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Telemedicine Final Report

Investigations of Sufficiency in Telemedicine Applications: Standards in Context of Populations and Technologies

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I. SUMMARY OF SALIENT RESULTS

Five projects focused on the *implementation* and the *evaluation* of telecommunications technologies in medicine; three on image quality, one on eye care, and one on videoconferencing in a remote trauma center.

Image quality findings included (1) general agreement that digital images are suitable for screening out pathology (specificity); but (2) wide disagreement on their usefulness for diagnosing specific eye disease (sensitivity). An image quality gold standard based on properties of film may be inappropriate for evaluating digital images.

Findings from studies that delivered eye care for underserved populations in community clinics demonstrated the immediate impact a digital system can make on diabetic eye care when implemented in the office of a primary care provider. The compliance rate for patients with diabetes who should receive annual eye exams improved from 53.7% to 83.2%, a proportional improvement of 55%, as a result of this particular study.

Videoconferencing over public phone lines is problem-prone. When available, more reliable and cost efficient IP solutions are preferred.

Telemedicine works, especially in underserved communities, when properly applied using the correct technologies. Portability and ease of implementation cannot be over-emphasized. Telemedicine has evolved from a fantastic idea to a concrete and commonplace reality.

II. EXECUTIVE SUMMARY

Authored by Steven H. Stumpf, Ed.D. and Rod Zalunardo, Ed.D.

This report presents results from five telemedicine studies conducted under a four-year contract with the National Library of Medicine, under the guidance and administration of the Advanced Biotelecommunications and Bioinformatics Center of the University of Southern California (USC-ABBC). Six Principal Investigators, more than twenty additional investigators (listed in Appendix A), and many more research assistants and clinical staff worked on these studies. Seven sites were involved as principal centers of clinical activity, the most unusual being the Hyperbaric Chamber on Catalina Island off the coast of Southern California (one of two telemedicine sites established by the ABBC on the island). As is typical of Southern California, diversity characterized the studies as a whole: populations were rural and urban; solutions were low tech and high tech; applications were store and forward and real-time; and medical disciplines included emergency medicine, ophthalmology, and primary care.

This report is dedicated to the memory of Frederick William George, III, MD, under whose leadership the award was received and these projects were conducted. Dr. George passed away in June 2000 following a 55-year long career in medicine, 33 of which were at the USC Keck School of Medicine. Dr. George founded the ABBC. The memoriam read at his funeral is attached under Appendix B.

Until wireless, remote, robotic procedures are commonly deployed, telemedicine really boils down to two media formats: store and forward, and live videoconferencing. This prima facie observation is the point at which early telemedicine research ends and new investigations begin. Our five studies fall within the realm of new telemedicine investigations. They are not really about ways in which telecommunications applications can be adapted to medical disciplines. The advance of technology into all areas of medicine is inevitable. The forthcoming wave of land-based, wireless transmission coupled with the arrival of widespread high bandwidth and mega-storage capacity on smart cards the size of credit cards, will once and for all enable telemedicine to be applied everywhere in virtually every form within at least our national borders.

The studies supported under this funding initiative were about identifying technical and clinical standards to guide providers who wish to deploy telemedicine applications in their own, not-so-unique contexts. Evaluation theorist Robert Stake argued that well described, specific cases have general utility for others facing similar situations. He referred to this as specific-case generalization. The five reports presented here describe their contexts very specifically: clinically, technically, and population-wise. The generalizability of the reports is dependent upon readers who can identify similar contexts in their own settings. Readers who wish to know more about how to deploy similar telemedicine solutions will find all the detail they could hope for in the individual project reports. Readers who wish to learn how these reports compared and contrasted, and what they have to say about standards in the context of populations and technologies will discover that information, hopefully, in the Executive Summary.

In the Final Report, the Executive Summary is followed by a Brief History that in turn precedes the five study reports. The Executive Summary attempts to "tie it all together" for the reader. The Brief History describes how the studies were developed. Each study report has been authored by the Project Director(s) for that particular study. Steven H. Stumpf, Ed.D., Senior Research Associate with the USC-ABBC, and Rod R. Zalunardo, Ed.D., Executive Administrator, authored the Executive Summary and edited the Final Report. The individual study reports presented to the editors received minor editing for ease of reading. For example, the headings within the reports were standardized to conform to a consistent outline, and ***most tables and figures were removed from the text and placed in the appendices for this report***. *[Editors' note: tables removed from the body of the report have been placed in Appendix C; figures have been placed in Appendix D. Two additional appendices (a text description of three study sites and connectivity diagrams not referenced in the Final Report) that may be of interest to readers are also provided.]* The most radical decision made by the editors involved moving certain tables, figures and pictures to the appendices. The disadvantage of forcing the reader to move back and forth within the document when referring to a table or figure versus the advantage of being able to format the document simply without recreating entire sections (e.g., where figures or tables in the original word processing file created significant formatting problems) was weighed and decided in favor of relocating tables and figures when necessary.

The Executive Summary is intended to provide the reader with three conveniences: (1) a brief description of the studies as they were implemented and evaluated; (2) a reference piece for comparing the five reports as telemedicine studies; and (3) a summation of the significant and important outcomes which emerged from the studies as they apply to telemedicine. The Executive Summary discusses the independent studies as a single body of work.

Readers interested in reviewing each specific study are strongly encouraged to read the individual reports that delve into considerable depth of detail. The investigators for each of the studies have described the implementation of their study and the evaluation methodologies employed point by point. The detail provided in terms of identifying equipment, sources, technical and medical standards, thought processes that led to key decisions, etc., is presented frankly and precisely. References are listed at the end of each report. Outcomes are discussed as they pertain to that study against the background of that medical discipline and telecommunications, in general.

Readers are fortunate in that our investigators and report authors were enthusiastic in documenting their work from project beginning through the end. Exemplifying this enthusiasm are the additional contributions of John Beecher, author of two addenda: the Emergency Telemedicine Connectivity addendum report (part of Study #4), and his own **A Short History of Digital Transmission.** This latter bonus document is made available for readers wishing background on how the telephone became the backbone for the internet and how future demand for traffic will be met by developing carrying capacities.

The reports present findings of interest to telemedicine investigators and providers everywhere. The study that took place on the Island of Catalina off the Southern California coast provides "mega-anecdotes" in the form of ordinary and extraordinary conundrums that providers can face when seeking to implement telemedicine systems. No matter how many resources or how fine the planning something completely unanticipated can always throw off the entire operation; from the phone company going about its routine business such as implementing an area code overlay, to semi-annual weather shifts that can sharply reduce the medical need for the new system. When things did fall into place, and the forces of mother nature and father phone company were at rest, our remote researchers working on the island determined they would not recommend ISDN as the technology of choice "when other more reliable and cost effective alternatives exist." This finding should stir discussion among telemedicine providers everywhere who must produce stable and cost-effective solutions for transmitting information between providers securely and effectively, as well as among providers who have already built extensive networks on public ISDN connections.

Several of these studies, especially those addressing image quality, have been or will be submitted for publication in peer-reviewed medical journals. Those studies, altered here for the sake of formatting consistency, will not veer substantially from the full reports contained in this Final Report. The findings of these studies are significant and important for future teleophthalmology studies. The USC-ABBC is implementing several new image quality studies, benefiting from lessons learned in reviewing outcomes of the studies funded under this contract. In our new studies we will replicate certain procedures and investigative methods in order to continue the investigation of digital images in regards to specificity and sensitivity.

The impact study on telemedicine applied to eye care at H. Claude Hudson Clinic, serving a predominantly underserved, Latino population in downtown Los Angeles, is presented last. This report is a necessary complement to the scientific questions investigated under the other studies. Outcomes from this down-to-earth project confirmed that telemedicine is profoundly useful when applied in a setting where barriers to care are the greatest. The compliance rate for patients with diabetes who should receive annual eye exams improved from 53.7% to 83.2%, a proportional improvement of 55%, as a result of this particular study. Clinical service performed under this and the Screening the Underserved projects effectively demonstrated how technology conjured in the laboratory can directly and immediately benefit the community.

Finally, the editor must point out that, as with all telecommunications technologies, capabilities are changing very rapidly and progress is being made at a pace that quickly renders many findings obsolete. This is certainly true in capturing digital images of the eye. The digital cameras used in these studies have been improved such that references to seven images and the 45° range of field (less than half the surface of the eye) only apply today in those cases where a new site might inherit an older camera. The newest cameras employ nine images and cover a 95° range of field. In telemedicine the more things change the *less* they stay the same.

Informed consents were collected from all study participants. Participants were fully informed regarding study protocols and advised their unwillingness to participate in a study would not impact their ability to receive health care in any way. Protocols for studies that involved human subjects were reviewed and approved by an Institutional Review Board at each institution prior to study implementation. Subjects who agreed to participate in a study signed an informed consent agreement that clearly described study intentions and that guaranteed their anonymity and confidentiality.

OVERVIEW

In October, 1996 the National Library of Medicine (NLM) made awards for nineteen, multi-year telemedicine proposals under its National Telemedicine Initiative. The NLM sought to evaluate the impact of telemedicine on cost, quality, and access to health care. The two primary goals of the National Telemedicine Initiative were to (1) assess approaches designed to ensure confidentiality of health data transmitted over electronic networks; and (2) test emerging health data standards. The NLM made awards such that a distribution of sites across rural, inner-city, and suburban areas was achieved.

The NLM was additionally interested in reviewing and applying recommendations from two National Academy of Sciences studies that investigated criteria for evaluation of telemedicine and practices to ensure confidentiality of electronic health data. These studies were the Institute of Medicine's Telemedicine: A Guide to Assessing Telecommunications in Health Care, and the National Research Council's For the Record: Protecting Electronic Health Information.

The Advanced Biotelecommunications and Bioinformatics Center (ABBC) of the University of Southern California (USC) was awarded a three year contract, which was subsequently extended to a fourth year, to oversee the conduct of telemedicine projects in the Los Angeles metropolitan area. The contract terminated at the end of June, 2000. The ABBC is a telemedicine applications research group located on the USC Health Sciences Campus in East Los Angeles. USC-ABBC is an Organized Research Unit of the University of Southern California authorized to enter into agreements within and outside the university that advance its research and education mission. Industrial corporations and research and development laboratories that support the ABBC include AT&T; Cisco Systems; Marconi Solutions; Imperial College, University of London; IBM; Jet Propulsion Laboratory at the California Institute of Technology; Northrop Grumman; and Pacific Bell. The ABBC has received grant awards from public and private sources to develop and evaluate telemedicine applications for the medical community. One of the ABBC's key initiatives is to build up telecommunications infrastructure and capacity for healthcare and community-based organizations (CBOs) that work with underserved and special populations in our region.

The USC-ABBC contracted to complete the following scope of work: (1) develop and use a test-bed network for health applications of advanced computing and communications; (2) using the network enable multiple health care providers to treat remote patients, create a system for transferring patient health information, collect

research data for multi-site clinical studies, and create and implement decision support services for healthcare providers (the contract required completing a minimum of two of five listed services); measure and evaluate applications impact; evaluate approaches to safeguarding patient data; and publicizing results.

Five studies emerged under which the scope of work was met. Raymond P. Briggs, Ph.D., has described the developmental history of the studies under section II of this report. The projects focused on teleophthalmology, emergency telemedicine, and primary care. A report describing the communications link to Avalon Hospital is included. For purposes of discussion the projects are referred to as the:

- Digital Gold project;
- Image Artifacts project;
- Screening the Underserved project;
- Remote ER project; and
- Eye Care for Underserved project.

Table 1 shows the relationship between the individual projects and the scope of work for the overall project.

Table 1: Scope of work for each telemedicine study

	treat patients	electronic transfer of information	collect clinical research data	implement decision support
Digital Gold		✓	✓	✓
Image Artifacts		✓	✓	✓
Screening the Underserved	✓	✓	✓	✓
Remote ER	✓	✓	✓	✓
Eye Care for Underserved	✓	✓	✓	✓

Each project shared two common purposes: the *implementation* and the *evaluation* of telecommunications technologies as applied to medicine. These broad project purposes subsumed several other objectives including assessment of confidentiality protocols and practices, and the investigation of technical standards across and within the various applications. Standards were addressed in the widest sense including the assessment of technical, electronic, and telecommunications standards in transmitting information, as well as standards in the production of information to be transmitted.

This project yielded or inspired products outside the studies. Some of these products were reports such as Beecher's "Short History of Digital Transmission" or Briggs' RealPlayer video on image quality (go to http://www.sciqeye.com/, click on image quality). SOAPnet was another product emerging from the NLM Project. SOAPnet is a state-of-art, web-based telemedicine application developed entirely by the USC-ABBC. SOAPnet contains a scaled down version of an electronic medical record fused with the ability to handle multimedia objects such as images, videos and sound that can be transmitted as encrypted data over the internet. SOAPnet has effectively been used in the

field and was the application of choice for the NLM project at the Noble and Hudson clinics. A newer version has been developed for use with future Teleophthalmology projects. The SOAPnet project was initiated in 1994 as the Collaborative Consultation Database, a store-and-forward telemedicine application for demonstration. It was demonstrated at the Pacific Bell Focus 99 conference as a feature application. SOAPnet has become an effective teaching tool for demonstrating electronic patient records for paper-based clinics.

THE IMAGE QUALITY STUDIES

Three studies examined the quality of digital images captured via an electronic, digital fundoscope as applied to ophthalmology. In particular, each project was concerned with the extent to which physicians believed they could rely on the images to diagnose and recommend treatment for eye disease, especially diabetic retinopathy.

Diabetic retinopathy is a condition that plagues poor populations who face the greatest barriers in access to healthcare. It is the leading cause of new blindness among Americans 20-74 years of age. Diabetic retinopathy is a condition which can be prevented almost entirely if diagnosis occurred in the early stages of disease. It is estimated that timely treatment of diabetic retinopathy can decrease blindness and visual impairment by 90%. Research has shown that preventing blindness is far less costly than providing services for the visually impaired. The Center for Disease Control reported in 1993 that yearly eye examinations and follow-up treatment could save the eyesight of many of the 40,000 Americans who become blind each year from diabetes.

Early diagnosis is customarily accomplished by proper screening through routine eye exams conducted by a trained ophthalmologist. Images are customarily captured in the ophthalmologist's office following dilation of the pupil and, should the physician so elect, a photo image is collected with a 35 mm camera. After the examination is completed the patient must be transported by car or bus since the blurred vision effect of dilation does not dissipate for several hours.

This is precisely where access to care becomes a barrier. Poor populations are most likely to face barriers in making arrangements to complete the extra steps required to obtain a retinopathy screen. Poor populations are, therefore, most likely to suffer from retinopathy because they have never been screened for the condition. Consequently, it is imperative to create new ways of treating and preventing diabetic retinopathy, especially in underserved communities, where the likelihood of diabetic patients receiving annual retinal screenings is extremely small. By placing a digital, non-mydriatic fundoscope in the office of the primary care physician several significant barriers to care can be surmounted and the numbers of screenings can be increased dramatically. The non-mydriatic fundoscope does not require dilation eliminating the need to be transported and forego a full day of work. The camera can be operated by a technician with minimal training and moderate practice. The digital image can be sent via email to a consulting eye care specialist. Remaining barriers are technical instead of functional: is the quality of the digital image sufficient to diagnose and recommend treatment for eye disease?

Each investigative team addressed the question of image quality sufficiency in a complementary and contrasting manner; acknowledging the barriers-to-care issues while examining the issues surrounding sufficiency of the images themselves, especially in terms of diagnostic suitability as judged by physicians.

The Digital Gold team from RAND reached for a kind of generalizability across physicians by utilizing multiple eye specialists (fifteen individual raters) to evaluate image quality at multiple levels of resolution. The Image Artifact team, located at the USC Keck School of Medicine Doheny Eye Institute, evaluated images in terms of clarity, using two independent raters to assess the quality of digital versus 35 mm slide images, categorizing the presence and frequency of flaws in the two image sets. The Screening the Underserved team from the Charles Drew School of Medicine searched for a qualified, context-referenced, definition of sufficiency; that is, for a population with virtually no access to specialty eye care. The Screening the Underserved team suggested sufficiency might be qualified to meet needs in underserved populations who suffer needless, catastrophic consequences.

Taken together, findings from each team answered the following questions:

- Are digital images sufficient to diagnose and recommend treatment for eye disease?
- How might the sufficiency of image quality change across a range of specialty physicians if technical specifications were incrementally heightened or lowered?
- Given that poor populations face the greatest risks and the greatest barriers, can a threshold be found for reducing risk from complications of diabetes, using digital images captured under the lowest technical quality standards, if the system overcomes access barriers to medical care?

The answers to these questions provide a rich background for future investigators to shape their own telemedicine studies. How high should the bar be set when it comes to utilizing medical information collected via methods still under development? What is the absolute threshold for sufficiency under the best of circumstances? Is sufficiency a fixed condition under all circumstances or must it shift according to context, e.g., populations being served, technologies being used and available, and urgency of needs?

THE DIGITAL GOLD STUDY

This team of investigators has made an important contribution to the body of work in telemedicine applied to eye care: a field that has generally emphasized evaluation of the fundus for diabetic retinopathy. The team recognized, historically, most if not all published fundus studies followed essentially the same approach: the studies involved one or two image-evaluators only; and none of the studies compared quality of digital images to the imaging "gold standard" of photographs collected under ideal if complicated conditions using 35 mm cameras on dilated pupils. The team also noted there was an absence in the literature of thorough technical specifications defining

sufficiency in evaluating analysis of digital images, "including monitor/display resolution, pixel density, color depth, image capture techniques and resolution, and, particularly, image handling and interpretation."
The purpose of this study was to establish standards for the sufficiency of image quality in order to diagnose diabetic retinopathy using telemedicine. Thirty retina specialists were presented with sixty digital images scanned from 35 mm slides. The pixel equivalent of 35 mm slides can be estimated (using 25.4 mm/inch and 1000 pixels to an inch) as 3726 X 2889. The images were initially scanned at 2400 x 1800 pixels. The resulting images were then presented at four different levels of image quality, 640 x 480 being the lowest, 1600 x 1200 being the highest.

The investigators observed numerous methods to maximize objectivity. For example, retina specialists reviewed the images in different sequences and at different quality levels for a subsample of the presentations. To reduce the likelihood of bias from repeated viewings of the same image at different image quality levels, researchers separated these image presentations by at least two slides, always presenting the lower-resolution image first. In addition, because the investigators wished to assess test-retest reliability, each participant viewed five to seven repeat images at the same quality level. Slides were selected at random; sets were reviewed to ensure no identical slides were adjacent in presentation. The Digital Gold study sought to answer two questions: (1) could retina specialists accurately identify diabetic retinopathy findings at the highest possible image quality via telemedicine? and (2) is there a minimum quality standard that ensures accurate findings?

Accuracy was measured in terms of specificity and sensitivity; clinical criteria for establishing pathology. Specificity is the more general standard; the ability to establish that pathology is *not present* on the image, i.e., the image is "clear." Sensitivity describes a finer criterion; the ability to establish presence of a particular condition. Multiple observers were explicitly used to investigate the usability and reproducibility of a telemedicine system operating in a community where the best possible resources and providers are available.

The Digital Gold team conceded the recognized gold standard - images collected via 35 mm camera - was by definition superior to digital images. They posited that sufficiency, however, might be found at a level lower of resolution than the highest attainable digitally (which was still below the gold standard). Digital images are inherently inferior to 35 mm images because digital technology cannot (*yet*) replicate the quality of an image captured using a 35 mm camera in a cost effective manner. The Digital Gold team hoped to identify a lower level of sufficiency, under the most favorable circumstances. They asked their raters to try and identify the most easily recognized disease conditions, such as a microaneurysm or neovascularization, arguing the ability to "identify accuracy at the most elemental level" satisfied their condition that the highest level of image quality might not be required to detect the simplest and most recognizable forms of eye disease. They also standardized the image source at the highest level possible, scanning the 278 digital images used in the study from 35 mm slides at a very high resolution level, then

manipulated with software at four levels of digital resolution, replicating resolution levels commercially available in 1996 using digital cameras, or forecast for availability in 2000. The Digital Gold team held numerous factors constant in order to attribute their findings as much as possible to the quality of the scanned images. Constants included using fellowship-trained retinal specialists who had been in practice at least five years as observers; using the same software application, Adobe Photoshop 4.0, to digitize, handle and manipulate all slide images; using the same monitor resolutions for viewing by raters; ensuring ample presence of the most important physical indicators of diabetic retinopathy, e.g., neovascularization of the disc (NVD), neovascularization elsewhere (NVE), vitreous hemorrhage, cotton-wool spots, macular edema, presence of lipids, and microaneurysms, were on the images; duplicating a sample of images for each rater to measure test-retest reliability; as well as numerous other considerations described in the complete report.

Findings were discouraging for sensitivity applications but encouraging for specificity. Generally, indicators of *retinopathy* could not be sufficiently identified at a rate high enough (above 80%) to recommend routine clinical use at the highest resolution quality of digital images. Sensitivities for certain other conditions (vitreous hemorrhage and cotton-wool spots), however, were above 75% for all image resolution levels, however, sensitivities for other basic conditions, including microaneurysms, were as low as 40%.

Specificities were generally above 90% at all resolution levels for most indicators *suggesting the use of digital images collected by digital cameras used in telemedicine is sufficient for screening out pathology*. In cases for both sensitivity and specificity, results improved with the higher resolutions.

These findings raise important considerations about the use of telemedicine images for assessing diabetic retinopathy, both favorable and unfavorable. The authors of this study cautioned that the benefit of telemedicine in reaching those who would otherwise have no eye exam (e.g., underserved populations) must be weighed against the harm suffered by those whose conditions are misclassified because telemedicine replaces their current care patterns. It must be stressed, however, that the cameras used in this study (as in the two others) could only photograph up to 45% of the eye. More advanced optical equipment (presently available in summer, 2000) could greatly improve sensitivity (as well as specificity) and allay concerns over the reliability of this technology.
The Digital Gold team's findings have helped define the limits of telemedicine as applied to the most popular and promising application in ophthalmology, screening for retinopathy. Their study has provided thorough technical specifications for defining sufficiency in evaluating digital images. Their findings also have provided the first range of scores that can be described as "confidence indicators" based on physicians' ratings in diagnosing basic eye disease from digital images. Given the limits of digital resolution, telemedicine can provide a clinician with confidence when ruling out the presence of pathology from an apparently clear image (specificity). However, telemedicine cannot provide a clinician with confidence when trying to identify kinds of pathology from a digital image (sensitivity). Finally, higher image resolution can be counted on to yield better results, in general. Image resolutions are constantly improving with available

technology. Very shortly, digital images will be equal to or better than 35 mm slides in resolution.

THE IMAGE ARTIFACT STUDY

Three retinal specialist ophthalmologists with an interest in the impact of image artifacts on clinical findings applied their interest to digital images used in telemedicine. The specialists based their study on their observation that, under the best of circumstances (the "gold standard" of dilated pupils and 35 mm film), artifacts can contribute to image error. The researchers designed a study to investigate to what extent the presence and impact of artifacts in digital, non-mydriatic, fundus photographs impacted their utility in a screening program for patients with diabetic retinopathy in a community clinic. The study used digital, fundus photographs collected without dilation as part of a diabetic retinopathy screening program in a community clinic. Unlike the Digital Gold study, images were collected under conditions identical to the typical telemedicine setting, using a non-mydriatic camera at 640 X 480 resolution. It is noteworthy that this and the Digital Gold study employed retinal specialists as raters whereas in the subsequent study (Screening the Underserved) general ophthalmologists performed the ratings.

Images were evaluated by two ophthalmologists for (1) completeness of the image, (2) types and frequency of artifacts, (3) incidence of all artifacts, and (4) effect of these artifacts on the acceptability of the images for diagnostic purposes. Artifact refers to the presence in images of artificial material or effects that can appear as clinical findings. This study addressed a concern often raised by ophthalmologists working with an image of the eye; that is, their wish to view an image that has not been manipulated in any way. Ophthalmologists fear any manipulation of a film image might hide or obscure clinically relevant information. However, given the basic differences between analogue and digital media – physical film and chemicals versus electronic digital pixels - it is not certain the concern about image manipulation on film necessarily holds in the digital medium where the issue central to image clarity is the signal to noise ratio. Image manipulation that reduces noise and enhances signal may in fact enhance a clinician's ability to view pathology. We raise this point as it has bearing on future research in image quality as investigated in these studies.

The Image Artifact team evaluated a sample of 108 images for image completeness, types and frequencies of artifacts present, incidence of all artifacts present, and effect of artifacts on the sufficiency for diagnostic purposes. Images were rated by a retina fellow and a vitreo-retinal specialist (as with the Digital Gold study). The raters were unfamiliar with the patients and had no knowledge of the duration of their diabetes. As in the Digital Gold study, researchers sought to test digital photographs against 35mm slide images to determine if informed diagnoses could be made just as accurately. Unlike the Digital Gold study, however, the digital photos were processed at only one resolution, 640 x 480. As with the Digital Gold study, images were viewed on a standard platform, a monitor with 1478 x 640 resolution. Images were not enhanced, or adjusted in any fashion. The goal was to collect an image (given the 45° range of field limitation) that included the temporal arcades, optic nerve, and areas one disc diameter nasal to the optic

nerve and temporal to the macula. The researchers challenged findings from earlier studies that found specificity and sensitivity rates for detecting or screening retinopathy as high as 99.5% and 84%, respectively.

The raters found one image in the set of 108 that contained all the components necessary to screen for diabetic retinopathy. They found 95% of the images contained artifacts. More than 96% of the photographs were independently graded as unacceptable for screening of diabetic retinopathy by both observers due to masking by the artifacts.

Better quality and fewer artifacts may be achieved if the pupils are dilated. Artifacts are noted in as many as 48% of fundus photographs taken with undilated pupils versus only 14% in dilated pupils. The Image Artifact team concluded non-mydriatic, digital fundus photography was not as effective in diagnosing pathology as with 35mm slides or in-person eye exams. They suggested dilation of the pupils might improve the quality of digital images in eliminating artifacts.

Researchers concluded non-mydriatic fundus photography cannot replace the "gold standard" of screening diabetic retinopathy through dilated pupils in person or by using the 7-field, 35-mm film fundus images. The Image Artifact study set the sufficiency bar as high as it could go, finding digital images did not measure up. Interestingly, the investigators did conclude digital images were sufficient for determining specificity, confirming the Digital Gold team's findings.

SCREENING THE UNDERSERVED STUDY

The study conducted by the research team at Charles Drew School of Medicine, led by a general ophthalmologist, produced findings confirming digital images are sufficient for specificity, especially in context of a population with the greatest need.

Inadequate access to medical care among underserved populations is common among inner city urban and rural communities. Studies have shown underserved populations are especially vulnerable to preventable and treatable blindness and visual impairment.

Increasing the urgency to conduct a study that applies digital imaging to screening for diabetic retinopathy among underserved populations is the knowledge that early screening for diabetic retinopathy can decrease blindness and visual impairment by as much as 90%. Sadly, fewer than half of all patients at risk receive annual dilated examinations as suggested by American Diabetes Association guidelines [Editors' note: Study #5 – the Eye Care for Underserved study - found that 86% of their sample of 491 patients with diabetes had not received an exam in the previous twelve months]. The failure to screen for retinopathy among inner-city, underserved populations is even greater. The researchers cited a recent study of outcomes for exams performed on inner-city, underserved patients with diabetes who had received their first screens for eye disease. Physicians found 62% of the patients with diabetes had clinically apparent ophthalmic disease; 40% already had advanced ocular disease; and 6.8% were legally blind.

The researchers employed protocols similar in some respects (grading criteria) but different in others (live digital images versus digital images from 35 mm film) to the Digital Gold and Image Artifact studies. The most important difference under this study was that repeated efforts were made to capture a suitable image of the patient's eye(s) *even if this meant dilating the pupil*.

A total of 370 eyes of 185 diabetic patients were photographed using the digital camera. Of these 87 patients (47%) also received an in-person eye examination. Sixty percent of their patients identified as Hispanic and 38% as Black. Sixty-one percent of patients in the study were uninsured while 46% were unemployed. All images were captured and stored at a resolution of 640 x 480 pixels and reviewed on a standard 17-inch monitor with resolution at 640 x 480 pixels. Remote site personnel underwent one to two months of training on image capture using non-mydriatic cameras to help increase image quality.

The images were transferred between clinics and specialists over the university's high-bandwidth telemedicine network combining fiber optic and category five copper wire. The network design allowed remote clinics to link directly to the university subspecialty clinics and the central file server simultaneously. Data throughputs of 25 Mb to the desktop were achieved through the use of the university ATM network over standard category 5 wiring. The patient data directory on the server was mapped to the PC telemedicine workstations at the remote and hub site specialty clinics. Workstations were able access patient data directory from a file server as though it was a directory on the hard drive. A hierarchical password assignment and 128 bit data encryption to maintain data security and maintain patient confidentiality was utilized. All telemedicine interactions took place over a closed network further strengthening data security and patient confidentiality. Telemedicine interactions were conducted in either real-time or store and forward.

The Screening the Underserved research team asked physician reviewers to identify the presence of five grades of retinopathy including no retinopathy (i.e., sensitivity and specificity) on the images or to record an "unable to grade" score. Outcomes were reported under two categories: whether a patient should be referred for a follow-up examination (if moderate to severe disease was detected on the digital images); and rates of sensitivity and specificity when using digital images to detect retinopathy and other eye disease compared to examination in person with a physician.

Of the 185 patients that underwent digital fundus photography, only seventeen (9%) yielded digital retinal images rated unreadable due to poor image quality. Equipment malfunction and operator error resulted in failure to obtain images for five (3%) of the 185 patients. All told, 163 (83%) of the 185 patients enrolled in the study yielded digital retinal photographs judged of *sufficient image quality* to grade and evaluate. This rate can be compared to the Image Artifact study that found 96% of all images were "graded as *unacceptable* for screening of diabetic retinopathy." In numerous respects findings from this study conflicted with the Image Artifacts study. It would be instructive to know

to what extent images collected on dilated pupils contributed to improvement in sufficiency as suggested by the Image Artifact team.

The Screening the Underserved team compared the rates of referral for follow-up examinations (presence of some kind of pathology detected) for exams by digital images only to in-person evaluations among the subset of 87 patients who were examined twice. The investigators reported rates were essentially the same. Twenty-five patients (29%) met the criteria for referral based on evaluation of the digital retinal images, while twenty-nine (33%) met the criteria of referral based on in-person evaluation. Findings would be strengthened if the reader knew how many of these forty-four patients were the same person.

The findings in this study suggest that on-site, digital photo documentation coupled with telemedicine linkage to an ophthalmologist is an effective strategy for improving rates of diabetic retinopathy screening. Investigators also recommended grading criteria should be implemented that minimize the referral threshold to compensate for the limitations of digital photography and to respond to the needs of underserved patients with diabetes. In addition, the frequency of follow-up screening photographs should be increased in relation to the patient's duration of diabetes and degree of unsuccessful glucose control. The Screening the Underserved investigators also noted that the success of a screening endeavor like theirs is highly dependent on the quality of the digital photos obtained in the remote site primary care clinics. Therefore, they strongly endorse dilating the pupil when indicated by age and other factors, as well as devoting time to training camera operators in order to ensure the highest quality photos are taken.

REMOTE ER STUDY

The purpose of this study was to explore the use and effectiveness of telemedicine for remote ER treatment and teleconsultation. The Remote ER study tested the ability of telemedicine applications to facilitate and provide better patient care in the most critical situations and under the most remote circumstances.

USC-ABBC installed a video teleconsultation system to link the Los Angeles County - USC Medical Center emergency department with the USC Catalina Hyperbaric Chamber at the Wrigley Institute for Environmental Studies on Catalina Island located 26 miles off the mainland in the Pacific Ocean. The hyperbaric chamber is used for emergency treatment of diving accident victims. Diving accidents occur when divers ascend to the surface too quickly developing decompression sickness, also know as "the bends," or cerebral air embolisms that result from the formation of bubbles from dissolved gas in the blood or tissues. Treatment for "the bends" is depressurization in a hyperbaric chamber, which simulates the pressure of a dive. The atmosphere in the chamber consists of hyperoxigenated air. The decision to treat a patient in the hyperbaric chamber is based on information obtained through a physical examination of the patient by paramedics and medical personnel as well as information volunteered by the patient.

The study had two main objectives. First, the researchers wished to determine the practicality and reliability of implementing and operating video teleconferencing technology in a rural, remote environment where technical staffing and support is limited. Second, the Remote ER investigators wished to measure the extent to which video teleconferencing contributed to medical management in a rural, remote environment. The focus of the study was not on patient outcomes, but rather on the responses of the nonmedical and medical personnel involved in the treatment of diving accident victims. The investigators predicted the teleconsultation system would be most useful when ambiguity was high concerning the patient's condition. Investigators theorized additional information gathered by a remote specialist who could see and speak to the patient via videoconferencing would help the attending caretaker (often a paramedic or EMT) decide whether or not to place the patient in the hyperbaric chamber. The expected outcome was better diagnoses made more rapidly and effectively. The types of personnel involved in the demonstration included: hyperbaric chamber supervisor and volunteer crew; LA County Lifeguard paramedics; US Coast Guard EMT members; and the LA County emergency room physicians consulting to staff at the chamber in the care of the diving accident victim.

The initial successful testing phase produced a tele-connection (primary rate ISDN) that performed ideally and consistently. The local phone company implemented an area code overlay within a few months following. Immediately, the tele-connection at the hyperbaric chamber began to fail intermittently and inexplicably. Many weeks passed as ABBC technicians made repeated trips to the island to ferret out the problem, checking every system element in a vain attempt to identify the hardware or software problem causing the continual system crashes. As the ABBC team began to widen the possible sources of the problem the question of the area code overlay came under scrutiny. The cause was subsequently tracked to a "lost line" on the island. The phone company was able to implement a fix and the problems disappeared.

Forty-four cases were seen during the study period. Twenty-four were treated in the hyperbaric chamber. Researchers tracked the operability of the telemedicine system through a problem log maintained at the chamber by staff. The site log documented hardware failure, software failure, communications failure, and video equipment failure during patient treatments, real and simulated.

The contribution of the telemedicine system to medical management was assessed by a short survey completed by chamber non-medical and medical staff. The survey addressed components of the telemedicine system: which were used, how they worked, and perceived effect of each component on the system as a whole in terms of diagnosis and treatment of the accident victim.

The Remote ER team concluded that off-the-shelf video teleconferencing equipment could be successfully implemented at a remote emergency treatment site with modest success. When the system was working and was utilized it was generally rated as being very helpful. However, the initial year of implementation during which the system was marked by repeated failure proved to be damaging in the minds of the end-users.

Additionally, a decline in diving accident victims was observed during the second half of the demonstration period.

Investigators made several additional observations. First, clinical personnel found the additional visual information helpful in the triage of diving accident victims. Researchers suspect this additional information reduced the ambiguity of cases and allowed for quicker treatment decisions. The connection time for assessing non-treated cases declined during the second demonstration period. In terms of quality, reliability and helpfulness to the patient encounter, the system was rated highly by the users, despite the fact that the system often required reconnection during the first demonstration period. The burden of reconnecting fell to the chamber supervisor and the remote physician.

In summary, investigators concluded the video teleconferencing system performed consistently well when it was working because it enabled simultaneous video and audio communication between the chamber and the physician. Investigators commented that communication might have been enhanced if the paramedics at the chamber had grown comfortable wearing the wireless headsets that would have permitted them to speak directly to the physician. At the same time, it would have reduced the pivotal role of the chamber supervisor during the triage phase. The research team suggested wireless headsets be implemented in future research in similar settings.

EYE CARE FOR UNDERSERVED STUDY

This study tested the applied model for telemedicine as it can and should be applied to populations most vulnerable to illnesses that are particularly vexing for populations living near or below the federal poverty level. The Eye Care for Underserved team's study provided the down-to-earth complement to the other studies that investigated concepts as much as applications. This study explored sufficiency in terms of the application of telemedicine; how well can it work in a typical inner city clinic that serves patients without any coverage or Medicaid coverage only. The investigation addressed the corollary promise of telemedicine. If the original promise of telemedicine was to deliver services to rural populations, the corollary promise sprouted from the minds of investigators and advocates for underserved populations who quickly realized telemedicine offered a solution to inner city populations facing the same problems; finding access to care that is, otherwise, frequently unavailable. This study is the prototypical model for inner city telemedicine.

The Eye Care for Underserved investigators placed one nonmydriatic fundus camera in a downtown Los Angeles, publicly funded, primary care clinic serving a large population of poor and underserved residents. A second camera was placed in a primary care clinic in Van Nuys, one of Los Angeles' urban centers in the San Fernando Valley. The digital cameras were the same models used in the image quality studies. The patient population at the clinic included a significant number of diabetics; four hundred and ninety one of who (each with diabetes) participated in the study. Each participant had a digital eye exam and completed a standard survey that elicited personal health information. Study goals included identifying the rate of eye disease among the patient population; the

factors contributing to barriers to care within the target group (poor patients with diabetes); and a measurement of the benefit gained from telemedicine, i.e., patient referrals for follow-up ophthalmological care based upon examination by captured digital images. The investigators for this study also conducted the Digital Gold image quality study.

Images were collected by a trained technician using the digital camera through undilated pupils. Images were interpreted by a retina specialist at the Doheny Eye Institute of the USC Keck School of Medicine. Each patient completed a standard survey. Survey data were cross-referenced to image outcomes based on the specialist's review. The investigative goal was to discern any association between clinical severity and need for follow-up to patient background characteristics. The questionnaire is reproduced in Appendix E, Volume II Appendices. Survey items covered health habits, demographic information, and health status. The survey consisted of validated questions from prior studies, including items from the SF-12 (a standard instrument widely used in health care research). The survey was individually administered in person at the clinic in English or Spanish.

The study sample was comprised of primarily poor, Latino women with diabetes in their 40s, covered by either public health plans or not at all who were receiving insufficient eye care. Demographic data showed a predominantly Hispanic population (86%), half of whom reported family incomes below $10,000; most patients had no more than an 8th grade education (60%); and nearly all were uninsured or covered by MediCal. Fourteen percent were 40 years or younger, while 10% were 65 years or older. Nearly three quarters were female (n = 356). The study participants described their overall health as comparatively poor. On average they had been diagnosed with diabetes for almost eight years. Thirty three percent were initially diagnosed past the age of 50.

Eighty four percent of the participants reported they had not received an eye examination during the prior 12 months (annual eye exams are the standard of care). Sixty four percent reported they had not received an eye exam in the previous two years. Almost one quarter of the patients (n = 133) reported never having had a complete eye exam, while half of these (12% of the total) had never received a basic vision check. Sixty five percent (n = 317) could not identify the type of provider who administered the exam. Nearly 40% of the study patients were unable to identify the type of provider responsible for their overall diabetes care.

The Access to Care Paradox: The investigators made an unexpected finding. While the patients in the study sample on the whole did not receive sufficient eye care they were receiving sufficient diabetes care; 84% reported seeing their providers at least three times during the previous year. This was in itself an important finding because it clearly supports the widespread supposition that telemedicine can help overcome barriers to care. Patients with diabetes in the study sample (the investigators point out this was an uncontrolled study) did access primary care for diabetes through their primary care physician. However, they did not access eye care emphasizing the dearth of specialty

care in underserved communities. The simple remedy of placing a digital camera in the primary care physician's office had immediate impact.

The Eye Care for Underserved team performed subsequent multivariate analyses on the survey data to discover factors that might help providers identify those patients at greatest risk to not access eye care. That is, investigators searched for a set of factors that, in combination, predicted which patients with diabetes were at the greatest risk to both suffer eye disease and not access care. They found that patients with high blood pressure, a personal belief that their vision was poor, who were taking insulin, and who had long travel times were about twice as likely to need referral for follow-up eye care.

The Eye Care for Underserved team drew two very important conclusions. First, they stated implementing a telemedicine solution where images are collected at the primary care site and sent via email to a specialist for review is both feasible and practical. *"The primary care providers' office did not have to change their office practices in any unique manner. Instead, they incorporated the eye camera as they would any new piece of lab equipment or new lab test."* The team was actually modest in making their point. The system they implemented demonstrated how portable telemedicine has become from the availability of high quality equipment to ease of connection and use. Portability and ease of implementation are essential points for persuading physicians that implementing such a system will not disrupt their routines. Implementing such a system can enable detection of serious eye complications of diabetes in time to save eyesight. Second, this approach is especially promising for delivering services in communities with substantial poor and underserved populations because a significant number of these patients are accessing sufficient primary care for their diabetes. Telemedicine can enable specialty care to be widely accessed, significantly improving health for the entire community.

IMPLICATIONS FOR FUTURE RESEARCH

The variation in judgment regarding sufficiency for the image quality studies suggests reconsideration of the familiar gold standard may be in order. This probably requires a paradigm shift in considering how to optimize the application of digital imaging to medicine. It can be argued that image quality studies evaluated quality according to terms incompatible with digital data, or at least under circumstances that did not, or could not, optimize the best features of the digital medium. It is highly likely that the entire concept of a gold standard must be reconsidered altogether in order to most effectively optimize the utility of digital images in medical care.

The advantages of digital imaging did not really weigh in the studies. For example, digital images do not suffer the image erosion found in photos as they are moved from capture to viewing device (film to photo stock). In analogue photography an image loses quality - including noise, resolution and dynamic range - every time it is transposed. This does not occur in the digital domain. The key to every high quality digital image is to acquire a noise free, high resolution, color accurate image at the outset. Ultimately, because of the nature of the medium, digital images may represent a superior method for attaining this objective.

In any digital medium three main phenomena affect overall perception of picture quality. These are (1) signal to noise (less noise is desirable to reduce errors in information), (2) resolution, i.e., the absolute level of detail of a digital picture, and (3) dynamic range, i.e., the capability to contrast light with dark, and to heighten color sharpness with great clarity and accuracy. In each of these considerations a 32 bit image yields higher quality than a 24 bit image. These three areas are the essence of all digital media including digital photography. Reductions in any one affects the overall quality of the image being produced. Conversely, the ability to exert greater control over each factor optimizes the image quality. Once the digital image is captured under the most optimal conditions (including not only lighting and lens but also pixel depth) that image can be manipulated so that the image is actually improved without distorting it.

An example of how digital photography can be more easily (and advantageously) manipulated without distorting and in fact enhancing the image is the ability change an image from a positive to a negative very easily in the digital domain. Certain phenomena can be seen more readily and even clearly in negative. A good example would be a picture of stars at night. With a regular photo it is very difficult to see low-light-level stars as white dots on a black background. However, the negative image wherein stars appear as black dots on a white background permits dim stars to be seen much more easily. This effect is due to the dynamic range of human eyes. We are able to more easily pick out a small black spot on a white background than a small white spot on a dark or black background. Future image quality research should approach quality on terms compatible and congruent with the digital medium instead of film. Established standards germane to film should be eschewed in favor of discovering new standards compatible with the strengths of digital images. Likewise, new and innovative methods of using digital images must be discovered to test the new standards. If the old rules do not apply then surely the old standards do not, as well.

As the deployment of telemedicine expands in rural and urban areas the reliability of bandwidth standards for connectivity (ISDN versus DSL) are being re-evaluated. The general usefulness of telemedicine (it can work wonders for increasing access to care) has been reconfirmed in our studies supporting findings in earlier studies. Portability and ease of implementation cannot be over-emphasized. New telemedicine projects should continue to critically investigate connection standards from point to point T1 circuits to land-based wireless networks. The Remote ER and Eye Care for Underserved studies provide blueprints for getting new projects off a running start. These studies demonstrate that telemedicine can be implemented fairly easily, to the benefit of more populations, utilizing more technologies. Telemedicine works when properly applied using the correct technologies. Telemedicine has evolved from a fantastic idea to a concrete and commonplace reality.