

National Library of Medicine

Telemedicine Final Report

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

NLM National Telemedicine Initiative
RFP-NLM-96-105/MVA
Proposal ID No. 41

The Advanced Biotechnical Consortium of the
University of Southern California

September 15, 2000

Final Report Prepared by:

John Beecher
Raymond P. Briggs, PhD
Jim Chiesa, PhD
Charles Flowers, MD
Catherine Jackson, PhD
Jennifer Lim, MD
Daniel Relles, PhD
Russ O'Brien
Steven H. Stumpf, EdD
Rod Zalunardo, EdD

Edited by Steven H. Stumpf, EdD and Rod Zalunardo, EdD

Table of Contents

I.	Summary of Salient Results	6
II.	Executive Summary	7
	Overview	10
	Digital Gold Study	13
	Image Artifact Study	15
	Screening the Underserved Study	17
	Remote ER Study	19
	Eye Care for Underserved Study	21
	<i>Access to Care paradox</i>	22
	Sustainability	23
	Implications for Future Research	23
III.	History of Project	25
IV.	Five Telemedicine Studies	28
	Study #1 – EVALUATION OF TELEMEDICINE IMAGE QUALITY FOR INTERPRETATION OF DIABETIC RETINOPATHY	28
	Introduction	28
	Implementation of Technology	29
	Evaluation of Application	29
	A. Determining Gold Standard Interpretations of Images from 35 mm Slides	
	B. Organization of Clinical Findings and Reviewer Interface	
	C. Power Calculations and Sample Size	
	D. Order of Image Tests for Reviewers	
	E. Practice and Evaluation	
	Analysis and Results	33
	A. Results, Specific Indicators	
	B. Findings	
	B. Aggregated Findings	
	C. Discussion	
	References	38
	Study #2 - ARTIFACTS IN DIGITAL NON-MYDRIATIC FUNDUS PHOTOGRAPHS OF DIABETIC PATIENTS: A PILOT STUDY	40
	Introduction	40
	Implementation of the Technology	40
	Evaluation of the Application	41
	Analysis and Results	41
	A. Discussion	
	B. Conclusions	
	References	44

Study #3 - THE UTILITY OF TELEMEDICINE FOR DIABETIC RETINOPATHY SCREENING IN UNDERSERVED POPULATIONS	45
Introduction	45
Implementation of Technology: Screening Protocol	46
Evaluation of the Application	48
Analysis and Results	49
A. Sociodemographics	
B. Diabetes Status	
C. Ophthalmic Surveillance	
D. Digital Retinal Image Evaluation	
E. Discussion	
References	54
 Study #4 - USE OF TELEMEDICINE FOR EMERGENCY MEDICAL TREATMENT AT A REMOTE LOCATION: TREATMENT OF DIVING ACCIDENTS AT THE HYPERBARIC CHAMBER ON CATALINA ISLAND	57
Introduction	57
A. Description of Catalina Island	
B. Treatment of Diving Accidents in the hyperbaric chamber	
Implementation of Technology	59
A. Conceptual Framework	
B. Data Collection	
Analysis and Results	61
 Addendum to Study #4 - EMERGENCY TELEMEDICINE ON CATALINA ISLAND: THE CONNECTIVITY REPORT	64
Introduction	64
A. Avalon Municipal Hospital	
B. Telecommunications Infrastructure	
C. Supporting Catalina Island	
Telemedicine Design Considerations.....	67
A. Design Issues	
B. Infrastructure Design for Hyperbaric Chamber to LAC+USC H.320 Link	
C. Chamber Building	
D. LAC+USC Facility	
E. Avalon Hospital to USC HSC H.323 Link	
F. The Avalon Hospital End	
G. USC-HSC End	
Implementation of the Technology	74
A. Avalon to USC-HSC	
B. Chamber to LAC+USC	
Evaluation of the Application	75
A. Applications Supported	
B. Avalon Hospital to USC-HSC	
C. Hyperbaric Chamber to LAC+USC	

Findings and Analysis	77
A. H.320 vs. H.323 for Telemedicine Applications	
B. Remote Monitoring, Troubleshooting and Maintenance	
Study #5 - IMPACT OF TELEMEDICINE ON EYE CARE FOR UNDERSERVED IN AN INNER-CITY PRIMARY CARE CLINIC.....	79
Introduction	79
Implementation of Telemedicine	79
A. Description of H. Claude Hudson Clinic	
B. Recruiting the Patient Population	
C. Description of the Patient Survey	
D. Standards for Referral	
Analysis and Results	82
A. Demographic Description of the Population	
B. Health Status of the Population	
C. Eye Care for Underserved Access and Use	
D. Bivariate Prediction of Urgent Care	
E. Multivariate Prediction of Urgent Care	
Conclusions	86
References	87
V. Bonus Report: A SHORT HISTORY OF DIGITAL TRANSMISSION	89
VI. APPENDICES REFERENCED IN THE FINAL REPORT	93
Appendix A: List of investigators.....	94
Appendix B: In Memoriam F.W. George III.....	96
Appendix C: USC-ABBC network diagram.....	98
Appendix D: Tables Referenced in Final Report	
Table 1 - Clinical findings assessed.....	100
Table 2 - Interpretation accuracies at each of the 4 image resolution levels.....	101
Table 3 -Statistical significance of the difference in sensitivities at two highest and two lowest levels of quality.....	103
Table 4 - DRS staging categories.....	104
Table 5 - Artifacts summary.....	105
Table 6 - Grading criteria	106
Table 7 - Drew demographic characteristics.....	107
Table 8 - Clinical characteristics.....	108
Table 9 - Conceptual model for information use in hyperbaric treatment decision making	109
Table 10 - Selected demographic characteristics of the surveyed population	110
Table 11 - Prior utilization of eye care services for the surveyed population	111
Table 12 - Common reasons for not having annual eye exams	112

	Table 13 - Variables examined for bivariate Relationships with referral indicator	113
Appendix E:	Figures Referenced in Final Report	
	Figure 1 - Image and data entry interface	115
	Figures 2 & 3 - Sensitivities and specificities by specific conditions	116
	Figures 4 & 5 - Sensitivities and specificities by aggregate	117
	Figure 6 - Drew network connectivity diagram	118
	Figure 7 - Diabetic retinopathy status based on digital image review	119
	Figure 8 - Diabetic retinopathy status based on in-person examination	120
	Figure 9 - Video-teleconference system at the hyperbaric chamber	121
	Figures 10 & 11 - Total patients by month and total cases	122
	Figure 12 - Total minutes for cases	123
	Figure 13 - Percent referred vs. logit prediction	124
Appendix F:	Response plots of survey items	125
Appendix G:	Description of three underserved sites - Hubert Humphrey Comprehensive Health Center, Nueva Maravilla, and King-Drew Medical Center	139

I. SUMMARY OF SALIENT RESULTS

Five projects investigated the *implementation* and *evaluation* of telemedicine standards and systems; three on image quality, one on eye care, and one on videoconferencing in a remote trauma center.

Image quality findings included (1) general agreement digital images are suitable for screening out pathology (specificity), contrasted with (2) wide disagreement on usefulness for diagnosing specific eye disease (sensitivity). For diabetic retinopathy, telemedicine use must match application purpose.

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. In one study the compliance rate for patients with diabetes who should receive annual eye exams improved from 54% to 83%, a proportional improvement of 54%.

Videoconferencing over public phone lines (ISDN) 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. Replication 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, and more than fifty additional investigators, research assistants, and clinical staff worked on these studies (listed in Appendix A). 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.

The Final Report is organized such that 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 D; figures have been placed in Appendix E. Two additional appendices not referenced in the Final Report that may be of interest to readers - a text description of three study sites and the USC-ABBC connectivity diagram - are also provided.]*

The most radical decision made by the editors involved moving certain tables, figures and diagrams 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. We believe 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 54% to 83%, 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.

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

Five studies:

- 1. Digital Gold**
- 2. Image Artifacts**
- 3. Screening the Underserved**
- 4. Remote ER**
- 5. Eye Care for Underserved**

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 ABBC network (see Appendix C) to 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 two of five listed services); (3) measure and evaluate applications impact; (4) evaluate approaches to safeguarding patient data; and (5) publicize 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.

The chart below shows the relationship between the individual projects and the scope of work for the overall project.

	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.

The NLM studies yielded or inspired products beyond the studies themselves. 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 dissipates over 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 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 that might define 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. Fifteen 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. Images were transferred over the internet employing encryption technology.

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 used 35 mm slides as the criterion gold standard. They investigated whether adequate levels of appreciation of diabetic retinopathy findings could be discerned at different resolution levels of digital images. 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 as measured by pixel density. 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

Digital images are inherently inferior to images collected on 35 mm film.

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 the images with software at four levels of digital resolution, replicating resolution levels commercially available in 1996 using digital cameras.

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 were on the images, e.g., neovascularization of the disc (NVD), neovascularization elsewhere (NVE), vitreous hemorrhage, cotton-wool spots, macular edema, presence of lipids, and microaneurysms; 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 indicated sensitivity was insufficient for identifying specific stages of retinopathy. However, sensitivity was sufficient for detecting the presence of retinopathy. 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.

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-mydratic, 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-mydratic 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.

96% of all digital images were unacceptable. Dilating pupils did improve quality.

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-mydratic, 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-mydratic 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 the 491 patients with diabetes in their sample 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-mydratic 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 to access patient data directly from a file server as though it was a directory on the hard drive. A hierarchical password assignment and 128 bit data encryption were utilized to maintain data security and maintain patient confidentiality. 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

83% of all images were judged to be sufficient compared to only 4% under the Image Artifact study.

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 known 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 hyperoxygenated 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 concerning the patient’s condition was high. 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 that better diagnoses would be 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 futile 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.

Video Conferencing worked great until the phone company changed the area code.

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 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.

Telemedicine works very well for overcoming access to care barriers.

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' suburban 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. This investigation conducted by the a team of ABBC investigators in collaboration with RAND.

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 USC 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. 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.

Underserved patients had been receiving sufficient general diabetes care but almost no eye care. Getting specialty care is the problem.

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. 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. This was in itself an important finding because it clearly supports the widespread supposition that telemedicine can help overcome barriers to care.

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. 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 convenient 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.

SUSTAINABILITY

Several studies have continued since the formal end of this project. The Tele-Remote ER Hyperbaric Program on Catalina has continued and will be expanded to include basic tele-triage between the local paramedics and clinical departments at the USC Keck School of Medicine Departments. An electronic link between the Avalon Hospital Medical Center and the remote community (population of 300) near the chamber, that would create a telemedicine primary care kiosk at the chamber, is in development. The willingness of the community to entertain a telemedicine solution is a direct result of the efforts and outcomes from this NLM study.

The two eye care screening programs continue to provide services to underserved populations in South and Central Los Angeles. Two additional sites which serve uninsured populations in East Los Angeles and Orange County have received non-mydratic fundoscopic cameras and are participating in studies replicating the eye care studies supported by the NLM project.

The USC-ABBC is exploring funding opportunities to further expand the Image Quality Studies in order to continue investigation of minimum standards and new models for appropriately evaluating digital images in healthcare.

IMPLICATIONS FOR FUTURE RESEARCH

The variation in findings 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.

Digital imaging, as a new medium, necessitates a new gold standard. Quality judged in terms of 35 mm film may simply not apply.

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 to 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.

Telemedicine works, especially for underserved areas, when systems using the correct technologies are properly applied.

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 from 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 to 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.

II. HISTORY OF PROJECT

Authored by Raymond P. Briggs, Ph. D.

BRIEF OVERVIEW

Following final contract negotiations with the NLM in August, 1996, USC-ABC proposed three study areas: (1) care for the socially isolated in North Hollywood; (2) care for the geographically isolated communities of Catalina; and (3) Teleophthalmology. The overarching study goal was to collect data on benefits, costs, and quality of care, and to use these data to investigate the sufficiency of telemedicine protocols and standards in different clinical and environmental contexts. Data were to be gathered by subcontractors at RAND under the hands-on supervision of Dr. Paul Lee, who shared a joint appointment at RAND and the USC Doheny Eye Institute.

ASSIGNMENT OF ROLES

Dr. Ron Smith, chairman of the USC Ophthalmology Department, and Dr. Fred George, Executive Director of USC-ABBC, served as co-PI's in negotiations with the NLM. At USC, Dr. George assumed overall responsibility for the Catalina Island project, and ultimately relied on Dr. Smith for support on the other two projects. Dr. Smith assigned Dr. Don Frambach, a retinal specialist, to work with Dr. Lee, who assumed responsibility for evaluation of the entire study with his RAND colleagues.

In August 1996, Raymond Briggs, Ph.D., Director of Research at Southern California College of Optometry (SCCO), was asked by Dr. Lee, with the concurrence of Drs. George and Smith, to participate in the NLM study. Dr. Briggs had experience developing teleophthalmology workstations and helping establish teleophthalmology research projects at UTMB, Galveston, the University of Houston, Tripler Army Medical Center in Hawaii, and SCCO in Fullerton. Dr. Briggs had carried out several image quality studies and developed prototype teleophthalmology instrumentation with a variety of strategic partners. Dr. Lee and Dr. Briggs, with support from Dr. Frambach, began meeting regularly to develop specific proposals for activities, instrumentation, and experimental evaluation.

IDENTIFYING THE PROJECT FOCUS

The focus was to deploy the ophthalmology group vis a vis instrumentation. It was believed necessary to identify a consultation model involving family medicine and ophthalmology in which telemedicine technology was a component. The monitoring of patients with diabetes became the obvious choice, since care of diabetics is one of the highest frequency activities

in family medicine, and untreated diabetic retinopathy is a leading cause of blindness. For research purposes, diabetics are a good population to study since they are a large population, and the onset and progression of diabetes varies significantly within the population. Diabetes is also associated with poverty and improper nutrition, and most diabetic retinopathy is treatable and nearly all blindness is preventable.

The link to telemedicine was demonstrated by the fact that patients with diabetes, referred by a family practice doctor to an ophthalmologist, often failed to make the follow-up appointment. Capturing information when the patient was with the family practice physician seemed critical since under our proposal every patient would automatically have the necessary ophthalmological consultation, presumably at greater convenience and reduced cost. By sending data to retinal specialists instead of general ophthalmologists the likelihood of enhancing quality of care was strengthened. Once the patient and family physician were both aware of the risk to patient eyesight, much could be done to help the patient avoid blindness. This focus on a diabetic consultation model drew the family medicine and ophthalmology activities in the NLM project closer together, while maintaining differences in needs and tasks.

IMPLEMENTATION ISSUES

From the general practice side, the technical telemedical problems were minimal, since the networking of workstations was well established and relational databases could be adapted to facilitate the gathering of data. Telemedical networks had already been implemented using these approaches. The problem was to identify a specific site and adapt the medical scheduling strategy of the site to accommodate telemedical consultations.

From the ophthalmology side, the technical problems were much more severe. A face-to-face evaluation of a diabetic for retinopathy involves not only the evaluation of case files, but also direct observation of the eye, especially the retina, using a variety of instruments, and the documentation and refinement of these observations through fundus photography. In teleophthalmology, the ophthalmologist was being asked to make *at least* a screening decision with limited photographic information alone. It wasn't clear that the retinal specialist would be given sufficient teleophthalmological information to make an informed decision. In the past, many ophthalmologists have declined to participate in telemedicine studies of any kind because of such informational inadequacies.

FOCUSING THE PROJECT

The technical problem was to provide sufficient image quality to the retinal specialist while making the image gathering process as simple as possible at the family practice site. The ideal technical diabetic retinopathy screening solution for the telemedical community was the nonmydriatic fundus camera, which gathered digital fundus snapshots while requiring very little from either the patient or a minimally trained technician to capture the images. The "compromise" solution for the retinal specialist was a set of high resolution stereo color

photographs, supported by dye-injected photos of the blood vessels, with the possibility of a real time virtual observation of the eye if necessary. It was clear that a single nonmydriatic digital image was unsatisfactory to the retinal specialist, and that the ideal teleophthalmic solution was both technically demanding and financially unfeasible; i.e., impossible due to time and cost constraints for this project.

It was possible to identify the image quality requirements necessary for any given teleophthalmic solution. We therefore proposed to *simultaneously* explore the image quality requirements necessary for any technical solution and describe the most effective short-term instrumentation deployment that could be used for diabetic retinopathy screening. We would deploy *something* so that we could evaluate the feasibility of diabetic retinopathy monitoring in later years of the study while further defining the requirements of a more satisfactory technical and clinical teleophthalmic solution.

The teleophthalmology and family practice components of the USC-ABC NLM project thus consisted of (1) evaluations of image quality in digital fundus images; (2) evaluations of fundus cameras and other instruments, currently available or in prototype form; and (3) the actual deployment and evaluation of diabetic retinopathy telescreening system, known to be less than ideal, and possibly totally unsatisfactory, but state of the art and cost effective at the time - a baseline for later rapid prototyping.

III. FIVE TELEMEDICINE STUDIES

THREE IMAGE QUALITY ASSESSMENT STUDIES

STUDY 1:

EVALUATION OF TELEMEDICINE IMAGE QUALITY FOR INTERPRETATION OF DIABETIC RETINOPATHY

Authored by:

Paul Lee, MD (1,2)

Dan Relles, PhD (1)

Christine S. Talicuran, MHA (3)

Dave Mann, MS (3)

Ray Briggs, PhD (4)

Don Frambach, MD (3)

Rod Zalunardo, EdD (3)

Catherine Jackson, PhD (1)

Jennifer Lim, MD (3)

Ronald E. Smith, MD (3)

Frederick George, MD (3)

(1) RAND, Health Sciences Program

(2) Duke University

(3) USC Keck School of Medicine

(4) Southern California College of Optometry

*Dr. Lee is recipient of a Lew Wasserman
Merit Award*

No proprietary interests.

INTRODUCTION

The use of telemedicine images to augment health care delivery has been of special interest to eye care providers. Preliminary studies have demonstrated both the potential of telemedicine and its current limitations.¹⁻⁵ Perhaps no use of telemedicine within eye care has been more explored than that of fundus evaluation for diabetic retinopathy. Several studies have focused on various aspects of the usability of such images and their appropriateness for use for monitoring diabetic retinopathy.⁴⁻⁹

The most common type of study has reported that accurate interpretation of stages of retinopathy is possible by a single observer. However, there has been no systematic study of the image quality necessary for perception of important clinical findings equivalent in accuracy to personal inspection or examination of photographs, which may be regarded as the "gold standard" for this purpose. Neither has any study provided complete technical specifications for image analysis, including monitor/display resolution, pixel density, color depth, image capture techniques and resolution, and, particularly, image handling and interpretation.

This is not to say that the use of telemedicine in eye care has a less rigorous foundation than that in other areas of medical care. Even within the two fields that have telemedicine image

standards - radiology and dermatology - such standards have often been arbitrarily determined and only subsequently tested for sufficiency.¹⁰⁻¹²

In the current study, we seek to address the issues surrounding technical image quality from a clinical perspective. Based on the findings of the Diabetic Retinopathy Study (DRS) and practice guidelines of the American Academy of Ophthalmology (AAO) and the American Diabetes Association, we used observations by trained and experienced physicians as our gold standard of comparison.¹⁰⁻¹² We used that standard to assess the ability of trained observers to accurately detect pertinent clinical pathologies present on a simulated telemedicine image. By seeking to identify specific pathologies underlying both the DRS and the Early Treatment of Diabetic Retinopathy Study (ETDRS), we identified accuracy at the most elemental level, independent of the aggregate grading or classification scheme used. An important advantage of this approach was that we did not require a full 7-field photo approach to classify diabetic eye disease, as, for example, employed by ETDRS criteria. Rather, we answered the more basic question of whether specific findings such as a microaneurysm or neovascularization can be detected accurately.

IMPLEMENTATION OF TECHNOLOGY

The photography was performed using a 45 degree fundus camera (Canon CR6-45NM, Lake Success, NY) coupled to Synemed modified digital back (Sony DXC-970MD, San Jose, CA) to capture a digital image with a resolution of 640 X 480 pixels. The digital images were processed with a digital image grabber (FlashPoint 3030 video card; Integral Technologies Indianapolis, IN) and saved on the hard drive of windows-95 based 166-MHz Intel Pentium (Santa Clara, CA) computer. The digital images were linked to patient data using Eyescape 1.1 software (Synemed, Benecia, CA). This program did not alter the images, and was used solely to link the patient data to the correct image. Standard telephone lines were used to transmit images to remote terminals. The digital information is reassembled and reconverted into a video image for display via a digital to analogue converter. The 640 X 480-pixel images were displayed on a computer screen with a 1478 X 640-pixel resolution capability. Thus, these images occupied only part of the screen. The images were not enhanced, or adjusted in any fashion.

An infrared-sensitive video camera was used to obtain the non-mydratic photographs. Use of infrared rays minimizes pupillary constriction. Photographs were taken in a dark room to enhance physiologic pupillary dilatation. A few minutes were allowed in between the photographs of the two eyes.

EVALUATION OF THE APPLICATION

We wanted to answer two specific research questions. First, could retina specialists accurately identify diabetic retinopathy findings at the highest possible image quality via telemedicine? Second, what was the effect on accuracy of using lower levels of image quality? Is there a "minimum" quality standard for accurate findings?

To answer these questions, we sought to create a realistic but tractable evaluation protocol for the formal testing of image interpretation. The protocol included the following eleven elements:

1. requirement that all observers be fellowship-trained retinal specialists in practice for at least five years after their fellowship; this minimized effects of variations in observer quality;
2. use of Adobe Photoshop 4.0 to digitize and handle all slide images through a standard algorithm using the program's "Levels" histogram; this helped factor out variations in image handling and transmission;
3. use of telemedicine images of the highest currently available resolution, even if not yet commercially available, to aid in judging telemedicine's potential;
4. sufficient numbers of images with the most important physical indicators of diabetic retinopathy, such as neovascularization of the disc (NVD), neovascularization elsewhere (NVE), vitreous hemorrhage, cotton-wool spots, macular edema, presence of lipids, and microaneurysms;
5. duplication of some images to allow for test-retest reliability;
6. greater emphasis on avoiding false-negative errors (i.e., not seeing an indicator when it is there) than for false positives, since patients with a negative finding would potentially not see an eye care provider for a year or longer;
7. use of telemedicine images reproduced only from 35-mm slide images that were themselves not subject to varying interpretation, because *the study was not designed to resolve disagreements that would occur even where gold-standard images were available*;
8. use of images representative of real-life conditions;
9. definition of a clinically meaningful difference in accuracy as that between a 90% probability of finding an indicator versus an 80% probability;
10. inclusion of images of other common retinal diseases and of normal fundi, since patients with diabetes may also have other retinal diseases or normal fundi; and
11. as stated above, testing at the greatest level of clinical detail possible, so that the fullest extent of telemedicine image analysis capability would be assessed.

A. DETERMINING GOLD STANDARD INTERPRETATIONS OF IMAGES FROM 35MM SLIDES

We first determined the gold-standard image interpretation against which the telemedicine image interpretations would be compared. From clinic files of the Doheny Eye Institute maintained by study investigators, 278 35-mm slides of the posterior pole and fundus were selected to demonstrate a range of diabetes-related ophthalmic findings and common posterior findings. These slides were digitized at the highest possible resolution (2400 x 1800 pixels).

The corresponding medical charts were reviewed to determine the gold standard clinical findings. To test the feasibility of the project design, we scanned the slides at the highest pixel density currently available through telemedicine (1600 x 1200 pixels) and asked two retina specialists to review them and list any physical findings. The review revealed the two specialists (and thus three including the charting physician) agreed upon the clinical findings in more than 200 cases thereby

supporting project feasibility. This demonstration confirmed the findings of the earlier studies with only one observer.^{1,2}

Further review was undertaken when either of the following events occurred:

1. The two digital-image reviewers disagreed with each other, but one was in agreement with the original 35 mm slide findings. In this case, one of the study retina specialists reviewed the 35-mm slide to confirm the clinical findings based on the slide.
2. The two digital-image reviewers both disagreed with the original 35 mm slide interpretation. These disagreements were perhaps the most important to understand since these were the ones most likely to result from telemedicine faults. In these cases, the two independent retina specialists examined the 35-mm slides. The image was retained if the interpretations of the 35 mm slide were identical. If they were not, the slide was not used because this reflected clinical disagreement that would occur regardless of the setting or method of patient evaluation. Thus, in all cases, the gold standard interpretation of an image was based on concurrence of three reviewers over the indicators on the original 35 mm slide.

B. ORGANIZATION OF CLINICAL FINDINGS AND REVIEWER INTERFACE

To facilitate comparisons of interpretations by the retina specialists reviewing the digitized images, the pertinent clinical findings from fundus photos were organized into 21 specific categories. These are detailed in Table 1, Clinical Findings Assessed (Appendix D), together with their larger clinical groupings for subsequent group analyses. This level of detail allowed for subsequent aggregation indicating the clinical stages of diabetic retinopathy, so that we could explicitly examine whether findings were accurate enough to enable observers to appropriately stage the severity of retinopathy.

We identified which one or more of the above findings were present in each of the 278 slides. 27% of the images were of normal fundi. 32% showed a single indicator of retinopathy. Multiple indicators occurred in about 40% of the slides, with 19% having 2 indicators, 14% with 3, and 8% with 4 or more. As noted above, the scanned slides were initially scanned at 3726 x 2889 pixels (resolution of 35 mm color slides converted to pixel form). The resulting images were then presented at 4 different levels of image quality at a standard resolution of 72 dots per inch and 24 bit color:

- 1280 x 1024
- 1024 x 768
- 800 x 600
- 640 x 480

These resolutions were chosen to cover a range from the best images now technically feasible with telemedicine through the best commercial products currently available (800 x 600) at the start of the project in 1996 to a more economical alternative.

Images were viewed on monitors with approximately 16 inches of viewable diagonal area, with at least 0.26 mm dot pitch. Screen outputs were standardized using standard screen testing.

As noted above, the scanned slides were initially scanned at 2400 x 1800 pixels. The resulting images were then presented at 4 different levels of image quality at a standard resolution of 72 dots per inch and 24 bit color:

- 1600 x 1200 pixels
- 1024 x 768
- 800 x 600; and
- 640 x 480.

These resolutions were chosen to cover a range from the best images now technically feasible with telemedicine through the best commercial products currently available (800 x 600) to a more economical alternative. Images were viewed on monitors with approximately 16 inches of viewable diagonal area, with at least 0.26 mm dot pitch. Screen outputs were standardized using standard screen testing.

The study retina specialist reviewers were asked to evaluate 60 images and to note all findings that they could identify on each image. They could take as much time as they wished for each image. Figure 1 (Appendix E) presents an example of the image and the interface for data entry used by the reviewers.

C. POWER CALCULATIONS AND SAMPLE SIZE

In order to answer questions about diabetic retinopathy recognition, we needed to ensure we had enough images to infer statistically significant differences in accuracy in the observer's viewing of critical diabetes indicators across image resolution levels. Because of our interest in being able to detect the most sight-threatening indicators consistent with high-risk disease, we were particularly concerned about including enough images with NVD, NVE, and vitreous hemorrhage.

Furthermore, because cotton-wool spots represent important non-proliferative (early-stage) findings, we wanted to ensure sufficient power to detect meaningful differences in the ability to also identify them. However, we also wanted some ability to detect differences for eye conditions other than diabetic retinopathy.

As noted above, many of the photographic images had multiple findings per slide. We determined that by sampling at random the following number of slides with specific conditions, we would be able to cover a wide range of other conditions that showed up as secondary pathologies (e.g., dot-blot hemorrhage).

CONDITION	N	CONDITION	N
cotton wool spots	6	disciform scars	5
vitreous hemorrhage	7	flame hemorrhage	3
NVE	8	Pigment in macula	4
NVD	8	macular edema	3
brvo / crvo	5	Other	3
cnvm	5	Normal	5
Subretinal hemorrhage	5		

We ultimately recruited 15 retina specialists to view the images. This gave us a minimum of 45 viewings of findings such as flame hemorrhages (15 x 3), and over 120 viewings of the critical neovascularization findings (15 x 8). The number of observations could be larger than these products because, for example, an image drawn from the 8 for NVE could show other pathologies. A sample size of 45 was determined to be sufficient to detect differences between 80% and 90% (one-tailed test) at a 95% level of significance.

D. ORDER OF IMAGE TESTS FOR REVIEWERS

Each of the retinal specialists participating in the study saw a unique presentation order of images for interpretation. Since an important goal of the study was to determine the relative accuracy at different levels of image quality, we included the same image at different quality levels for a subsample of the presentations. To minimize the likelihood of bias from repeat viewings of the same image (albeit at different image quality levels), we separated the image presentations by at least 2 slides and always presented the lower-resolution image first.

In addition, because we wished to assess test-retest reliability, each participant viewed 5 to 7 repeat images at the same quality level presented. Again, slides were selected at random for this step, and we made sure that no identical slides were adjacent in their showing.

E. PRACTICE AND EVALUATION

At the time of registration for the study, all observers were instructed as to the purpose of the testing and the opportunity we gave for practice evaluations at the time of participation. Study staff was present for practice images and the first two images of the evaluation to review the steps required for completing each image assessment. Physicians were not disturbed, though staff was available for questions, until completion of the testing at that sitting.

ANALYSIS AND RESULTS

Participating specialists entered their interpretations online into a spreadsheet. The spreadsheet results provided the basis of the data analyses. Because the results were entered as specific clinical findings, analyses of accuracy at four image resolution levels could be conducted at the following levels of detail:

1. identifying each of the 21 specific clinical findings (the greatest level of detail);
2. for the diabetes images, aggregating the specific findings into widely used clinical categories (such as proliferative retinopathy or background retinopathy);
3. for the diabetes images, aggregating into either "no retinopathy" or "any degree of retinopathy" (to determine, if telemedicine cannot support specific findings, whether basic screening is feasible);
4. aggregating each of the 4 larger categories in Table 1 (plus normal, as a fifth);
5. identifying normal fundi as opposed to those in which any findings are present (to detect if any referral is warranted).

A. RESULTS, SPECIFIC INDICATORS

Table 2 (Appendix D) presents interpretation accuracies at each of the 4 image resolution levels for some of the key specific indicators assessed in the study. Accuracy is quantified by two measures: (1) sensitivity, i.e., the probability of identifying a condition which is present, and (2) specificity, i.e., the probability of not identifying a condition which is absent. The results raise important considerations about the use of telemedicine images for assessing diabetic retinopathy, both favorable and unfavorable.

B. FINDINGS

First, sensitivities for detecting specific indicators of retinopathy are not sufficiently high to recommend their routine clinical use at tested levels of image resolution. The sensitivities for detecting vitreous hemorrhage and cotton-wool spots are indeed above 75 percent for all image resolution levels, and those for dot-blot hemorrhages and lipids run from about 70 percent upwards. However, the sensitivities for NVD, NVE, and microaneurysms are between 40 and 70 percent, and those for flame hemorrhages are below 40 percent. Thus, the ability to detect the specific indicators associated with vision loss in diabetes is problematic.

Second, with respect to other pathologies, laser burns and scars are readily detected, but the ability to detect macular edema is only 33% at the highest resolution level, reflecting the lack of stereo in telemedicine images. As for age-related macular degeneration, drusen and subretinal blood are detected with sensitivities of 50 to 90 percent. Sensitivities for pigment changes and disciform scars drop below 40 percent at some resolutions and those for CNVMs is below 10 percent at all resolutions. With respect to other conditions, sensitivities for branch vein occlusions are also all below 10 percent. Thus, ability to detect most nondiabetic retinopathies is also insufficient for routine clinical use.

The sensitivity profiles by image quality of the specific clinical findings were marked by two general patterns, as shown in Figures 2 and 3 (Appendix E). The vast majority of findings, such as dot-blot hemorrhages, cotton wool spots, NVD, pigment, and subretinal hemorrhage, showed a downward trend in which the lower image resolution levels were less accurate than the two highest quality levels. Other findings, such as disciform scars, flame hemorrhages, and lipid demonstrated similar

sensitivity at lower levels of resolution. Only microaneurysms were significantly more likely to be detected at one of the two lower resolution levels (level 3) than at the higher resolution levels. Table 3 (Appendix D), which shows the statistical significance of the difference in sensitivities at the two highest and two lowest levels of quality, attempts to quantify these effects.

Finally, specificities are generally high--above 90% at all resolution levels for most indicators. This reflects favorably on telemedicine's diagnostic potential but is less relevant than the lower sensitivity ratings when a premium is placed on finding a retinopathy for fear that if missed it will not be identified for some time.

Thus, three findings are apparent from the results. First, specificities are generally high--above 90% at all resolution levels for most indicators. Second, use of the higher resolution levels generally results in higher levels of sensitivity. Third, sensitivities for detecting specific findings of retinopathy are not sufficiently high to recommend their routine clinical use at tested levels of image resolution.

C. AGGREGATED FINDINGS

We aggregated the specific problems in the preceding tables into DRS staging categories (see Table 4, Appendix D). For example, background diabetic retinopathy was judged as accurately identified if lipids and/or microaneurysms had been identified. An erroneous identification was charged (for calculating specificity) if problems were identified that did not meet that condition.

On aggregation, sensitivity improved substantially, as seen in Table 4 (Appendix D) and Figures 4 and 5 (Appendix E). For each of the DRS retinopathy stages, sensitivity levels higher than 80% were achieved at one or more image resolution levels. Thus, relative to the analysis of specific indicators that make up each stage, telemedicine images would be more likely to support identification of DRS retinopathy stages. However, the specificities of identifying these stages were somewhat less than those for the specific indicators.

When data were further aggregated to determine whether, in patients with diabetes, any diabetic retinopathy could be detected, sensitivities at all image resolution levels exceeded 80% ("Group A Conditions" in the table; see Table 1 for group definitions). Again, specificities were substantially lower for the overall question of diabetic retinopathy or not (in the neighborhood of 50%) than for specific indicators.

Identification of other aggregated categories of pathologies could not be made with high sensitivity. The worst numbers were for "other retinal diseases" (Group D), where the sensitivities fell between 25 and 50%. The final aggregated category comprises all specific problems or combinations thereof warranting referral for further examination. Here, sensitivities ranged from 67 to 74%, with specificities under 50%. Thus, additional investigation and development appear to be required before using telemedicine to screen for any retinal disorder warranting subsequent eye exams.

We also examined the test-retest reliability of image interpretation. As noted in the methods, the images were separated by at least 2 other images to minimize the chances of recall bias. Not surprisingly, the reliability results exceeded 90% for specificity for virtually all specific findings, except for dot-blot hemorrhage (88%), microaneurysms (85%), and pigmentary changes (81%). Test-retest reliability from a sensitivity standpoint also exceeded 90% for all specific findings except for flame hemorrhage (80%), laser burns (83%), lipid (88%), pigmentary changes (85%), and pigmentary changes (43%).

D. DISCUSSION

The use of telemedicine for interpreting fundus images of diabetic patients is of great interest. Because 50% or more of these patients do not receive the annual recommended eye exam¹, telemedicine has been proposed as a key advance in improving their care. As such, several investigators have sought to answer two critical issues: 1) can fewer than the 7 photos required for ETDRS staging suffice for the detection or diagnosis of diabetic retinopathy, and 2) what is the performance of telemedicine images relative to that of photos or live examiners.²⁻⁷ Prior studies of the second issue have either incompletely specified the technical standards used to capture, process, or display the image for interpretation, or they have reported a single observer's interpretations of previously seen images. In this study, we have sought to remedy these problems and thus answer the second question with more confidence. *Our major finding is that, at the technology levels used in this study, telemedicine applications for diabetic retinopathy will need to be carefully considered and designed. In particular, attention must be paid to the application's purpose.*

For example, retina specialists could identify the DRS stage of retinopathy in 67 to 85% of scanned video images made from still photos. They could tell that some kind of retinopathy was present 83% to 89% of the time. While this may seem quite disconcerting, we should remember that agreement between observers and photographic interpretation in the DRS and ETDRS studies were in the 90% range as well.

Thus, it appears that current levels of achievable image capture and presentation may aid in cost-effective screening by detecting 85% or more of those with retinopathy. However, we would recommend that screening include more than just image capture, since sensitivities of 90% or less are not really sufficient if a method is to be used as a stand-alone test.

While telemedicine would appear to have a role in screening, the current study does not support its use to stage or to otherwise manage patients absent from the care provided by an ophthalmologist or other trained provider. Retinal specialists had limited ability to detect specific clinical problems such as NVD and NVE from scanned video images. The study results clearly indicate that adjusting follow-up intervals based on the findings of the image capture is subject to significant error. And, detecting the presence of diabetic macular edema, especially that of clinical

significance, was beyond the capability of the current system (which does not permit stereo viewing). While many eye care providers may not follow the recommendation of the ETDRS to treat clinically significant diabetic macular edema prior to the onset of vision loss, it is vital to remember that over 40% of the vision loss from diabetes occurs through diabetic macular edema. Knowing the ability of any telemedicine system to detect such findings thus remains important to evaluating the performance of telemedicine systems relative to a gold standard.

Purpose must also be taken into account in drawing implications from the findings related to resolution. For screening purposes, lower resolution imaging performs similarly to higher resolution, as seen in Figure 4 (Appendix E) and Table 4 (Appendix D). Thus, use of existing video technology at 800 x 600-pixel resolution does not appear to significantly compromise the accuracy of generic findings such as identifying whether any retinopathy is present.

However, the study results do show a clear and significant trend towards greater sensitivity at higher resolution levels when identifying specific clinical problems. It is clear that use of higher image resolution levels will be needed to advance the use of telemedicine to levels of care and management beyond screening.

This study does not address the issue of how many photos are needed for accurate diagnosis of the true state of the eye. Instead, it is meant to determine whether an observer can accurately detect the presence of specific clinical problems at specified image resolution levels, regardless of which of any one of 3, 5, or 7 fields is presented. The findings are usable and useful regardless of which staging system is used, the DRS or ETDRS. It is important to note that the results of this study do not show the high accuracy rates of over 95% reported in other studies comparing telemedicine images to clinical exams or 35 mm slides. We did not find such accuracy rates even though the reported image quality levels used in the other studies were equivalent to the middle levels used here.

Other studies may have yielded more favorable results because the same observer made the repeated observations at different image quality levels. And in fact, in our own test-retest analyses, we found higher sensitivities. In this study, *we explicitly used multiple observers to recreate the usability and reproducibility of a telemedicine system running in the community using the best possible resources and providers available there.*

It is also important to understand why the actual field results demonstrated sensitivities that were less than might initially be expected at the 1600 x 1200 level of resolution. While the images were selected based on agreement among at least 2 of 3 retina specialists, the study explicitly included images that resulted in disagreement between the image and the original gold standard 35 mm slide. Since 10% of the included images in the study sample had some disagreement initially, the level of performance of the reviewer specialists is commensurate with that of the original

"gold standard" specialists. We used only trained, experienced retinal observers because we wanted to minimize variation based on observer skills.

In addition, the study demonstrated important test-retest reliability performance across 15 different reviewers. At the highest level of detail of determining the presence (sensitivity) or absence (specificity) of detailed clinical findings such as drusen, NVD, or NVE, test-retest reliability exceeded 90% for both sensitivity and specificity. We explicitly separated reliability for sensitivity and specificity so that the large number of cases where the findings are not present would not overwhelm the reliability parameters for sensitivity. Thus, at the image levels tested in this study, there was a high degree of test/retest reliability.

What do our results imply for the use of tele-ophthalmology for fundus assessment in patients with diabetes? First, additional studies need to be conducted to see if the results of this study are indeed representative. Second, given verification, it would behoove all of us to modify or limit ongoing telemedicine efforts to reflect these findings. Proponents of an expanded role for telemedicine would clearly have the burden of establishing the validity of their techniques for detecting specific pathologies in the retina. Third, the effectiveness and tradeoffs inherent in moving towards telemedicine screening or care need to be assessed. The benefit of telemedicine in reaching those who would otherwise have no eye exam must be weighed against the harm suffered by those whose conditions are misclassified because telemedicine replaces their current care patterns.

References

1. Flowers CW, Baker RS, Khanna S, et al. Teleophthalmology: rationale, current issues, future directions. *Telemed J* 1997; 3: 43-52.
2. Blackwell NA, Kelly GJ, Lenton LM. Telemedicine ophthalmology consultation in remote Queensland. *Med J Aust* 1997; 167: 583-86.
3. Li HK. Telemedicine and ophthalmology. *Surv Ophthalmol* 1999; 44: 61-72.
4. Briggs R, Bailey JE, Eddy C, Sun I. A methodologic issue for ophthalmic telemedicine: image quality and its effect on diagnostic accuracy and confidence. *J Am Optom Assoc* 1998; 69: 601-05.
5. Aiello LM, Bursell SE, Cavallerano J, et al. Joslin vision network validation study: pilot image stabilization phase. *J Am Optom Assoc* 1998; 69: 699-710.
6. Lamminen J, Salminen L, Uusitalo H. Teleconsultations between general practitioners and ophthalmologists in Finland. *J Telemed Telecare* 1999; 5: 118-21.
7. Taylor R, Lovelock L, Tunbridge WM, et al. Comparison of non-mydratic retinal photography with ophthalmoscopy in 2159 patients: mobile retinal camera study. *Br Med J* 1990; 301: 1243-47.
8. Williams R, Nussey S, Humphry R, Thompson G. Assessment of non-mydratic fundus photography in detection of diabetic retinopathy. *Br Med J*. 1986; 293: 1140-42.

9. de Sonnaville JJJ, van der Feltz van der Sloot D, Ernst L, Wijkle D, Heine RJ. Retinopathy screening in type 2 diabetes: reliability of wide angle fundus photography. *Diabetic Medicine* 1995; 13: 482-86.
10. Goldberg MA, Rosenthal DI, Chew FS, et al. New high-resolution teleradiology system: prospective study of diagnostic accuracy in 685 transmitted clinical cases. *Radiology* 1993; 186: 429-34.
11. Leshner JL, Davis LS, Gourdin FW, English D, Thompson WO. Telemedicine evaluation of cutaneous diseases: a blinded comparative study. *J Am Acad Dermatol* 1998; 38: 27-31.
12. Lowitt MH, Kessler II, Kauffman CL, et al. Teledermatology and in-person examinations: a comparison of patient and physician perceptions and diagnostic agreement. *Arch Dermatol* 1998; 134: 471-76.

STUDY 2:

ARTIFACTS IN DIGITAL NON-MYDRIATIC FUNDUS PHOTOGRAPHS OF DIABETIC PATIENTS: A PILOT STUDY

Authored by Neelakshi Bhagat, MD, Laurie Labree, MS, and Jennifer I. Lim, MD
USC Keck School of Medicine

INTRODUCTION

An adjunct image quality assessment study was conducted by a group of USC Department of Ophthalmology researchers using a subsample of images collected under the NLM funded USC-ABBC Telemedicine study. The description of that study is included.

Diabetic retinopathy is one of the leading causes of blindness in the United States.¹ Diabetic retinopathy is noted in 50% of patients after 7 years of diagnosis of the disease. Some patients, however, develop severe disease in much earlier years. Thus, screening for diabetic retinopathy is very important.

Thus far, 35-mm transparencies have been the gold standard for fundus photography. Use of digital fundus imaging has become quite popular. Recently, non-mydratiac fundus photography has been advocated as a possible screening tool for diabetes, drusen, and macular degeneration.^{2,3}

Non-mydratiac fundus photography (non-digital) is reported to have high sensitivity and specificity for the diagnosis of vision threatening retinopathy.^{4,5} Williams et.al.⁴ reported the predicted positive accuracy rate of 84% and the predicted negative accuracy rate of 99.5%. The sensitivity to proliferative retinopathy was reported to be higher than the clinical fundus examination of diabetologists.⁶ Taylor et.al.⁷ found it as effective as direct ophthalmoscopy in detecting retinal neovascularization. Unsatisfactory non-mydratiac fundus photographs, however, were reported only in 10% of patients due to miotic pupils and lens opacities.^{8,9}

Artifacts are noted in as many as 48% of fundus photographs (non-digital) taken through undilated pupils versus only 14% in dilated pupils.² These may be due to miotic pupils or hazy media-cataract or inflammation. The purpose of our pilot study was to evaluate the digital non-mydratiac fundus photographs used in a screening program for diabetic retinopathy in a community clinic for 1) the completeness of the image, 2) the types and frequency of artifacts, 3) the incidence of all artifacts, and 4) the effect of these artifacts on the acceptability of the images for diagnostic purposes.

IMPLEMENTATION OF THE TECHNOLOGY

Non-mydratiac fundus digital photographs were taken of each eye of 33 consecutive diabetic patients in a community clinic. The photography was performed using a 45 degree fundus camera (Canon CR6-45NM, Lake Success, NY) coupled to Synemed modified digital back

(Sony DXC-970MD, San Jose, CA) to capture a digital image with a resolution of 640 X 480 pixels. The digital images were processed with a digital image grabber (FlashPoint 3030 video card; Integral Technologies Indianapolis, IN) and saved on the hard drive of a Windows 95, 166-MHz Intel Pentium (Santa Clara, CA) computer. The digital images were linked to patient data using Eyescape 1.1 software (Synemed, Benecia, CA). This program did not alter the images, and was used solely to link the patient data to the correct image. Standard telephone lines were used to transmit images to remote terminals. The digital information was reassembled and reconverted into a video image for display via a digital to analogue converter. The 640 X 480-pixel images were displayed on a computer screen with a 1478 X 640-pixel resolution capability. Thus, these images occupied only part of the screen. The images were not enhanced, or adjusted in any fashion.

An infrared-sensitive video camera was used to obtain the non-mydratric photographs. Use of infrared rays minimizes pupillary constriction. Photographs were taken in a dark room to enhance physiologic pupillary dilatation. A few minutes were allowed in between the photographs of the two eyes. The goal was to get a 45 degree image to include the temporal arcades, optic nerve, as well as areas 1 disc diameter nasal to the optic nerve and temporal to the macula.

EVALUATION OF THE APPLICATION

The photographs were evaluated by the retina division at Doheny Eye Institute, i.e., a retina fellow (NB) and a vitreo-retinal specialist (JL). The evaluators were unfamiliar with the patients and had no knowledge of the duration of diabetes. Each image was analyzed for:

- 1) the degree of completeness; i.e., whether the optic nerve, area 1 disc diameter nasal to the optic disc, superior and inferior arcades, and macula were all photographed;
- 2) the size, location, type and incidence of artifacts - white dust, central dark, light reflex, and peripheral crescent;
- 3) area of the fundus photo which could not be evaluated because it was missing or masked by an artifact, and
- 4) the effect of these artifacts on the acceptability of the images for diagnostic purposes.

The artifacts were noted in regards to their number, size, location, type and extent. Inability to evaluate the optic nerve, fovea and macula was also documented for each artifact. A correlation was sought for the extent and location of artifact with the acceptability of the photograph.

ANALYSIS AND RESULTS

A total of 108 digital non-mydratric fundus photos were taken of 33 patients. There were an average of 1.6 +/- 0.6 images of each eye, ranging from 1-3 images per eye with a median of 2 images.

Only 1 of 108 photos was graded by both examiners as containing all the components necessary to screen for diabetic retinopathy. 95% of the photos were missing some part of the superior arcade or the 1 disc diameter area of retina nasal to the optic nerve.

Table 5, Artifacts Summary (Appendix D), depicts the types, incidence, and the location of artifacts noted. These were either peripheral crescent artifacts, white dust artifacts on the lens, light reflex or dark central shadows.

More than 95% of the photos had some type of artifact. Artifacts were noted by observer 1 and/or observer 2 as follows: central dark in 63% / 81%, large white dust in 31% / 29%, small white dust 48% / 80%, light reflex in 18% / 20%, and crescent in 70% / 34% of eyes. Artifacts impaired evaluation of optic nerve in 50%, macula in 66%, superior arcade in 58%, inferior arcade in 18% and fovea in 69% of photographs.

White dust or crescent artifacts did not hinder analysis of the picture. Central artifacts caused inability to evaluate the fovea or central macula for diabetic changes in almost 100% of the cases. The central artifact was present in over 60% of the photos. More than 96% of the photographs were graded as unacceptable for screening of diabetic retinopathy by both independent observers due to masking by the artifacts.

Table 5 also shows the photograph grading for the 108 photographs. Table 6 (Appendix D) defines the grading system. The photographs were graded for the photographic quality as previously reported by other authors^{4,9}. Only grades 1 and 2 were good enough to be used for screening purposes. These comprised 46% of the cases evaluated by observer 1 and 21% by observer 2. Grades 3, 4 and 5 were unacceptable. These were 55 % of the photographs by observer 1, and 74% by observer 2.

A. DISCUSSION

The two examiners in this study were a retina fellow and a vitreo-retinal specialist, who had extensive training in ophthalmoscopy and fundus photography. There were only minor differences in their assessment.

Photographs of acceptable quality were obtained only in 1% of 108 images. An average of 1.6 photos were used for each eye. Various prior reports have reported good quality of non-mydratic fundus photographs. Our study is in conflict with their findings.²

No prior study has addressed the issue of artifacts. Over 50% of the photographs could not be evaluated because of artifacts. This is consistent with 48% reported by Klein et.al.²

The crescent artifacts were caused by the pupillary edge or the rim of the camera. The crescent edge artifacts did not cause a reduced ability to evaluate the macula, but did cause partial obscuration of the optic disc with an edge artifact. This was found more often in the eye that was imaged second. This may be reduced by waiting for a little more time in between the photographs to allow for the recovery of the pupil.

The multiple white dust artifacts, obviously can be avoided by keeping the lens system free of dust particles. These, however, did not usually hinder the observer's ability to evaluate diabetic retinopathy.

In contrast, the central dark artifacts markedly prevented an optimal evaluation of the macula or optic disc. These central artifacts were due to problems with image focus, miotic pupils, cataracts or other media opacities. These may be also correlated to the learning curve of the photographer.

From the above analyses of the data it is evident that the non-mydratic digital fundus photographs are associated with a high incidence of artifacts. Central artifacts are the only ones that are clinically significant which render the pictures unacceptable.

Better quality and fewer artifacts may be achieved if the pupils are dilated. Dilated fundus photos should be used if the photographer notes unavoidable dark and light central artifacts covering the optic nerve and the macula.

B. CONCLUSIONS

Digital fundus imaging is a great tool for remote areas where community hospitals and family practice clinics do not have access to ophthalmologists. Digital images can be transferred long distances instantly via telecommunications and evaluated without loss of quality. Thus, teleophthalmology wherein digital imaging is transmitted via phone lines to a specialist for consultation may be a cost effective way to detect and follow diabetic retinopathy in such areas.

In our study, most of the photos were unacceptable due to technical reasons, i.e., a large proportion of fundus images were judged incomplete. Since the superior arcade and retina 1 disc diameter nasal to the disc was not included in most of the photos, one can miss proliferative changes in these areas and falsely recommend a longer follow-up period. This issue can be resolved by making the photographers aware of the critical areas that should be photographed. One may still miss 8% to 15% of diabetic retinopathy that occurs outside the arcades in the periphery.^{2,10}

Also, from the analyses of our data, it is evident that the non-mydratic digital fundus photographs are associated with a high incidence of artifacts, approximately 50%. Most of the central artifacts were on the macula and one can miss diagnosing macular edema and proliferative changes in these areas. These central artifacts are due to miotic pupils and suggest that dilated pupils may avoid this artifact.

Improved quality of images is needed so that the retina specialists can be confident in screening diabetics with nonmydratic digital photographs. Dilated digital fundus photographs may do a better job in eliminating artifacts and improving the quality of the photos. This may lead to improved acceptability of such a tool in the field of ophthalmology.

Our study is a prototype for future settings where these digital non-mydratiac fundus imaging systems will be used in community clinics where ophthalmologists and professional fundus photographers are not available. As shown here, at this time non-mydratiac fundus photography cannot replace the diabetic retinopathy screening examination through dilated pupils, clinically or using the 7-field, 35-mm film fundus images. Although, non-mydratiac digital fundus imaging for detection of diabetic retinopathy has a high specificity rate, the sensitivity rate is low.¹¹

We believe that on-line digitization offers many advantages in the acquisition, storage, retrieval, transfer and analysis of fundus images. Although the technology is still in infancy, future advances will provide higher resolution and fewer artifacts to improve the quality of non-mydratiac fundus images. Good quality digital non-mydratiac fundus photography without artifacts certainly has an important role in screening diabetic patients in areas where ophthalmologists are not available.

References

1. National society to prevent blindness. Vision problems in the US; Data analysis: Definitions, Data sources, Detailed data tables, Interpretation. New York: National Society to prevent Blindness, 1980.
2. Klein R, Klein BEK, Neider MW, Hubbard LD, Meuer SM, Brothers RJ. Diabetic retinopathy as detected using ophthalmoscopy, a nonmydratiac camera and a standard fundus camera. *Ophthalmol* 92:485-491, 1985.
3. Klein R, Meuer SM, Moss SE, Klein BEK. Detection of drusen and early signs of age-related maculopathy using a nonmydratiac camera and a standard fundus camera. *Ophthalmol* 1992; 99:1686-1692.
4. Williams R, Nussey S, Humphry R, Thompson G. Assessment of non-mydratiac fundus photography in detection of diabetic retinopathy. *BMJ* 1986; 293: 1140-2.
5. Buxton MJ, Sculpher MJ, Ferguson BA, Humphreys JE, Altman DJ, Spiegelhalter DJ et al. Screening for treatable diabetic retinopathy: a comparison of different methods. *Diabetic Med* 1991; 8: 371-7.
6. Sussman ES, Tsiaras WG, Soper KA. Diagnosis of diabetic eye disease. *JAMA* 1982;247:3231-4.
7. Taylor R, Lovelock L, Tunbridge WMG, Alberti KGMM, Brackenridge RG, Stephenson P et al. Comparison of non-mydratiac retinal photography with ophthalmoscopy in 2159 patients: mobile retinal camera study. *BMJ* 1990; 301: 1243-7.
8. Barrie T, MacCuish AC. Assessment of non-mydratiac fundus photography in detection of dibetic retinopathy. *BMJ* 1986; 293:15;1304-5.
9. Mohan R, Kohner EM, Aldington SJ, Nijhar I, Mohan V, Mather HN. Evaluation of a nonmydratiac camera in Indian and European diabetic patients. *BJO* 1988; 72: 841-845.
10. Feman SS, Leonard-Martin TC, Semchyshyn TM. The topographic distribution of the first sites of diabetic retinal neovascularization. *Am J Oph* 1998;125704-706.
11. Lim JI, LaBree L, Nichols T, Cardenas I. A comparison of digital nonmydratiac fundus imaging with standard 35-mm slides for diabetic retinopathy. Forthcoming, *Ophthalmology* 2000.

STUDY 3:

THE UTILITY OF TELEMEDICINE FOR DIABETIC RETINOPATHY SCREENING IN UNDERSERVED POPULATIONS

Authored by Charles Flowers, MD
Charles Drew School of Medicine

INTRODUCTION

It has been well documented that members of the lower socioeconomic strata of our society face significant barriers to receiving basic health care.¹⁻⁵ Members of this population subgroup suffer from higher rates of effective life loss and poorer outcomes from medical treatment, primarily because of lack of access to appropriate health care.¹⁻⁶ The problem of inadequate access to medical care is magnified to an even greater extent when it comes to specialty care. Individuals belonging to this medically underserved group, as they are commonly referred to, tend to be concentrated in both inner city urban and rural areas where the physician to population ratios are the lowest, specialty care is extremely limited, and health care facilities suffer from overcrowding, inadequate infrastructure and grossly inefficient organizational structures.^{1, 2, 4-8}

Eye care has been one of the specialty services frequently identified as poorly allocated among the medically underserved.⁹⁻¹³ Several large epidemiologic studies have shown high prevalence rates of preventable and treatable blindness and visual impairment among lower income inner-city and rural populations.¹⁰⁻¹³ Tielsch and associates,¹³ for example, conducted a population-based survey of blindness and visual impairment among the urban population of East Baltimore Maryland and found a significantly higher prevalence of blindness and visual impairment among lower socioeconomic groups. In a follow up study of bilateral blindness among this same study population, Sommer and associates¹⁰ found that in nearly half of the individuals suffering from bilateral blindness, the blindness was either preventable or treatable.

Research has shown that preventing blindness is far less costly than providing support services for the visually impaired.¹⁴⁻¹⁷ 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 and could save the federal government as much as \$109 million each year in averted disability payments.¹⁷

Diabetic retinopathy is the leading cause of new blindness among Americans 20-74 years of age.¹⁸ Yet, it is estimated that timely measurement of diabetic retinopathy can decrease blindness and visual impairment by 90%.¹⁹ Screening has been demonstrated to be of great potential benefit for this condition.²⁰ Annual dilated ophthalmic examination of diabetics at risk for ocular complications has been shown to be a highly cost effective means of identifying treatable diabetic retinopathy.²¹ However, national studies indicate only 50% of at risk diabetics patients undergo annual dilated examination as suggested by American Diabetes Association guidelines.²² Preventive ophthalmic surveillance of high-risk diabetic

individuals is even worse in urban under served communities. In a recent study conducted to assess the clinical and sociodemographic characteristics of diabetic patients newly presenting to an inner city public hospital eye clinic, Baker and colleagues²³ demonstrated that 62% of the diabetics presenting for the first time had clinically apparent ophthalmic disease, 40% already had advanced ocular disease including 6.8% of the sample who were legally blind on presentation.

Optimal clinical outcomes and maximum cost effectiveness could be achieved if 100% of at risk diabetics underwent preliminary ophthalmic screening at the point of medical care and only those patients truly at risk for ocular complications were referred for detailed ophthalmic examination. On-site photo documentation in the primary care setting, with subsequent evaluation of the acquired retinal image by an ophthalmic specialists is a strategy that has the potential of maximizing patient accessibility to appropriate ophthalmic surveillance, producing objective documentation to facilitate serial comparison, and eliminating unnecessary referrals for detailed ophthalmic evaluation.

Clinical investigations evaluating the use of 45^o non-mydratic fundus cameras with selective pupillary dilation for documenting the status of diabetic retinopathy indicate that this modality has the potential of providing reliable on site photo documentation in the primary care setting.²⁴ Through the use of a telemedicine linkage and digital image capture of the fundus, an ophthalmic specialist could screen for diabetic retinopathy and triage patients accordingly within the primary care setting thereby obviating the likelihood the patient fails to complete the follow-up appointment using the traditional referral mechanism. In order to test this hypothesis, we set out to investigate the relative accuracy (sensitivity and specificity) of a telemedicine based strategy for screening for diabetic retinopathy.

IMPLEMENTATION OF THE TECHNOLOGY: SCREENING PROTOCOL

Each study participant underwent nonstereoscopic 45^o retinal photographs through non-dilated or pharmacologically dilated pupils using a non-mydratic digital retinal camera. The desired 45^o fundus image included an area above and below the temporal arcades, as well as areas just nasal to the disk and temporal to the macula. A Topcon TRC NW5S digital retinal camera (Topcon America Corporation, Paramus NJ) was utilized at the Hubert Humphrey and Maravilla clinics and a Canon non-mydratic digital retinal camera (Canon CR6-45NM, Lake Success, New York combined with a Sony DXC-970MD San Jose, CA) was utilized at the Diabetes clinic at KDMC.

In order to increase the yield of acceptable photographs, participants manifesting poor quality retinal photographs in the absence of dilation were pharmacologically dilated using phenylephrine 2.5% and mydracyl 1.0%. A second attempt to capture the image was made with the non-mydratic camera. Remote site personnel underwent 1-2 months of training on image capture using the respective cameras to ensure that quality images were obtained. The designated retinal photographers were also encouraged to take multiple shots of a given eye until an acceptable image was obtained.

The non-mydratic digital retinal cameras were linked to desktop personal computing (PC) workstations (CPU Intel 200MHz) equipped with Flashpoint 3030 video capture cards (Integral technologies Indianapolis, IN). The PC workstations were also equipped with Asynchronous Transfer Mode (ATM) network cards, which were used to link the remote site telemedicine workstations to a central file server at Drew University via a high bandwidth T1 connection (See Appendix E, Figure 6 – Network Connectivity Diagram).

The Drew University telemedicine network utilizes a switched-network architecture to link all of the remote telemedicine clinics back to the University via T1 (1.5 Mb) telecommunication lines. The T1 lines terminate into a Nortel Networks FVC ATM switch (Nortel Networks, Santa Clara, CA) at the University. A 155 Mb fiber optic linkage connects this FVC switch to the central file server, where patient data is stored and archived electronically. The server currently being utilized for this purpose is a Dell 6300 Power Edge server (Dell Computers Inc., Austin TX) with 100 gigabytes of storage, 1 gigabyte of RAM, dual Pentium III 750 MHz processors, and an optical tape drive for data backup. To ensure uninterrupted functioning of our network and optimal data integrity, the Dell 6300 server is connected via a 100 Mb Ethernet connection to two backup servers (Dell 2300 Power Edge Server), which mirror the entire server. Thus, in the event the main file server (Dell 6300 Power Edge) fails, the backup servers assume all of the main server functions.

The FVC switch where the T1 lines from the remote clinics terminate, and the main file server is linked, is connected via a 155 Mb fiber optic line to a Nortel Networks Centillion 100 switch, which is part of the Drew University network backbone. From this Centillion 100 switch, a 155 Mb fiber optic connection is used to link the University backbone network to a FVC switch in the King-Drew Medical Center. The various subspecialty clinics (ophthalmology, otolaryngology, endocrinology, and dermatology currently) are linked via standard category 5 copper wiring.

This network design allows the remote telemedicine clinics to be directly linked to the various subspecialty clinics at the University medical center and the central file server simultaneously. Through the use of the ATM transport protocol, we were able to achieve data throughputs of 25 Mb to the desktop over standard category 5 wiring. The high bandwidth network capacity in combination with the ATM transport protocol allowed for real-time videoconferencing across the network between the remote clinics and subspecialty clinics. This network design allowed the patient data directory on the server to be mapped to the client PC telemedicine workstations at the remote and hub site specialty clinics. By utilizing this mapping configuration, the client workstations at each of these clinics were setup to treat the patient data directory located on the central file server as another directory on their respective hard drives. Consequently, all of the patient data captured in the remote clinic was stored directly on the central file server, and all of the patient data accessed at the hub site specialty clinics was retrieved from the central file server.

Hierarchical password assignment and 128 bit data encryption was used to maintain data security and maintain patient confidentiality. Data security and patient confidentiality were further enhanced by conducting all telemedicine interactions over a closed network. Telemedicine interactions were conducted in either real-time, store and forward, or both.

Digital still images of the retina were captured and stored using Second Opinion™ software (Second Opinion Software, LLC, Torrance, CA). Second Opinion™ is a client-server software package that allowed the retinal images to be captured and stored directly into the respective patient's electronic medical record on the central file server. Once the retinal images were acquired at the remote clinic and transmitted to the central file server, the images could be retrieved immediately from the central file server by the ophthalmologist for review. All images were captured and stored at a resolution of 640 by 480 pixels and reviewed on a standard 17 inch super VGA non-interlaced monitor with a refresh rate of 75 Hz and the resolution set to 640 by 480 pixels.

EVALUATION OF THE APPLICATION

Subjects were all type I and/or type II diabetics, 18 years of age or older, being seen at one of three remote telemedicine clinics (Appendix G):

- Hubert Humphrey Comprehensive Health Center
- Maravilla telemedicine clinic
- Diabetes clinic, King-Drew Medical Center

Informed consent was obtained from all patients participating in the study.

Subsequent to photo documentation using the digital non-mydratic fundus camera, all patients recruited in the KDMC diabetes clinic were scheduled to undergo indirect ophthalmoscopy through pharmacologically dilated pupils. These in-person examinations were scheduled within two weeks after the digital retinal image was obtained depending upon the severity of the retinopathy detected at the time of the digital retinal image capture and review. Both 20 diopter and 90 diopter lens evaluations were performed during the in-person. The in-person examiner was the same individual who reviewed the digital retinal image one - two weeks earlier. Patients were scheduled randomly in attempt to reduce examiner bias.

The digital retinal images were evaluated with respect to six grading criteria for diabetic retinopathy:

1. No retinopathy (NR)
2. Mild or early non-proliferative diabetic retinopathy (ER)
3. Moderate-to-severe non-proliferative diabetic retinopathy (MSR)
4. Proliferative diabetic retinopathy (PDR)
5. Clinically significant macular edema suspected (ME)
6. Unable to grade (CG)

A grade of mild non-proliferative was assigned to a retinal image if the image contained less than 5 retinal microaneurysms alone, or less than or equal to five occurrences of any of the following retinopathy findings in any combination: cotton wool spots, dot/blot/flame hemorrhages, hard exudates, or microaneurysms.

A grade of moderate-to-severe non-proliferative diabetic retinopathy was assigned to a retinal image if the image contained greater than 5 microaneurysms alone, or greater than five occurrences of any of the above mentioned retinopathy findings.

A grade of moderate-to-severe was also given if venous beading was detected in the presence of any number of the other retinopathy findings.

A grade of proliferative diabetic retinopathy was assigned to a retinal image if neovascularization was detected anywhere on the image or any level of preretinal or vitreous hemorrhage was detected.

The finding of clinically significant macular edema was assigned to a retinal image if there were one or more hard exudates anywhere within the macular region.

Because the focus of this project was to evaluate digital retinal imaging as a screening tool, the unit of analysis for the primary objective of this project was the patient. The primary outcome measure was the assigned referral status of the patient based on the level of retinopathy detected on the digital retinal image. Any patient found to have moderate-to-severe non-proliferative diabetic retinopathy, proliferative diabetic retinopathy, and/or suspected clinically macular edema in either eye met the criterion for referral. Therefore, the referral status of a patient was classified as refer, if either eye met any one of the above stated criteria. The reviewer was asked to assign a patient referral status, based upon the level of retinopathy inferred from the digital retinal images.

The secondary objective of this project was to assess the relative accuracy of digital retinal imaging compared to in-person evaluation with respect to classifying the level of retinopathy. Therefore, both eyes from each patient contributed to this analysis. The primary outcome measure of this analysis was the sensitivity and specificity of the digital retinal images for detecting the status of diabetic retinopathy.

ANALYSIS AND RESULTS

A. SOCIODEMOGRAPHICS

A total of 370 eyes of 185 diabetic patients underwent digital retinal photography. Of these 185 diabetic patients 87 (47%) underwent both digital photography and in-person evaluation. The demographic profile of the study participants is listed in Table 7 (See Appendix D - Demographic Characteristics). The study cohort was predominantly composed of women (55%). The mean age was 49.1 years with the 70% of subjects falling between 40 and 60 years. The racial composition was principally Hispanic (60%) and Black (38%). Both the employment and insurance status were indicative of the at risk nature of our study population. The majority of *study participants was unemployed (46%) and had no insurance coverage (61%).*

B. DIABETES STATUS

Our study population was principally comprised of type II diabetics (82%). The mean duration of diabetes for our study cohort was 5.6 years, with the majority of

patients having the disease for greater than two years (60%). The clinical characteristics of our study population are listed in Table 8 (See Appendix D, Clinical Characteristics).

C. OPHTHALMIC SURVEILLANCE

The majority of study participants reported never having a dilated fundus examination (56%). Of the 86 patients who reported having had a previous eye examination, 38 (44%) patients reported their last examination occurred more than 2 years prior. Twenty three patients (12%) reported never having had an eye examination.

D. DIGITAL RETINAL IMAGE EVALUATION

Of the 185 patients that underwent digital fundus photography, 17 (9%) patients had digital retinal photographs that were unreadable due to poor image quality. In the majority of these cases, the poor image quality was due to operator error. Lenticular opacities accounted for 4 (24%) of the 17 poor images. Equipment malfunction resulted in images not being obtained in 5 (3%) of the 185 patients. Thus, 163 (88%) of the 185 patients enrolled in the study had digital retinal photographs of sufficient image quality to grade.

Evidence of diabetic retinopathy on digital retinal photography was present in 56 (34%) of the 163 patients with readable photographs in our study. The distribution of diabetic retinopathy status based on digital retinal image review is shown in Figure 7 (See Appendix E - Diabetic Retinopathy Status based on Digital Image Review).

Of the 326 readable digital photographs taken with the non-mydratic digital retinal camera, 72 (22%) were obtained through pharmacologically dilated pupils. Patients requiring pupil dilation were uniformly older. The reason for pupil dilation was generally due to inadequate pupil size in combination with media opacities. The mean age for patients requiring pupil dilation was 61.5 years.

Most of the patients in this study were found to have no evidence of any, or early evidence of retinopathy. In general, patients in this clinical group had a shorter duration of diabetes with a mean duration of 3.2 years for patients with no retinopathy and 6 years with patients with early retinopathy.

By contrast, patients with moderate-to-severe or proliferative retinopathy, and patients with suspected clinically significant macular edema, had a mean duration of diabetes of 10.8 years. In our grading scheme, all patients with moderate-to-severe diabetic retinopathy, proliferative diabetic retinopathy, or suspected clinically significant macular edema in either eye were referred for in-depth ophthalmic evaluation. Based on these referral thresholds 30 of the 163 patients (18%) met the criteria for referral based on review of the digital retinal images alone. Of the patients referred, 15 (50%) required photocoagulation to stabilize their retinopathy.

Of the 87 patients that underwent digital retinal photography in conjunction with in-person evaluation, the distribution of diabetic retinopathy closely mirrored that of the

overall group, except that a slightly higher number of patients in this group were found to have macular edema compared to the overall study cohort (Figure 8 - Diabetic Retinopathy Status based on In-Person Examination, Appendix E).

Given the primary outcome measure for this study was the assigned referral status of the patient based on the level of retinopathy detected in either eye, digital retinal imaging was compared to in-person evaluation to assess whether the status of diabetic retinopathy detected by digital photography would elicit the same referral response as an in-person evaluation. Among this subset of study patients, digital retinal photography exhibited a detection rate for threshold diabetic retinopathy essentially equivalent to that of in-person evaluation. Using the referral criteria established for the purposes of this study, 25 (29%) of the 87 patients that underwent dual evaluation met the criteria for referral based on evaluation of the digital retinal images, while 29 (33%) of the 87 patients met the criteria for referral based on in-person evaluation.

When compared to in-person evaluation for identifying the level of retinopathy present, digital retinal imaging showed relatively low sensitivity for detecting early non-proliferative diabetic retinopathy and high sensitivity for detecting moderate-to-severe and proliferative diabetic retinopathy. With respect to identifying any level of retinopathy, digital retinal photography demonstrated a sensitivity of 81% and a specificity of 98%.

In patients manifesting early non-proliferative diabetic retinopathy on in-person evaluation, digital retinal photography demonstrated a significantly lower sensitivity of 52%. The specificity, however, remained high at 94%. In patients manifesting moderate-to-severe or proliferative diabetic retinopathy on in-person evaluation, digital photography demonstrated 86% sensitivity and 100% specificity. In patients identified with clinically significant macular edema, the sensitivity and specificity of digital retinal imaging was 83% and 95% respectively.

It is important to note that although there was a high level of agreement between digital retinal imaging and in-person evaluation with respect to assigning referral status, the reviewers found that digital retinal photography showed definite limitations in its ability to display the full extent of specific retinal findings such as microaneurysms, dot/blot hemorrhages and macular edema. Digital retinal photography consistently displayed fewer retinopathic lesions than in-person evaluation. However, in most cases digital retinal photography displayed a sufficient number of lesions to assign a referral status comparable to in-person evaluation.

E. DISCUSSION

Public hospital systems are the primary source of medical care for socioeconomically disadvantaged, and medically underserved individuals living in inner city urban communities throughout the United States.²⁶ This population is less likely to receive the benefits of preventative services or continuity of care and is at a significantly higher risk of experiencing increased morbidity and mortality when compared to other segments of society.^{27,28} Prior to the institution of our tele-ophthalmology

program at Drew, there was a 6 to 9 month waiting list for patients to be seen in the eye clinic. Consequently, we were seeing very high rates of treatable and preventable blindness in patients presenting to our clinic for the very first time.²⁹ One of the major sources of preventable or treatable visual impairment in our patient population is diabetic retinopathy. As previously documented in a study published by our department²³ approximately 40% of diabetic patients had advanced ocular pathology on initial presentation to our clinic and 7% were legally blind.

It was in this setting of high ocular morbidity associated with treatable diseases such as diabetes, glaucoma, cataracts, and others that we began to pursue the telemedicine delivery system as a potential solution for overcoming the resource barriers to accessing appropriate eye care for this medically underserved inner city population. Current clinical guidelines recommend that diabetic patients receive annual dilated fundus examination from a qualified eye care specialist.²⁹ Based on the recent report by Thompson and colleagues,³⁰ complying with this clinical guideline has proved unfeasible in the majority of health care settings throughout the United States. Thompson and co-workers found that annual diabetic eye examination was the HEDIS preventive measure with the lowest performance rate. Among the medically underserved inner city population we serve, we have documented compliance rates with this guideline are abysmal in comparison to the national average.²³ We found that *among our service population only 7.4% of patients with diabetes of 1 year or greater underwent appropriate ophthalmic surveillance*, while data from a national probability sample showed one year surveillance rates of 49%.³¹ *Clearly, better surveillance strategies are needed to insure that diabetic patients receive appropriate eye care and avoid sight threatening complications.*

The findings from this study suggest that *on site digital photo documentation in the primary care setting coupled with telemedicine linkage to an ophthalmologist is an effective strategy for diabetic retinopathy screening*. Based on the referral criteria established for the purpose of conducting this study, we found that digital retinal photography yielded similar results to in-person evaluation for detecting threshold diabetic retinopathy.

During this investigation, digital retinal image review identified 25 of 87 patients (29%) with sufficient diabetic retinopathy to warrant referral, while in-person evaluation identified 29 of 87 patients (33%) as having threshold disease. This finding has enormous implications for enhancing our ability to provide preventive eye surveillance for diabetic patients. Screening for diabetic retinopathy at the primary care point of service using high resolution non-mydratic digital fundus cameras with subsequent transmission of the digital image to an ophthalmologist for review and triage holds the potential of greatly increasing the number of diabetics receiving appropriate ophthalmic surveillance, increasing the number of diabetics undergoing timely recognition of treatment of ocular disease, and decreasing the number of diabetics undergoing unnecessary referral.

Although the findings of this study offer a potential solution for improving ophthalmic surveillance of diabetics, there are several factors that must be considered before the findings of this study can be generalized to other populations and other settings. First, it is important to recognize that review of the digital images was conducted using a well structured clinical protocol that was designed to have a low threshold for referral. The grading criteria used in this study to categorize the various levels of diabetic retinopathy were more stringent than criteria utilized in previous studies²⁴ to evaluate the efficacy of non-mydriatic fundus photography for diabetic retinopathy screening. The more stringent grading criteria were intended to minimize the referral threshold and thereby increase the sensitivity of digital retinal imaging for detecting visually significant diabetic retinopathy.

Other aspects of the study design used to enhance the disease detection rate included intensive training of the remote site personnel recruited to take the photographs, and the liberal use of pharmacologic dilation to increase the photographic yield and enhance image quality. These measures were taken to compensate for the *inherent limitations of digital retinal photography*. Digital images captured and displayed at a resolution of 640 by 480 pixels provides significantly less information than a 35 mm film image, which has a digital image resolution approaching 3000 by 3000 pixels. Because of the image resolution limitations of current digital non-mydriatic fundus cameras, we expected the digital images to be less sensitive in detecting very subtle diabetic retinopathy changes. Our finding of a 52% sensitivity in detecting early non-proliferative retinopathy certainly confirms this expectation. The inability to assess depth on digital retinal images completely prohibits the evaluation of retinal thickening. Consequently, we set the criteria for macular edema fairly broad.

Beyond the resolution issues, it is important to recognize that between 8% and 15% of diabetic retinopathy may be missed because it falls outside the 45° field taken with a non-mydriatic fundus camera.²⁴ Recent evidence suggests, however, that surveillance of the retinal fields captured within a 45° fundus photograph will detect 90% of eyes with proliferative diabetic retinopathy.^{32,33}

In summary, there are several conclusions that can be drawn from this study and applied in other clinical settings. First, the *transmission of digital retinal images from the primary care setting to an ophthalmic specialist through a telemedicine linkage appears to be a viable solution for increasing the ophthalmic surveillance of at risk diabetic patients*. However, given the inherent limitations of the digital retinal imaging devices in current use, *the limit of ophthalmic surveillance that realistically can be achieved is simple screening*. Current digital retinal imaging technology does not provide sufficient resolution to make detailed diagnostic inferences.

The second important conclusion from this study pertains to the grading criteria used to evaluate the digital photos. The results of the present study indicate that the *grading criteria should be designed to minimize the referral threshold* to compensate for the limitations of digital photography. In addition, the frequency of follow up screening photographs should be increased in relation to the patient's duration of

diabetes and glucose control to account digital photography's lower sensitivity for detecting subtle findings of early diabetic retinopathy. The association of clinically significant ocular pathology with increasing duration of diabetes is well described³⁴ and documented in the present study. We found patients with no retinopathy had a mean duration of diabetes of 3.2 years, while patients with moderate-to-severe and proliferative diabetic retinopathy had a mean duration of 10.8 years. Moreover, we found that digital retinal photographs had a sensitivity of 52% for detecting early non-proliferative diabetic retinopathy.

Finally, the success of a screening endeavor such as the one taken in this study is largely dependent on the quality of the digital photos obtained in the remote site primary care clinics. Given that all of the individuals who will be selected to obtain photographs in these settings will not be trained ophthalmic photographers, it is imperative that a significant investment in time be made to train these individuals to take high quality photos prior to launching the screening program. Training should focus on enabling these individuals to make a rudimentary assessment of the various levels of diabetic retinopathy by acquainting them to the modified Airlie House classification of diabetic retinopathy. These individuals should be trained to distinguish between high and low quality images by familiarizing them with the seven standard photographic fields utilized in the ETDRS study. Additionally, the remote site photographers should be given a standardized protocol outlining the indications for pharmacologic dilation and educated about the pharmacologic agents and the risks associated with the use of these agents.

Although the findings of this study do provide encouraging information about the utility of teleophthalmology for screening at-risk diabetic populations for visually threatening ocular disease, the findings are preliminary and will require further validation through follow-up and comparable studies by other institutions with similar patient populations.

References

1. Health status of minorities and low-income groups. 3rd ed. U.S. Department of Health and Human Services, 1991;5-8. Public Health Service, HRS, 271-848/40085, pp. 37-84.
2. Haywood LJ, Francis CK, Cregler LL, Freed MD, Skorton DJ. Task force 1: The underserved. *J Am Coll Cardiol* 1994;24:282-290.
3. 23rd Bethesda Conference: access to cardiovascular care. *J Am Coll Cardiol* 1992;19:1449-60.
4. McCord C, Freeman HP. Excess mortality in Harlem. *N Engl J Med* 990;322:173-177.
5. Blendo RJ, Aiken LH, Freeman HE, Corey CR. Access to medical care for black and white Americans. A matter of continuing concern. *JAMA* 1989;261:278-81.
6. Lieu TA, Newacheck PW, McManus MA. Race, ethnicity and access to ambulatory care among US adolescents. *Am J Public Health* 1993;83:960-5.

7. American Hospital Association Hospital Statistics. 1992-93 ed. Data compiled from the American Hospital Association 1991 Annual Survey of Hospitals. Chicago: American Hospital Association.
8. Mulhausen R, McGee J. Physician need. An alternative projection from a study of large, prepaid group practices. *JAMA* 1989;261:1930-4.
9. Seddon JM. The differential burden of blindness in the United States. *N Engl J Med* 1991;325:1440-2.
10. Sommer A, Tielsch JM, Katz J, et al. Racial differences in the cause-specific prevalence of blindness in East Baltimore. *N Engl J Med* 1991;325:1412-7.
11. Dana MR, Tielsch JM, Enger C, Joyce E, et al. Visual impairment in a rural Appalachian community. *JAMA* 1990;264:4200-2405.
12. Tielsch JM, Sommer A, Katz J, Quigley H, et al. Socioeconomic status and visual impairment among urban Americans. *Arch Ophthalmol* 1991;109:637-41.
13. Tielsch JM, Sommer A, Witt K, Katz J, Royall RM. Blindness and visual impairment in an American urban population. *Arch Ophthalmol* 1990;108:286-290.
14. Javitt JC, Aiello LP, Bassi LJ, et al. Detecting and treating retinopathy in patients with type 1 diabetes mellitus: savings associated with improved implementation of current guidelines. *Ophthalmology* 1991;98:1565-1574.
15. Javitt JC, Aiello LP, Ferris FL. Preventive eye care in people with diabetes is cost-saving to federal government: Implications for health care reform. *Diabetes Care* 1994;17:909-17.
16. Javitt JC, Die Cas R, Chiang YP. Cost-effectiveness of screening and cryotherapy for threshold retinopathy of prematurity. *Pediatrics* 1993.
17. Public health focus: prevention of blindness associated with diabetic retinopathy. *CDC Morbidity and Mortality Weekly Report* 1993;42:191-205.
18. Klein R, Klein BEK. Vision disorders in diabetes. In *Diabetes in America*. 2nd ed. Harris MI, Cowie CC, Stern MP, Boks EJ, Reiber GE, Bennett PH. Eds. Washington DC. US Government Printing Office 1995 (NIH publication no. 95-1465).
19. Ferris FL III. How effective are treatments for diabetic retinopathy? *JAMA* 1993;269:1290-1291.
20. Bachman MO, Nelson SJ. Impact of diabetic retinopathy screening on a British district population: case detection and blindness prevention in an evidence-based model. *J Epidemiol Community Health* 1998, 52:45-52.
21. Javitt JC, Ferris FL, Aiello LP et al. Preventive eye care in people with diabetes in cost-saving to the federal government: implications for health-care reform. *Diabetes Care* 1994;17:909-917.
22. Brechner RJ, Cowie CC, Howie LJ et al. Ophthalmic examination among adults with diagnosed diabetes mellitus. *JAMA* 1993;270:1714-18.
23. Baker RS, Wilson MR, Watkins N et al. Clinical and sociodemographic characteristics of patients newly presenting to an urban public hospital eye clinic. *Ophthalmol* 1998;105:1373-1379.
24. Klein R, Klein BEK, Neider MW et al. Diabetic Retinopathy as detected using ophthalmoscopy, a nonmydriatic camera and a standard fundus camera. *Ophthalmology* 1985;92:485-491.

25. The Diabetic Retinopathy Study Research Group. Report 7. A modification of the Airlie House classification of diabetic retinopathy. *Invest. Ophthalmol. Vis Sci* 1981;210-226.
26. Siegel B. Re-engineering the public hospital system: saving the safety net. *Bull NY Acad Med* 1996;73:357-69.
27. Rask KJ, Williams MV, Parker RM, McNagny SE. Obstacles predicting lack of a regular provider and delays in seeking care for patients at an urban public hospital. *JAMA* 1994;271:1931-3.
28. Burns R, Nichols LO, Graney MJ, Applegate WB. Mortality in a public and a private hospital compared: the severity of antecedent disorders in Medicare patients. *Am J Public Health* 1993;83:966-71.
27. Screening guidelines for diabetic retinopathy. American College of Physicians, American Diabetes Association, and American Academy of Ophthalmology. *Ann Intern Med* 1992;116:683-5.
28. Thompson JW, Bost J, Ahmed F, et al. The NCQA's quality compass: evaluating managed care in the United States. *Health Affairs* 1998;17:152-8.
29. Brechner RJ, Cowie CC, Howie LJ, et al. Ophthalmic examination among adults with diagnosed diabetes mellitus. *JAMA* 1993;270:1714-8.
30. Moss SE, Meuer SM, Klein R, et al. Are seven standard photographic fields necessary for classification of diabetic retinopathy? *Invest Ophthalmol Vis Sci* 1989;30:823-8.
31. Aldington SJ, Kohner EM, Meuer SM, et al. Methodology for retinal photography and assessment of diabetic retinopathy: the EURODIAB IDDM Complications Study. *Diabetologia* 1995;38:437-44.
32. Kahn HA, Hiller R. Blindness caused by diabetic retinopathy. *Am J Ophthalmol* 1974; 78:58-67.

STUDY 4:

USE OF TELEMEDICINE FOR EMERGENCY MEDICAL TREATMENT AT A REMOTE LOCATION: TREATMENT OF DIVING ACCIDENTS AT THE HYPERBARIC CHAMBER ON CATALINA ISLAND

Authored by Catherine A. Jackson, Tora Bikson, Dan Relles and Paul P. Lee

INTRODUCTION

The delivery of medical care in emergency situations must be quick and decisive. In metropolitan and suburban situations, fire department paramedics are able to respond quickly, stabilize the patient and transport them to often nearby emergency rooms for care. However, such organized systems are often not available in rural or remote locations. It is too expensive to locate such highly trained personnel and their associated equipment in rural areas where the need is infrequent and sporadic. But when accidents occur, it is important to be able to provide on-site personnel with communications capacity with medical personnel who can assist or advise in the care of the accident victim. Such situations are ideal for introducing telemedicine technology.

To test the utility of an off-the-shelf technology for a telemedicine application the University of Southern California (USC) Advanced BioTelecommunication and BioInformatics Center / Advanced Biotechnical Consortium (USC-ABBC) installed a video teleconsultation system to link the Los Angeles County - USC Medical Center emergency department and the USC Catalina Hyperbaric Chamber at the Wrigley Institute for Environmental Studies on Catalina Island. This remote facility is used for emergency treatment of diving accident victims. Previous communication between the USC Emergency Room and the hyperbaric chamber was done using the standard telephone system. The introduction of the video teleconsultation system added video and simultaneous audio communication. Thus, the emergency medicine physician could communicate with the chamber staff and Baywatch paramedics who provide initial assessment and treatment in diving accident cases. This paper describes the video telemedicine installation at the hyperbaric chamber and its contribution to treating diving accident victims.

A. DESCRIPTION OF CATALINA ISLAND

Catalina Island lies 22 miles off the coast of California. The island has two population centers: Avalon and Two Harbors. Avalon is the year-round commercial center of the island. Located at Avalon is a small medical facility staffed with medical personnel that provides care for most of the year-round population and summer tourists. Two Harbors, on the other hand, is more frequently visited during the summer. One year-round "business" is the University of Southern California Wrigley Institute for Environmental Studies. Associated with the Institute is a hyperbaric chamber that is used for the specialized treatment of diving accidents. The hyperbaric facility is staffed 24 hours a day, 7 days a week, by non-medical personnel who have been trained in the treatment of diving accidents. The paid chamber staff is supported by volunteer staff, predominantly diving enthusiasts, who have been trained in the use of the chamber.

B. TREATMENT OF DIVING ACCIDENTS IN THE HYPERBARIC CHAMBER

Diving accidents occur when divers ascend to the surface too quickly. The divers develop decompression sickness, that is “the bends,” or cerebral air embolisms that result from the formation of bubbles from dissolved gas in the blood or tissues. To avoid such problems, divers can limit the depth and duration of their dives to a range that does not require decompression stops on ascent, or they can follow the dive and ascent parameters found in an air decompression table, e.g., the US Navy Diving Manual table. These dive parameters in the table allow the normal release of excess gas. However, the diver must make accurate assessments about the length and depth of the dive in order to determine the appropriate ascent or decompression procedures. Decompression sickness seldom occurs after dives that are conducted within the appropriate parameters, and often does when such procedures are not followed. The treatment for “the bends” is depressurization in a hyperbaric chamber. The hyperbaric chamber simulates the pressure of a dive and the atmosphere in the chamber consists of hyperoxygenated air. The pressure and the hyperoxygenated air cause the gas to redissolve into the body. Once this occurs, the chamber makes a controlled simulated ascent to allow for the safe release of the excess.

Diving accident victims may present to the Catalina Hyperbaric chamber on their own or are delivered by the LA County lifeguard paramedics, Bay Watch, or the US Coast Guard helicopter EMT after rescue and evacuation. The paramedics and chamber operations staff perform initial evaluations of these patients and communicate with physicians at the LAC+USC Medical Center Department of Emergency Medicine through the LAC Medical Alert Center (LAC MAC) with conventional telephone communications. If sufficient information is obtained, a treatment decision can be made.

Currently, when the Coast Guard or the Emergency Medical Team is notified of an emergency, the LAC Medical Alert Center (LAC MAC) is alerted. The LAC MAC notifies (beeps) the Catalina hyperbaric chamber and the USC Medical Center emergency room that a patient is headed to the chamber. All telephone communications through the MAC are recorded on a reel tape recorder. In addition, by the time the patient arrives at the Catalina chamber, a video teleconferencing link has been established between the supervising physician at the LAC-USC Medical Center and the chamber crew and /or the lifeguard paramedics.

Patient assessment information consisting of history of the presenting complaint, past medical history, dive profile, and physical examination findings is presented to the supervising physician. A working diagnosis is made; it may or may not be a condition requiring recompression therapy. If recompression therapy is indicated, treatment is started.

If there is insufficient information to reach a conclusion, a physician is dispatched (via helicopter) to the chamber to evaluate the patient. Once the dispatched physician has arrived at the chamber facility and completed an assessment, he/she presents the

finding and conclusions to the supervising physician and a diagnostic and treatment decision is made. If treatment is now determined to be indicated, the decision is documented and treatment begun. Communication between physicians will be done through the video teleconferencing link.

If decompression therapy is not indicated, or if the patient declines treatment, the supervising physician provides additional instructions to the paramedics and/or the patient regarding aftercare procedures and education regarding risks. Patients leaving the chamber who do not require chamber treatment, or decline chamber treatment, will communicate with the supervising physician via a video teleconferencing link for counseling and aftercare instructions.

IMPLEMENTATION OF TECHNOLOGY

The video-teleconference system installation at the chamber is configured with a supervisor control station node and two video cameras (see Figure 9, Appendix E). Located at the chamber supervisor's station, the chamber building entry way and inside the chamber can be individually switched on from this station, although only one camera can be operational at a given time. Two of the chamber site cameras are fixed but portable; that is, one can physically dismount and carry the camera to a different location within certain distance restrictions to transmit a different scene/image. The camera inside the chamber is mounted in a pressure-resistant housing¹. The video camera installed inside the chamber conforms to the 1996 National Fire Protection Association standards. While not portable, the camera can rotate 360 degrees, as controlled by the chamber supervisor.

Both the chamber supervisor and the emergency medicine physician have two video image windows: a local window showing what is being transmitted from their location, and a remote video window showing what is being transmitted from the remote location. Initial communications are established between the two locations from the respective workstations. The system was designed to have the capacity for a shared a white board image, but this was not used.

Basic audio communication is available through the standard phone line. However, the video-teleconference set-up also provides various alternative means audio mechanisms including: tethered audio headsets that only the supervisor and chamber tender use; wireless audio headsets that can be used outside the chamber by the supervisor, the chamber crew, and paramedics; and a public audio address system. Under all cases, only a tethered handset is available to the chamber tender because of the chamber's environmental conditions.

A separate headset hooked to the video-teleconference system allows anyone at the supervisor's station to have a private conversation with the LAC+USC node by flipping a

¹ Technical specifications were researched by the study technical partners of Northrop Grumman Corporation. In addition, the specifications and plans for inside chamber equipment were submitted to the USC Catalina Hyperbaric Chamber Safety Review Panel for their analysis and recommendation.

switch to “Private.” If the switch is in the “Public” position then this headset is connected to whichever audio system (hardwire or wireless) is set up to transmit to the video-conference system.

The decision to treat a patient in the hyperbaric chamber is based on information obtained a physical examination of the patient as well as from the patient him/herself. Paramedics and chamber staff look for signs and symptoms of diving sickness, such as pain and neurological deficits. Paramedics conduct a neurological examination. In addition to the clinical information, paramedic and chamber personnel question the patient and his/her diving partner about the characteristics of the dive to determine if the diver violated the parameters of the diving tables

Scuba diving today has been influenced by improved technology. In particular, there are better instruments that divers can use to determine the depth to which they dive, the amount of time they spend under water, etc. Coupled with this dive-specific information, divers use what are called dive tables. These tables have been developed by the U.S. Navy to inform divers of the amount of time they can spend under water, at what depths, and the length of time needed to depressurize on ascent (ref). Thus, knowing the characteristics of the victim’s dive, it is possible to determine the likelihood that recompression is required.

If a treatment decision cannot be made with the available information, a physician is dispatched to the chamber (via helicopter from USC) to further evaluate the patient. If the dispatched physician is a resident physician, the treated/evaluated patient and the activities of the physician are not directly observed by the supervising physician who remains at the USC LAC Emergency Room. Some patients released from the chamber site without recompression treatment may not have had any direct contact with a physician.

A. CONCEPTUAL FRAMEWORK

Our objective for this demonstrative was to determine the “added value” that telemedicine technology could contribute to service delivery at the hyperbaric chamber on Catalina Island, a remote, emergency care treatment facility. Since the treatment decision was based on specific types of information – violations of dive tables, case symptoms, and medical findings – we developed a typology of how the information was used in making a treatment decision. Table 9 (Appendix D) displays our conceptualization of how information is used. According to the conceptual model, the teleconsultation will be useful when there is ambiguity and the additional information gained by seeing and / or talking to the patient helps the physician make the decision whether or not to treat in the hyperbaric chamber.

According to our conceptual framework, if a diving accident victim presents to the hyperbaric chamber having violated the parameters of the diving table, with physical symptoms of depressurization, and additional medical findings, then the patient needs recompression and treatment in the hyperbaric chamber. This situation is exemplified on the first line of the table. In this situation, the physician is not at all ambiguous about the treatment decision. The additional information conveyed by the video-conference is minimal, and thus, the technology would not be considered very

useful. Similarly, if a diving accident victim presents and did not violate the diving table and there are no symptoms or physical findings of decompression sickness, the physician knows that recompression is not necessary. Any additional information provided by the video-teleconference would not prove helpful.

Analogously, we hypothesize that the teleconsultation technology will be helpful to those who can best use the information. Thus, we expect that if the video-teleconference system provides any information, the physician would be most likely to say that it contributed to his/her being able to make a diagnosis and treatment decision. Other personnel involved may or may not find the technology useful to the treatment decision. However, one could hypothesize that clinical personnel would find the use of the video-conference equipment more helpful, than non-clinical personnel, because they appreciate the additional value the communication – visual and verbal – to the disposition of the patient.

B. DATA COLLECTION

The demonstration had two main objectives. First, we wanted to determine the practicality and reliability of implementing and operating video teleconferencing technology in a rural, remote environment where technical staffing and support limitations exist. Second, we wanted to measure the effect of video teleconferencing on the ability to provide medical management in a rural, remote environment. The focus of the evaluation was not on patient outcomes, but rather the responses of the nonmedical and medical personnel involved in the treatment of diving accident victims.

The types of personnel involved in the demonstration include: Hyperbaric chamber supervisor and volunteer crew; LA County Lifeguard paramedics; US Coast Guard EMT members; and the emergency room physicians supervising the nonphysician and nonclinical staff at the chamber in the care of the diving accident victim.

We tracked the operability and reliability of the telemedicine system through a problem log maintained at the hyperbaric chamber by chamber staff. The log documented hardware failure, software failure, communications failure, and video equipment failure during patient treatments, real or simulated.

We assessed the medical management impact of the telemedicine system on the nonmedical and medical staff through a short, self-administered survey. This survey asked what components of the telemedicine system were used, how they worked, and the perceived effect the system as a whole had on the diagnosis and treatment of the accident victim.

ANALYSIS AND RESULTS

The demonstration ran two years from October 1997 through December 1999. The first year was set-aside as a break-in period during which the installation, testing and adjustment of the

equipment took place. Unfortunately, the system was not particularly dependable. Indeed, a new area code was introduced into Los Angeles County that caused many of the technical problems experienced by the system to disappear. However, the exact cause of the malfunctions was never determined. The second year was dedicated to examining how the video-conferencing system added to the triage and treatment of diving accident patients.

Use of the hyperbaric chamber declined during this period of time such that there was a 10 percent decline in the number of cases between the first and second years of the demonstration. Many associated with the chamber and the diving community hypothesized the decline was due to the increased temperature of the waters off Southern California and the improvement in diving technology and training. Figure 10 (Appendix E) displays the total number of cases, treated and not treated, who presented to the chamber when the video-teleconference equipment was used.

Over the two-year period of the demonstration, 44 cases were seen and of these 24 were treated and 20 were not. For the year-period in which we received self-reported survey information from those using the video-teleconference facility, the number of cases was 20, of these 9 were treated and 11 were not.

As mentioned earlier, the system during the first year was not particularly dependable. This is illustrated in Figures 11 and 12 (Appendix E).

These statistics show that the number average length of time for a call for a treated case on October 1997 - September 1998 was 105 minutes, while for non-treated cases it was 169 minutes. The following year, the length of calls stabilized at 111 minutes for treated cases, and 87 minutes for non-treated cases. These numbers however are confounded with the first-year practice of maintaining a connection whenever possible. In the first year, the average number of calls for treated cases was 4.1 and for non-treated cases 3. These declined to 3.2 calls per case for treated cases, and 2.8 calls per case for non-treated cases. Despite the possible bias, the length of time required to determine not to treat a patient declined by half over the period suggesting that the video-teleconference did provide information allowing the physician to make the treatment decision faster.

For the 9 treated cases in year 2, we received 12 surveys from involved personnel for 5 cases.² The cases were split 3:2 between treated and non-treated cases. The majority of surveys came from paramedics and the chamber supervisor.

All clinical personnel – physician and paramedics – rated the system as being very helpful to the outcome of the patient encounter. The chamber supervisor generally rated the system as being very helpful, but once indicated that it was somewhat unhelpful and commented that the video-teleconference set-up was “a toy.” First time users (4 of 11 responses) thought the system was very helpful. The average number of experiences with the system for the non-

² Undoubtedly the low response rate was a function of the infrequency of case presentation as well as the urgency with which cases are dispatched at the chamber.

first time users was 3.3. Overall, the modal rating for the video-teleconference system effect on the interactions between the physician and paramedics and chamber crew was very good.

Technically, the system performed fairly well during the patient encounters that were surveyed. The quality of the audio and video transmission was rated most frequently as very good. The ratings ranged from neither good nor poor to very good; there were no instances where the ratings were somewhat or very poor. The system was rated very to somewhat reliable for the encounters reported. It should be remembered, however, that the first year of implementation showed the system was not reliable but this was due to factors outside of the control of the chamber and USC-ABBC staff.

While the video-teleconference system had more advanced, presumably more convenient hardware attached, most often the traditional tethered headphones were used. The wireless headsets were available to use, but they were never employed. At one point, it was commented that the wireless headsets required batteries and the infrequent use sometimes meant that the batteries were dead and no replacements were available.

The application of an off-the-shelf technology of video-teleconferencing at a remote emergency treatment site was a modest success. When the system was working and was used, it was generally rated as being very helpful. However, there was an initial year of implementation during which the system proved to be unreliable. Much of this unreliability was associated with conditions that were beyond the control of the chamber and USC-ABBC staff, and were ultimately resolved by the phone company changing their area code overlay. The success of this demonstration was also modest due to the decline in diving accident victims during the demonstration period.

While the number of cases presenting at the hyperbaric chamber on Catalina Island was small during the demonstration period, a number of additional observations can be made. First, clinical personnel found the additional visual information helpful in the triage of diving accident victims. We suspect, although cannot be absolutely certain, that this additional information reduced the ambiguity of the case and allowed a quicker treatment decision. This supposition is confirmed in the lowered connection time of non-treated cases in year 2.

On the dimensions that the system was rated – quality, reliability and helpfulness to the patient encounter – the system was rated highly by the users. This is despite the fact that the system often required reconnection. The burden of the reconnection was on the chamber supervisor and the physician. Feedback from the chamber supervisor suggests that this reduced the helpfulness of the system, and perhaps could be viewed as a hindrance.

The video-teleconferencing system was used consistently, when it was working, because it did enable simultaneous video and audio communication between the chamber and the physician. However, the wireless headsets that would have permitted the paramedics to talk directly to the physician were not used. This certainly would have enhanced communication. At the same time, it would have reduced the pivotal role of the chamber supervisor during the triage phase. Thus, the technology of the wireless headsets as well as the added value of inter-clinical personnel needs to be further explored.

ADDENDUM TO STUDY #4:

EMERGENCY MEDICINE ON CATALINA ISLAND: THE CONNECTIVITY REPORT

John Beecher, Logicon IS

INTRODUCTION

Although Catalina Island lies between 25 and 35 miles off the Southern California coast in international waters, it falls under the jurisdiction of the State of California and the County of Los Angeles. The island is 27 miles long, encompassing 72 square miles. Roughly 4,000 persons populate the island permanently. The population swells to more than 1.4 million during the summer months. The majority of the 4,000 permanent residents can be



found in the incorporated town of Avalon on the east end of the island. Roughly 200 people live in the small unincorporated community of Two Harbors, also known as The Isthmus, on the west end of the island. Travel between the two communities is accomplished over land via dirt road or over sea by boat. The University of Southern California (USC) has had a marine research center within several miles of The Isthmus for many years.

A. THE HYPERBARIC CHAMBER

USC has long had a hyperbaric chamber on Catalina Island in conjunction with the Wrigley Marine Science Center. Eight laboratories accommodate up to 24 researchers and groups of up to 60 students. Housing can host 65 overnight guests and provide meals for up to 150 people. The lab is currently used by faculty and students from USC and other regional universities and is available for a broad range of research and educational activities. The chamber is owned by USC who also supplies local staffing and support. The Los Angeles County Fire Department supplies the local medical support. The hyperbaric physician's are part of the staff of Los Angeles County's Department of Health and of USC³. There is no medical staff resident at the Marine Science Center.

³ USC is on contract to supply doctors and nurses to the Los Angeles County Medical Center. The Los Angeles County Medical Center and the USC Health Sciences Campus are adjacent to one another.

In mid 1995 discussions were under way of how to manage the health care for the staff and students at the Marine Science Center and what opportunities the chamber may bring. It was decided that focusing on the chamber was the prudent thing to do as its requirements could easily be defined, vs. the general health needs of the staff.

The USC Catalina Hyperbaric Chamber is a steel cylinder capped at both ends. There is a lock at one end that allows caregivers to enter and leave the chamber during treatments.



There is also a small lock for exchanging items like drugs and equipment. The chamber is used to put SCUBA divers back under pressure when they have either come up too quickly or have not properly decompressed. At 24 feet long, 9 1/2 feet in diameter the size of the Chamber allows the possibility of treating multiple patients simultaneously (to date, the maximum number of patients treated

simultaneously is four) and allows room to perform CPR and Advanced Life Support for patients who arrive in cardiac arrest. The Chamber facility is an extension of the L.A. County/USC Medical Center Emergency Room and is part of the countywide Medical Alert Center (MAC).

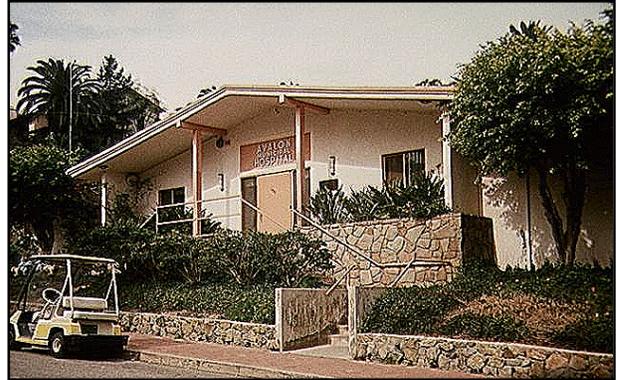
Patients are brought to the chamber either by the local paramedics or via Coast Guard helicopter. In either case the paramedics do an initial medical and neurological assessment outside the chamber. Base station contact is made with the Los Angeles County + University of Southern California (LAC+USC) Emergency Department (ED) where the hyperbaric doctors determine if a chamber treatment is indicated. If the treatment is indicated the chamber crew, numbering from two to four, readies the chamber. This includes starting the compressors and getting any medical instruments ready.

The patient is put on one of two beds in the chamber and the doors are closed and secured. One paramedic is with the patient at all times. The treatments can last from an hour to more than ten hours. During this time the paramedic remains in contact with the chamber crew via an intercom system that links all the members of the chamber crew. The lead operator is in contact with the physician at LAC+USC via the telephone. If the patient is critical, the doctor is flown from the mainland to the chamber. This is done via a County Fire Department or Coast Guard helicopter. In periods of inclement weather the Coast Guard is the only option as the County helicopters are not equipped with the proper radar and navigation equipment. It should be noted that once a person is put under pressure, that person has to remain in the chamber for proper decompression. At the completion of the treatment the patient

is either released to find his own way back to the mainland or transported via private helicopter for further medical treatments.

B. AVALON MUNICIPAL HOSPITAL

The Avalon Municipal Hospital is a nine-bed hospital with one Emergency Room (ER) and an attached clinic. In 1995 the hospital was not affiliated with any other medical facility on the mainland. During the investigation phase for this NLM contract, the Department of Family Medicine at USC assumed control of the medical and business aspects of the hospital. The hospital supported one full time doctor,



several nurses and one psychologist. Patients were seen in the clinic or ER for routine or acute medical care. When the situation became critical or required services not available at the hospital, patients had to take the one and one half to two hour boat ride to the mainland. Commercial helicopter services are available but at a substantially higher cost. Evacuations of critical patents was considered an inter-facility transfer and therefore not eligible for County or Coast Guard assistance (with the exception being the weather). It was not uncommon for residents to take an entire day or two to travel to the mainland, rent a car, travel to a specialist, drive back to the boat landing, and make the crossing home. There are no specialists on the island.

C. TELECOMMUNICATIONS INFRASTRUCTURE SUPPORTING CATALINA ISLAND

Telecommunications for Catalina is the responsibility of Pacific Bell (Pac Bell) and falls within the California's Local Access Transport Area (LATA) five.⁴ There is a Lucent 5ESS telephone switch in Avalon. The switch is a remote from the Torrance California switch. The Island is linked to the mainland via an old analog microwave radio system. The systems capacity is three T-3s.⁵ At the time the Telemedicine systems were being developed, dedicated services and Primary Rate ISDN⁶ were the only product available from Pac Bell.

⁴ A LATA is a geographically defined area established by the Modified Final Judgement set forth by Judge Green during the breakup of the AT&T monopoly in 1984. Any phone or data traffic that does not cross a LATA boundary is defined as local and can be carried by local phone companies like Pac Bell (Local Exchange Carrier or LEC). Any traffic crossing a LATA boundary is requires the assistance of a long distance carrier (Inter eXchange Carrier or IXC) like AT&T or Sprint). LATA 5 encompasses all of Los Angeles.

⁵ A T-3 is a level of multiplexing within the telephone system.

⁶ ISDN, or Integrated Services Digital Network, is a digital service, which supports both voice and data. The connections are established in the classic phone company method, by dialing. Outside of a monthly service charge, billing only occurs when a call is placed. Typically for a 384K video call, six channels are used resulting in six channels being billed.

Pacific Bell, with funding from USC, installed a fiber optic infrastructure on the island. The USC Marine Science Center and the chamber are linked to the Avalon Central Office (CO) via the fiber.

TELEMEDICINE DESIGN CONSIDERATIONS

Both the Avalon Hospital and the Hyperbaric Chamber presented specific and unique networking design challenges. The basic linkages required were between the Avalon Hospital to the USC Health Sciences and the chamber to the LAC+USC ED. The chamber was already linked to the USC data backbone for e-mail and web access but not “cleanly” to the County’s backbone while Avalon had nothing. Both locations required interactive video conferencing, e-mail, and web access.

The video between the chamber and the LAC+USC ED was perceived to have the requirement of being as loss-less as possible. No frame of video and voice could be lost. Internet Protocol (IP) networks by their very nature lose information. It was decided that an IP network would not be the best solution for the chamber video link. Since Avalon’s video was perceived to be less critical than the chamber’s there would be an opportunity to ask the person at the other end to repeat if data were lost. Other considerations at the chamber included the amount of lighting within the chamber, the physical penetration through the chamber wall, and the incorporation of a very out dated intercom system.

There were no clearly defined Federal, State, or local interpretations of the National Fire Protection Associations National Electric Code (NEC) 70 for the chamber.⁷ There were many factors suggesting the team use the Avalon and Chamber locations for the development of Telemedicine. All the parties were politically linked with managerial cognizance and approval. Avalon’s medical staff was from USC and the City of Avalon wanted their hospital to remain a viable operation (the Hospital was almost insolvent but it had great community support). The chamber is owned and operated by USC, the paramedics’ “scope of practice” is defined by the County Fire Department and the Department of Health Service, and the LAC+USC facility is maintained by the same County Department of Health Service with USC under contract to provide the clinical staff. Luckily, all the potential network locations fell within Pac Bell’s service area. For these reasons Catalina appeared to be an ideal location for the development and testing of Telemedicine systems.

The following sections address the technical issues pertaining to the chamber and Avalon sites. The video and voice services deployed in each setting through the use of H.320 and H.323 video will be compared and contrasted. Conclusions and next steps will be discussed in the concluding section of this project report.

A. DESIGN ISSUES

Development of the Statement of Work (SOW) for the application to support Avalon and the Chamber resulted from interviews with Avalon Hospital staff and the

⁷ NEC 70 is the basic document that almost all Federal, State and local jurisdictions base their fire codes from.

Chamber Manager. Avalon's requirements included access to e-mail, Continuing Medical Education (CME), exchanging documents, and World Wide Web browsing. The most functional application was interactive video conferencing. The initial perception for Avalon was that the equipment reside in the Emergency Room (ER) to support acute patents. The equipment could also be used for radiology as the x-ray machine and radiology room were across the hall from the ER. The Chamber had a slightly different requirement which was to allow the hyperbaric doctor at LAC+USC to see and hear what was going on inside and outside the chamber even though the chamber area already had access to the USC intranet and Internet. Therefore, the team only had to deal with the video conferencing.

One of the overall design requirements was to stay as compliant with standards as possible using off-the-shelf technologies and products. Standards in this instance were in keeping with the standards body's recommendations for networking and software along with the proper installation of networking and associated equipment. Those bodies included the Internet Engineering Task Force (IETF), the Institute of Electrical and Electronics Engineers (IEEE) the International Telecommunications Union (ITU), American National Standards Institute (ANSI), Federal Communications Commission (FCC), Electronics Industries Association (EIA), International Organization for Standards (ISO), National Electrical Manufacturers Association (NEMA), National Fire Protection Association (NFPA), Telecommunications Industries Association (TIA), and Underwriters Laboratories (UL).

Pac Bell supplies the telephone services for the island and at the time only offered Primary Rate ISDN (PRI) as a high capacity digital service. For this reason, PRI interfaces had to be designed into the networking infrastructure at both Avalon and the Chamber. A PRI in the United States is a dial service with a digital capacity from 64 Kbps to 1.536 Kbps. The service is delivered on a T-1 line.

There are many software applications that support interactive video conferencing. There are also two main video conferencing standards, H.320 and H.323, as defined by the ITU. Only software products conforming to either of these standards were considered. The H.320 standard is used with synchronous communications networks. An advantage to H.320 was that every frame of information presented to the network on the island guaranteed delivery at the LAC+USC ED (barring any network failures). H.320 provided high resolution images at 30 frames per second and could be directly interfaced with the PRI line. H.320 cannot cleanly incorporate other types of data like IP to support e-mail and web browsing.

H.323 on the other hand was developed for operation on an IP network infrastructure. The frame rate and picture resolution is the same as H.320 but by the very nature of an IP network, information is lost.⁸ H.323 is an ideal option in instances when other IP related applications are required (like web and e-mail).

⁸ The suit of protocols that make up the Internet, and hence an intranet, are designed to loose information when the network becomes congested. This was a design parameter from the inception

It was decided that H.320 with its guaranteed information delivery would be the proper solution for the chamber while H.323 would be better suited for Avalon. The detailed design issues revolved around the implementation of an IP backbone infrastructure to connect the Avalon Hospital to the USC Health Science Campus. A synchronous infrastructure with the ability to support H.320 video was constructed to support video communications between the chamber and LAC+USC.

B. INFRASTRUCTURE DESIGN FOR THE HYPERBARIC CHAMBER TO LAC+USC

H.320 LINK

There were several design considerations for implementing H.320 video for the chamber. The overall requirements included:

- high-resolution color video from inside the chamber in such a manner as to allow both the Chamber crew and the hyperbaric doctors to see the patient;
- both cameras were to be remotely controllable from the lead chamber crew member's location;
- the triage camera was to have the capability to be relocated outside the chamber building allowing the LAC+USC crew to view the helicopter pad and dock areas along with the triage area;
- the lighting inside the chamber could not be modified to allow a more natural light or to increase the abundance of light;
- the existing and aging intercom system had to be incorporated into the video system allowing the doctors to have two-way communications between any and all of the chamber crew, the paramedic and patient;
- system designed had to meet all local, state, and federal fire codes;
- a second monitor had to be provided above the platform for the chamber crew; and
- a secure or private conversation capability had to be provided for the lead chamber crew member to communicate to the doctors without the rest of the crew and the patient over hearing.

C. CHAMBER BUILDING

The chamber building is shown at the right; the floor plan of the Chamber and the staging area is shown in the photographs below. The inside camera had to be resistant to the pressures inside the chamber at full depth; e.g., 7.8 atmospheres or an equivalent depth of 225 feet of seawater. The specification for the interior camera articulates the requirements for the



of the Internet. The upper layer applications were responsible for re-transmitting lost information. This has become a design consideration when incorporating time sensitive information on the Internet, like voice and video. There is no sense re-transmitting lost voice or video traffic as it has lost its relevance to the conversation. It is a given that H.323 will lose information.

fire specifications. At the time of the design and installation, there were no fire marshals willing to give detailed requirements for the installation and operation of a remote camera inside the hyperbaric chamber. The specification used by the networking engineer was one derived from the NFPA documents.



The inside camera was the UWC-185/H from Outland Technologies. It was a high resolution, remotely controlled internal pan, tilt, zoom, focus, down-looking, color underwater camera with a 8 – 64 millimeter lens. The cable to connect the inside camera to the switching box had to be constructed in such a way as to allow it to be spliced into a pressure gland. The gland allowed the electrical signals to pass through the wall of the chamber without compromising its structural integrity. The cable was a C-5500, eight conductor video cable with power, pan, tilt, zoom control leads. The cable was fed through the wall of the chamber using a Conax Buffalo Sealing Gland, part number PL-18-B12 (3/4" NPT, 10 wire, 18-gage assembly). The camera mount was custom fabricated by the installation team from galvanized pipe. The galvanize coating was ground and buffed off, the galvanize coating could produce toxic gasses under pressure.

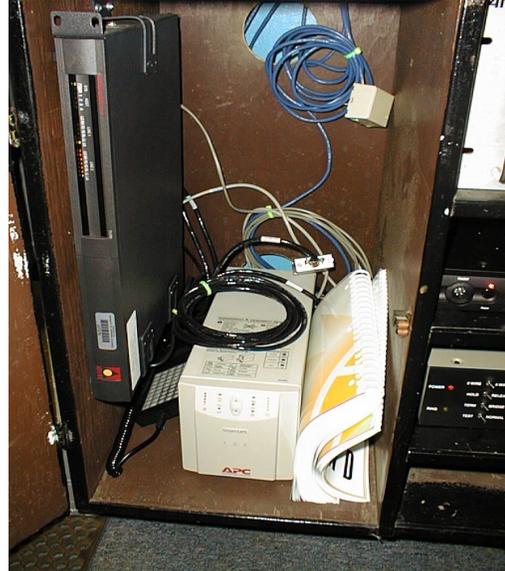
The photograph above shows the inside camera mounted in the chamber. In late November 1998, one of the chamber crew investigated the ramifications of a fire resulting from the video equipment.

An Elbex model number EXC92-7 camera was selected as the most suitable camera for outside the chamber. It is a high resolution, 12VDC, wall mount, dome camera with pan, tilt, zoom, focus capabilities with a 10x zoom lens. The camera was mounted to a piece of plastic, which fit into a window-frame-like assembly that was subsequently attached to the wall inside the chamber building. The plastic fitting had two handles allowing a person to slide the camera out of its mount for transport up to fifty feet. This allowed the camera to be placed outside the chamber building.



The video switcher that controlled both the inside and outside cameras was an Elbex EXS142 CCTV switcher/controller with four channels, manual selector with audio, pan, tilt, zoom and focus controls. The switcher was located at the lead chamber crew member's location. The cameras were controlled from this spot. The output of the switcher was fed into the video auxiliary video input of the video conferencing system.

The chamber had a two-segment intercom system for communications inside and outside the chamber. When the compressors were running the ambient noise levels became very high, making it hard to hear around the chamber. Since the chamber is made of steel, the technicians outside the chamber could not communicate verbally with the caregivers in the chamber without an intercom system. The existing system had two separate circuits with separate headphones, one for the smaller room and

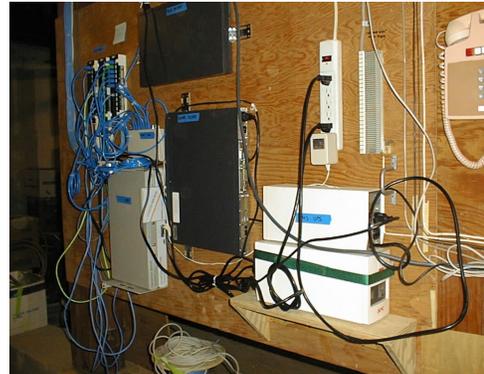


another system for the main portion of the chamber. Headsets and microphones outside the chamber were attached to one of the two systems. The challenge facing the installation team was to design an interface to the existing intercom system that allowed duplex conversations to and from the video conferencing system without interfering with the two separate systems. In addition, a Telex Communications, Inc. wireless intercom system was purchased to augment the communications systems. The installation team designed and fabricated an interface device that allowed the three separate entities to have simultaneous full duplex communications with the video conferencing system.

VCon Telecommunications Ltd. of Herzliya Israel's Cruiser 150 video system was chosen as the video conferencing system. It was chosen over several other systems because of its open architecture and because it was the only vendor (at the time) capable of handling both H.320 and H.323 with the same software. The system was also deployed on a PC rather than the more conventional, separate, stand-alone system. This allowed the incorporation of other telemedicine equipment applications. A Pentium 166 MHz PC with 64M of RAM was used as the PC platform. The video system was augmented with a V.35 and RS-366 dialer card for adapting to the PRI ISDN line. Both the Elbex video switcher and the custom intercom interface were attached to the VCon system.

An Ascend Multiband Plus T-1 multiplexer was used to interface the VCon enabled PC (actually to the V.35 card in the PC) to the Pac Bell PRI. The sequence of events for dialing was:

- Crew member requested a call to the LAC+USC via the VCon software.
- The software interfaced with the V.35 card via the motherboard of the PC.
- The V.35 card communicated the dialing instructions to the Ascend Multiband via the RS-366 dialing interface which set up and dialed the call.
- Once the call was connected, the PCs communicated at 384Kbps via the V.35 interface.



The PC was housed in an existing cabinet next to the chamber. The cabinet was modified to include cooling fans to help with heat dissipation from the PC and Ascend. Figures below show the PC, Ascend and cabinet.

Several other modifications were made to the stock VCon system to accommodate the chamber's unique requirements. The system's small camera was extended from the PC to the lead chamber member's work location along with the keyboard monitor and mouse. Installation was accomplished over a one-week period without major problems occurring during the installation phase.

D. LAC+USC FACILITY

The LAC+USC Emergency Department is located on the ground floor of the building in East Los Angeles. The Hyperbaric Doctors are Emergency Physicians. Another Vcon Cursor conferencing system was installed in the Medical Alert Center in the ED. This is the same room used for communications with LAC+USC's paramedic squads. The PC was installed in a corner of the room with a second 21-inch monitor on a modular desktop. The stock VCon monitor-top camera was used along with the standard handset for audio communications. Compared to the Chamber, the equipment and installation at LAC+USC was far less complicated.



E. AVALON TO USC HSC H.323 LINK

The communications linkage between the Avalon Hospital and the Health Sciences Campus (HSC) of USC was fundamentally different than that of the Chamber. Along with the video and audio requirements, the hospital needed Internet access and e-mail. The best way to accommodate all of the requirements was to implement an IP network.

F. THE AVALON HOSPITAL END

The Avalon Hospital is housed in a building on the outskirts of the city. It is a two level building with the hospital on the top floor and a clinic on the bottom. There is a large basement under the hospital and adjacent to the clinic. The facility had twisted-pair wiring for the aging AT&T Partner phone system but nothing with the ability to support modern data networks. For the long-term benefit of the hospital, Mr. Ralph Morrow of Catalina Cable (owner of the cable TV franchise on the Island) donated an EIA/TIA 568A and 569 compliant infrastructures with Category 5 cable.⁹ The cable plant included drops to almost every room in the hospital and clinic. The other end was terminated in the basement



(affectionately referred to as the Dirt Room as there is only a dirt floor). The networking equipment was mounted on a 4x8-foot piece of three-quarter inch plywood. A Cisco 3620 router was used to terminate the PRI circuit. The Ethernet output of the router was distributed to the hospital and clinic via an Allied Telesis 3216, 12 port Ethernet 10 Base-T hub. A VCon Cursor 150 system was installed in the Emergency Room of the hospital. It was the team's impression that the system was best placed in the ER.

G. USC-HSC END

The networking hub for the Health Sciences Campus is in the Telecom Vault, located under the Eastwood parking lot. The facility houses the AT&T 5E telephone switch along with all the fiber and copper interfaces to the local telephone companies and to the main USC campus. A Cisco 3640 router was installed in a 19-inch open rack and connected to a Pac Bell PRI and the HSC intranet. There were several VCon Cursor 150 video conferencing systems installed throughout the Health Sciences Campus. These multiple placements meant that when the Avalon ER needed support from a specialist the specialist did not have to travel very far on the HSC to video conference. Web access to the Internet and the USC intranet was available through a

⁹ The Electronics Industries Association (EIA) and Telecommunications Industries Association (TIA) have adopted several standards describing inside building wiring and pathways for supporting local area networks. The specifications define the installation, termination, distances, cable type, fire stopping, labeling, and much more within the realm of local area network infrastructure.

standard web browser while e-mail was deployed on the Netscape platform. The Avalon to USC-HSC Internetwork is shown in Appendix C.

IMPLEMENTATION OF THE TECHNOLOGY

A. AVALON TO USC-HSC

The infrastructure was installed without incident. A problem arose when the routers attempted to communicate via the PRI. The connection was established but no intelligible data were being passed. The ISDN system uses 64 Kbps channels with an out-of-band signaling channel.¹⁰ The calls between the routers were being established without a problem with each router able to see the call being established. Once the routers attempted to authenticate one another the connection dropped. Several weeks were dedicated to resolving the problem. Eventually we found there was an old Alternate Mark Inversion (AMI)¹¹ T-1 trunk in the system of which Pac Bell was unaware. The unfortunate point was that it took repeated phone calls to the Pac Bell ISDN trouble desk to convince someone they had a problem. Only after much argument with the technical staff from Pac Bell was a detailed examination of their T-1 trunking facility performed. This examination uncovered the older, undocumented, AMI trunk between the Los Angeles 70T Tandem switch and the LA-23 switch. Once identified, the routers communicated without a problem for the duration of the grant period. The Pac Bell switch configuration is shown in Figure 14 – Pacific Bell Switch Configuration.

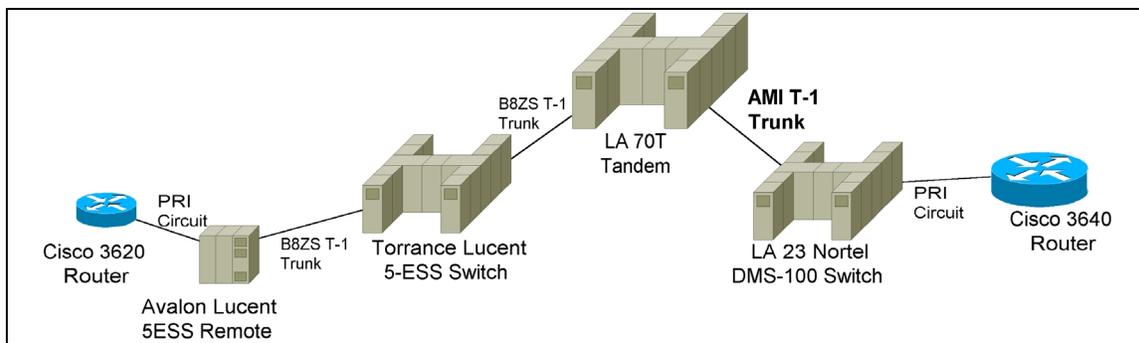


Figure 14 - Pacific Bell Switch Configuration

¹⁰ Out-of-band signaling uses a separate logical channel for call establishment, monitoring and tear down, versus an in-band where the call establishment is done over the same channel that the conversation will take place. An example of this is when one places a phone call, one can hear the dial digits going to the telephone switch when the buttons on the phone are being pushed, this is in-band signaling.

¹¹ T-1 lines have been around for years. The original line encoding (the way bits were electrically put on the copper wires) mandated that no more than seven consecutive zero could be transmitted in succession. AMI circuits can not support 64Kbps calls. Newer line encoding schemes, like Binary 8 Zero-Bit Substitution (B8ZS) allow more than seven zeros. All is well except when a 64Kbps call is placed over T-1s that are set for 64K but are sent over AMI trunks. In essence, every eighth bit is stepped on resulting in massive data errors.

B. CHAMBER TO LAC+USC

The installation of the video conferencing equipment at the Chamber and LAC+USC went without incident. The PRI routing problem was resolved prior to the installation at the Chamber. There were subsequent ISDN problems with this link that will be discussed in the results section of this report.

EVALUATION OF THE APPLICATION

A. APPLICATIONS SUPPORTED

Strictly in terms of networking and infrastructure, both Telemedicine links worked well. Once the initial system problems were resolved, the systems operated as designed. Problems occurred during the contract period from several directions. Pac Bell ISDN call routing problems negatively affected audio on the Chamber link, and uncoordinated software and hardware changes resulted in several system outages. Unplanned network traffic on the Avalon LAN affected video and audio quality on the Avalon Hospital link.

B. AVALON HOSPITAL TO USC-HSC

The initial purpose for linking the Avalon Hospital to the Health Sciences Campus was to support the Emergency Room. During the next several months the benefits of the system were found in several other departments. For example, the system was used to practice psychiatry as the local Social Worker involved a USC psychiatrist by remote video in patient care. Patients became very comfortable with the video system. The second unanticipated application was to support Quality Assurance (QA) activities. USC reviews their residents' progress through QA assessments. When residents were placed on the island for a rotation the QA assessments were conducted using the video conferencing system. E-mail and Web browsing usage also increased with time.

In an attempt to keep the video conferencing systems up-to-date and to fix small applications bugs, application software and hardware was changed without thorough testing. This sometimes compounded problems.

During the contract period, the Avalon Hospital contracted with an outside billing agency. The billing agency installed an Ethernet bridge adjacent to the router and hub supporting the Telemedicine application. Even though the bridge was on a separate IP subnet, the traffic it added to the network adversely affected the video and audio quality of the video conferencing software. This addition was not realized until several weeks prior to the end of the contract.

C. HYPERBARIC CHAMBER TO LAC+USC

The Chamber's video system configuration remained fairly static throughout the contract period. However, several small items were added. A VCR recorder was added in the chamber building to record the video and audio. This was for two

purposes, first for training and second for periods of network outages (outages will be explained in the Discussion Section).

Several times during the contract period chamber personnel manipulated the Windows 95 Operating System in the chamber PC. This resulted in several trips by support persons to the chamber to resolve the resultant problems.

Hardware and software configuration management also contributed to some of the outages. Software and hardware were changed at the LAC+USC end in attempts to rectify problems without thorough testing. For several months the support teams attempted to rectify a problem that manifested itself by dropping only the audio portion of the session. The team looked to the hardware and software configurations. They downgraded the hardware and software to their original configurations. The ISDN lines were tested for proper call completion. Vendors for the conferencing equipment were consulted but nothing seemed to fix the audio drop-out problem. The calls would connect just fine and, initially, the video and audio would operate properly. However, within seconds or sometimes minutes the audio dropped, requiring the chamber manager to call the LAC+USC on the phone. This worked well for the chamber manager but did nothing to help the paramedic in the chamber.

A test location was established at a contractor's location in the city of Hawthorne CA. The contractor was responsible for the initial system design and installation. A PRI line and test video system was left in place for subsequent system testing. During the time the chamber was experiencing the audio drop problem, calls to and from the test system did not experience the same audio problem. But calls to and from the test system to LAC+USC did experience the problems. The Hawthorne test system's location in the 323 area code turned out to be significant. The Chamber was in the 310 area code while LAC+USC and the test system were in the 323 area code.

At the same time the audio drop was being experienced Pac Bell was implementing an overlay area code change in the 310 area code.¹² The new area code was going to be 424. After several months of a "get acquainted" period during which the customers within the 310/424 area code were able to dial either seven or ten digits, the California Public Utilities Commission (CPUC) repealed the overlay plan.

Mysteriously, at the same time the area code overlay was removed enabling users to dial seven digits, the audio dropout problem went away. The team attempted to get information on the problem from Pac Bell but to no avail. There were so many changes to the Pac Bell network at the time that the answer will probably never be identified.

¹² There are two ways to implement an area code change within an area when code runs out of numbers, a geographical split or an overlay. A geographical split defines new, smaller, boundaries for an existing area code and remaining area gets the new area code. An overlay keeps the same geographical area but the area would have two area codes. This requires the customers within the overlay area to dial ten digits all the time (1 + area code +number) for all calls regardless of whether the call is within the same area code.

FINDINGS AND ANALYSIS

A. H.320 Vs. H.323 FOR TELEMEDICINE APPLICATIONS

In the initial stages of the contract, it was assumed that H.320 video would be best suited for the Chamber while H.323 IP based video would be best suited for the Avalon Hospital. After investigating the two methods, interviewing the customers, and evaluating the ongoing support costs, it was determined that the IP based H.323 was by far the better application to deploy. If a network is designed correctly in advance, the H.323 video and audio fidelity is equal to the H.320 at the same encoding rates. There have been many studies which show the cost of sending a bit of information over a classic IP network is roughly 25% the cost of an equivalent voice network bit. Since Telemedicine usually adds an additional overhead cost to any operation, lower operating costs is highly desirable. An IP network also supports all the rest of the classic Internet applications, like e-mail, web browsing and a like.

B. REMOTE MONITORING, TROUBLESHOOTING AND MAINTENANCE

It became apparent about midway through the contract period there were three problems that needed addressing: system monitoring; the ability to troubleshoot problems; and performance of routine maintenance on the systems.

At both Avalon and the Chamber, persons reconfigured the systems by either adding other application programs that interfered with the video conferencing software or in some way changing the configuration settings. Somehow the video settings on the PC in the chamber building were changed to obscure settings which required reloading the Windows operating system. Later versions of the operating system allowed a System Administrator to restrict the ability of a user to change the configuration. Restrictions such as adding a password-restricted System Administrator or implementing remote control software such as Timbuktu or PC Anywhere greatly diminished the number of “tinkering” problems, increased the responsiveness of troubleshooting, and reduced the need for associate repair travel to the two island sites.

The inclusion of network monitoring and maintenance software is strongly recommended in future telemedicine projects like these two. Our team had no way of proactively monitoring the network for problems. With remote network monitoring software we would have had the ability to pinpoint the source of trouble with the link between Avalon and USC-HSC. Many trips made to Avalon to troubleshoot the PC, suspecting it was the source of poor video and audio quality, would have been avoided. Several trips were required for the technician to confirm that another network had been added to the Telemedicine network. The second system was added in an area not frequented by anyone and only a trained networking person would realize something had been added to the network.

The fact that a rogue network could be installed without a system manager’s knowledge originates with the original conception of the Avalon network as one that would handle very little traffic. Real-time applications, like video conferencing,

require very short network latency times to provide a natural look and feel to the end users. The arrival rate of the information must be relatively consistent (referred to as jitter). There are two ways to accomplish this, design the network for minimal traffic or deploy tools to regulate the flow of traffic. Both of these are referred to as Quality of Service (QoS). QoS was designed into this system by limiting the number of workstations. This assured that the time sensitive video traffic would traverse the network with little latency and jitter. Costs of adding software tools (remote network monitoring) were thus avoided. Traffic from the billing service interfered with the video traffic to the point that it could not traverse the network.

In retrospect, analog modems should have been placed on all the networking and PC equipment. This would have allowed out-of-band testing and troubleshooting. In-band access was fine until the network became overwhelmed with congestion or went down. An alternate means of access is necessary.

ISDN is a fine tool for many applications. It is widely available and provides relatively good service. The down side to ISDN is that troubleshooting is almost impossible. It takes a well-coordinated, small army of people to isolate and resolve problems. In terms of newer access methods, ISDN is very expensive. Frame Relay, ATM, DSL, and Cable Modems all support virtual private IP network at a fraction of the cost of ISDN.

Overall, the Avalon and Chamber systems proved the viability of using off-the-shelf, cost effective, standards based video conferencing systems for supporting remote Telemedicine applications. We determined that H.323 video systems on a well-engineered and maintained network are just as functional and more cost effective than H.320 systems. ***ISDN is not the technology of choice when other more reliable and cost effective alternatives exist.*** Remote monitoring and maintenance tools are essential in maintaining a good operating environment. This portion of the project also demonstrated that an IP based network in a small rural hospital, when attached to a large medical teaching facility, can dramatically increase the local physician's and clinical staff's education and access to up-to-date information.

STUDY 5:

IMPACT OF TELEMEDICINE ON EYE CARE FOR UNDERSERVED IN AN INNER-CITY PRIMARY CARE CLINIC

Authored by Catherine Jackson and Dan Relles (RAND) and Paul Lee (Duke)

INTRODUCTION

Patients with diabetes continue to suffer preventable vision loss. Diabetic retinopathy is the leading cause of blindness among working age Americans.¹ While many reasons contribute to this, a major factor is the lack of timely use of eye care services. Even today, nearly half of all Americans with diabetes do not obtain an annual eye exam.^{2,3} The numbers of those who obtain annual eye exams in two consecutive years is even lower, under 20 percent. This lack of use of eye care among patients with diabetes is particularly marked among vulnerable and minority populations in urban centers in the United States.⁴ While some older Americans may not need to have annual eye exams, according to theoretical models,⁵ the vast majority of patients with diabetes will eventually develop some form of diabetic retinopathy.^{6,7} Applying new knowledge about the importance of glycemic and blood pressure control, as well as the use of ACE inhibitors, to routine care may well reduce the future incidence of vision loss due to diabetes.⁸ However, there remains the problem of caring for today's patients, especially among the vulnerable subpopulations at greatest risk for diabetes and its complications, such as vision loss and blindness.

Previous studies have explored the utility of telemedicine as a means of providing eye exams to those patients with diabetes who do not routinely obtain eye care.^{9,10} In a companion paper, we demonstrated technical feasibility and validity of telemedicine as a screening paradigm for those with diabetes to obtain an eye exam.¹¹ In this paper, we describe the application of this screening paradigm to a population of patients with diabetes in an inner city population in Los Angeles. We sought to determine the undetected burden of diabetic eye disease among this population as a means of assessing the usefulness of telemedicine screening to supplement care. In addition, we specifically ascertained the relevance of specific barriers to obtaining eye care among these patients as a means of measuring the ability of telemedicine to overcome some of these concerns.

IMPLEMENTATION OF TELEMEDICINE

We selected a public health clinic--the H. Claude Hudson Clinic--in downtown Los Angeles as the site for the study. We chose Hudson for two reasons: (1) clinic personnel were willing to accommodate the evaluation of the use of telemedicine, and (2) the clinic serves a large population of poor and underprivileged, a group that might be expected to benefit from better access to ophthalmologist services.

We also attempted to gather data from the Noble Clinic, an outpatient clinic in Van Nuys operated by the Tenet Healthcare Corporation. We monitored the clinic for several weeks.

But traffic meeting our eligibility criteria was very light, and we ultimately obtained only 27 usable cases from this source. Because this is such a small fraction of the total, we focus mostly on the experiences of the Hudson Clinic population in discussing our results, although we do include the Nobel cases in our analysis.

We placed two nonmydriatic fundus imaging cameras in the primary care clinics. We then recruited patients with diabetes from the waiting room. In total, 1,519 patients visited the Hudson Clinic during the study period. Eight hundred and four (804) did not meet inclusion criteria for our study, having received an eye exam in the previous year. Seven hundred and fifteen (715) who met inclusion criteria were approached, of whom 461 (64 percent) agreed to participate in the study. Add to this some 30 patients from Noble. The study consisted of a patient survey administered by trained interviewers, an image of each fundus obtained by a digital camera through undilated pupils taken by a trained technician, and an interpretation of the image by a retina specialist at the Doheny Eye Institute of the USC School of Medicine. We linked the survey information with the outcome information from the specialist's review. Our goal was to relate clinical severity and follow-up need to the background characteristics recorded in the questionnaire. The questionnaire itself was provided in a quarterly report during the project cycle.

A. DESCRIPTION OF H. CLAUDE HUDSON CLINIC

The Hudson clinic is a public facility of the Los Angeles County health system located just south of Downtown Los Angeles. This clinic has no eye care services and all patients needing eye care are referred to another County facility. Except for emergencies,



the patients seen at this clinic generally experience a six month or longer wait to be seen for their eye care, given the case loads at the County eye clinics. Since most patients seen at this clinic have no other source of health care and have no health insurance that would enable them to see other providers of health care, they have no means of otherwise obtaining eye care except for charitable and other non-profit organizations.

The Clinic population is mostly Hispanic, educated at 8th grade or less, uninsured and on Medicaid. Family incomes are generally under \$10,000.

B. RECRUITING THE STUDY POPULATION

We enrolled 461 patients with diabetes seen at the Hudson Clinic for one year beginning December 14, 1998; also, 30 patients at the Noble Clinic between April and September 1999. Eligible patients were identified through several means. First, all scheduled patient visits were reviewed by study investigators to identify patients with diabetes. Second, the records of any walk in or unscheduled patients were also reviewed by study investigators to determine if they had previously been diagnosed as having diabetes. Finally, patients who were newly diagnosed as having diabetes on that visit were

identified by the nursing staff. During the study period, 715 eligible patients were identified.

C. DESCRIPTION OF THE PATIENT SURVEY

We designed a patient survey to collect information about health habits, demographic information, and health status. The survey consisted of validated questions and instruments from prior studies, including the SF-12 (12). The survey was pilot-tested and refined, with an estimated time to completion of 45 to 60 minutes. Questionnaire data were entered into a database program. Scoring of the SF-12 questions was performed using standard, published scoring algorithms.

The survey was interviewer administered in person at the clinic visit in either English or Spanish. Interviews were conducted prior to seeing the health care provider among those with previous diagnoses of diabetes. Those newly diagnosed were interviewed after the diagnosis. Because of this difference, the results are presented separately below for those with a new diagnosis compared to those with a prior diagnosis.

The Spanish version used prior validated translations for questions where available. All questions without such validations were then translated into Spanish. All questions, including previously validated questions were then back-translated to ensure fidelity in our population of Spanish speakers (given the multi-cultural nature of the Hispanic population in Los Angeles). Disagreements among the different translators were adjudicated through a consensus process. The interviewers were trained using a standard protocol and inter-interviewer reliability assessments were conducted.

D. STANDARDS FOR REFERRAL

The images of the fundi were captured by use of a Canon CR5-45NM nonmydriatic fundus camera, using an electronic data capture back. Images were captured at the H. Claude Hudson Clinic and transmitted over the internet to the ABBC where they were accessed by clinicians on a secure server. The technicians were also re-tested by the head ophthalmic photographer at regular intervals to ensure continuing accuracy in photographic technique.

The camera back used was capable of capturing an image of 640 by 480 pixels, with a density of 24 bit color. Once the image was captured electronically, it was downloaded to a secure server at the USC-ABBC central office and the image logged in and stored. Each night, a retina specialist at the Doheny Eye Institute would read the stored images and provide an interpretation, using a standard reporting form. The form would state whether a trained eye care provider would need to assess the patient in person. This report form would then be electronically sent to the clinic so that the nurses and primary care providers could access the report and then contact the patient as needed. In other words, this study utilized a screening paradigm to organize its operations, while also incorporating a "lab test" approach to the screening for diabetic eye disease (like a send-out HbA1c level in the past).

For analytical purposes, we needed to characterize how serious the findings in the captured images were. We used whether the findings suggested that the patient needed to be seen in an expeditious fashion or could have an eye exam scheduled using the standard county appointment system (6 months to next available). This was supplied in text provided by the retina specialist. We reviewed the text, and determined that patients would be assigned to expedited referral for care or standard appointment, according to the following rules:

Expedited referral -

1. anything indicative of proliferative disease, such as NVD, NVE, pre-retinal hemorrhage, traction, detachment, membranes;
2. anything indicative of a more serious eye condition whether or not related to diabetes, such as retinitis or age-related macular degeneration;
3. any of the following:
 - a. foveal lesions of unknown type not indicative of scarring or inactive / old process
 - b. any suspicion of macular edema, including cotton wool spots in macula OR dot-blot hemorrhages PLUS hard exudates

Deferred to 6 months (usual appointment system) -

1. only dot/blot hemorrhage in macula
2. only hard exudate in macula
3. only cotton wool spots outside macula
4. only microaneurysms
5. inactive chorioretinal atrophy or scar process
6. soft or hard drusen

ANALYSIS AND RESULTS

Our analysis utilized two sources of information: the patient questionnaire results and the image evaluation provided by the retina specialist. The former provide background patient characteristics that we use to characterize the potential beneficiaries of the intervention. The latter tell us something about the potential benefits. Given that these patients would ordinarily have to wait several months to be seen by an ophthalmologist, we are interested in how serious their eye problems are and what fraction of this population might benefit from the presence of telemedicine. A companion paper describes the accuracy of the paradigm used here, and other papers have compared the validity of in-person to telemedicine evaluations.^{13, 14} Instead, we look at the kind of findings present.

A. DEMOGRAPHIC DESCRIPTION OF THE POPULATION

Table 10 (Appendix D) describes the participants' demographic characteristics. As expected, the large majority of participants (423) were of Hispanic background, similar to the overall clinic population composition. Sixty-nine (14 percent) were aged 40 or younger, while forty-eight were 65 or older. Nearly three quarters were female (356 of 491). Similarly, 298 (60 percent) had an 8th grade or less education, while less than 11 percent (50) had some college education. Nearly half (244) had a household income of less than \$10,000 in the prior year, with the majority (284) supporting 3 or more people in their household.

B. HEALTH STATUS OF THE POPULATION

In terms of their diabetes, the patients had diabetes for an average of 7.9 years +/- 7.0 years (S.D.), with a range of 0 to 41 years. Forty-five of the 356 women were initially diagnosed with diabetes during a pregnancy. Only 43 were 30 years of age or younger at diagnosis. One hundred sixty four (33 percent) were initially diagnosed at age 50 or older. The diabetes was significantly severe enough at diagnosis that 141 patients (29 percent) were placed on insulin at the time of diagnosis.

The overall health state described by the study participants was relatively poor, with only 15 (3 percent) describing their overall health as excellent or very good, 69 (14 percent) as good, and 291 (59 percent) describing their health as fair. Overall, 215 (44 percent) stayed in bed at least once during the prior year because of an illness or injury.

C. EYE CARE ACCESS AND USE

As seen in Table 11 (Appendix D), only 78 (16 percent) of the participants reported receiving an eye examination in the prior 12 months, with another 175 reporting an exam between 1 and 2 years ago. Of critical importance, nearly a quarter of the patients (133) reported never having had a complete eye exam, while half of these (63) never had even a vision check. Three hundred seventeen could not state the type of provider who gave them the eye examination. This is consistent with the observation that nearly 40 percent of the patients could not tell what type of provider was responsible for their overall diabetes care.

Table 12 (Appendix D) provides the most common reasons given by the patients for not having had an eye exam, using a list generated from a prior study involving focus groups of primary care patients and patients with diabetes seen in a primary care office setting.

This lack of use of eye care services is notable because the patients are otherwise regular users of primary and diabetes related health care. The questionnaire determined that only 77 (16 percent) patients saw their primary care provider two times or fewer in the prior 12 months; the rest saw their providers at least 3 times. Thus, lack of use of overall or general health care does not appear to be an explanatory variable in the low prior use of self-reported eye care services.

D. BIVARIATE PREDICTION OF URGENT CARE

We attempted to determine if eye care need could be related to the background characteristics obtained about each patient in our survey. These include demographic characteristics, health habits, access to care, and severity of diabetes. Our dependent variable is whether the patient was referred for expedited examination, as described above.

We were able to link the referral indicator to our survey for 422 (86 percent) of the cases. Reasons why a case might not link are due to administrative problems in assigning the case for review. The unlinked cases were distributed uniformly in time. Further, we examined the surveyed characteristics of the linked versus unlinked samples, and concluded the populations displayed no systematic differences: chi-squared test statistics comparing the distributions of each characteristic were always less than 1.0. The remainder of our discussion refers to the matched sample of 422 cases.

In our initial exploration, our methods were mostly graphical. We had a large number of candidate explanatory variables, and we wanted to screen these for reasonableness before using them in multivariate models. Thus, we plotted the probability of needing expedited referral against the candidate explanatory variables. Based on the assumption that better health habits would lessen the probability of needing referral, we judged whether the plots showed an expected direction of effect, and, if so, the strength of the relationship: was it linearly related and was the slope of the relationship suggestive of a relationship? We limited the list to variables thought to be exogenous to the decision to seek an eye exam. Thus, we did not include whether the patient saw an ophthalmologist within the past three months, but we did include whether the patient had reported high blood pressure. Table 13 (Appendix D) identifies the variables that we examined. All but two are drawn directly from specific items in the questionnaire; the other two are the SF-12 health mental and physical functioning indices, which we used as a surrogate for general health status. The plots themselves are reproduced in Appendix F.

We viewed the bivariate plots as screening tools to determine if a variable should be included in the multivariate models. The presence of a bivariate relationship does not guarantee that the variable contributes to multivariate explanatory power. However, the questionnaire characteristics we used had very low correlations with one another (maximum R-square in regressing any independent variable on all other independent variables was .2), suggesting that relationships discovered in bivariate models would carry over to multivariate models.

E. MULTIVARIATE PREDICTION OF URGENT CARE

We took the variables identified in the bivariate plotting that appeared to offer some predictive power in modeling the probability of referral. We added certain demographic variables as well--gender, ethnicity, education level--to test their effects. The existing scales for all of these variables was arbitrary -- 1 through 6. We transformed these scales to produce a series of dummy variables, as follows:

Health and Behavioral (H&B) Variables

hiblood	1 if B1b = 1	0 if 2
trblsee	1 if B4 = 3,4,5	0 if 1,2
poordiag	1 if C1 = 4,5,6	0 if 2
didnknow	1 if C30a = 1	0 if 2
cost	1 if C30b = 1	0 if 2
where2go	1 if C30c = 1	0 if 2
nowaytgt	1 if C30d = 1	0 if 2
thinkns	1 if C30e = 1	0 if 2
insulin	1 if D3 = 1	0 if 2
hightrav	1 if E2 = 4,5	0 if 1,2,3

Demographic Variables

male	1 if f2 = 1	0 if 2
black	1 if f6 = 1	0 if 2-6
hispanic	1 if f6 = 2	0 if 1,3-6
highcol	1 if f7 = 3,4,5,6	0 if 1,2

The C30 variables, reasons not to receive an eye exam, were further combined into the composite variable

$$\text{reasons} = \text{didnknow} + \text{cost} + \text{where2go} + \text{nowaytgt} + \text{thinkns}.$$

We also used the SF-12 variables PSF12 and MSF12 and the ethnicity indicators. Where data was missing, we set it equal to the variable's mean value.

We fit logit models to the referral outcome. The individual reasons for not getting an exam turned out to be unimportant, so were replaced by the composite reasons variable. Regression models were also fit to examine the amount of collinearity among the H&B variables and between H&B and demographic variables: the maximum R-square in regressions of H&B variables on all other H&B plus demographic variables was 0.2.

We tried several different logit models. Because of the low levels of collinearity, our observations in the bivariate study held up quite well: coefficients were of the expected sign and magnitude. The one exception was the PSF12 score, which looked to be important in the plot, but which turned out to be unimportant when entered jointly with the other variables.

We sought a simple model which could summarize the predictive strength of the H&B characteristics. The ethnicity variables turned out to be statistically significant, but we chose to drop them from the models because the percentage of Hispanics was so high (87 percent in the linked sample). Keeping variables with t-statistics greater than 1.0, we arrived at the following, which fit about as well as all of the models we tried:

sample size	422
successes	125
chi-squared	23.4157
log likelihood ratio	11.7079

variable	coefficient	estd std dev	t
Constant	-1.6376	.2077	-7.8830
hiblood	.7005	.2242	3.1246
poordiag	.4085	.2461	1.6594
insulin	.6172	.2382	2.5913
hightrav	.3463	.2403	1.4407
referral	dependent variable		

Scoring high on each of these variables (high blood pressure, judgment that vision is poor, taking insulin, and having high travel times) increases the log odds by about 2.0 of needing referral, or the odds by a factor of about 7.4. This is a significant finding, because it targets individuals among patients with diabetes whose need to be screened is quite high. Figure 13 (Appendix E) shows the fitted and actual probabilities for ranges of fitted referral probabilities. The right-most point is based on only four cases, so the uncertainty of predicted values is high there, but the plot nevertheless demonstrates that the model does have significant predictive ability.

CONCLUSIONS

The results of the study illustrate two important concepts. First, a telemedicine concept based on a "send out" lab test paradigm in the offices of busy primary care providers to under-served populations is feasible and practical. Second, the installation of such systems will detect serious eye complications of diabetes mellitus and potentially save the vision of many who would otherwise lose their eyesight.

The implementation system in this study required the training of primary care nurses and office assistants in the use of a non-mydratic camera, the placement of the camera in the primary care group practice, the successful use of the camera, the transmission of a "sample" (the retinal image) to an outside interpretation site, and the return of the interpretation in a timely manner to the primary care provider office for patient contact and action. None of these steps is novel and therein lies the promise of this system. The primary care providers' office did not have to change their office practices in a unique manner. Instead, they incorporated the eye camera as they would any new piece of lab equipment or new lab test. Further, the periodic reliability and validity checks on the photographic skills of the office staff demonstrated continuing ability to use the camera in an effective manner. Further, this parallels the intermittent certification for specific pieces of lab equipment or of personnel skills.

This finding parallels that of other studies. The ability of mobile health screening vans to take valid photographs as well as the ability of trained technicians in large population-based studies, such as Beaver Dam, appears to carry over to the public clinic setting.¹⁵

The second major finding of the ability to detect significant ocular diabetic complications is reassuring, since it provides independent confirmation of the realistic feasibility of a screening paradigm for diabetic screening. Our companion study demonstrated the reliability of image interpretation at the resolutions and methods used in this study on a technical level, a result reinforced by the actual results of this study. The results of this study are in line with those of other studies using more traditional examination methods on the degree of retinopathy and poor access to eye exams noted in poor and under-served populations with diabetes. For example, the risks of developing diabetic retinopathy are higher among those with hypertension and poorer glycemic control.⁸

Multivariate analyses indicate that those with findings indicating a need for referral for care sooner than 6 months were those with high blood pressure (Odds Ratio = 2.02 +/- .46), those taking insulin (OR = 1.85 +/- .45), those with high travel times (OR = 1.41 +/- .34), and those with "poor" self-described general health status (OR = 1.51 +/- .37). These factors, especially high blood pressure and requiring insulin in this type 2 population, are those that have been identified as risk factors for progression and vision loss in the UKPDS results.⁸ Thus, the multivariate analyses further support the validity of the findings of the study in this uncontrolled study population.

The implications of this study for the future use of eye care services delivery in poor and under-served communities are quite promising. While most patients with diabetes do not have an annual eye exam, especially among the poor and minorities, patients with known DM have regular contact with their primary care provider. In our study, the average patient had three contacts with their primary care provider in the prior year, while only 53.7 percent had an eye exam during that time. By placing cameras in primary care offices, eye care services can be effectively placed within reach of the patient and their primary care provider. By involving the primary care provider, the patient is also assured of professional feedback and follow-up to the results, as well as immediate guidance on where to go and who to see next. Unlike health fairs, or screenings at churches, the patient is already in a relationship with a health care provider who can advise and assist the patient.

References

1. National Diabetes Data Group. Diabetes in America. Bethesda, MD: US Department of Health and Human Services (NIH Pub No. 85-1468) 1985, Chapter 1.
2. Brechner RJ, Cowie CC, Howie J, Herman WH, Will JC, Harris MI. Ophthalmic examination among adults with diagnosed diabetes mellitus, JAMA 1993; 270: 1714-18.
3. Will JC, German RR, Schuman E, Michael S, Kurth DM, Deeb L. Patient adherence to guidelines for diabetes eye care: results from the diabetic eye disease follow-up study. American Journal of Public Health 1994; 84: 1669-71.

4. Sprafka JM, Fritsche TL, Baker R, Kurth D, Whipple D. Prevalence of undiagnosed eye disease in high-risk diabetic individuals. *Archives of Internal Medicine* 1990; 150: 857-61.
5. Vijan S, Hofer TP, Hayward RA. Cost-utility analysis of screening intervals for diabetic retinopathy in patients with type 2 diabetes mellitus. *JAMA* 2000; 283: 889-96.
6. Klein R, Klein BEK, Moss DE, Davis MD, DeMets DL, The Wisconsin Epidemiologic Study of Diabetic Retinopathy, II: prevalence and risk of diabetic retinopathy when age of diagnosis is less than 30 years. *Archives of Ophthalmology* 1984; 102: 520-26.
7. Klein R, Klein BEK, Vision disorders in diabetes. In: National Diabetes Data Group, *Diabetes in America*. Bethesda, MD: US Department of Health and Human Services (NIH Pub No. 85-1468) 1985, Chapter 12.
8. Stratton IM, Adler AI, Neil HA, Matthews DR, Manley SE, Cull CA. Association of glycemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35); prospective observational study. *British Medical Journal* 2000; 321: 405-412.
9. Flowers CW, Baker RS, Khanna S, et al. Teleophthalmology: rationale, current issues, future directions. *Telemedicine Journal* 1997; 3: 43-52.
10. Li HK, Telemedicine and ophthalmology. *Survey of Ophthalmology* 1999; 44: 61-72.
11. Lee, PP et al. Evaluation of Telemedicine Image Quality for Interpretation of Diabetic Retinopathy, in *Investigations of Sufficiency in Telemedicine Applications: Standards in Context of Populations and Technologies*, National Library of Medicine, 2000.
12. Ware JE, Kosinski M, Keller SD. A 12-item short-form health survey: Construction of scales and preliminary tests of reliability and validity. *Medical Care* 1996; 34: 220-233.
13. Briggs R, Bailey JE, Eddy C, Sun I. A methodologic issue for ophthalmic telemedicine: image quality and its effect on diagnostic accuracy and confidence. *Journal of the American Optometric Association* 1998; 69: 601-05.
14. Aiello LM, Bursell SE, Cavallerano J, et al. Joslin vision network validation study: pilot image stabilization phase. *Journal of the American Optometric Association* 1998; 69: 699-710.
15. Bresnick GH, Mukamel DB, Dickinson JC, Cole DR. A screening approach to the surveillance of patients with diabetes for the presence of vision-threatening retinopathy. *Ophthalmology* 2000; 107: 19-24.

V. BONUS REPORT

A SHORT HISTORY OF DIGITAL TRANSMISSION

Authored by John Beecher, Logicon IS

The genesis of digital transmission finds its roots in the Telephone company. In the early 1960s AT&T needed a better method to maximize the efficiency of their existing copper cable plant. A scheme of turning analog voice into digits (or bits) was developed along with a way of combining multiple digital voice signals into one large single bit stream. The new Digital Signal, DS, used a scheme known as Pulse Code Modulation. This scheme turned analog voice into a single bit stream.

The phone system was designed to pass voice signals from roughly 300 Hz to 4,000 Hz. In 1933 Harry Nyquist demonstrated that an analog signal, like voice, can be encoded (turned into bits) and subsequently decoded (turned back into analog) when sampled at twice the highest frequency (4,000 Hz for analog voice vs. 16 to 32,000 for music on today's CDs). This scheme would allow enough resolution to understand tonal inflections while not sounding like Donald Duck. Carrying Nyquist's calculations out for the phone companies 4000 Hz maximum signal would be 4,000 times 2 or 8,000 samples per second. The samples were encoded into eight bits each. This works out as 8,000 samples per second times eight bits per sample yields 64,000 bits per second. It takes 64,000 bits per second to carry one voice call. This is referred to as Digital Signal Level Zero or DS-0. *A DS-0 is the foundation for the entire digital hierarchy within all phone systems used throughout the world today.*

In order to maximize the efficiency of the existing copper cable plant a multiplexing (combining) scheme was developed with the DS-0 as the fundamental building block. In the early 1960s AT&T Bell Lab combined 24 DS-0s into one signal bit stream (the number 24 was empirically derived from then state-of-the-art electronics and the ability to transmit digital signals on the existing copper wires). Combining 24 DS-0s produces 1,536,000 bits per second (bps). Several overhead bits were inserted (the phone company needs some for synchronization) with a final bit rate of 1.544 Mega bits per second (Mbps). This is called Digital Signal Level One or DS-1. The term T-1 is also used for DS-1; for accuracy there is a difference between DS-1 and T-1 but for the sake of this discussion the two are synonymous.

The state-of-the-art in electronics allowed Telephony Engineers to combine bit streams to a DS-5 level (7,680 DS-0s or 565.148 Mbps). Unfortunately there was a lot of overhead associated with the larger transmission DS levels and overhead equated to lost revenue.

In a quest to increase their call carrying capacity, Bell Labs developed fiber optic cable in the late 1960s and early 1970s. Fiber was first used for communications in 1979 in Turnbull Connecticut. Since then the DS-0 building block has been used to develop the Optical Carrier System, or OC. The multiplexing scheme for Optical Carriers is called the

Synchronous Optical Network, or SONET. SONET is a fault tolerant ring topology and is being installed throughout the world today.

The Optical Carrier (SONET) hierarchy starts with a bit rate roughly equivalent to a DS-3 (44.736 Mbps or 672 DS-0s) and is referred to as OC-1. An OC-1 has a bit rate of 51.48 Mbps. The reason for the difference is to accommodate the international equivalent to a DS-3, an E-3. In theory the SONET hierarchy will be standard throughout the world. Optical Carrier levels increase in increments of 51.84 Mbps. An OC-3 is three OC-1s, or three times 51.48, or 155.52 Mbps. Bell Labs has chosen several Optical Carrier levels for specifying SONET multiplexing equipment. Those levels are OC-3, 12, 48, 96 and 128. Theoretically there is no limit to the OC hierarchy, but OC-128 is the furthest Bell Labs has identified to date.

What does the future hold? No one has been able to define the upper limit of Optical Carriers as the upper limit of fiber cable has not been reached. *Unlike copper where we have reached the physical limits of physics we have not yet found the physical limit of fiber.* This is not to say that the bandwidth through copper has reached its limit, higher bandwidths will be achieved via more suffocated modulation schemes.

Optical Carriers are transmitted on one eight-micron diameter fiber cable. Recent developments from Bell Lab and others are showing wave length division multiplexing schemes for fiber cable (dividing the fiber into separate channels via color; almost like having a red channel, a green channel, blue channel and so on). Current technology is able to operate twelve independent channels of six gigabits per second each (Gbps or 1,000,000,000 bps) over one fiber. This works out to an overall throughput of 72 Gbps, that's equivalent to 1,125,000 DS-0s. Today the gating factor for increasing the throughput of fiber is the current state-of-the-art in electronics (again mainly in clock recovery circuitry).

All these digital transmission schemes can carry data. To the phone companies bits are bits and bits are revenue. One must keep in mind voice and data are two drastically different animals. Voice requires a constant bit rate where data tends to be "bursty" in nature. There are schemes today to take advantage of the phone companies' digital hierarchy by statistically multiplexing data. Some of the current schemes are Frame Relay, Switched Multimegabit Date Service (SMDS) and Asynchronous Transfer Mode (ATM). All of these data passing schemes were designed and built around the phone companies' digital hierarchy.

Other digital services: Digital service below 64,000 bps are available from the phone companies with data rates between 300 and 56,000 bps. These are made possible by taking a lower speed bit stream, say 9,600 bps, and adding bits, stuffing bits, to get to the 64,000 bps level. This is then multiplexed into a DS-1 for transmission. At the other end the system removes the stuffing bits and transmits the original 9,600 bps.

Basic Rate Integrated Services Digital Network (ISDN) is a term used to describe a broad spectrum of digital communications. The lowest of which is called Basic Rate or BRI. BRI takes advantage of recent advances in transmission technology to offer two DS-0 channels on one pair of wires (same telephone cable that goes into your house today but it can carry two

logical DS-0 channels and they can be voice, data or both). BRI is a switch technology exactly like the telephone. Voice or data connections are established by dialing a phone number. The connection is broken when the transmission or conversation is complete. Some of the uses for BRI are video conferencing, data communications to sites that don't have the traffic for a dedicated link and telecommuting.

Primary Rate ISDN is the combination of DS-0s from Basic Rate ISDN into a DS-1 level signal. This service has several uses. It can be thought of as multiple BRIs in one pipe. Each BRI can initiate and receive calls independently. For those sites that have a lot of ISDN traffic, it would be more economical to have one PRI rather than several BRIs. There are also advantages to using a PRI DS-1 rather than a regular DS-1 for carrying voice traffic from a PBX (Private Branch eXchange, a company with its own telephone switch) to the phone company for outgoing and incoming calls.

Fractional DS-1 (T-1) is used when a company has more than 56,000 bps of data to transmit but not enough to fill a DS-1. This service breaks up a DS-1 signal into sub rates. These sub rates are usually at 112, 384, 512 and 768 Kbps but can be any multiples of 56,000 or 64,000 up to the limit of the DS-1. These sub rate channels can carry voice or data. There can also be multiple sub rate channels on a single DS-1 with different end points. Fractional DS-1 is a very popular service today for point-to-point data and Frame Relay.

Fractional DS-3 (T-3) is much the same idea as Fractional DS-1 but the sub rates are in increments of 1.544 Mbps. Fractional DS-3 is not nearly as popular as Fractional DS-1 due mainly to cost. It is used for point-to-point data and for Switched Multimegabit Data Service.

TELEPHONE COMPANY DIGITAL HIERARCHY

Level	No DS-0s	Bit Rate (Mbps)	Media	Purchasable	Current Status
DS-0	1	0.064	None	No	Basic building block, can buy one as a part of a Fractional T-1
BRI ISDN	2	0.128	Twisted Pair	Yes	Widely available for both home and business
DS-1 & DD1	24	1.544	Twisted Pair	Yes	Widely available, also used for fractional T-1 service.
DS-1C	48	3.152	Twisted Pair	No	Obsolete
DS-2	96	6.312	Twisted Pair	No	Part of the internal multiplexing scheme in a DS-3
DS-3	672	44.736	Coax	Yes	Available, but expensive
DS-4	4032	274.176	Radio	No	Obsolete
DS-5	7680	567.148	Radio	No	Obsolete
OC-1	672	51.84	Fiber	No	Part of an OC-3
OC-3	2,016	155.52	Fiber	Yes	Widely available in most metropolitan areas
OC-12	8,064	622.08	Fiber	Yes	Available in most metropolitan areas
OC-48	32,256	2,488.32	Fiber	Yes	Long haul for Telco and limited private companies
OC-96	64,512	4,976.64	Fiber	Not yet	Testing in Telco and private industry
OC-128	86,016	6,635.52	Fiber	Not yet	In limited testing

APPENDICES
REFERENCED IN THE
FINAL REPORT

Appendix A: List of investigators and researchers who worked on the projects

Gail Anderson, MD, Investigator, Chair, USC Emergency Medicine
Richard S. Baker, MD, Investigator from Drew School of Medicine Ophthalmology
Eva Barber, MHA, Graduate Student Lead on Clinical Studies, USC-ABBC
Richard Bates, Catalina island Paramedic
John Beecher, MS, Lead Investigator from Northrop Grumman/Logicon
Fred Berrong, Radio Engineering, Northrop Grumman/Logicon
Neelakshi Bhagat, MD, Investigator, USC Ophthalmology
Tora Bikson, PhD, Investigator from RAND
William D. Boswell, MD FACR, Co-PI and PI*, USC Keck School of Medicine
Ray Briggs, PhD, Director of Research, Southern California College of Optometry
Fred Campo, Video Engineering, Northrop Grumman/Logicon
Robert Chen, MHA, PhD Candidate, Graduate Student Project Lead, USC-ABBC
Jeff Chaffin, Networking Support, Northrop Grumman/Logicon
Ignatio deArtola, MD, Medical Director, Nobel Community Health Center
Terry DeCleen, MBA, Business Case Modeling, Pacific Bell
Randy DeGregori, Chief, Los Angeles County Lifeguards
Dan Douglas, Catalina Island Paramedic
Kelly Eom, MHA, Graduate Student Project Support, USC-ABBC
Charles Flowers, MD, Lead Investigator and Co-PI, Drew School of Medicine
Don Frambach, MD, Investigator, USC Ophthalmology
Kurt Fredrick, Catalina Island Paramedic
Clara Gelbard, MD, Investigator, Medical Director H. Claude Hudson Clinic
Frederick W. George, MD FACR, Project PI and Founding Executive Director, USC-ABBC
Ricardo G. Hahn, MD, Investigator, Chair, USC Family Medicine
Bonnie Hanson, Student Project Support, USC-ABBC
Karla Hernandez, Student Project Support, USC-ABBC
Carl Huggins, Director, USC Catalina Hyperbaric Chamber
Catherine Jackson, PhD, Lead Investigator from RAND
William La, MD, Investigator, USC Family Medicine
Laurie Labree, MS, Investigator, USC Ophthalmology
Karen Lam, MHA, Graduate Student Project Support, USC-ABBC
Paul Lee, MD, Co-PI, USC Ophthalmology, RAND, and Duke University
Jennifer Lim, MD, Co-PI, USC Ophthalmology
Shelly Lockett, RN, MPH, Investigator, USC Family Medicine
Dave Mann, MS, Web Application Development, Director of Technology, USC-ABBC
Kevin Marble, Catalina Island Paramedic
David McMillan, Student Project Support, USC-ABBC
Beth McGregor, MA, Project Planning and Documentation, USC-ABBC
Ralph Morrow, Catalina Island Cable
Tracy Nichols, Eye Imaging, USC Ophthalmology
Russ O'Brien, Overall Project Manager from USC-ABBC/ABC
Sidney Ontai, MD, Co-PI, USC Family Medicine
Rick Pinckert, Technical Support, USC-ABBC

Jeegar Rana, MHA, Graduate Student Project Support, USC-ABBC
Daniel Relles, PhD, Investigator from RAND
Marc Reynolds, Video and Audio Integration, Northrop Grumman/Logicon
Leigh Rodriguez, MHA, Graduate Student Lead on Clinical Studies, USC-ABBC
Georgeanne Sanders, MD, Investigator, USC Family Medicine
Mooni Shah, Student Project Support, USC-ABBC
Rakesh Shah, MHA, Graduate Student Project Support, USC-ABBC
Jeff Sipse, MD, Co-PI, USC Emergency Medicine
Ronald E. Smith, MD FACS, Investigator, USC Ophthalmology
Christine S. Talicuran, MHA, Graduate Student Lead on Image Quality Study, USC-ABBC
Aashish Thakker, MS, Network Support, USC-ABBC
Steve Troeger, Catalina Island Paramedic
Elvie Tuttle, Manger, H. Claude Hudson Clinic
Steven H. Stumpf, EdD, Final Report Preparation and Senior Researcher, USC-ABBC
Tom Viren, Chief, Los Angeles County Lifeguards
Francis Walonker, PhD, Investigator, USC Ophthalmology
Lori Young, MHA, Graduate Student Project Support, USC-ABBC
Rod Zalunardo, EdD, Project Administration and Final Report Preparation, USC-ABBC
Edward Zee, Graphics Support, USC-ABBC
Oliver Zee, Student Project Support, USC-ABBC
Erika Zimmerman, Student Project Support, USC-ABBC

* Dr. Boswell replaced Dr. George as Project PI upon his retirement. Dr. Boswell was a Co-PI.

Appendix B

IN MEMORIAM

FREDERICK WILLIAM GEORGE, III, MD FACR

1923-2000

On June 11, 2000, Frederick William George III, MD FACR, departed this earth. Dr. George's contributions to the Keck School of Medicine of the University of Southern California, and to medicine in general, have been significant. We will all miss his inspiration and spirit.

Dr. George had a distinguished academic history. He completed his undergraduate work at MIT and the University of Pittsburgh, receiving a B.S. in biology. He received his Medical Doctorate Degree from the University of Pittsburgh in 1947. He first came to Los Angeles as an intern at Queen of Angels Hospital. Upon completing his Radiology training at the US Navy Hospital in San Diego he accepted a fellowship program at the University of Chicago/Argonne Cancer Hospital in Radiation Therapy and Nuclear Medicine. He began his professional medical career in 1952 as a Force Medical Officer for the US Sixth Fleet. He rose in the ranks to the rank of Captain, concluding his Naval medical career as the Chief of Radiology for the Regional Naval Medical Center in Long Beach in 1967.

Dr. George began his USC medical career as a Professor of Radiology in 1967. He immediately demonstrated his leadership by developing the Radiation Therapy program at the Los Angeles County University of Southern California Medical Center. When the Radiology Department became two divisions he accepted an appointment as Professor of Radiation Oncology. Although first and foremost a physician, Dr. George was also an educator and researcher. He confided to friends the professional achievement of which he was most proud was his selection as a Distinguished Professor by the Salerni Collegium, a USC award for outstanding teaching.

He was elected to Fellowship in the American College of Radiology. He served as the first President of University Imaging Associates. His national leadership in Radiation Therapy led to his election as President of the American Radium Society. On the University Park Campus of USC, he was a Senior Research Associate at the USC Social Science Research Institute. He held an appointment at Loma Linda University as Clinical Professor of Radiology. Dr. George received many awards during his illustrious academic career including a Special Award from the National Cancer Institute and a Surgeon General Commendation for Outstanding Leadership in the U.S. Navy.

Dr. George served on numerous commissions and was a member of many professional societies. He authored a variety of articles on telemedicine, radiation therapy, and automation and use of computers in radiation therapy departments. He was an outstanding speaker, presenting the Keynote Address to the Japanese Congress of Radiology in 1975 and served as a lead presenter during the late seventies and early eighties for the joint USA-

USSR Oncology Program. He had an extended sabbatical at the National Institutes of Health, where he initiated a program for the development and deployment of advanced radiation therapy tools.

During his years at USC, Dr. George was active academically and clinically. In 1993 Dr. George attempted to retire. He quickly realized his work was not completed. He envisioned a new multi-disciplinary group of technicians and physicians at the School of Medicine; one that would work with any and all faculty on the Health Sciences Campus, across any and all medical disciplines, to explore all possible avenues for merging new digital technologies with healthcare practice. Dr. George foresaw the coming marriage between technology and healthcare and recognized the opportunity for USC, with its breadth of disciplines and flexibility as a private entity, to become the handmaiden in this marriage.

In 1993, with approval of Dean Stephen Ryan and Senior Associate Dean for Administration Fermin Vigil, the USC Advanced BioInformatics and BioTelecommunications Center (USC-ABBC), an Organized Research Unit of the University, was created. Through his work with the ABBC Dr. George established himself and the ABBC as pioneers in demonstrating and prototyping advanced telehealthcare and informatics applications at USC, nationally and internationally.

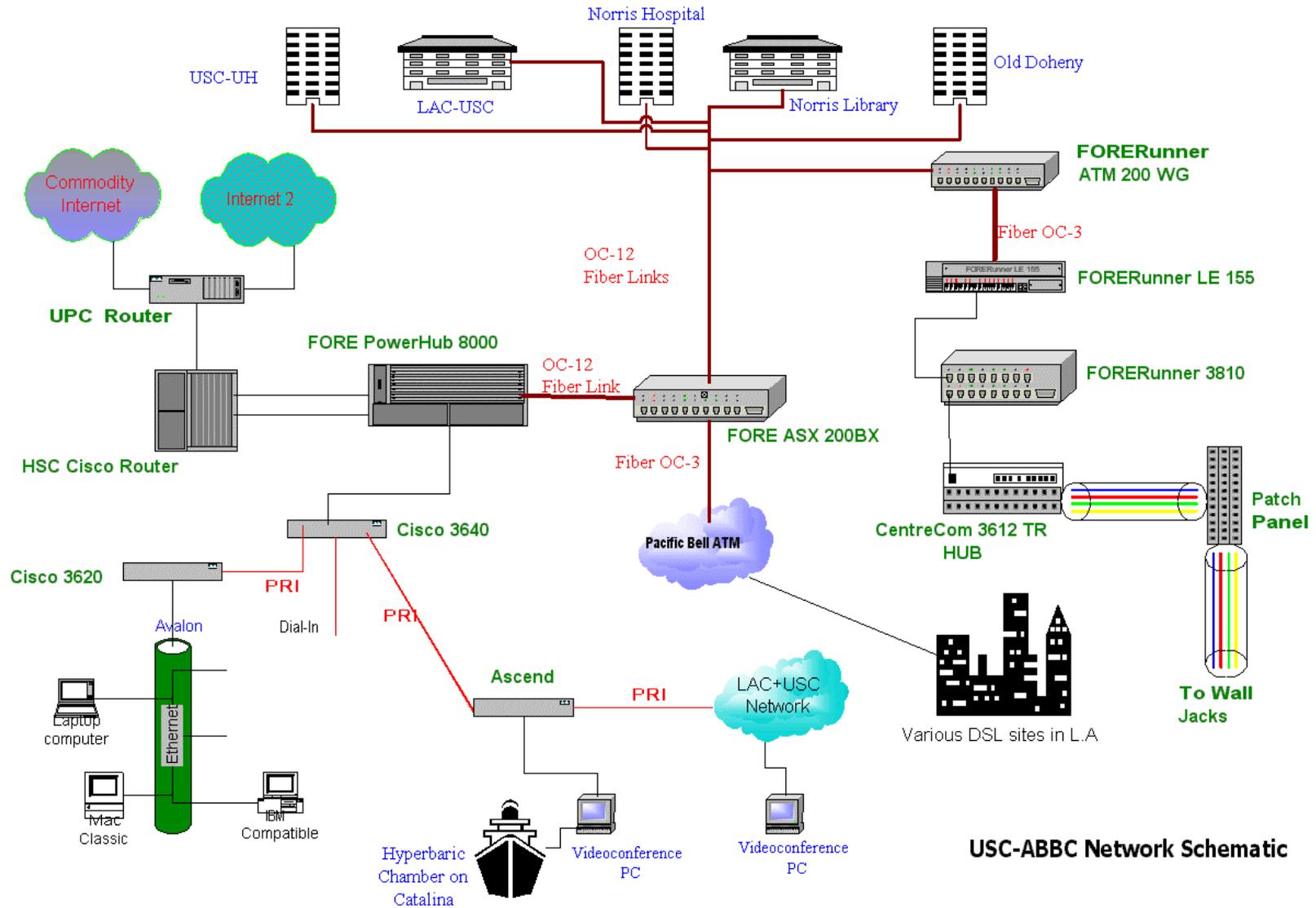
He worked on numerous programs and grants including the Pegasus project, which developed the VOXAR 3D volumetric and tissue classification application for CT, MRI, and PET/SPECT images. In April of 2000, a patent was granted for the application. He laid the groundwork for the USC PET Imaging Science Center, and medical cyclotron at USC. Dr. George was the Principal Investigator for the \$2.9 million Pacific Bell-CalREN Biomedical ATMnet and Testbed Grant, and most recently the \$2.5 million National Library of Medicine Telemedicine Contract.

Following a two-month hospitalization in late 1999, Dr. George stepped down from the day-to-day operations at the ABBC, retiring from USC in January 2000 following 33 years of work.

The ABBC will continue extending its operations, developing telemedicine applications as envisioned by Dr. George. We are all grateful to have worked under his stewardship at USC. His vision and drive will be noticeably absent, but his dreams will live on.

A memorial service was held on Thursday, June 15, 2000, at the San Marino Community Church where Dr. George was a member.

Appendix C: USC Network Diagrams



USC-ABBC Network Schematic

Appendix D:
Tables
Referenced in
Final Report

Table 1 - Clinical Findings Assessed

Grouping	Condition
A. Diabetic retinopathy	
	cotton-wool spots
	Dot-blot hemorrhage
	flame hemorrhage
	intraretinal microvascular abnormalities
	lipid / hard exudates
	microaneurysm
	neovascularization of the disc
	neovascularization elsewhere
	venous beading
	vitreous hemorrhage
B. Laser burns / Scars	
	laser burns
	macular edema
C. Age-related macular degeneration	
	choroidal neovascular membrane
	disciform scar
	drusen
	geographic atrophy
	pigment changes
	subretinal hemorrhage
D. Other	
	epiretinal membrane
	branch vein occlusion
	central vein occlusion
	other

Table 2 - Interpretation accuracies at each of the 4 image levels

Type of Problem	Image Quality	Sensitivity		Specificity	
		N	Percent Correct	N	Percent Correct
cotton-wool spots	1	20	95	204	94
	2	21	86	182	96
	3	32	81	179	97
	4	22	77	184	98
dot-blot hemorrhage	1	46	87	178	65
	2	43	93	160	67
	3	43	81	168	58
	4	33	70	173	66
flame hemorrhage	1	26	35	198	89
	2	24	29	179	87
	3	20	20	191	91
	4	19	37	187	90
lipid / hard exudates	1	50	86	174	79
	2	42	79	161	80
	3	53	89	158	80
	4	26	69	180	78
microaneurysm	1	47	51	177	82
	2	56	46	147	81
	3	53	66	158	81
	4	48	44	158	85
nvd	1	40	60	184	98
	2	30	57	173	99
	3	39	41	172	99
	4	24	50	182	97
nve	1	42	57	182	99
	2	29	55	174	99
	3	28	57	183	99
	4	23	43	183	99
vitreous hemorrhage	1	31	81	193	97
	2	26	88	177	94
	3	18	78	193	95
	4	36	89	170	96
macular edema	1	21	33	203	95
	2	9	22	194	91
	3	27	11	184	95
	4	19	26	187	97
laser burns	1	34	88	190	94
	2	24	83	179	93
	3	36	92	175	93
	4	37	89	169	95
cnvm	1	26	4	198	96
	2	26	8	177	99
	3	16	6	195	98
	4	27	7	179	99
disciform scar	1	28	61	196	100
	2	19	58	184	99
	3	18	39	193	99
	4	20	60	186	98

drusen	1	21	86	203	87
	2	22	55	181	87
	3	22	64	189	87
	4	15	73	191	85
pigment changes	1	20	60	204	80
	2	17	65	186	78
	3	14	57	197	84
	4	30	30	176	72
subretinal hemorrhage	1	24	58	200	92
	2	25	80	178	96
	3	29	62	182	95
	4	14	57	192	94
ranch vein occlusion	1	17	12	207	97
	2	25	12	178	99
	3	13	15	198	96
	4	20	10	186	97

Table 3 - Statistical significance of the difference in sensitivities at Two highest and Two lowest levels of quality.

Condition	A	B	C	D	Bdr	Ppdr	Pdr	Diabret	Referral
dot-blot hemorrhage	x								x
flame hemorrhage	x								x
lipid / hard exudates	x				x			x	x
microaneurysm	x				x			x	x
cotton-wool spots	x					x		x	x
neovascularization of the disc	x						x	x	x
neovascularization elsewhere	x						x	x	x
vitreous hemorrhage	x						x	x	x
Laser burns / Scars		x							
Macular edema		x							x
central vein occlusion			x						x
disciform scar			x						x
drusen			x						
pigment changes			x						
subretinal hemorrhage			x						x
branch vein occlusion				x					x
epiretinal membrane				x					
other				x					

Table 4 - DRS staging categories

Type of Problem	Image Quality	Sensitivity		Specificity	
		N	Percent Correct	N	Percent Correct
needs referral	1	189	74	224	41
	2	170	71	203	45
	3	178	74	211	43
	4	168	67	206	46
diabetic retinopathy (dbr)	1	120	85	224	66
	2	95	85	203	67
	3	116	87	211	71
	4	98	81	206	68
background dbr	1	78	72	205	71
	2	69	67	174	71
	3	71	85	176	71
	4	61	54	193	73
pre-proliferative dbr	1	20	95	204	94
	2	21	86	182	96
	3	32	81	179	97
	4	22	77	184	98
proliferative dbr	1	73	75	217	95
	2	56	84	202	93
	3	54	63	207	94
	4	61	77	204	93
Group A Conditions	1	123	88	224	49
	2	99	87	203	52
	3	118	89	211	51
	4	101	83	206	53
Group B Conditions	1	54	67	223	90
	2	32	69	202	85
	3	57	63	205	89
	4	53	72	203	94
Group C Conditions	1	77	68	224	67
	2	77	66	203	68
	3	66	61	211	72
	4	76	47	206	61
Group D Conditions	1	39	49	224	84
	2	41	24	203	81
	3	28	39	211	81
	4	40	32	206	85

Table 5 – Artifacts Summary

	NB	JL
<u>Incomplete images</u>	105 (97%)	103 (95%)
<u>Images with incomplete superior arcade or the area 1 disc area nasal to the nerve</u>	102 (95%)	101 (94%)
<u>Artifacts</u>		
Small white dust	52 (48%)	86 (80%)
Large white dust	34 (31%)	31 (29%)
Central dark	68 (63%)	87 (81%)
Light reflex	19 (18%)	22 (20%)
Crescent	76 (70%)	37 (34%)
<u>Areas that could not be evaluated due to artifacts</u>		
Optic nerve, ON	52 (48%)	56 (52%)
ON & 1 disc area nasal to it	94 (87%)	101 (94%)
Fovea	66 (61%)	75 (69%)
Superior arcade	63 (58%)	60 (56%)
Inferior arcade	15 (14%)	19 (18%)
Macula	71 (66%)	68 (63%)
<u>Images unacceptable</u>	104 (96%)	105 (99%)
<u>Image grade</u>		
Excellent	2 (2%)	0
Good	47 (44%)	22 (21%)
Limited	51 (47%)	55 (52%)
Gross	6 (6%)	27 (25%)
No Detail	2 (2%)	2 (2%)

Table 6 - Grading Criteria

Grade	Quality
1	Excellent clarity
2	Good definition of most retinal details, easily assessable
3	Definition limited, assessable with some difficulty
4	Only gross detail visible
5	No detail visible, not assessable

Table 7 – Drew demographic characteristics

Characteristic	n (%)
Gender	
Females	101 (55)
Males	84 (45)
Age(years)	
Mean	49.1
Range	18-74
Race	
Black	70 (38)
Hispanic	112 (60)
Other	3 (2)
Employment status	
Employed	62 (34)
Not Employed	86 (46)
Retired	37 (20)
Insurance status	
No insurance	113 (61)
Insurance	72 (39)

Table 8 - Clinical Characteristics

Characteristic	n (%)
Diabetes Category	
Type I	34 (18)
Type II	151 (82)
Age (yrs)	
20-40	24 (13)
41-50	56 (30)
51-60	74 (40)
60+	31 (17)
Duration of Diabetes	
New Onset	18 (10)
≤ 2 years	56 (30)
> 2 years, ≤ 5 years	37 (20)
> 5 years, ≤ 10 years	48 (26)
> 10 years	26 (14)

**Table 9 - Conceptual Model for Information Use in
Hyperbaric Treatment Decision Making**

Violations of Dive Table	Case Symptoms	Medical Findings	Physician Interpretation of case as presented	Usefulness of Teleconsultation for Diagnosis and Treatment (Yes/No) and Plan Decisions*
T	T	T	Not at all ambiguous	Less useful
T	T	F	Not odd	↓ Useful ↑
T	F	T	A little odd	
T	F	F	A little odd	
F	T	T	More odd	
F	T	F	Still more odd	
F	F	T	Very odd	
F	F	F	Not at all ambiguous	Less useful

T=True, F=False

Table 10: Selected Demographic Characteristics of the Surveyed Population

Characteristic	Cases	Description
Ethnicity:	32	African-American or Black
	423	Hispanic or Latino
	1	Native American
	13	Asian or Pacific Islander
	11	White or Caucasian
	11	Other
Age:	11	18-29
	58	30-39
	113	40-49
	164	50-59
	94	60-69
	19	70-79
	4	80-89
	28	Missing
Gender:	134	Male
	356	Female
	1	Missing
Education:	298	8TH grade or less
	78	Some high school, but did not graduate
	51	High school or GED
	31	2-year college degree or some college
	19	4-year college degree
	6	Post-graduate education
	8	Missing
Household size	94	01
	109	02
	83	03
	84	04
	49	05
	24	06
	14	07
	8	08
	4	10 or more
	22	Missing

Table 11: Prior Utilization of Eye Care Services for the Surveyed Population

Quest Item#	Question and Possible Responses	Number of Respondents
C22a.	Have you had a complete eye examination within the last 12 months?	
(blank)		41
1	Yes	78
2	No	370
8	don't know	2
C26.	When was your last complete eye exam? Was it . . .	
(blank)		267
1	3 -5 years ago	68
2	Over 5 years ago	20
3	Never had a complete eye exam	133
8	don't know	3
C27.	When did you have your last eye examination that was just a vision check?	
(blank)		96
1	Within last 12 months	83
2	1 -2 years ago	140
3	3 - 5 years ago	77
4	Over 5 years ago	32
5	Never had a vision check	63
C28.	Type of doctor who performed last vision check	
(blank)		157
1	optometrist	98
2	ophthalmologist	76
3	Physician but not an ophthalmologist	25
8	don't know	135

Table 12: Common Reasons for Not Having Annual Eye Exams

Quest Item#	Statements	# Cases	Percent
C30a.	You didn't know that you should have annual exams	134	27.3
C30b.	It cost too much	138	28.1
C30c.	You didn't know where to go	110	22.4
C30d.	You didn't have a way to get there	88	17.9
C30e.	You didn't think the problem was serious enough	132	26.9
C30f.	You just forgot to schedule it	70	14.3
C30h.	You didn't have insurance	84	17.1
C30i.	You were afraid of surgery	41	8.4
C30j.	It's too hard to get an appointment	72	14.7
C30k.	You didn't think the eye doctors could help you	50	10.2
C30l.	You were concerned your eye would hurt	54	11.0
C30m.	You would lose time from work	47	9.6
C30n.	You did not feel up to going to see an eye doctor	38	7.7
C30o.	You don't like going to doctors	41	8.4
C30p.	You don't feel welcome	29	5.9
C30q.	The doctor's visit takes too long	71	14.5
C30r.	You don't want your pupils dilated	30	6.1
C30s.	You feel worse after seeing the doctor	29	5.9
C30t.	You don't trust the eye doctor	24	4.9
C30u.	You don't want to know if something is wrong	41	8.4
C30v.	The eye doctors are no good	20	4.1
C30w.	You were afraid of the eye exam	33	6.7
C30x.	Any other reason	21	4.3

Table 13: Variables Examined for Bivariate Relationships with Referral Indicator

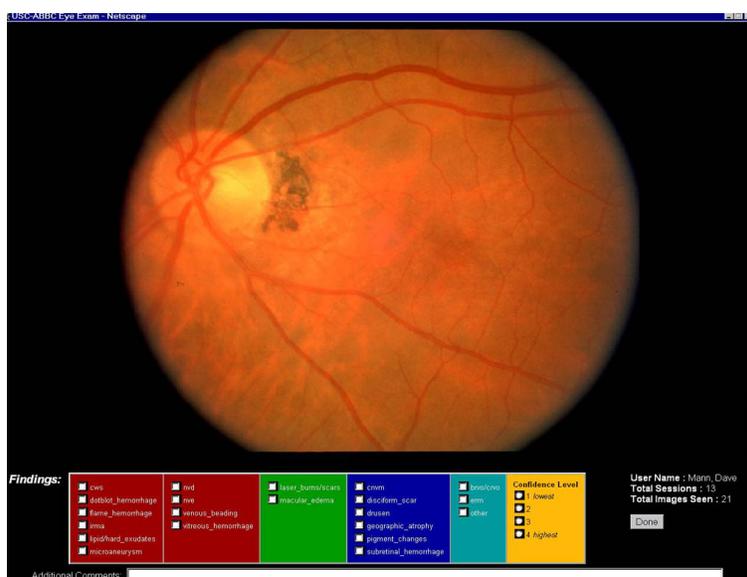
Quest Item#	Description	Results fit Hypothesized Direction?	Linear / Monotone Effect?	Strength of Relationship?
A1	1-item General Health status	no	--	--
B1b	High blood pressure or hypertension?	yes	yes	strong
B4	How often have you have trouble seeing?	yes	no	mild
B6	Have you ever smoked tobacco regularly?	no	--	--
B14	Recent advice to quit smoking?	no	--	--
B16	How long since last wine, or hard liquor?	no	--	--
C1	Self-evaluation of quality of eyesight.	yes	yes	strong
C30a	Didn't know that you should have annual exams?	yes	yes	mild
C30b	It cost too much for annual exams.	yes	yes	mild
C30c	Didn't know where to go for annual exams.	yes	yes	mild
C30d	Didn't have a way to get to annual exams.	yes	yes	mild
C30e	Didn't think serious enough for annual exams.	yes	yes	mild
D3	Currently taking insulin injections.	yes	yes	strong
D16a	Check blood sugar (glucose) levels yourself?	no	--	--
D19	When last urine test for protein?	no	--	--
E2	How long to get to the doctor's office today?	yes	no	mild
F2	Are you male or female?	(a)	--	--
F5	Marital status	(a)	--	--
F6	Ethnicity	(a)	--	strong
F7	Highest grade in school completed.	(a)	--	--
F8	Current employment status.	(a)	--	--
F9	Total household income before taxes, in 1997.	(a)	--	--
MSF12	Mental functioning score SF-12	yes	yes	mild
PSF12	Physical functioning score SF-12	no	--	--

(a) We made no assumptions about the effect of demographic characteristics.

Appendix E:
Figures
Referenced in
Final Report

Figure 1 - Image and data entry interface used by the reviewers

Fig1--Retina Image, As It Appears in the Image Exam



cotton wool spots	6	disciform scars	5
vitreous hemorrhage	7	flame hemorrhage	3
NVE	8	Pigment in macula	4
NVD	8	macular edema	3
brvo / crvo	5	Other	3
cnvm	5	Normal	5
subretinal hemorrhage	5		

Figures 2 & 3 - Sensitivities & Specificities for Specific Conditions

Fig2--Sensitivities for Specific Conditions, By Quality of Image

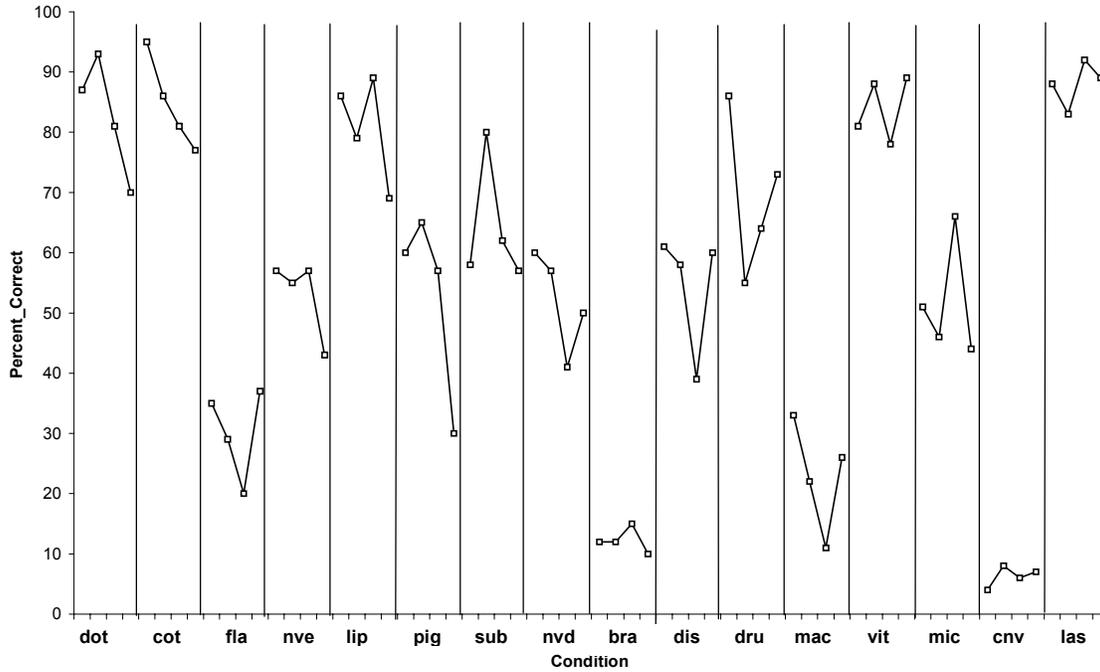
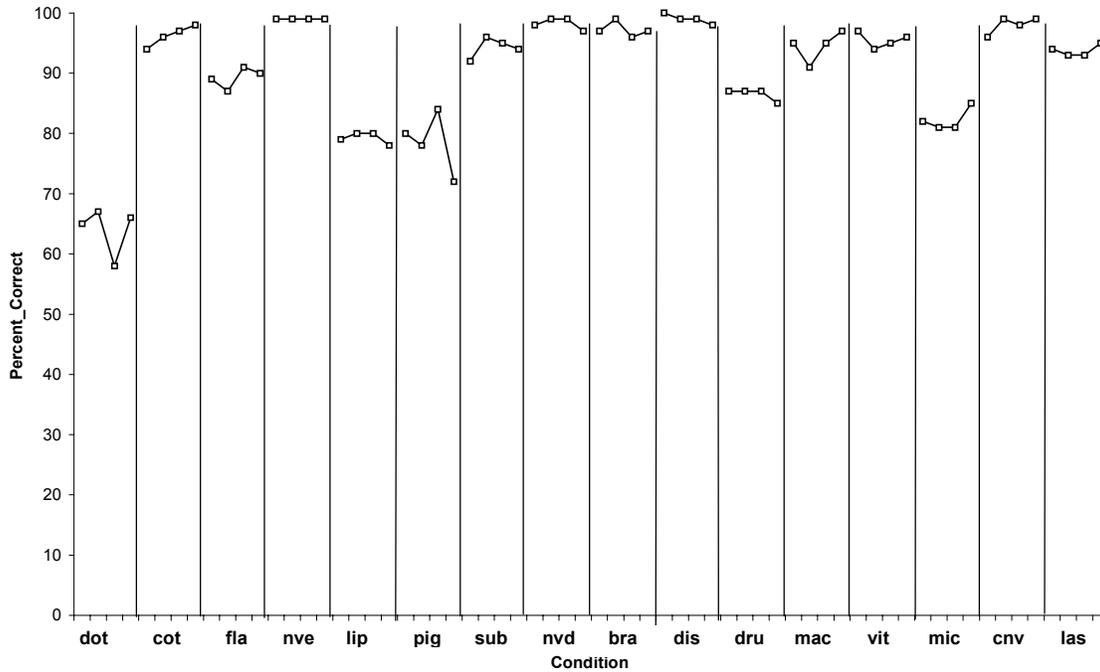


Fig3--Specificities for Specific Conditions, By Quality of Image



Figures 4 & 5 - Sensitivities & Specificities for Aggregate Conditions

Fig4--Sensitivities for Aggregate Conditions, By Quality of Image

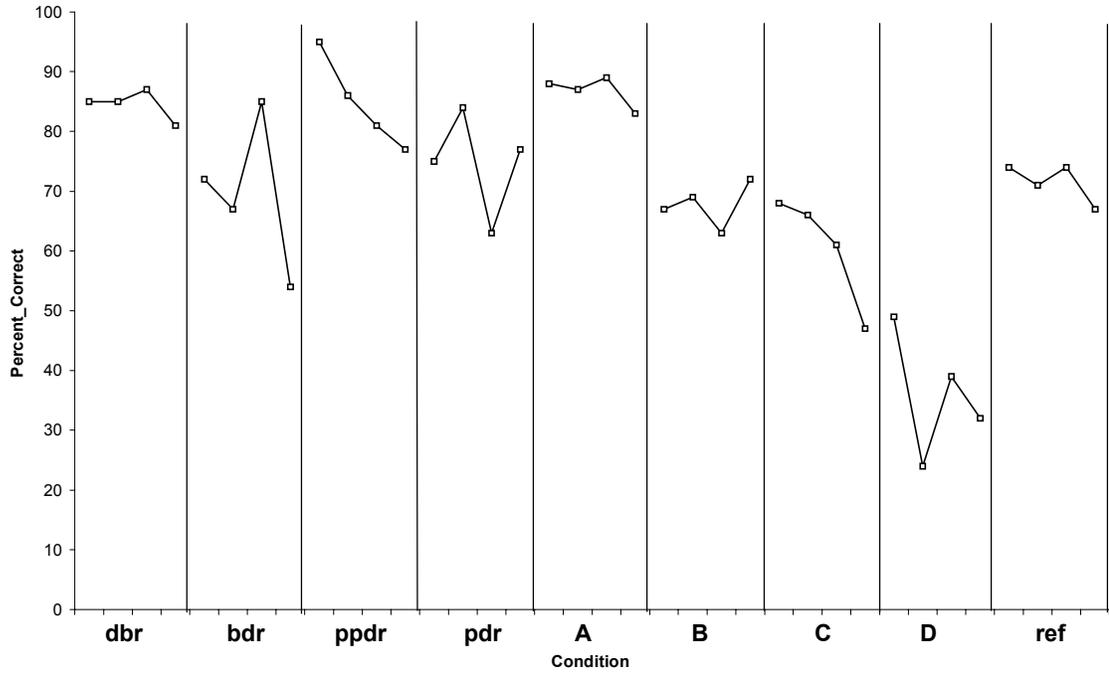


Fig5--Specificities for Aggregate Conditions, By Quality of Image

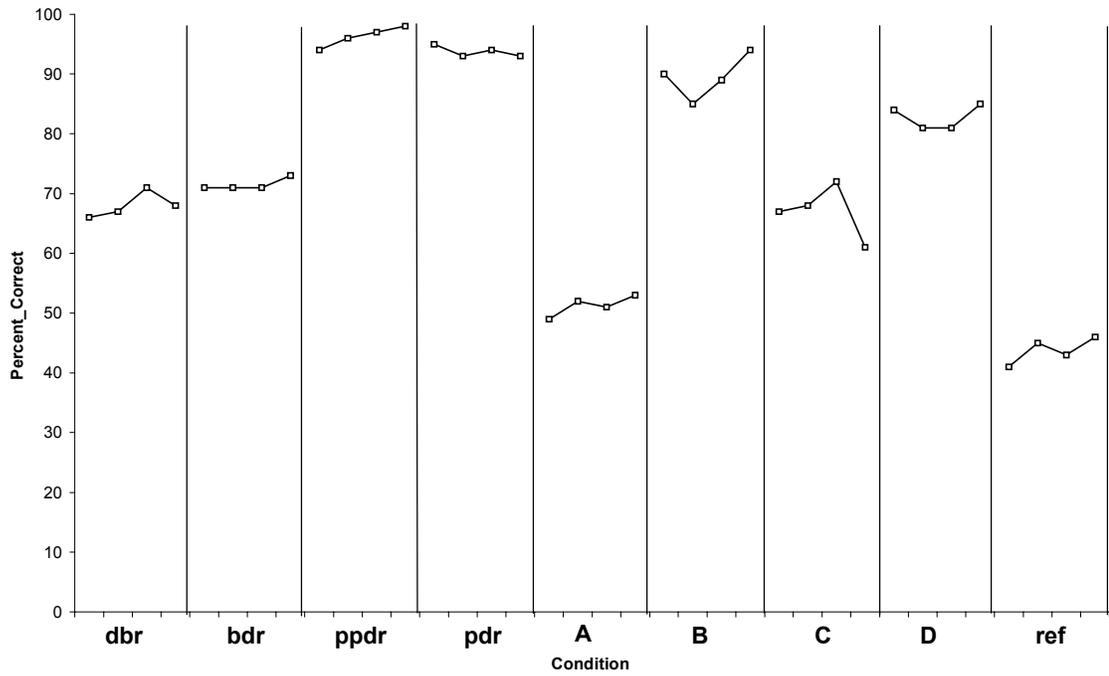


Figure 6 – Drew Connectivity Diagram

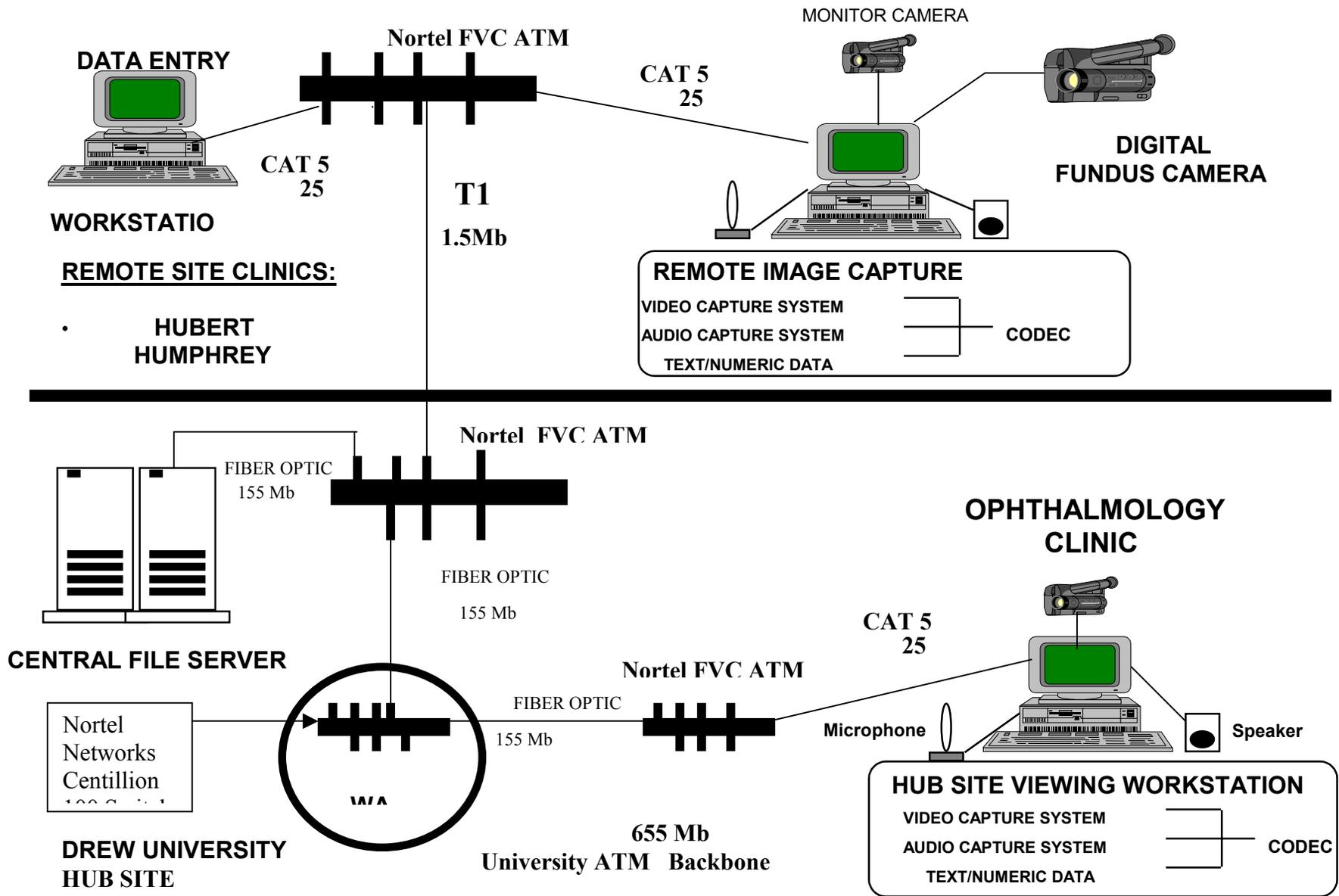


Figure 7 - Diabetic retinopathy status based on digital image review

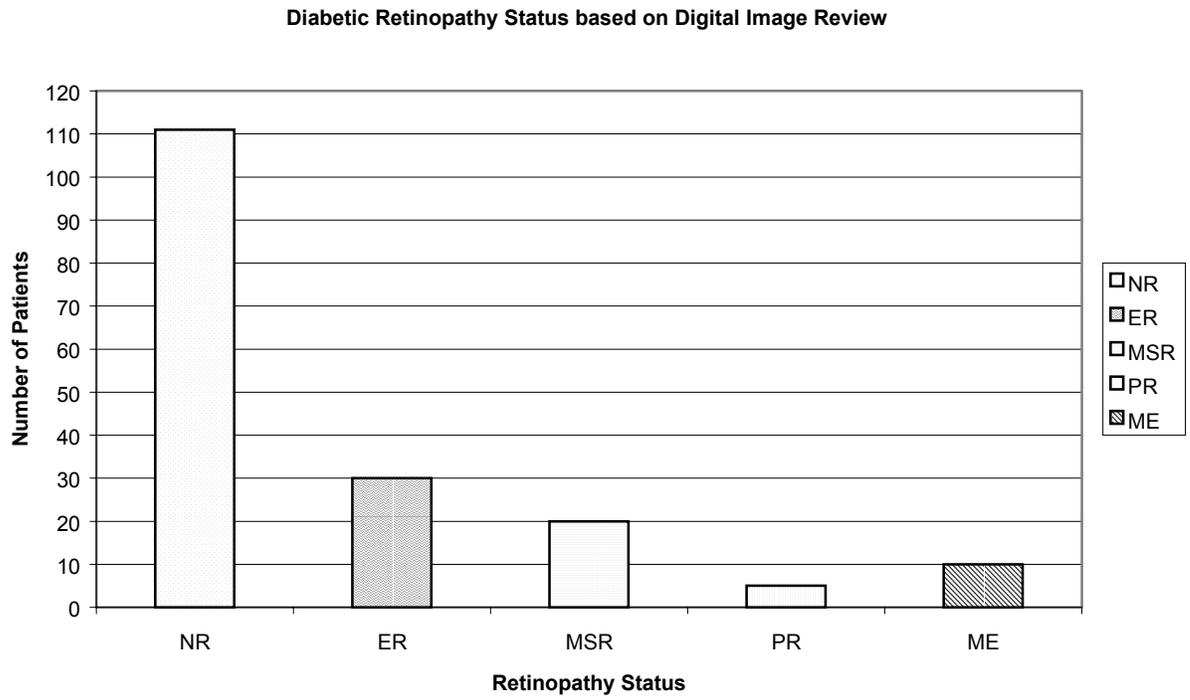


Figure 8 - Diabetic retinopathy status based on in-person examination

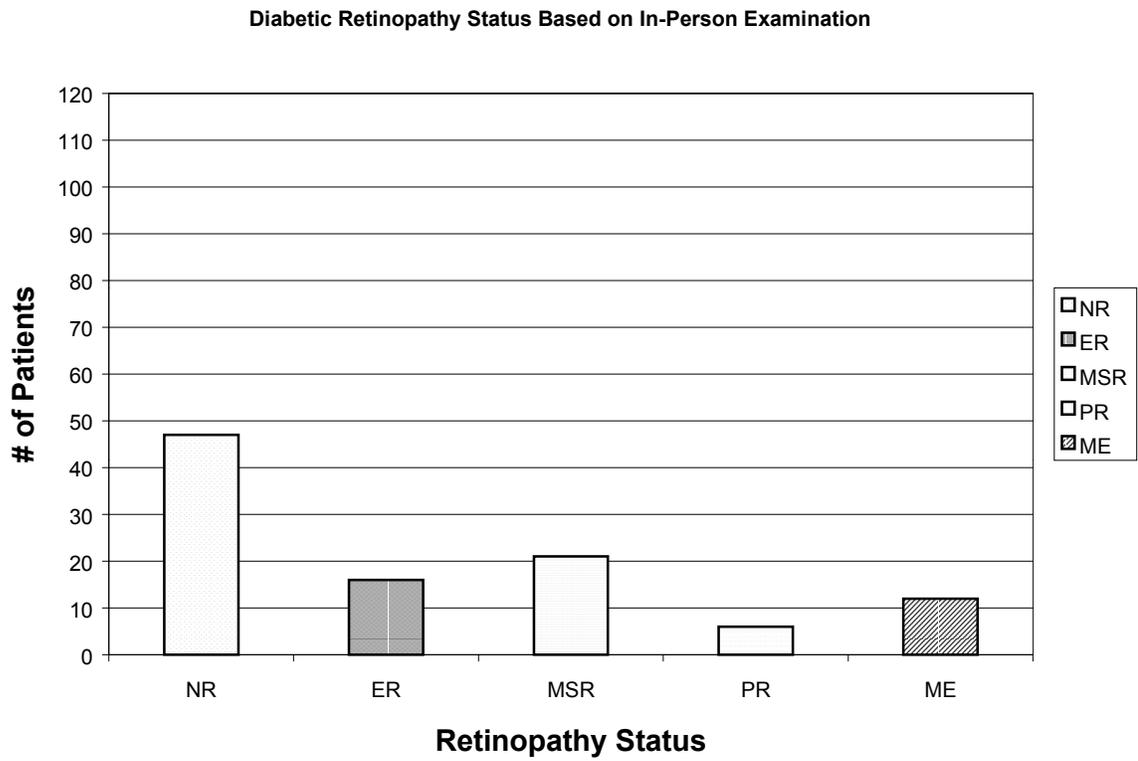
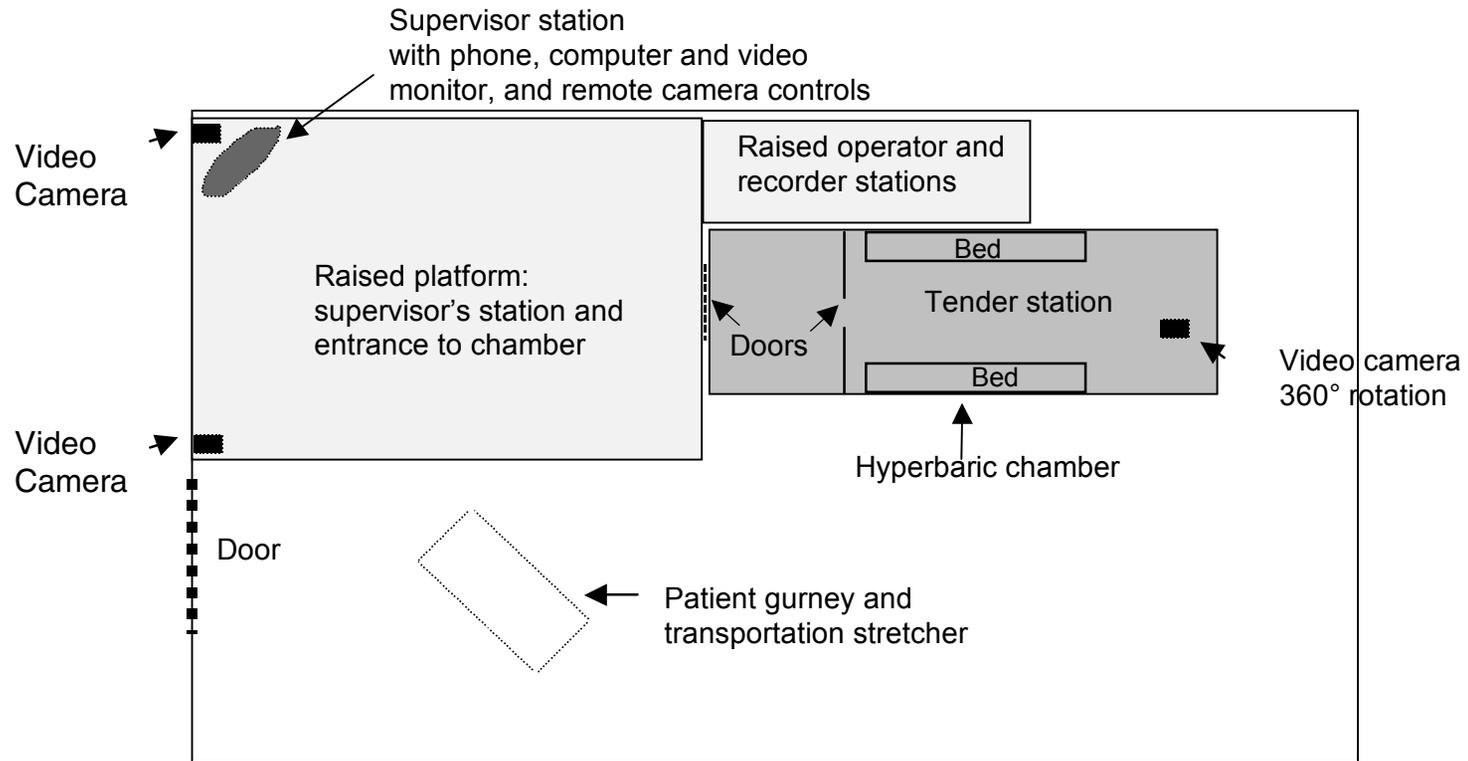


Figure 9 - Video-teleconference system at the hyperbaric chamber



Not to scale

**Figure 10 - Distribution of patients treated at the Catalina Hyperbaric Chamber
October 1997- September 1999**

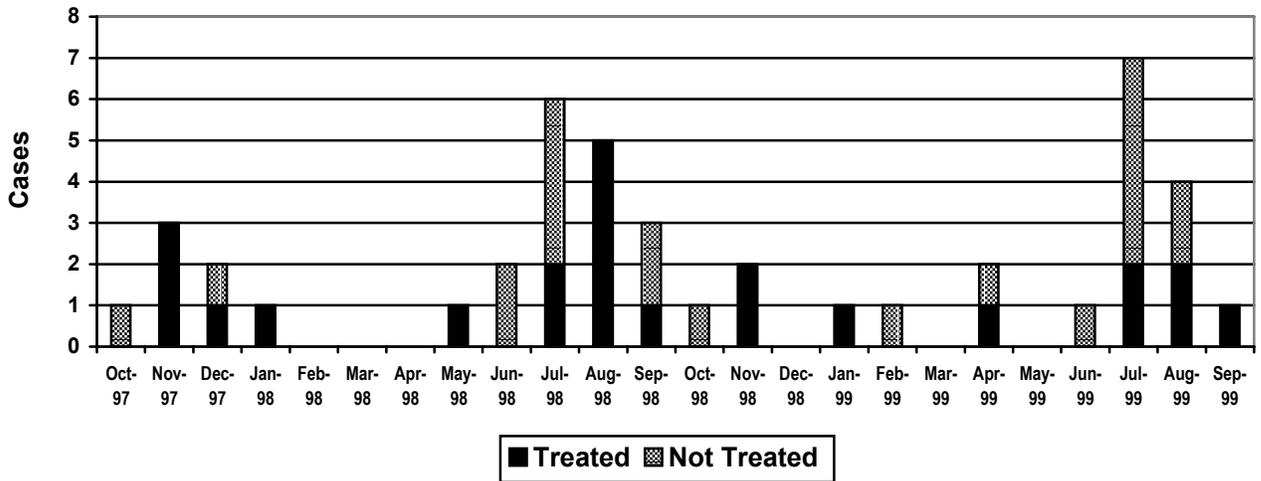


Figure 11 - Number of Case Calls

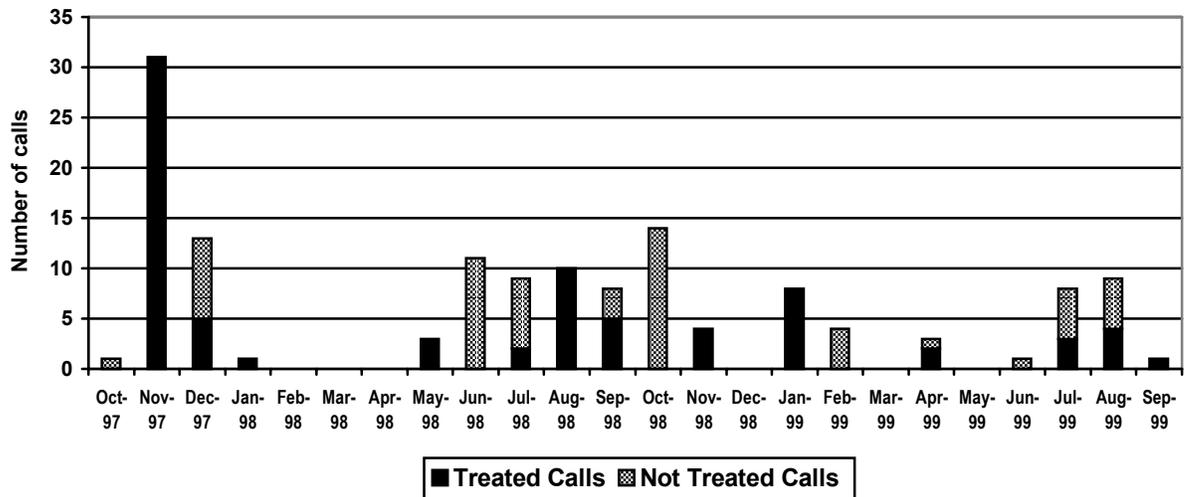


Figure 12 - Number of Total Minutes for Case Calls

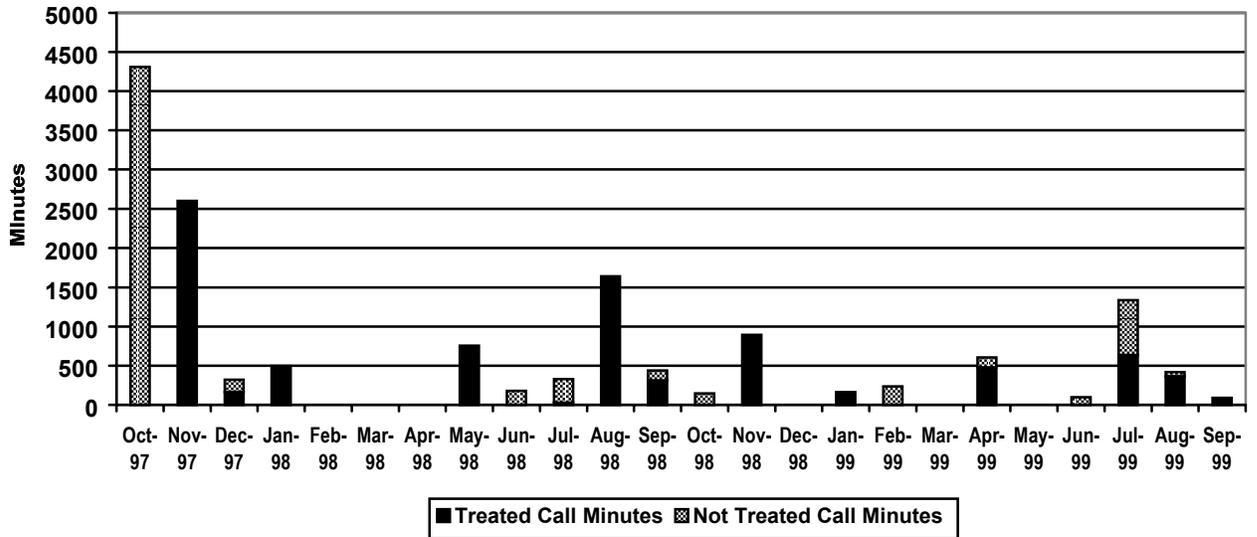
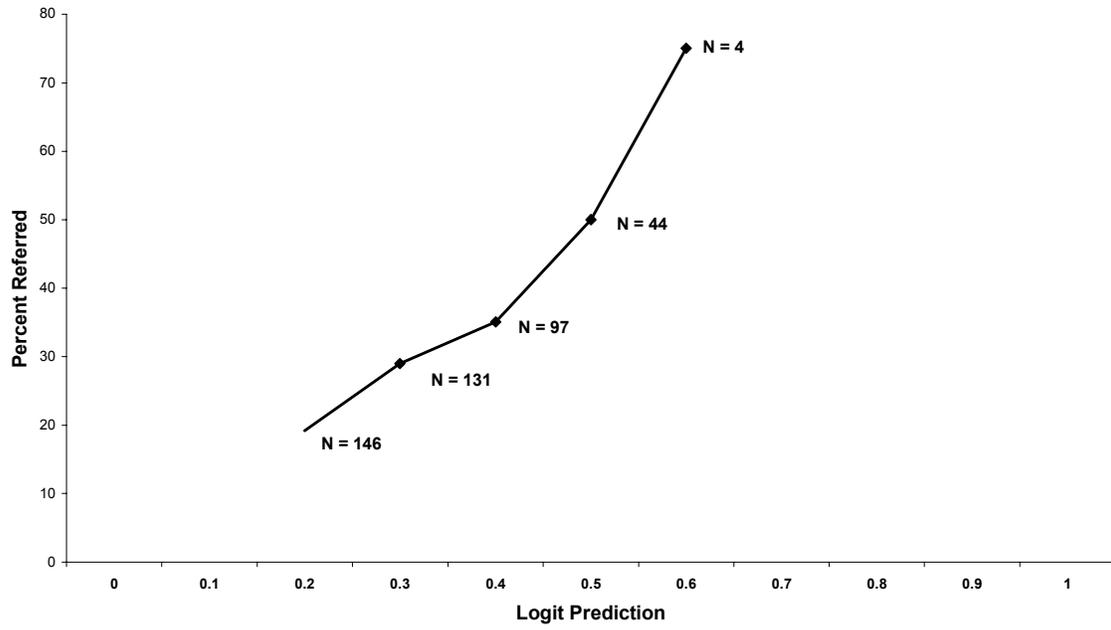


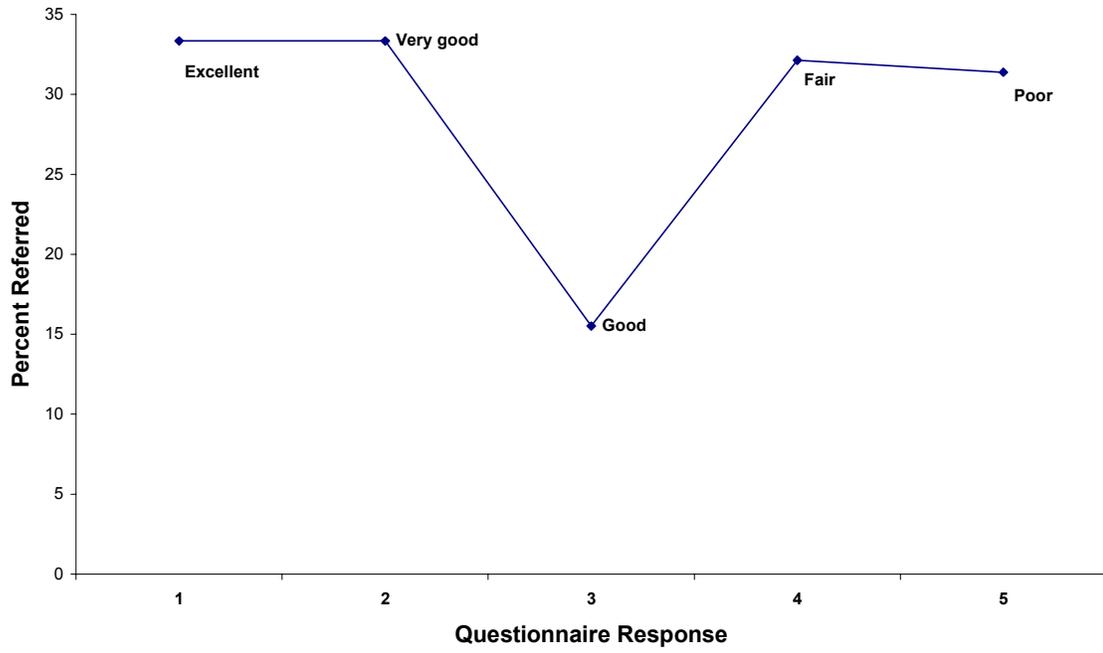
Figure 13: Percent Referred vs. Logit Prediction



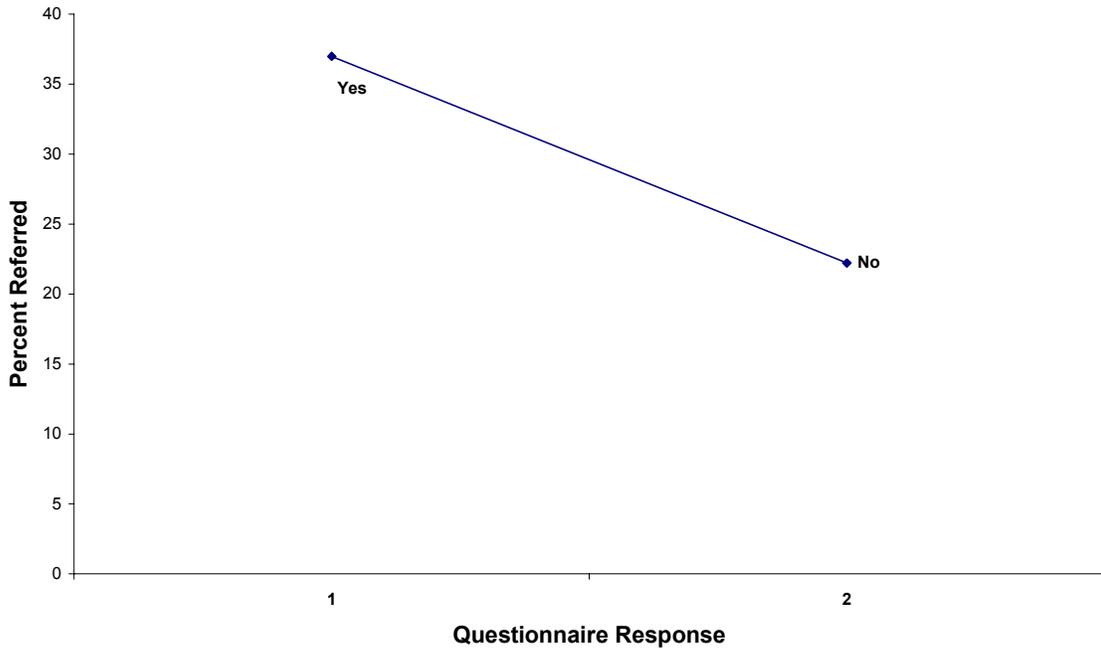
Appendix F:

Plots of responses to survey items on patient's health status

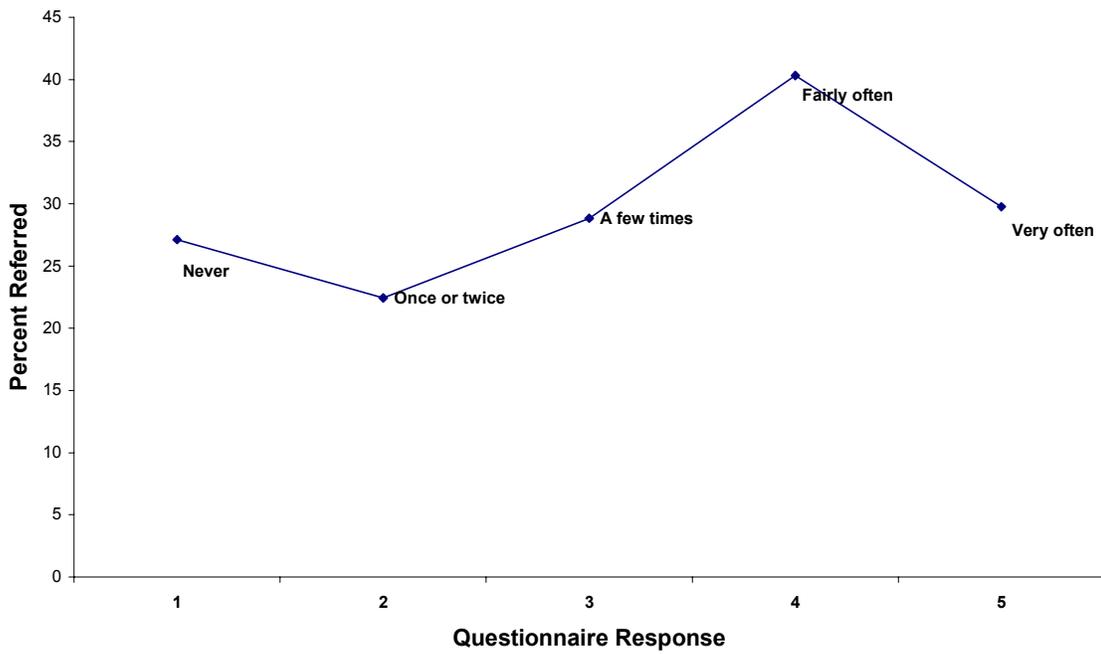
Health status



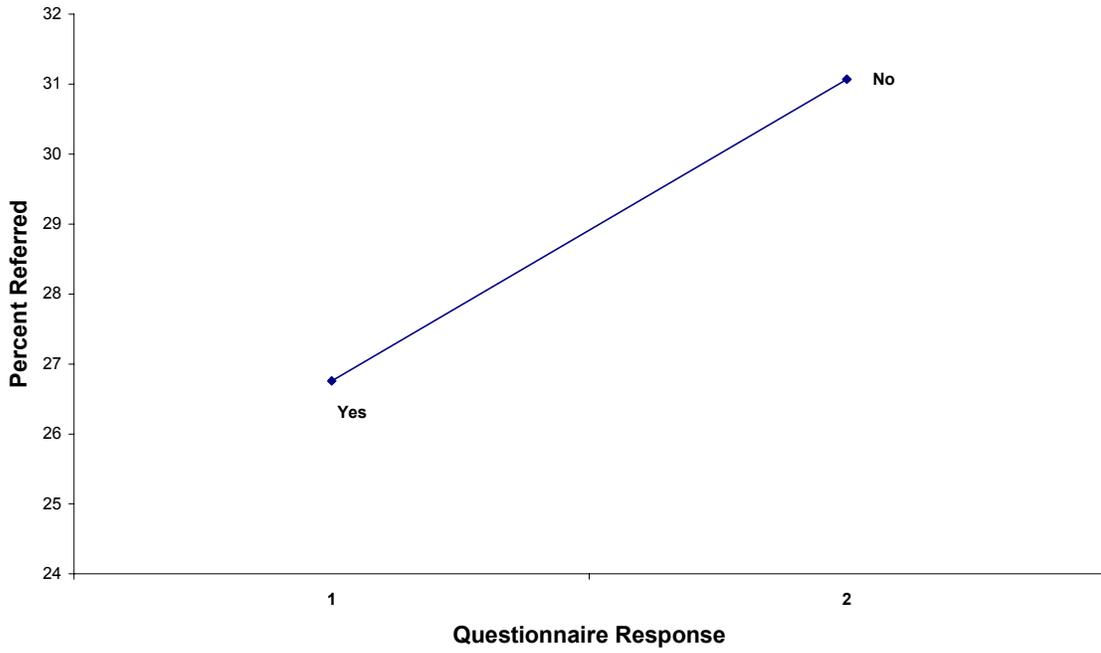
B1B: High blood pressure or hypertension?



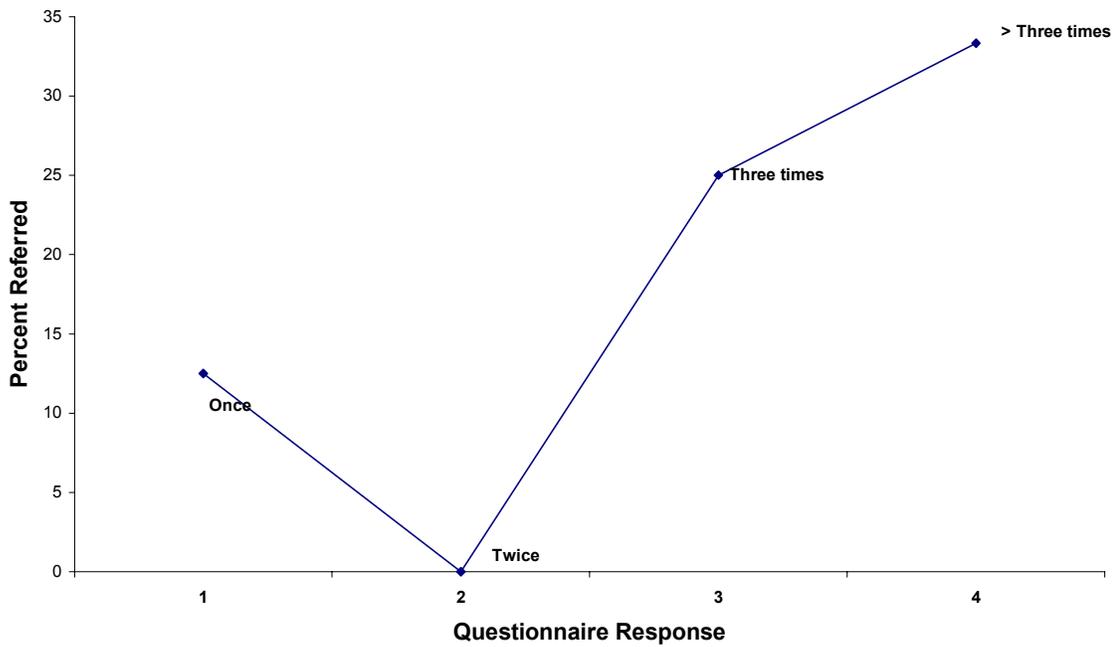
B4: How often have you have trouble seeing?



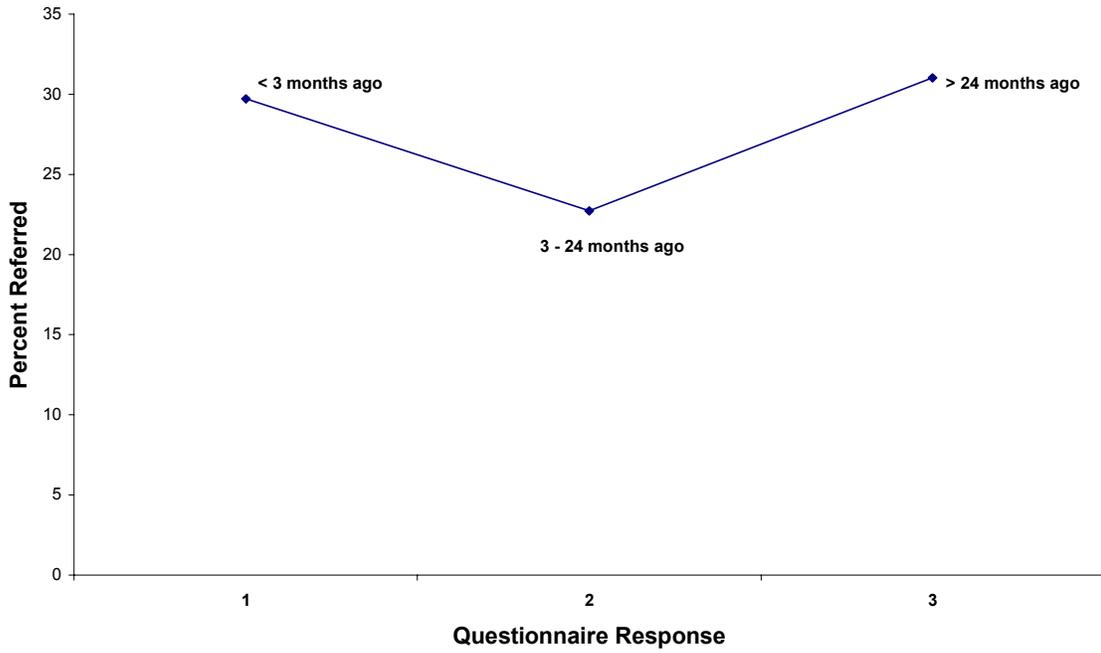
B6: Have you ever smoked tobacco regularly?



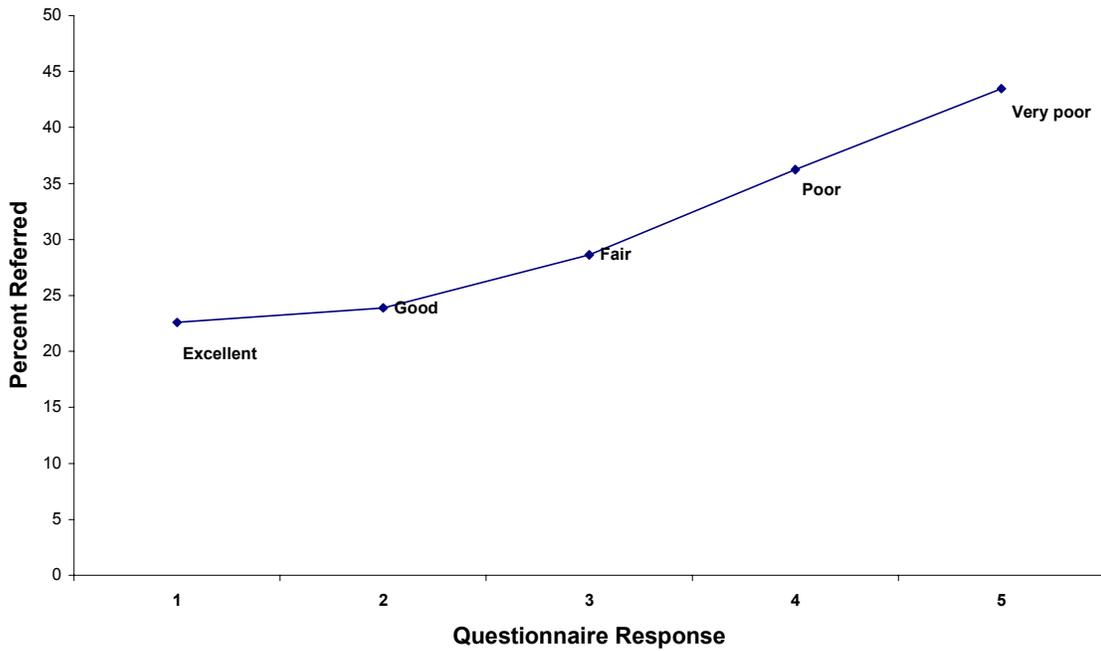
B14: Recent advice to quit smoking?



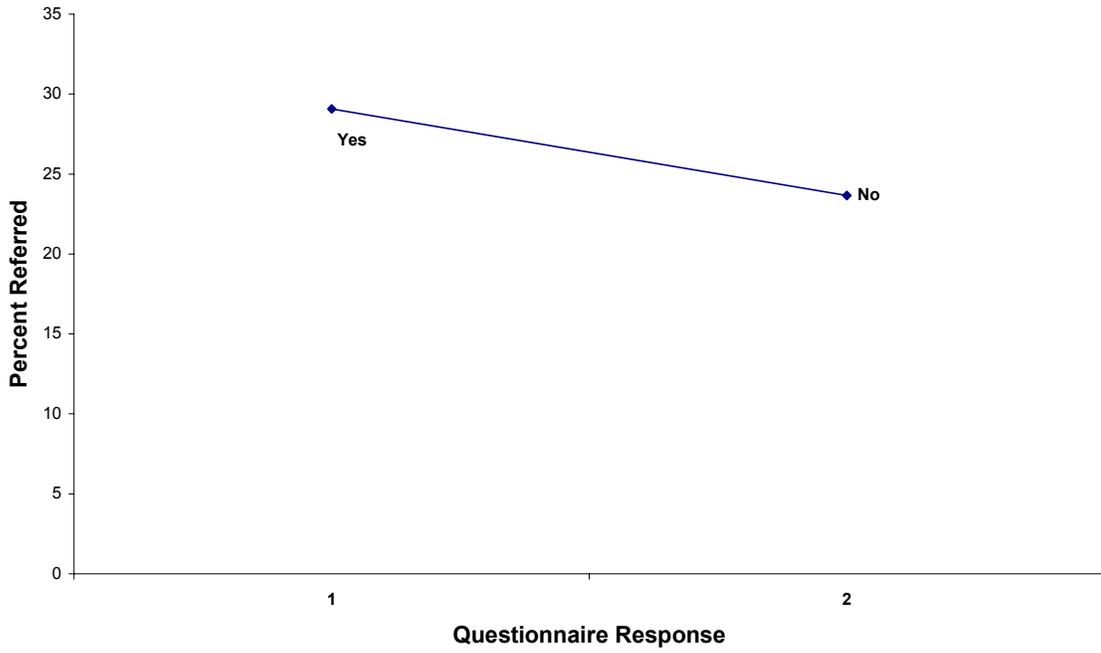
B16: How long since last wine, or hard liquor?



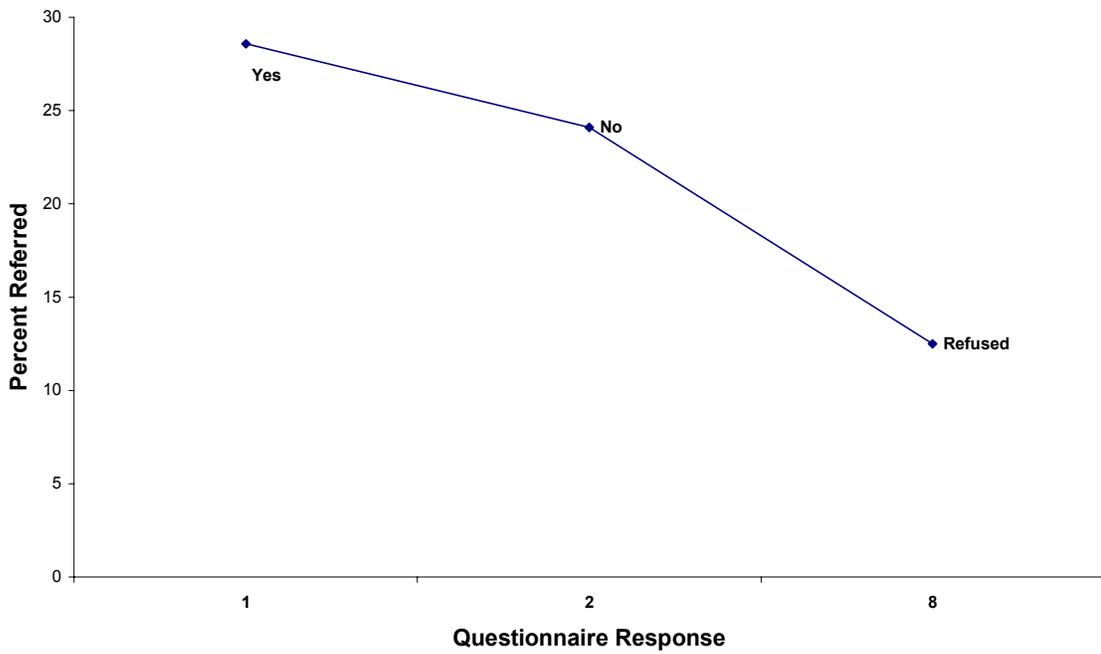
C1: Self-evaluation of quality of eyesight.



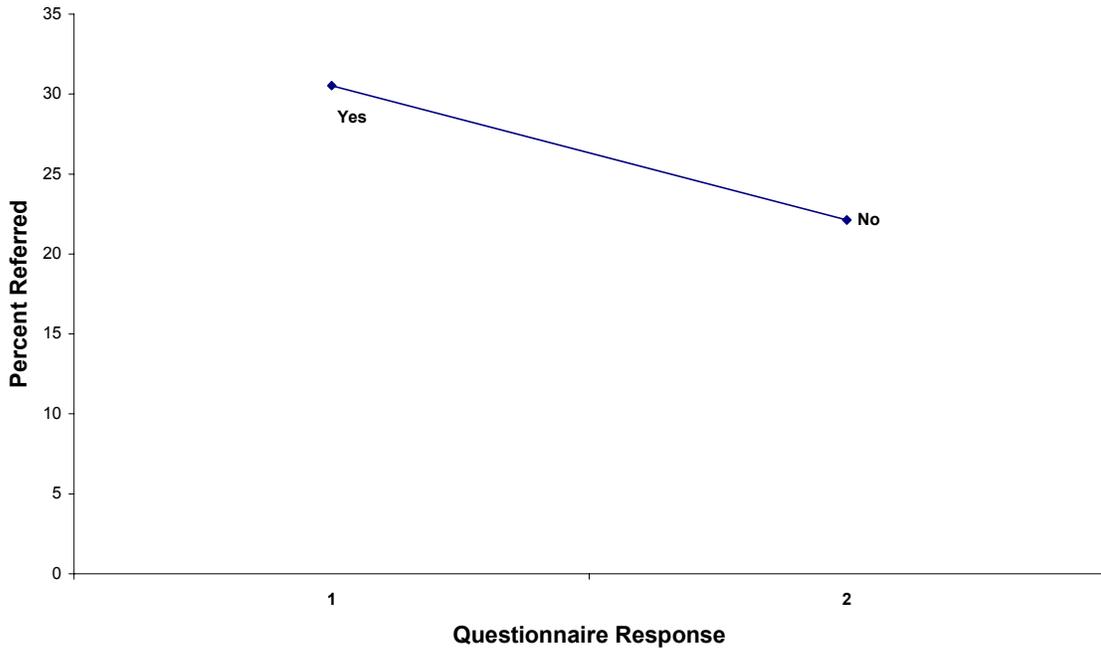
C30A: Didn't know that you should have annual exams?



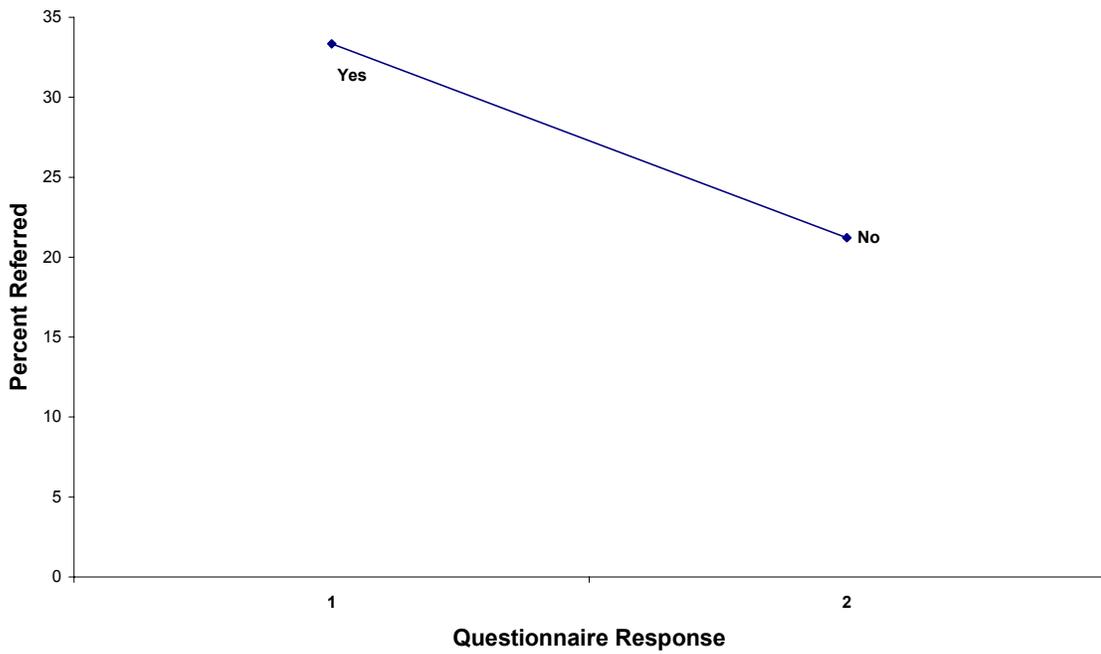
C30B: It cost too much for annual exams.



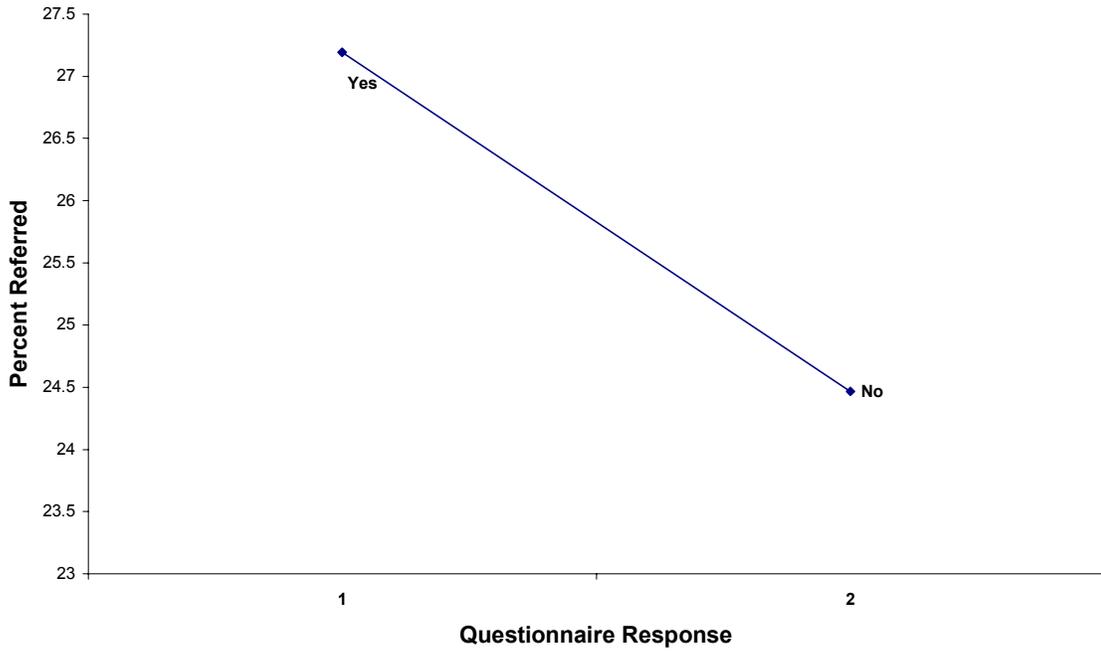
C30C: Didn't know where to go for annual exams.



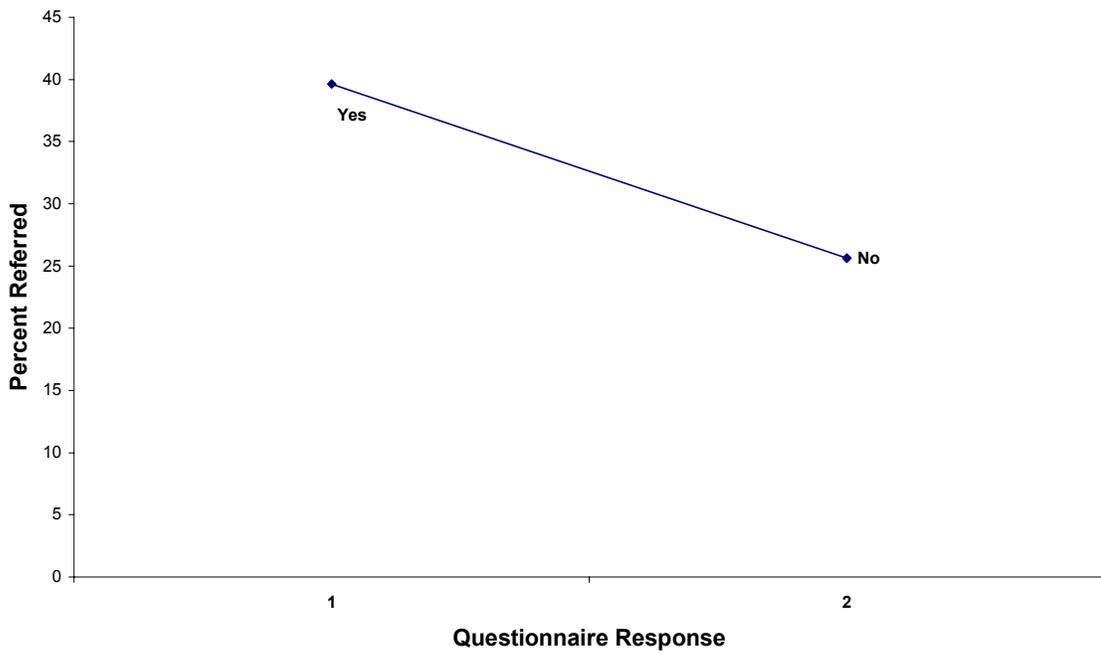
C30D: Didn't have a way to get to annual exams.



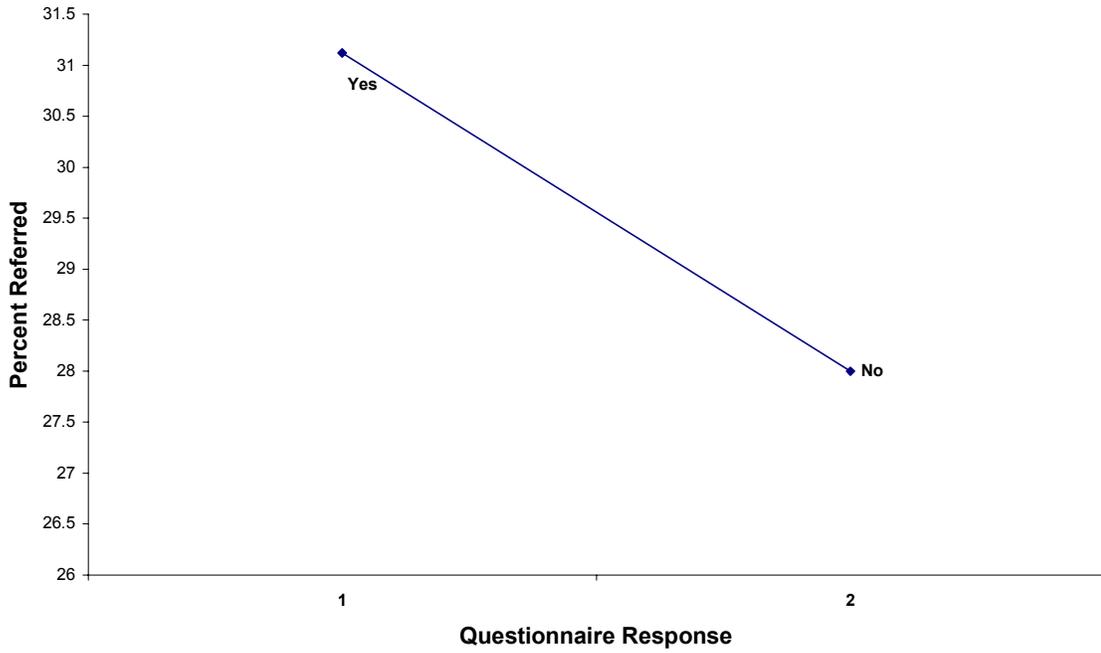
C30E: Didn't think serious enough for annual exams.



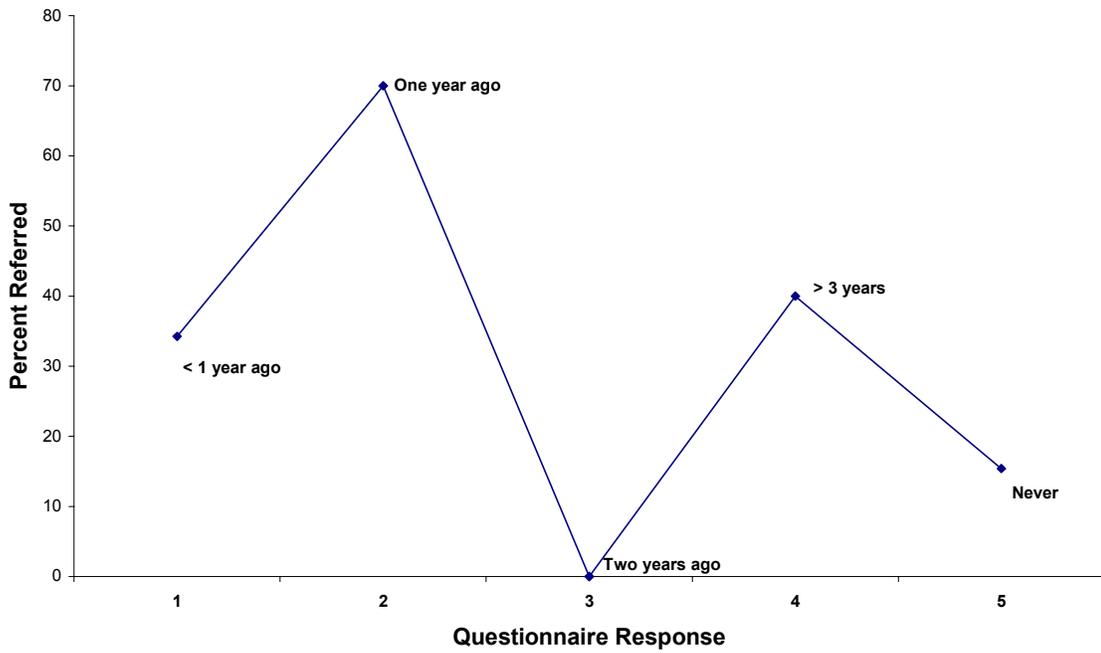
D3: Currently taking insulin injections.



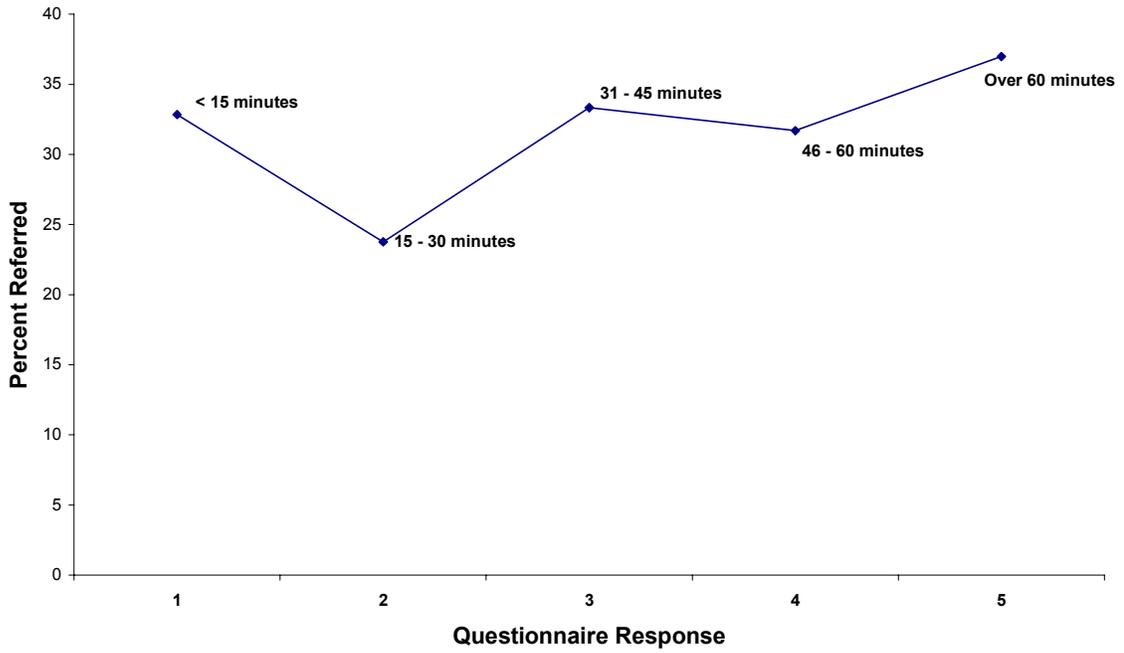
D16A: Check blood sugar (glucose) levels yourself?



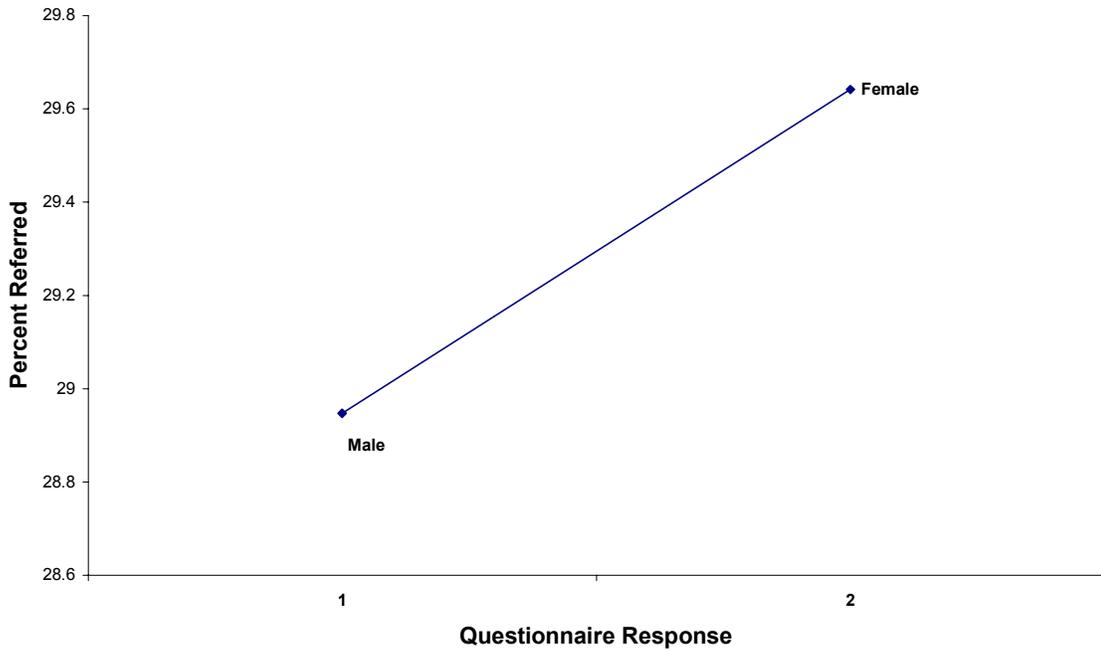
D19: When last urine test for protein?



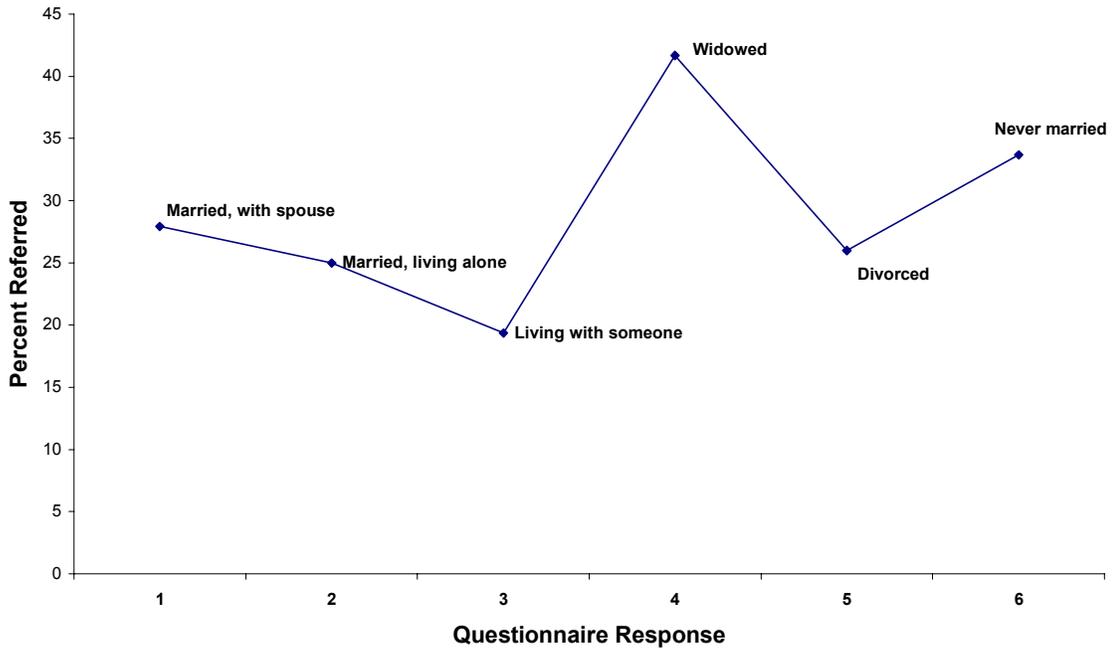
E2: How long to get to the doctor's office today?



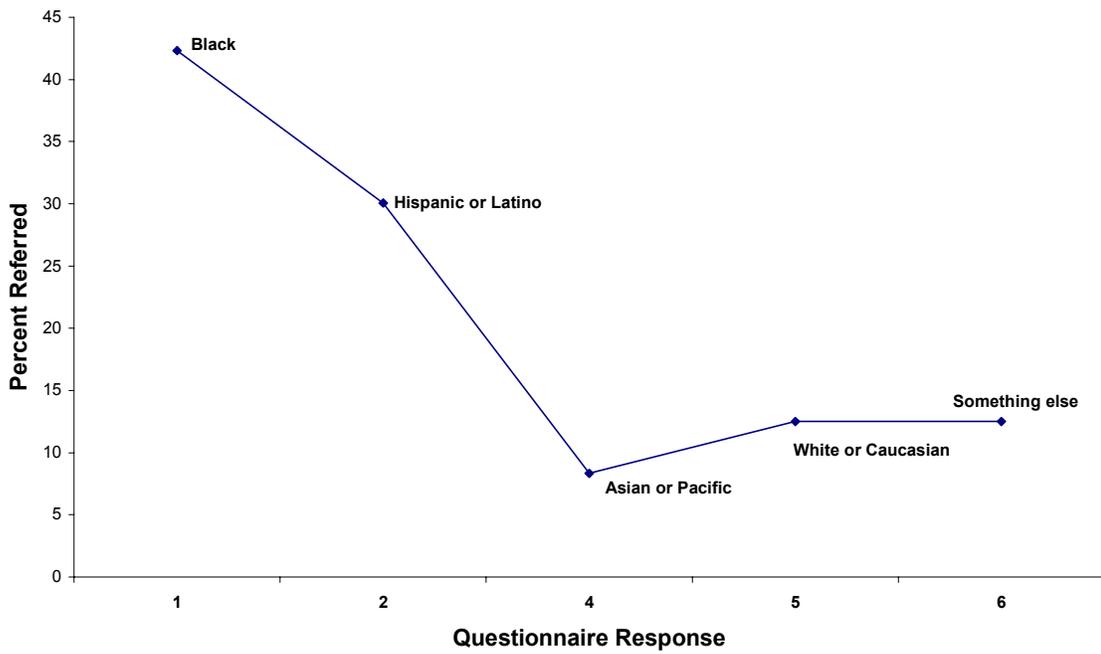
F2: Are you male or female?



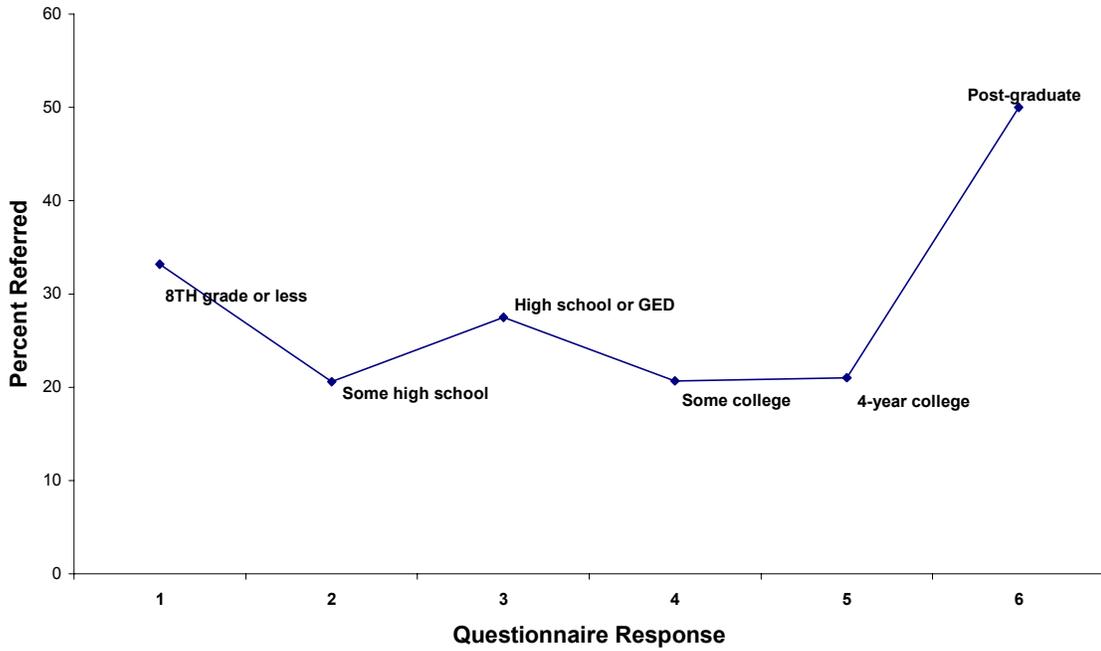
F5: Marital status



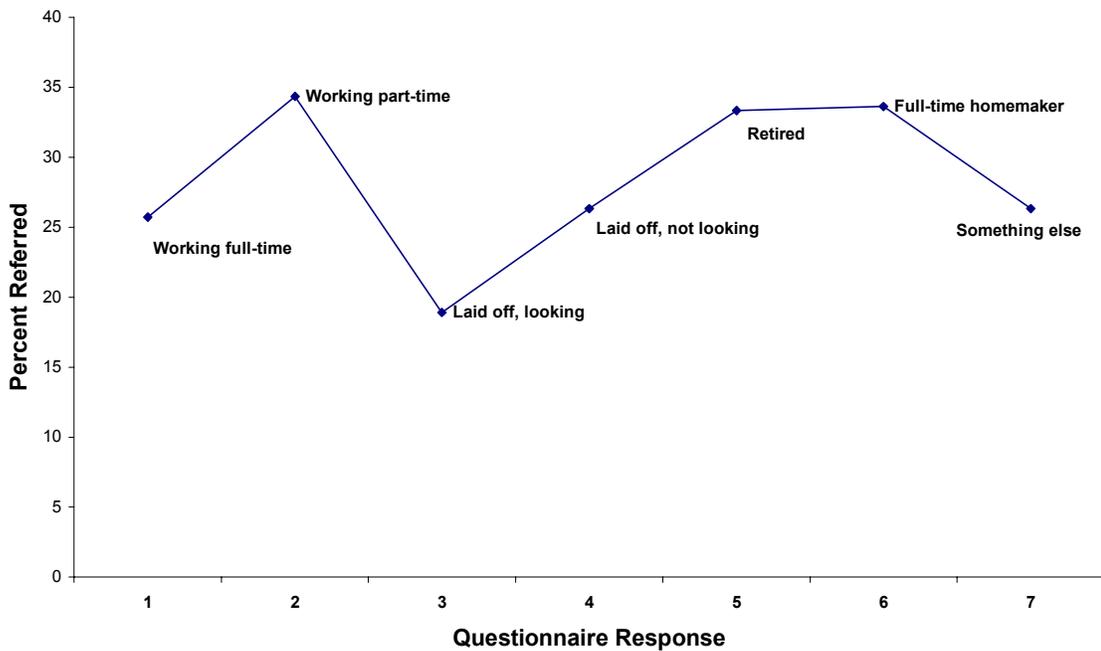
F6: Ethnicity



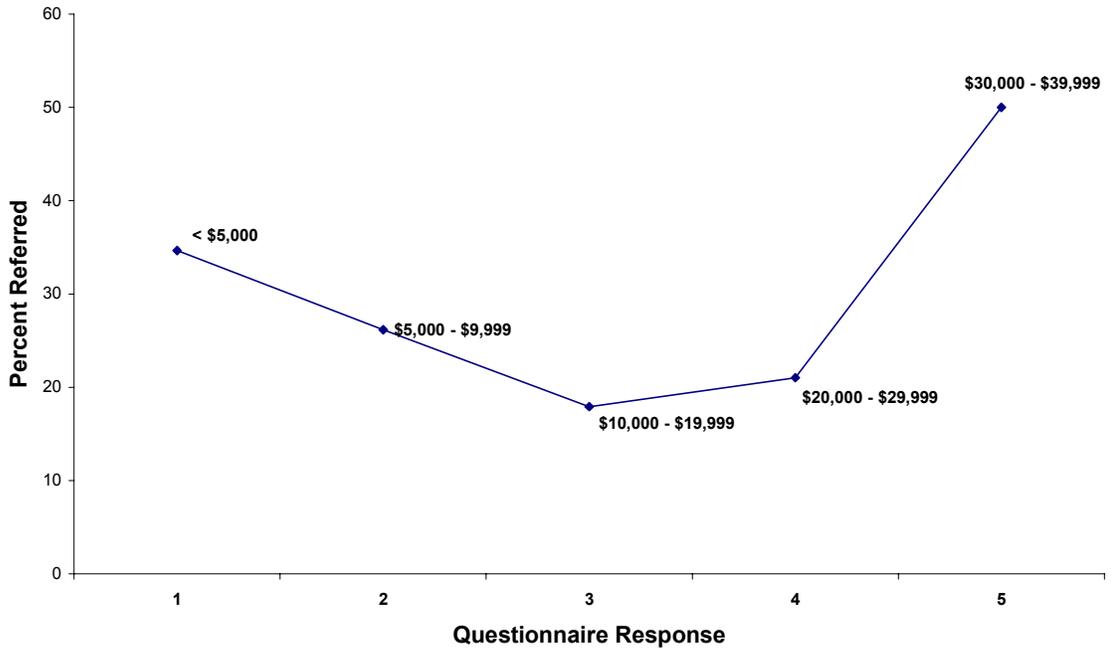
F7: Highest grade in school completed.



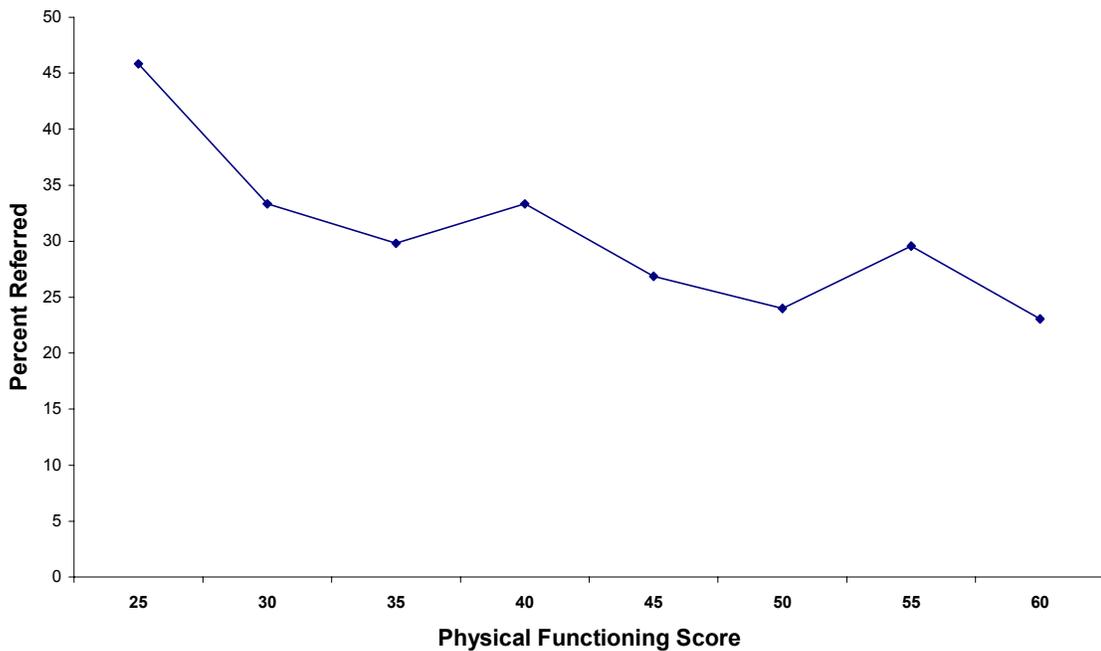
F8: Current employment status.



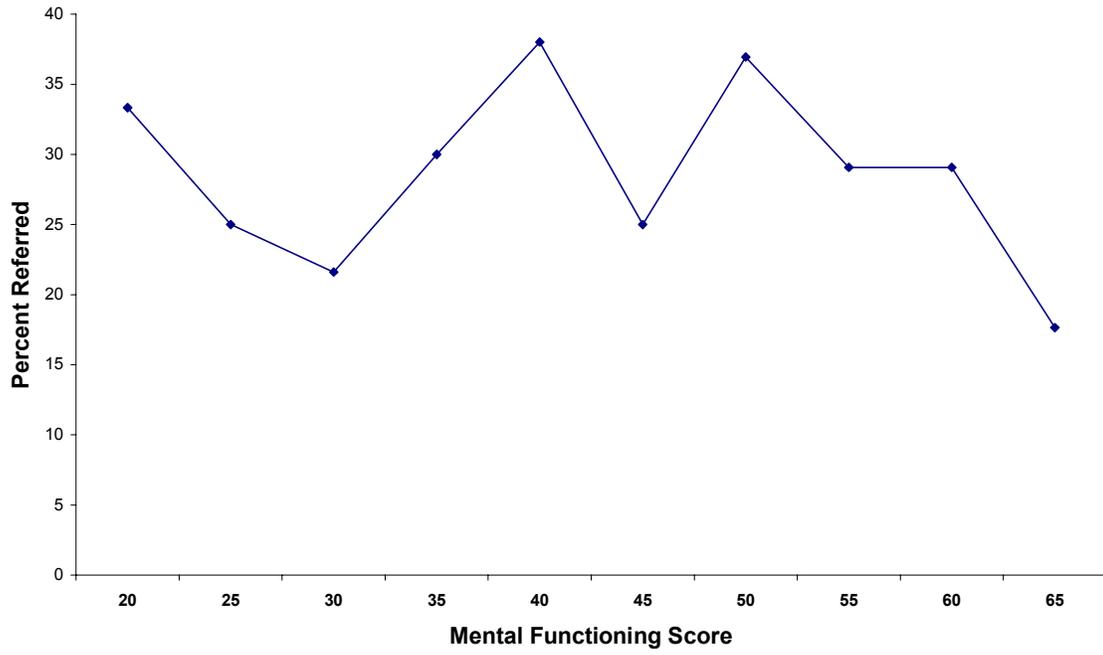
F9: Total household income before taxes, in 1997.



PSF12: SF-12 Physical Functioning Score



MSF12: SF-12 Mental Functioning Score



Appendix G: Description of Three Underserved Sites

The Hubert Humphrey Comprehensive Health Center (HHCHC) is the primary out patient facility and headquarters for all public and ambulatory services for the Los Angeles County Department of Health Services Southwest Cluster Service area. As a comprehensive health center, this facility offers a full range of medical, dental, mental health care, public health, and preventive health care services. The physical plant of this facility covers 3.5 acres and contains 70 examination rooms, 12 treatment rooms, and an observation room in the Urgent Care Center. HHCHC served a total of 236,069 outpatients for fiscal year (FY) 92/93 averaging 19,672 outpatients per month. Projections for patient volume for FY 96/97 and beyond are dependent upon the uncertain status of surrounding satellite community clinics. The densely populated Southwest Cluster area served by HHCHC has a disproportionate share of health and socioeconomic problems and classically low community access to medical, dental, and public health services. Although regional primary care and public health services reside at HHCHC, virtually all specialty and advanced diagnostic services for this high volume facility reside at the King-Drew Medical Center (KDMC).

A high volume of referrals occur between HHCHC and KDMC, however, the number of patient no shows and patients lost to follow up are substantial. Moreover, depending on the condition in question, both inappropriate under-referral and over-referral have been noted to be operative barriers to an efficient, cost-effective referral process. Other factors that have been shown to negatively impact the referral process include lack of provider communication, absence of point of service patient information, duplication of test and procedures, disparate administrative systems, lack of continuity of care, and geographic distance between facilities.

The Nueva Maravilla public housing development located in East Los Angeles, services a significantly at risk population. A large majority of residents living at Nueva Maravilla are Hispanic, comprising 93% of the population. Four percent of residents are Black, 2% are White, and 1% are Asian. Individuals 5-11 years and 31-50 years of age make up the largest portion of the population (42%, while 20% are over 51 years of age. Fifty-nine percent of households are categorized as family households, 29% elderly, 9% are disabled, and 3% are handicapped. Fifty-two percent of residents are female. Approximately 49% of residents earn less than \$10,000 per year. There access to health care is extremely limited with less than 2% of working adults having medical insurance.

The Charles R. Drew University of Medicine/King-Drew Medical Center, the major academic health center for South Central Los Angeles County, is located in the Watts/Willowbrook community of Los Angeles County and is the hub site of the Los Angeles County and Los Angeles County Southwest Cluster specialty care services. The immediate service area for the Southwest Cluster, and approximately, 40% of children live below the poverty line, which is the highest ratio of any health service cluster. South Central Los Angeles has the distinction of being the region with the highest concentration of ethnic minorities and the lowest average income of all of the communities of Los Angeles. This community is comprised of 60% Hispanic, 35% African American and 5% white and other.