privacy, a situation that the computerized patient record (CPR) only promises to exacerbate [1-7]. CPR advocates argue to the contrary that the entire progress of health reform including improvements in maintaining patients' privacy depends upon adopting electronic record keeping systems and their associated technologies such as universal health identifiers[8-12]. How should a contemporary health care provider responsibly act in the face of such diverse and uneasily mediated positions? Congress and the Department of Health and Human Services will provide guidelines within the next two years thanks to a variety of medical record reform efforts underway. As with all such guidelines, nonetheless, health care providers will have to interpret and indeed go well beyond the legal requirements in order to meet their obligations to both their patients and themselves. This paper presents general principles and case examples of how health care providers might prepare themselves to become data security capable organizations; that is, organizations in which ensuring the security and confidentiality of medical information becomes incorporated into the every day working routines of all staff. Building a security capable organization requires institutionalizing a security surveillance process, not just implementing security measures.

Implementing a security surveillance process requires several steps, including:

1. Monitoring the changing legal and regulatory environment;
2. Enhancing patient understanding of the organization's data security efforts, and;
3. Continuously updating data security policies, procedures and practices in light of changing mission.

Some of these tasks clearly fall under the responsibility of professional staff dedicated to managing medical records. When properly implemented, however, a comprehensive security surveillance process incorporates everybody including patients, all individual staff, an organization's general administration and the data security team. Like universal precautions for infectious disease, maintaining the security of our organizations' and patients' valuable medical information should become simply part of how we do our jobs rather than another in an ever expanding list of onerous supplemental tasks. After having begun the process of data security surveillance, we will discover that we have created a new relationship with our "customers" in which we are accountable to them for our business practices in addition to our medical care. As we institutionalize the data security surveillance, we should coopt, not simply coerce our health care colleagues into the process.

Monitoring the legal and regulatory environment

Questions of medical privacy occupy center stage in the contemporary United States. Hardly a day goes by that the Washington *Post*, New York *Times*, or *USA Today* do not feature an article about some aspect of medical privacy. Opinion polls document that the American public regards the data management practices of most large organizations with great skepticism. In partial response to these and other expressions of public concern, President Clinton commissioned a task force on medical privacy as part of his health care reform efforts. Although the recommendations of the privacy task force died along with Clinton's plan, federal legislators have incorporated some of their intent (particularly the requirement of federal medical privacy legislation) into the piecemeal approach to health care reform developed during the last three years. The Health Insurance Portability and Accountability Act of 1996 (HIPA) otherwise known as the Kennedy-Kassenbaum Act creates specific requirements for the Congress and the Department of Health and Human Services. Because of Kennedy-Kassenbaum, within two years the legal and regulatory environment for managing patient medical records will dramatically change. Either Congress will pass comprehensive medical privacy legislation or the Department of Health and Human Services will implement regulations requiring health care providers throughout the United States to adopt new policies, procedures and practices in managing medical information. DHHS must also lead the way by designing model rules to guide Congress and/or implement the laws it passes.

Under the rubric of "Administrative Simplification", HIPA requires Congress to pass laws that "improve... the efficiency and effectiveness of the health care system by encouraging the establishment of standards and requirements for the electronic transfer of certain health care information" (PL No. 104-191). In sections 261 through 264, HIPA calls for standards and laws for two circumstances, namely 1) the electronic interchange of financial and administrative data between health plans, healthcare clearinghouses and health care providers, and 2) maintaining the privacy of individually identifiable medical information. HIPA also establishes a timetable by which Congress and DHHS must act.

Under the direction of the National Committee on Vital and Health Statistics, the Healthcare Finance Administration (HCFA) leads the DHHS effort to draft transaction and model privacy standards. By any stretch of the regulatory imagination, HIPA establishes an aggressive timetable for DHHS to draft, release for comment and recommend for adoption such a complex, extensive and important set of regulations. Although behind schedule, DHHS has made a valiant effort. New regulations are regularly released for comment in the Federal Register. As of August 12, 1998, the status of the various sets of recommendations is listed below. For summaries of all released NPRM, see Appendix A.

The HIPA Timetable as of August 12, 1998

Date	Event
July 31, 1996	HIPA enacted
Sept 11, 1997	Confidentiality recommendations
May 7, 1998	NPRM:Provider Identifier
May 7, 1998	NPRM:Electronic Transaction Standards
May 7, 1998	NPRM:Medical Code Set Standards
June 16, 1998	NPRM:Employer Identifier
July 6, 1998	White Paper: Unique Health Identifier – Individuals
August 12, 1998	NPRM: Security Standards
Pending	NPRM: Identifier -Health Plans

Several federal legislators have introduced privacy bills. To consult the text and follow the legislative status of each bill, go to the federal legislation website, http://thomas.loc.gov and search on "medical privacy".None of these bills is yet law; but, the DHHS recommendations on maintaining confidentiality of individually identifiable information both provides a model of what any federal law should address and stipulates what actual regulations will take effect if Congress fails to act. To consult the text of these recommendations as well as the existing draft regulations for electronic transactions, please consult the DHHS website, http://aspe.os.dhhs.gov/admnsimp/pvcrec/htm. Please consult Appenidx B for a summary of the recommendations

You may also enroll to receive email notice of new posted draft regulations through this same website. A security capable organization will study, understand and begin to formulate responses to possible legislation on the basis of the DHHS recommendations on medical privacy. Although these recommendations do not exhaust the changes health care providers will have to make in response to upcoming legal and regulatory reforms, they will certainly constitute the foundation of any organization's plan of action. In the months to come, Congress and the DHHS will make new laws and rules based on these principles. Although the legislative process will undoubtedly affect the precise requirements, health providers, payers, service organizations and other organizations potentially affected should begin now to ready their responses. Preparing themselves to meet the new federal guidelines constitutes the first step in becoming security capable organizations.

Enhancing patient understanding of organization's data security efforts

As the DHHS recommendations on confidentiality make clear, we will face new obligations in informing our patients about how they manage health information. The DHHS recommendations signal some broad social changes, however, whose significance transcends the narrow legal and regulatory context of their development. Our relationship with our patients is fundamentally changing. On the one hand, the reforms in health care finance (specifically the emergence of managed care) are refocusing some aspects of health care from the doctor-patient relationship to the health care organization-patient relationship. On the other hand, chronic illness has emerged as the dominant context of medical care. These major changes mean that we are accountable to our patients as organizations in new ways. In addition to being accountable for health care processes and outcomes, we are becoming accountable to our patients for our business practices, particularly for what we do with information about their individual cases. As our relationship to our patients thus changes, we must reexamine some of the ethical principles guiding our practice. The doctrine of informed consent stands at the heart of the doctor-patient relationship in medical care and research. We must therefore ask, "What implications do all these changes have for informed consent?"

Case Study: *Kaiser Permanente Online* and Changing Patient Relations in an HMO

Today, many healthy patients have a closer relationship, for better or worse, with their health plan than with a specific physician. The provider is no longer the sole source of health information for patients, as consumers frequently shift their health plan coverage, and subsequently their personal physician. This change in the doctor-patient relationship is often most evident in managed care settings, where there are no established processes to help patients develop a relationship with a regular physician. Informed consent is then primarily a process between a health plan and a patient instead of between the patient and physician.

At the same time, consumer access to health information has greatly increased as television, print media and the Internet extensively cover health issues. One of the most positive results of this information explosion is seen in patient support groups being formed throughout the world, either in face-face settings or via Internet discussion groups. This has enabled many patients to gain practical advice from other patients about treatment options, coping mechanisms and other relevant information regarding their health condition. However, since there is little quality control on the Internet, people are routinely reading about unproven health treatments and suggested therapies for health conditions that may result in harm.

Physicians and other health care professionals' who are comfortable helping patients to interpret and make reasoned health decisions do well in this context. The health care organization, on the other hand, is being forced to assume a new role as provider of consumer health information, requiring an entirely new set of informed consent policies and practices.

Kaiser Permanente actively embraces this new role as a provider of consumer health information, and recognizes that 80% of the health care today is "self-care", practiced by consumers. Every new member is mailed a self-care handbook which teaches them about common health conditions, injuries and how to treat these effectively at home. Kaiser Permanente believes in directly providing consumers the information they need in order to practice self-care most effectively.

A promising trend in the organization is the emergence of interactive technologies, which enable this to happen more effectively and in a customized, personalized manner. This was the rationale behind *Kaiser Permanente Online*, our members-only web site. This interactive program provides personalized, confidential health care services to Kaiser Permanente members with Internet access. With the click of a mouse, members can research health conditions and medications, join health discussion groups, get advice from a nurse or pharmacist, request appointments, learn about health education classes, get information about Kaiser Permanente medical facilities, and link to recommended medical and health web sites.

The goal is for all Kaiser Permanente members with Internet access to be able to use *Kaiser Permanente Online* by the year 2000. Rather than the traditional marketing website, Kaiser Permanente provides a wealth of health information, online access to physicians, pharmacists and nurses, and the ability to communicate directly with other health plan members. This approach provides a direct relationship between the health plan and the consumer, and involves and supports the care that the physician provides. It also recognizes that not every consumer has a personal physician, or takes the time and effort to contact their provider by telephone or through an office visit.

Members provide informed consent online by requesting and using a password-protected website. Information on the site is only collected in the aggregate form, so that an individual user's activities are not tracked.

Three main objectives guided development of *Kaiser Permanente Online*:

1. *Customized health information for individual users*. Members in different parts of the country viewing *Kaiser Permanente Online* will view information tailored specifically to their area, depending on health plan coverage and services. Eventually, members will view their own personal health information.
2. *Convenience and choice for members*, achieved through the ability to access the Internet 24 hours a day, rather than traditional doctor office hours of 9:00 –5:00 PM. Kaiser Permanente Online encourages members to learn more about their health and take responsibility by directly accessing health information, including when to see the doctor, and how to effectively treat minor illnesses and injuries at home. Members report more appropriate use of medical care services, such as coming in earlier for treatment and avoiding unnecessary phone calls and visits to physicians.
3. *Connecting members with each other and health care providers,* by enabling members to post questions and answers in discussion groups that others can view. For example, someone can post a message stating his or her concern about getting through the appointment system. Kaiser Permanente responds within 24 hours, enabling all users to see and use the information posted in the reply.

Case Study: "HelpBot" and Data Security in Project Phoenix

Lance Hoffman, Anya Kim, and Arwa Al-aama from George Washington University in collaboration with Georgetown have developed a World Wide Web instructional tool known as "HelpBot" to inform patients about how we safeguard the security of patient information in Project Phoenix, a telemedicine in hemodialysis project funded by the National Library of Medicine. In addition to presenting material about our data security program specifically written for HelpBot, the tool contains links to other sources of information on the Internet. The design of "HelpBot" incorporates principles of human-computer interface theory and computer-based education to make it easy for anyone to use with little or no support. Because HelpBot resides on the World Wide

Web, anyone with Internet access may use it. To view the current version of "HelpBot", please see http://www.seas.gwu.edu/seas/projects/phoenix or http://www.telemedicine.georgetown.edu/ProjectPhoenix.htmand click on "HelpBot".

The key point is that "HelpBot" enables patients and family members to explore our approach to data security as deeply as individually required simply by clicking through various levels of the tool. Four basic levels exist, including a homepage that introduces the whole project, a level that explains the telemedicine network, a level that explains the risks to data security found during our risk assessment of the telemedicine network, and a level explaining our risk management plan. A user can migrate through the tool in an infinite number of ways depending on their own need to know and personal approach to learning. For example, if a patient wants to go straight from the beginning to the end, he can proceed horizontally from the introduction to the risk management plan. If a family member wants vertically to explore a particular component of the system, the telemedicine unit for example, she can click on the telemedicine unit, then click on the risks in the telemedicine unit and finally click on how the risks are being handled. At any point, a user can change the search pattern, return to the beginning or exit. In relevant sections, a user can activate hot links to other sites (for example, the firewall guide of the International Computer Security Association) while staying literally within the HotBot frame. We thus provide as detailed an explanation as possible of our approach to data security with the patient determining the level of detail actually searched.

Please note: HelpBot demonstrates our process of data security management as much as it explains its components. HelpBot explains that the telemedicine network exists physically in a particular setting, contains certain types of equipment, moves information along certain pathways, and depends on the actions of certain people. HelpBot also explains, however, that we performed a risk assessment of the telemedicine network; that is, we searched for risks to breaches of data security in the physical plant, the dialysis and telemedicine equipment, the information flow and the people. HelpBot also demonstrates that having identified the risks to data security, we developed policies, procedures and practices to secure the physical facility, maintain the equipment, manage the flow of information and educate the people. "HelpBot" illustrates how we would proceed given any other data security project. Thus "HelpBot" is both a model of and model for our approach to data security management at Georgetown.

"HelpBot" illustrates several critical dimensions of how we are incorporating our patients into building a security capable organization at Georgetown. First, "HelpBot" synthesizes the two key pillars of our data security program in Project Phoenix, namely:

1) HelpBot explains the process whereby we evaluated the risks to data security in the telemedicine system, developed a plan for managing them, and implemented our plan, (that is, it demonstrates how we addressed Hypothesis One in Project Phoenix) and;

2) HelpBot makes the information available to patients in a readily accessible, highly reviewable form over which they have control (that is, it embodies the central idea of Hypothesis Two of Project Phoenix).

Second, "HelpBot" reflects our recognition of the organizational relationship between Georgetown University Medical Center, TRC, Inc and our patients. Our end stage renal disease patients are chronically ill. Although some will leave because they receive kidney transplants, become disaffected with our care, move from the region or die, we will maintain long term care relationships with many if not most of them. Moreover, the patients directly develop that relationship with TRC and Georgetown as recipients of renal care, not secondarily simply as a service to the nephrologist. Third, "HelpBot" will certainly become part of our response to the new requirements to provide written explanation of Georgetown's approach to information management. Although currently focused on Project Phoenix, we can easily adapt "HelpBot" to document and explain the institutional approach to data security management of Georgetown or any other health care organization.

"HelpBot" also reflects our approach to a more fundamental problem, informed consent in the context of contemporary health care. When we think of informed consent in the traditional way, we tend to think of doctors and patients discussing a procedure in the context of an acute episode or a research project. Clinical or research care may occur over an extended period, but the process of informed consent as represented by the act of reading, questioning and ultimately signing a consent form appears as an event. We have such consent forms in Project Phoenix. Indeed, we have incorporated two different explanations of our approach to data security in Project Phoenix into the experimental design and the consent forms of Project Phoenix. We are evaluating whether or not patients vary in their willingness to participate in telemedicine projects depending on the comprehensiveness of the explanation about data security management received in the consent form. The preliminary data indicates that no, our patients have almost without exception agreed to join Project Phoenix irrespective of the consent form. We have nonetheless resisted drawing the conclusion that patients do not require detailed explanations of our data security practices. On the contrary, we have reconceptualized the process of informed consent from being an event to being a continuous process. Given the chronic nature of our patients' illness, the long term nature of the relationship between the patient and our organization, and our emerging new legal obligations, keeping patients continuously informed about our business and medical practices must become key to how we remain accountable to them and their families. As all the opinion polls document, trust is the issue. "HelpBot", a dynamic, patient controllable, easily accessible online tool should therefore replace the fixed, provider-controlled, inaccessible consent form as the central image of a new process of informed consent.

Updating data security policies, procedures and practices

Security capable organizations continuously update their data security policies, procedures and practices to manage the risks emergent from their changing mission. The security team must take primary responsibility for coordinating this effort but an organization's administration and individual staff members must all contribute. Even if they accept the need for maintaining the confidentiality of patient identifiable information, the administration and staff will probably resist taking on new tasks or complicating the work necessary to discharge their current tasks. The security team must recognize that enhancing the organization's security capability requires transforming institutional resistance into work in service of the security effort. In summary, security capable organizations coopt not coerce their members into the security surveillance process.

Case Study: Securing Kaiser Permanente Online

Kaiser Permanente's Information Technology Services recently developed guidelines for securing clinical systems. Data are classified as "general", "confidential", and "restricted". All features of *Kaiser Permanente Online* that involve transmission of patient information require a "confidential" level of security. During initial development the project team acknowledged the necessity of security features, in order to meet our long-term goal of providing members with a "gateway" to their clinical record. Although the early pilot did not contain features that required the highest level of security, the team implemented a password and PIN system for two major reasons. First, some of the content on the site was licensed from third parties, and Kaiser Permanente needed to ensure that only members had access to it. Second, the team was aware that some members would not want to be identified as they viewed sensitive health information, e.g., pages on sexually transmitted disease.

Additional features, such as pharmacy refill and lab results, which are in the development stage, will be protected by a firewall. While protecting the information being transmitted to and from the website by patients, *Kaiser Permanente Online* also conducts research and evaluation on the website. Our goal is to determine the overall cost-benefit of a website for members. In order to achieve this, it is necessary to study, in aggregate form, the patterns of use on the site in relationship to use of health care services. An early finding is that over 25 percentage of health plan members report that the site saved them an office visit and/or a phone call to an advice nurse.

Over time, we expect to validate this self-reporting by comparing the actual office visits of the group using *Kaiser Permanente Online* to a control group of health plan members. For security purposes, the management team regularly determines which staff members have access to confidential patient information. We consider these questions: Who may access data? Under what circumstances? For what purposes and uses? How should we handle sensitive content areas? Staff is regularly reminded of the overall importance of patient confidentiality, regardless of source of the information, and each of us signs a confidentiality statement annually.

Once it was determined which security measures were required, the team implemented a number of them. These include:

- posting the security policy on the website for members to view,
- implementing a firewall,
- authentication system using PINS,
- adopting the highest level of secure sockets layer technology available
- educating staff about the overall security process.

The security policy covers the specific use of patient data, including who has access to it and how it may be used in aggregate form.

Case Study: Securing the ISIS Center

The Imaging Science and Imaging Systems (ISIS) Center, Department of Radiology, Georgetown University, conducts research in applications of advanced computing and telecommunications technology to health care. The ISIS Center faces major changes in its research environment. On the one hand, projects in all aspects of its work are beginning to acquire, manipulate and archive patient identifiable information on the ISIS Center local area network. This includes running clinical trials for government and commercial funding agencies subject to Food and Drug Administration rules and regulations. On the other hand, investigators, physicians, and patients increasingly require remote access to such data using dial-up and web-based technology. Whereas the ISIS Center has historically not faced major data security problems in its links with untrusted networks, these two new conditions require developing new access controls and enhanced authentication methods for using the LAN. Toward those aims, we developed and issued a Request for Proposals (RFP) for firewall and secure remote access technology. The process of designing our new network architecture and preparing the RFP provides an example of coopting rather than coercing users into contributing to major changes in security management.

The ISIS Center currently operates its LAN in an open, unrestricted mode. Because the ISIS LAN is connected to untrusted networks, we designate it as open. Moreover, it functions in a relatively unrestricted mode because few access controls or authentication measures exist beyond those provided by individual computers on the LAN. Data security policies have been the responsibility of individual investigators with little or no effort to educate users in or enforce a center wide security policy. Investigators also determine what services they use in their research, including modem access, telnet, web access and other functions. This approach to data security met the needs of ISIS when research projects functioned without patient identifiable data and before we conducted clinical trials.

The ISIS Center intends in the future to operate its LAN in an open, restricted mode. The ISIS LAN will remain connected to untrusted networks. Access controls and authentication measures will be installed to enforce new policies protecting patient identifiable data and meeting data security requirements of our funding agencies. Individual investigators will retain the right to determine access and use privileges for data in their own projects consistent with the data security policies of the ISIS Center and their funding organizations. Their policies will be documented and included formally as appendices to the written ISIS Center data security policies, including lists of authorized users and their privileges. Each investigator will collaborate with the ISIS Center network administrator in appropriately programming access and authentication tables in firewalls and databases to enforce policy. The ISIS Center will sponsor regular staff training sessions in the new policies and procedures. This approach will attempt to incorporate the autonomy and responsibility of investigators conventionally associated with a research environment into practices increasingly expected of all organizations creating, manipulating and archiving computerized patient identifiable data.

Because the new data security policies and procedures will affect the work of independent investigators and highly sophisticated staff who have enjoyed wide autonomy in their use of services, all ISIS staff collaborated in designing the new system. Over a period of several months, ISIS staff convened meetings to discuss key issues related to the firewall, including our individual and collective need to communicate with networks outside of the ISIS LAN and potential architectures of the ISIS LAN after installation of the firewall. Although most of the staff are technically trained and experienced in advanced computing and telecommunications technology, few claimed any real expertise in "computer security". Above all few had direct knowledge or experience with firewalls or their impact upon system performance. These discussions were an initial opportunity to investigate the technology and implications of enhanced network security. Throughout the entire discussion, ISIS staff expressed great concern about potential declines in service as a result of installing the firewall, particularly reductions in network speed and the possibility of firewall failure. The debate about access to the outside world and the future architecture of the ISIS LAN fundamentally concerned negotiating the tradeoff between security and service the ISIS staff was willing to accept in light of its new responsibilities and mission. Although organizations can mandate such tradeoffs, we tried to coopt not coerce our colleagues into making the decisions.

The question for the ISIS staff was whether to create one or two trusted domains on the ISIS LAN. After much discussion we decided that upon installation of the firewall, two ISIS domains will exist, an internal, trusted domain protected by the firewall and an external, untrusted domain not protected by a firewall. Please consult Figure 1 illustrating this architecture.

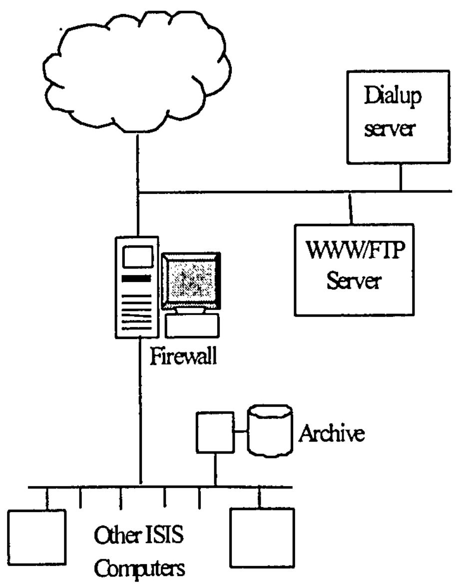

Figure 1. Proposed ISIS LAN Architecture

The answers to several questions conditioned our final approach to the firewall, including:

1. Where will the patient identifiable data reside? In our discussions of the firewall, we reviewed our use and storage of patient data. We have purchased a magnetic tape silo with the intent of modeling a centralized archive. We decided nonetheless to plan as if data might be stored and/or used on almost all ISIS computers, including but not limited to the magnetic tape silo. This decision reflects two fundamental features of ISIS work; namely, that principle investigators manage projects, not the ISIS Center administration and data potentially moves throughout the ISIS LAN during use irrespective of where it may become archived. We should create an infrastructure that supports the principle

investigators and that protects patient identifiable data wherever it may temporarily or permanently reside.

2. How shall ISIS researchers access patient data? ISIS researchers now gain access to and manipulate data from any point on the ISIS LAN including their desktops, home and other remote locations. On the one hand, everybody understood that some kind of restrictions on access from outside the ISIS Center were necessary. The question remained of how much control should be exerted on traffic on the ISIS LAN itself. This question depended in part on the answers to the question above because, as we studied the issue, we realized that we do not clearly draw the line between investigators and other staff as well as the line between "workstation" and "archive". Potentially every person and every machine could become responsible for patient identifiable information. We decided that traffic inside the trusted ISIS domain should flow unimpeded by the firewall.

3. How much effort do we want to invest in maintaining interfaces? Our lack of experience with firewalls raised concerns about the effort and expertise needed to maintain multiple interfaces. Purchasing expert support was possible and inevitably necessary. The fact remained that our own staff would function on the frontline of the firewall war. We also did not want to mortgage the ISIS Center just to maintain the firewall. The ISIS staff adopted the KISS principle. Until we become more experienced and confident of our ability to manage problems with the firewall, we should minimize potential sources of trouble.

In light of all these conditions, we selected the option of a single trusted domain and a single untrusted domain as illustrated above. Such an arrangement will create a secure domain for managing confidential patient information while supporting the ISIS Center's investigator driven approach to managing research projects. We could more easily maintain the firewall as we gained experience in its use and operation. Finally, we would compensate for potential losses of security by training ISIS staff and depending on their sense of professional responsibility

The concept of "cooptation" describes well the process we tried to implement in choosing our firewall. While recognizing the need for enhanced security on our LAN, the ISIS staff remains loathe to sacrifice its ready access to the Internet, the World Wide Web and all the other functions upon which each person depends every day in their work. They worry that the firewall will exact too high a performance price or will crash leaving them detached completely from the outside world. All in all, they would rather not have a firewall. Without enhancing our network security, however, we cannot continue to grow and accept the kinds of projects that seem critical to the ISIS Center's future. When your staff does not want to adopt a step it recognizes as necessary, it is best to coopt them; that is, include them in the process of and responsibility for the unpleasant decision. When you face this situation, before you try coopting your staff ask yourself the following questions?

When should the consultation end? Our experience suggests that staff will contribute to the design phase of the project, expect a recommendation on a course of action and want the opportunity to assent to a decision. Actively evaluating bids for new technology will interest some more than others depending on individual competence.

How widely can consultation occur in large organizations? The ISIS Center has a staff of approximately thirty people that routinely supports collective projects. In spite of its potential impact on the ISIS Center, installing the firewall is a joint project like many others at the ISIS Center. The small scale and general operating philosophy supports cooptation. Although quite feasile, making cooptation function in larger scale organizations requires careful planning and perhaps more formal approaches than we found necessary.

Finally, will cooptation work in organizational settings more hierarchical than the ISIS Center. Some element of cooptation, engaging people in making the unpleasant decisions that affect their lives, is necessary for all organizations in the area of data security if we are to create security capable organizations. The question is how to accomplish this task outside the context of small, face-to-face settings like the ISIS Center.

Conclusion

Becoming a security capable organization requires, above all, recognizing that maintaining data security and confidentiality is everybody's business. What does this well-worn phrase mean in practice for the data security team, the organization's administration and individual staff? The data security team has responsibility for conducting risk assessments, proposing risk management plans (including security policies, organizational procedures and technical practices) and measuring the organization's performance. These duties include the kinds of things people generally mean when they refer to "data security". Yet, in my opinion, the best security team in the world can only implement security measures. It cannot on its own build a security capable organization. That requires an organization's administration and individual staff to participate in the process.

An organization's administration has responsibility for authorizing and supporting the security surveillance process. It must also sponsor broad-based staff education programs in sound security practices. In order to give meaning to the cooptation process, the administration must also enforce good security discipline through appropriate rewards and punishment. Individual adherence to sound security practices constitutes the foundation of a security capable organization. Individuals should learn the organization's data security policies, procedures and practices and implement them as required. Finally, individuals should alert the organization of data security deficiencies and problems encountered in their work

What results can you expect from this process? By incorporating sound security practices into the everyday work of all members of an organization, you create conditions unfavorable to most security breaches. You minimize the chance of careless breaches and force somebody to work hard to execute intentional breaches. By building a security capable organization, you keep faith with your patients, facilitate the work of your employees and protect your organization.

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Appendix A

REVIEW OF PROPOSED REGULATIONS ON SECURITY AND CONFIDENTIALITY OF COMPUTERIZED PATIENT RECORD SYSTEMS

The Health Insurance Portability and Accountability Act of 1996 (HIPA) otherwise known as the Kennedy-Kassenbaum Act creates specific requirements for the Congress and the Department of Health and Human Services. Because of Kennedy-Kassenbaum, within two years the legal and regulatory environment for managing patient medical records will dramatically change. Either Congress will pass comprehensive medical privacy legislation or the Department of Health and Human Services will implement regulations requiring health care providers throughout the United States to adopt new policies, procedures and practices in managing medical information. DHHS must also lead the way by designing model rules to guide Congress and/or implement the laws it passes.

Under the rubric of "Administrative Simplification", HIPA requires Congress to pass laws that "improve… the efficiency and effectiveness of the health care system by encouraging the establishment of standards and requirements for the electronic transfer of certain health care information" (PL No. 104-191). In sections 261 through 264, HIPA calls for standards and laws for two circumstances, namely 1) the electronic interchange of financial and administrative data between health plans, healthcare clearinghouses and health care providers, and 2) maintaining the privacy of individually identifiable medical information. HIPA also establishes a timetable by which Congress and DHHS must act.

The HIPA Timetable - Enacted

Date	Scheduled Release
July 31, 1996	HIPA enacted
July 31, 1997	DHHS recommendations on confidentiality
February 28, 1998	DHHS draft transaction standards
August 21, 1999	Deadline for federal privacy legislation

Under the direction of the National Committee on Vital and Health Statistics, the Healthcare Finance Administration (HCFA) leads the DHHS effort to draft transaction and model privacy standards. By any stretch of the regulatory imagination, HIPA establishes an aggressive timetable for DHHS to draft, release for comment and recommend for adoption such a complex, extensive and important set of regulations. Although behind schedule, DHHS has made a valiant effort. New regulations are regularly released for comment in the Federal Register. The table below indicates the status of progress on HIPA requirements as of August 12, 1998.

The HIPA Timetable as of August 12, 1998

Date	Actual Release
July 31, 1996	HIPA
Sept 11, 1997	Released: Confidentiality recommendations
July 6, 1998	Comment Period Closed: Provider Identifier
July 6, 1998	Comment Period Closed: Transaction Standards
July 6, 1998	Comment Period Closed: Code Set Standards
August 16, 1998	Comment Period Closed: Employer Identifier
July 6, 1998	White Paper: Unique Health Identifier – Individuals
August 12, 1998	NPRM: Security Standards
Pending	NPRM: Identifier -Health Plans

To consult the text of these recommendations and the existing draft regulations for electronic transactions, please consult the DHHS website, http://aspe.os.dhhs.gov/admnsimp/pvcrec/htm. You may also enroll to receive email notice of new posted draft regulations and comment on the proposed rules through this same website.

A. Summaries of Proposed DHHS Rules and Regulations

Standard Definitions for All Proposed Rules

A common set of definitions exists for all proposed rules so far released.

1. Health care clearinghouse: a public or private entity that processes or facilitates that processing of nonstandard data elements of health information into standard elements. Such an entity receives healthcare transactions from health care providers and other entities, translates the data from a given format into one acceptable to the intended recipient and forwards the processed transaction to appropriate health plans and other health care clearinghouses, as necessary, for further action.

2. Health care provider: a provider of medical or other health services and those entities that furnish, or bill and are paid for health care services in the normal course of business.

3. Health information: any information, whether oral or recorded in any form or medium, that
   a. Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
   b. Relates to the past, present or future physical or mental health of condition of an individual, the provision of health care to an individual, or the past,

present or future payment for the provision of health care to an individual (see below for definition of "individually identifiable health information".

4. Health plan: an individual or group health plan that provides, or pays the cost of, medical care
   a. Including group health plans, health insurance issuers, health maintenance organizations, Part A or Part B of Medicare Act, Medicaid, Medicare supplemental policies, long term care policies, employee welfare plans that provide health benefits, the health plan for active military personnel, the veterans health plan, CHAMPUS, the Indian Health Service, the Federal Employees Health Benefits Program, and other plans as designated by the Secretary of DHHS.
   b. Not including plans such as property and casualty insurance plans or workers compensation plans.

5. Individually identifiable health information: any information, including demographic information collected from an individual, that--
   a. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
   b. Relates to the past, present or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and
      (i) Identifies the individual, or
      (ii) With respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

6. Medical care: the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any body structure or function of the body; amounts paid for transportation primarily for and essential to these items; and amounts paid for insurance covering the items and the transportation specified in this definition.

7. Participant: any employee or former employee of an employer, or any member or former member of an employee organization, who is or may become eligible for to receive a benefit of any type of from an employee benefit plan that covers employees of such an employer or members of such organizations, or whose beneficiaries may be eligible any such benefits, including an individual treated as an employee under section 401 (c)(1) of the IRS code.

8. Small health plan: a group health plan with fewer than 50 participants.

9. Standard: a set of rules for a set of codes, data elements, transactions, or identifiers promulgated either by an organization accredited by the American National Standards Institute (ANSI) or the Department of Health and Human Services for the electronic transmission of health information.

10. Transaction: the exchange of information between two parties to carry out financial and administrative activities related to health care.

Implementation Requirements for all Standards

DHHS proposes a common set of implementation requirements for all HIPA relevant standards and rules. All health care plans and clearinghouse except small health plans must implement the standards and code sets within 24 months of their enactment. Small health plans must adopt the standards within 36 months of enactment. Please note: only health care providers that conduct transactions of health information in electronic form covered in the rules must implement the rules. Such health care providers must also implement the rules within 24 months of enactment. Once the rules are adopted, health plans may not delay or refuse to process claims submitted in the standardized format. Civil monetary penalties are proposed for violations of the rules. The DHHS rules will supersede any state law contrary to their requirements except where specifically waived. Financial institutions (such as credit card companies) or their agents may but are not required to comply with the rules. For more details on alternatives to the recommendations and the process whereby DHHS developed its proposals, please consult the Federal Register for each proposed set of rules. You may gain access to these documents, by consulting the Administrative Simplification website, http://aspe.os.dhhs.gov/admnsimp/pvcrec/htm.

Penalties for Violations of the Proposed Rules

The Social Security Act establishes a civil monetary penalty for violation of the provisions under which the proposed rules would enter, subject to several limitations. Penalties may not be more than $100 per person per violation and not more than $25,000 per person for violations of a single standard for a calendar year. The procedural provisions in section of the Act, "Civil Monetary Penalties," are applicable. The Act establishes penalties for a knowing misuse of unique health identifiers and individually identifiable health information: (1) A fine of not more than $50,000 and/or imprisonment of not more than 1 year; (2) if misuse is "under false pretenses," a fine of not more than $100,000 and/or imprisonment of not more than 5 years; and (3) if misuse is with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, a fine of not more than $250,000 and/or imprisonment of not more than 10 years. Note that these penalties do not affect any other penalties which may be imposed by other Federal programs, including ERISA. Under section 1178 of the Act, the provisions of part C of title XI of the Act, as well as any standards established under them, supersede any State law that is contrary to them. However, the Secretary may, for statutorily-specified reasons, waive this provision.

1.1.1 Proposed Standards for Electronic Transactions and Code Sets

Standardizing the form and code sets of electronic transactions between health care providers, plans and clearinghouses constitutes a major goal of the Administrative Simplification section of HIPA. HIPA requires DHHS to evaluate existing standards, consult with relevant constituencies about their recommendations and propose rules to impose a uniform set of transaction forms and code sets for use in electronic data interchange by all. DHHS proposed standards for and the code sets to be used in eight types of transactions, including:

1. Health claims or equivalent encounter information
2. Health care payment and remittance advice
3. Coordination of benefits
4. Health claim status
5. Enrollment and disenrollment in a health plan
6. Eligibility for a health plan
7. Health plan premium payments
8. Referral certification and authorization

Standards for first report of injury and health claims attachments will receive later treatment. The Secretary of DHHS may also adopt standards for other types of transactions as deemed necessary in the future.

The rules apply to health plans and healthcare clearinghouses for all designated transactions. Health plans that use agents to process their transaction must assure their agents also follow the rules. Transactions within a corporate entity are not subject to the rules. Please note: the rules apply to healthcare providers only when transmitting health information in electronic form in connection with transactions covered under the rules. Healthcare providers may send and clearinghouses may accept nonstandard data for the sole purpose of having the clearinghouse translate the data into standard form. "Electronic transmissions" include all media; that is items such as magnetic tapes or disks when physically transported from one location to another as well as electronic transmission media such as the Internet, dialup lines and private networks. If adopted, the standards would become part 142 of title 45 of the Code of Federal Regulations entitled "Administrative Requirements".

Table One lists the proposed standards for each type of transaction. "ASC X12N" standards refer to version 4010 of standards developed by the subcommittee of the ANSI X12 Accredited Standards Committee (ASC) for electronic standards in the insurance industry, including health insurance. "NCPDP" refers to the National Council of Prescription Drug Programs Telecommunication Claim version 3.2 or equivalent Batch Standard Version 1. For more details, consult the Federal Register at the Administrative Simplification website, http://aspe.os.dhhs.gov/admnsimp/pvcrec/htm.

Transaction Type	Transaction Subtype	Standard
Health Care Claim		
	Retail Drug	NCPDP
	Dental Claim	ASC X12N 837: Dental
	Professional Claim	ASC X12N 837: Professional
	Institutional Claim	ASC X12N 837: Institutional
Health Care Payment		ASC X12N 835: Paymt/Advice
Benefit Coordination		
	Retail Drug	NCPDP
	Dental Claim	ASC X12N 837: Dental
	Professional Claim	ASC X12N 837: Professional
	Institutional Claim	ASC X12N 837: Institutional
Health Claim Status		ASC X12N 276/277
Plan Enroll/Disenroll		ASC C12 834
Plan Eligibility		ASC X12 270/271
Plan Premium Pymnts		ASC X12 820
Referral Cert/Auth		ASC X12N 278

Table 1: Proposed standards for electronic health transactions

Implementation guides for the NCPDP Telecommunication Standard Format Version 3.2 and the Batch Standard Version 1.0 are available from the National Council for Prescription Drug Program, 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016. You may contact them by telephone at (602) 957-9105, by fax at (602) 955-0749 or by website at http://www.ncpdp.org.

Implementation guides for the ASC X12N standards are available from Washington Publishing Company, 806 W. Diamond Ave, Suite 400, Gaithersburg, Maryland, 20878. You may contact them by telephone at (301) 590-9337, by fax at (301) 869-9460 or by website at http://www.wpc-edi.com/hipaa/.

Table 2 lists recommended code sets for different types of medical data. "ICD-9-CM" refers to the International Classification of Diseases, 9th edition, Clinical Modification as maintained and distributed by the National Center for Health Statistics, CDC, DHHS. "CPT" refers to the Current Procedural Terminology as maintained and distributed by the American Medical Association. "CDT" refers to the Current Dental terminology maintained and distributed by the American Dental Association. "NDC" refers to the National Drug Code maintained and distributed by the Food and Drug Administration. HCPCS refers to the Health Care Financing Administration Procedure Coding System (levels 1,2, and 3) as maintained and distributed by the Health Care Financing Administration, DHHS. The proposal requires modifications to the current HCPCS, including eliminating the CDT from level 1 and developing a national process for reviewing and approving health insurer codes currently met by local codes in level 3.

Medical Data Types	Medical Data Subtypes	Recommended Code Set
Diseases and causes of injury		ICD-9-CM, Vol 1 & 2
Procedures		
	Physician Services	CPT
	Dental Services	CDT
	Inpatient Hospital Services	ICD-9-CM, Vol 3
Other Health-Related Services		Modified HCPCS
Drugs		NDC
Other Substances and Equipment		Modified HCPCS

Table 2: Recommended code sets

1.1.2 Proposed National Standard for Health Care Provider Identifier

HIPA mandates developing a single, national provider identifier for use in all electronic transactions as a major element in its administrative simplification effort. DHHS proposes adopting the "National Provider Identifier" (NPI) as the standard in conjunction with a central electronic enumeration method to be designated the "National Provider System" (NPS).

The NPI includes the following characteristics:

- ASC X12N compliant;
- 8 position alphanumeric identifier;
- eighth position functions as a check digit following the ISO standard;
- intelligence free(that is, identifier contains no empirical signifiers subject to change)
- universal identifier for use in all health care transactions;
- under final testing for use in HCFA transactions;
- not proprietary
- widely available to health care industry
- maintained by HCFA
- safeguarded under federal Privacy Act, and;
- supports approximately 20 billion unique identifiers.

DHHS discusses two options for enumerating providers, that is, assigning them NPI. Option 1 creates a new federally-directed registry for enumerating all providers. Option 2 designates a combination of federal programs named as health plans, Medicaid state agencies and a Federally-directed registry. DHHS recommends Option 2 for financial reasons. Although less centralized, Option 2 would cost less because 85% of providers already participate in federal or state health plans. Enrollment and enumeration can thus be accomplished in the same process. The enumeration process would begin with providers participating in Medicare followed by Medicaid and non-Medicare federal health plans. If providers conduct business with more than one federal or state health plan, they may select any one for enumeration. The federal registry would enumerate only those providers who do not conduct business with federal or state health plans. DHHS expects this phase of the enumeration process to require two years. The NPS would extend NPI to providers who do not conduct any business using electronic transactions only after enumerating all other providers and identifying funds to support the process.

DHHS proposes creating two levels of access to information about providers in the National Provider database. Level I grants enumerators only access to all the information. Level 2 grants access to selected data elements to the general public. For the details of restricted and unrestricted data elements, please consult Federal Register, Vol 63, No.88, Thursday, May 7, 1998, page 25338 using the Administrative Simplification website, http://aspe.os.dhhs.gov/admnsimp/pvcrec/htm. You may also consult the same location (pages 25340-54) for a detailed analysis of financial and administrative impacts of the NPI.

Proposed National Standard for Employer Identifier

HIPA mandates developing a single, employer identifier for use in all electronic transactions as a major element in its administrative simplification effort. DHHS proposes adopting as the standard the "employer identifier number" (EIN) assigned by the Internal Revenue Service and as defined in the Code of Federal Regulations. The EIN is "the taxpayer identifying number of an individual or other person (whether or not an employer) that is assigned pursuant to 26 U.S.C. 60011 (b) or corresponding provisions of prior law, or pursuant to 26 U.S.C. 6109, and in which nine digits are separated by a hyphen, as follows: 00-0000000.

Proposed National Standard for Health Plan Identifier

Notice of Proposed Rule Making pending

Proposed Unique Health Identifier for Individuals

Although the DHHS has not yet released a Notice of Proposed Rule Making for the Unique Health Identifier for Individuals, a White Paper exists outlining the various options currently under consideration including their strengths, weaknesses, supporters and cost. You may consult the White Paper using the Administrative Simplification website, http://aspe.os.dhhs.gov/admnsimp/nprm/noiwp1.htm.

1.1.3 Proposed Standards for Data Security and Electronic Signature

The DHHS makes general changes in the data security standards that broaden their scope and impact from earlier regulations. The transaction standards apply to electronic transactions between organizations thus leaving unaffected health care providers who do not use electronic transmission media. In contrast, individualized health information becomes subject to the new rules when

1. electronically stored, maintained or transmitted;
2. exists in any format (standard transaction or proprietary format), and;
3. communicated either internal or external to a corporate entity.

A health care provider who stores patient data on magnetic tape, for example, but sends paper documents to a health plan must comply with the data security rules even though not required to comply with the electronic transaction rules. As with the transaction rules, the data security rules apply to health information on any electronic media except telephone voice and faxback systems.

The proposed rules also address electronic signatures. Although DHHS does not recommend requiring electronic signatures at this time, they specify mandatory rules for implementing an electronic signature if an organization so chooses. Use of this standard would satisfy any Federal or State requirement for a signature, either electronic or on paper.

DHHS firmly places responsibility for determining implementation of specific data security measures with health care providers, plans and clearinghouse. DHHS defines a standard as "a set of requirements with implementation features that providers, plans and clearinghouses must include in their operations to assure that electronic health information pertaining to individuals remains secure" (Federal Register, August 12, 1998, p. 43249). The standard does not require or reference specific technological solutions or address the extent to which a particular entity should implement specific features. The standard does require each affected entity to assess its own security risks and develop methods to manage them. The proposal emphasizes many times that providers, plans and clearinghouses must create and keep current detailed documentation of their data security assessments, plans, policies and procedures. The people responsible for maintaining data security should have ready access to the documentation.

For presentation purposes DHHS groups the security requirements in four categories, including Administrative procedures, Physical safeguards, Technical security and Technical security mechanism. DHHS requires only that the security measures be taken, not necessarily organized according to their groups. A general description and matrix enumerating the requirements and implementation features of each grouping follow.

1. Administrative procedures to guard data integrity, confidentiality, and availability--these are documented, formal practices to manage the selection and execution of security measures to protect data and the conduct of personnel in relation to the protection of data.

Requirement	Implementation
Certification	
Chain of trust partner agreement	
Contingency plan (all listed implementation features must be implemented).	Applications and data criticality analysis. Data backup plan. Disaster recovery plan. Emergency mode operation plan. Testing and revision.
Formal mechanism for processing records	
Information access control (all listed	Access authorization.

implementation features must be implemented).	Access establishment. Access modification.
Internal audit	
Personnel security (all listed implementation features must be implemented).	Assure supervision of maintenance personnel by authorized, knowledgeable person. Maintenance of record of access authorizations. Operating, and in some cases, maintenance personnel have proper access authorization. Personnel clearance procedure. Personnel security policy/ procedure. System users, including maintenance personnel, trained in security.
Security configuration mgmt. (all listed implementation features must be implemented).	Documentation. Hardware/software installation & maintenance review and testing for security features. Inventory. Security Testing. Virus checking.
Security incident procedures (all listed implementation features must be implemented).	Report procedures. Response procedures.
Security management process (all listed implementation features must be implemented).	Risk analysis. Risk management. Sanction policy. Security policy.
Termination procedures (all listed implementation features must be implemented).	Combination locks changed. Removal from access lists. Removal of user account(s). Turn in keys, token or cards that allow access.
Training (all listed implementation features must be implemented).	Awareness training for all personnel (including mgmt) Periodic security reminders. User education concerning virus protection. User education in importance of monitoring log in success/ failure, and how to report discrepancies. User education in password management

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2. Physical Safeguards to guard data integrity, confidentiality, and availability--these relate to the protection of physical computer systems and related buildings and equipment from fire and other natural and environmental hazards, as well as from intrusion. Physical safeguards also cover the use of locks, keys, and administrative measures used to control access to computer systems and facilities.

Requirement	Implementation
Assigned security responsibility	
Media controls (all listed implementation features must be implemented).	Access control. Accountability (tracking mechanism). Data backup. Data storage. Disposal.
Physical access controls (limited access) (all listed implementation features must be implemented).	Disaster recovery. Emergency mode operation. Equipment control (into and out of site). Facility security plan. Procedures for verifying access authorizations prior to physical access. Maintenance records. Need-to-know procedures for personnel access. Sign-in for visitors and escort, if appropriate. Testing and revision.
Policy/guideline on work station use	
Secure work station location	
Security awareness training.	

3. Technical Security Services to guard data integrity, confidentiality, and availability--these include the processes that are put in place to protect and to control and monitor information access.

Requirement	Implementation
Access control (The following implementation feature must be implemented: Procedure for emergency access. access. In addition, at least one of the following three implementation features must be implemented: Context-based access, Role-based access, User-based access. The use of Encryption is optional).	Context-based access. Encryption. Procedure for emergency Role-based access. User-based access.
Audit controls	
Authorization control (At least one of the listed implementation features must be implemented).	Role-based access. User-based access.

Data Authentication	
Entity authentication (The following implementation features must be implemented: Automatic logoff, Unique user identification. In addition, at least one of the other listed implementation features must be implemented).	Automatic logoff. Biometric. Password. PIN. Telephone callback. Token. Unique user identification.

4. Technical Security Mechanisms --these include the processes that are put in place to prevent unauthorized access to data that is transmitted over a communications network.

Requirement	Implementation
Communications/network controls (If communications or networking is employed, the following implementation features must be implemented: Integrity controls, Message authentication. In addition, one of the following implementation features must be implemented: Access controls, Encryption. In addition, if using a network, the following four implementation features must be implemented: Alarm, Audit trail, Entity authentication, Event reporting).	Access controls. Alarm. Audit trail. Encryption. Entity authentication. Event reporting. Integrity controls. Message authentication.

The Electronic Signature Standard

In the electronic environment, the same legal weight associated with an original signature on a paper document may be needed for electronic data. Use of an electronic signature refers to the act of attaching a signature by electronic means. DHHS requires electronic signatures to include certain implementation features, specifically:

- Message integrity.
- Nonrepudiation.
- User authentication.

No technically mature techniques provide the security service of nonrepudiation in an open network environment, in the absence of trusted third parties, other than digital signature- based techniques. If electronic signatures are employed, DHHS requires that digital signature technology be used.

Requirement	Implementation
Digital signature (If digital signature is employed, the following three implementation features must be implemented: Message integrity, Nonrepudiation, User authentication. Other implementation features are optional).	Ability to add attributes. Continuity of signature capability. Countersignatures. Independent verifiability. Interoperability. Message integrity. Multiple Signatures. Nonrepudiation. Transportability. User authentication.

Appendix B

Summary of DHHS Recommendations on Confidentiality

Legislators have introduced several privacy bills into the federal Congress including bills from Senator Leahy and Congressman McDermott. To consult the text and follow the legislative status of each bill, go to the federal legislation website, http://thomas.loc.gov and search on "medical privacy". The DHHS recommendations on maintaining confidentiality of individually identifiable information both provides a model of what any federal law should address and stipulates what actual regulations will take effect if Congress fails to act. For that reason, a summary of the DHHS recommendation follows.

Recommendations on Confidentiality of Individually Identifiable Information

The DHHS begins discussion of its recommendations on the confidentiality of individually identifiable information by addressing their scope of coverage; that is, to whom, to what activities and to what information should the recommendations apply.

To whom do the recommendations apply? All health care providers, payers and others who receive health information without authorization (such as health oversight, public health and research organizations) should be subject to the new privacy legislation. Health service organizations are third parties who process health information from providers and payers as part of services rendered. The recommendations should apply to deceased persons for two years after death with specified rights being exercised on deceased's behalf. Conventional rules apply to minors, people with power of attorney and people unable to act on own behalf. The recommendations should not apply to self-pay patients, prison inmates or detainees, liability insurers, life insurers, workers' compensation carriers, or employers unless acting as payers or providers. Federal departments responsible for members, civilian employers and contractors of the military should develop their own regulations. The Department of Veteran's Affairs should have the right to release information without authorization for internal departmental use only.

To what activities should the recommendations apply? The recommendations should apply to three general types of activities, including:

1) Any preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, counseling, service or procedure with respect to the physical or mental condition or functional status of a patient or affecting the structure or function of the body;
2) Any sale or dispensing of a drug, device, equipment or other item pursuant to a prescription, and;
3) Procurement or banking of blood, sperm, organs or any other tissue for administration to patients.

To what information should the recommendations apply? The recommendations should apply to any information, oral or recorded, in any form or medium, including demographic information that has the following characteristics, including:

1) relates to past, present, or future physical or mental health or conditions of a patient, the provision of health care to a patient, or the past, present, or future payment for the provision of health care to a patient;
2) is received, created, used or maintained by a health care provider in the ordinary course of business or practice of a profession, or by a health care payer, or received by entities receiving information under the provisions of the legislation without authorization, and;
3) identifies the individual, or with respect to which there is reasonable basis to believe that the information can be used to identify the patient.

In summary, the recommendations should apply to most people working in the health care business, to most of their patients, to almost everything they do that involves patients and almost all the information created, interpreted and stored thereby as a matter of federal law. Although important, the exceptions to coverage underscore rather than minimize the change we face in the health care business.

The DHHS articulates five basic principles and makes specific recommendations implementing each basic principle of confidentiality. In general, the recommendations increase restrictions on the release of information to third parties, expand obligations to explain and document information management practices to patients, and impose new penalties for breaches of patient confidentiality. The DHHS also tries to balance patients' rights to confidentiality with society's need for knowledge derived from aggregating confidential information in the context of public health efforts.

Five principles underlie the DHHS recommendations, including:

1) Boundaries: an individual's health care information should be used for health purposes and only those purposes, subject to a few carefully defined exceptions;
2) Security: organizations to which we entrust health information ought to protect it against deliberate or inadvertent misuse of disclosure;

3) Consumer Control: Patients should be able to see what is in their records, get a copy, correct errors, and find out who else has seen them;
4) Accountability: Those who misuse personal health information should be punished, and those who are harmed by its misuse should have legal recourse, and;
5) Public Responsibility: Individual's claims to privacy must be balanced by their public responsibility to contribute to the common good, through use of their information for important, socially useful purposes, with the understanding that their information will be used with respect and care and will be legally protected.

In order to implement these principles, federal law should therefore accomplish the following tasks, namely:

1) impose a legal duty of confidentiality on those who provide and pay for health care and on other entities who receive health information from them. This duty has an affirmative and a negative component. An affirmative duty should exist only to use or disclose health information as authorized by patient or required by law. No duty should exist to disclose information except to patients. The federal laws, moreover, should provide only a privacy "floor" thus supporting and maintaining other laws providing grater protection for patient confidentiality to remain in effect. Health information should moreover be used only for purposes compatible with and directly related to the original purposes for obtaining the information and for which health entities are authorized to disclose it. Please note: the DHHS directly addresses in this context the release to and use of health information by employers.

2) require security measures. The DHHS recommends requiring by federal law that health providers, payers and service organizations maintain reasonable and appropriate administrative, technical and physical safeguards to ensure the integrity and confidentiality of health information and protect it against threats, hazards or unauthorized disclosures.

The DHHS synthesizes the boundary and security principles in what one might call "The Rule of Minimum Disclosure". Instead of releasing whole chunks of a patient's record without regard to a requestor's required use, organizations should in the future restrict all uses and disclosures, as practicable, to the minimum amount of information necessary to accomplish the purpose for which it is requested. In my opinion, this recommendation virtually requires adoption of the computerized patient record with its automated indexing and segmenting capabilities.

The DHHS recommends a complete overhaul in how health care providers and payers manage their patients' access to and control over personally identifiable health information. They must strengthen the ability of consumers to understand and control what happens to their information in the following ways, including:

1) providing written explanation of the organization's information practices and patient's rights with respect to their health information;
2) granting patients access to own records for the purpose of inspecting and/or copying them;
3) permitting patients to seek correction and/or amendment of health information under certain conditions, and;
4) maintaining records of most disclosures of information;

The DHHS recommends allowing organizations to deny patients access to their record when access might cause grave harm to a third person or jeopardizes an oversight activity, legal proceeding or clinical trial. In the event that an organization refuses a patient's request to correct and/or amend health information, it must inform the patient of the refusal and allow the patient to file a concise statement explaining the requested correction and reason for disagreeing with refusal to change. The patient's statement should be included in the record, but the burden of proof for correction lies on the patient. None of these recommendations should abrogate existing reporting laws about such things as vital statistics and infectious disease or abrogate existing state or federal laws that impose greater restrictions on use of private information.

The DHHS recommends providing new sanctions and new avenues for redress for consumers whose privacy rights are violated, including:

1) civil proceedings: actual and equitable relief including physical, mental and pecuniary losses. Attorney's fees should be paid in cases of knowing violation of confidentiality, and;
2) criminal proceedings: criminal penalties for obtaining health information under false pretenses and knowing and for unlawfully obtaining, using, or disclosing health information.

In an acknowledgement of its own interests in the debate about patient confidentiality, the DHHS recommends identifying those limited arenas in which public responsibilities warrant access to individual medical information but sharply limiting uses and disclosure of information. The issue in this case affects the ability of NIH and other public health research agencies to aggregate data originally obtained from the records of individual patients into large databases that could potentially reflect broad trends. The problem requires simultaneously stripping aggregate records of individual identifiers while maintaining the ability to trace the original sources.

Appendix C
REQUEST FOR PROPOSAL

Securely Managing Computerized Patient Identifiable Data on the ISIS Network

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0.0 REVISION HISTORY

REVISION DATE	AUTHOR	NOTES
March 13, 1998	J. Collmann	First draft
March 14, 1998	J. Collmann	Hoffman comments
March 25, 1998	J. Collmann	Meeting comments
April 3, 1998	J. Collmann	Anya's Comments
April 5, 1998	J. Collmann	Anya's Comments
April 7, 1998	A. Kim	Tables/diagram

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PROJECT OVERVIEW

Organizational Environment of the ISIS Center

The Imaging Science and Imaging Systems (ISIS) Center, Department of Radiology, Georgetown University, conducts research in applications of advanced computing and telecommunications technology to health care. In its capacity as an important civilian research laboratory for the Department of Defense, the ISIS Center has established its reputation for technical sophistication and organizational effectiveness through projects such as DINS (the prototype and technical specifications for the DOD filmless radiology system known as MDIS), Project DEPRAD (the deployable teleradiology network built in support of NATO troops in Bosnia), and digital mammography (proof of concept and working model of digital mammography adapting computed radiography technology). The ISIS Center also successfully competes for extramural funding from other government agencies including the National Institutes of Health and the National Science Foundation in the areas of image processing, computer-aided diagnosis, telemedicine, and image guided therapy.

The ISIS Center faces major changes in its research environment. On the one hand, projects in all aspects of its work are beginning to acquire, manipulate and archive patient identifiable information on the ISIS Center local area network. This includes running clinical trials for government and commercial funding agencies subject to Food and Drug Administration rules and regulations. On the other hand, investigators, physicians, and patients increasingly require remote access to such data using dial-up and web-based technology. Whereas the ISIS

Center has historically not faced major data security problems in its links with untrusted networks, these two new conditions require developing a plan for managing the security and confidentiality of patient identifiable information on its LAN. This RFP addresses important technical components in the ISIS Center's approach to managing data security. Ongoing risk analyses, risk management plans and data security policies support the technical approach being sought in this RFP (see Appendix for supporting documentation). The ISIS Center will not function as a repository for clinical information; but, must nonetheless protect the security and confidentiality of patient identifiable information used in pursuit of its research mission.

The ISIS Center research mission includes demonstrating approaches to the secure and confidential management of computerized patient data, particularly but not exclusively in its telemedicine projects. Hence, the ISIS Center's approach to data security must function to protect its patient data and to demonstrate how such work may be accomplished. This RFP therefore also performs two functions, namely soliciting solutions to the ISIS Center data security problems and providing an example of the process by which one searches for such solutions. As such the RFP will be central to the ISIS Center's reports to funding agencies, scholarly publications, and government agencies in the area of computerized patient data security and confidentiality.

Technical Environment of the ISIS Center

The ISIS Center currently operates its LAN in an open, unrestricted mode (Collmann, Meissner et al 1997). Because the ISIS LAN is connected to untrusted networks, we designate it as open. Moreover, it functions in a relatively unrestricted mode because few access controls or authentication measures exist beyond those provided by individual computers on the LAN. Anyone with rights to work on ISIS projects may use the equipment and the network with minimal password control. Vendors, other university investigators and students with whom ISIS investigators collaborate have unencumbered remote and local access to the ISIS LAN. Data security policies have been the responsibility of individual investigators with little or no effort to educate users in or enforce a center wide security policy. Investigators also determine what services they use in their research, including modem access, telnet, web access and other functions. This approach to data security met the needs of ISIS when research projects functioned without patient identifiable data and before we conducted clinical trials.

The ISIS Center intends in the future to operate its LAN in an open, restricted mode. The ISIS LAN will remain connected to untrusted networks. Access controls and authentication measures will be installed to enforce new policies protecting patient identifiable data and meeting data security requirements of our funding agencies. Individual investigators will retain the right to determine access and use privileges for data in their own projects consistent with the data security policies of the ISIS Center and their funding organizations. Their policies will be documented and included formally as appendices to the written ISIS Center data security policies, including lists of authorized users and their privileges. Each investigator will collaborate with the ISIS Center network administrator in appropriately programming access and authentication tables in firewalls and databases to enforce policy. The ISIS Center will sponsor regular staff training sessions in the new policies and procedures. This approach will attempt to incorporate the autonomy and responsibility of investigators conventionally associated with a research environment into practices increasingly expected of all organizations creating, manipulating and archiving computerized patient identifiable data.

The decision-making environment of the ISIS Center

Because the new data security policies and procedures will affect the work of independent investigators and highly sophisticated staff who have enjoyed wide autonomy in their use of services, all ISIS staff have been collaborating in designing the new system. All ISIS staff who express an interest will independently evaluate responses to this RFP and submit their opinions to a task force for consideration in the final choice. All ISIS staff will be encouraged to participate in the task force. In this way, we hope and expect that all ISIS staff will better understand and accept the new system that they have helped build.

THE ISIS LAN

Current Situation

The ISIS LAN connects directly to the Georgetown University network through a router located on the first floor of 2115 Wisconsin Avenue with two hubs in a communications closet across the hall from the ISIS Center which is located on the sixth floor of the building. No firewall currently limits access to the ISIS LAN or to the 2115 segment of the Georgetown University LAN.

The ISIS LAN network:

Media: 10BaseT Ethernet, ATM
Protocols: TCP/IP, IPX/SPX,

The ISIS LAN includes the following types and numbers of equipment:

Type	Hardware	Operating System	Software	Qnty
File Server	Firmware	Novell 4.1	POP3, SMTP, ArcServe	1
FTP/WWW Server	Sun Sparc5	Solaris 2.4	FTP/WWW	1
Dialup server	Shiva LANRover	Shiva		1
Archive	Wolfcreek magnetic tape silo			1

	Sun Sparc5	Solaris 2.5.1	ACSLS	1
	Sun Sparc20	Solaris 2.5.1	Reelbackup	1
Workstations	Silicon graphics ONYX	IRIX 6.4	Customer written applications, Open G-L Open_inventor, C++, OSF Motif Fortran 77, InPerson, ImageVision, JAVA, Visual Basic, HTML	2
	Silicon Graphics Indigo 2	IRIX 5.3		1
	Sun Sparc20	Solaris 2.4		2
	Sun Sparc5	Solaris 2.4		2
	SunSprac10	Solaris 2.4		1
	DEC Alpha	Digital Unix		2
Supercomputer	Cray J916	UNICOS		1
Desktop units	IBM PC-compatible desktops	One of Windows 95, Windows NT, OS/2, Windows 3.1	Deployed Software: Microsoft Office, Netscape Explorer, JAVA	20
	IBM PC-compatible laptops			7
	MAC desktops	System 7.6		4

Table 1. Equipment used at the ISIS Center

Proposed Situation

We want to enhance the security of the ISIS LAN, software and data by installing a firewall between some parts of the ISIS LAN and the Georgetown University network. After installation of the firewall, two ISIS domains will exist, an internal domain protected by the firewall and an external domain not protected by a firewall. Please consult Figure 1 illustrating this architecture.

The firewall shall provide proxies for services as listed below. We also seek methods for providing secure, user-authenticated, web-based and dialup access to confidential databases on the internal ISIS domain from untrusted networks.

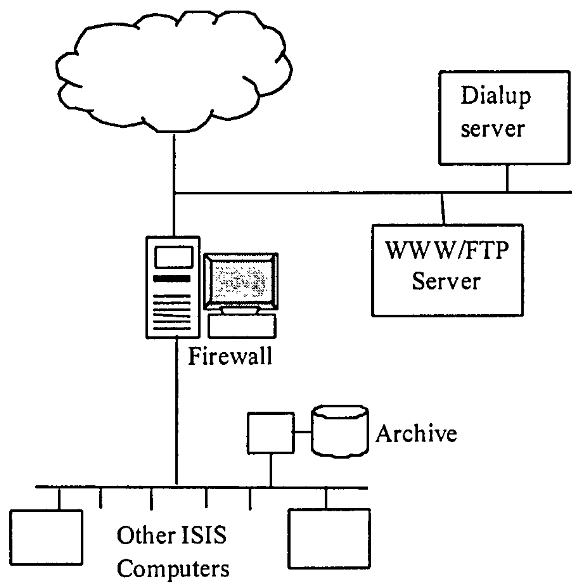

Figure 2. Proposed ISIS LAN Architecture

1.1.4 Protected Units

A firewall shall protect the units listed below from untrusted networks. Please note: patient identifiable data could potentially reside on any and all of these machines.

Type	Hardware	Operating System	Software	Qnty
File Server	Firmware	Novell 4.1	POP3, SMTP, ArcServe	1
Archive	Wolfcreek magnetic tape silo			1
	Sun Sparc5	Solaris 2.5.1	ACSLS	1
	Sun Sparc20	Solaris 2.5.1	Reelbackup	1
Workstations	Silicon graphics ONYX	IRIX 6.4	Customer written applications, Open G-L Open_inventor, C++, OSF Motif Fortran 77, InPerson, ImageVision, JAVA, Visual Basic, HTML	2
	Silicon Graphics Indigo 2	IRIX 5.3		1
	Sun Sparc20	Solaris 2.4		2
	Sun Sparc5	Solaris 2.4		2
	SunSprac10	Solaris 2.4		1
	DEC Alpha	Digital Unix		2
Supercomputer	Cray J916	UNICOS		1
Desktop units	IBM PC-compatible desktops	One of Windows 95, Windows NT, OS/2, Windows 3.1	Deployed Software: Microsoft Office, Netscape Explorer, JAVA	20
	IBM PC-compatible laptops			7
	MAC desktops	System 7.6		4

1.1.5 Unprotected Units

The following units on the ISIS LAN shall NOT be protected from untrusted networks:

Type	Hardware	Operating System	Software	Qnty
FTP/WWW Server	Sun Sparc5	Solaris 2.4	FTP/WWW	1
Dialup server	Shiva LANRover	Shiva		1

1.1.6 Protocol Support

1.1.6.1 Present Protocols

The firewall shall support the following protocols:

Protocol	Services for Internal Users[1]	Services for Public Users[2]	Services for Remote Users[3]
FTP	X		X
Telnet	X		X
SSL	X		X
SMTP	X		X
DNS	X		X
NNTP	X		
HTTP	X		

1. Services for Internal Users: users residing on the internal ISIS domain may use services marked with an "X" on external networks

2. Services for Public Users: unauthenticated users residing on untrusted networks may use the services marked with an "X" on the internal ISIS domain.
3. Services for Remote Users: authenticated users only residing on untrusted networks may use the services marked with an "X" on the internal ISIS domain.

1.1.6.2 Future Protocols

Please describe your plans, timeframe and cost of developing proxies for the following protocols:

A. DICOM 3.0
B. Videoconferencing

Protocol	Application
H.320	Standard videoconferencing protocol (not IP-based).
H.323	Standard videoconferencing protocol for Internet (IP-based).
T.120	Standard for shared application.

1.1.6.3 Firewall Transparency

To make the transition to the installation of a firewall as smooth as possible, it is important that users are not intimidated by the firewall and that the firewall does not burden the users in any way. Therefore we feel that the transparency of the firewall is an important issue. Please describe the extra burden in time imposed by the firewall on transactions into and out of the ISIS LAN.

1.1.7 Firewall Features

The firewall should have as a minimum, the features listed below. Please explain in detail how your firewall offers/supports each of these features(also address the bullets under each feature). If you anticipate any changes in the future, please explain them.

If there are any other features that your firewall provides that are not listed here, but you think would be useful to us, please include them.

1) NCSA certified firewall or equivalent
   - When was the product last certified?

2) User-authenticated access control

- How does your firewall provide user authentication from the most simple methods to the most secure methods?

3) Token and password authentication
   - What types of tokens are compliant with your firewall?
   - How do these tokens work?

4) Content control
   - Does your firewall provide access control to outside Web sites?
   - What type of content control method or content labeling method is used?

5) Console and remote GUI administration
   - Does your firewall provide a graphical user interface?
   - Explain in detail how you provide remote administration.
   - Do you provide remote management?

6) Ability to incorporate 3rd party products on platform
   - How?

7) Support 10BaseT Ethernet and ATM
   - In particular, what solution would you provide in the case of using IPX?

8) Intrusion Detection
   - If your firewall supports intrusion detection, explain how.
   - If you do not support intrusion detection, describe contracts or arrangements you have with intrusion detection companies and how your firewall would work with their product.

9) Intrusion alerts
   - Describe all options your firewall supports for intrusion alerts.

10) Transaction logging
    - Describe how logging of firewall transaction occurs?
    - What is the granularity of logging capabilities?
    - What types of alarms do you provide?

11) Encryption
    - What encryption algorithms are supported?
    - Is it easy for the user to use?

12) Virus checking
    - Does the firewall provide anti-virus capabilities? If so, what are they?
    - Is this feature available for all sorts of files? (e.g. encrypted files, email, downloaded files from the web)

Comparison of Prostate Biopsy Protocols using 3-D Computer Simulation

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Abstract

Urologists to detect prostate cancer routinely use the systematic sextant needle biopsy technique. This patterned biopsy technique has been adopted with little quantitative or scientific evidence to support its use. Using 136 digitized radical prostatectomy specimens, we developed a 3-D computer simulation software to compare the detection rate of cancer among various biopsy protocols. We further investigate the correlation between needle core tumor volume and total tumor volume. The 10- and 12- pattern biopsy protocols had a 98.5% detection rate, whereas, the sextant biopsy protocol was only 72.8%. The 5-region biopsy protocol had a 90.4% detection rate and the 14- pattern, which includes all the biopsies used in the patterns above only added one additional positive case (0.7%) All the patterns showed a significant correlation between core tumor volume and total tumor volume. Our results suggest that the 10-pattern biopsy protocol is statistically superior to the routinely used sextant prostate biopsy pattern.

1. Introduction

Transrectal ultrasound (TRUS) guided biopsy is routinely used for diagnosis of prostate cancer. The current biopsy protocol is systematic sextant biopsy [1]. However, studies have shown that this protocol results in a positive predicted value of only 32% [2]. Therefore, a significant number of patients with prostate cancer are not being diagnosed. Some researchers have suggested that the sextant technique may not be optimal [3] and others have investigated new biopsy protocols that may give better results [4]. In addition, two-dimensional (2-D) computer-based simulation of prostate cancer has been shown to be useful in evaluating existing biopsy protocols [5]. We feel that since treatment for advanced prostate cancer is currently minimally beneficial emphasis on early detection at the earliest stage is essential. By identifying the most accurate biopsy protocol we may increase the early detection of this disease.

Current screening tests for prostate cancer include prostate specific antigen (PSA) and digital rectal exam (DRE). The combination of these two tests has led to an increased number of patients undergoing prostate needle biopsy. However, as noted above, the accuracy of current biopsy techniques needs to be improved. A recent article in *Urology Times* reported that patients undergoing repeat prostate biopsy (after negative prior biopsy) still had a negative biopsy rate of 18% for tumors of 0.5 cc to 1 cc; in addition, 15% of the repeat biopsies were negative when the tumor burden exceeded 1 cc in volume. Daneshgari et al [5], developed a 2-D computer simulation of the prostate based on 159 radical prostatectomy specimens. The computer then generated random prostates and tumors. This computer model was used to simulate the sextant biopsy protocol and verify its ability to detect low-volume tumors. Various biases for the angle of biopsy and distribution of cancer foci were incorporated in the model. The simulation showed that only 20.3% of the simulated prostates had a tumor distribution in which sextant biopsy had a 95% probability of tumor detection. In fact, 26.8% of prostates had a distribution that was completely disjointed from the sextant locations. These prior findings show that a significant number of patients who have prostate cancer are not diagnosed at their initial biopsy. Accordingly, improving the predictive value of TRUS guided biopsy by optimizing biopsy protocols will improve its value as a screening and diagnostic tool.

A number of researchers have investigated techniques for improving the accuracy of biopsy protocols; however, several issues remain to be resolved. For example, Eskew et al. introduced a new protocol called 5-region biopsy in which additional needles are added systematically in addition to traditional sextant biopsy [4]. The 5-region biopsy and the traditional sextant biopsy were compared with a total of 119 patients who underwent transrectal ultrasound guided needle biopsy of the prostate. It was shown that of 48 cancer patients, 17 (35%) were detected as having cancers only by the additional needles of the 5-region biopsy method within this group. As a result, the new 5-region biopsy method was claimed to improve biopsy results. Eskew's results are promising, but his study group of 48 patients is small. Therefore, this protocol needs to be validated further, and the underlying rationale for using 12 needles instead of some other number should be examined. Our research group has developed a computer-based 3-D visualization of digitized prostate specimens and has found that the 5-region protocol showed a slightly statistically significant advantage over the sextant method based on 89 cases [6]. The computer simulates the actual biopsy procedure for both 5-region and sextant protocols by calculating the position of each needle within the prostate and determining if the needle has hit the cancer [7]. Stamey conducted a clinical study to evaluate existing biopsy protocols and to study the correlation of estimated findings with clinical significance [8]. This study revealed new information on prostate cancer patterns: a biopsy core length of 3 mm or more can reliably predict cancer of clinically significant volume, and poorly differentiated cancer areas (with high grades) on biopsy should always be considered to represent clinically significant tumors. Another research group has suggested that new biopsy strategies may be developed based on probability maps of cancer distribution within the prostate [3]. But issues such as how these maps should be built and how new biopsy protocols could be derived from the maps remain to be investigated.

Our research effort will focus on the development of a statistically optimized biopsy protocol using a 3-D computer-based simulation of radical prostatectomy specimens. Various standard biopsy protocols and new schemes will be evaluated. Since the new biopsy protocol will be based on statistical analysis of a quantitative database of digitized prostate specimens, it should significantly improve the accuracy of prostate cancer detection.

2. Methods

2.1 Construction of Individual 3-D Computerized Prostate Models

Individual 3-D prostate models are constructed from radical prostatectomy specimens. The prostates are step-sectioned using a meat cutter at 2.5mm intervals and then digitized with a scanning resolution of 1,500 dots per inch. Each digitized image is segmented by a single pathologist (IAS) to identify the key pathological structures including the surgical margins, capsule, urethra, seminal vesicles and tumor. The contours of each structure identified on each slice are then stacked and interpolation between the contours is carried out using a 3-D elastic model-based technique [9]. One hundred and thirty six 3-D individual prostate models have been constructed using an SGI Onyx 2 Infinite Reality 10000 Workstation. An interactive biopsy interface was developed to allow real-time rotation and insertion of the ultrasound probe, and depth of needle placement before the biopsy device was fired.

2.2 Evaluation of Biopsy Protocols

A single urologist (JJB) completed a total of 18 biopsies on each of the 136 prostate models. The various regions of the prostate were sampled in a similar manner. The tip of the needle was brought up to the capsule of the prostate and then fired in the interactive mode. The computer then automatically determined if the biopsy was positive for tumor and calculated the core tumor volume. Several patterns were completed as defined in table 1. Bilateral transitional zone and seminal vesicle biopsies were also completed.

2.3 Data Analysis

The needle core biopsy data was analyzed for variance using the Wilcoxon Scores (Rank Sum) 2-sample test. The correlation of core tumor volume to total tumor volume was analyzed using the Spearman Correlation Coefficient analysis.

3. Results

Table 2 is a summary of the individual positive needle core frequencies. Of the 136 prostate models, both the 10- and 12- pattern biopsy protocols detected cancer in 134 models for a detection rate of 98.5%. In comparison, the sextant (6-pattern) biopsy protocol only detected 99 models with cancer (72.8%). As noted in table 2, with the addition of the laterally placed biopsies, the 10-, 12-, 14- pattern and 5-region biopsy protocols have a higher detection rate. The extra biopsies used in the 14- pattern biopsy protocol only added one additional positive model where cancer was detected (0.7%). The 5-region biopsy protocol had a positive detection rate of 90.4% (123/136). The transitional zone and seminal vesicle biopsies added little to the detection rate. One model was detected with cancer solely by the transitional zone biopsy (0.7%, 1/136). The seminal vesicle biopsies where never positive when all other biopsies were negative. The overall positive frequencies for the transitional zone biopsies were 29/136 models (21.3%) and for the seminal vesicle biopsies were 4/136 models (2.9%).

When the various patterns where analyzed for variance of positive hits using the Wilcoxon Score (Rank Sums) 2-sample test, the 10- and 12-pattern protocol was significantly different from the sextant biopsies (p=0.012, p=0.014, respectively). When the 14-pattern and 5-region protocol were compared to the sextant biopsy protocol there was no significant difference in the variance of positive hits (p=0.106, p=0.2841, respectively). When all other pattern combinations were compared there was no significant difference in the variance of positive hits, except that the 10-pattern and 5-region biopsy protocols were significantly different (p=0.050).

The correlation of core tumor volume and total tumor volume was significant in all biopsy protocols. The Spearman Correlation Coefficients for each of the biopsy protocols were: sextant (0.550), 10-pattern (0.552), 12-pattern (0.571), 14-pattern (0.571) and the 5-region (0.530). A representative scatter plot with a fitted correlation line for the 10-pattern biopsy protocol is shown in figure 1.

4. Conclusions

The accurate 3-D reconstruction of the radical prostatectomy specimens with spatial anatomy that includes the urethra, ejaculatory ducts, seminal vesicles, capsule, surgical margins and the tumors allows for evaluation of various prostate biopsy protocols. In general it was noted that the majority of the tumors were near the posterior-lateral surface of the prostate. The laterally placed biopsies in the posterior-mid and apex regions of the gland resulted in the highest positive biopsy frequencies, most above 50%. It is important to note that actually placing the tip of the needle into the prostate before the biopsy is performed results in a higher negative biopsy rate since the tumors are so close to the posterior capsule.

When we compare the various biopsy patterns our results suggest that the 10-pattern biopsy protocol provides the highest relative detection rate for the number of biopsies performed during a single procedure. When compared to the 10-pattern protocol, the additional biopsies of the 12-, 14- and 5-region biopsy protocols do not add significantly to the detection rate or to the correlation of the core tumor volume to the total tumor volume. The results suggest that the correlation of core tumor volume and total tumor volume is significant for all the patterns tested. The objective was to find a biopsy pattern that was significantly better than the commonly used sextant biopsy protocol, however, not at the expense of a much larger number of biopsies per procedure.

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Table 1: Biopsy pattern definitions

		# OF BX'S
6-Pattern:	Sextant= R/L Base + R/L Mid + R/L Apex	6
10-Pattern:	6-Pattern + R/L lateral Mid + R/L lateral Apex	10
12-Pattern:	10-Pattern + R/L lateral Base	12
14-Pattern:	12-Pattern + Middle Base + Middle Apex	14
5-Region:	6-Pattern + Middle Base + Middle Apex + R/L lateral Base + R/L lateral Apex	12

Table 2: Needle biopsy frequencies by prostate regions

Prostate Region	Negative	Positive	% Positive
****LEFT****			
Base	103	33	24.3%
Mid	73	63	46.3%
Apex	85	51	37.5%
Lateral Base	83	53	39.0%
Lateral Mid	63	73	53.7%
Lateral Apex	66	70	51.5%
****RIGHT****			
Base	109	27	19.9%
Mid	87	49	36.0%
Apex	91	45	33.1%
Lateral Base	86	50	36.8%
Lateral Mid	72	64	47.1%
Lateral Apex	62	74	54.4%
MIDDLE			
Base	109	27	19.9%
Apex	106	30	22.1%

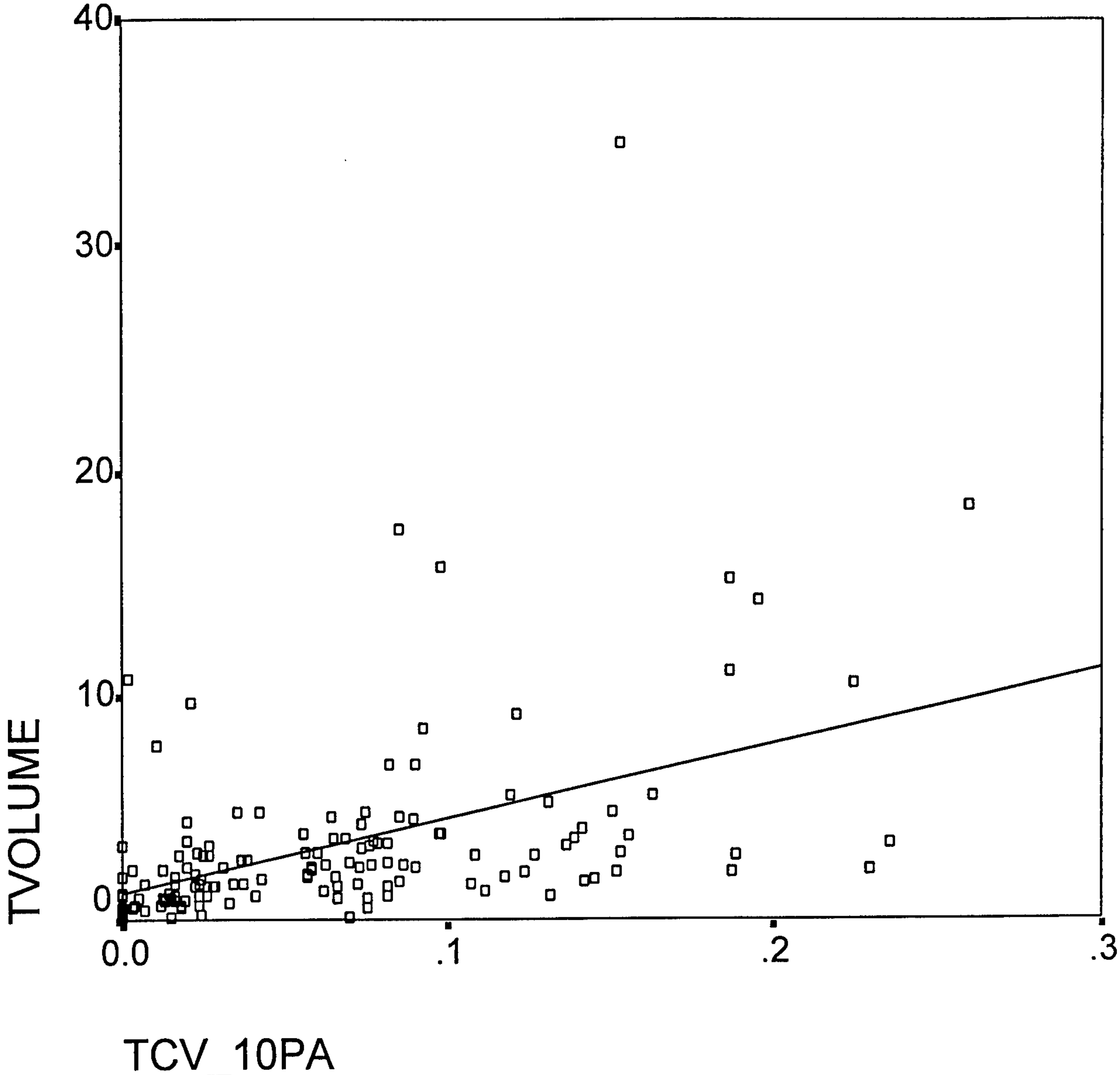

Figure 1: Correlation of core tumor volume vs total tumor volume for the 10-pattern biopsy protocol

Visualization and Evaluation of Prostate Needle Biopsy

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Abstract. Three-dimensional (3-D) computer visualization is playing an increasingly important role in medical imaging applications. Visualization is helpful and important because it provides more flexibility for medical education, training and pre-operative planning, and it offers a better method to evaluate schemes currently used in the clinical environment for their improvements and optimizations. We have developed a 3-D visualization system for prostate needle biopsy simulation. Surface models of the prostate are reconstructed from the digitized pathological tissue images of the real prostate specimens. The needle biopsy of the prostate can be visualized and simulated automatically by the system or interactively by a urologist with a 6 degree-of-freedom (DOF) tracking device. This system has been used to validate the effectiveness of the automatic simulation for the evaluation of prostate needle biopsy. It has also been used to compare the performance of the existing biopsy schemes. In this paper, further experiments are conducted using this visualization system with a total of 107 reconstructed 3-D prostate surface models to evaluate the correlation between tumor volume and positive needle core volume. Preliminary experimental results are also given.

1 Introduction

The screening methods of prostate cancer include prostate specific antigen (PSA) and digital rectal exam (DRE). Based on the screening results, a transrectal ultrasound (TRUS) guided prostate needle biopsy may be recommended which currently is the gold standard for the diagnosis of prostate cancer. Due to the low resolution of the ultrasound images, however, a urologist can hardly differentiate abnormal tissues from normal ones during the biopsy. Therefore a number of schemes have been developed to help urologists in doing the prostate needle biopsy, such as the systematic sextant biopsy [Hodge et al. 1989] and the 5-region [Eskew et al. 1997], which designate locations of needles on the prostate as well as number of needles to use. It is reported that the current biopsy schemes need to be improved in terms of their accuracy in cancer detection [Bankhead 1997]. In addition, since tumor volume plays an extremely important role in helping a physician decide which method to use for the cancer treatment, it is necessary to develop a practical approach for the physician to estimate tumor volume from the positive needle core volumes of the biopsy results. Currently there is no accurate approach available used in the clinical environment.

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We have developed a 3-D visualization system that can be used to help physicians solve these problems in prostate needle biopsy. Surface models of the prostate are reconstructed from the digitized pathological tissue images of the real prostate specimens. The needle biopsy of the prostate can be visualized and simulated automatically by the system or interactively by a urologist with a 6 DOF tracking device. Experiments have been conducted using the visualization system to show that the automatic simulation is reliable to be used for the evaluation of prostate needle biopsy by comparing its performance to that of a urologist [Zeng, Kaplan et al. 1998]. This system has also been used to evaluate the existing sextant and 5-region biopsy schemes, and it is shown that the 5-region scheme is performing better than the sextant scheme in terms of the rate of tumor detection, and the amount of positive core volume. In this paper, we conduct further experiments with this system to investigate the correlation between the tumor volume and the positive needle core volume. In section 2, the visualization system is briefly described, followed by the evaluation experiments and the preliminary experimental results in section 3. Conclusions are given in section 4.

2 The 3-D Visualization System

2.1 Reconstruction of the 3-D Prostate Surface Models

As the first step of developing a visualization system for the prostate needle biopsy, 3-D prostate surface models are constructed from the real specimens of prostates with localized cancer, which were resected from the patients and sliced at 4 μm thickness and 2.25 mm intervals. Each slice was then filmed and digitized with a scanning resolution of 1,500 dots per inch, and the contours of key pathological structures, such as urethra and the seminal vesicle as well as the tumors, were extracted by a pathologist. In order to realize real-time visualization performance, surface modeling is used in the model reconstruction process, which is sufficient for the purpose of visualization of prostate needle biopsy. For each structure, the contours are stacked up and interpolation between each pair of contours is performed using a 3-D elastic model-based technique. The interpolation between adjacent contours C1 and C2 is completed by generating a force field that acts on C1 and forces it to gradually move and conform to C2. The volumes of the tumor and the prostate gland are calculated based on each pair of contours of the structures (tumor and prostate gland) after interpolation, which are important parameters for later evaluation experiments. The 3-D model of each structure in the prostate is finally constructed by tiling triangular patches onto the interpolated contours using a deformable surface-spine model which uses a second order partial differential equation to control the deformation of the surface [Xuan et al. 1997]. After a 3-D model is constructed for each structure, a complete 3-D prostate surface model is then constructed by combining the models of all the structures in the prostate. Currently, more than 200 digitized prostate specimens have been acquired, and more than 100 3-D prostate surface models have been constructed on an SGI Onyx Infinite Reality 10000 Workstation.

2.2 Visualization of the Prostate Biopsy

The visualization system is developed using C++ and the object-oriented 3-D visualization development toolkit Open-Inventor on the SGI Onyx Workstation. Graphical user interface is realized based on the Motif toolkit. While menu operations are mostly performed using a two-dimensional (2-D) mouse, the interactive biopsy simulation is mainly carried out using a 6 DOF tracking device (6-D mouse) which is especially integrated in the visualization system. In addition to general visualization functions, such as model manipulation (e.g., rotation, translation and zooming) and model property change (e.g., transparency and color), this system primarily provides functions specific for the prostate needle biopsy. It has two simulation modes: an automatic simulation and an interactive simulation. The whole process of a prostate needle biopsy with any specific scheme can be simulated based on the reconstructed 3-D prostate surface models. In the automatic simulation mode, the locations for needle insertion on the surface of the prostate are calculated automatically by the computer based on the requirement of the specific biopsy scheme. Thirty degrees of angle with respect to the local normal vector of the prostate surface are also calculated automatically for each needle. Needles are then mounted to the positions in the calculated poses. After shooting the needles, the system then detects which needles are hitting the tumors inside the prostate by calculating ray intersection along the needle direction with the tumors. If there is any (the biopsy is then called positive), the system calculates the positive needle core volumes by the amount of intersection and displays the results on the screen. Since this whole process is controlled by the system, it can be finished very quickly, making it possible to apply this simulation to a large number of samples (3-D prostate models) for later statistical analysis if its performance can be validated. Each step of the automatic biopsy simulation process can also be visualized from any perspective by manipulating the 3-D prostate model in real time. Figure 1 shows the needle locations on the prostate for the sextant and 5-region schemes. Figure 2 shows the needles mounted in these locations in their initial poses. Figure 3 shows the side view of the needles after being fired in the prostate. An example of needle biopsy results for both the sextant and 5-region schemes is shown in Figure 4, where the prostate is displayed in semi-transparency for see-through purpose.

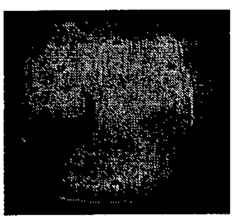

Fig.1 Needle locations calculated for the sextant and 5-region schemes

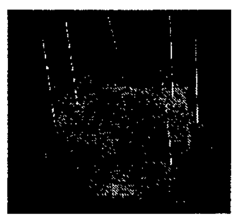

Fig.2 Needles mounted in their initial locations and poses after

Fig.3 Side view of the needles being fired in the prostate

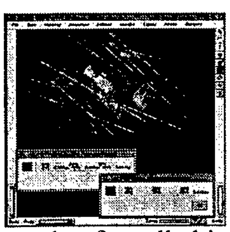

Fig.4 An example of needle biopsy result for sextant and 5-region

Fig.5 Virtual ultrasound probe and the needle in use

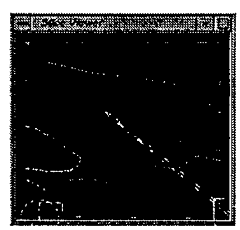

Fig.6 Synthesized ultrasound image with needle path and fired needle

For the interactive simulation, a 6 DOF tracking device is integrated to simulate the ultrasound probe used during actual prostate biopsy procedure. The tracking device consists of an ultrasound transmitter, a controller, and a freely movable receiver device that serves as a tracker. With this device, the system can track both the position (x, y, z) and the orientation angles (Pitch, Yaw, Roll) of the receiver in real time (50Hz). The tracking information is simultaneously used in controlling movement of the virtual ultrasound probe in the visualization system. The synthesized ultrasound images are refreshed in real time to follow the movement of the probe. The ultrasound images show intersectional anatomical slices of the prostate as biopsy guidance for the user (a urologist). With this interactive simulation mode, the urologist can perform a virtual needle biopsy as though he/she is performing a real biopsy on a patient. He/she determines the location for each needle insertion based on a specific biopsy scheme under the guidance of the synthesized ultrasound image. The angle of the needle is fixed with the ultrasound probe, and the upcoming path of the needle is always displayed and overlaid on the ultrasound image so that the urologist knows where the needle will go through inside the prostate. The result of a biopsy is automatically calculated by the system after each biopsy and is displayed to tell the urologist whether the biopsy is positive or negative and how much the positive needle core volume is. Figure 5 shows the virtual ultrasound probe and the needle in use, while Figure 6 shows the corresponding synthesized ultrasound image with needle path and the fired needle.

3 Evaluation and Experiments: Correlation between Tumor Volume and Positive Core Volume

Tumor volume is one of the key parameters to be used for the determination of cancer stage and therapy methods [Tanagho and McAninch 1995]. For example, the therapy for patients with low-stage prostate cancer is currently radical prostatectomy or radiation therapy, while patients with locally extensive cancer are advised to have radiation therapy and surgery is not recommended. It is therefore important for a physician to be able to estimate the tumor volume as accurately as possible, especially when the tumor is still small and non-palpable. Currently there is no practical approach that can help a physician estimate the tumor volume. It is even not sure if it is possible to have such an approach. In this paper, we investigate this possibility by first considering the correlation of the tumor volume to the positive needle core volume. If there is a strong correlation, it suggests that there may be a possibility to estimate the tumor volume from the positive needle core volume. We also investigate the correlation in terms of the PSA values and the race to see if the correlation shows any special features for these special groups of patient.

3.1 Correlation in General Cases

We use 107 3-D prostate models on the needle biopsy visualization system with both sextant and the 5-region. Figure 7 shows a correlation result of tumor volume vs. positive core volume with the sextant biopsy scheme. Table 1 gives the corresponding correlation coefficient and the level of significance. Since the level of significance is 0 which is smaller than 0.01, the correlation is significant between the two volume variables with the sextant scheme. The results with the 5-region scheme are shown in Figure 8 and Table 2, which also indicates that the correlation is significant.

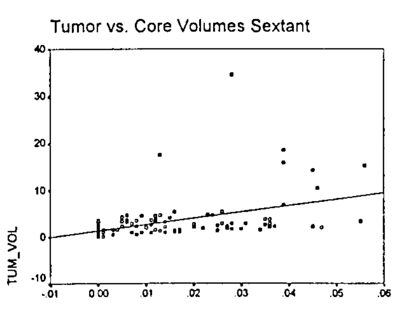

Fig.7 Plot of tumor volume vs. core volume with sextant scheme

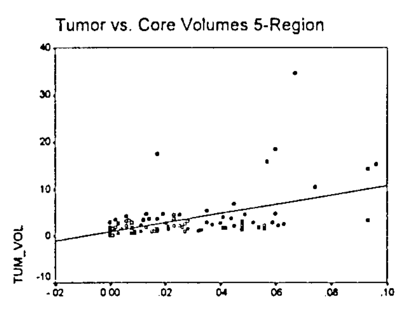

Fig.8 Plot of tumor volume vs. core volume with 5-region scheme

Table 1 Correlation coefficient and the level of significance with sextant scheme (Tumor volume not normalized)

Correlations of Tumor vs. Core Volumes Sextant

		CORE_STA	TUM_VOL
Pearson Correlation	CORE_STA	1.000	.440**
	TUM_VOL	.440**	1.000
Sig. (2-tailed)	CORE_STA	.	.000
	TUM_VOL	.000	.
N	CORE_STA	107	107
	TUM_VOL	107	107

**. Correlation is significant at the 0.01 level (2-tailed).

Table 2 Correlation coefficient and the level of significance with 5-region scheme (Tumor volume not normalized)

Correlations of Tumor vs. Core Volumes 5-Region

		CORE_5RE	TUM_VOL
Pearson Correlation	CORE_5RE	1.000	.509**
	TUM_VOL	.509**	1.000
Sig. (2-tailed)	CORE_5RE	.	.000
	TUM_VOL	.000	.
N	CORE_5RE	107	107
	TUM_VOL	107	107

**. Correlation is significant at the 0.01 level (2-tailed).

Volume of a prostate gland may also need to be considered since it can affect on capsular penetration which is also a key factor in determining methods for therapy. A tumor may still be confined to a larger prostate gland while another tumor of the same size has already penetrated the capsule of a smaller prostate gland. To further validate the correlation between the tumor volume and the core volume, we first normalize the tumor volume by the volume of prostate gland, and then investigate its correlation to the positive needle core volume for both the sextant and 5-region schemes. The results are shown in Figure 9 and Table 3, and Figure 10 and Table 4, respectively.

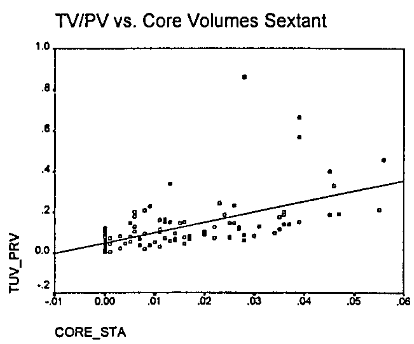

Fig.9 Plot of normalized tumor volume vs. core volume with sextant scheme

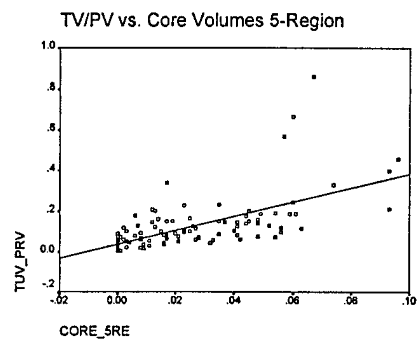

Fig.10 Plot of normalized tumor volume vs. core volume with 5-region scheme

Table 3 Correlation coefficient and the level of significance with sextant scheme (Normalized tumor volume)

Correlations

		CORE_STA	TUV_PRV
Pearson Correlation	CORE_STA	1.000	.585**
	TUV_PRV	.585**	1.000
Sig. (2-tailed)	CORE_STA	.	.000
	TUV_PRV	.000	.
N	CORE_STA	107	107
	TUV_PRV	107	107

**. Correlation is significant at the 0.01 level (2-tailed).

Table 4 Correlation coefficient and the level of significance with 5-region scheme (Normalized tumor volume)

Correlations

		CORE_5RE	TUV_PRV
Pearson Correlation	CORE_5RE	1.000	.635**
	TUV_PRV	.635**	1.000
Sig. (2-tailed)	CORE_5RE	.	.000
	TUV_PRV	.000	.
N	CORE_5RE	107	107
	TUV_PRV	107	107

**. Correlation is significant at the 0.01 level (2-tailed).

As can be seen, the results show a stronger correlation between the normalized tumor volume and the positive needle core volume. The correlation coefficients increase by 0.145 and 0.126 for the sextant and 5-region schemes, respectively. Therefore it can be said that the normalized tumor volume (by the volume of prostate gland) shows a better association with the positive needle core volume than the absolute tumor volume alone.

3.2 Correlation by PSA Values

The elevated PSA value is a very important marker to indicate suspicion of prostate cancer. Therefore it may be reasonable to expect that the higher the PSA value the stronger the correlation between the tumor volume and the positive needle core volume. To investigate this possibility, we segment the PSA values into groups and calculate the correlation for each group separately.

(1) Group 1: PSA Values 0-4

The sample size (number of 3-D prostate models) for this group is 16. The results for both sextant and 5-region schemes are shown in Figure 11 and Table 5, and Figure 12 and Table 6, respectively.

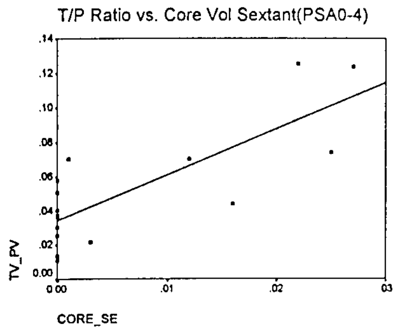

Fig.11 Plot of normalized tumor volume vs. core volume with sextant scheme (PSA0-4)

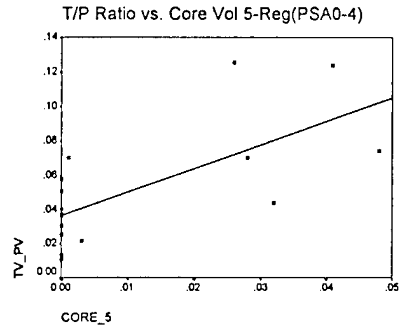

Fig.12 Plot of normalized tumor volume vs. core volume with 5-region scheme (PSA0-4)

Table 5 Correlation coefficient and the level of significance with sextant scheme (PSA0-4) (Normalized tumor volume)

Correlations

		CORE_SE	TV_PV
Pearson Correlation	CORE_SE	1.000	.788**
	TV_PV	.788**	1.000
Sig. (2-tailed)	CORE_SE	.	.000
	TV_PV	.000	.
N	CORE_SE	16	16
	TV_PV	16	16

**. Correlation is significant at the 0.01 level (2-tailed).

Table 6 Correlation coefficient and the level of significance with 5-region scheme (PSA0-4) (Normalized tumor volume)

Correlations

		CORE_5	TV_PV
Pearson Correlation	CORE_5	1.000	.685**
	TV_PV	.685**	1.000
Sig. (2-tailed)	CORE_5	.	.003
	TV_PV	.003	.
N	CORE_5	16	16
	TV_PV	16	16

**. Correlation is significant at the 0.01 level (2-tailed).

(2) Group 2: PSA Values 4-10

The sample size for this group is 64. The results for both sextant and 5-region schemes are shown in Figure 13 and Table 7, and Figure 14 and Table 8, respectively.

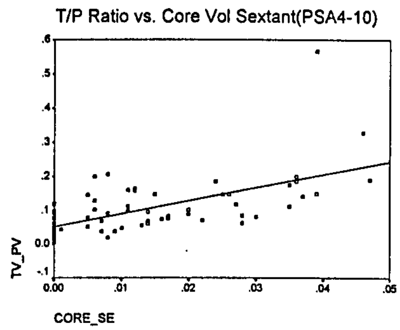

Fig.13 Plot of normalized tumor volume vs. core volume with sextant scheme (PSA4-10)

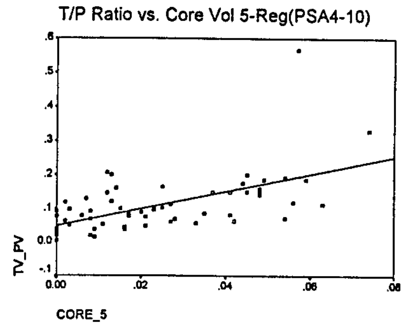

Fig.14 Plot of normalized tumor volume vs. core volume with 5-region scheme (PSA4-10)

Table 7 Correlation coefficient and the level of significance with sextant scheme (PSA4-10) (Normalized tumor volume)

Correlations

		CORE_SE	TV_PV
Pearson Correlation	CORE_SE	1.000	.607**
	TV_PV	.607**	1.000
Sig. (2-tailed)	CORE_SE	.	.000
	TV_PV	.000	.
N	CORE_SE	64	64
	TV_PV	64	64

**. Correlation is significant at the 0.01 level (2-tailed).

Table 8 Correlation coefficient and the level of significance with 5-region scheme (PSA4-10) (Normalized tumor volume)

Correlations

		CORE_5	TV_PV
Pearson Correlation	CORE_5	1.000	.603**
	TV_PV	.603**	1.000
Sig. (2-tailed)	CORE_5	.	.000
	TV_PV	.000	.
N	CORE_5	64	64
	TV_PV	64	64

**. Correlation is significant at the 0.01 level (2-tailed).

(3) Group 3: PSA Values More Than 10

The sample size for this group is 27. The results for both sextant and 5-region schemes are shown in Figure 15 and Table 9, and Figure 16 and Table 10, respectively.

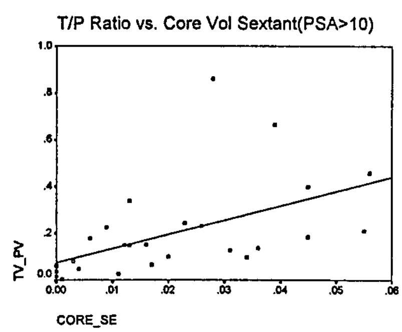

Fig.15 Plot of normalized tumor volume vs. core volume with sextant scheme (PSA>10)

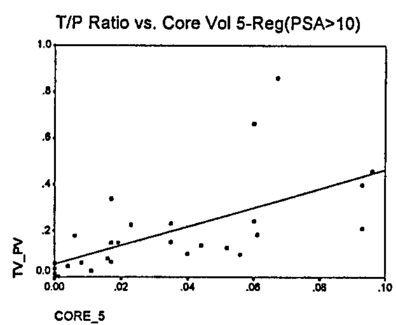

Fig.16 Plot of normalized tumor volume vs. core volume with 5-region scheme (PSA>10)

Table 9 Correlation coefficient and the level of significance with sextant scheme (PSA>10) (Normalized tumor volume)

Correlations

		CORE_SE	TV_PV
Pearson Correlation	CORE_SE	1.000	.531**
	TV_PV	.531**	1.000
Sig. (2-tailed)	CORE_SE	.	.004
	TV_PV	.004	.
N	CORE_SE	27	27
	TV_PV	27	27

**. Correlation is significant at the 0.01 level (2-tailed).

Table 10 Correlation coefficient and the level of significance with 5-region scheme (PSA>10) (Normalized tumor volume)

Correlations

		CORE_5	TV_PV
Pearson Correlation	CORE_5	1.000	.618**
	TV_PV	.618**	1.000
Sig. (2-tailed)	CORE_5	.	.001
	TV_PV	.001	.
N	CORE_5	27	27
	TV_PV	27	27

**. Correlation is significant at the 0.01 level (2-tailed).

Unfortunately, the results are not as they were expected: the correlation coefficients do not increase with the PSA values. However, at the moment we cannot conclude that there is no direct association between the PSA values and the correlation since the sample sizes are not large enough for some of the groups. Further investigations will be conducted in this respect.

3.3 Correlation by Race

It is recognized that prostate cancer grows differently in different races. In general, African Americans have more chance to grow prostate cancer than Caucasians. In this respect, we investigate the correlation between the tumor volume and the positive needle core volume among African Americans and Caucasians.

(1) African Americans

The sample size for the African Americans is 28. The results for both sextant and 5-region schemes are shown in Figure 17 and Table 11, and Figure 18 and Table 12, respectively.

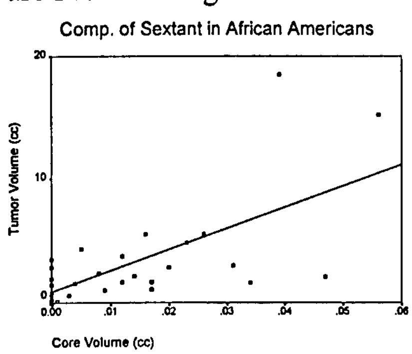

Fig.17 Plot of normalized tumor volume vs. core volume with sextant (African Americans)

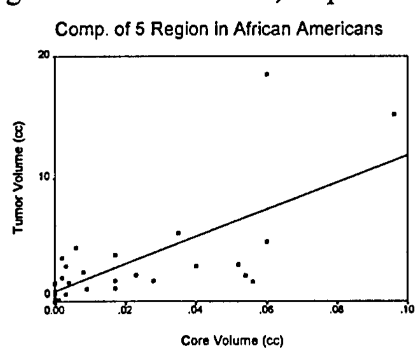

Fig.18 Plot of normalized tumor volume vs. core volume with 5-region (African Americans)

Table 11 Correlation coefficient and the level of sig. with sextant (African Americans)

Correlations

		CORVOL	TUMVOL
Pearson Correlation	CORVOL	1.000	.643**
	TUMVOL	.643**	1.000
Sig. (2-tailed)	CORVOL	.	.000
	TUMVOL	.000	.
N	CORVOL	28	28
	TUMVOL	28	28

**. Correlation is significant at the 0.01 level (2-tailed).

Table 12 Correlation coefficient and the level of sig. with 5-region (African Americans)

Correlations

		CORVOL	TUMVOL
Pearson Correlation	CORVOL	1.000	.681**
	TUMVOL	.681**	1.000
Sig. (2-tailed)	CORVOL	.	.000
	TUMVOL	.000	.
N	CORVOL	28	28
	TUMVOL	28	28

**. Correlation is significant at the 0.01 level (2-tailed).

(2) Caucasians

The sample size for Caucasians is 77. The results for both sextant and 5-region schemes are shown in Figure 19 and Table 13, and Figure 20 and Table 14, respectively.

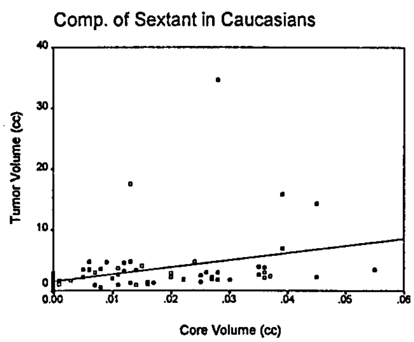

Fig.19 Plot of normalized tumor volume vs. core volume with sextant (Caucasians)

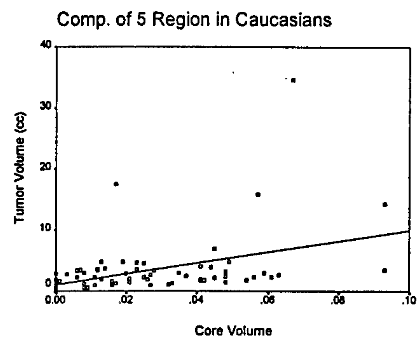

Fig.20 Plot of normalized tumor volume vs. core volume with 5-region (Caucasians)

As expected, the correlation for the African Americans is much stronger than that of the Caucasians. The correlation coefficients increase by 0.295 and 0.250 for the sextant and 5-region schemes, respectively. This may imply that race is an important factor in estimating the tumor volume from the positive needle core volume. Further investigations will be done to confirm this possibility.

3.4 Summary

We have experimentally shown that in general there exists a significant correlation between the tumor volume and the positive needle core volume. This correlation is even stronger between the normalized tumor volume (by the volume of prostate gland) and the positive needle core volume. This result supports the possibility that the

Table 13 Correlation coefficient and the level of sig. with sextant (Caucasians)

Correlations

		CORVOL	TUMVOL
Pearson Correlation	CORVOL	1.000	.348**
	TUMVOL	.348**	1.000
Sig. (2-tailed)	CORVOL	.	.002
	TUMVOL	.002	.
N	CORVOL	77	77
	TUMVOL	77	77

**. Correlation is significant at the 0.01 level (2-tailed).

Table 14 Correlation coefficient and the level of sig. with 5-region (Caucasians)

Correlations

		CORVOL	TUMVOL
Pearson Correlation	CORVOL	1.000	.431**
	TUMVOL	.431**	1.000
Sig. (2-tailed)	CORVOL	.	.000
	TUMVOL	.000	.
N	CORVOL	77	77
	TUMVOL	77	77

**. Correlation is significant at the 0.01 level (2-tailed).

larger the core volume the larger the tumor volume. Since there may be other factors, such as locations of the positive needles, that contribute to the prediction of tumor volume, more controlled experiments will be needed to confirm the cause-and-effect relationships between the positive core volume and the tumor volume.

Due to insufficient data, the correlation between the tumor volume and the positive core volume does not increase with the PSA values. However, this correlation does increase for African Americans in comparison to Caucasians.

4 Conclusions

We have developed a 3-D computer visualization system, and have conducted experiments with a large number of 3-D prostate models using this system. To explore the possibility of estimating tumor volumes from the positive needle core volumes, we have investigated the possible correlation between the tumor volume and the positive needle core volumes with 107 3-D prostate models. A significant correlation is found between these two kinds of volumes, which supports the possibility that the tumor volume may be reasonably estimated from the positive needle core volumes. More controlled experiments will be conducted to confirm the cause-and-effect relationships before we will move forward to develop a mathematical model that can predict and estimate the tumor volumes from the positive needle core volumes. In addition, new prostate models will be reconstructed and used to verify the prediction model of tumor volume, and clinical evaluation will also be conducted.

The 3-D visualization system provides an ideal platform for the simulation and evaluation of prostate needle biopsy. It is also useful for education, especially for visualizing anatomy of prostate, and training of residents and medical students. With the advancement of imaging technologies and improvement of imaging quality, it becomes quite possible to develop an on-line prostate needle biopsy system which provides real time augmented 3-D prostate images to help a urologist to quickly and precisely identify the abnormality in the prostate inside the patient's body. This idea is not limited to the prostate needle biopsy; it may be applied to any type of biopsy, such as kidney biopsy. It may also be applied to other surgeries beyond biopsies, making it possible to realize a real on-site image-guided minimally-invasive surgery system.

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Optimizing prostate needle biopsy through 3-D simulation[1]

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ABSTRACT

Prostate needle biopsy is used for the detection of prostate cancer. The protocol of needle biopsy that is currently routinely used in the clinical environment is the systematic sextant technique, which defines six symmetric locations on the prostate surface for needle insertion. However, this protocol has been developed based on the long-term observation and experience of urologists. Little quantitative or scientific evidence supports the use of this biopsy technique. In this research, we aim at developing a statistically optimized new prostate needle biopsy protocol to improve the quality of diagnosis of prostate cancer. This new protocol will be developed by using a three-dimensional (3-D) computer-based probability map of prostate cancer. For this purpose, we have developed a computer-based 3-D visualization and simulation system with prostate models constructed from the digitized prostate specimens, in which the process of prostate needle biopsy can be simulated automatically by the computer. In this paper, we first outline our approach to developing a statistically optimized prostate needle biopsy protocol using the visualization and simulation system that is overviewed next. In the preliminary experiments, we develop an interactive biopsy simulation mode in the system, and evaluate the performance of the automatic biopsy simulation with the sextant biopsy protocol by comparing the results by the urologist using the interactive simulation mode with respect to 53 prostate models. This is required to confirm that the automatic simulation is accurate and reliable enough for the simulation with respect to a large number of prostate models. In addition, we compare the performance of the existing protocols using the automatic biopsy simulation system with respect to 107 prostate models, which will statistically identify if one protocol is better than another. Since the estimation of tumor volume is extremely important in determining the significance of a tumor and in deciding appropriate treatment methods, we further investigate correlation between the tumor volume and the positive core volume with 89 prostate models. This is done in order to develop a method to estimate the tumor volume from the corresponding positive core volumes. Preliminary experimental results are given for each of these experiments.

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1. INTRODUCTION

Prostate cancer is the most prevalent male malignancy and the second leading cause of death by cancer in American men. In 1997, more than 40,000 deaths are predicted for prostate cancer, and 342,000 new cases will be diagnosed. Current screening tests for prostate cancer include prostate specific antigen (PSA) and digital rectal exam (DRE). The combination of these two tests has led to an increased number of patients undergoing prostate needle biopsy. However, as noted above, the accuracy of current biopsy techniques needs to be improved. A recent article in Urology Times reported that patients undergoing repeat prostate biopsy (after negative prior biopsy) still had a negative biopsy rate of 18% for tumors of 0.5 cc to 1 cc; in addition, 15% of the repeat biopsies were negative when the tumor burden exceeded 1 cc [Bankhead 1997]. Daneshgari [Daneshgari et al. 1995] developed a 2-D computer simulation of the prostate based on 159 radical prostatectomy specimens. The computer then generated random prostates and tumors. This computer model was used to simulate the sextant biopsy protocol and verify its ability to detect low-volume tumors. Various biases for the angle of biopsy and distribution of cancer foci were incorporated in the model. The simulation showed that only 20.3% of the simulated prostates had a tumor distribution in which sextant biopsy had a 95% probability of tumor detection. In fact, 26.8% of prostates had a distribution that was completely outside the range the sextant locations. These prior findings show that a significant number of patients who have prostate cancer are not diagnosed at their initial biopsy. Accordingly, improving the predictive value of TRUS guided biopsy by optimizing biopsy protocols will improve its value as a screening and diagnostic tool.

A number of researchers have investigated techniques for improving the accuracy of biopsy protocols; however, several issues remain to be resolved. For example, Eskew et al. introduced a new protocol called 5-region biopsy in which additional needles are added systematically in addition to traditional sextant biopsy [Eskew et al. 1997]. The 5-region biopsy and the traditional sextant biopsy were compared with a total of 119 patients who underwent transrectal ultrasound guided needle biopsy of the prostate. It was shown that of 48 cancer patients, 17 (35%) were detected as having cancers only by the additional needles of the 5-region biopsy method; within this group, 83% had Gleason scores of 6 or more. As a result, the new 5-region biopsy method was claimed to improve biopsy results. Eskew's results are promising, but his study group of 48 patients is small. Therefore, this protocol needs to be validated further, and the underlying rationale for using 13 needles instead of some other number should be examined. Our research group has developed a computer-based 3-D visualization of digitized prostate specimens and has found that the 5-region protocol showed a statistically significant advantage over the sextant method based on 107 3-D prostate models [Kaplan, Zeng, Lynch et al. 1998a]. The computer simulates the actual biopsy procedure for both the 5-region and sextant protocols by calculating the location for each needle within the prostate and determining if the needle has hit the cancer [Hayes et al. 1997]. Stamey [1995] conducted a clinical study to evaluate existing biopsy protocols and to study the correlation of the estimated findings with clinical significance. Goto [Goto et al. 1996] has suggested that new biopsy strategies may be developed based on probability maps of cancer distribution within the prostate. But issues such as how these maps should be built and how new biopsy protocols could be derived from the maps remain to be investigated.

Our research effort will focus on the development of a statistically optimized biopsy protocol using a 3-D computer-based probability map of prostate cancer. A 3-D probability map will be built by incorporating a large number of individual digitized prostate specimens with localized cancers. This probability map gives the 3-D distribution of prostate cancers and shows the probability of cancer detection at each location in the prostate. Based on this probability map, a statistically optimized needle biopsy protocol will be developed by incorporating the needle locations with the highest probability of tumor detection. This protocol will be compared and evaluated with existing biopsy protocols, such as the sextant and 5-region, on our 3-D visualization and simulation platform using 3-D prostate models reconstructed from the specimens resected from the patients. Since the new biopsy protocol will be based on statistical analysis of a quantitative database of digitized prostate specimens, it may significantly improve the accuracy of prostate cancer detection.

This paper is organized as follows. Section 2 outlines the approach to optimizing a prostate needle biopsy protocol. In section 3, the 3-D visualization and simulation system is overviewed in some details. Preliminary experiments will be presented in section 4 on performance evaluation of the automatic vs. interactive biopsy simulation techniques, on comparison of the biopsy protocols of sextant to 5-region using the automatic biopsy simulation, and on the correlation of prostate tumor volume and the positive needle core volume. Conclusions are made in section 5 with future research directions.

2. OUTLINE OF OPTIMIZING THE NEEDLE BIOPSY PROTOCOL

2.1 Construction of individual 3-D computerized prostate models

The individual 3-D prostate models are constructed from radical prostatectomy specimens of prostate. The prostate specimens are step-sectioned in 4μm sections at 2.25mm intervals and then digitized with a scanning resolution of 1,500 dots per inch. Each digitized slice is then segmented by a pathologist to identify key pathological structures including surgical margin, capsule, urethra, seminal vesicles as well as tumor. The contours of each structure identified on each slice are then stacked and interpolation between the contours is carried out using a 3-D elastic model-based technique [Xuan et al. 1997]. The interpolation between adjacent contours C1 and C2 is completed by generating a force field that acts on C1 and forces it to gradually move and conform to C2. The 3-D model of each structure in the prostate is finally constructed by tiling triangular patches onto the interpolated contours using a deformable surface-spine model. This model uses a second order partial differential equation to control the deformation of the surface. After a 3-D model is constructed for each structure, an individual 3-D computerized prostate model can then be constructed by combining the structure models.

Currently, more than 200 digitized prostate specimens have been acquired, and more than 100 3-D individual prostate models have been constructed using an SGI Onyx Infinite Reality 10000 Workstation. One example of a prostate model is shown in Figure 1.

Figure 1 An example of reconstructed prostate model.

2.2 Development of a 3-D integrated prostate model based on a large number of individual 3-D computerized models

To develop an integrated model, the average volume of the sample computerized 3-D individual models are first calculated, which can be automatically conducted by the current modeling system by accumulating volumes confined between each pair of contours after contour interpolation [Kaplan, Zeng, Lynch et al. 1998b]. Next, each individual model will be normalized to the average volume. The normalization is conducted by uniform scaling of the individual model in x, y and z directions in 3-D space [Udupa and Herman 1989, Rogers and Adams 1990]. Each individual model will then be registered in 3-D position to a common coordinate system (such as the screen coordinate system) by translating its center of gravity to the coordinate origin. Each model is also registered in 3-D orientation by first aligning its central axis to the z-axis of the common coordinate system. The central axis is the axis that is perpendicular to all the original contours of the prostate. Then, the model is rotated about the z-axis to align the front of the prostate (as defined in the contouring process) with the positive direction of the y-axis.

2.3 Establishment of a 3-D probability map of prostate cancer spatial distribution

Based on the 3-D integrated prostate model, the spatial distribution of cancer will be obtained by calculating the occurrence rate of the cancers at each 3-D position inside the prostate. Here the occurrence rate Or(x,y,z) is defined as the number of tumors that contribute to each location (x,y,z) inside the prostate divided by the total number of tumors in the integrated prostate model. A greater occurrence rate represents a higher probability of detection at the corresponding location.

2.4 Development of a statistically optimized biopsy protocol based on the 3-D probability map of tumor distribution.

A biopsy protocol consists of several key parameters, including needle position, needle angle, needle depth, and the number of needles. Since current clinical instruments for needle biopsy fix the needle angle with respect to the ultrasound probe, changing the needle angle will require new instrumentation and therefore will not be considered in this study. In addition, the needle depth using current triggering devices is fixed at 15-22 mm and therefore we will not consider changing the needle depth in this study. We thus have two parameters to investigate: needle position and the number of needles.

The 3-D probability map of spatial distribution gives a quantitative measure of where the cancers are most likely concentrated in the prostate. This map can be used to develop a statistically optimized biopsy protocol with optimal needle positions. The needle positions will be determined based on regions of high cancer concentration. Here we propose the following algorithm to determine the positions and the number of the needle in the new biopsy protocol.

Step 1: Calculate the occurrence rate Or(x,y,z) at each location of the 3-D integrated model from the 3-D probability map of prostate cancer spatial distribution.

Step 2: Select the location P(x1,y1,z1) that has the largest the value of Or(x1,y1,z1) as the first needle location.

Step 3: Remove the individual models that have cancers which have contributed to the location P(x1,y1,z1). Assume that the number of such individual models is N1. It is anticipated that the number of models that will be removed at this step will be relatively small compared to the 200 sample cases. At this point, the sensitivity of cancer detection is S1=N1 /200.

Step 4: Recalculate the Or(x,y,z) at each location of the 3-D integrated model with N1 individual models removed as described in Step 3.

Step 5: Select the location P(x2,y2,z2) that has the largest value of Or(x2,y2,z2) as the second needle location.

Step 6: Again, remove the individual models that have cancers which have contributed to the location P(x2,y2,z2). Assume the number of such individual models is N2. Therefore at this point, the sensitivity of cancer detection is S2 = (N1 + N2) / 200. The sensitivity gain by the second needle is SG2 = N2 / 200.

Step 7: Repeat this process as long as the sensitivity gain SGi is larger than 2%. Assume that the last location selected this way is P(xk,yk,zk).

Following the above procedure, the positions P(xi,yi,zi) (i = 1, 2, ..., k) and the number k of needles required will be statistically optimized based on the 200 digitized prostate specimens.

2.5 Evaluation of the new protocol

The evaluation process compares the new protocol against existing biopsy protocols (sextant and 5-region) by examining the detection rate (based on finding at least one positive core) and the number of positive cores. An additional 100 3-D individual models are constructed from new digitized prostate specimens for this purpose. With these new models, there are 80% power to detect a 12% difference in sensitivity (i.e., 80% versus 92%) when comparing the proposed optimized biopsy approach to an existing biopsy protocol. The power calculation was based on a matched-pair test with a

5% significance level using the method of [Breslow and Day 1987] (Section 7.6.b). After testing the new protocol on the 3-D visualization and simulation platform, a clinical trial needs to be conducted where the new biopsy protocol will be evaluated on a large number of patient subjects (e.g., 200 patients) to verify the effectiveness of the new protocol. The same parameters measured in the simulation study need to be investigated here, namely, the detection rate and the number of positive cores.

2.6 Data analysis

Data analysis is designed to assess the improvement in sensitivity of the new protocol over the existing prostate biopsy techniques. Sensitivity is defined as the proportion of individuals with the disease who have a positive test. Specificity, defined as the proportion of individuals without the disease who have a negative test, is 1.0 in the context of needle biopsies and so needs not be considered. Statistical tests to assess the differences between the two protocols include McNemar's test [Breslow and Day 1980] for comparing detection rates and the paired t-test for comparing quantitative variables (number of positive cores, length of positive cores, etc.) and the Wilcoxon signed-rank test. Differences in rates or means are considered statistically significant if they attain the 0.05 level of significance.

3. 3-D VISUALIZATION AND SIMULATION SYSTEM

The visualization and simulation system has two simulation modes: an automatic simulation and an interactive simulation. The whole process of a prostate needle biopsy with any specific protocol can be simulated based on the reconstructed 3-D prostate models. This simulation system can be used to evaluate the performance of difference biopsy protocols. It can also be used as a training or testing system for the residents to practice their skills of biopsy, or a planning system for the urologists before they undergo a complex real biopsy procedure.

In the automatic simulation mode, the locations for needle insertion on the surface of the prostate are calculated automatically by the computer based on the requirement of the specific protocol. Thirty degrees of angle with respect to the local normal vector of the prostate surface are also calculated automatically for each needle. Needles are then mounted to the positions in the calculated poses. After shooting the needles, the system then detects which needle or needles are hitting the tumors inside the prostate, and if any, calculates the positive core volumes and displays the results on the screen. Since this whole process is controlled by the system, it can be finished quickly, making it possible to apply this simulation to a large number of samples (3-D prostate models) for statistical analysis if its performance can be confirmed. Each step of the biopsy simulation process can be visualized from any perspective by manipulating the 3-D prostate model in real time with a two-dimensional mouse. Figure 2 shows the needle locations on the prostate for the sextant (pink) and 5-region (pink + blue) protocols. Figure 3 shows the needles mounted in their initial locations and poses. Figure 4 shows the side view of the needles after being fired in the prostate. An example of needle biopsy results for both the sextant and 5-region protocols is shown in Figure 5.

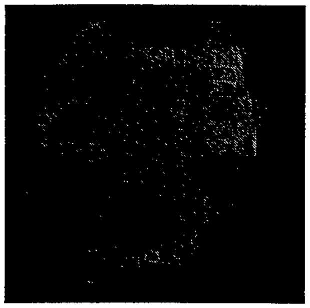

Figure 2 Needle locations calculated for the sextant and 5-region protocols

Figure 3 Needles mounted in their initial locations and poses

Figure 4 Side view of the needles after being fired in the prostate

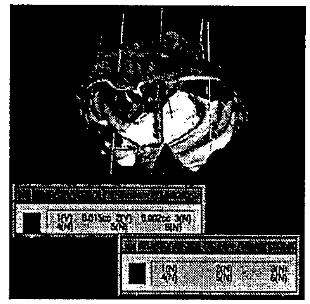

Figure 5 An example of needle biopsy result for sextant and 5-region

For the interactive simulation, six-degree-of-freedom tracking device has been integrated to simulate the ultrasound probe used during actual prostate biopsy procedure. The tracking device consists of an ultrasound transmitter, a controller, and a freely movable receiver device that serves as a tracker. With this mode, the system can track both the position (x, y, z) and the orientation angles (Pitch, Yaw, Roll) of the receiver in real time (50Hz). The tracking information is simultaneously used in controlling movement of a virtual ultrasound probe in the visualization and simulation system. The synthesized ultrasound images are refreshed in real time to follow the movement of the probe, which display intersectional anatomical slices of the prostate as biopsy guidance for the user (a urologist). With this interactive simulation mode, the urologist can perform a virtual needle biopsy as though he/she is performing a real biopsy on a patient. In the interactive simulation mode, the urologist determines the location for each needle insertion based on a specific protocol under the guidance of the synthesized ultrasound image. The angle of the needle is fixed with the ultrasound probe, and the upcoming path of the needle is always overlaid on the ultrasound image so that the urologist knows where the needle will go through inside the prostate. The result of a biopsy is automatically calculated by the system after each biopsy and displayed to tell the urologist whether the biopsy is positive or negative and how much the positive needle core volume is. Figure 6 shows the virtual ultrasound probe and the needle in use, while Figure 7 shows the synthesized ultrasound image with needle path and the fired needle.

Figure 6 Virtual ultrasound probe and the needle in use

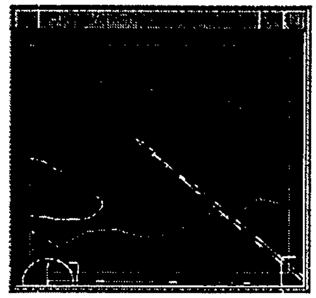
Figure 7 Synthesized ultrasound image with needle path and fired needle

4. PRELIMINARY EXPERIMENTS

4.1 Automatic vs. interactive needle biopsy

In order to verify the performance of the automatic biopsy simulation, comparison of the automatic and interactive biopsy simulation modes has been conducted with 53 3-D prostate models using the following three variables: rates of positive biopsy, positive core volumes, and the number of positive needles for each sample. The sextant protocol is employed. McNemar's test is used for analysis of the rates of positive biopsy, and the results are shown in Table 1. Given the level of significance α=.05, since the test statistic T = b = 4 which is larger than t(=2) and smaller than n-t(=b+c-t=7), the null hypothesis is accepted which indicates that the difference between the two simulation methods is not significant [Conover 1980]. We have used paired-t test to analyze the other two variables. For the positive core volume, the results are shown in Table 2. Since the p value is 0.12, which is larger than 0.05 with test statistic t=1.581, it also indicates that the difference is not significant between the 2 biopsy simulation methods. The 95% confidence interval is [-7.3E-04, 6.14E-03]. For the number of positive needles, the results are shown in Table 3. Since the p value is 0.107, which is also larger than 0.05 with test statistic t=-1.642, these results also suggest that the difference is not significant. The 95% confidence interval is [-0.67, 6.71E-02]. As a result of this analysis, we may conclude that the automatic biopsy simulation is performing as well as a human urologist.

Table 1 Number of positive biopsies for automatic and interactive biopsy simulation

		Interactive	
		Positive	**Negative**
Automatic	**Positive**	a = 31	b = 4
	Negative	c = 7	d = 11

Table 2 Mean values of the positive core volumes for automatic and interactive biopsy simulation

	Mean values
Automatic biopsy	10.6E-03cc
Interactive biopsy	7.88E-03cc

Difference	2.71E-03cc

Table 3 Number of positive needles for automatic and interactive biopsy simulation

	Mean values
Automatic biopsy	1.42
Interactive biopsy	1.72
Difference	-0.30

4.2 Comparison of current biopsy protocols: sextant vs. 5-region with automatic simulation

We have evaluated sextant protocol against 5-region protocol in order to identify if there is any difference that is statistically significant, using the prostate needle biopsy simulation system with 107 3-D prostate models [Kaplan, Zeng, Lynch et al. 1998a]. This evaluation can provide evidence to show that one protocol is advantageous over another before applying them to the patients. After the new protocol is developed in this research, it will be first evaluated using the simulation system before conducting a clinical trial. We have used McNemar's test to evaluate the rates of positive biopsy and used paired t-test to evaluate the positive core volumes. The results of the rates of positive biopsy for the sextant and 5-region protocols are shown in Table 4. Given the level of significance α=.05, since the test statistic T = b = 0 which is smaller than t(=1), the null hypothesis is rejected which indicates that the difference between the two protocols is significant. Five-region protocol is advantageous over the sextant protocol. In addition, the results of the positive core volumes are shown in Table 5. Since the p value is 0.00, which is smaller than 0.05 with test statistic t=8.907, it also indicates that the difference is significant between the 2 biopsy protocols. The 95% confidence interval is [7.51E-03, 1.18E-02]. As a result of this analysis, we may conclude that the 5-region protocol is performing better than the sextant protocol.

Table 4 Number of positive biopsies for the sextant and 5-region protocols

Five-region protocol

Sextant protocol		Positive	Negative
	Positive	a = 76	b = 0
	Negative	c = 8	d = 23

Table 5 Mean values of the positive core volumes for the sextant and 5-region protocols

	Mean values
Five-region protocol	2.38E-02cc
Sextant protocol	1.42E-02cc
Difference	9.60E-03cc

4.3 Correlation of tumor volume vs. positive core volume

As a step toward estimation of tumor volume from the corresponding positive core volumes, we have investigated the correlation between these two kinds of volumes. We have used 89 3-D prostate models on the needle biopsy simulation system with both sextant and the 5-region protocols [Kaplan, Zeng, Lynch et al. 1998b]. Figure 8 shows a correlation result of tumor volume vs. positive core volume with the sextant biopsy protocol. Table 6 gives the corresponding correlation coefficient and the level of significance. Since the level of significance is 0.002 which is smaller than 0.01, the correlation is significant between the two volume variables with the sextant protocol. The results with the 5-region protocol are shown in Figure 9 and Table 7, which also indicates that the correlation is significant

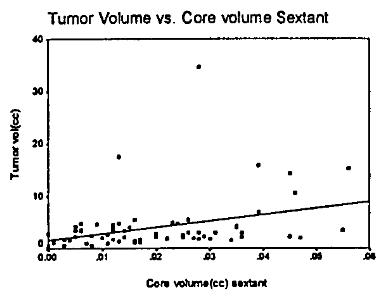

Figure 8 Plot of tumor volume vs. core volume with sextant protocol

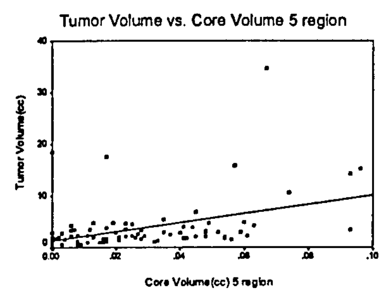

Figure 9 Plot of tumor volume vs. core volume with 5-region protocol

Table 6 Correlation coefficient and the of significance with sextant protocol

Correlation of Sextant vol to Tumor Volume

		Tumor vol	Tot# Sex
Pearson Correlation	Tumor vol	1.000	.344**
	Tot# Sex	.344**	1.000
Sig. (1-tailed)	Tumor vol	.	.002
	Tot# Sex	.002	.
N	Tumor vol	89	71
	Tot# Sex	71	71

**. Correlation is significant at the 0.01 level (1-tailed).

Table 7 Correlation coefficient and the level of significance with 5-region protocol

Correlation of 5 region to tumor volume

		CORVOL	TUMVOL
Pearson Correlation	CORVOL	1.000	.426**
	TUMVOL	.426**	1.000
Sig. (1-tailed)	CORVOL	.	.000
	TUMVOL	.000	.
N	CORVOL	89	89
	TUMVOL	89	89

**. Correlation is significant at the 0.01 level (1-tailed).

5. CONCLUSIONS

In order to optimize the prostate needle biopsy protocols, we have developed a 3-D computer visualization and simulation system, and have conducted various experiments with a large number of 3-D prostate models based on the simulation system. To verify the performance of the developed visualization and simulation, an interactive biopsy mode is developed and integrated in the simulation system. A urologist can hold a six-degree-of-freedom tracking device to control a virtual ultrasound probe on the screen to guide his/her biopsy procedure. Since the tracking device can provide a real time tracking ability, the urologist can perform the virtual prostate needle biopsy as though he/she is using a real ultrasound probe on a patient. A synthesized ultrasound image is refreshed in real time following the movement of the tracking device in the user's hand. With 53 sample prostate models on which the needle biopsies have been conducted by both the computer and the urologist using the sextant protocol, it is shown statistically that the biopsy simulation by the computer system is performing as well as the urologist. On the other hand, different biopsy protocols can be automatically simulated and evaluated for their performance analysis on our developed simulation system, which provides a quantitative measure to statistically compare various biopsy protocols before trying them on the patients. With 107 sample models, we have shown that the systematic 5-region protocol gives better results than the systematic sextant protocol. Further, to explore the possibility of estimating tumor volumes from the positive needle core volumes, we have investigated the possible correlation between the tumor volume and the positive needle core volumes with 89 3-D sample prostate models. A significant correlation is found between these two kinds of volumes, which provides an evidence that the tumor volume may be reasonably estimated from the positive needle core volumes. Finally, we have proposed a detailed algorithm to find a statistically optimized prostate needle biopsy protocol, which is currently being implemented in this research. Evaluation and data analysis methods are also provided and are being implemented.

With the advancement of new imaging technologies, 3-D prostate models may be obtained *in vivo,* which will have a great impact on the way the prostate needle biopsy is performed. More 3-D prostate models can be conveniently acquired directly from the patients at screening tests, making a statistical analysis more useful and powerful and reducing the time cycle of research. Meanwhile, it becomes possible to develop an on-line prostate needle biopsy system which provides real time augmented 3-D images to help a urologist to quickly and precisely identify the abnormality in the prostate inside the patient's body. This idea is not limited to the prostate needle biopsy, it may be applied to any type of biopsy, such as kidney biopsy. It may also be applied to other surgeries beyond biopsies, making it possible to realize a real on-site image-guided minimally-invasive surgery system.

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Anatomic Region-Based Dynamic Range Compression for Chest Radiographs Using Warping Transformation of Correlated Distribution

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Abstract— **The purpose of this paper is to investigate the effectiveness of our novel dynamic range compression (DRC) for chest radiographs. The purpose of DRC is to compress the gray scale range of the image when using narrow dynamic range viewing systems such as monitors. First, an automated segmentation method was used to detect the lung region. The combined region of mediastinum, heart, and subdiaphragm was defined based on the lung region. The correlated distributions, between a pixel value and its neighboring averaged pixel value, for the lung region and the combined region were calculated. According to the appearance of overlapping of two distributions, the warping function was decided. After pixel values were warped, the pixel value range of the lung region was compressed while preserving the detail information, because the warping function compressed the range of the averaged pixel values while preserving the pixel value range for the pixels which had had the same averaged pixel value. The performance was evaluated with our criterion function which was the *contrast* divided by the *moment*, where the *contrast* and the *moment* represent the sum of the differences between the pixel values and the averaged values of eight pixels surrounding that pixel, and the sum of the differences between the pixel values and the averaged value of all pixels in the region-of-interest, respectively. For 71 screening chest images from Johns Hopkins University Hospital (Baltimore, MD), this method improved our criterion function at 11.7% on average. The warping transformation algorithm based on the correlated distribution was effective in compressing the dynamic range while simultaneously preserving the detail information.**

Index Terms—**Anatomic information, chest radiograph, correlated distribution, dynamic range compression, image processing, lung region, warping transformation.**

I. Introduction

In digital radiography, various image processing algorithms have been developed to generate clinically useful images. In the case of chest radiographs, the aim of these methods is to enhance both the lungs and the mediastinum equally in spite of their normally large difference in X-ray transmission. In routine chest radiographs, the mediastinum is often underexposed and vascular structures are obscured by the diaphragm. If images are observed with a cathode-ray tube (CRT), the global window-and-leveling technique may improve visualization for diagnosis. However, this is complicated and time consuming for routine diagnosis. If images are observed on printed film, enhancing the contrast and brightness of the underexposed mediastinum area by this windowing technique may degrade visualization of the lung field.

Image enhancement methods are generally classified into two groups: 1) the frequency manipulation, such as unsharp masking or gradient operator techniques, and 2) the density conversion, such as histogram equalization (HEQ) or dynamic range control techniques.

Unsharp masking techniques [1] have been widely used in crispening the edges of structures and enhancing high-frequency information of an image. Conventional unsharp masking methods are based on spatial operations, such as convolution with a spatial mask, performed on the original image. In general, there are two types of unsharp masking methods: linear and nonlinear [2]. In the linear approach, a high-pass-filtered image is first multiplied by a global constant weighting factor and then added to the original image in a pixel by pixel manner. In the nonlinear approach, before being added to the original image, the highpass filtered image is weighted by the factors whose values depend on the pixel intensity of the original image. Rogowska and Sezan [2], [3] have done extensive studies on the evaluation of linear and nonlinear unsharp masking techniques to enhance digital chest radiographs. An anatomically selective unsharp masking method, using a threshold to distinguish between the lungs and the mediastinum, and an asymmetric unsharp masking method to suppress artifacts, such as overshoots and undershoots, were proposed by Sezan [3]. Tahoces [4] used the linear combination of two smoothed images generated by spatial lowpass filtering of different mask sizes. The idea is to enhance not only high-frequency (a small mask size), but also medium-frequency components (a large mask size). Tahoces also proposed the nonlinear contrast stretching function based on the difference between the histograms of the original image and the averaged image. Lin developed a density-based image processing algorithm to enhance selective radiodense regions on digital radiographs. The wavelet filtering technique was used to locate the radiodense region-of-interest ROI, which controlled the combination ratio between the original and the unsharping images [5].

Gradient operators are well-known forms of edge detection which are based on digital approximations of local differential equations. Daponte investigated the difference between the

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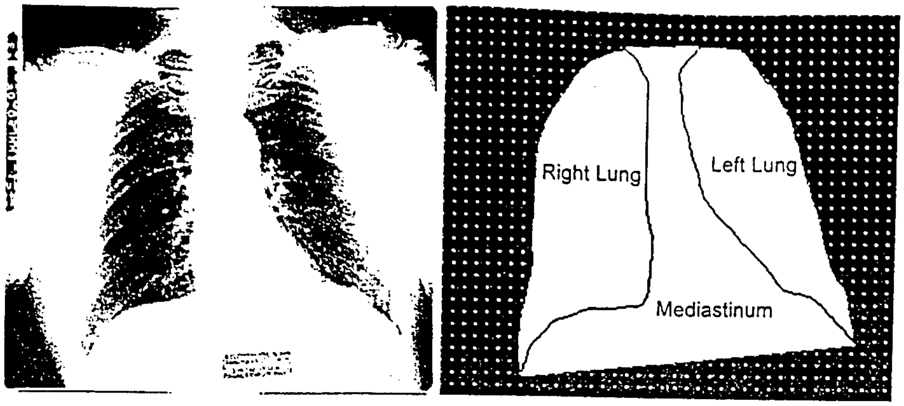
Sobel operator and the Robert operator, and evaluated the noise reduction processes, such as the pill box, the Gaussian, and the median filters, followed by the gradient operator [6]. Ji proposed a blockwise adaptive unsharp masking method which tailors the required amount of contrast enhancement based on the local contrast of the image and the observer's just-noticeable-difference [7].

HEQ is a well-known technique where image quality is improved by equally distributing pixel intensity throughout the available gray scale range. This is accomplished by creating a look-up table gray scale transformation based on the cumulative distribution function. If this technique is performed on the entire image, the contrast is improved only if the global histogram shape is restricted in smaller subregions of the gray scale range. For chest radiographs, it is better to perform a local area histogram equalization, thereby improving contrast in these smaller regions. Pizer improved this time-consuming procedure, i.e., adaptive histogram equalization (AHE), where the local histograms were calculated on a number of sample points, and the resulting pixel values were interpolated by the four nearest sample points [8]. Then, he introduced a clipped AHE to avoid overenhancing the noise. The clipping limit was determined by specifying the limiting slope, which controlled the amount of contrast enhancement [9]. Zimmerman carefully investigated the diagnostic effectiveness of AHE using computed tomography (CT) images. He concluded that there was no significant difference in the ability of the windowing technique and AHE in diagnostic task [10]. Sherrier evaluated a regionally adaptive histogram equalization technique where anatomic regions were estimated from the cumulative distribution function of the $K \times K$ grid. In this method, the lungs were not processed and there was a smooth transition, provided by the bilinear interpolation, between the lungs and the processed mediastinum and diaphragm [11]. Crooks proposed the unique histogram shift algorithm for the edge detection and edge enhancement of medical images where the resulting pixel value is a subtraction between the original value and the minimum or maximum value, multiplied by a scaling factor, within the kernel centered by each pixel. Varying this scaling factor will result in either edge enhancement or in edge detection as desired [12]. McNitt-Gray developed an automatic enhancement system for a PACS in which a global histogram is used to determine a look-up table which enhances the dense tissue or the soft tissue as desired [13].

Dynamic range compression (DRC) is an indirect method of image enhancement. In general the dynamic range of chest radiographs is too wide to diagnose both the lungs and the mediastinum with a single fixed-windowing image. Consequently, DRC, while preserving detail and important information, is classified as an image enhancement technique. Fuji Photo Film Co., Ltd. has developed a DRC processing technique which can generate a wide diagnosis field in a single-image display [14]. This method has been generalized with reference to a self-assurance digital filter developed by Otani [15]. His DRC technique did not make use of anatomic region information, and automated methods to define parameters for DRC were not mentioned.

In this paper, we propose three automated image enhancement techniques: 1) anatomic region-based histogram equalization (AHEQ), 2) anatomic region-based dynamic range compression (ADRC), and 3) the combination of AHEQ and ADRC (AHEQ +ADRC). All three methods above are processed based on the segmentation results, i.e., the lung, the mediastinum and others. Some methods of extracting the anatomic regions are reviewed below. In general they are classified into two groups. One is the pixelwise segmentation based on its image features such as density, histogram, entropy, gradients, and cooccurrence matrix, etc. [16]–[18]. The determination approach usually consists of neural networks. Although this method is stable, its output gray scale images from neural networks have coarse lung contours. The other is to detect the edge lines in profiles, signatures, or kernels of its original two-dimensional image [19]–[22]. Although lung contours from this edge method are often very clear, it sometimes extracts wrong contours from unusual images. We proposed a novel method which is sensitive to contours and yields robust performance [23], and evaluated its performance by using an adaptive-sized hybrid neural network [24]. Using the features of anatomical relative address, normalize density and histogram equalized entropy, the neural network classified the lungs at 92% accuracy for 71 test images.

The goal of proposed methods is to develop a method to simultaneously 1) compress the gray level dynamic range in the lung region, and boost its average intensities, and 2) stretch the contrast of the mediastinum. Since the global HEQ takes into account the background which has no meaning in diagnosis when it calculates the cumulative distribution function of the pixel intensities, we proposed AHEQ which takes into account only the pixels in ROI. The global contrast between the lungs and the mediastinum is very important for diagnosis of chest radiographs. In that sense, AHE, even improved by Pizer, cannot be applied to chest radiographs, because unlike windowing and global HEQ, it does not preserve the rank ordering of the intensity values. Our proposed AHEQ preserves the rank ordering by using an cumulative distribution function of the pixel intensities of a ROI. In order to apply AHE to digital chest radiographs, Sherrier proposed two major factors: 1) no process should be performed in the lungs, 2) the transition from the mediastinum to the unprocessed lung must be smoothed and processed free of artifacts. The locally calculated cumulative distribution function was used to classify the region into one of four anatomical segments, i.e., lung, mediastinum, the transition region between lung and mediastinum, and subdiaphragm. Therefore, his algorithm is classified into the method based on the segmentation results. A weak point of his method is that the lung region is not improved at all. When chest radiographs are diagnosed with CRT's, the lung region is sometimes too dark, and has too wide dynamic range to be diagnosed. In that case, if we assume that the windowing technique is not used, then the enhancement method for the lung region will be needed. ADRC is proposed to improve the visualization in the lung region. It is a process using anatomic segmentation, where pixel intensities in the lungs are selectively warped based on the correlated distributions between individual pixel intensities



(a) (b)

Fig. 1. (a) The original image and (b) the segmented image: The regions surrounded by the outlines represent the right and left lungs and the mediastinum in (b).

and neighborhood averaged intensities of pixels within the lungs and mediastinum. The combination method of AHEQ and ADRC is introduced 1) to improve the contrast in the mediastinum, which will not be enhanced by ADRC, using AHEQ, and 2) to compress the lung region dynamic range, which might be overexpanded by AHEQ, using ADRC.

II. Materials and Methods

A. Acquisition of Digital Chest Radiographs

A total of 71 screening chest radiographs from Johns Hopkins University Hospital were digitized to 2×2.5 K pixels with 12-b gray scale using a Lumisys laser scanner. To reduce the amount of information, the images were smoothed and subsampled to 256×310 pixels with rescaling from 12-b to 8-b based on the image maximum and minimum. The kernel used for smoothing was 8×8 pixels, which is identical to 1.4×1.4 mm. Although the diagnostic goal is that the image processing is applied to the full spatial resolution images, we assume that those subsampled and rescaled images still have enough information to evaluate the effectiveness.

B. Definition of Anatomic Regions

ADCR and AHEQ will improve visualization of "lungs" and "mediastinum" for diagnosis. For our purposes, the "mediastinum" is defined as the combined region which includes the heart, the diaphragm, and the subdiaphragm regions as well as the mediastinum region.

For ADRC and AHEQ, every pixel should be classified into one of three regions: 1) the lungs, 2) the mediastinum, and 3) other. However, our segmentation method classifies each pixel into one of two regions, i.e., the lung and other [23]. So we introduce a simple method to extract the mediastinum region using the outline of the lungs as follows. First, the top points of each lung are connected, as are the bottom points. Then the region, surrounded by the line connecting each top point, the line connecting each bottom point, and the inner (medial) edges of the lungs, is defined as the mediastinum region. The original image and the segmented image are shown in Fig. 1(a) and (b), respectively. In Fig. 1(b), the regions surrounded by the outlines represent the right and left lungs and the mediastinum. The ADRC method utilizes the difference among the correlated distributions of anatomic regions. We assume that there is not much difference among the heart, the diaphragm, the subdiaphragm, and the real mediastinum.

C. AHEQ

HEQ is a well-known technique wherein image quality is improved by equally distributing pixel intensity throughout the available gray scale range. The difference between AHEQ and a conventional HEQ is that AHEQ takes into account pixel intensities only within the lung and the mediastinum regions, and distributes these intensities equally throughout the available gray scale range. It is not meaningful for the study of chest radiographs to take into account the regions outside the lungs and the mediastinum when making a histogram of the density distribution. The algorithm of AHEQ is explained as follows. Let $I[n, m]$ denote the pixel value at coordinate (n, m), where $0 \le n \le N-1$, $0 \le m \le M-1$. N is the number of columns and M is the number of rows. Since the pixel value $I[n, m]$ represents an inverse of film density, the higher the film density, the lower the pixel value. Suppose the pixel values u_i in the observation area, i.e., the lungs and the mediastinum, have the probabilities $p(u_i)$ defined by

$$p(u_i) = \frac{h(u_i)}{\sum_{j=0}^{L-1} h(u_j)}, \qquad 0 \le i \le L-1 \tag{1}$$

where $h(u_i)$ represents the histogram of the pixel values $I[n, m]$ within the observation area, and the level number L represents how many gray levels there are in an image. Then the cumulative probabilities v_i, up to the pixel value u_i, are defined as

$$v_i = \sum_{j=0}^{i} p(u_j). \tag{2}$$

The AHEQ output value v_i' is given by

$$v_i' = \mathrm{int}\left[\frac{v_i - v_{\min}}{1 - v_{\min}} \times (L' - 1) + 0.5\right] \tag{3}$$

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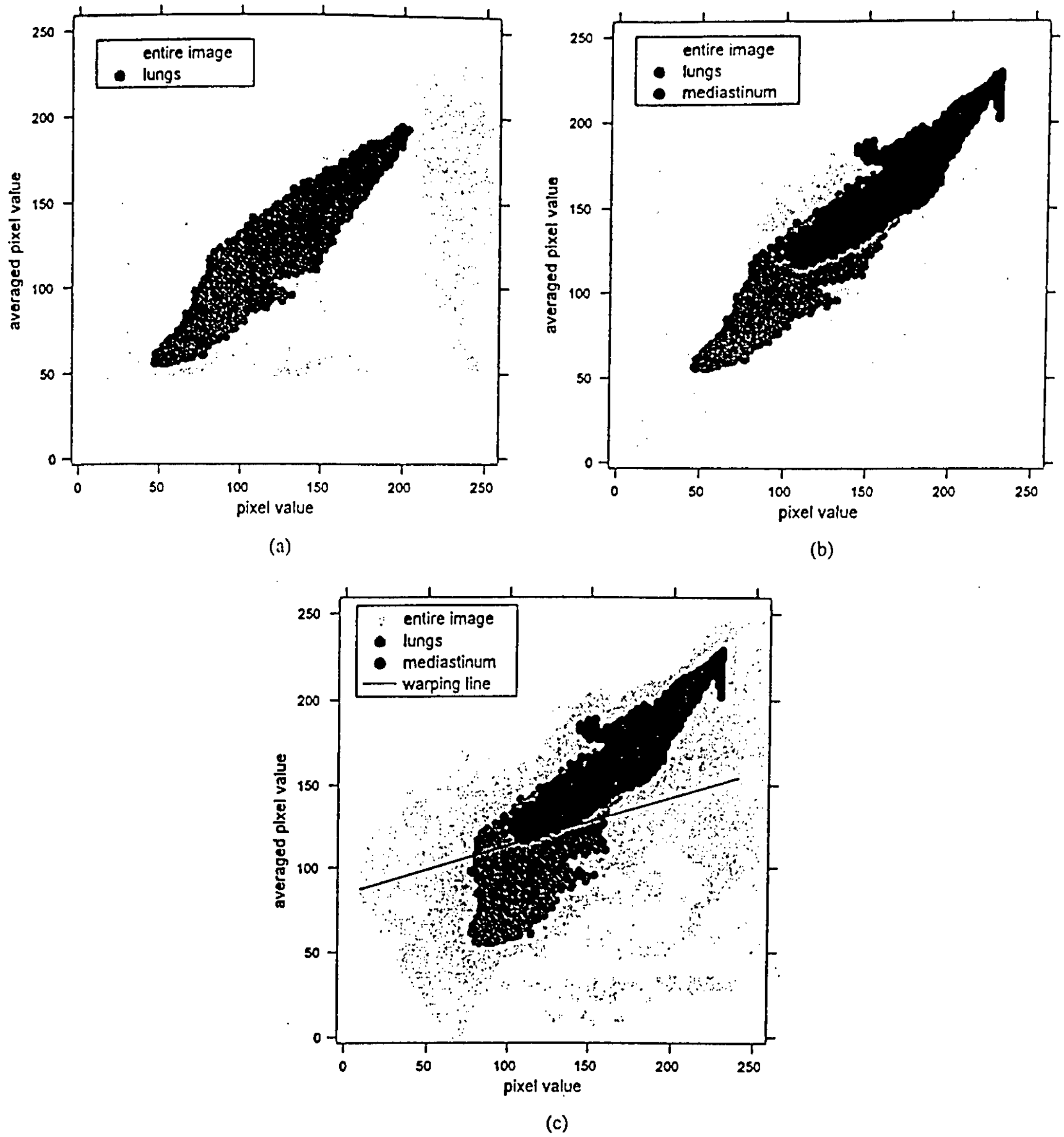

Fig. 2. (a) The correlated distributions of the entire image and the lungs shown Fig. 1. Light gray circles and dark gray circles represent the correlations of the entire image and the lungs, respectively. The distribution of the lungs overlaps on the distribution of the entire image. (b) The distribution of the mediastinum, represented by the black circles, overlaps on the distributions of the lungs and the entire image. (c) The warped distribution by ADRC, which makes the pixel value range of the lungs narrower while preserving the distribution of the mediastinum. Light gray circles, dark gray circles, and black circles represent the warped distributions, of the entire image, the lungs, and the mediastinum, respectively.

where int represents integer part, L' is the maximum number of levels in the output image and $v_{\min}$ is the smallest positive value of v. v' will be approximately uniformly distributed in the observation area approximately. The pixel values other than the pixels in the observation area are also converted following (2) and (3). If the pixel value $I[n, m]$ is bigger than u_{L-1}, it will be converted to u_{L-1}. Similarly, if the pixel value $I[n, m]$ is smaller than u_0, it will be converted to u_0. As explained above, the entire image is processed using a histogram equalization table derived from the density distributions of the lungs and the mediastinum.

D. ADRC

The key idea of ADRC is to make the pixel value range of the lungs narrower while preserving the distribution of the mediastinum. ADRC is a process based on the correlated distributions of the lungs and the mediastinum where the correlation is between the pixel value $I[n, m]$ and the averaged pixel value $Ia[n, m]$ within the $K \times K$ kernel located at (n, m). The averaged pixel values $Ia[n, m]$ are defined by

$$Ia[n, m] = \frac{1}{K^2} \sum_{i=-(K/2)}^{K/2} \sum_{j=-(K/2)}^{K/2} I[n+i, m+j] \quad (4)$$

where K is the kernel size, an odd number, which is empirically 15 pixels, i.e., about 20 mm. Varying this kernel size K causes the change of the warping transformation. K is the only parameter to determine the correlation distribution. The variation of the kernel size K is discussed in Section IV. Typical correlated distributions of the entire image and the lungs for chest radiographs are shown in Fig. 2(a). Light gray circles and dark gray circles represent the correlations, between $I[n, m]$

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and $Ia[n, m]$, of the entire image and the lungs, respectively. The distribution of the lungs overlaps the distribution of the entire image. The distribution of the mediastinum, represented by black circles, overlaps the distributions of the lungs and the entire image in Fig. 2(b). As seen in Fig. 2(a) and (b), the distribution range, i.e., the area, of the lungs is generally wider than that of the mediastinum. This widely distributed range makes it more difficult to diagnose the lungs with a single-image display. In Fig. 2(c), light gray circles, dark gray circles, and black circles represent the warped distributions, of the entire image, the lungs, and the mediastinum, respectively. The mediastinum distribution is actually not warped at all. The warping line, i.e., the boundary line which determines which areas will be warped or not, is placed just below the mediastinum distribution and the warping process is done only for the distribution below the warping line. As seen in Fig. 2(b) and (c), the pixel value range of the lungs becomes narrower after warping.

1) Extraction of the Warping Lines of ADRC: The algorithm to extract candidates of the warping line is explained below. Note that warping lines are not necessarily linear lines on the correlated distribution, they can be polynomials. Moreover, we can use more than one warping line for more complicated applications. However, here we assume one linear warping line to simplify the explanation of this algorithm.

Candidate lines, placed just under the mediastinum distribution, preserve the mediastinum distribution. First, three pixels of the smallest averaged pixel values $Ia[n, m]$ in the mediastinum distribution are extracted as

$$y_2 = \min\{Ia[n, m]\}$$
$$x_2 = I[n, m], (x_2, Ia[n, m]) \in MD \quad (5.1)$$
$$y_1 = \min\{Ia[n, m]\}$$
$$x_1 = I[n, m], Ia[n, m] > y_2, (x_1, Ia[n, m]) \in MD \quad (5.2)$$
$$y_3 = \min\{Ia[n, m]\}$$
$$x_3 = I[n, m], Ia[n, m] > y_2, (x_3, Ia[n, m]) \in MD \quad (5.3)$$

where MD is the mediastinum distribution and $0 \le x_1 < x_2 < x_3 \le L-1$ is satisfied. The search process for the three smallest averaged values follows from (5.1)–(5.3), sequentially. Note that x and y axes denote $I[n, m]$ and $Ia[n, m]$, respectively. The coordinates of the above three pixels represent (x_1, y_1), (x_2, y_2), and (x_3, y_3), respectively. If more than one pixel has the minimum value y_1, the averaged address of x_1 is calculated. Using these three coordinates, the three candidates $WL1$, $WL2$, and $WL3$ of the warping line are defined as

$$WL1: (x_2 - x_1)y = (y_2 - y_1)x + y_1x_2 - y_2x_1$$
$$WL2: y = y_2$$
$$WL3: (x_3 - x_2)y = (y_3 - y_2)x + y_2x_3 - y_3x_2 \quad (6)$$

where the line $WL1$ goes through coordinates (x_1, y_1) and (x_2, y_2), the line $WL2$ goes through the coordinate (x_2, y_2) with zero slope, and the line $WL3$ goes through coordinates (x_2, y_2) and (x_3, y_3). According to this algorithm, if x_2 is found as the minimum point in the x-direction range of MD, the coordinate (x_1, y_1) sometimes cannot be found in the distribution of the mediastinum. In such a case, the coordinate (x_1, y_1) is defined to be identical to the coordinate (x_2, y_2). Fig. 3 shows three candidates $WL1$, $WL2$, and $WL3$ of the warping line based on three coordinates (x_1, y_1), (x_2, y_2), and (x_3, y_3). Dark gray circles and black circles represent the correlated distribution of the lungs and the mediastinum, respectively. As seen in Fig. 3, a warping line controls the area which will be warped. In general the warping line $WL3$ warps a wider area than the others.

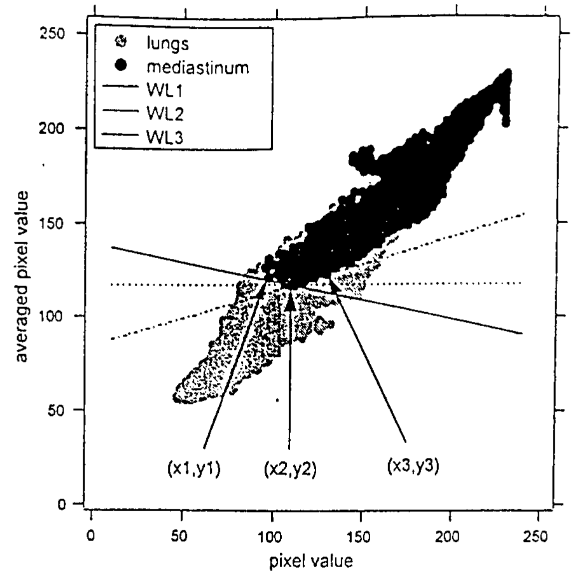

Fig. 3. Three candidates $WL1$, $WL2$, and $WL3$ of the warping line based on three coordinates (x_1, y_1), (x_2, y_2) and (x_3, y_3). Dark gray circles and black circles represent the correlated distribution of the lungs and the mediastinum, respectively.

2) Extraction of the Warping Angle of ADRC: Before evaluating the three candidates of the warping line, appropriate warping angles for each candidate are extracted. A warping angle represents a scaling factor which controls an amplitude of warping. If a warping angle is bigger than an appropriate level, ADRC might induce conspicuous artifacts in an image, so the warping angle is determined not to reverse the size relationship between any two pixels. Following this policy, the extracting algorithm of a warping angle is explained as follows. First, in the correlated distribution between the pixel value $I[n, m]$ and the averaged pixel value $Ia[n, m]$, the coordinate (x_4, y_4), where the warping line WL meets the left outline of the lung distribution, is extracted. The detail algorithm is explained as follows. The coordinate (x_u, y_u) of the pixel, which pixel value $I[n, m]$ is the minimum in the upper-lung distribution (ULD), is extracted as

$$x_u = \min\{I[n, m]\}, \ (I[n, m], y_u) \in ULD \quad (7)$$

where the ULD represents the upper part, divided by the warping line WL, of the lung distribution. If more than one pixel has the minimum pixel value x_u, the minimum averaged pixel value y_u is selected by

$$y_u = \min\{Ia[n, m]\}, \ (x_u, Ia[n, m]) \in ULD. \quad (8)$$

The coordinate (x_l, y_l) of the pixel, which is nearest to the coordinate (x_u, y_u) in the lower-lung distribution (LLD), is

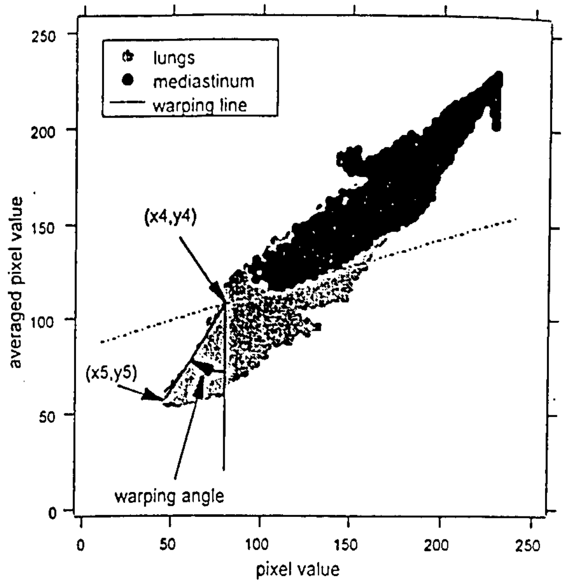

Fig. 4. The coordinates (x_4, y_4), (x_5, y_5) and the extracted warping angle φ for a warping line $WL3$.

extracted as

$$x_l = \min\{\|(x_u, y_u) - (x_l, y_l)\|\},\ (I[n, m], y_l) \in LLD \quad (9)$$

where LLD represents the lower part, divided by the warping line WL, of the lung distribution. $\|\bullet\|$ denotes the Euclidean norm. The coordinate (x_4, y_4) is defined as the coordinate where WL intersects the line through (x_u, y_u) and (x_l, y_l).

Next, the coordinate (x_5, y_5) of the pixel, for which the value is the minimum in the lung distribution, is extracted as

$$x_5 = \min\{I[n, y]\},\ I[n, m] < x_4,\ Ia[n, m] < y_4 \\ \cdot (I[n, m], y_5) \in LD \quad (10)$$

where LD represents the lung distribution. If x_4 is the minimum value of the x-direction range of LD, the coordinate (x_5, y_5) sometimes cannot be found in the distribution of the lungs. In such a case, the coordinate (x_5, y_5) is defined to be identical to the coordinate (x_4, y_4).

Then the warping angle φ between the line, which goes through (x_4, y_4) and (x_5, y_5), and the perpendicular line, from (x_4, y_4) to the x axis, is defined as

$$\varphi = \begin{cases} 0, & (y_4 = y_5) \\ \tan^{-1} \dfrac{x_4 - x_5}{y_4 - y_5}, & (y_4 \neq y_5). \end{cases} \quad (11)$$

The coordinates (x_4, y_4), (x_5, y_5), and the extracted warping angle φ for a warping line $WL3$ are shown in Fig. 4. As seen in Fig. 4, the warping angle extracted by this algorithm follows the policy of the ADRC. The pixel values $I[n, m]$ on the line, which goes through (x_4, y_4) and (x_5, y_5), are converted to the same pixel value. No smaller pixel is converted to be bigger.

3) Evaluation of Warping Lines and Angles: Using a warping line WL and a warping angle φ, the warping value is introduced as follows. Let the coordinate (x_0, y_0) belong to the LLD. Note that this warping transformation is processed not only for the pixels in the lower-lung distribution LD, but also for every other pixel under the warping line WL, otherwise artifacts would be induced. Let the coordinate (x_w, y_0) represent the warped coordinate from the coordinate (x_0, y_0). Suppose the warping line WL is defined by

$$ax + by + c = 0 \quad (12)$$

where a, b, and c are real numbers, and $b \neq 0$. The warping line WL intersects the line, parallel to the y axis through the coordinate (x_w, y_0), at the coordinate $(x_w, -(ax_w - c)/b)$. These (x_0, y_0) and $(x_w, -(ax_w - c)/b)$ satisfy (11) as

$$\tan \varphi = \frac{x_w - x_0}{\dfrac{-ax_w - c}{b} - y_0}. \quad (13)$$

Then from (13), we obtain the warped pixel value x_w

$$x_w = \frac{x_0 - \left(\dfrac{c}{b} + y_0\right) \tan \varphi}{1 + \dfrac{a}{b} \tan \varphi}. \quad (14)$$

Although the entire image is processed in the pixelwise manner, the pixels under the warping line WL are selectively applied to (14) as shown in Fig. 5(a). White circles and black circles represent original pixels and warped pixels, respectively. The schematic result of the warping is shown in Fig. 2(c), which is drawn to help the reader understand the warping transformation. By increasing the pixel values (due to the warping process), the neighborhood averages are also being recalculated which results in the entire lung distribution being warped upward as shown in Fig. 5(b). As seen Fig. 5(b), ADRC narrows the averaged pixel value range, which means ADRC compresses the dynamic range of the lungs.

E. AHEQ + ADRC

Although AHEQ processes both the lung and the mediastinum regions, it sometimes reduces the visualization performance for the lung region due to overexpanding its gray scale dynamic range, which make pixel values in the center of the lungs too dark to be diagnosed. On the other hand, ADRC is used to enhance the contrast of the lungs selectively, so AHEQ followed by ADRC method is introduced 1) to improve the contrast in the mediastinum using AHEQ, and 2) to compress the lung region dynamic range, which might be overexpanded by AHEQ, using ADRC.

F. Evaluation of Improvement

We introduce the criterion function to evaluate the performances of both AHEQ and ADRC as well as the three candidates of the warping line. Our criterion function G is defined by

$$G = \frac{\text{contrast}}{\text{moment}}$$
$$\text{contrast} = \frac{1}{8W} \sum_{S[n,m] \in OA} \sum_{i=-1}^{1} \sum_{j=-1}^{1} \cdot |S[n, m] - S[n + i, m + j]|,\ (i, j) \neq (0, 0)$$
$$\text{moment} = \frac{1}{W} \sum_{S[n,m] \in OA} |S[n, m] - \text{average}|$$
$$\text{average} = \frac{1}{W} \sum_{S[n,m] \in OA} S[n, m] \quad (15)$$

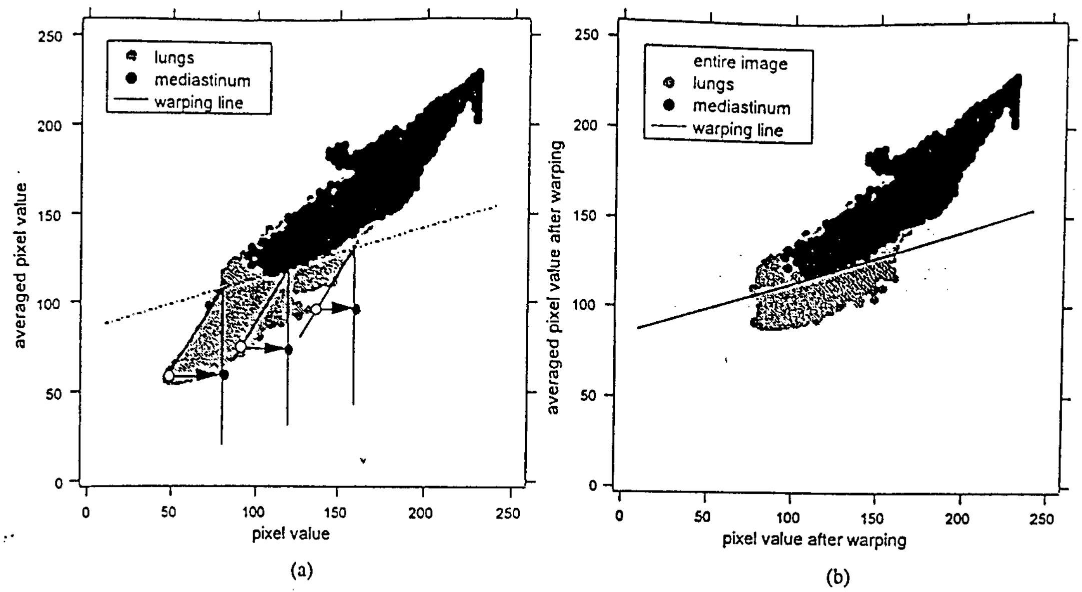

Fig. 5. (a) Every pixel under the warping line WL is applied to (14). White circles and black circles represent original pixels and warped pixels, respectively. The schematic result of the warping is shown in Fig. 2(c), which is drawn to help the reader understand the warping transportation and (b) the true distribution after warping which is warped upward, because the averaged pixel values also become bigger due to the warping transformation. ADRC narrows the averaged pixel value range as well as the pixel value range of the lungs.

where $S[n, m]$ is an image, and W is the number of the pixels in the observation area OA, i.e., the lungs and the mediastinum. The generally used contrast criterion is defined as $|A-B|/(A+B)$, where A and B are the pixel intensities. As you can imagine in Fig. 5(a), the function of ADRC is simplified as the process of adding a bias, which depends on the neighborhood average, to the target pixel. So if neighborhood averaged values for A and B are equal to bias, the resulting general contrast $|A - B|/(A + B)$ of ADRC process will be $|A + \text{bias} - (B + \text{bias})|/(A + \text{bias} + B + \text{bias}) = |A - B|/(A + B + 2 \times \text{bias})$, where bias is not negative. Since $|A - B|/(A + B + 2 \times \text{bias})$ is less than $|A - B|/(A + B)$, this general *contrast* value indicates that ADRC decreases the visualization performance. However, we can find the effectiveness of ADRC as shown in Fig. 6(c). Therefore, we proposed the novel criterion G to quantize the visual improvement of ADRC. The *contrast* part of G represents the local contrast between the pixel value and the local average value. The *moment* part represents the global contrast between the pixel value and the global average value. In general the *contrast* value decreases due to the dynamic range compression. If the *moment* value becomes smaller than the decrease ratio of the *contrast* value, the criterion G increases. We suppose that the bigger the criterion G, the easier the diagnosis. The improvement ratio R [%] is defined by

$$R = 100 \times \frac{G_{\text{proc}} - G_{\text{org}}}{G_{\text{org}}} \tag{16}$$

where G_{proc} and G_{org} represent the criteria of a warped image and an original image, respectively.

III. Results and Discussion

For 71 screening chest images from Johns Hopkins University Hospital, both AHEQ and ADRC were applied. The computational times of AHEQ and ADRC for 256×310 pixel images were about 3 s and 7 s, respectively, using an ONYX workstation (Silicon Graphics, Inc.) consisting of two 190-MHz MIPS R10000 Processors and MIPS R10010 Floating Point Processor. The segmentation cost around 30 min using the same computer, because we used about 5000 neurons in the neural network to segment the lung regions. Examples of an original, an AHEQ, and an ADRC image are shown in Fig. 6(a)–(c), respectively. The mediastinum has less contrast, and the pixel values in the center of the lungs were too dark to diagnose on the original image. The *contrast*, *moment*, and criterion values of the original image are $c = 4.7$, $m = 62.5$, and $G = 7.57 \times 10^{-2}$, respectively. These values are calculated based on the observation region, i.e., the lungs and the mediastinum. The area ratios of the lungs and the mediastinum against the entire image are 30.1% and 18.5%, respectively. After applying AHEQ, the contrast of the mediastinum was improved, but the visualization of the lungs became worse due to expansion of the pixel value range. The *contrast*, *moment*, criterion, and improvement values of the AHEQ image are $c = 5.1$, $m = 64.5$, $G = 7.87 \times 10^{-2}$, and $R = 4.0\%$, respectively. After ADRC, the contrast of the mediastinum was not improved, as a matter of course ADRC did not process the mediastinum region, but the visualization of the lungs became better due to compression of the pixel value range. The *contrast*, *moment*, criterion, and improvement values of the ADRC image are $c = 4.7$, $m = 57.8$, $G = 8.09 \times 10^{-2}$, and $R = 6.9\%$, respectively. The ADRC compresses the *moment* value while preserving the *contrast* value. The warping slope, defined by $-a/b$ in (12), and the warping angle of the warping transformation are $s = 0.08$ and $\varphi = 24.4°$, respectively.

The profiles of an original, an AHEQ, and an ADRC image in Fig. 6 are shown in Fig. 7(a). The position of the profile is indicated as the black line in Fig. 6(a). As seen in Fig. 7(a), AHEQ improved contrast of the mediastinum, where some

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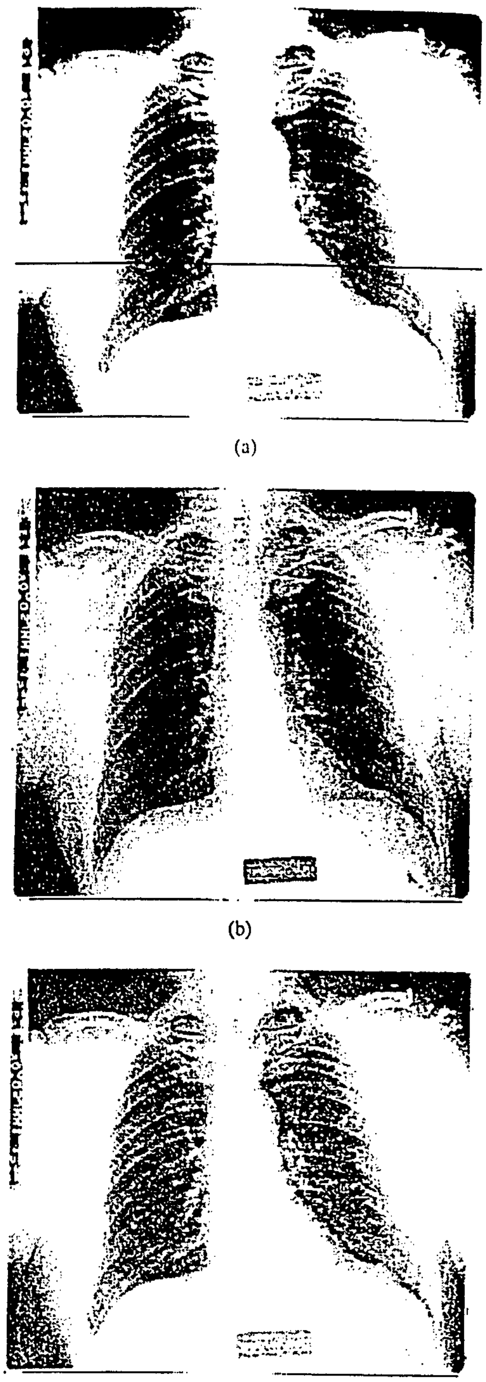


Fig. 6. Examples of an original, an AHEQ, and an ADRC image are shown in (a)–(c), respectively. The *contrast*, *moment*, and criterion values of the original image are $c = 4.7$, $m = 62.5$, and $G = 7.57 \times 10^{-2}$, respectively. The *contrast*, *moment*, criterion, and improvement values of the AHEQ image are $c = 5.1$, $m = 64.5$, $G = 7.87 \times 10^{-2}$, and $R = 4.0\%$, respectively. The *contrast*, *moment*, criterion, and improvement values of the ADRC image are $c = 4.7$, $m = 57.8$, $G = 8.09 \times 10^{-2}$, and $R = 6.9\%$, respectively.

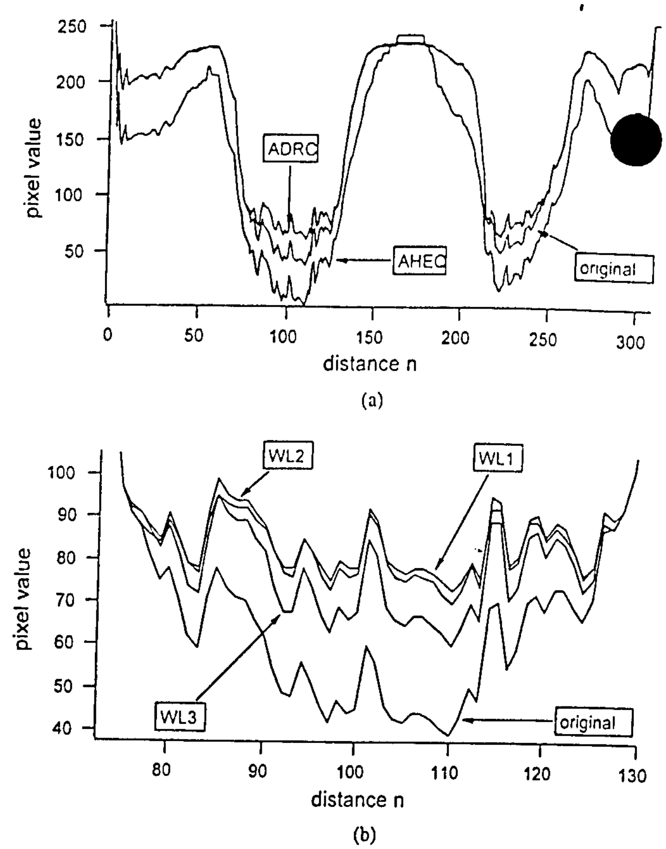
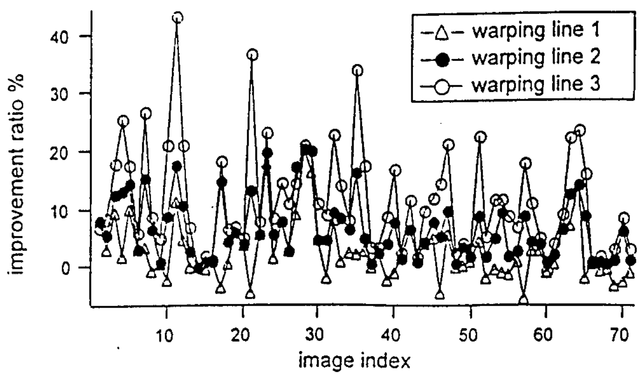


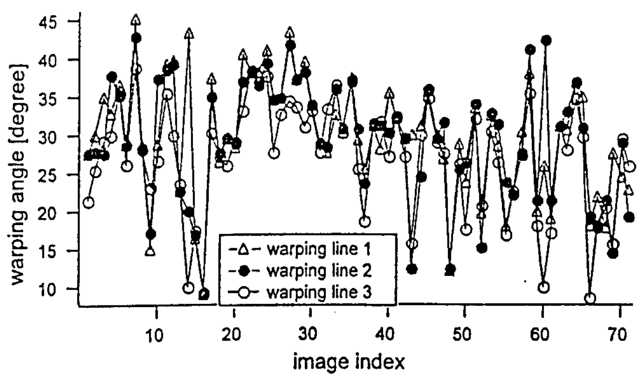
Fig. 7. (a) The profiles of original, AHEQ, and ADRC images shown in Fig. 6. The position of the profiles is indicated as the black line in Fig. 6(a) and (b) the profile variations among three candidates of the warping line. These are enlarged profiles at the right part of the lung of (a).

pixel values were saturated, but unnecessarily expanded the pixel range of the boundary region between the lungs and the mediastinum. ADRC compressed only the pixel value range of the lungs. The profile variation among the three candidates of the warping line is shown in Fig. 7(b). These were enlarged profiles at the right-lung part of Fig. 7(a). As the slope of the warping line $WL1$ is negative, lower pixel values were warped more than higher pixel values. Thus, the center part of the lung was warped more. The bottom part of the lung profile was flattened. The *contrast*, *moment*, criterion, improvement, warping slope, and warping-angle values of $WL1$ are $c = 4.3$, $m = 56.5$, $G = 7.68 \times 10^{-2}$, $R = 1.4\%$, $s = -0.5$, and $\varphi = 28.2°$, respectively. As the slope of the warping line $WL2$ is zero, lower pixel values and higher pixel values were equally warped. Although in the bottom part of the lung profile the size relationship of pixel values were preserved, both side parts of the lung profile seemed to be overwarped. The *contrast*, *moment*, criterion, improvement, warping slope, and warping-angle values of $WL2$ are $c = 4.6$, $m = 56.3$, $G = 8.17 \times 10^{-2}$, $R = 7.9\%$, $s = 0$, and $\varphi = 27.5°$, respectively. As the slope of the warping line $WL3$ is positive, higher pixel values were warped more than lower pixel values. Therefore, both side parts of the lung profile were warped more. However, in general the warping angle of $WL3$ is extracted to be smaller than those of other warping lines, and the profile of $WL3$ seemed to be most appropriate. The *contrast*, *moment*, criterion, improvement, warping slope, and warping-angle values of $WL3$ are $c = 4.8$, $m = 57.7$, $G = 8.29 \times 10^{-2}$, $R = 9.5\%$, $s = 0.25$, and $\varphi = 21.5°$, respectively.

The improvement ratios of $WL1$, $WL2$, and $WL3$ for the 71 images are shown in Fig. 8(a). The averaged improvement ratios of $WL1$, $WL2$, and $WL3$ are 2.5%, 6.6%, and 11.7%, respectively. The improvement ratios of $WL3$ are greater than



(a)



(b)

Fig. 8. (a) The improvement ratios of $WL1$, $WL2$, and $WL3$ for the 71 test images. The averaged improvement ratios of $WL1$, $WL2$ and $WL3$ are 2.5%, 6.6%, and 11.7%, respectively. (b) The warping angles of $WL1$, $WL2$ and $WL3$ for test images. The averaged warping angles of $WL1$, $WL2$, and $WL3$ are 30.0°, 28.2°, and 27.7°, respectively.

the others even with smaller warping angles, because $WL3$ usually covered more pixels under its warping line. As the improvement ratio depends on the correlated distributions of the lungs and the mediastinum as well as the warping function, the ratios for some images indicate very big values. Actually, the improvement ratio increases when the LLD is wider. The improvement ratios of $WL1$ are often negative due to the overwarping at the center of the lung profiles. In these cases the *contrast* values typically become too small. The warping angles of $WL1$, $WL2$, and $WL3$ for the 71 images are shown in Fig. 8(b). The averaged warping angles of $WL1$, $WL2$, and $WL3$ are 30.0°, 28.2°, and 27.7°, respectively. The warping angle depends on the shape of the correlated distributions. The warping angles become small when the entire image is underexposed and the correlated distributions of the lungs and the mediastinum overlap each other.

Examples of applying AHEQ, ADRC, and AHEQ + ADRC to an underexposed image are shown in Fig. 9. The correlated distributions of these AHEQ, ADRC, and AHEQ + ADRC applications are also shown in Fig. 10. The area ratios of the lungs and the mediastinum against the entire image are 30.1% and 17.6%, respectively. The *contrast*, *moment*, and criterion values of the original image in Figs. 9(a) and 10(a) are $c = 3.2$, which is very low contrast, $m = 38.1$, and $G = 8.32 \times 10^{-2}$, respectively. As seen in Figs. 9(b) and 10(b), due to AHEQ the contrast of the mediastinum was improved a little, but most pixels in the abdomen were saturated. The visualization of the lungs became worse due to overexpansion of the pixel value range. The *contrast*, *moment*, criterion, and improvement values of the AHEQ image are $c = 5.3$, $m = 64.2$, $G = 8.22 \times 10^{-2}$, and $R = -1.0\%$, respectively. As seen in Figs. 9(c) and 10(c), with ADRC, the visualization of the lungs was improved a little. But the averaged pixel value in the lung region should be lower. The warped distributions of the lungs and the mediastinum massed in a small area of the upper part of the entire space. The *contrast*, *moment*, criterion, improvement, warping slope, and warping-angle values of ADRC are $c = 3.2$, $m = 32.1$, $G = 9.82 \times 10^{-2}$, $R = 18.0\%$, $s = 0.09$, and $\varphi = 38.4°$, respectively. Figs. 9(d) and 10(d) show the image and the correlated distribution processed with AHEQ followed by ADRC. The mediastinum was improved with AHEQ, and the visualization of the lungs, which was worse after AHEQ, was recovered a little. The *contrast*, *moment*, criterion, improvement, warping slope, and warping-angle values of AHEQ + ADRC are $c = 5.2$, $m = 58.0$, $G = 9.10 \times 10^{-2}$, $R = 9.4\%$, $s = 0.11$, and $\varphi = 29.2°$, respectively.

As seen in Figs. 9 and 10, ADRC did not work well for an underexposed image, which had very narrow correlated distributions. And it is difficult to compare the visual improvement of ADRC with that of AHEQ + ADRC. In AHEQ + ADRC, AHEQ process improved the global contrast between the lungs and mediastinum, but the following ADRC process could not recover the visualization loss, seen in the upper area of the lungs, of the previous AHEQ process. In ADRC, the visual improvement could be found in the upper part of the lungs, but the lung area remained gray and the global contrast between the lungs and mediastinum was low. The criterion R values of AHEQ + ADRC and ADRC were 9.4% and 18.0%, respectively, which result indicates that ADRC alone was much better. We also found the mismatch of the criterion G in Figs. 6(c) and 9(c). Although the visualization result of Fig. 6(c) seems better than that of 9(c), the criterion G of Fig. 6(c), i.e., 8.09×10^{-2}, is smaller than that of Fig. 9(c), i.e., 9.82×10^{-2}. Here, we discuss the above mismatch between the visualization result and the criterion value. The criterion G was introduced to evaluate the performance of ADRC. The reason why we introduced G was mentioned in Section II. However, the *moment* part seems to control the criterion G more than we expected. Actually, the *moment* of Fig. 9(c) is much smaller than those of Figs. 6(c) and 9(d). On the other hand, the small *moment* of Fig. 9(c) might comes from the evaluation method, in which we used the combined region of lungs and mediastinum as the observation area. The low global contrast between the lungs and mediastinum such as Fig 9(c) will induce the small *moment*. We should have evaluated the visualization result for only the lungs as well.

The improvement ratios of AHEQ, ADRC, and AHEQ + ADRC for the test images are shown in Fig. 11. The averaged improvement ratios of AHEQ, ADRC, and AHEQ + ADRC are 2.6%, 11.7%, and 7.7%, respectively. The averaged warping angles of ADRC and AHEQ + ADRC are 27.7° and 15.5°, respectively.

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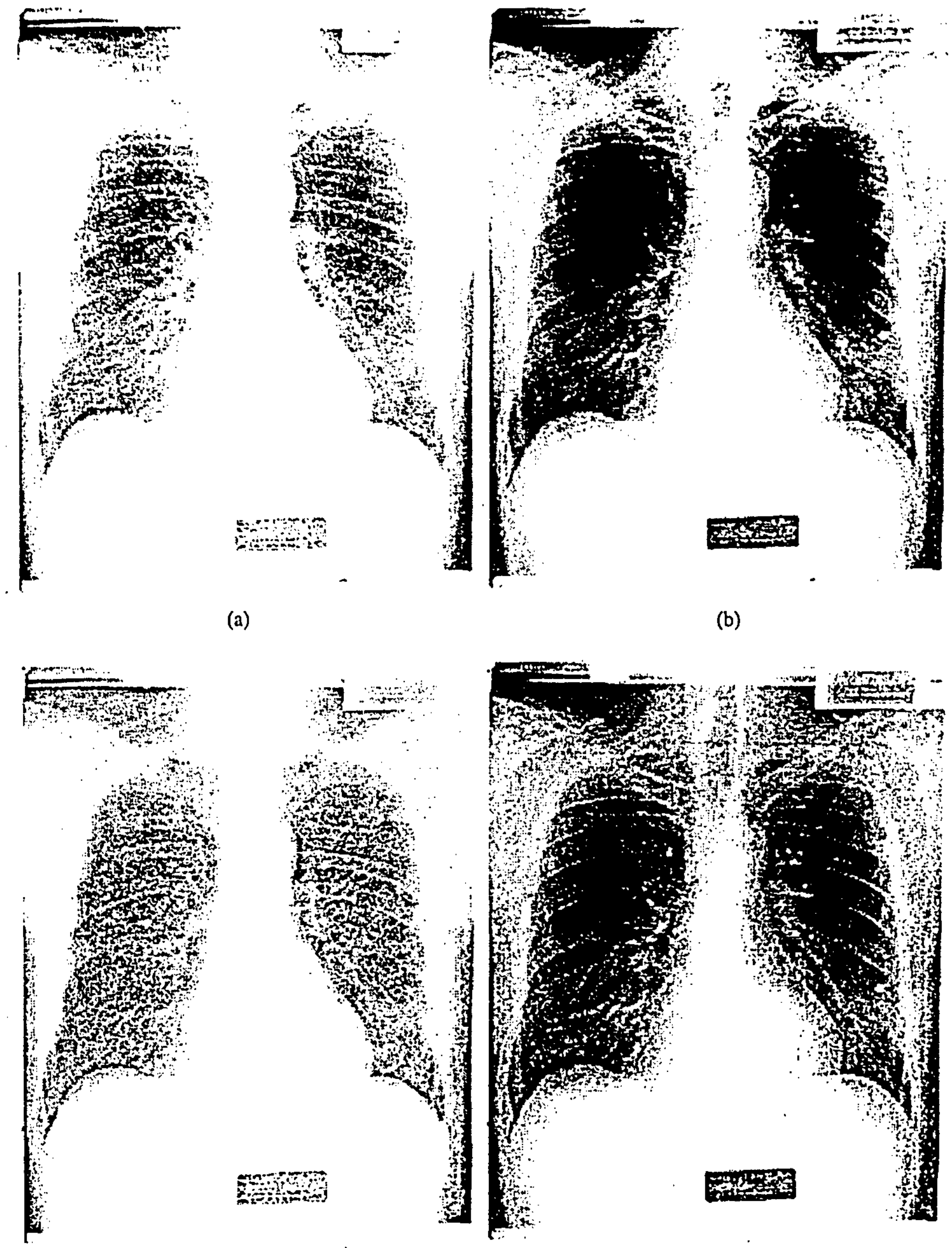

(a) (b)

(c) (d)

Fig. 9. (a) Original image and its processed images applying (b) AHEQ, (c) ADRC, and (d) AHEQ + ADRC. The *contrast*, *moment*, and criterion values of the original image are $c = 3.2$, very low contrast, $m = 38.1$, and $G = 8.32 \times 10^{-2}$, respectively. The *contrast*, *moment*, criterion, and improvement values of the AHEQ image are $c = 5.3$, $m = 64.2$, $G = 8.22 \times 10^{-2}$, and $R = -1.0\%$, respectively. The *contrast*, *moment*, criterion, improvement, warping slope, and warping-angle values of ADRC are $c = 3.2$, $m = 32.1$, $G = 9.82 \times 10^{-2}$, $R = 18.0\%$, $s = 0.09$, and $\varphi = 38.4°$, respectively. The *contrast*, *moment*, criterion, improvement, warping slope, and warping-angle values of AHEQ + ADRC are $c = 5.2$, $m = 58.0$, $G = 9.10 \times 10^{-2}$, $R = 9.4\%$, $s = 0.11$, and $\varphi = 29.2°$, respectively.

Varying this kernel size K for the correlation distributions causes a change of the warping transformation. In this study we used 15×15 pixel kernels, equal to 20×20 mm. If bigger kernels are used, the correlated distributions are extended in the averaged pixel direction, i.e., the y axis. Thereby, the warping angles become smaller. However, the improvement ratios are not much different. Even if a warping angle is smaller, at the same time the distance between the pixel and the warping line is longer.

Finally, we discuss the relationship between ADRC and AHEQ processes and the performance of the segmentation task. The average accuracy of our segmentation method was 92.4% for 71 unknown images [23], which were the subset of 85 images used in this study, and the remaining 14 images were used to train the neural network. Our segmentation method is classified as the pixelwise segmentation method using local image features. Generally, the pixelwise segmentation is stable (the segmentation accuracy for the worst case was around 85% using our method), but cannot generate precise edges. Both ADRC and AHEQ use the pixel value distributions, i.e., the correlated distributions and the histogram of the ROI's, and no edge information were used in those methods. Therefore, our segmentation method is suitable for ADRC and AHEQ.

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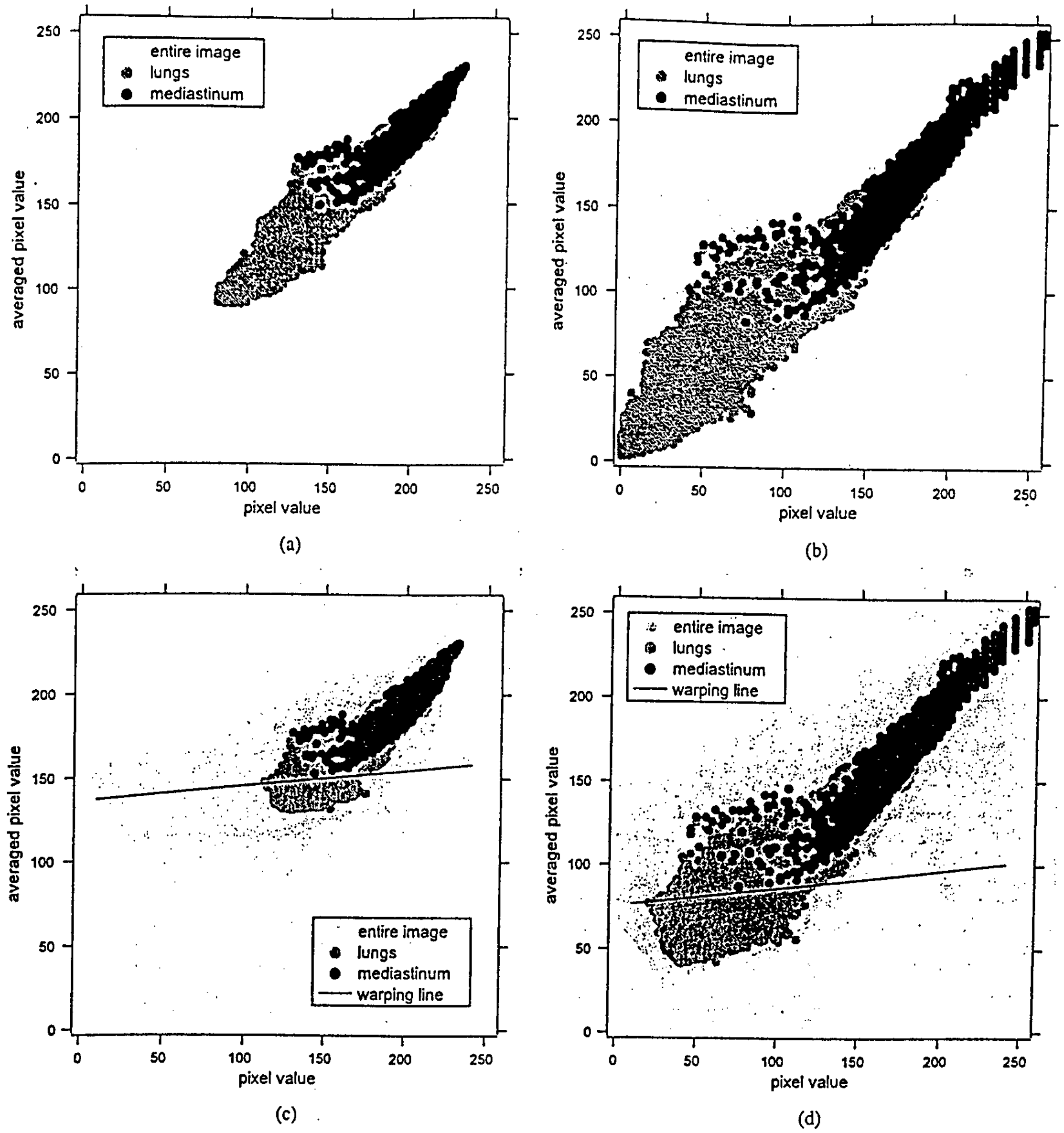

Fig. 10. The correlated distributions of (a) original image and its processed images applying (b) AHEQ, (c) ADRC, and (d) AHEQ + ADRC shown in Fig. 9, respectively. The *contrast*, *moment*, criterion, improvement, warping slope, and warping-angle values are referred to in caption of Fig. 9.

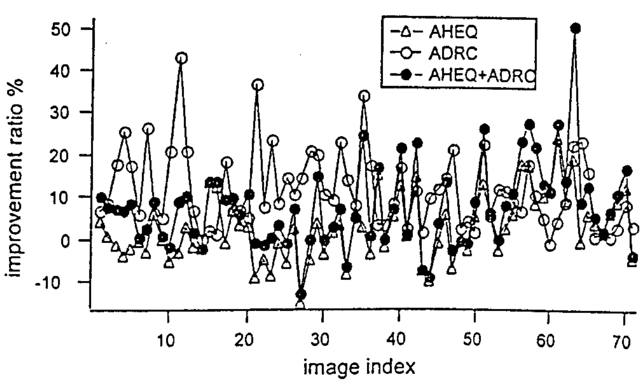

Fig. 11. The improvement ratios of AHEQ, ADRC, and AHEQ + ADRC for the 71 test images. The averaged improvement ratios of AHEQ, ADRC, and AHEQ + ADRC are 2.6%, 11.7%, and 7.7%, respectively. The averaged warping angles of ADRC and AHEQ + ADRC are 27.7° and 15.5°, respectively.

IV. Conclusion

For 71 screening chest images from Johns Hopkins University Hospital, AHEQ, ADRC, and AHEQ + ADRC improved our criterion function at 2.6%, 11.7%, and 7.7%, respectively, on average.

Generally, AHEQ improves the contrast in the mediastinum region very well, but sometimes makes it harder to accurately diagnose the lung region due to overexpansion of the pixel value range. ADRC improves the visualization of the lungs. ADRC is effective in compressing the dynamic range while simultaneously preserving the detail information. Three candidates, $WL1$, $WL2$, and $WL3$, for the warping line were evaluated based on the proposed criterion which is *contrast* divided by *moment*. $WL3$, which warps more pixels than the others, indicates the best performance.

On the other hand, in addition to ADRC, the process of expanding contrast is necessary for underexposed images. For that reason, we introduced the combined process of AHEQ

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followed by ADRC. AHEQ + ADRC improved the visualization of the lungs as well as contrast of the mediastinum. ADRC is useful for other applications where the correlated distributions are different between regions. Using ADRC, we focused on the visual improvement of the lung regions in chest radiographs, but using the same technique the mediastinum can be improved, where we can use the generally used contrast criterion for evaluation. ADRC could be used to delineate the structure of the skin line in mammograms, which would be our future work.

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Workshop: Technical Requirements for Image-Guided Spine Procedures

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1 Workshop Overview

This three-day workshop is being organized by the Imaging Science and Information Systems (ISIS) Center of Georgetown University Medical Center, the Department of Radiology of The Johns Hopkins Medical Institution, and the Biomedical Engineering Program of The Catholic University of America. The workshop will be held April 17-20, 1999, at Turf Valley Country Club in Ellicott City, MD. An international organizing committee will oversee the design of the workshop program. The general objective of the workshop is to determine the technical requirements for image-guided procedures in the spinal column and the spinal cord. A report on the "Technical Requirements for Image-guided Spine Procedures" will be the primary outcome of the conference and will be made available over the Internet as well as in printed form.

An international group of invited experts in the technologies associated with image-guided spine procedures will meet to define the barriers to progress and to propose technological developments needed to solve them. Clinical, biomedical engineering, and computer science experts will be invited from the academic, defense, and industrial research and development communities. The workshop will be small, highly interactive, focused, carefully structured, and with ample time to promote discussion. Through specialized working groups, needs will be identified and an action plan for their adaptation and development will be produced. The summaries, needs assessments and action plan will be made available in a format that can be distributed to researchers holding potential solutions through new technologies.

The workshop process is as follows:

- Participants will be asked to identify 3-5 key papers in the field prior to the workshop
- Selected papers, planned discussion topics, and the agenda will be distributed to participants before the meeting

- A review of image-guided procedures in the spine will be presented in a plenary session prior to dividing into small working groups
- Working group chairs will be given a list of issues to address
- Working groups will meet to identify and define requirements
- Working groups will report and make recommendations to the organizing committee
- The working groups will meet again, redefine their recommendations, and provide a final summary to the complete conference
- The document "Technical Requirements for Image-guided Spine Procedures" will be completed shortly following the workshop and will be made available over the Internet and in hard copy

2 Workshop Objectives

2.1 General Objective

The general objective of the workshop is to determine the technical requirements for image-guided procedures in the spinal column and the spinal cord. The focus will be on advanced imaging techniques such as intraoperative MRI and CT, 3-D ultrasound, image registration, fusion of instrument location into clinical images, and 3-D visualization. Specific clinical applications such as the resection of spine tumors, spine trauma repair, and spine reconstructive procedures will be examined as to what role image guidance might play in improving the procedure.

2.2 Plan of Attack

The general objective of the workshop will be attained through the following four steps.

Step One. Define the current status and clinical needs in spine procedures, particularly those that might benefit from image guidance.

Procedures that are typically done in the spine will first be surveyed to determine those procedures where image guidance is already in use or where advanced imaging methods could play a role in improving the procedure. A list of procedures will be compiled before the workshop and refined during the workshop.

Step Two. Elaborate the requirements for image guidance in selected procedures.

From the list of procedures developed in step one, a set of technical requirements for image guidance will be established. Requirements such as image resolution and tracking accuracy will be established. The expected value of 3-D visualization, image registration, and other advanced techniques will be assessed.

Step Three. Establish priority areas for research and development

Based on the technical requirements established in step 2, the state-of-the-art of image-guided technology will be examined to determine where further research and development is needed.

Step Four. Configure the diagnosis and therapy team for image-guided procedures of the 21st century

To ensure the continued successful introduction of image guidance in clinical procedures, a new team of physicians, engineers, and other specialties will be required. Recommendations as to the formulation and composition of this team and its training needs will be made.

3 Specific Program and Logistical Arrangements

3.1 Workshop Date

The workshop program will be a three-day meeting to be held April 17-20, 1999. This date was selected far in advance to allow sufficient planning time. In addition, an effort was made to avoid conflicts with clinical meetings such as those sponsored by the American Association of Neurological Surgeons (AANS), the American Academy of Orthopaedic Surgeons (AAOS), and the North American Spine Society (NASS). Conflicts were also avoided with technical meetings such as those sponsored by the Institute of Electrical and Electronics Engineers (IEEE) Engineering in Medicine and Biology Society (EMBS) and the Biomedical Engineering Society (BMES).

3.2 Workshop Site

The workshop site is the Turf Valley Country Club in Ellicott City, MD, which is between Baltimore and Washington, DC. Turf Valley was selected for its excellent conference facilities, proximity to airports, and reasonable price. Turf Valley has more than adequate facilities for this conference, including 25 conference rooms and 223 hotel rooms.

3.3 Workshop Program

The final program is still being formulated by the organizing committee, but the preliminary program has been completed and is shown at the end of this document in Section 8. The format and agenda for the meeting will also be discussed in the next section. The meeting is a three-day event that begins on Saturday, April 17, 1999, and concludes on Tuesday, April 20, 1999. The meeting will consist of talks by selected speakers, break-out sessions for working groups, and opportunities for interactive formal and informal discussions.

4 Format and Agenda

4.1 Principal Topics

The principal topics to be covered include both clinical and technical aspects of image-guided procedures in the spine. Presentations on the state-of-the-art and spine surgery in the 21st century are planned. Most of the workshop discussion will occur within the working groups. A brief summary of the six working groups proposed by the organizing committee are listed below.

Working group 1: **Pain management**. Low back pain affects 60-80% of adults at some time during their life [Frymoyer 1988]. Pain in the lower back can be managed with CT-guided interventional procedures, including periradicular infiltration, percutaneous laser disk decompression, facet joint blocks, and percutaneous vertebroplasty [Gangi 1998]. In some of these procedures, such as L5-S1 discography, advanced interventional techniques such as 3-D visualization and the use of curved approach paths may be applicable. The goal of this group will be to investigate the use of these techniques and others in pain management.

Working group 2: **Trauma**. While radiography is still the basic imaging method in the assessment of traumatized patients, technical improvements and new imaging modalities are becoming increasingly important [Wolf 1997]. The goal of this group will be to discuss the use of advanced imaging techniques in spinal trauma cases and potential minimally invasive methods for spinal cord decompression, and reduction and stabilization of the vertebral column.

<u>Working group 3</u>: **Tumors**. The spine is the most common place for skeletal metastases to occur. Plain radiographs, radionuclide scans, CT, and MRI are each used to diagnose and treat tumors of the spine. MRI has become the modality of choice for localizing spine tumors [Levine 1998]. However, for intraoperative use, MRI is currently expensive. The use of newly developed mobile CT scanners that can be used at multiple sites in the hospital provides a more cost-effective solution, but with new problems to solve. Since some tumors are not easily localized on CT, image registration of CT and MRI would greatly assist the surgeon in obtaining a complete tumor resection. The goal of this working group is to address issues such as what imaging modalities are needed and how they can best be used for spine tumor management.

<u>Working group 4</u>: **Deformity**. Due to its superior soft tissue contrast, MRI represents the single best modality in the evaluation of a patient with any deformity [Gundry 1994]. However, other modalities such as CT are important in cases where metallic instrumentation is used since this can cause artifacts on MRI. In addition, computer graphics and advanced visualization techniques may be useful in assessing spinal deformities [Vandegriend 1995]. The focus of this group is to discuss the use of advanced imaging techniques in the treatment of spinal deformity.

<u>Working group 5</u>: **Simulators**. Surgical simulation is the use of medical imaging, computer graphics, biomechanical analysis, and virtual environments to simulate surgery for medical education, scientific analysis, and pre-treatment planning [Delp 1996]. For developing new spine procedures, surgical simulation could be invaluable. While a great deal of work has already been done in surgical simulation [Cleary 1997], to the best of the committee's knowledge almost no work has been done in spine surgery simulation.

<u>Working group 6</u>: **Outcome analysis**. The purpose of outcome analysis is to provide objective measurements of the results of patient care. Outcome analysis includes evaluation of patient condition using tools such as the SF-36 questionnaire and economic evaluation. In this era of managed care and emphasis on prudent use of health care resources, outcome analysis is increasingly important, particularly as new technologies are introduced. The focus of this group will be to examine the role outcome analysis will play in the introduction of new, image-guided procedures in the spine.

4.2 Problems to be Addressed

While the working groups presented above are divided primarily by clinical area, there are a number of technical issues that each group will be expected to address including:

- How useful are advanced imaging techniques such as intraoperative MR or CT, 3-D ultrasound, image registration, and 3-D visualization?
- What are the obstacles to integrating new technology into clinical procedures?
- What is the estimated level of funding required to develop these new technologies?
- How can physicians and scientists better collaborate to develop this new field?

Each working group will be provided with the questions in written form, and expected to provide a written response by the end of the conference. To keep the working groups on track, time will also be scheduled for the working groups to report their progress to the organizing committee and the entire conference.

4.3 Developments or Contributions

The results of this workshop will have the following significant benefits:

- Provide direction for the technology developments needed to advance the use of image-guided procedures in the spine

- Identify clinical applications that could benefit most from image-guided techniques
- Help foster the collaboration between physicians and engineers that is necessary for this field to develop
- Focus engineering attention on specific emerging technologies to promote their rapid application and development in image-guided procedures
- Identify specific challenges to educating engineering students to work in this field
- Identify potential improvements in the cost and quality of patient care

5 Organizing Committee

The organizing committee consists of physicians and engineers who are actively working in the area of image-guided procedures of the spine or related areas. The organizing committee members are listed in Table 1 below.

Name	Degree	Title	Department	Institution	Location
Kevin Cleary	PhD	Assistant Professor	ISIS Center	Georgetown	Washington, DC
Seong Ki Mun	PhD	Director	ISIS Center	Georgetown	Washington, DC
Matthew Freedman	MD	Clinical director	ISIS Center	Georgetown	Washington, DC
Corinna Lathan	PhD	Assistant Professor	Biomedical Eng.	Catholic	Washington, DC
James Anderson	PhD	Professor	Radiology	Johns Hopkins	Baltimore, MD
Micheal Brazaitis	MD	Chairman	Radiology	Walter Reed	Washington, DC
Gilbert Devey	MS	Research Associate	ISIS Center	Georgetown	Washington, DC
Anthony DiGioia	MD	Physician	Orthopaedics	Shadyside Hospital	Pittsburgh, PA
Dietrich Gronemeyer	MD	Professor	Radiology	Witten/Herdecke University	Bochum, Germany
Heinz Lemke	PhD	Professor	Medical Informatics	Tech. Univ. of Berlin	Berlin, Germany
Donlin Long	MD	Professor	Neurosurgery	Johns Hopkins	Baltimore, MD
Russell Taylor	PhD	Professor	Computer Science	Johns Hopkins	Baltimore, MD

Table 1. Organizing Committee Members

The role of the organizing committee is to develop the workshop agenda, select the workshop participants, prepare the pre-workshop reference materials, and oversee the preparation of the final report. The organizing committee members were selected based on their expertise, their willingness to contribute, and their participation in and experience with organizing similar workshops in previous years. An effort was also made to have a balanced organizing committee in terms of specialization and institutional affiliation

6 Related Meetings

There have been several related meetings that will be mentioned here. The Second International Workshop on Robotics and Computer Assisted Medical Interventions [DiGioia 1996] was held in Bristol, England, in 1996 and covered the areas of image-guided therapy, robotics, surgical simulation, and teleintervention. While many of these technologies are important to our proposed workshop, the difference is that our workshop will focus exclusively on the spine, while the Bristol workshop considered a wide variety of clinical areas.

The "High Care" meetings in Bochum, Germany, include discussions on micro therapy, high tech medicine, telemedicine, patient care, and design. The first meeting was in January 1997 and the second meeting will be held in February 1999. Several members of the organizing committee have attended or plan to attend these meetings. The meetings are organized by Dietrich Gronemeyer, MD, a member of the organizing committee, and spine related topics are included.

A program on Computer Assisted Orthopaedic Surgery (CAOS) is sponsored by UPMC Shadyside in Pittsburgh and is organized by Tony DiGioia, a member of the organizing committee. The first CAOS/USA program was held in June 1997 and the second will be held in June 1998. The course covers image-guided and computer assisted surgical systems as well as medical robotics.

Another important meeting was the NSF Workshop on Computer-Assisted Surgery [Taylor and Bekey 1993]. This workshop was held in Washington, DC, in 1993 and the working groups included neurosurgery, quantitative and microsurgery group, image-guided and minimally invasive surgery, orthopaedics, and virtual reality and endoscopic surgery. While many of the issues raised in this workshop are still important to the field today, we feel there is a need to focus specifically on the spine and discuss how these issues affect image-guided spine procedures.

The last workshop that will be mentioned is a National Cancer Institute supported workshop, "Imaging-Guided Stereotactic Tumor Diagnosis and Treatment" [Jolesz 1991]. This was only of the earliest workshop on the use of image guidance and the agenda was divided into three parts: 1) current and potential clinical applications; 2) current and future technologic developments; and 3) discussion of main research directions.

7 Workshop Program

The meeting is a three-day event that begins on Saturday evening, April 17, and concludes on Tuesday, April 20. Please note that the final program is still being formulated. The preliminary program with the confirmed speakers as of Oct. 1998 is shown next.

7.1 Day 0 (Saturday)

1800-2000 Opening reception

7.2 Day 1 (Sunday)

0730-0830 Breakfast buffet

0830-1200 Overview & vision

0830-0840 Opening remarks: Seong Ki Mun, PhD

- Welcome, workshop format and objectives, acknowledge sponsors

0840-0940 Overview and historical perspective

0840-0900 Demographics and procedures of the spine

0900-0910 Q & A

0910-0930 Clinical state-of-the-art: Dietrich Gronemeyer, MD

0930-0940 Q & A

0940-1010 Morning coffee break

1010-1150 Vision and long view
    1010-1030 Spine surgery in 21st century: Donlin Long, MD
    1030-1040 Q & A
    1040-1100 Coupling information to action: Russ Taylor, PhD
    1100-1110 Q & A
    1110-1150 Panel discussion

1150-1200 Conference business: introduction of working groups (Kevin Cleary, PhD)

1200-1400 Lunch by working group (separate rooms)
Working group meeting 1: define the current status and clinical needs in image-guided procedures of the spine (review questionnaire results)

1400-1700 Working group presentations (10 minute presentations, 15 minute Q & A)
(review questionnaire and present comments from working group)
    1400-1425 Group 1: Pain management: Dietrich Gronemeyer, MD
    1425-1450 Group 2: Trauma
    1450-1515 Group 3: Tumors
    1515-1545 Afternoon coffee break
    1545-1610 Group 4: Deformity
    1610-1635 Group 5: Simulators
    1635-1700 Group 6: Outcome analysis

1800-2000 Dinner by working group (separate rooms)
Working group meeting 2: Clinical analysis
Using clinical areas identified in questionnaire, discuss how image guidance might be applied.
Prepare summary statement for Monday morning presentation.

7.3 Day 2 (Monday)

0730-0830 Breakfast buffet

0830-0930 Working group summaries to entire conference (5 minutes, then 5 minutes Q&A)

0930-1200 Technology applications in the spine (10 minute presentations, 5 minute Q&A)
Suggested topics: all are preliminary and to be confirmed
    0930-0945 TBD
    0945-1000 Intraoperative CT for spine tumor resection
    1000-1030 Morning coffee break
    1030-1045 Accuracy issues in image-guided spine surgery
    1045-1100 TBD
    1100-1115 Safety and standards
    1115-1130 TBD
    1130-1145 Intraoperative MRI and potential for spine
    1145-1200 Visualization for spine procedures

1200-1400 Lunch by working group (separate rooms:)
Working group meeting 3: Engineering analysis
Based on the clinical applications discussed in meeting 2, define the technical requirements for these applications and brainstorm potential solutions

1400-1600 Therapy team of the future (how does one make a team of experts?)
Each presenter should address:

- Breakthrough technologies
- Patient-surgeon interface
- Performance and training
- Engineer and physician collaboration
- Evaluation and economic impact
- Challenges for biomedical engineering educators

Speakers:

- Gene Barnett, MD, Cleveland Clinic

1600-1800 Working group meeting 4: Wrap-up and report preparation.
Summarize results of first three meetings, prepare viewgraphs for presentations Tuesday morning.

1800-1900 Working group chairs meet with organizing committee (progress report)

1900-2200 Banquet with speaker

7.4 Day 3 (Tuesday)

0730-0830 Breakfast buffet

0830-0930 Summary speaker

0930-1200 Working groups present reports (20 minutes per group and ½ hour coffee break)

1200-1300 Group lunch

1300-1500 Working groups complete reports

1500 Departure

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Mobile CT Scanner, Spine Tumor Resection, and Image Registration

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1 Overview

This brief technical note describes our work with a mobile CT scanner that the ISIS Center has purchased as part of our work in image-guided procedures of the spine. The use of this scanner in spine tumor resection is described along with related work in image registration.

2 Mobile CT Scanner

Earlier this year, the ISIS Center purchased a mobile CT scanner to investigate how intraoperative CT imaging could be used in a variety of procedures, including spine tumor resection. The scanner gantry and table is shown in Figure 1, and the workstation is shown in Figure 2.The ISIS Center has been responsible for integrating the scanner into hospital procedures, including procedures in the neurosurgery, radiology, and radiation medicine departments. The scanner is a unique device in that it can be moved throughout the hospital, but this mobility can also cause maintenance and operational problems as noted below.

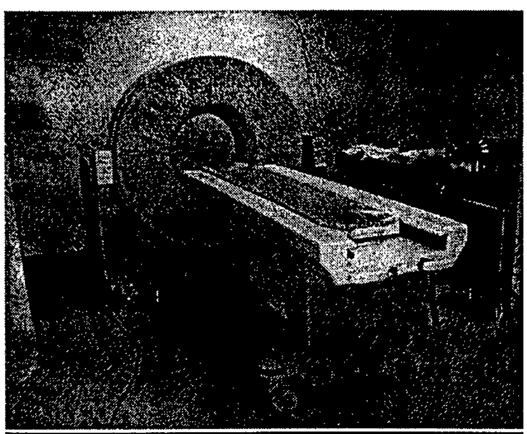

Figure 1. Mobile CT Gantry and Table

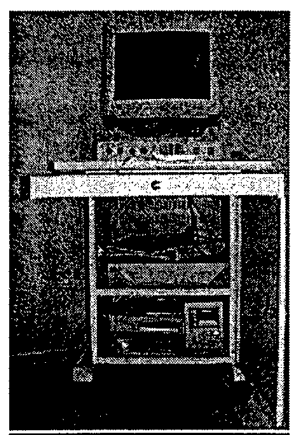

Figure 2. Mobile CT Workstation

From March until September 1998, the scanner was used for a total of 27 studies, including procedures in the operating room, interventional radiology, radiation medicine, and the pediatric intensive care unit. During this period, research team members found and solved important problems resulting from the addition of this unit into existing interventional and surgical procedures. The unit was not designed to meet the needs for intra-procedural guidance.

Mechanical and software problems had to be addressed including modifications of patient positioning, separation of the table from the gantry to allow for adequate surgical access, DICOM image transfer problems, database problems, and software glitches providing incorrect information on tube heating resulting in unexpected shutdown of the system. Operational problems in the integration of this system into the operating room environment have been overcome and the frequency of use of the system is increasing. Radiation issues have been addressed in conjunction with the Radiation Safety Office. Radiation levels have been measured during typical procedures, and the Radiation Safety Office has recommend that all personnel remain at least 12 feet away from the grant during scanning. This distance requirement is met by positioning the operator workstation at least 12 feet from the gantry and ensuring all other personnel are at least 12 feet away during scanning.

3 Spine Tumor Resection

Dr. Fraser Henderson is a neurosurgeon specializing in the spine who has performed an average of 25 operations per year for the resection of vertebral metastases over the past 3 years. For these cases CT and/or MRI was obtained preoperatively and fluoroscopy or projection radiography were used intraoperatively. This year Dr. Henderson began working with researchers from the ISIS Center of the Radiology Department to use intraoperative CT in the operating room for spine tumor resection. In the operating room, we have used intraoperative CT on eight cases of which five were spine cases. In two of these five cases, the intraoperative CT images resulted in modifications of the surgery that would be expected to improve long-term outcome. The high degree of enthusiasm of the surgeons using this method has encouraged us to develop a randomized prospective trial to prove the benefit of this system and justify its cost. Images obtained by the mobile CT unit are used for the visualization of bony margins and landmarks, determination of the extent of tumor removal, and confirmation of the position of stabilization devices, polymethylmethacrylate (PMM) and hardware.

For spine tumor procedures, intraoperative CT was used with three goals in mind:

1) to identify, if present, residual tumor following resection
2) to ensure adequate filling of the resection cavity with polymethylmethacrylate
3) to verify optimum placement of instrumentation for mechanical stabilization

While only a limited number of cases have been performed thus far, the intraoperative scans provided additional valuable information to the surgeon in all five spine tumor cases. In one of the cases the intraoperative CT images resulted in two identified changes in the procedure: (1) additional tumor was resected after CT scanning showed the tumor resection to be incomplete; and (2) the polymethylmethacrylate initially placed did not fill the resection cavity and was removed and replaced with better cavity filling. This case is reported below. In a second case, an orthopedic hook was identified as misplaced and was repositioned.

Case Report: A 41 year-old woman with a history of breast cancer ($T_1N_0M_0$ at presentation) was found on MRI to have a C2 vertebral metastasis. CT showed lytic destruction of C2 including approximately 70% of the vertebral body volume with extension into the base of the odontoid process as shown in Figure 3. Though radiation was considered first, concern for the possibility of fracture and instability made surgery necessary. The surgery was performed in the operating room on the CT table. The patient was positioned supine. Through a left extrapharyngeal approach, the tumor was resected, leaving only the cortical shell of C2 and its ligamentous attachments. The cavity was then filled with Omnipaque™ and an intraoperative CT performed (the CT gantry and patient during a typical scan are shown in Figure 4). The CT revealed residual tumor in the left lateral mass (Figure 5). The patient was removed from the CT and the residual tumor resected. The cavity was then filled with polymethylmethacrylate (PMM), and another CT performed to verify structural integrity and adequate filling of the C2 cortical shell. The PMM failed to completely fill the cavity and was therefore removed and replaced with improved filling of the cavity (Figure 6). Postoperatively, the patient's presenting symptom of neck pain had improved. The patient is now 16 weeks post surgery with continuing excellent surgical results.

Figure 3. Preoperative CT showing C2 tumor

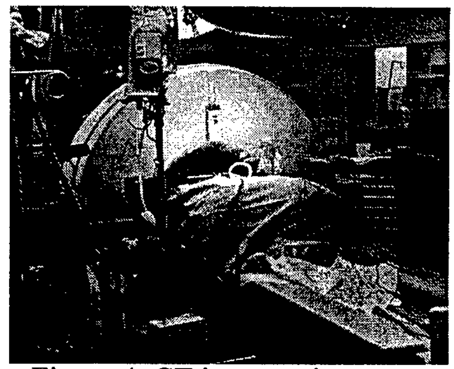

Figure 4. CT in operating room

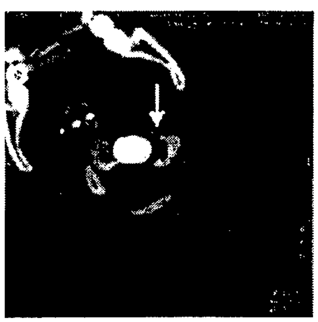

Figure 5. Imaging with Omnipaque™ reveals residual tumor (arrow) after first resection

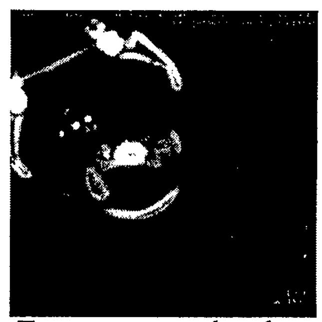

Figure 6. Tumor removed and cavity filled with polymethylmethacrylate

4 CT and MR Spine Image Registration

As part of our preliminary work towards the development of image guided spine surgery, we have registered CT and MR spine images. We have used images from both a volunteer and patients. The CT images were obtained from our mobile CT scanner, and the DICOM medical image standard was used to transfer the image data sets. We have consulted with and obtained image registration software packages from three international experts in the image registration field for testing. We have also written our own software for image registration based on standard theories for mutual information registration in order to better understand the method and to work towards solving problems we have encountered in current software packages when applied to 3D registration of multimodality spine images.

With our own software, once the approximate starting point for the images is chosen, the program automatically registers the images into a common coordinate system. Shown in Figure 7 is a sample set of images that were registered using our software and then fused into a single image.

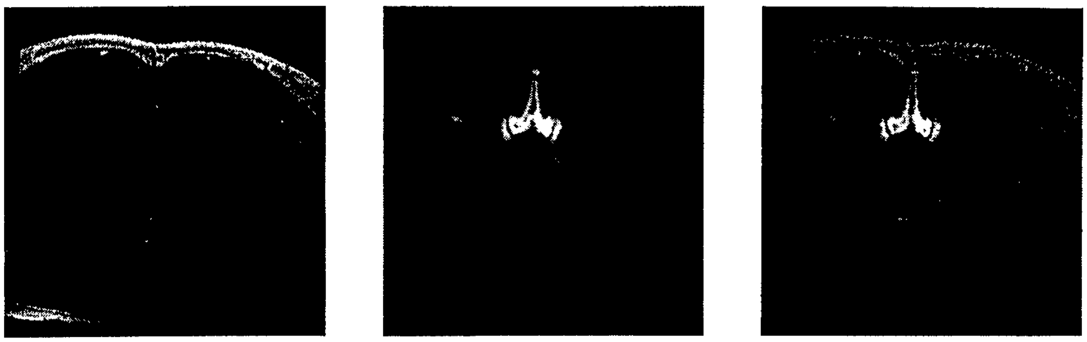

Figure 7. Preoperative MR and mobile CT automatic image registration

The left image is a MR image. The spinal canal and muscle groups are easily seen. The aorta and inferior vena cava, which contains flowing blood, have dark lumina. The middle image is from the mobile CT. In this image the facet joints, lamina and spinous process are white, the color of bone on CT. The muscle groups and vessel lumina are not well seen. The right image is a registered and fused image in which the white bone from the CT is seen as well as the muscle groups from the MRI. The aorta shows its dark lumen from the MRI.

In conjunction with Lou Arata, PhD, of Picker International, we have worked to register the intraoperative CT with preoperative MR for two of the spine tumor cases done to date. In both of these cases, the registration had to be done manually as automated methods failed. The exact reason for the failure is not known. We expect that at least two factors contributed: (1) the intraoperative CT has a large area of different appearance caused by the surgical incision and tissue retraction and removal; and (2) the preoperative MR images had to be digitized using a film scanner as they were not acquired at Georgetown and therefore could not be transferred directly as digital images. Since Georgetown is a tertiary referral center for spine surgery, methods for working with outside images that are sent to us on film will have to be improved.

5 Summary

The addition of a mobile CT scanner earlier this year has enabled us to start our program in image-guided procedures of the spine. We have used the CT scanner in several departments in the hospital, including in the operating room for the resection of spine tumors. We have also obtained several test data sets for our work in image registration of preoperative MRI and intraoperative CT. In the coming year, we plan to expand on this effort and introduce image registration into the operating room as part of an initial clinical evaluation.

Performance in a Spine Biopsy Procedure: Developing a Semi-Autonomous Surgical-Assist

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Biopsy procedures are often needed to acquire tissue samples for pathological analysis so a treatment plan can be developed. Computed Tomography (CT) directed needle biopsies are routinely performed by interventional radiologists to gather tissue samples near the spine. As currently practiced, this procedure requires a great deal of spatial reasoning, skill, and training on the part of the radiologist. Image-guided systems that could assist the radiologist in needle placement and alignment would be a great improvement. Even further gains could be realized by the development of a semi-autonomous surgical-assist that would still place the needle under the guidance of the radiologist. A high fidelity spine biopsy surgical simulator is being developed to mimic the current procedure and to serve as a development testbed for a surgical-assist biopsy system.

Figure 1 shows a conceptual model that allow for the important human-centered parameters of the system to be identified and assessed. On the right side, the flow of information through the interface to the simulated environment forms a closed loop that starts and ends with the user. The user makes a physical motion within the simulated environment. Motion sensors track and relay this information to the computer. The computer uses dynamic algorithms to calculate haptic (force) sensation that the user should feel as a result of the physical motion as well as the defined contents and structure of the simulated environment. Haptic sensations are then produced by driving a set of actuators producing real forces which get to the user through the force feedback mechanical device.

On the left side of Fiure. 1, a simple model of the human processing system is shown. This is an idealized model of human information-processing capabilities where the user is described in terms of three processors: perceptual, cognitive, and motor.[1] Such theoretical models can help to approach the evaluation of input devices for 2D and 3D tasks.[2,3] In the model shown, sensory information is gathered from the interface or virtual environment. For surgical simulation, the information is primarily visual and haptic. This sensory information flows into working memory through the perceptual processor where it can then be accessed by the cognitive processor to decide if and how to act on it. Finally the motor processor executes any actions decided upon through the force-feedback device.

The information flow through the perceptual processor to working memory is considered to be a low-capacity channel. In other words, there is a limited ability of a person to pay attention to all of the sensory input available or to process the available information. From the point of view of human-technology interfacing, the key is not to overload channel capacity, but to give the optimal information for successful human performance. A good human-machine system design will take into account user capabilities. As activities change and new tasks are initiated, there will be a dynamic distribution of attentional resources. Understanding the distribution of attentional resources during each task will aid designers by providing predictions of human performance. For example, improving the visual feedback through a 3-d display or allowing a robot to take over some of the motor function should improve the overall procedure outcome.

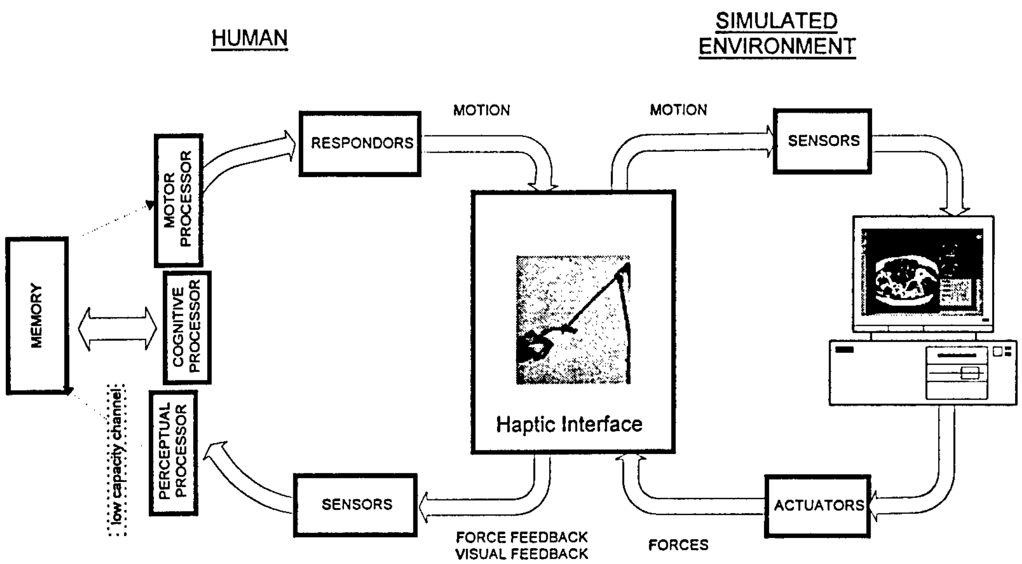

Figure 1. Multimodal sensory interface: the human and computer control loops

This model of the human information processor has been applied to the human control of robots.[4] The perceived states of the haptic interface (robot or needle) are integrated with the actions to be carried out by the human operator using resources of knowledge and cognitive processes. For example, the robot (needle) orientation and position, the orientation of the observer to the needle, and the perceived self-orientation of the observer will all influence the movement path plan. The key is to use technology to relieve the human operator of workload thereby optimizing performance.

The first phase of our simulator development included a task analysis to identify critical areas that could be targeted for improvement. Task analysis is a standard method in human factors engineering and has been used for other surgical simulator applications.[5,6] Both Higgins et al and Beagley et al [1997] used a hierarchical task analysis[7] to determine the key cognitive and motor skills needed by the surgeon in order to complete a surgical procedure. Figure 2 shows a hierarchical task analysis (HTA) of the Biopsy Needle Progression subtask which begins with CT imaging and ends with a movement of the needle, and may occur many times within one biopsy procedure. HTA allows one to take larger tasks and goals and break them into subtasks to fully understand the demands on the system.

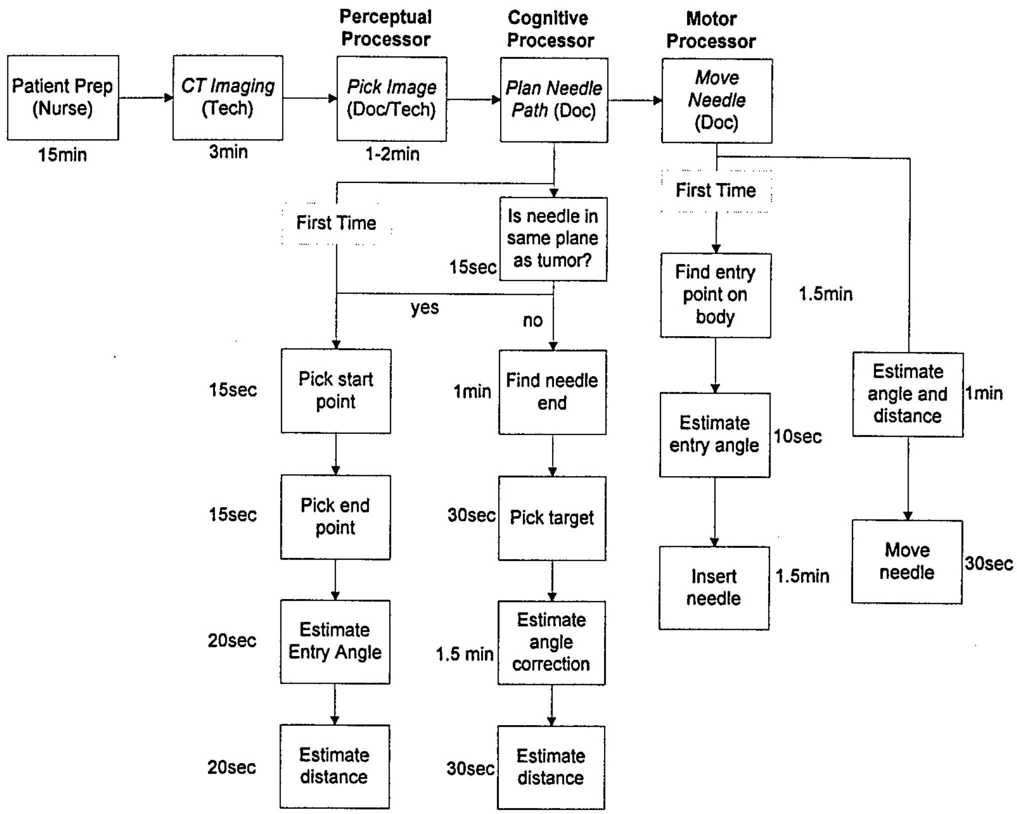

Figure 2. The Biopsy Needle Progression subtask Hierarchical Task Analysis (HTA)

From the task analysis, three critical task components of the spine biopsy procedure emerged: *Selecting* the best CT slice for viewing the lesion; *Planning* the path between the skin entry point and the end-point; and *Moving* the needle to the biopsy location. This procedure can be time consuming and tedious since the biopsy needle must be advanced slowly and its position checked several times to ensure vital organs are not damaged. While this technique is generally effective, there is a time-accuracy tradeoff. The error tracking the planned path may be large, resulting in an increase in time, however, the error in end-point accuracy is usually low since the procedure continues until the desired endpoint is reached. The goal of an automated procedure would be to both decrease path tracking error and increase precision.

The current biopsy procedure, as represented by Figure 3(a), shows that the human operator carries most of the perceptual (*select image*), cognitive (*path planning*), and motor (*move needle*) workload. The radiologist controls the insertion of the needle directly and only uses occasional "snapshots" from the CT scanner for visual feedback. The system in Figure 3(b) is still manually controlled, but the visual feedback has been enhanced greatly to give the radiologist real-time image guidance during the insertion. Real-time 3-D image guidance would relieve some of the operator workload as well as reduce path planning error.

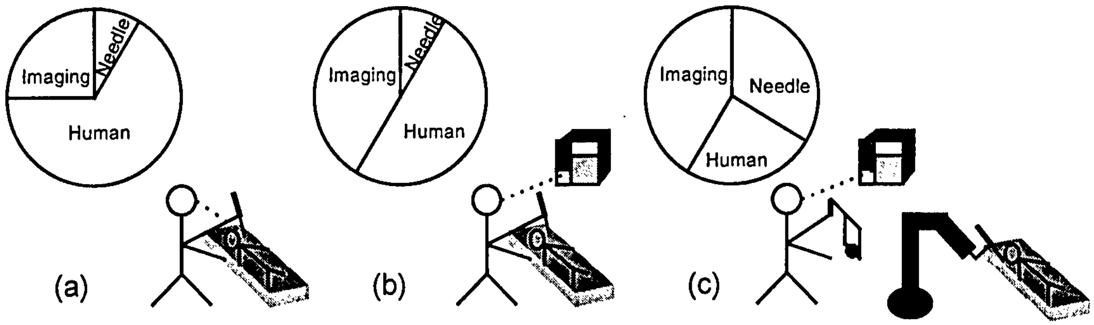

Figure 3. Relative function allocation of system components: the human operator, imaging information, and needle insertion.

Figure 3(c) depicts a semi-autonomous system in which a haptic master arm provides force feedback to help guide the radiologist and drive a robotic system that actually performs the task. In this scenario, the functions handled by the human are significantly reduced, allowing the radiologist to concentrate on the parts of the procedure where human judgment is required most. Shared control will reallocate some of the motor function from the human to the robot, reducing total error and improving accuracy. Finally, note that the progression from Figures 3(a) to 3(c) is downward compatible; it does not preclude the semi-autonomous system from being operated in manual mode.

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Research Protocol for Improvements in Image-Guided and Minimally Invasive Spine Procedures

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ABSTRACT

The goal of this project is to improve the state of the art of image-guided and minimally invasive spine surgery by developing a new generation of clinical techniques along with the computer-based software and hardware needed for their implementation. This will be accomplished through a coordinated research and development effort involving clinical departments at Georgetown University Medical Center (GUMC) and Walter Reed Army Medical Center (WRAMC) and the engineering expertise of the Imaging Sciences and Information Systems Center (ISIS) at GUMC.

The central hypothesis of this project is that by increasing the accuracy with which instruments can be placed and manipulated, diagnosis and treatment will be improved and costs will be decreased. The specific aims of this project include:

- Increasing the accuracy of spine instrument placement and manipulation through several technology developments including intraoperative CT, MRI and CT registration, 3-D visualization, instrument tracking, and mechanical guidance.
- Investigating the feasibility of using intraoperative CT guidance for spinal procedures such as tumor resection, the removal of spinal canal bony fragments, and laparoscopic single level discectomy.
- Evaluating the clinical and economic effectiveness of these techniques through a formal outcome analysis.

The successful completion of this project will provide a prototype system for a new generation of image-guided spine surgery and improve care for both military and civilian beneficiaries, specifically patients with both degenerative and traumatic spine injuries. The techniques for the traumatized spine that will be developed here should be transferable to the "golden hour" of care and be applicable close to the battlefield.

1. PROJECT AIMS

The long-range goal of this project is to improve the state of the art of minimally invasive spine surgery by developing a new generation of image-guided clinical techniques along with the necessary technology and equipment for their implementation. As our main objective in pursuit of this goal, we have planned a combination of clinical and technical work to develop image-guided systems for increasing the accuracy of spine instrument placement and manipulation. The project goal is to place the tip of a thin, tubular-shaped instrument percutaneously to any specified location within a vertebral body, or its adjacent bone or soft tissue structure, while avoiding obstacles. We call this periscopic surgery. The central hypothesis of this project is that by increasing the accuracy with which instruments can be placed and manipulated, diagnosis and treatment will be improved and costs will be decreased. We plan to measure the accuracy obtainable and time needed for precise placement of instruments using current techniques such as fluoroscopy and compare it to the accuracy obtainable and time needed using the image-guided techniques proposed here. We also plan to do a formal outcome analysis of existing minimally invasive spine surgery as currently performed at Georgetown University Medical Center (GUMC) while at the same time working to improve these methods. We expect to show that diagnosis and treatment will be improved while costs are decreased. In addition, image guidance during spine surgery for metastatic and traumatic spine lesions should improve the speed and accuracy of spinal canal and cord decompression. We will be assessing the role of image guidance in these decompressive procedures that should have direct applicability to battlefield injuries.

The specific aims of this project are to:

1. Measure the accuracy of spine instrument placement and manipulation using existing techniques such as fluoroscopy.
2. Increase the accuracy of spine instrument placement and manipulation through several technology developments including intraoperative CT, 3-D visualization, instrument tracking, MRI and CT registration, and mechanical guidance.
3. Investigate the feasibility of increasing instrument placement and manipulation accuracy using intraoperative CT guidance for spinal procedures such as the removal of spinal canal fragments and laparoscopic single level discectomy.
4. Evaluate the effectiveness of these techniques through a formal outcome analysis including clinical and economic measures.

The successful completion of this project will provide a prototype system for a new generation of image-guided spine surgery and improve care for both military and civilian beneficiaries, specifically patients with both degenerative and traumatic spine injuries. Image-guided techniques for the spinal cord decompression/spinal canal restoration should be transferable to "golden hour" care and be applicable close to the battlefield.

2. BACKGROUND AND SIGNIFICANCE

The surgeon of the future will use minimally invasive, image-guided therapies to simulate surgery, integrate information from multiple media concerning diverse physiological parameters, and effectively deploy scarce medical resources. The Joint Science and Technology Plan for Telemedicine (JSTPT) calls for similar new tools and modes of organization to promote medical readiness, incorporate health awareness into battlefield awareness, and achieve effective employment of medical forces in caring for American war fighters. By developing and evaluating the clinical impact of new tools for periscopic surgery, particularly for spinal cord and spinal column injuries, this project will support JSTPT's new paradigm of improving military medicine through dynamically synchronizing diverse, scattered medical resources at the point of care.

Spinal cord and spinal column injuries make excellent clinical models for periscopic surgery in military medicine because of their relevance to war fighters, combat support personnel, and dependents. Treatment of battlefield trauma requires experienced surgeons to rapidly synthesize medical information from diverse sources for immediate intervention. Practicing spine surgery using computer-based simulations promotes readiness of combat surgeons in the absence of battlefield casualties. Basic engineering tools required for simulation development (3-D image reconstruction and display, image registration, and instrument tracking) make possible the real-time acquisition, fusion, and unified presentation of patient information for use on actual casualties. Military surgeons may deploy the same tools to treat low back pain, a major non-combat source of disability among soldiers and dependents. Because minimally invasive surgical techniques lessen collateral damage, they return to duty war fighters and combat support personnel more rapidly than conventional, open spine surgery.

However, these new methods have some limitations that must be overcome to advance this field, including:

1. Oblique paths cannot be visualized: 3-D visualization and graphical overlay of instruments in 3-D will allow oblique paths to a target that crosses several adjacent axial CT slices.
2. Instrument tracking is limited: tracking of surgical instruments and graphical overlay on medical images will allow path planning and path recording. In path planning, there is a need to follow both straight and curved paths to the target. In path recording, there is a need to know where instruments have been to prevent repeated entry into a previously created but no longer desired path. In practice instruments will tend to follow the previously created path.
3. CT and MR spine images not concurrently available: CT and MR spine images provide different information about bone and soft tissue structures, both of which are useful in planning and execution of diagnosis and treatment. Because one cannot, at a reasonable financial cost, obtain CT and MR images concurrent with surgery, CT and MR spine images need to be registered into a single image that can be made available in the OR for operative guidance for both bony and soft tissue structures.
4. Instrument placement slow and inaccurate: mechanical instrument guidance will assure accurate placement of instruments from the skin entry point to the target and increase the speed of minimally invasive surgery.
5. Suitable instruments do not exist: appropriate instruments must be developed for many of these procedures.
6. Outcome data of conventional and new techniques not available: outcome studies are required to determine the effectiveness of these new procedures.

3. RESEARCH DESIGN AND METHODS

Our long-range goal is to improve the state of the art of minimally invasive spine surgery by developing a new generation of image-guided clinical techniques along with the necessary technology and equipment for their implementation. Towards this goal, we propose a combination of clinical and technical work in this section. The clinical work consists of a series of experiments to document improvements in patient care resulting from image guidance and minimally invasive procedures. The technical work includes research, development, and integration issues specifically related to the current clinical needs and the future evolution of these treatment methods. In addition, an outcome analysis will be done to validate the clinical studies.

Six clinical experiments based on the following procedures and diseases are planned to answer questions such as those posed below:

1. Facet and dorsal nerve root block: Will 3-D visualization improve clinical results?
2. Treatment of vertebral metastatic disease: What is the role for minimally invasive methods?
3. Osteoporotic compression fractures: What is the long-term outcome of methylmethacrylate vertebroplasty?
4. L5-S1 discography comparing fluoroscopy with CT guidance: Will CT guidance improve the success rate and decrease procedure time?
5. 3-D visualization in the removal of spinal canal bony fragments. Will CT intraoperative guidance increase spinal canal decompression? (Feasibility study)
6. Laparoscopic single level lumbar discectomy: Will CT guidance decrease procedure time? (Feasibility study)

Experiments 1, 2, 3 and 4 are evaluations of procedures currently being performed at GUMC, at WRAMC, or at both. Experiments 5 and 6 are feasibility studies.

Our specific aims are related to the clinical experiments as follows:

1. Measure the accuracy of spine instrument placement and manipulation using existing techniques such as fluoroscopy (experiments 1, 2, and 4).
2. Increase the accuracy of spine instrument placement and manipulation through several technology developments including intraoperative CT, MRI and CT registration, 3-D visualization, instrument tracking, and mechanical guidance (experiments 1, 2, and 4).
3. Investigate the feasibility of increasing instrument placement and manipulation accuracy using intraoperative CT guidance for spinal procedures such as image-guided surgical decompression, the removal of spinal canal bony fragments, and laparoscopic single level discectomy (experiments 3, 4, and 5).
4. Evaluate the effectiveness of these techniques through a formal outcome analysis including clinical and economic measures (experiments 1, 2, and 3).

The proposed technical developments are of two types: those needed to perform the clinical experiments and those necessary for future developments in minimally invasive spine surgery. Thus, in this project, we will be assessing current techniques, improving current techniques, and laying the technical groundwork for new clinical procedures. The technical developments required are:

1. Integrate mobile CT into intraoperative procedures (experiments 1, 2, 4, 5, and 6).
2. Develop a 3-D visualization of medical images (required for experiments 4 and 5 and desired for experiments 1, 2, and 3).
3. Integrate a tracking component into intraoperative procedures and provide path planning (required for experiment 4 and desired for experiments 1, 2, and 3).
4. Register CT and MR images (for future development of new procedures and the improvement of existing procedures).
5. Provide mechanical instrument guidance (for future development of new procedures and the improvement of existing procedures).

No new technology is required to perform experiment 3. Each of the technical developments will be applied to multiple clinical needs. Table 1 shows how the technical developments are related to the clinical experiments.

Table 1. Clinical Experiments Versus Technical Developments

	Mobile CT Integration	3-D Visualization	Instrument Tracking	Registration CT/MRI	Mechanical Guidance
1. Facet Block	R	D	D		D
2. Vertebral Body	R	D	D		
3. Osteoporotic	D	D	D		D
4. L5-S1 Discography	R	R	R	F	F
5. Spinal Canal	R	R		F	
6. Discectomy	R		F	F	F

Key: R=required, D=Desirable, F=Future

4. SUMMARY

This research protocol outlines six clinical experiments and five technical developments to develop a new generation of clinical techniques along with the computer-based software and hardware needed for their implementation. The successful completion of this project will require a collaborate effort between physicians, engineers, and support staff. This project may be viewed as a step towards developing the high technology operating room of the future.

Tactile Mapping of Breast Palpation for Improving Physical Breast Examination

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Introduction

Palpation is one of the most cost-effective and inexpensive methods of detecting breast cancer. The most common symptom of breast cancer is a lump, and studies show that the majority of breast cancers were found by palpation. Palpation complements mammography, since palpation can evaluate breast tissue near the chest wall and axilia that is not accessible to mammography and accounts 50% of breast cancer. In addition, studies have found that as many as 16% of cancers that were detected by physical examination were not apparent on mammograms. Thus, *one of nation's major cancer control objectives for the year 2000 is to increase the frequency and efficacy of physical breast examinations for breast cancer screening and early detection.*

Unfortunately, palpation is a poorly understood process that has been largely neglected in previous research. One problem is that palpation techniques are of variable and largely unknown quality. Quantitative analysis of detected breast lumps is a difficulty problem in current clinical breast examination (CBE). For example, a physician may determine that a palpable abnormality is unlikely to be cancerous but that continued monitoring is indicated. This requires maintaining a record of the examination results, which at present is limited to verbal notes about parameters such as the position, size, and hardness of the lump, Because it is difficult to verbalize tactile sensations, the subjective and arbitrary nature of these notes makes effective follow-up exams problematic.

We propose to advance fundamental understanding of palpation and solve these practical problems through the creation of new *tactile mapping device* technology. This device will measure three key variables during palpation: the examinees finger motions, the applied forces, and the, small-scale pressure variations at the skin due to lumps. The feedback will be based on video hand tracking and an instrumented breast model with force and tactile sensing. We have investigated and integrated a prototype system consisting of a novel three-dimensional (3D) camera, which can track hand motion in video speed. A six degree-of-freedom (DOF) force sensing device called the Stewart platform, and a novel tactile pressure distribution mapping system that can measure and record key parameters of lumps. A probe containing sensors will have to be pressed against the skin at the site of the detected lump. Neural network technique, based on a nonlinear model of breast tissue with hard inclusions, will extract invariant properties of the lump. This system will make it possible for the first time to quantitatively and objectively record the processes and findings of breast palpation.

Research Plan

Our goal is to extend the range and resolution of palpation methods, thus increasing palpation sensitivity and specificity (i.e, the ability to detect and distinguish cancerous lumps). Using video, tactile, and force sensors we can create reproducible tactile maps of the breast. The novel 3D camera invented by Genex Technologies, Inc. is able to provide real-time 3D position and/or motion measurement (for hand and fingers) and surface profile measurement (for soft tissue deformation) at 30 frames per second rate. To the best of our knowledge, there is no commercially 3D sensor available that can achieve such capability. We have also proposed, evaluated, and applied various touch sensing technologies including tactile sensor array and six-axes force/torque sensor to extract tactile information from breast palpation to display the sensor-tissue interaction in terms of tactile images. Laboratory experiments aimed at detecting tumors in breast phantom have demonstrated that simulated tumors can be located to within 1 mm and the experiment is undergoing for clinical evaluation with real breast tissues.

Current documentation is limited to a verbal description of the suspect mass. We will use our proposed system, which incorporates a force sensor and a tactile array sensor mounted on a probe hold by the physician's finger, to make a tactile "image" of the suspect mass. The system aims to extract key tactile topological features of a lump that can be derived from breast palpation: size, shape, edge definition, hardness, and mobility. The physician will perform a routine CBE, and upon finding a possible tumor, place the sensor probe on the finger tip and indent and roll it over the suspect region. The computer will record the resulting pressure distribution and impression force and save it for comparison at subsequent exams. The goal is to determine the requirements to produce a sufficiently accurate record so that relatively small changes can be reliably detected and used to ascertain the nature provide documentation of the adequacy of the of the breast mass. The system would also examination the force applied. While initially the system will be used to perform documentation after clinical examination, we believe that eventually it may be possible to detect small masses.

Experimental Result

The objective of this experiment is to evaluate pressure distribution due to detected lump in terms of the accuracy and reproducibility. In this experiment, we need to collect sufficient data of the pressure distribution from the tactile sensor system in conjunction with recorded force/torque data. The experiment systems are consists of the following equipment.

Personal computer
Tactile array system
- 8X8 element array sensor
- Sensor electronics
- Data acquisition card
- Data acquisition software

- Power supply
- Sensor cables

6DOF force/torque sensor

- JR3 monolithic 6DOF force sensor
- JR3 intelligent support system
- Signal condition board
- Data acquisition board
- Processor board
- Sensor cables

Breast Phantom

After we received the tactile array system, we ran a test to see the system performance in terms of reliability, validity, and safety. We found out that we need a crude calibration set of numbers. This numbers can be obtained by applying a pseudo uniform pressure on the array sensor. The data that we collected from the tactile array sensor should be divided by this set of numbers to compensate for the variation in gain from one element to another. We test our tactile array sensor by pressing the array sensor against the lump inside the breast phantom and recorded the pressure distribution of the array sensor. After we got the data, we import our data to MATLAB. By using MATLAB, we can display the pressure distribution of the tactile array sensor in 3-dimension.

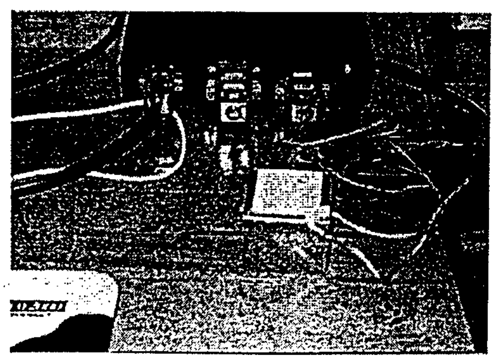


Figure 1: 8x8 tactile array system used in the tactile imaging of palpable breast lesions project.

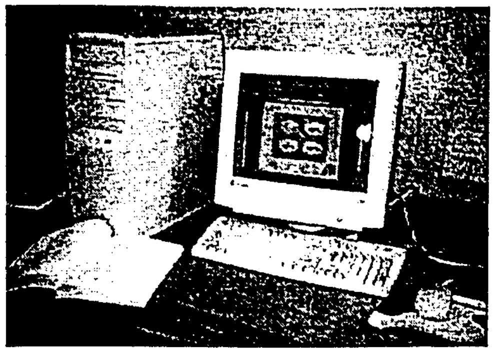


Figure 2: The data collecting from the tactile array system can be display to show the pressure distribution of the sensor by using MATLAB.

We also ran a test for the JR3 6DOF force/torque sensor. The force/torque give the total output of six parameters. We want to see the performance of the force sensing in terms of accuracy, reliability and sensitivity. We need to see how accuracy the force sensor is and how can we used the force/torque sensor output data in conjunction with the output data from the tactile array sensor in our experiment.

The breast phantom that we used in this experiment consists of four lesions. The position of the lesions is defined below.

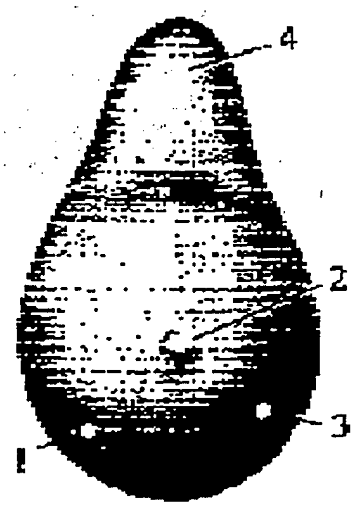


Figure 3: Breast phantom and its lump location

After we ran the test for both tactile array sensor and JR3 6DOF force/torque. We conclude that both sensors are suitable for our experiment. By combining both tactile array sensor and 6DOF force/torque sensor together, we can get sufficient data for our analysis. We let the JR3 force/torque to be a base and we put the breast phantom on top of the force/torque sensor. After that we used the tactile array sensor to pressed on the lesions inside the breast phantom and record the pressure distribution from the tactile array sensor and at the same time we also recorded the six parameters of the force/torque sensor simultaneously. The setup of the experiment is shown below.

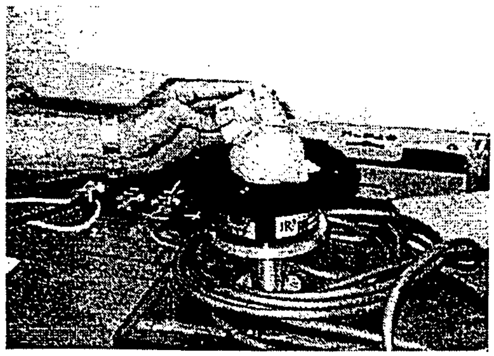


Figure 4: Tactile sensing and 6DOF force/torque sensing to localize and determine the size and the depth of the lesions.

Figure 5: The setup of the developed tactile imaging of palpable breast lesions for soft-tissue modeling, diagnosis and documentation.

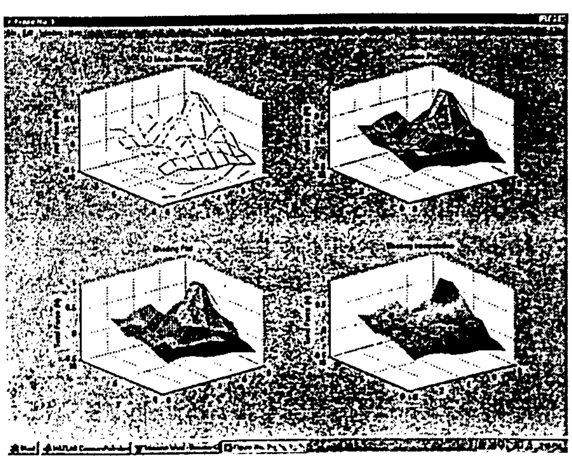
In this experiment, we will collect sufficient data for each lesion for further analysis. We decide to apply five directions of forces on each lesions that being press by the tactile array sensor. The direction of the force that applies on the lesion is defined as follow; Direction 1 is defined as the force that pushes from the top of the lesion. Direction 2 is defined as the force that pushes forward. Direction 3 is defined as the force that pushes backward. Direction 4 is defined as the force that pushes to the right, and Direction 5 is defined as the force that pushes to the left. The results of this experiment are shown below. The table consists of the crude calibration of the force/torque sensor, the output data from the tactile array sensor and the output from the force/torque sensor for each position that each lesion being pressed.

Lesion #	Position	Tactile Output	6DOF Force & Torque (lb/inlb)					
			Fx	Fy	Fz	Mx	My	Mz
	Calibration		-0.11	-0.05	-0.15	-0.10	0.40	-0.99

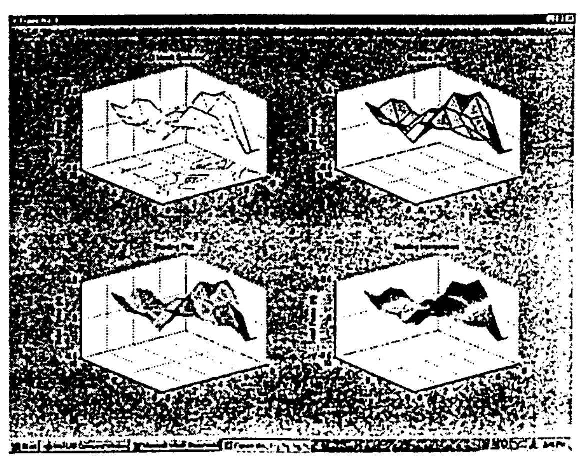
1	1	Lesion11.m	-3.17	1.77	-0.16	5.85	25.59	-0.89
	2	Lesion12.m	-2.08	2.48	-0.22	4.37	18.35	1.78
	3	Lesion13.m	-8.81	-0.03	-0.09	1.98	10.71	0.20
	4	Lesion14.m	-3.67	-1.72	0	2.18	10.01	0.39
	5	Lesion15.m	-4.77	4.02	-0.34	2.18	10.81	3.97
	Calibration		-0.23	-0.11	-0.21	-0.40	-0.50	-0.89
2	1	Lesion21.m	-4.07	0.37	0.10	-1.29	-4.36	1.49
	2	Lesion22.m	4.06	1.67	0.09	1.59	5.56	1.49
	3	Lesion23.m	-11.29	-2.61	0.18	-4.86	-15.67	5.55
	4	Lesion24.m	4.15	-5.90	0.58	3.97	15.97	-1.29
	5	Lesion25.m	-3.01	3.85	-0.34	-0.10	-0.49	0.89
	Calibration		-0.09	0	-0.18	-0.40	-0.40	-0.40
3	1	Lesion31.m	0	-4.50	0.24	4.07	16.57	-4.06
	2	Lesion32.m	-1.47	-3.56	0.21	0.30	1.59	-0.10
	3	Lesion33.m	-4.06	-4.84	0.18	1.89	8.34	-2.77
	4	Lesion34.m	1.54	-8.55	0.52	3.18	13.99	-10.11
	5	Lesion35.m	-1.57	-4.36	0.24	3.57	15.28	-3.87
	Calibration		-0.09	0.37	-0.24	-0.10	0.99	-0.50
4	1	Lesion41.m	-0.89	0.44	-0.13	-2.58	-10.81	0.50
	2	Lesion42.m	-2.34	2.50	-0.10	-5.26	-22.02	1.59
	3	Lesion43.m	1.69	2.96	-0.03	-2.28	-10.51	3.57
	4	Lesion44.m	3.20	-0.38	0.27	0.40	0.40	2.09
	5	Lesion45.m	-1.83	0.38	-0.03	-2.38	-9.32	1.99

By using MATLAB, the data that we collect can be display in 3-dimension as shown below.

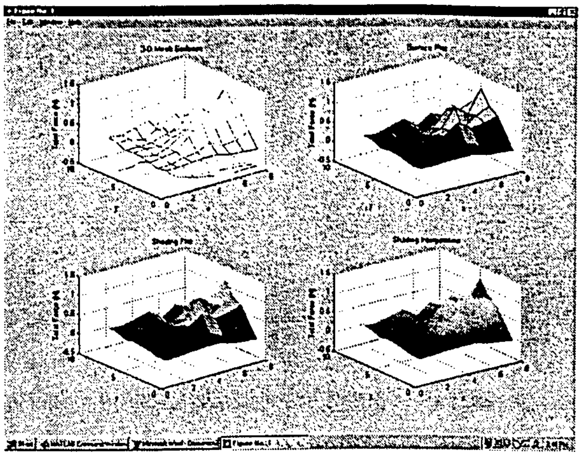
Lesion1



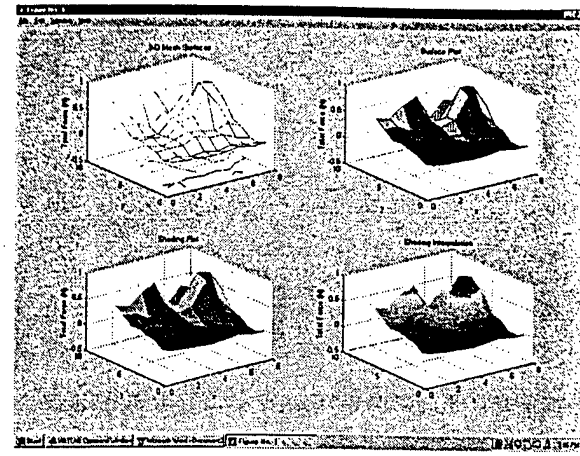
Position 1



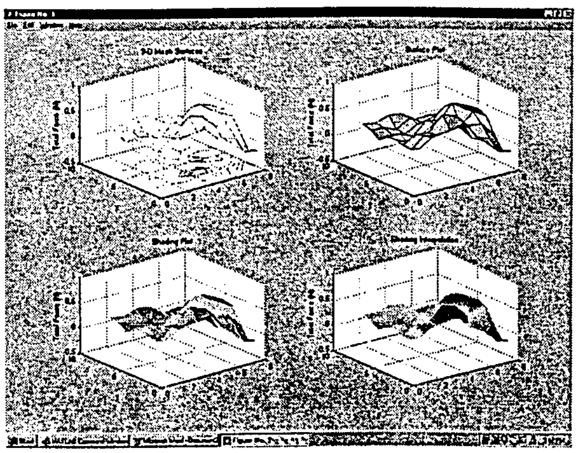
Position 2



Position 3

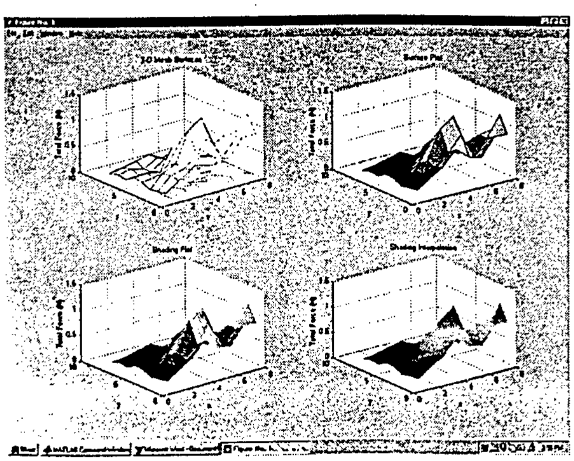


Position 4

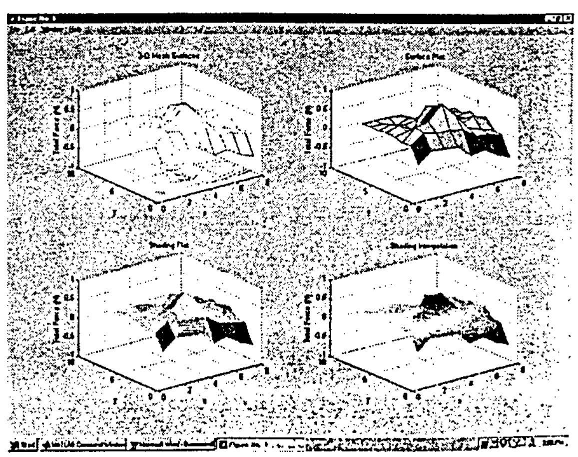


Position 5

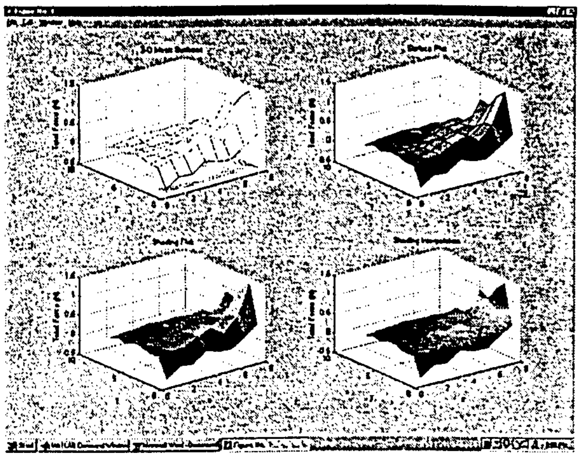
Lesion 2



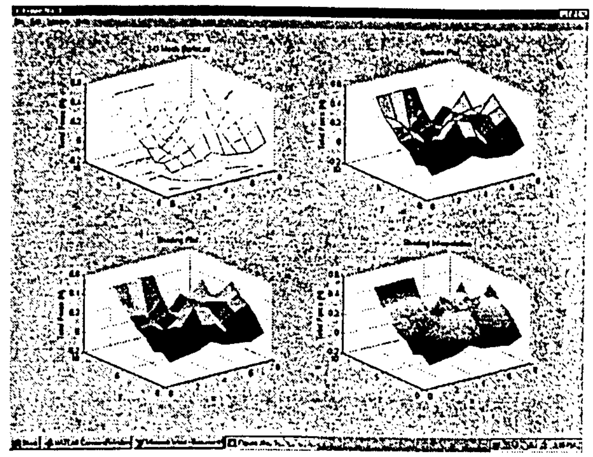
Position 1



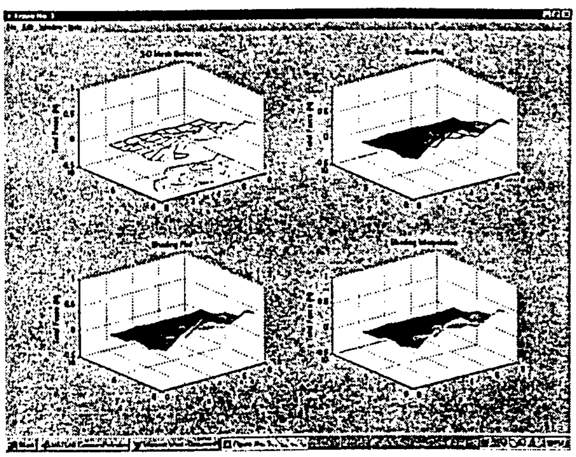
Position 2



Position 3

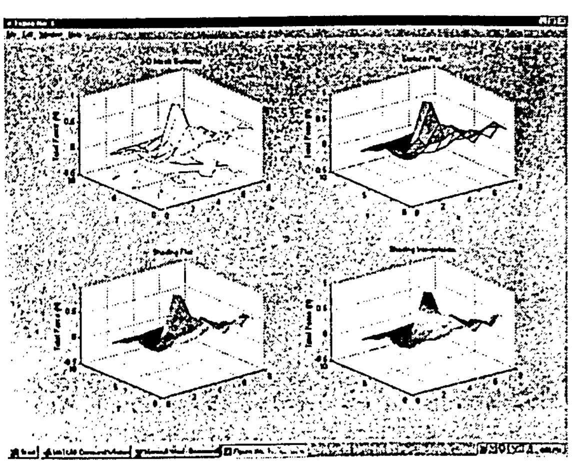


Position 4

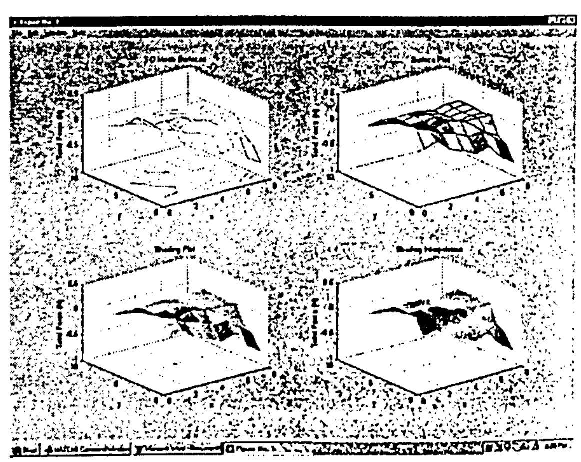


Position 5

Lesion 3



Position 1



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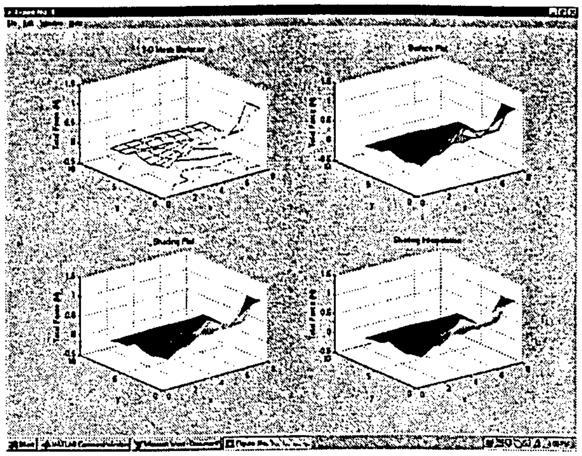

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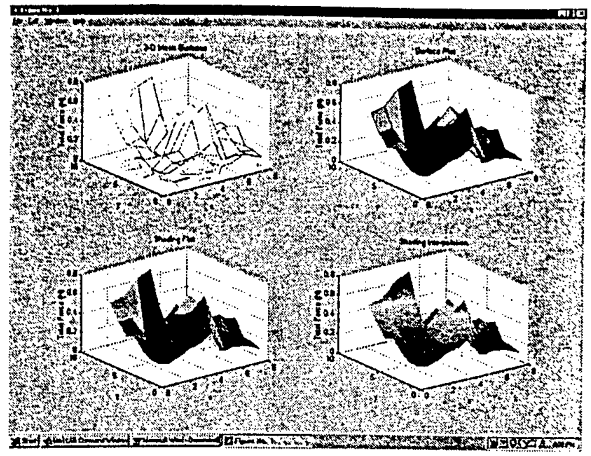

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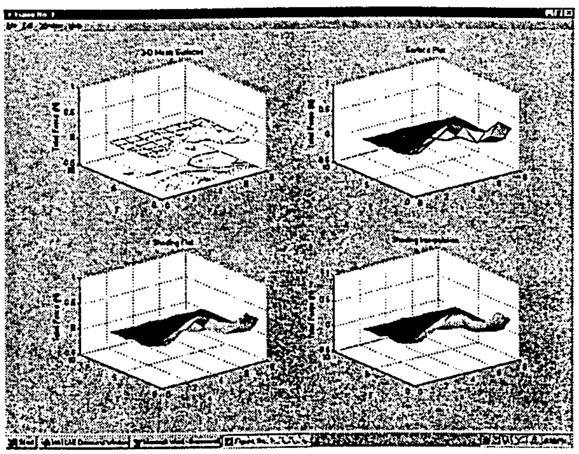
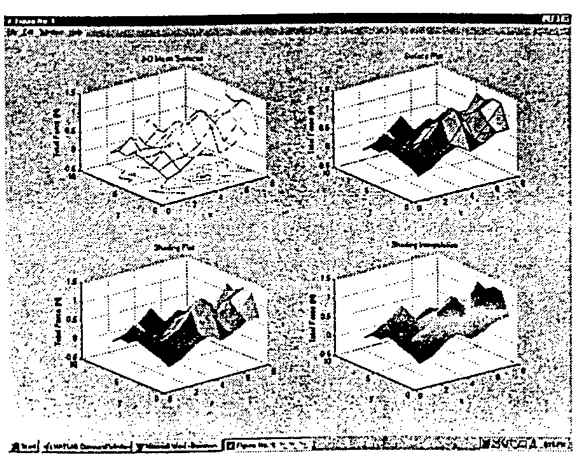
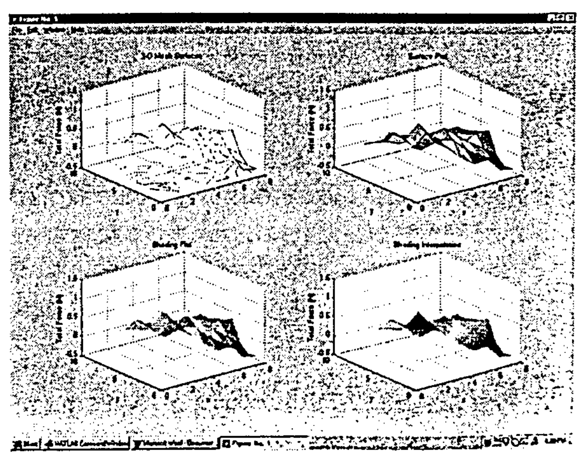


Position 5

Lesion 4



Position 1



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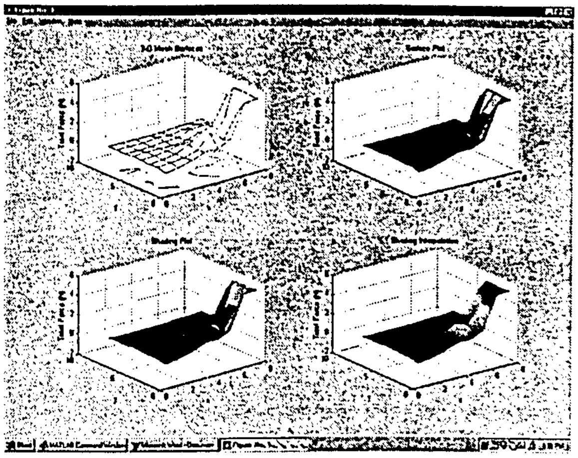
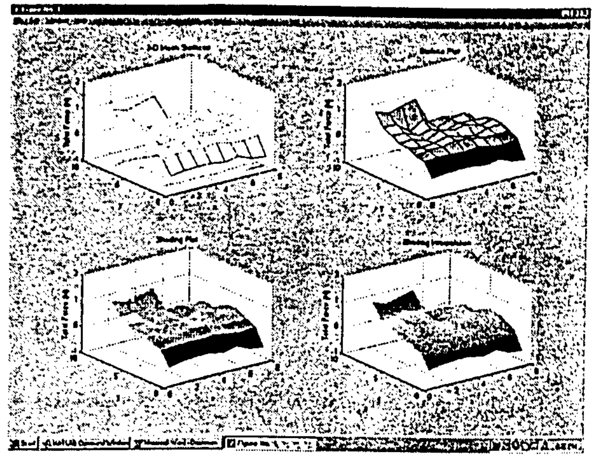


Position 3



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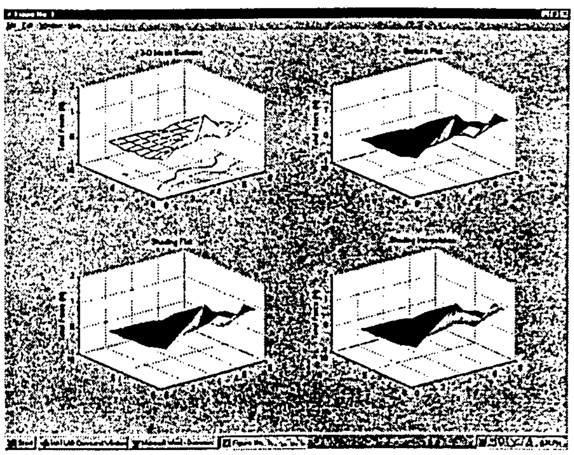

Position 5

Discussion and Conclusion

The result from our experiment shows that we can detect the lump inside the breast phantom by using the tactile array sensor. By collecting data of pressure distribution from the tactile array sensor in conjunction with the six parameters from the force/torque sensor, we can locate the actual lump position in the breast phantom and be able to differentiate between the lesion and the non-lesion in the breast phantom.

For the accuracy in the data collecting in our experiment, we need to reset our tactile array system due to the noise and we also need to recalibrate the force/torque for every time we start a new experiment.