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Introduction

The IMITS: Information and Clinical Technologies for the Advancement of Healthcare is focused on implementation of advanced technology solutions that eliminate inefficiencies, increase utilization, and improve quality of care for active duty forces. The work on this project includes the development and implementation of prototype telemedicine systems and advanced technology applications at United States Air Force bases. Emphasis has been placed on the incorporation of sound evaluation methodologies for each of the sub-projects with special attention to the areas of cost effectiveness and end-user satisfaction within the AFMS.

Body

Teleradiology

All IMITS FY04 deliverables were accomplished and documented in the 2006 Annual Report.

FY05 - Distributed Radiology Dynamic Workload Allocation (DRDWA) Phase I Complete

The DRDWA project team conducted a six-month evaluation phase in order to identify the requirements and concerns of the USAF radiology community. Several findings and recommendations follow; however a detailed explanation of the findings and recommendations are contained within the DWA Phase I Report (Dated: 07May2007) submitted to and approved by SGR (Appendix 1)

During the evaluation phase, UPMC ensured that a requirement for DRDWA / Enterprise Radiology existed. By engaging the appropriate AFMS partners, the DRDWA project team was able to confirm the need for a DWA solution and begin to accurately define an acceptable DRDWA prototype solution. The continual participation of these USAF entities was crucial for the success of this initial phase of the project.

In order to accurately define a prototype solution, it was necessary for the project team to define the business rules requirements in order to effectively determine how to traffic radiology images throughout the USAF. The project team has identified two sets of business rules: 1.) A local rules engine is required to automatically identify candidate studies that will be exported for remote diagnoses. 2.) A global rules engine is required to automatically route candidate/exported studies to remote MTF capable of handling the additional volume in workload or providing sub-specialty expertise required in order to perform diagnosis.

Distributed Radiology Dynamic Workload Allocation Phase II in Process

The proposed DRDWA prototype solution has entered Phase II of the project. During Phase II, the project team will complete software development of the DWA prototype. The DRDWA development team has completed several integral components of the project. These components will be displayed in a two base DRDWA Functional Demonstration (March 2008). The primary

purpose of the upcoming functional test is to evaluate and receive feedback on the software development work created by UPMC and SAIC/ICDB for the DRDWA project. This testing will also afford an opportunity for the team to offer suggestions for improvements. The functional test does not include the automatic routing and logic rules being developed for the complete DRDWA. The sites chosen for participation are Wright-Patterson Air Force Base and Dover Air Force Base.

Upon completion of the software development, the DWA project team will work with SGR to demonstrate the prototype solution in conjunction with the start of Phase III. Once the demonstration has been successfully completed, the project team will continue to work with SGR during the interim accreditation and certification process for the prototype software. UPMC IMITS will investigate provisional accreditation through IATT and IATO. This process may require additional documentation and/or modifications to the software in order to explore DIACAP accreditation. The project team will complete the necessary requests from the IA review team and acquire the appropriate accreditation at the conclusion of Phase III. During Phase IV, the project team will conduct full-scale testing of the prototype software to successfully demonstrate the capabilities and the need for this software solution throughout the AFMS. Additional development or modification to the Scope of Work (SOW) may be required by mutual contract accepted by UPMC and SGR. The enterprise roll-out of the DRDWA solution will assist/provide the solution, training, and tools allowing the USAF to become self-supported with synchronous and asynchronous collaboration tools for the existing PACS. The enterprise implementation is not contained within the FY05 SOW; therefore UPMC IMITS will require additional funds in order to complete the final accreditation and roll-out.

Reportable Outcomes

Presentations

- Phase I DRDWA Evaluation Report
 - *Submitted: 07May2007*
 - *Presented to Gen. Casey: 18July2007*

Conclusions

Phase I of the four-phased DRDWA project was to conduct a detailed evaluation of the current AFMS radiology workflow by the DRDWA project team and deliver an analysis report for SGR's review and approval. The project team – consisting of several members of UPMC Health System, UPMC IMITs Center (DoD Program Management Office), the SGR Congressional project manager, and with input from the AF Radiology Consultant, completed an evaluation and developed recommendations for a successful design and implementation of DRDWA prototype.

The DRDWA prototype will demonstrate increased productivity, cost savings, and above all enhanced patient care regardless of physician staffing constraints or patient location. The proposed solution and the iDIS infrastructure will support a symmetrical load-balanced distributed workflow model across MAJCOMS and in multiple PACS environments. The prototype solution will allow dynamic bi-directional transmission of clinical studies and optimal workflow load-balancing to effectively leverage resources irrespective of location, PACS vendor

or particular local workload demands. The prototype solution will also provide to the physician relevant patient history required for an accurate diagnosis in a continually moving patient population throughout the AFMS. The proposed iDIS infrastructure will be the baseline architecture for enterprise imaging exchange through the AFMS regardless of medical discipline, and the intra/inter-base communication infrastructure for efficient clinical data exchange for all future healthcare information technology AFMS providers. This infrastructure will allow for more flexibility with regard to workload distribution during AFMS radiologist deployments, TDY, on-call support and the development and availability of subspecialty expertise.

During evaluation of Phase I, the project team became aware of a DoD / VA Wounded Warrior Imaging initiative. The proposed DRDWA and iDIS solution would provide the foundation and several components in the solution to the Wounded Warrior Imaging initiative. In addition, the DRDWA prototype and the iDIS infrastructure could be the foundation for an AFMS business continuity / disaster recovery plan. Upon completion of the prototype systems, the AFMS could initiate the necessary processes to ensure that Enterprise Radiology is approved and funded for implementation. In order to provide a flawless implementation of the solution to the AFMS / MHS, the UPMC IMITs Center intends to strategically partner with SAIC/ICDB. This partnership could implement an aggressive roll-out approach of the solution to quickly enhance the patient care of the future.

Evaluation

We have planned to evaluate the capabilities, efficiency, utility, and effectiveness of the Distributed Radiology Dynamic Workload Allocation System (DRDWA). We intend to show that the DRDWA will be able to effectively and efficiently allocate radiology cases throughout specified sites based on specific parameters of each site (i.e. radiologist availability, read preference, performance history, etc.). We also intend to examine whether the DRDWA will be well utilized and accepted throughout the specified sites as a satisfactory system for reallocating workloads.

We have obtained approval from the University of Pittsburgh IRB for this study. USAF IRB approval has been granted at Andrew, Lackland, and Wright-Patterson AFBs. We have begun collecting baseline radiology statistics and survey data from developers.

Teleaudiology

Conduct Feasibility Study to evaluate remote access, monitor, and adjust cochlear implants.

Individuals from Wilford Hall Medical Center (WHMC) and UPMC continued to participate in the project team based on their expertise in Audiology throughout 2007. The project team continued to investigate a remote mapping solution with the three cochlear implant manufacturers within the United States. The manufacturers used in the process were Cochlear Americas, Advanced Bionics, and Med-El. All three manufacturers attempted to participate on the project; however they continue to have very limited resources to dedicate to the project during 2007. A detailed evaluation, by the project team, was conducted to document the current requirements and procedures with regard to cochlear implant mapping. In addition to the current

requirements and procedures, the project team documented the requirements and procedures for the proposed remote mapping process. A needs assessment and a gap analysis will be provided in the next annual report and will be provided to the office of the Surgeon General of the US Air Force in March 2008. The feasibility study is undergoing final review by the investigators.

Remote cochlear implant mapping uses video conferencing equipment (VTC) and remote control software. Project assessments of the requirements for remote cochlear implant mapping were conducted to determine equipment specifications and suitable option for remote cochlear implant monitoring for UPMC and WHMC. Based on the assessments, UPMC selected and purchased two Polycom MediCart for their VTC equipment with Windows Remote Desktop as the remote control software. Project staff received training from UPMC audiology domain experts and successfully conducted initial feasibility tests between office locations within UPMC. For their VTC equipment, WHMC selected and purchased two Polycom Mobile Responder using Dame Ware as the remote control software. Project investigators are conducting initial pilot testing of the equipment with no human subject involvement. UPMC has also acquired test devices from the manufactures known as “implant in a box” in order to conduct the on-site non-human subject testing. These devices will be shared between the physicians at WHMC and UPMC to complete their testing

The manufactures were informed of the DIACAP approval requirements for their software products. Currently, only Advanced Bionics has taken the initial steps to initiate the DIACAP process with the USAF by submitting an SSAA application to the USAF for review. Advanced Bionics is attempting to investigate what their response will be based on their review findings from the DIACAP process.

Conclusions

The proposed remote cochlear implant mapping solution will require two approval processes. The first approval process is the Air Force DIACAP certification. The second approval process is an FDA approval. The both approval processes requires testing and documentation from only the manufacturers. Testing of this solution will require between six month and twelve months. The testing will only be conducted by the manufacturers and without human subjects initially and then possibly with human subjects in order to meet FDA requirements. Currently, the manufactures are unsure if they will be able to dedicate the appropriate level of resources to the both of these approval processes. The project team is continuing to investigating additional funding sources for the approval and implementation processes for the proposed remote cochlear implant mapping solution.

Telepathology

IMITS FY05 - Telepathology Project:

Strategic Support of Telepathology Development in the Air Force

The FY05 project builds on accomplishments and products from the previous projects through the continued implementation and evaluation of telepathology systems and clinical applications. The FY05 project also addresses the need to improve the level of telepathology experience, expertise and adoption within the Air Force. At the completion of the project the AFMS will

have a cadre of champions familiar and comfortable with telepathology and a strong rationale for the adoption of these technologies.

Project 1: Create a whole slide image (WSI)-Based Educational Slide/Image Collection

During the course of the year, Telepathology team members mapped the schema for software based on the needs of UPMC and USAF pathologists. The repository includes 150 WSI pathology cases categorized across multiple anatomic domains and diagnostic findings. USAF and UPMC case contributors will be able to annotate their images to highlight areas of interest. This site will also support digital courses developed by domain experts that can support those seeking to expand or refresh their digital and diagnostic skills. Project software was completed in December 2007 and cases are currently being added to the repository. A UPMC server has been designated to host the site and it is anticipated that UPMC and USAF pathologists will have full, secure access to this repository by February 2008.

UPMC purchased an Olympus Bacus NanoZoomer whole slide imaging system to extend research in digital pathology applications. The system was installed at Shadyside Hospital in August and is being used to scan slides for FY05 evaluation studies and for additional image quality research being conducted by UPMC project personnel. There is particular interest in research exploring the system's digital capabilities for brightfield and immunofluorescence microscopy.

Evaluation

Over the past several years of working with the Air Force on static, robotic, and WSI systems, it has become apparent that an educational slide collection could be of benefit. This collection not only would be used as a reference and teaching tool in pathology, but also as a mechanism to assist participating AFMS personnel in becoming familiar and comfortable with this emerging technology. The goals of the Educational Slide Collection are to: 1) provide an educational resource to multiple facilities including the AFMS 2) measure the utility of a WSI Telepathology training system.

At least 150 de-identified pathology cases will be collected from the participating sites and scanned. Images will be reviewed for quality and sent to a designated site where they will be stored and made available as an educational resource for UPMC and Air Force participants. Questionnaires will be completed before and after the study to track user perceptions of satisfaction, usefulness, and feasibility. In addition to surveys, we are asking pathologists to submit interesting cases from their own collection.

An Evaluation Team from the University of Pittsburgh (Department of Biomedical Informatics) has been contracted to provide evaluations for the Educational Slide Collection known as PathEd. The Evaluation Team has developed pre- and post-implementation questionnaires that record the Air Force's current telepathology capabilities as well as provide information on PathEd's utility, feasibility, effectiveness, and user-satisfaction. Our study forms have been IRB approved for exempt research by the University of Pittsburgh, as well as several Air Force sites. These sites can be found in the table below.

IRB Approval List		
Site	Date of Submission	Date of Approval
University of Pittsburgh	10/18/06	12/4/06
SGR	2/19/07	2/20/07
Lackland AFB	2/21/07	6/8/07
Keesler AFB	2/20/07	4/27/07
Offutt AFB	6/13/07	6/13/07
Travis AFB	7/07	7/25/07

A Needs Assessment Questionnaire (pre-implementation) was distributed to bases that have given IRB approval. This questionnaire evaluated current capabilities of telepathology as well as current practices. As of December 19, 2007 six pathologists have submitted a completed Needs Assessment Questionnaire.

Project 2: Conduct WSI-Based Inter-Facility Quality Assurance (QA) Evaluation

Digital pathology QA controlled trial studies were conducted at UPMC in FY04, and the results of those studies suggested the reliability and usefulness of WSI in the clinical setting. The goal of this project is to determine the utility of inter-facility QA based on WSI technology within the AFMS.

A database of 30 cases was created to electronically collect data from UPMC and Air Force pathologists. The cases span across multiple tissue types. Participating pathologists are asked to complete surveys on each slide viewed. These surveys are available electronically and will monitor image quality, ease of use, etc. Participants are free to complete as many cases as they wish, and all collected data will be kept anonymous via an honest broker. Questionnaires will be completed before and after the study to track user perceptions of satisfaction, usefulness, and feasibility. At the time of this report, four pathologists from UPMC have started the WSI-QA study. Completion for said pathologists is projected to be March 1, 2008.

Additional research activities are aimed at expanding studies initiated during FY02 and FY04. An immunohistochemistry validation study was completed early in 2007 and results were accepted for publication by Human Pathology, a professional pathology journal (in press). Study results were presented at the American Telemedicine Association national conference (Nashville, TN – May 2007) and at the Advancing Practice, Instruction, and Innovation through Informatics (APIII) national conference (Pittsburgh, PA - Sept 2007).

A pilot study was conducted to test the capabilities of WSI for the use of viewing and diagnosing frozen section pathological slides and images. The pilot study revealed a number of design variables and results, though inconclusive, provided evidence supportive of WSI applications for prompt frozen section diagnosis.

A team researcher summarized a study that evaluated digital images (scanned on Trestle) for stain utility and cell number. The process by which the study was conducted and the

evaluations of the digital slides are relevant to QA based on digital images. The researcher presented her findings as a poster: *Immunohistochemical Evaluation of the Intraepidermal Component of Primary Melanocytic Lesions* at the American Society of Dermatopathologists Conference (Baltimore, MD).

UPMC team members are developing a task-based image quality assessment tools for pathologists, based in part on our research findings covering imaging systems, image quality and diagnostic capabilities. Such an assessment tool can help determine best digital options for decision support across a variety of clinical circumstances.

Project 3: Compare Robotic Microscopy with WSI for Real Time Consultation

Evaluation

In the emerging world of digital pathology, it is important to have a definitive study that compares side-by-side real-time robotic Telepathology with WSI-based Telepathology. The goal of this project is to determine the utility of robotic microscopy for real-time consultation in the Air Force, and compare it with the utility of WSI consultation. We have planned a study where participants will look at 20 cases using each technology and render a diagnosis as well as rate image quality. Results will be compared to the “Gold Standard” already established. Questionnaires will be distributed before and after the study to participants that ask them about their experiences.

Project 4: Promote Telepathology Champions in the Air Force

In September 2007, advocates /leaders for USAF digital pathology met for the first time at the annual Advancing Practice, Instruction, and Innovation through Informatics (APIII) national conference, held in Pittsburgh. This symposium provided a forum for USAF pathologists to collaboratively present digital pathology experiences within the United States Armed Services, to share knowledge and expertise gained from real life telepathology applications; to assess their needs for digital pathology; and to begin development of a comprehensive plan to improve current USAF standard of practice. At this time, the Telepathology team is working to reunite the USAF pathology leaders to continue to develop the initiatives fostered during the September 2007 digital pathology symposium. During the upcoming meeting, a robotic microscopy lab will be set-up for the pathologists to receive applications training from the manufacturer and WSI training from UPMC project team members. Pathologists will also be able to apply their digital diagnostic skills to the project's evaluation studies, which include a needs assessment and participation in digital pathology validation research, initiated with the FY04 project. This course will offer CME credits through the University of Pittsburgh and may lead to the establishment of a formal certification program for digital pathology.

The FY05 Telepathology project purchased several robotic microscopy systems for the USAF bases; these robotic microscopes are the initial devices required in order to establish a digital pathology lab and networking among the bases. Presently, the robotic microscopy systems have received Department of Defense Information Assurance Certification and

Accreditation Process (DIACAP) certification and the project team is waiting for the final Authority to Connect (ATC) from the USAF in order to complete the final on-site installation.

Project 5: Enhance Visibility of Telepathology in the Air Force

Joint USAF and UPMC presentations were given at the American Telemedicine Association national conference (Nashville, TN – May 2007) and at the Advancing Practice, Instruction, and Innovation through Informatics (APIII) national conference (Pittsburgh, PA - Sept 2007).

Project 6: Strategize Development of Telepathology in the Air Force

USAF and UPMC project personnel drafted a Charter for USAF Telepathology. This draft charter was presented to USAF pathologists during the APIII symposium. Pathologists used this document as a foundation for building a strategic plan for telepathology across the AFMS. Pathologists USAF strategic planning will continue at the ATA conference in April 2008.

UPMC researchers are appraising digital pathology experiences at UPMC and other leading academic and medical institutions. This research is being summarized and a comprehensive report is near completion.

Project 7: Establish an Annual Symposium on Telepathology Establishment of a symposium that highlights the accomplishments of the USAF telepathology efforts.

One of the more crucial initiatives of the FY05 Telepathology Congressional Project was to educate the United States Air Force (USAF) on digital pathology in order to illicit acceptance within the USAF pathology community. In September 2007, the annual Advancing Practice, Instruction, and Innovation through Informatics (APIII) national conference was held in Pittsburgh. This conference focused on anatomic pathology informatics and imagining support for translational medicine. The IMITs Center Telepathology Project team was an active participant in planning this year's conference and incorporated sessions and workshops that merited the interest of the military. As part of this conference, in conjunction with support from the Surgeon General's (USAF) office, the IMITs Center Telepathology team was able to coordinate and facilitate a digital pathology symposium dedicated to identifying and addressing USAF pathology requirements. This provided a forum for USAF pathologists to unite and begin development of a comprehensive plan to improve current USAF standard of practice. The success of this meeting alerted the USAF to a need as well as provided the methodology for establishing an annual digital pathology symposium, which potentially may be held during future American Telemedicine Association (ATA) national conference meetings.

Project 8: Support Air Force Initiative to Achieve DITSCAP for Aperio - monitor, support, advise and assist Air Force efforts as needed.

The USAF continues to work on DITSCAP; no support requested.

FY 05 Project Delays

DIACAP certification for the Trestle Robotic Microscopes, anticipated for early 2007, was not achieved until Sept 2007. In order to connect the systems to the internet, an Approval to Connect (ATC) security certification is being requested from the Air Force Communications

Agency. ATC is still pending. The robotic microscopes cannot be deployed at the participating Air Force bases until the ATC is granted.

FY 05 Reportable Outcomes

Publications

Jeffrey L. Fine, JL; Grzybicki, DM; Silowash, R; Ho, J; Gilbertson, JR; Anthony, L; Wilson, R; Parwani, AV; Bastacky, SI; Epstein, JI; and Jukic, DM (in press). *Evaluation of whole slide image immunohistochemistry interpretation in challenging prostate needle biopsies.* Human Pathology.

Presentations

Jukic, DM; Ho, J; Zalme, RC; Duboy, J; Anthony, L; George, L; and Parwani, AV. Practical Whole Slide Imaging Digital Pathology Workshop. 2007 Advancing Practice, Instruction, and Innovation through Informatics (APIII) Conference. (Pittsburgh, PA - Sept 2007).*

- Anthony, L. (facilitator). Evolution of Digital Pathology in the Armed Forces: Breakout Session. 2007 Advancing Practice, Instruction, and Innovation through Informatics (APIII) Conference. (Pittsburgh, PA - Sept 2007).*
 - Zalme, R.C. *Telepathology Vision: Enabler of Revolutionary Healthcare*.
 - Kaplan, K.J. *History of Army Telepathology Program: 1999 – 2006*.
 - Williams, B. *Reinventing Consultation at the AFIP: The Advent of Virtual Slides*.
 - Lacy, T. *Air Force Telepathology Moving Forward*.
 - Gilstrap, S. *UPMC Innovative and Medical Information Technologies (IMITS) Center*
- Silowash, R; Anthony, L; Wilson, R; Grzybicki, DM. Developing a Validation Tool for Evaluating Whole Slide Images. 2007 Advancing Practice, Instruction, and Innovation through Informatics (APIII) Conference. (Pittsburgh, PA - Sept 2007).
- Silowash, R; Anthony, L; Wilson, R; Grzybicki, DM. Introducing Digital Pathology to the Air Force: A Preview of Intra-facility QA Studies. 2007 Advancing Practice, Instruction, and Innovation through Informatics (APIII) Conference. (Pittsburgh, PA - Sept 2007).
- Ho, J; Fine, JL.; Gilbertson, JR; Parwani, AV; and Jukic, DM; A Novel Whole Slide Image User Interface Designed for Anatomic Pathology Workflow 2007 American Telemedicine Association Annual Conference (Nashville, TN, May 2007).
- Grzybicki, DM.; Wilson, R; Silowash, R; and Anthony, L. Pathologist Cognitive Factors in Telepathology Acceptance and Practice Integration 2007 American Telemedicine Association Annual Conference (Nashville, TN, May 2007).
- Jukic, DM.; King, S; Helfrich, C; Melville; A; Sukthankar, R; Wali, A; and Satyanarayanan, M. Modeling of Content-based Image Retrieval Tools for Dermatopathology Applications: "Diamond" Software 2007 American Telemedicine Association Annual Conference (Nashville, TN, May 2007).
- Anthony, L; Jukic, DM.; Zalme, RC.; George, L; and Ho, J. USAF and UPMC Modernization Initiative: IMITS Telepathology 2007 American Telemedicine Association Annual Conference (Nashville, TN, May 2007).*
- Duboy, J; Ahmed, I; Castine, M; Jukic, DM.; and Parwani, AV. Technical and Workflow Requirements for Creation of Virtual Images for Use in Telepathology. 2007 American Telemedicine Association Annual Conference (Nashville, TN, May 2007).

- Fine, JL.; Ho, J; Parwani, AV.; Gilbertson, JR; and Jukic, DM. Building a Business Case for Digital Pathology. 2007 American Telemedicine Association Annual Conference (Nashville, TN, May 2007).
- Parwani, AV.; Suh, N; Fine, JL.; Ho, J; Grzybicki, DM.; Anthony, L; and Jukic, DM. Whole Slide Imaging and Telepathology for Intraoperative Frozen Section Examination. 2007 American Telemedicine Association Annual Conference (Nashville, TN, May 2007).
- Ray, S and Jukic, DM. A Virtual Slide Tray Platform. 2007 American Telemedicine Association Annual Conference (Nashville, TN, May 2007).
- Silowash, R; Wilson, R; Grzybicki, DM.; and Anthony, L. Improving Study Design and Technique in Whole Slide Imaging Studies. 2007 American Telemedicine Association Annual Conference (Nashville, TN, May 2007).

***IMITS FY 04 Telepathology Project:
Clinical Implementation of Whole Slide Imaging (WSI)***

The primary goals of this project were to evaluate whole slide imaging as a potential platform for pathology and to advance the integration of telepathology systems at UPMC and the Air Force. In summary, we assessed the capabilities of current telepathology systems, especially whole slide imaging, and they proved capable of providing useful level of surgical pathology reviews across distributed health systems and they will only get better over time. Work still needs to be done, however, especially in slide navigation, presentation speed and data integration for digital pathology to research full potential in the clinical space.

In 2006, UPMC completed all deliverables associated with the FY 04 project. Findings helped verify that digital images are virtually identical to glass slide-based reviews of pathology cases. The results indicated that images produced by current devices have enough image information to allow pathologists to produce accurate, complex, and detailed diagnostic reports, even for difficult and complex cases. Yet, current images have significant limitations including areas of sub-optimal focus and artifacts that appear to be related to over-compression and limited dynamic range that can cause diagnostic confusion. These limitations must be kept in mind if digital pathology is to be used for routine clinical primary diagnosis or other clinical applications such as quality assurance or second opinion collaboration. Pathologists are beginning to understand these technologies more clearly and this should allow pathologists to better use and manufacture superior systems in the future. Exactly when digital pathology will be accepted as a tool for clinical practice will depend on both advances in technology and mainstream acceptance of the value of digital pathology in clinical practice. Operating telepathology as a clinical service within a working medical center will require more than an imaging robot. In the experience of this project, factors such as the stability of the health system's network, the speed of servers, the performance of the pathologist's workstation and monitor, and even the functionality of the image presentation and navigation software proved more important (caused more difficulties) for the pathologists than the performance of the imagers. While this project did not measure all those parameters explicitly, it is clear that additional research is required. Furthermore, it appears that for telepathology to reach its potential, informatics groups will need to have better control (or at least visibility) across the entire IT environment, from imager to desktop as well as image integration with the LIS.

All project deliverables were completed and a comprehensive FY 04 Telepathology Final Project Report was submitted to SGR in July 2006.

IMITS FY 02 Telepathology Project:

Telepathology Static Image Implementation Evaluation Project
Gain information about perceived and actual barriers to and support for the adoption and use of the telepathology equipment and the interactive consultative process.

In 2006, UPMC completed all deliverables associated with the FY 02/04 Telepathology Static Image Implementation Evaluation Project. A comprehensive final evaluation report, *IMITS Telepathology Project Static Image Implementation Research Study Final Evaluation Report*, was prepared and delivered to the USAF SGR in July, 2006, in conjunction with the FY 04 Telepathology Final Project Report.

FY 04 Reportable Outcomes

A complete list of publications and presentations are included in the FY 04 Telepathology Final Project Report.

Conclusions

The Telepathology projects are being successfully implemented and results are encouraging. Primary goals include evaluation of WSI and robotic microscopy as potential platforms for USAF pathology. USAF advocates and leaders for digital pathology are working to strategize integration of digital pathology into the AFMS. It is hypothesized that digital slides can be effectively implemented within existing workflows, and will be useful in establishing timely inter-facility diagnoses and consultations across multi-facility health systems. In summary, current telepathology systems, especially whole slide imaging, are capable of providing useful levels of surgical pathology reviews across distributed health systems and they will only improve over time.

Extra-Corporeal Membrane Oxygenation (ECMO)

Perform a needs assessment and planning initiative to develop a Pediatric ECMO Center in Hawaii for the Pacific Rim, leveraging UPMC's extensive knowledge and experience in this area.

The initial plan was to perform a needs assessment in the Pacific Rim to determine the feasibility of developing a regional Pediatric ECMO Center. Simultaneous to this IMITS agreement being signed, funding for an ECMO center was appropriated to the Army in Hawaii to develop a Pediatric ECMO Center. IMITS funded was directed to support this initiative and equipment was purchased by UPMC with delivery to Hawaii in December 2005. This equipment was moved and installed at Kapi'olani Women's Medical Center in summer 2007.

A lab training protocol and a clinical protocol were developed for assessing the equipment and processes. A research protocol was designed to determine if the Jostra Rotaflow can be used for neonatal ECMO and whether it might deliver a superior result with greater safety and improved outcomes when compared with two traditional centrifugal pumps. A series of three clinical trials were conducted and a summary of the results was submitted to SGR with the 2006 annual report. Additional research trials are needed in order to fully assess and know how to regulate the ECMO processes. These trials will be conducted in with future congressional funding

channeled through TATRC and awarded to the University of Hawaii. All UPMC project deliverables were completed and a closure letter was provided to SGR in March.

Conclusions

The project sufficiently planned and prepared for the ECMO initiative in Hawaii. Training and research protocols were developed and research findings are guiding development of future clinical protocols.

All project deliverables were completed and a closure letter was provided to SGR in 05October2007 (Appendix 2).

Simulation and Training

Advanced Medical Education

Advanced Simulation for Medical Education and Training in the Pacific Rim Develop Medical Education capability with advanced medical simulators, leveraging expertise of UPMC's WISER Institute.

A detailed evaluation of the University of Hawaii's (UH) simulation requirements was conducted by members of the UH, UPMC, and University of Pittsburgh WISER Simulation Institute. The project team was able to develop a collaborative model to assist in the development of the UH simulation center. The collaborative team developed Memorandum of Agreement (MOAs) and licensing agreements to share curriculum and technologies. This collaborative process assisted in the design of the UH simulation center's hardware and software solution. The project team was able to use the University of Pittsburgh WISER Simulation Institute's SIMS application to effectively create a solution to deliver Internet based simulation and non-simulation training to UH. This solution is also compatible with the programs currently developed at the University of Pittsburgh WISER Simulation Institute. Upon completion of the solution, UH was able to requisition the required hardware and simulator equipment to complete the project. The system was implemented in October 2006 and officially conducted their grand opening in February 2007. A final report was submitted to SGR 30May2007 to officially close this project. The final report is included in this report as Appendix 3.

During this collaborative process, University of Pittsburgh WISER Simulation Institute members were able to identify existing partnerships between Asia and UH. UPMC and University of Pittsburgh WISER Simulation Institute were able to continue developing these partnerships to increase the UPMC WISER Institute exposure in Asia. Several members of the UPMC and University of Pittsburgh WISER Simulation Institute were invited to participate and present in the Annual Asia Pacific Military Medicine Conference in May 2007.

Simulation at Wilford Hall Medical Center

Conduct a "Needs Analysis" for incorporating simulation into the existing WHMC training programs

The Pilot Simulation Center was started using equipment borrowed from the Laerdal Corporation and Medical Educational Technologies, Inc (METI) and one METI HPS simulator owned by WHMC. The equipment needed to conduct training for various programs, such as monitors, defibrillators, ventilators, and furniture, was acquired through Defense Reutilization and Marketing Office (DRMO), Ft. Sam Houston-(surplus but useable military medical equipment is turned in here and available at no cost to other military programs) at no cost to either WHMC or the IMITS Congressional cooperative agreement. Space in the main building at WHMC was allocated by the WHMC leadership and WHMC Space Committee in the ICU area of the hospital. The pilot center has been in operation since July 2005. Since the opening of the pilot center, 1,500+ students have received training in 2,000+ encounters.

Briefings and discussions were also held with WHMC Patient Safety Committee and the Chief of Hospital Services, the San Antonio Uniformed Services Health Education Consortium (SAUSHEC) Graduate Medical Education program directors and staff, the WHMC Medical Readiness Office, Readiness Skills Verification Program Managers, WHMC/UPMC Congressional Steering Committee, and WHMC Level 1 Trauma Center leadership and training staff. Suggestions from these groups are used during working group meetings to identify training opportunities that could be developed and used for data collection for the needs assessment. Methods for data collection include observations, discussions with stakeholders, training guidance, and literature reviews. Outcomes have included a study done on Pediatric Advanced Life support training outcomes and retention and reports from WHMC subsequently deployed to IRAQ following pre-deployment training.

The center has continued to grow steadily through 2007. Feedback has been very positive especially regarding “hands-on” skills practice compared to a classroom PowerPoint Presentation or briefing. The Pediatric residents have been using the center extensively to improve skills in the care of critically ill pediatric patients. The Pediatric ICU census has been steadily decreasing with less and less training availability on complex patients. The Pediatric ICU staff has also created a Conscious Sedation Verification Program using simulation of pediatric sedation cases. They have also used the simulation center for a resident study on compliance with PALS Protocols.

Readiness personnel have used the center for medical technician and nursing Readiness Skills Verification. In fact, the center will be used monthly to perform these checks on all skills rather than testing different skills on a tri-monthly rotating basis. The Emergency Department and Surgical Intensive Care Unit have used the center for all required annual skills testing. The Trauma Department has developed a pre-deployment trauma course that teaches critical deployment care skills using the Simulation Center. This pre-deployment course is built on the Emergency War Surgery Course and the feedback has been extremely favorable. Currently, the WHMC Pilot Simulation Center is awaiting feedback from the participants that have just been deployed. This feedback will be used to adjust, add, or delete subjects in the course.

A needs assessment was completed and submitted to SGR. The needs assessment incorporated the findings and the current observations from the newly formed WHMC simulation center. Both UPMC and WHMC stakeholders are pursuing several funding opportunities that will

continue to establish a “center of excellence” in simulation training for the San Antonio Medical Center area.

“Patient Transfer” Simulation Training

Develop an innovative educational “Patient Transfer” simulation course

A detailed evaluation of the UPMC Nursing’s current training methods for the prevention of back-related injuries was conducted by members of the UMPC, the Beckwith Institute, and the University of Pittsburgh WISER Simulation Institute. The project team was able to obtain relevant information pertaining to the specific programs/training and the support structure required in preventing back-related injuries. From this evaluation, the project team was able to develop the course goals, objectives, curriculum, and educational tools. The course and the curriculum were incorporated in to the University of Pittsburgh WISER Institute’s SIMS application for both traditional and online training delivery methods. The course was designed for integration with high fidelity patient simulators and other mannequins designed for bio-mechanic and “patient” move simulations. Several evaluation and feedback methods were incorporated into the course materials. Evaluation methods such as pre and post patient transfer observations, trainee performance assessment tools, learning system effectiveness methods, programs leadership and support evaluations, instructor evaluations, and satisfaction surveys were be used. The course and the curriculum was completed and submitted to SGR.

Upon completion of the course design, a research study protocol was developed to accurately observe the effects of the course on the nursing participants. The protocol outlined a control group and a treatment group. The control group will consist of one nursing unit that will only be supplied with tradition back injury prevention training through the Internet. The treatment group will consist of two nursing units that will receive the new course material. This protocol was approved by the University of Pittsburgh Institutional Review Board (IRB). This protocol will be submitted to the US Army Human Subject Review Board (HSRRB) as an expedited study, for second level review. HSRRB deferred their second level review requirement to SGR. The protocol is still under review by the Air Force for second level approval. The program management at SGR is attempting to provide UPMC with a final letter of approval from SGR to complete the second level review requirement.

The project team has completed all the evaluation observations listed: pre and post patient transfer observations, trainee performance assessment tools, learning system effectiveness methods, programs leadership and support evaluations, instructor evaluations, and satisfaction surveys. The project team has completed the analysis of the observations and will present the final report to SGR 04April2007. The final report is attached as Appendix 4. Final results were presented at several national conferences, listed in the key research accomplishments section,

Delays

This protocol was approved by the University of Pittsburgh Institutional Review Board (IRB) in December 2006. HSRRB deferred second level review requirement to SGR. The protocol remains under review by the Air Force for second level approval.

Telemental Health

Explore opportunity for development of advanced telehealth applications for the treatment of post-traumatic stress disorders in mass casualty situations.

This project was officially closed and reported to SGR as closed in 2006 and 2007.

Platelet Gel

Create a model to evaluate the efficacy of Platelet Gel Therapy on non-healing diabetic foot wounds.

Members of WHMC and UPMC continued their participation in Platelet Gel project throughout 2007. The original study protocol was designed to demonstrate the safety and efficacy of Platelet Gel Therapy on non-healing diabetic lower extremity wounds. The implementation of the study protocol, “A Randomized Prospective Multi-Centered, Investigator-blinded Trial of Platelet Rich Plasma (PRP) Gel Versus Control for the Treatment of Diabetic Neurotrophic Leg Ulcers”, was approved for implementation by the Office of the Air Force Surgeon General as part of the FY '05 Diabetes New Projects Statement of Work (SOW). This protocol was submitted several times, throughout 2005, 2006, and 2007, to the Food and Drug Administration (FDA) in order to receive final approval. The study protocol was rewritten several times to address several concerns and requirements from the FDA. The protocol was approved by the FDA August 17, 2007 (Protocol – Appendix 5 and FDA Approval Letter – Appendix 6). The most notable changes were with regard to the number of human subjects (decreased from 400 to 90 - pilot study) and the introduction of Autologous Thrombin (instead of Bovine Thrombin) as the activator for the PRP.

The Platelet Gel project team initiated the pre-review process with the University of Pittsburgh Institutional Review Board (IRB) in order to receive approval to conduct the research study. Once approval has been obtained, the project team will submit the research protocol for approval to the WHMC IRB and the Office of the Surgeon General of the Air Force for second level approval. Then the implementation and management of the pilot study will transition to the FY '05 Diabetes New Projects in the fall 2008.

Delays

The FDA denial of the research protocol has caused a delay of several years. Initially the FDA was unable to approve the research study by the close of 2006; however they were able to approve it before the close of 2007. The FDA required several modifications to the research protocol that significantly affect the research study design. The Platelet Gel project team conducted several “Type C” meetings with the FDA in order to negotiate which items required additional modification in order to gain final approval. This process delayed the initiation of the IRB approval process.

During the pre-review process the Platelet Gel project team became aware of ownership issues with regard to the study protocol. The issues were in reference to whether UPMC or the University of Pittsburgh should be the owner and manager of the protocol implementation.

While investigating a potential resolution to this issue, the pre-review process with the University of Pittsburgh IRB has been suspended by the project team.

Teleophthalmology

Develop and implement an image transfer system and enterprise image archive for retinal images

The IMITS Teleophthalmology Project created an image-capture and transfer system and workflow process for effectively screening individuals for diabetic retinopathy. The teleophthalmology system was designed to efficiently gather medical information, merge this information with digital images of the retina and transfer the merged sets to a specialist for follow-up examination. The system is basically comprised of five separate software components: registration, imaging, grading, tracking and reporting. Each component is modular and customizable to specific locations and needs. The registration component, a web page that is accessible from the central server, was designed for efficient registration of new patients including collection demographics and key medical information. The information collected is minimal, focused on diabetes and eye conditions.

The imaging component consists of customized software running on a computer attached to the camera that drives retinal image acquisition. From the registration data, a worklist is created of patients who are ready to be imaged. A patient is selected from the worklist and the imager takes photographs of up to three retinal images of each eye, in any order. The imaging software includes areas for comments on any additional or unique attributes of the patient being imaged as well as any technical issues that may have been encountered during the imaging process. Once the images are captured, the entire study (i.e., retinal images and patient data) is ‘packaged’ together and transferred to a designated, central server.

The grading component allows the specialist to access the server, via the internet, to view a worklist of patients. The grader selects a patient, with either graded or ungraded images, and reviews patient specific data and images. For ungraded images, the specialist can use the grading software to manage the retinal images for examination. Based on analysis of the images, the level of retinopathy, maculopathy, quality of images and recommendations for follow-up eye care are recorded and saved in the database. For graded patients, results of a quality assurance review can also be saved.

Clinic staff can ‘track’ information regarding graded and ungraded image sets. This information contributes to efficient follow-up communications with patients regarding their examination and compliance with recommendations for care. Finally, the reporting component is designed to generate customizable statistical reports for the screened populations.

Software components were developed using basic architectural decisions about middleware, security, timing, portability, and the organization of data. For portability, the core of the system is a laptop with adequate processing power and memory to act as a server with an SQL database. System functions are worklist driven, eliminating typing errors and improving productivity. A server-generated unique identifier tracks patient movement through the screening process, possibly non-sequentially depending on the setting and system-configured layout. Time for each

participant to complete each component of the imaging process is tracked and enables assessment of the throughput of the system. Patient data is stored in the central server and customized reports can be created to support clinical processes and follow-up communications with patients.

The aim of the project was to develop a flexible, modular, mobile method for screening individuals that could be used effectively in a variety of medical and community settings. The project was successfully implemented and the results are encouraging. The design of a distributed architecture supports on-demand access to central repositories for rapid tie-in to other databases (central or otherwise) for healthcare information. Individually customized software components for workflow make the system readily adaptable to applications for other health conditions. For example, in cases of triage of wounded soldier, modifications to the software would enable immediate entry of medical information with digital images of injuries for rapid transfer to remote specialists for real time or delayed review. The software's customizable reporting features facilitate on-demand access to related hospital or battlefield statistics, which can be significant in tracking disease trends and localities.

A final report was submitted to SGR on 05October2007 (Appendix7).

Reportable Outcomes

Presentations

- Wilson, R; Eller, A; Zgibor, J; Ward, J; Petrick, R; & Anthony, L. (5/2006) Assessing the Capabilities and Effectiveness of a Teleophthalmology Screening Program. 2006 ATA Conference, San Diego, CA.
- Uttecht, SD; Eller, A; Smail, J; Ward, J; & Chang, PJ. (5/2006). Retinal Screening Workflow of the Populace at Health Fairs. Oral Presentation. 2006 ATA Conference, San Diego, CA.
- Waller, S; Lane, G; Flynn, W; Ward, J; Eller, Bursell, SE; & Anthony, L. (5/2006). Lessons Learned from a Teleophthalmology Program in the US Air Force. Poster Presentation. 2006 ATA Conference, San Diego, CA.
- Eller, A; Chang, PJ; & Flynn, W. (5/2006) IMITS Teleophthalmology Project: Seeing Tomorrow's Vision for the Future, Today. Poster Presentation in UPMC Exhibit Area. 2006 ATA Conference, San Diego, CA.
- Wilson, R., Eller, A.W., Silowash, R., & Anthony, L. Implementation and Acceptance of Teleophthalmology Program for Retinal Screening in Clinical Settings. 2007 ATA Conference, Nashville, TN.
- UPMC Project Team Teleophthalmology Project- PowerPoint Loop Presentation Exhibit Area Presentation. 2007 ATA, Nashville, TN.
- Cecil, RA and Eller, A. Software Architecture Discoveries in a Telemedicine System. 2007 Advancing Practice, Instruction, and Innovation through Informatics (APIII) Conference.
- Wilson, R; Silowash, R; Anthony, L; Eller, A, Bettencourt, L; and Zgibor, J. (10/25/2007). Telemedicine Process Used to Implement an Effective and Functional Screening Program for Diabetic Retinopathy. Diabetes Technology Society Conference, San Francisco, CA.

Evaluation

Assess the capabilities and effectiveness of the technology and workflow process being created to support a Teleophthalmology screening program for diabetic retinopathy.

An IRB approved research study was conducted to assess the capabilities and effectiveness of the technology and workflow process developed for the teleophthalmology project. The following summary of findings serves to satisfy the outcome of data analysis required for this project:

- 706 subjects with diabetes were successfully consented, registered, imaged, and had their eye images graded. 337 were from community sites and 369 from clinical sites.
- Mean time for subjects to be registered, imaged, and have eye images graded was 00:12:53.
- 51% of the subjects reported that their last eye exam was “Greater than 12 Months” or “Never”
- 76% of our sample were instructed to follow-up with their eye doctor in one year (had no retinopathy or micro aneurysms). Only six (0.8 %) were asked to see their eye doctor within 6 weeks (proliferative retinopathy).

Conclusions

Deliverables for the Teleophthalmology Project were completed and the feasibility of the system applications was demonstrated in health clinics using stationary equipment and in communities using portable equipment. Patient recruitment difficulties were not associated with the software, but rather with needs to better educated consumers. Alternative applications of the prototype system are currently under consideration, and UPMC ophthalmologists are meeting with health plan administrators and optical businesses to strategize incorporation of routine screenings into preventative healthcare curriculums.

A comprehensive FY 04 Teleophthalmology Final Project Report was submitted to SGR in August 2007.

Education

LEADERSHIP TRAINING

Provide recommendations for development of a leadership training program in the Air Force

This project was officially closed and reported to SGR as closed in 2006 and 2007.

Diabetes Self Management Tool

Develop and deploy a Diabetes Self Management Tool in the office setting leveraging existing technology at UPMC (Italy)

This project was officially closed and reported to SGR as closed in 2006 and 2007.

Major Barriers

Development of Teleradiology-Load Balancing Distributed Radiology Statement of Work

Several uncertainties have materialized during Phase II of the DRDWA project as a result of the partnership between UPMC, the USAF, and ICDB. The location of the global image registry for the Air Force is the first example of an unknown in the project. USAF partner development resources had been temporarily removed from the DRDWA and reallocated to alternative projects. These temporary, yet significant, setbacks have delayed several deliverable items in the DRDWA (Phase II) project. Therefore, the completion dates for Phase II, Phase III, and Phase IV have to be adjusted.

Emerging technologies in diagnostic imaging have also presented several obstacles to the DRDWA project. Various corporations have begun to develop imaging interoperability solutions encompassing multiple concepts of the DRDWA. The focus of these competing products is to extract images from disparate PACS vendors. Although these competing systems can extract images from a PACS, they do not insert to native PACS viewers. The insert process of the PACS image is foregone, in order to use a commercially available propriety viewer. The DRDWA project will continue to use all native viewers to reduce cost and system training.

The initial SOW document will require modifications based on discoveries in Phase I and Phase II of the DRDWA Project. Throughout the development in Phase II, it has become apparent that key components must be added to the DRDWA project to maintain viability in the future. During discussions with individual Air Force bases, participants have expressed a need for workflow, professional charging, and reporting enhancements. UPMC IMITS would like to accommodate these enhancements with a potential one year no cost extension of the DRDWA project using existing FY05 congressional funding.

DIACAP and ATC Approval Processes for Robotic Microscopes

DIACAP certification for the Trestle Robotic Microscopes, anticipated for early 2007, was not achieved until Sept 2007. In order to connect the systems to the internet, an Approval to Connect (ATC) security certification is being requested from the Air Force Communications Agency. ATC is still pending. The robotic microscopes cannot be deployed at the participating Air Force bases until the ATC is granted.

Manufacture Available Participation for Teleaudiology Project

The proposed remote cochlear implant mapping solution will require two approval processes. The first approval process is the Air Force DIACAP certification. The second approval process is an FDA approval. The both approval processes requires testing and documentation from only the manufacturers. Testing of this solution will require between six month and twelve months. The testing will only be conducted by the manufacturers and without human subjects, to meet

FDA requirements. Currently, the manufactures are unsure if they will be able to dedicate the appropriate level of resources to the both of these approval processes. The project team is now investigating additional funding sources for the approval and implementation processes for the proposed remote cochlear implant mapping solution.

FDA Approval of the Platelet Gel Study Protocol

The FDA denial of the research protocol has caused a delay of several months. Initially the FDA was unable to approve the research study by the close of 2006; however they were able to approve it before the close of 2007. The FDA required several modifications to the research protocol that significantly affect the research study design. The Platelet Gel project team conducted several “Type C” meetings with the FDA in order to negotiate which items will require additional modification in order to gain final approval. This process delayed the initiation of the IRB approval process. The project team has completed the study protocol, which addresses all of the FDA’s concerns and requirements. Now that FDA approval has been obtained, the project team will submit the research protocol for approval to the University of Pittsburgh IRB, WHMC IRB, and the Office of the Surgeon General of the Air Force for second level approval throughout 2008.

During the pre-review process the Platelet Gel project team became aware of ownership issues with regard to the study protocol. The issues were in reference to whether UPMC or the University of Pittsburgh should be the owner and manager of the protocol implementation. While investigating a potential resolution to this issue, the pre-review process with the University of Pittsburgh IRB has been suspended by the project team.

Key Research Accomplishments

Teleradiology

Dynamic Workload Allocation Phase I

- Identified and defined USAF business rules
- Identified USAF Information Technology system partners
- Identified technical, business, and policy areas of concern
- Consent among UPMC and SGR of initial DRDWA system diagram and documentation
- Refined the initial DRDWA system diagram and documentation
- Assessed, documented, and measured existing USAF DRDWA IT systems partners (local PACS)
- Provided DRDWA Phase I report/initial concept documents to USAF/SGR
- Phase I analysis report and presentation given to Gen. Casey

Dynamic Workload Allocation Phase II

- Create a web-based system/maintenance command panel
- Establish a workload accounting process
- Master and local command dashboards

- Central image routing engine
- Image compression process
- DICOM image transmission process
- Functional image transfer demonstration (March 2008)

Teleaudiology

- Determined the Audiologist and Otolaryngology surgeon subject matter experts from WHMC and UPMC and enrolled them as members of the project team.
- Demonstrated the proposed solution using video conferencing equipment and remote control software at WHMC.
- Evaluated the current requirements and procedures for cochlear implant mapping. Procured two Polycom MediCart for VTC equipment with Windows Remote Desktop remote control software for UPMC.
- Procured two Polycom Mobile Responder using Dame Ware as the remote control software for WHMC.
- Developed a working draft of the feasibility study for the proposed solution.
- Trained staff and successfully conducted initial feasibility tests between office locations within UPMC.
- Procurement of VTC equipment and software for remote cochlear
- Continued involvement of the three US manufactures – Cochlear Americas, Advanced Bionics, and Med-EL, and obtained their participation in the project.
- Acquired letters of intent to participate from the manufactures.
- Investigating additional funding sources for the approval and implementation processes for the proposed remote cochlear implant mapping solution.

Telepathology

IMITS FY05 Telepathology

- Developed and implemented a series of IRB approved controlled clinical validation studies.
- Secured IRB approval to conduct studies with four USAF participating locations.
- Published results from three studies in professional pathology journals (one, in press).
- Designed schema, developed software and initiated case entry for WSI repository.
- Purchased and installed an Olympus-Bacus WSI system at UPMC to support research.
- Continued digital pathology validation studies at UPMC.
- Established military track at APIII.
- Established digital pathology systems showcase/workshop at APIII – based on collaborative relationships formed with vendors as part of FY 04 project.
- Provided forum for USAF pathologists to convene and begin development of a comprehensive plan to improve current USAF standard of practice.
- Drafted a charter for USAF digital pathology.
- Developed digital pathology training course for USAF pathologists.
- Purchased four robotic microscopes for USAF bases.
- Facilitated formation of core group of USAF pathology advocates/leaders.

- Gave collaboratively developed presentations at ATA and APIII.
- Established USAF digital pathology symposium at APIII.

Extra-Corporeal Membrane Oxygenation (ECMO)

- Equipment was purchase and delivered to Hawaii.
- Research lab training and clinical protocols were completed.
- A research protocol was designed to assess the equipment for neonatal ECMO.
- Three clinical trials were conducted and summarized.

Simulation and Training

Advanced Medical Education

- Developed a collaborative model to assist in the development of the University of Hawaii (UH) Center.
- Continued efforts to enhance the existing Asia partnerships with UH to leverage other WISER or UH collaborations.
- Completed UH design of the SIMS application.
- SimTiki is now officially open for student simulation and non-simulation training.
- Multiple simulation and non-simulation based courses are now available for UH via the UH version of the SIMS application.
- Final Report was submitted to the Office of the Surgeon General of the Air Force.

Simulation at Wilford Hall Medical Center

- WHMC Simulation Working group established-including SAUSHEC, USAFSAM, Readiness Annual training, RSV managers, and UPMC.
- Continual identification of interested “users” and their needs identified.
- Simulation center space was expanded in WHMC ICU and equipped with existing WHMC mannequins, loaners, and excess property.
- 2000+ simulation encounters (encounters are the number of times a person comes to the simulation center for example TNCC thirteen nurses for two days equals twenty six encounters).
- Trained approximately 1,500+ students.
- WHMC Office of Personnel Management and Human Resources Committee have approved four simulation center civilian positions and have begun to fill these positions.

“Patient Transfer” Simulation Training

- Submitted protocol to USAF for Second Level Approval.
- Completed all pre-training observations.
- Complete both the control and treatment groups’ participation in the nursing training on the new curriculum.
- Completed all post-training observations.
- Completed statistical analysis of all training observations.
- Completed the final report for submission to SGR

- Project featured in UPMC/IMITS Exhibit Booth at 2007 American Telemedicine Association (ATA) Annual Conference, Nashville, TN.
- Project featured in 2007 American Association of Nurse Anesthetists poster presentation.
- Project featured in 2007 Society for Simulation in Healthcare (IMSH) Annual Conference, Orlando, FL.

Platelet Gel Therapy

- A new research study protocol was developed with the following new characteristics: Stratified Population, Growth Factor Characterization, Autologous Platelet Gel, and Autologous Thrombin.
- Submitted an Investigational Device Exemption (IDE) application to Food and Drug Administration (FDA) for the research study protocol in 2005, 2006, and 2007. The protocol was approved by the FDA on August 17, 2006.
- The new research pilot study protocol is complete.
- Started the pre-review process with the University of Pittsburgh IRB
- Completed review of clinical trial studies designed to assess impact of autologous, blood derived wound healing products in order to develop a research study protocol (including platelet gel and thrombin).

Teleophthalmology

- Designed, developed, and implemented a prototype image and metadata transfer system.
- Created screens and software components to support registration, imaging, grading, tracking, and reporting processes.
- Purchased equipment to support the technologies associated with acquisition, management and archiving of image sets.
- Design developed with input from Wilford Hall Medical Center (WHMC).
- Supported WHMC assessment of retinal screening options for their Diabetes Center.
- Conducted an IRB approved research study designed to assess the feasibility and functionality of prototype system
- Based in part on results of the research study, adjusted clinical workflow processes and increased monthly patient enrollment figures by over 300%.
- Successfully demonstrated that the retinal screening software and workflow process can be used to overcome challenges of providing adequate screening and diagnostic services for people at risk for diabetic retinopathy.
- Assessed feasibility of integrating system for integration into hospital enterprise (i.e., Stentor PACS).
- Provided recommendations for improvements of software and network configurations.
- Project accomplishments disseminated to audience of professionals through abstracts, presentations, posters, informational brochures, and demonstrations of equipment.

Education - Leadership Training

- This project was officially closed and reported to SGR as closed in 2006.

Reportable Outcomes

Please see Appendices for work product documentation.

Conclusions

The Air Force has benefited from the joint development and implementation of the multi-disciplinary IMITS Program initiatives. The IMITS program has gained momentum since it was able to build upon the previous years of effort. During the next quarter, UPMC will complete all remaining deliverables for the FY04 IMITS projects. UPMC will continue to build upon the accomplishments of this past year to develop the deliverables required for the FY05 Teleradiology and Telepathology continuation projects.

References

None

Appendices

Appendix 1



IMITS Center

To: John W. Marsh, Maj, USAF, MSC, FACHE
Deputy Chief, Management and Program Support Division, AF/SGRM
Office of the Assistant Surgeon General, Modernization
5201 Leesburg Pike
Falls Church VA 22041

From: Jeananne Nicholls
Associate Director of Operations
University of Pittsburgh Medical Center
200 Lothrop Street
Quantum 1 Building, Suite 079.1
Pittsburgh, Pa 15232

Date: May 7, 2007

Re: FY05 IMITS – Congressional Research Project Radiology Dynamic Workload
Allocation (DWA) Phase One Evaluation Report (Cooperative Agreement DAMD1703-
2-0017)

Major Marsh,

The FY05 congressional research project: Integrated Medical Information Technology Systems (IMITS) Distributed Radiology Dynamic Workload Allocation (DRDWA) System evaluated the utility of a load-balanced distributed radiology/imaging dynamic workload allocation infrastructure. The DWA project is divided into Four Phases. Phase One was to conduct a detailed evaluation of the current AFMS Radiology workflow by the DWA project team and deliver a analysis report for SGR review and approval. The project team – consisting of several members of UPMC Health System, UPMC IMITs Center (DoD Program Management Office), the SGR Congressional project manager, and with input from the AF Radiology Consultant, completed the evaluation, and is providing recommendations for a successful design and implementation of DWA prototype (Phase Two) within this document.

The DWA prototype will demonstrate increased productivity, cost savings, and above all enhanced patient care regardless of physician staffing constraints or patient location. The proposed solution and infrastructure will support a symmetrical load-balanced distributed workflow model across Major Commands (MAJCOMS) and in multiple AFMS Picture Archive and Communication Systems (PACS) or imaging environments. The prototype solution will allow dynamic bi-directional transmission of clinical studies and optimal workflow load-balancing to effectively leverage resources irrespective of location, PACS vendor or particular local workload demands. The prototype solution will also provide to the physician relevant patient history required for an accurate diagnosis in a continually moving patient population throughout the AFMS.



In addition, the proposed infrastructure will be the baseline architecture for enterprise imaging exchange through the AFMS regardless of medical discipline, and the intra/inter-base communication infrastructure for efficient clinical data exchange for all future healthcare information technology AFMS providers. This will allow for more flexibility in regards to workload distribution during AFMS Radiologist deployments, TDY, on-call support and the development and availability of subspecialty expertise.

At this time, UPMC has accomplished the Phase One report deliverable for the FY05 IMITS Congressional Research Project Radiology Dynamic Workload Allocation (DRDWA) Project (Cooperative Agreement DAMD1703-2-0017). The attached document fulfills this deliverable requirement for this project.

Based on the outcomes of Phase One, and unless otherwise notified within fourteen days of receipt of this report, the DWA project team will begin moving forward on Phase Two of the project, which is to develop a DWA system prototype for select MTFs. One of the initial steps within Phase Two will be for the DWA project team to provide a project review at SGR headquarters (Skyline). Phase Two is expected to be completed within four to six months. (Phase Three is obtaining necessary approvals to implement the DWA at select MTFs. Phase Four is the actual implementation of the DWA.) At the completion of the entire project, the AFMS will have strong rationale for the adoption of this distributed radiology dynamic workload allocation telemedicine infrastructure model through-out the AFMS.

Feel free to contact me as needed.
Sincerely,

Jeananne Nicholls
Associate Director of Operations

Attachment

(1) DWA Phase One Report

cc:

Tess Ellis
James Mason
Aaron Yanuzo
Carlos Betancourt
Jeff Roberts
Goran Momiroski

AWARD NUMBER:

DAMD17-03-2-0017

TITLE:

Integrated Medical Information Technology System (IMITS) program – FY05
Congressional Research Project Radiology Dynamic Workload Allocation (DWA)

CONTRACTING ORGANIZATION:

University of Pittsburgh Medical Center
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REPORT DATE:

05/01/2007

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Purpose

The FY05 - Radiology Dynamic Workload Allocation (DWA) project was commissioned to develop a prototype solution for current Air Force Medical Services radiology workflow processing deficiencies. The Statement of Work for the entire project is included here as Appendix One. During Phase One of this project, it has become evident that the DWA prototype solution should also include workflow efficiency capabilities for clinical areas beyond radiology.

Current AFMS staffing constraints, limited AFMS system capabilities, and a mobile patient population requires a sophisticated load-balanced distributed radiology/imaging workflow model and supporting infrastructure. These continually changing circumstances within the military healthcare community have identified the need for a sophisticated workflow model that supports an enterprise view. This prototype solution must result in increased productivity and enhanced patient care across the AFMS regardless of AFMS physician staffing constraints, AFMS systems capabilities and patient location. The infrastructure must support a load-balanced distributed workflow model across multiple Major Commands (MAJCOMS) and within a multiple AFMS Picture Archiving Communication Systems (PACS) environment. The prototype solution must allow dynamic bi-directional transmission of clinical studies and optimal workflow load-balancing to effectively leverage resources irrespective of location, PACS vendor or particular local workload demands. With a mobile patient population, this prototype solution must provide relevant patient history to the radiologist/physician in order to provide an accurate diagnosis. With regard to workload distribution, these capabilities will allow maximum workload flexibility during AFMS Radiologist deployments, TDY, on-call support, and the development and availability of subspecialty expertise.

An AFMS-wide sophisticated load-balanced and distributed radiology workflow model and supporting infrastructure will result in increased productivity; AFMS cost savings, and above all enhanced patient care across the AFMS regardless of medical staffing constraints or patient location. In addition, the proposed infrastructure will be the baseline architecture for enterprise imaging exchange throughout the AFMS regardless of medical discipline, and the intra/inter-base communication infrastructure for efficient clinical data exchange for all future AFMS healthcare information technology providers.

Radiology DWA Project: Phase I Objectives

The primary objective of the FY05 DWA Phase One was to analyze existing AFMS radiology operations and information systems technologies to determine the feasibility of a sophisticated load-balanced distributed workflow model and supporting infrastructure (DWA). The analysis included evaluation of the following AFMS areas: clinical information systems, clinical information systems policies, vendors, networking, and information technology security.

The FY05 – DWA Phase One objectives are defined as follows:

- To assess the level of participation and support for the DWA project within all areas of the AFMS command including: Base, Major Command (MAJCOM) and Headquarters (HQ) levels.
- To establish a baseline for clinical information systems, technology, and infrastructure for the MTFs participating within the scope of the DWA project.
- To document the current clinical information systems' capability to distribute and capture clinical information and clinical images.
- To assess information assurance (IA) policy and procedures, such as DITSCAP/DIACAP, required for accrediting/certifying the prototype solution(s) developed within the scope of the DWA project.
- To effectively define the AFMS business rules and requirements essential in determining the exchange of clinical information and clinical images.
- To assess, document, and measure the existing AFMS diagnostic imaging system performance. This is required in order to effectively determine the image transmission and central cache/repository requirements.
- To provide SGO with the results and recommendations for a DWA solution that will provide the necessary foundation for the creation of an Initial Concept Document (ICD). The ICD will include network requirements to include: bandwidth availability, saturation point/base, AFMS clinical business rules such as expected turnaround time, and MAJCOM Information Technology Security Requirements. The ICD will outline a conceptual design for a DWA solution, and will provide the necessary supporting information to DoD/USAF required in order

to decide if prototype implementation will be initiated. This DoD/USAF decision may present limitations altering the outcome/deliverables of the DWA project.

Evaluation

During the investigation of a potential sophisticated load-balanced distributed workflow model and supporting infrastructure (DWA) prototype solution, the existing operational and systems environments were evaluated by members of the project team in order to determine potential effective and efficient solutions for the AFMS.

FY05 – DWA Phase One Evaluation:

- The project team conducted an evaluation of the following stakeholders within the AFMS community: local bases, MAJCOM(s), and SGO for available participation and support of proposed project.
 - Introductory meetings were held to introduce the project and evaluate the potential level of participation and support from the initially selected MTFs for contribution to this project.
 - The Radiology Flight Commanders were found to be supportive and willing to participate in the DWA project. During the introductory meetings, the Radiology Flight Commanders presented additional information on the current status of radiology concerns/issues that should be addressed within the scope of the DWA project.

The concerns/issues are defined as:

- Under current AFMS local radiology workflow processes, a radiologist is not always provided with the necessary quantity of studies required for continual sub-specialty development. Therefore, it is expected that the proposed DWA prototype solution must take this problem into consideration by providing additional exposure to studies related to their sub-specialty.
- The current AFMS radiology processes do not accommodate tools for effective peer reviews at the base level. The proposed DWA prototype solution must facilitate the creation of an enterprise level

location independent environment for peer review such as sub-specialty peer review.

- o The current AFMS teleradiology environment is unable to provide enterprise policies or best practices of image acquisition. Radiologists often display reservations in providing a diagnostic evaluation of an exam due to poor image acquisition.
 - o Due to deployment, TDY and other career duties, often times MTF radiologist resources are limited and unable to fulfill radiology workload demands. As a result of this inability to provide adequate radiology services, MTFs occasionally utilize out-sourced radiologist services. The proposed DWA prototype solution will facilitate an environment that minimizes or eliminates the need of non-AFMS radiologist support services.
- The project team conducted an investigational assessment of existing AFMS PACS vendors. More specifically, the project team consulted with the following AFMS PACS vendors: AGFA, Phillips (Stentor), and Fuji. The results of the investigation obviously have direct implications for organizations participating in such ventures. Upon communications with the AFMS PACS vendors, they were understanding of the potential benefits of the proposed project and are willing to participate in the development of a solution within their current PACS environment. The current AFMS PACS vendors are able to accommodate interfaces following accepted healthcare interfacing standards such: Digital Image and Communications in Medicine (DICOM), Health Level 7 (HL7), or Integrated Healthcare Enterprise (IHE).
- No AFMS Service Oriented Architecture (SOA) systems framework is currently present within the AFMS community. An SOA framework would accommodate clinical information data exchange capabilities with various AFMS Health and Radiology Information Systems (HIS/RIS) as well as provide an easier systems integration and interoperability environment.
- An initial assumption of the project was the non-existence of a usable CHCS bi-directional interface. However, during the evaluation of the existing AFMS clinical information systems, viable CHCS bi-directional interfaces were discovered. The proposed prototype solutions will require integration with one or more of the following available interfaces: Dictaphone Powerscribe (HL7), ICDB (HL7/Cache), AGFA (HL7), and BHIE.
- The current network infrastructure will require further evaluation throughout all four phases of the project. The project team will be unable to effectively evaluate the performance of the network infrastructure until the proposed

prototype solution testing has commenced. The ability to achieve a desired efficient solution is directly correlated with the performance of the USAF network infrastructure.

The following network infrastructure attributes will affect the performance of the proposed solution:

- Quality of Service (QOS)
 - Bandwidth
 - Firewalls
 - Security
 - Hardware
- The proposed prototype solution(s) will require submission to the USAF Information Assurance Accreditation process. The proper authorization and/or accreditation, as required, must be completed prior to implementation into a USAF testing environment.
- Although beyond the scope of the DWA project, a need for a business continuity plan, including disaster recovery, for existing AFMS imaging systems has been identified. Network Quality of Service (QOS), AFMS study volumes along with other business continuity issues will require further investigation in order to determine the feasibility of establishing a business continuity plan and system.
- At this time, it has become evident that there are several ongoing imaging initiatives under consideration within the AFMS. Under the Defense Business Transformation (DBT) process, multiple initiatives will require evaluation and direction for continuation or termination. The project team discovered the absence of a central AFMS systems integration program management office (IPMO). As a result of this deficiency, vendors and research partners responsible for implementation and management of clinical information systems are forced to communicate and integrate their systems with each other without collaboration of all affected AFMS entities. This environment causes significant delays and redundancy in the development and implementation of proposed solutions.
- While there is an AFMS CIO, currently there is no Chief Medical Informatics Officer (CMIO) within the AFMS. A CMIO should be a medical and clinical informatics domain expert responsible for providing direction, evaluation, and decision making for AFMS medical information systems and medical information systems research. The CMIO position should be an active duty officer who understands medical practice(s) and IT solutions, and how IT solutions can benefit medical practices. The CMIO should be a consultant with authoritative power to the AFMS CIO.

- A CMIO primary expertise should be as a practicing physician with a secondary expertise as informatician with a thorough understanding of IT
 - A CMIO would provide AFMS headquarters-level authority to evaluate and would consult on all AFMS medical IT proposed solutions.
 - A positions such as this could help expedite implementation of medical and clinical IT solutions
 - The DWA project may require assistance and guidance in project implementation and reduction of duplicate efforts from one organization to the next
- During the DWA evaluation process, the project team was made aware of a RadNet Concept Design Document (CDD). The RadNet CDD was written by the USAF Chief of Teleheath, Lt. Col. Timothy Lacy. This document defines a conceptual approach for enterprise data and image exchange. This document has been submitted and approved by USAF leadership. The DWA project team believes the CDD outlines the need for a DWA solution for all imaging applications throughout the AFMS. The document provides justification for the DWA project, and is attached here as background in Appendix Two.

Risk Matrixes

Type	Anticipated Risk	Severity	Probability	Comments/ Mitigation
Technology - Infrastructure	Network	High	Medium	Improved network QOS may be required. To be determined base by base.
	Security	Low	Low	DIACAP certification process will be observed and followed by the project team
	Hardware	Medium	Low	Will employ AFMS-approved hardware platforms.

Type	Anticipated Risk	Severity	Probability	Comments/ Mitigation
Technology – Software	Microsoft .Net 3.0 framework – Workflow Foundation – Communication Foundation	Low	Low	AFMS Approved
	Microsoft Server 2003 – IIS 7 – ASP Net	Low	Low	AFMS Approved
	Microsoft SQL Server 2005	Low	Low	AFMS Approved
	Microsoft BizTalk 2006	Low	Low	AFMS Approved
	IE Explorer 6.x	Low	Low	AFMS Approved
	Development Libraries – Merge DICOM Libraries – Compression Libraries (TBD)	Low Medium	Low Medium	AFMS Approved

Type	Anticipated Risk	Severity	Probability	Comments/ Mitigation
Technology – Vendors (In Scope)	PACS – DICOM performance – Versions	Medium	Medium	Based on PACS version level capabilities upgrades may be required. (This will be determined through continual integration meetings with the PACS vendors)
	CHCS – Capability of bi-directional interfaces	Medium	High	Multiple AFMS application specific CHCS bi-directional interfaces exist. Will utilize existing AFMS application CHCS bi-directional interface. Suggest universal CHCS bi-directional interface for all AFMS applications
	Cache Technologies – SAN Systems – Grid Systems	High	Medium	Will coordinate DWA cache solution with AFMS to ensure continuity with future AFMS business continuity plans.

Type	Anticipated Risk	Severity	Probability	Comments/ Mitigation
Technology – Vendors (Out of Scope)	Dictation/Transcription/ Speech Recognition	Low	Low	Will be reviewed and evaluated as future potential integration projects.
	Archive – External to MTF: Business Continuity Disaster Recovery	High	Medium	Will coordinate DWA cache solution with future AFMS business continuity and/or disaster recovery solutions.

Type	Anticipated Risk	Severity	Probability	Comments/ Mitigation
Operational	RadNet Implementation	High	High	RadNet plan not final. Appears that multiple parties are influencing the RadNet design. DWA and RadNet should be the one vision.
	Active Duty issues – Chain of Command – Rotations – Clinical vs. career duties	High	High	Continuity of any implementation requires a certain level of authority be maintained. AFMS management level changes could impact the operations of the proposed solution.
	EHR-Imaging Implementation	High	High	AFMS needs to ensure coordination of all imaging initiatives. Unmanaged access to AFMS PACS by competing systems may cause projects and applications to fail.

Type	Anticipated Risk	Severity	Probability	Comments/ Mitigation
Operational [Continued]	Policies – Comm. – Security – DIACAP – DINPACS – Enterprise Wide Radiology	Medium	Medium	In order to create an enterprise solution AFMS and DoD enterprise policies must be clear and unambiguous. MTFs must adhere, without deviation, to AFMS and DoD enterprise policies.
	Performance Measurements – RVUs – Technical – Professional	Medium	Medium	DWA to calculate and report RVUs at enterprise level external to CHCS.

Recommendations

After completion of the AFMS radiology operations and systems environment evaluations the following recommendations are submitted for review and consideration:

- Engage appropriate AFMS partners to accurately define acceptable DWA prototype solutions. The participation of these entities will be crucial for the success of the project.
 - The project team recommends the following AFMS partners/stakeholders:
 - USAF Headquarters Staff
 - SGO/SGR (particularly the Chief of Telehealth)
 - All MAJCOMs
 - AFMSA
 - AFMLO
 - USAF Medical Staff
 - Radiologists
 - Clinicians
 - Technologists
 - Transcriptionists
 - Internal Support Services
 - Network Communications Department
 - Hospital Information Technology Department
 - External Support Services
 - SAIC (CHCS and ICDB)
 - PACS Vendors
- Due to a continually changing environment within the military healthcare system, information technology changes that impact a physician's daily

responsibilities, duties, and performance must be minimized. In order to accomplish an effective DWA environment, the current methods for processing daily radiology workflow will be impacted; however, in order to establish acceptance within the military radiology community, the modifications required to implement a DWA solution must be transparent, with minimal to no impact, on the radiologist's traditional workflow processes. The DWA prototype solution and supporting infrastructure can support this requirement through back office and service applications to route the data and the images to the corresponding locations without impacting the current radiologist's processes.

- Externalize management of RVUs from CHCS to an enterprise system level where information can be properly processed and RVUs properly calculated based on who performs technical and/or professional components of RVU.
- In order to accurately define a prototype solution, it was necessary for the project team to define the business rules requirements in order to effectively determine how to traffic radiology images throughout the USAF. The project team has identified two sets of business rules. Both of these business rules must be addressed in order to ensure a successful prototype solution.

Business Rule 1:

- A local rules engine is required to automatically identify candidate studies that will be exported for remote diagnoses. The following attributes must be addressed in order to effectively design and process a local rules engine:
 - Management of local staff availability
 - Staffing, sub-specialty RVUs
 - Average RVUs per local radiologist
 - Procedure codes

Business Rule 2:

- A global rules engine is required to automatically route candidate/exported studies to remote MTF capable of handling the additional volume in workload or providing sub-specialty expertise required in order to perform diagnosis. The project team has identified the following inputs/attributes required to properly route candidate studies:
 - Management of staff availability at each MTF
 - Understanding of staff ability
 - Sub-specialty expertise

- Average RVUs per radiologist
 - Network infrastructure Quality of Service (QOS).
 - Must measure throughput and its change through time
 - Must be able to address loss of connectivity to participating MTFs
- The proposed DWA prototype solution will require interface capabilities with various Picture Archiving Capture Systems (PACS). The solution must be able to support all PACS vendors/systems currently present in the USAF healthcare system. The solution must be able to facilitate communication with all PACS systems through accepted healthcare standards such: DICOM, HL7, or IHE.
- The proposed DWA prototype solution must accommodate clinical information data exchange with various AFMS Health Information Systems (HIS) and Radiology Information Systems (RIS). In addition, this proposed prototype solution must provide interface capabilities to secondary infrastructures supporting clinical information exchange. This HIS/RIS and infrastructure independence will promote effective distribution of clinical information throughout the proposed solution.
- An internal USAF partner should be commissioned to develop a Service Oriented Architecture (SOA) framework for facilitating and managing intra and inter-base clinical data exchange and communications.
 - MTF and local base network communications and information technology departments often demonstrate differences in interpretation of information technology and security policies. This may elicit conflicting support for the DWA project and the policy changes required for implementation from base to base and MAJCOM to MAJCOM. Although the project is receiving individual support from MTFs and local bases, when looking from an enterprise perspective, the project team concluded that differences in interpretations of policies and potential policy changes may lead to communication issues. These issues may impact the ability to provide an enterprise accepted DWA solution that would alleviate potential delays in patient care. Hence, it is important that there is a consistent approach in handling the implications of policy changes. An appropriate chain of command should be established to assess, mitigate, and disseminate any and all medical system effects as a result of the implementation of policy change(s) to ensure efficient patient care delivery. Presently, responses to policy changes are delegated to local MTFs, which results in varying interpretations and potential negative impact on

patient care. Patient care will benefit from well-specified response procedures mandated at the enterprise level.

- Establish a baseline of information systems, technology and infrastructure at participating MTFs. As a result of our investigation a DWA prototype solution will require integration with the following systems:
 - CHCS/CHCSII/AHLTA
 - PACS
 - Network/Communication
 - Dictation/Transcription
 - Teleradiology
- Based on the current USAF requirement for methods/solutions to address business continuity and disaster recovery system needs, the following areas should be evaluated during prototype development and testing:
 - Bandwidth availability
 - Necessary network QOS to ensure optimal system performance
 - Analysis of MTFs study volume
- The project team conducted an assessment of the information assurance (IA) policy and procedures that would affect the prototype solution. Based on previous USAF certification process experiences with IMITS Teleradiology projects and interactions with Headquarters Information Assurance groups, MTF and base security, the DWA prototype should be divided into two parts:
 - Inter-base workflow: The prototype solution requires an enterprise communication infrastructure. This component will address all inter-base communication and workflow. Selected internal USAF system partners will manage IA policies and procedures for the enterprise communication infrastructure.
 - Local base workflow: Specific prototype applications will be designed to address workflow at the local base level. These applications will interface with the enterprise communication infrastructure as a node of the enterprise prototype solution. This will ensure IA policy and procedures for local base applications and intra-base communication will be applied to these prototype applications. As a result of these prototype applications functioning as a node on the enterprise communication infrastructure, the IA certification of the applications will exclude inter-base communication IA policy and procedure.
- Initial communication with AFMS had originally identified that open CHCS bi-directional interface capabilities were unavailable. If a CHCS bi-

directional interface is not available as a tool within the scope of the proposed solution, effective clinical information data exchange will be unattainable. The DWA prototype solution must take advantage of any and all efforts within the AFMS working towards the completion of a bi-directional interface with CHCS.

- The proposed DWA prototype solution should be submitted to the AFMS for review under the RadNet CDD and the Defense Business Transformation (DBT) process. The RadNet CDD and DBT process should present positive findings in order to proceed to the subsequent phases of the DWA project.
- * Consult Appendix Three for the preliminary DWA prototype concept based on the current recommendation.

Conclusion

The FY05 congressional research project: Integrated Medical Information Technology Systems (IMITS) Distributed Radiology Dynamic Workload Allocation (DRDWA) System evaluated the utility of a load-balanced distributed radiology/imaging dynamic workload allocation infrastructure. The DWA project is divided into Four Phases. Phase One was to conduct a detailed evaluation of the current AFMS Radiology workflow by the DWA project team and deliver a analysis report for SGR review and approval. The project team – consisting of several members of UPMC Health System, UPMC IMITs Center (DoD Program Management Office), the SGR Congressional project manager, and with input from the AF Radiology Consultant, completed the evaluation, and is providing recommendations for a successful design and implementation of DWA prototype (Phase Two) within this document.

The DWA prototype will demonstrate increased productivity, cost savings, and above all enhanced patient care regardless of physician staffing constraints or patient location. The proposed solution and infrastructure will support a symmetrical load-balanced distributed workflow model across MAJCOMS and in multiple PACS environments. The prototype solution will allow dynamic bi-directional transmission of clinical studies and optimal workflow load-balancing to effectively leverage resources irrespective of location, PACS vendor or particular local workload demands. The prototype solution will also provide to the physician relevant patient history required for an accurate diagnosis in a continually moving patient population throughout the AFMS. The proposed infrastructure will be the baseline architecture for enterprise imaging exchange through the AFMS regardless of medical discipline, and the intra/inter-base communication infrastructure for efficient clinical data exchange for all future healthcare information technology AFMS providers. This will allow for more flexibility in regards to workload distribution during AFMS radiologist deployments, TDY, on-call support and the development and availability of subspecialty expertise.

This report is the deliverable for Phase One of the FY05 Congressional project: Integrated Medical Information Technology Systems (IMITS) Distributed Radiology Dynamic Workload Allocation (DRDWA) System (Cooperative Agreement DAMD1703-2-0017). Based on the outcomes of Phase One, and unless otherwise notified within fourteen days of receipt of this report, the DWA project team will begin moving forward on Phase Two of the project, which is to develop a DWA system prototype for select MTFs. One of the initial steps within Phase Two will be for the DWA project team to provide a project review at SGR headquarters (Skyline). Phase Two is expected to be completed within four to six months. (Phase Three is obtaining necessary approvals to implement the DWA at select MTFs. Phase Four is the actual implementation of the DWA.)

At the completion of the entire project, the AFMS will have strong rationale for the adoption of this distributed radiology dynamic workload allocation telemedicine infrastructure model through-out the AFMS.

Appendix One – FY05 SOW

STATEMENT OF WORK

DISTRIBUTED RADIOLOGY DYNAMIC WORKLOAD ALLOCATION INFRASTRUCTURE PROTOTYPE

Develop and implement a Distributed Radiology Dynamic Workload Allocation Infrastructure Prototype at select Air Force Medical Treatment Facilities (MTF).

Phase 1 - Analyze and document select MTFs existing Information Systems and Infrastructure to determine Distributed Radiology Dynamic Workload Allocation Systems Feasibility: (4 to 6 Months)

USAF Principal Investigator: Col Christopher Lisanti
UPMC Principal Investigator: Paul Chang, M.D.

Timeframe	Task
Weeks 1-12	Assess Base, MAJCOM and Headquarters level staff for participation and support of proposed project.
Weeks 1-12	- Establish a baseline of information systems, technology and infrastructure at participating MTFs. - Document current systems' distribution and capture capabilities
Weeks 1-16	- Assess information assurance and workload crediting policy and procedures. - Discuss and coordinate with Information Assurance departments at Base, MAJCOM and Headquarters level to obtain information and input. - Assessment of DoD system security policies and procedures (i.e. IATO, ICTO, CoN, DITSCAP). - Document and obtain policy and approval for bidirectional interface to participating MTFs local systems (i.e. Composite Health Care Systems/II(CHCS/CHCSII). - Coordinate and discuss project at each level.
Weeks 12-24	- Define business rules requirements to determine traffic of images. - Ensure that documented business rules incorporate radiologist, availability, desired study type, historical site performance and professional currency requirements to determine traffic of images. - Investigate and document healthcare workload policies and procedures between sites within a distributed environment. E.g Relative Value Unit (RVUs) allocation between sites/providers performing the work. - Capture existing practice processes and rules relating to radiology.
Weeks 12-24	Assess, document and measure existing diagnostic imaging system performance (e.g image transmission requirements, repository/central cache requirements...)

Timeframe	Task
Weeks 20-24	Provide SGR with a report which will serve as an Initial Concept Document (ICD). The ICD will include network requirements (bandwidth availability, saturation point/base), business rules (expected turnaround time), and MAJCOM Security Requirements. ICD will support a concept decision regarding USAF and/or DoD limitations that may alter the outcome/deliverables of the research project.

Phase 2 - Develop a Distributed Radiology Dynamic Workload Allocation System prototype for select USAF MTFs: (4 to 6 Months) (Conditional upon report findings) (Phase 2 to begin upon completion, by SGR, of NDAA Certification)

Timeframe	Task
Weeks 24-48	- Establish system administrator privileges. - Create a web-based system command panel to monitor system maintenance events. - Incorporate common issues found during testing into the maintenance panel.
Weeks 24-48	- Establish a workload accounting process in system: - Workload crediting available by site of acquisition (technical component). - Workload crediting available by site of interpretation (professional component). - System accurately credits the correct number of relative value units. Coordinate with Composite Health Care System (CHCS) and radiology personnel at each base to determine acceptable methods for adding shared work credit Relative Value Unit (RVU)/Current Procedure Terminology (CPT) codes to the Composite Health Care System (CHCS). - System will auto register patients into the remote Composite Health Care System (CHCS) system. - Summary report of results to SGR.
Weeks 24-48	Create a central repository storage and system infrastructure
Weeks 24-48	- Create a master command dashboard and local command interface - The dashboard will be available for the appointed Air Force Radiologist to monitor the flow and statistics of teleradiology. - This command window will produce aggregate statistics of image reads and transfers. - Master Command Dashboard will be web-based. - Dashboard will compile aggregate and historical statistics to aid the SG Radiology representative in making strategic, enterprise radiology decisions. - The local command interface will be available to the local system administration designee to indicate site preferences. - These preferences will include, but are not limited to, availability to perform reads, desired type of reads and rules for export of data. - Local Command Interface will be web-based. - Summary report of results to SGR.

Timeframe	Task
Weeks 24-48	▪ Create a central image routing engine that includes the following features: 1) The image routing engine will contain the necessary algorithms to efficiently route images. 2) Algorithms may be adjusted from the Master Control Panel. 3) The image routing engine will use radiologist availability, desired study type, and historical site performance to determine quantity and type of images to forward. 4) The image routing engine will follow a 'round robin' pattern in distribution. 5) The image routing engine will have safeguards so that it does not overwhelm a site. 6) The image routing engine will have logic to retransmit images to an alternate location if a remote site is unexpectedly not conducting reads. Final read location for failed reads will be Wilford Hall Medical Center radiology department. 7) Summary report of results to SGR.
Weeks 24-48	▪ Create a Combat Trauma Imaging Simulator: 1) System will store HIPAA-compliant, combat radiology images for training purposes. 2) Images will be available to read for training purposes. 3) Practice interpretations will be contrasted against actual archived reads. 4) Summary report of results to SGR.
Weeks 24-48	▪ Establish imaging and image transmission technical processes: 1) Ensure ability to utilize network compression for transmission purposes without data loss (lossless or clinical compression). 2) Ensure ability to present current images along with all relevant prior images and reports from acquisition site is provided. 3) Ensure exams are identified by site of original acquisition for command and control purposes. 4) Create notification of study availability via local Picture Archive and Communication System (PACS) work list, independent of site of image acquisition. 5) Image delivery will be transparent to the radiologist. 6) System will meet Air Force firewall requirements. 7) Establish bidirectional communication through Virtual Private Network to sites. 8) Summary report of results to SGR.
Weeks 24-48	▪ Ensure system meets all integration requirements: 1) Product shall have a Digital Imaging and Communications in Medicine (DICOM) transmitter available for local integration with other applications. 2) Compose and submit to SGR a thorough document detailing the minimum Input/Output (I/O) & processing capabilities of any local stores to prevent queuing when the pilot is scaled up to the enterprise.
Weeks 24-48	▪ Build a DICOM transmitter to relay images to secondary source: 1) The transmitter will have the option to be turned off and will be deployed in the 'off' setting. 2) Before deploying the product, the transmitter will be tested in a developmental environment to gauge theoretical throughput. This will assist personnel interfacing with the system in knowing what throughput could be expected. 3) Summary report of results to SGR.

Timeframe	Task
Weeks 24-48	▪ Determine referential system interfacing requirements: 1) Create a document that outlines the ideal requirements of a referential imaging system that could interface with the Diagnostic Imaging System without performance degradation. 2) Indicate the robustness of hardware required on the Diagnostic Imaging side to support a secondary Referential Imaging system. 3) Create and submit to SGR a detailed disclaimer outlining the negative effects on the <u>primary Diagnostic Imaging System if proper interfacing guidelines are not followed.</u>
Weeks 24-48	▪ Ensure system meets all prescribed clinical requirements: 1) The system must dynamically allocate workflow among Air Force Radiologists such that a balance workload exists that maximizes available manpower. 2) The system must be able to send differentiated types of images configured by Radiology representative through the local command panel. 3) The system must reliably credit Radiologists for their work. 4) The system must seamlessly display local and remote images in the same manner so that no prejudice or priority is given to different locations. 5) The system shall conform to all AF & DoD Security guidelines, HIPAA standards. Best practices for disaster recovery will be documented for an enterprise deployment. 6) The system must be able to deliver images in an expeditious manner such that patient care standards and read times are maintained. 7) Structure of system must allow for it to be the technical substrate for other DICOM format Telehealth initiatives (ophthalmology, pathology, etc.). 8) Summary report of results to SGR.

Phase 3 - Obtain necessary MAJCOM interim approvals to operate (IATO, ICTO...) for Distributed Radiology Dynamic Workload Allocation System prototype for select USAF MTFs (6 months):

NOTE: For this project, the MAJCOMs interim approvals to operate process are estimated to be completed in 6 months. The MAJCOMs approval to operate process time is co-dependent on the MAJCOMs. If Project funds are expended due to MAJCOM interim approval to operate delays, the MAJCOMs and USAF will be responsible for interim approval to operate completion, DITSCAP accreditation and system implementation.

Timeframe	Task
Weeks 48-72	▪ Provide monthly updates to SGR on status of approval to operate status.
Weeks 48-72	▪ Obtain necessary MAJCOM interim approvals to operate for length of Distributed Radiology Dynamic Workload Allocation research project.

Phase 4 - Implement a USAF and DoD accredited Distributed Radiology Dynamic Workload Allocation System prototype at select MTFs (4 to 6 Months):

Timeframe	Task
Weeks 72-104	- Implementation: Install Distributed Radiology Dynamic Workload Allocation infrastructure at central location and select MTFs. - Provide summary report to SGR.
Weeks 72-104	- Evaluation: Test installed Distributed Radiology Dynamic Workload Allocation at central location and select MTFs. - Provide summary report to SGR.
Weeks 72-104	- Documentation: Finalize System and User documentation for Distributed Radiology Dynamic Workload Allocation infrastructure. - Provide summary report to SGR.
Weeks 72-104	- Training: Train all users at select MTFs and central location. - Provide training documentation and summary report to SGR.
Weeks 72-104	- Go-Live and provide Distributed Radiology Dynamic Workload Allocation demonstration to USAF, including SGR. - Provide summary report of demo to SGR.
Weeks 72-104	- Turn over Distributed Radiology Dynamic Workload Allocation hardware and UPMC developed Distributed Radiology Dynamic Workload Allocation software to USAF for support. Provide summary report to SGR. - NOTE: If Air Force approves Distributed Radiology Dynamic Workload Allocation project DITSCAP certification will be required to replace timed approval to operate from participating MAJCOMs.
Weeks 72-104	Project Complete: Present project completion documentation to SGR and USAF Principal Investigator.

EVALUATION

Conduct rigorous and professional evaluations of the Distributed Radiology Dynamic Workload Allocation System prototype project.

UPMC Principal Investigator: TBD

Timeframe	Task
Week 1-12	- Establish evaluation teams. - Establish administrative contacts across sites. - Establish IRB contacts across sites.
Week 13-35	- Develop detailed evaluation plans across studies. - Submit copy of evaluation plan to SGR. - Submit evaluation proposals to participating IRBs and secure approvals.
Week 21-80	- As IRB approvals are obtained and project objectives are actively implemented: - Conduct evaluation studies. - Manage data collection, processing and reporting. - Provide accrued results to formulate redesign of technologies and workflow models as appropriate.
Week 53-104	As evaluation studies are completed:

Timeframe	Task
	▪ Analyze results and disseminate findings to SGR. ▪ Complete final report for distributed radiology dynamic workload allocation system prototype project evaluation studies project and submit to SGR.

Appendix Two - RadNet Concept Design Document

CAPABILITY DEVELOPMENT DOCUMENT

FOR

Air Force Medical Service Radiology Network (AFMS RadNet)

Increment: I

Date: 9 May 2006

UNCLASSIFIED

Executive Summary:

Current radiology staffing constraints in the Air Force Medical Service (AFMS) will require a more sophisticated symmetrical load-balanced distributed radiology workflow model and supporting infrastructure. This radiology workflow model will result in increased productivity and enhanced patient care across the AFMS regardless of AFMS radiology staffing constraints. The supporting infrastructure must support a symmetrical load-balanced distributed workflow model across MAJCOMs and in multiple Picture Archive and Communication System (PACS) environments. The model will allow dynamic bi-directional transmission of radiology studies and optimal workflow load-balancing to maximally leverage resources irrespective of location, type of PACS or particular local workload demand. The model will also allow for more flexibility regarding the sharing of workload during deployments of radiologists, TDYs, on-call support, and sharing of subspecialty expertise.

This model will require electronically linking each radiologist to a global system that provides access to all studies across all radiology departments throughout the AFMS on a 24/7/365 basis. The symmetrical model creates a system of load-balancing, where physicians can complete their own local patient studies first. Afterwards, they can review and service any remaining cases in the system. This model will also reliably credit radiologists for their work. This maximizes physician workload regardless of location. This is in contrast to traditional telemedicine models, designed as hub-and-spoke workflow systems that frequently increase the caseload gap between large central medical centers and smaller community hospitals.

Revision History:

Original	
Revision 1	N/A
Revision 2	N/A
Revision 3	N/A

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1. Capability Discussion

There are personnel shortages in several medical specialties with an increasing number of consultations and procedures per patient. This disparity can be offset with automation and telehealth consultative services. Current systems and business processes do not allow for timely specialty consult reports. There is no compatibility with legacy systems between specialties outside of radiology due to expense, perceived lack of available equipment, capable and sufficient bandwidth, and IM/IT infrastructure amongst medical specialists.

Novel commercial-off-the-shelf (COTS) compression algorithms allow for a more economical approach to telehealth with less cumbersome equipment. Compression of large format medical images also allows for low-bandwidth transfer of images, increasing storage capability while decreasing transmission times. This is especially helpful in forward-deployed settings with limited bandwidth and equipment size limitations. CONUS disaster situations with communications and power outages may require transmission over conventional internet service during times with high casualty flow. Compression and low-bandwidth solutions would be necessary for transmissions of “digital wet reads” during these disaster situations. It is well known that there is a tradeoff with compression and quality of images. However, in times of need, compressed “lossy” (lower resolution) images may be better than none at all. Best practices for disaster recovery will be documented for an enterprise-wide deployment.

Portability has not been considered in legacy systems in a world where providers are expecting handheld patient data entry and portable diagnostic solutions. Legacy systems, including CRTs (cathode ray tubes) are bulky and need to be hardened and portable like popular flat panel displays and handhelds.

There is a lack of accessible archived digital data although this is possible with current compression, transmission, and storage technologies. Crucial patient data and images (for example, old chest x-rays, photos of dermatological lesions or mammograms) are not always available. This lack of availability could entail unnecessary cost and loss of patient lives. Duplication of effort or unnecessary patient exposure to radiation causes harm. For example, not having a previous mammogram with a positive finding or a current mammogram may lead to unnecessary surgery or lead a surgeon to an inappropriately conservative or aggressive approach. Compression of images may allow for longer storage, especially for images that need to be stored for up to 30 years (for example, chest x-rays with asbestos exposure). Computerized Tomography (CT), Magnetic Resonance Imaging (MRI), and Ultrasound (US) images can be compressed up to 9 times without apparent loss of quality because of their inherent low quality acquisition (512 x 512 pixels).

A virtual consultation network connecting all military treatment facilities (MTFs) with each other and remote, deployed/front-line medics will enable availability of diagnosis and consultative services on a 24/7/365 basis worldwide. Compression algorithms such as wavelet transformations will allow for web-based systems to provide telemedicine services globally at all times. A repository of all data (including images from all specialties) available to all MTFs with redundancy will be possible with compression of thousands of large format images.

Sustainability and 24/7/365 maintenance are necessary for continual quality patient care. Integration of medical documentation SOAP notes, doctors’ orders, nursing notes, and consultant narratives with a handheld device compatible with other administrative systems is also necessary. Voice-directed intelligent communications need to be compatible with Composite Healthcare System II (CHCS II) or any future DoD Electronic Health Record (EHR) and Picture Archive and

Communication System (PACS) systems. Deployable systems should be forward compatible with fixed facility technologies to create a more homogeneous level of healthcare across the continuum of operations. The system must collect data on all interventions for each beneficiary to establish a basis for evidence-based clinical and administrative management decisions. Furthermore, the system must give workload credit on each side of the telemedicine continuum. That is, the site that performs an imaging procedure must receive technical credit and the site that interprets the image must receive workload credit in the form of Relative Value Units (RVUs).

Educational benefits include providing students without high-end computer systems access to patient data and images that are removed for sharing on digital teaching files. The compression can be applied to a point where the pathology is still seen and stored in that format on university databases.

2. Analysis of Alternatives to an Enterprise Solution

There are several alternatives to an enterprise-wide teleradiology network system (AFMS RadNet). These alternatives are all very costly in terms of time and finance and are not consistent with developing DoD telemedicine and imaging solutions. While they allow for the purchase of local vendor services, they do not allow for systemic storage of images throughout the network and may lead to variable levels of care. They include:

- a. Storing digital images on a CD and mailing it to a radiology contractor for reading. This alternative would require several days for the CD to be read and sent back to the facility.
- b. Sending digital images directly to civilian providers via networking on an MTF by MTF basis.
- c. Refer patients to civilian imaging facilities.

3. Concept of Operations Summary.

- 3.1. **Mission Area.** An enterprise-wide AFMS RadNet will enhance aeromedical evacuation (AE) of casualties. This initiative directly supports the USAF's Global Mobility and Homeland Security as well as the Agile Combat Support Concepts of Operations (CONOPS).
- 3.2. **Operational Outcomes.** Interactive and store-and-forward telehealth services such as teleradiology are an appealing healthcare delivery model for the AFMS, given the nature of Air Force operations in a resource-constrained environment. Telehealth can ameliorate the impact of geographic isolation on access to service, service provider educational needs and resources, and address gaps in local specialty medical services.
- 3.3. **Desired Effects.** The challenge of addressing these gaps and disparities will continue to increase in the future years as a result of the projected growth of the retiree/dependent population, the tempo of operations, and rapidly escalating healthcare costs. Rather than using more resources, deploying new technologies and changing business processes so that available resources are used more effectively and efficiently will provide a superior solution. Proven teleradiology technologies are currently available at lower costs with enhanced capabilities that can meet the

increased demand. The long-term goal is to establish an enterprise teleradiology network solution that is sustainable and cost-effective. The desired outcomes include:

- o Clinically relevant teleradiology solutions for all stakeholders
- o Utilization of the outcomes and products from the congressionally funded Integrated Medical Information Technology System (IMITS) project with the University of Pittsburgh Medical Center (UPMC)
- o Improved access to quality radiological services 24/7/365, regardless of location
- o Improved utilization of resources; standardized PACs solution set
- o Interoperability with future Air Force telehealth initiatives and ultimately Tri-Service initiatives

3.4. **Joint Force Integration.** This capability can be used by all Services and will interface with future DoD MHS Electronic Health Record (EHR) and image management solutions.

3.5. **Enabling Capabilities.** A symmetrical workload-balanced distributed radiology workflow model will support present and future radiology workload and workflow requirements across the AFMS as well as provide increased performance and scalability. Synchronous and asynchronous collaboration tools, as part of the developed symmetrical workflow model, will significantly improve radiologist productivity irrespective of geographical location.

4. Threat Summary.

4.1. Mission requirements dictate teleradiology must be capable of operating from worldwide locations day and night under most operational atmospheric conditions, including hot, cold, humid, arid, and high altitude. The AFMS RadNet must be capable of operating in a CBRNE environment and withstanding threats such as a strategic or tactical use of electromagnetic pulse (EMP) and directed energy (DE) environments. There are specific threat considerations for teleradiology. The AFMS RadNet will integrate with the Global Information Grid (GIG). Therefore, it will be susceptible to information operations threats. The environment in which the system will operate may include typical battlefield threats such as electronic warfare (EW), DE weapons, and nuclear weapons with their electromagnetic pulse effects. Radio frequency weapons can degrade, damage, or destroy electronics, command & control, computers, and automated systems. Furthermore, simple power outages and system component failure may shut down the system. Alternative solutions for these eventualities should be provided. For specific information on threats to the platforms that carry teleradiology, refer to the system specific threat documentation. For additional detailed threat information on the warfare areas, see the following documents:

4.1.1. **(U) Information Operations Capstone Threat Assessment, Vols. 1-5, 4-14 and 16, DI-1577-31-05, March 2005, (S//NF//20291202).**

4.2. **Threat Organizational Resources.** Contact the Defense Intelligence Agency's (DIA) Defense Warning Office Acquisition Support Division for further assistance.

5. Program Summary.

The AFMS RadNet is a spiral development program. Initial Operational Capability (IOC) is targeted for FY07 with Full Operational Capability (FOC) targeted for FY10. The AFMS RadNet program strategy is to use a combination of Government-Off-The-Shelf (GOTS) solutions developed within SGR or as a product of congressionally funded research, as well as a competitive process to select a vendor(s) with expertise to manufacture and install certain capabilities in a cost effective manner to agreed specifications. In the future, the AFMS RadNet will function with other telehealth technologies such as teledermatology, telepsychiatry, teleophthalmology, etc....

6. System Capabilities Required for the Current Increment.

Refer to the Requirements Matrix in Appendix A for detailed descriptions of all the Key Performance Parameters (KPPs) and Key System Attributes (KSAs) necessary for an enterprise-wide teleradiology network.

7. Family of Systems and System of Systems Synchronization.

- 7.1. The AFMS RadNet is designed as a stand-alone system but will interface with other telehealth technologies, such as teledermatology, telepsychiatry, teleophthalmology, etc., in the future. The AFMS RadNet is envisioned to become a part of a telehealth family of systems (FOS), operating in accordance with the Ground Contingency Medical Support System (GCMSS) Initial Capabilities Document (ICD). Therefore, the structure of the AFMS RadNet system must enable it to serve as the technical foundation for other DICOM (Digital Imaging and Communications in Medicine) format telehealth initiatives (for example, teleophthalmology, telepathology, teledermatology, etc...).
- 7.2. Appropriate operation of the AFMS RadNet requires interface with the DoD EHR (AHLTA or any future DoD or DoD/VA solution), any DoD imaging or storage solutions (such as MEDIA), and the Global Information Grid (GIG). Successful use of the AFMS RadNet requires integration with existing Air Force equipment and systems. Compatibility with AHLTA is essential.

8. Information Technology and National Security Systems Supportability.

The required bandwidth for the AFMS RadNet system is dependent upon the workload for a facility and the average size of the transmitted images. The Integrated Medical Information Technology System (IMITS) pilot project involving Wright Patterson Medical Center, Wilford Hall Medical Center, Eglin, and MacDill will provide further insight on the amount of bandwidth required.

9. Intelligence Supportability.

Teleradiology will not produce, consume, process, or handle any intelligence data. It will only transmit and receive medical data and images that are already protected under the Health Insurance Portability and Accountability Act (HIPAA) and other privacy statutes and regulations.

The teleradiology system shall conform to all Department of Defense (DoD) and Air Force security instructions and directives.

10. Electromagnetic Environmental Effects (E3) and Spectrum Supportability.

This section is not applicable to the enterprise-wide teleradiology network initiative.

11. Assets Required to Achieve Initial Operational Capability (IOC).

Adequate PACS units and bandwidth will be required for IOC. IOC will be achieved when all CONUS MTFs are equipped with either PACS or teleradiology systems. Dynamic Workload Allocation will be available at Full Operational Capability (FOC). Secure and climate controlled areas for the PACS units and teleradiology workstations will also be required. Storage and support capability in areas such as Information Technology (IT) and communications will be required at each location.

12. Schedule and Initial Operational Capability (IOC) and Full Operational Capability (FOC) Definitions.

IOC is projected for FY07 when all CONUS MTFs are equipped with either PACS or teleradiology systems. FOC will be achieved when there is a global teleradiology system with dynamic workload allocation.

13. Other DOTMLPF and Policy Considerations.

- 13.1. **Doctrine:** Other documents may have to be developed to describe methods of employment of this technology. These additional documents include concept of employment documents to address operations and usage of the AFMS RadNet system. Other documents may be required to address tactics, techniques, and procedures. Examples of changes in policy and doctrine that must be enacted for the AFMS RadNet system to be successful include:

- 13.1.1 **Telehealth Credentialing:** The AFMS must enact a policy that allows providers to be credentialed at their local MTF for the practice of their particular type of telehealth specialty (such as teleradiology, teledermatology, teleophthalmology, telepsychiatry, etc....). Without such credentials, Air Force providers will be unable to receive appropriate workload credit for their work and local commanders will not support the effort.
- 13.1.2. **Enterprise-wide Credentialing:** The credentials mentioned above must be sufficient for DoD (not just Air Force) telehealth credentialing standards.
- 13.1.3 **Telehealth Operational Policy:** The AFMS must establish the operational functioning of telehealth modalities as they apply to the overall Air Force mission. Without a clear policy, modernization efforts will lack clarity and coherent vision. The policy must describe who is to direct, maintain, and coordinate the telehealth modernization solutions developed by the AFMS Modernization Directorate. Otherwise, sustainment responsibility will be

unclear and system failures are likely to occur.

13.1.4 **Air Force Medical Technology Infrastructure Policy:** There is currently no uniformity between MAJCOMs regarding issues related to Information Assurance (IA) and security. Furthermore, rules that are necessary for operational warfighting are more restrictive than is generally needed for medical information transfer. These restrictions and structural inconsistencies create unnecessary problems for the AFMS and make telehealth modernization difficult. In this instance, the Air Force is making it difficult to modernize itself. Ideally, a separate medical “enclave” for IM/IT should be created. This type of structural change will facilitate medical modernization without compromising military operations. This policy will need to be created by the Secretary of the Air Force or the Chief of Staff of the Air Force.

13.1.5 **Enterprise-wide Enrollment:** Enrollment in one MTF should result in enrollment of the patient in the entire DoD MHS. Without this change, telehealth solutions are cumbersome.

13.1.6 **Telehealth Quality Assurance Policy:** Quality assurance policies for teleradiology need to address the following issues: 1) dose to the patient and staff 2) image quality (including image transmission fidelity) 3) repeat/reject rates 4) image plating usage.

Independent testing must be performed by a qualified diagnostic medical physicist before clinical use of the system. This includes but is not limited to image transmission fidelity, image resolution, evaluation of image processing algorithms, and image plate processing requirements per American Association of Medical Physics guidelines. This testing is beyond the basic manufacturer’s required acceptance testing and Medical Equipment Repair Center (MERC) evaluations. Also, the medical physicist shall be consulted on the establishment of a routine quality control program for the system. The medical physicist must also provide an annual evaluation of the system in addition to consultative and/or on-site support to the various network sites, including the Area of Responsibility (AOR).

13.2. **Organization:**

13.2.1. **Telehealth Program Office:** The AFMS should create a Telehealth Program Office to maintain and sustain telehealth operations developed by

the AFMS Modernization Directorate (as described in 13.1.3 above). Telehealth must be recognized as a substantial component of the 21st century MHS and given appropriate management and sustainment structure in order to survive. Without such an office, sustainment will be conducted by each MAJCOM separately and coordination between MAJCOMs will become an exercise in political management with no central body coordinating the operations. In this climate, disparities in operations will result in difficulty identifying and correcting problems within the system as a whole and the success of the operations will be dependent on the communication and interpersonal skills of the various parties involved.

- 13.3. **Training:** Medical personnel must be trained about the new workload allocation methods as well as how to use the new technology. The training will encompass device operations and processing of patient data handling methods. Training will be applied in Air Force Specialty Code (AFSC) specific and Unit Type Code (UTC) training events. Applicable Air Force publications must be updated to reflect the training process and requirements. The telehealth policy mentioned above must specify who maintains the various components of the system (internet lines, PACS machines, computers, etc...).

13.4. **Materiel:**

- 13.4.1. Reliability: The objective of reliability is to minimize the risk of system failure. The system will be designed for maximum reliability IAW Key Performance Parameters (KPPs), attributes, Test and Evaluation Master Plan, and the Life Cycle Management Plan.
- 13.4.2. Maintainability: The objective is to reduce time and cost to maintain the system. Routine maintenance will be conducted by the MTF IM/IT staff and users, such as providers and medical technicians. Non-routine maintenance, such as equipment repair and software updates, will be conducted through contract with the applicable vendor.
- 13.4.3. Transportability: This section only pertains to the deployed environment. Equipment installed at fixed facilities will not move. The objective is sufficient resources, processes, and procedures to ensure the system is globally transportable via multiple platforms in its operational or storage configuration. Specialized cargo configuration equipment or specialized cargo handling procedures may be required to move the devices. This specialized equipment is part of an Expeditionary Medical Support (EMEDS) package and is transported along with the EMEDS package.
- 13.4.4. Supportability: The objective is to reduce the time and cost to support the system. Supportability includes:

- Maintenance: MTF users and IM/IT specialists will perform minor

maintenance. Non-routine maintenance, such as equipment repair and software updates will be performed by the applicable vendor.

- Manpower and personnel: May require additional manpower authorizations.
- Supply support: The scope of this support depends on the final product solution.
- Support equipment: New support equipment may be required. PACS middleware will meet all Information Assurance (IA) DITSCAP (DoD Information Technology Security Certification and Accreditation Process) requirements.
- Supporting technology: The functioning of the AFMS RadNet and other forms of expeditionary telemedicine is complicated by the absence of a working expeditionary EHR that can interface with imaging modalities and attach Health Information System (HIS) information to the image. Furthermore, inclusion of images into the non-expeditionary “brick and mortar” EHR will facilitate teleradiology and other telehealth efforts. Until these supporting technologies are available, telehealth solutions must rely on “work-arounds”.
- Technical data: The vendor must supply technical data at delivery of the first system.
- Training and training support: This will be required for existing medical personnel. Initial user training will be developed and provided by the manufacturer. Medical personnel training standards will be defined by the AFMS.
- Facilities: This system must be stored in an environmentally and access controlled area.
- Packaging, handling, storage and transportation: Equipment items will require a unique identifier designation (UID); there are no cargo movement constraints. The life cycle management plan will include standard management processes to ensure compliance with OSHA, HAZMAT and any additional handling requirements.
- Design interface: the system will comply with standards for Reliability and Maintainability; Human Factors; System Safety; Survivability and Vulnerability; HAZMAT Management; Standardization and Interoperability; Energy Management; Corrosion; Nondestructive Inspection; and Transportation.

- 13.5. Leadership and Education: Leadership and Command and Control (C2) agencies must be knowledgeable of the policies and employment characteristics of the teleradiology system in order to effectively use it for its designed purpose. Decision-making processes, C2 relationships, and sequenced actions will be addressed in the AFMS RadNet Concept of Operations (CONOPS), which will be consistent with the recently approved TMA Teleconsultation CONOPS.
- 13.6. Personnel: The teleradiology system may require additional unit manpower requirements. For example, the Medical Operations Directorate (SGO) or the Air Force Medical Force Development Directorate (SGC) may determine the need for additional training of IT technicians or biomedical technicians in “Telemedicine Technologies”. The Telemedicine Program Office along with the Air Force Medical Modernization Directorate’s (SGR) Telehealth Team can assist in the development of training programs leading to certification of additional training.
- 13.7. Facilities: The facilities must be environmentally controlled for proper storage and access to the storage area must be controlled to prevent unauthorized use or tampering. Back-up power supplies and replacement parts must be available to manage contingencies.

14. Other System Attributes.

There are no additional system attributes to define and describe beyond those already discussed.

- 15. Program Affordability:** A business case analysis (BCA) is currently being conducted by HQ AF/SGR.

Appendix A: Teleradiology Requirements Definition Matrix (*Refer to attachment*)

Appendix B: Architecture Products

OV-5 Diagrams: 1) Radiology Workflow Architecture 2) AFMS Enterprise-Wide Radiology Network

Net-Centric Operations and Warfare (NCOW) Reference Model Compliance Statement: N/A

Initial Interconnectivity and Interoperability Capability Profile: TBD

NR-KPP statement. This program/system does interface with, provide services to, or consume information/data from the Global Information Grid Enterprise Services. This program/system will comply with all applicable DOD data processing, data correctness, data availability, and information assurance directives and requirements.

IA Statement of Compliance

Key Interface Profiles (KIPs) Applicability Statement: N/A

APPENDIX B-Architecture Products

Refer to the following attached architectural diagrams: 1) Radiology Workflow Architecture and 2) AFMS Enterprise-Wide Radiology Network.

Appendix C – References

- a. White Paper on Telemedicine, Virtual Consultation Portal, 1 October 2003.
- b. White Paper on Low Bandwidth Telehealth Initiative, 4 November 2003.
- c. Teleradiology High Performance Team (HPT) Meeting, 7-9 September 2005.
- d. Meeting with 311th Human Systems Wing (Lt Col Vicki Shanks, Dr. James Rader, 1st Lt Maurice Edmondson, Mr. Alex Slate, and Ms. Nancy Morales), Brooks City Base, Texas, 21-22 September 2005.
- e. Teleradiology Dynamic Workload Allocation Statement of Work, 12 August 2005.
- f. Discussion with Mr. David Powell, Information Management Specialist, 59th Medical Wing, 3 October 2005.
- g. Discussion with Mr. David Smith, PACS Administrator, 59th Medical Wing, 4 October 2005.
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- j. CJCS Manual 3500.04C, 1 Jul 2001, “Universal Joint Task List (UJTL).”
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- l. Joint Publication 4-02.1, 6 Oct 1997, “Joint Tactics, Techniques and Procedures for Health Service Support in Joint Operations.”
- m. Joint Publication 4-02.2, 30 Dec 1996, “Joint Tactics, Techniques and Procedures for Patient Movement in Joint Operations.”
- n. CSAF CONOPS 15 May 2004, “United States Air Force Homeland Security.”
- o. CSAF CONOPS (DRAFT) 15 Oct 2002, “Global Mobility.”

- p. AFDD 2-6.1, 13 Nov 1999, "Airlift Operations."
- q. AFDD 2-4.2, 11 Dec 2002, "Health Services."
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- s. CJCS Instruction 3010.02A, 15 Apr 2001, "Joint Vision Implementation Master Plan (JIMP), Enclosure A, Appendix C."
- t. HQ AMC, Oct 2001, "Air Mobility Strategic Plan 2002."
- u. CJCS Instruction 3010.01E, 1 Oct 2002, "Joint Strategic Capabilities Plan FY 2002."
- v. Agile Combat Support Threat Environmental Description (TED) (U) NAIC-1574-0664-01 Aug 01 (S//NF//MR).
- w. DIA-1577-26-04, Feb 2004, "Information Operation Capstone Threat Assessment."
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- y. CJCS Manual 3170.01B, 11 May 2005, "Operation of the Joint Capabilities Integration and Development System."
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- aa. Joint Publication 4-02, 21 Mar 2005 (DRAFT), "Doctrine for Health Service Support in Joint Operations"
- bb. DOD Directive 3025.15, 18 Feb 1997, "Military Assistance to Civil Authorities."
- cc. DODAF, Version 1.0, Feb 2004.
- dd. DOD Directive 4650.1, Jun 2004, "Policy for Management and Use of the Electromagnetic Spectrum."
- ee. AFMAN 23-110, Volume V, 1 Jun 2005, "USAF Supply Manual."
- ff. AFRPD 41-2, 16 Aug 93, "Medical Support."

- gg. AFI 41-106, 2 Dec 04, “Medical Readiness Planning and Training.”
- hh. FDA Guide, “Center for Devices and Radiological Health.”
- ii. Military Standards 1472, 23 Aug 1999, “Human Engineering Design Criteria for Military Systems.”
- jj. AFRD 63-12, 1 Feb 2000, “Assurance of Operational Safety, Suitability, and Effectiveness.”
- kk. AFI 48-123, 22 May 2001, “Medical Evaluations and Standards.”
- ll. AFI 41-209, 10 Mar 2004, “Medical Logistics Support.”
- mm. USAMRIID, August 2004, “Bluebook, 5th Ed.”

Appendix D - Acronym List

AE	Aeromedical Evacuation
AF	Air Force
AFI	Air Force Instruction
AFMS	Air Force Medical Service
AFSC	Air Force Specialty Code
AOR	Area of Responsibility
AoS	Analysis of Solutions
BCA	Business Case Analysis
BMETS	Biomedical Equipment Technician
BRN	Biological, Radiological, Nuclear
C2	Command and Control
CBRN	Chemical, Biological, Radiological, Nuclear
CBRNE	Chemical, Biological, Radiological, Nuclear and High Yield Explosive
CC	Commander
CDD	Capabilities Development Document
CHCS	Composite Healthcare System
CJCS	Chairman of the Joint Chiefs of Staff
CONOPS	Concept of Operations
CONUS	Continental United States
COORD	Coordination
COTS	Commercial Off The Shelf
CPD	Capabilities Production Document

CSAF	Chief of Staff of the Air Force
CT	Computerized Tomography
DE	Directed Energy
DICOM	Digital Imaging and Communications in Medicine
DITSCAP	DoD Information Technology Security Certification and Accreditation Process
DOD	Department of Defense
DOTMLPF	Doctrine, Organization, Training, Materiel, Leadership and education, Personnel, and Facilities
EHR	Electronic Health Record
E3	Electromagnetic Environmental Effects
EMEDS	Expeditionary Medical Support
EMP	Electromagnetic Pulse
EW	Electronic Warfare
FOC	Full Operational Capability
FoS	Family-of-Systems
FY	Fiscal Year
FYDP	Future Years Defense Program
GCMSS	Ground Contingency Medical Support System
GIG	Global Information Grid
GOTS	Government Off the Shelf
HIPAA	Health Insurance Portability and Accountability Act
HIS	Health Information System
HQ	Headquarters
IA	Information Assurance
IAW	In Accordance With

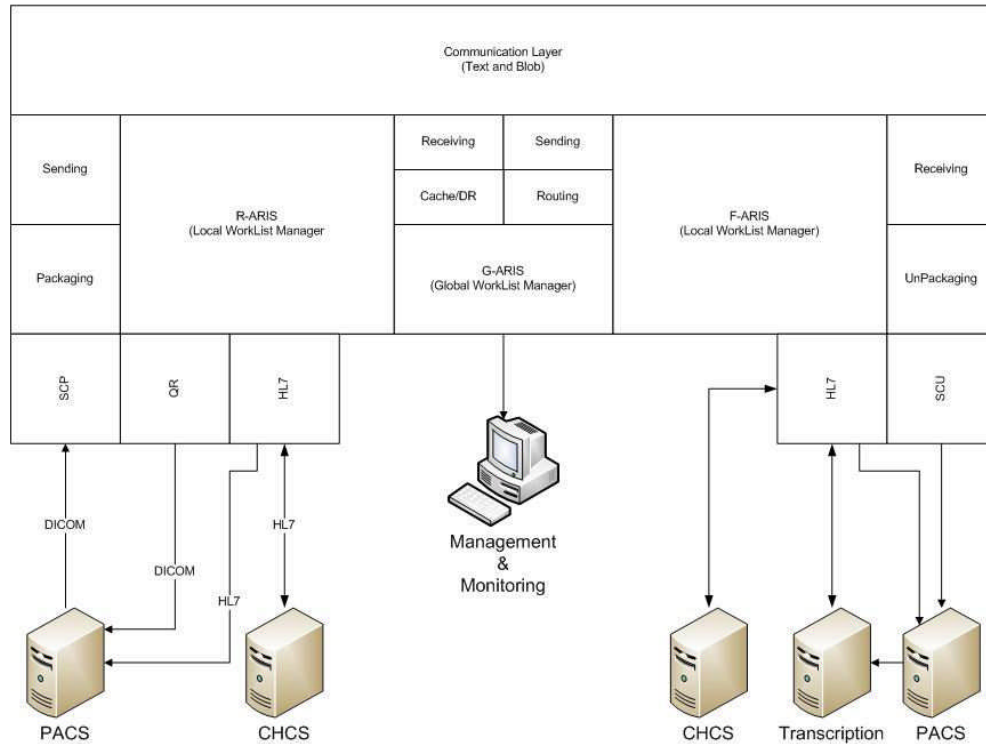
ICD	Initial Capabilities Document
IMITS	Integrated Medical Information Technology System
IOC	Initial Operational Capability
IT	Information Technology
ITS	Information Technology System
JCD	Joint Capabilities Document
JCIDS	Joint Capabilities Integration and Development System
JROC	Joint Requirements Oversight Committee
KIPS	Key Interface Profiles
KPP	Key Performance Parameters
LCC	Life Cycle Cost
MERC	Medical Equipment Repair Center
MRI	Magnetic Resonance Imaging
MTF	Military Treatment Facility
OV	Operational View
PACS	Picture Archive and Communication System
R&D	Research and Development
SGC	Air Force Medical Force Development Directorate
SGO	Air Force Medical Operations Directorate
SGR	Air Force Medical Modernization Directorate
SoS	System of Systems
SPO	System Program Office
T	Threshold
TBD	To Be Determined
US	United States

USAF United States Air Force

UTC Unit Type Code

Appendix Three – DWA DIAGRAM

IMITS/AFMS Partner Collaboration



Appendix 2



IMITS Center

To: John W. Marsh, Maj, USAF, MSC, FACHE
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From: Jeananne Nicholls
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University of Pittsburgh Medical Center
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Pittsburgh, Pa 15232

Date: October 5, 2007

Re: FY04 IMITS – ECMO Project (Cooperative Agreement DAMD1703-2-0017)

Major Marsh,

At this time, all UPMC deliverables for the FY04 IMITS – Extra Corporeal Membrane Oxygenation (ECMO) Project (Cooperative Agreement DAMD1703-2-0017) are complete. All of the attached documents fulfill the deliverable requirements for this project.

The following deliverables have been provided:

1. List of ECMO equipment purchased: ECMO equipment purchased by UPMC IMITS with delivery to Hawaii in December 2005. In Sept 2005, a list of purchased equipment was submitted to SGR.
 - a. 1x MAQUET 2-Position Perfusion Systems
 - b. 1x ECMO CSZ Cooler/Heater
 - c. 1x Flowmeter, Transit Time
 - d. 1x Flowsensor, Tubing OD: 3/8"
 - e. 1x Sechrist Blender
 - f. 1x Manual Operation 3500HL English
 - g. 1x Hose Assy., Air, 14 Ft
 - h. 1x Hose Assy., Oxygen, 14 Ft.
2. Copy of research lab training protocols: Research training protocols, procedural checklists and training manuals were completed. In April 2006, a research lab training protocol was submitted to SGR (Attachment 6).
3. A clinical protocol: The new ECMO equipment required effective evaluation. A research protocol was designed to determine if the Jostra Rotaflow can be used for neonatal ECMO and whether it might deliver a superior result with greater safety and



improved outcomes when compared with two traditional centrifugal pumps. In September 2006, a series of three clinical trials were conducted; a summary of the results was submitted to SGR with the 2006 annual report (Attachment 3).

Results are very promising and tend to confirm that the Jostra RotoFlow can be used for neonatal ECMO and it delivers a superior result with greater safety than either of the two traditional pumps. However, as stated in the summary report, due to the limited data set, the results must be examined with caution. Larger studies are recommended to control process variables and to enable statistically significant comparisons, which will be address in the TATRC sponsored ECMO initiative in Hawaii.

The project has sufficiently planned and prepared for the ECMO initiative in Hawaii. Training and research protocols have been developed and research findings are guiding development of future clinical protocols. UPMC would like to request the official closure of this project. It was recommended that you be informed and approve this decision. Please indicate your concurrence with completion of these deliverables.

Feel free to contact me as needed.
Sincerely,

Jeananne Nicholls
Associate Director of Operations

Attachments

- (1) - Report: Findings from Baseline Evaluation of Clinical Practices and Perceived Impact
- (2) - ECMO FLOWSHEET
- (3) - Feasibility study examining the Jostra RotaFlow and its applicability to ECMO
- (4) - Strategic Plan for Short and Long-Term Implementation of Operational Plan
- (5) - ECMO TRAINING
- (6) - ECMO Research Lab Protocol
- (7) - Proposed ECMO Circuit
- (8) - Proposed RotaFlow & Minimax Circuit
- (9) - Roller head & Sci-med Circuit

cc:
Tess Ellis
Aaron Yanuzo
Leslie Anthony
Ralph Caputo

Attachment 1

FY04 Integrated Medical Information Technology Systems (IMITS) Extra Corporeal Membrane Oxygenation (ECMO)

Report: Findings from Baseline Evaluation of Clinical Practices and Perceived Impact

**By Dr. Larry Burgess, Principal Investigator
April 2006**

Initial baseline meetings were conducted with ECMO subject matter experts in Hawaii in September and October 2004. The following summarizes the findings:

- a. A Hawaii ECMO group had been formed approximately 10 months earlier. It consisted of both clinicians and administrators from three hospitals primarily: Kapiolani Medical Center for Women and Children (KMCWC), Tripler Army Medical Center (TAMC), and Kaiser Permanente Medical Center (KPMC).
- b. The proposed Center would be civilian-military, and housed at a civilian hospital, KMCWC. The primary reason for this was the depth of the nursing staff in supporting this new mission. Staff from all three hospitals would assist in staffing the Center, but primary staffing would be from the host hospital.
- c. Currently, clinical cases are being conducted at KPMC.
- d. Perfusion is supplied under contract to the Center, and a perfusion based model is being adopted.
- e. Implementation funding for the Center is in the process of being appropriated for FY05.

Minutes from the initial baseline meetings with the existing Hawaii working group and the IMITS group are on the following pages (pages 2-7).

Contact Information

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Attachment 1

PEDIATRIC DOD-CIVILIAN ECMO CENTER – SEPTEMBER 2, 2004

I. Introductions. Contact information and e-mail working group finalized after meeting. If you do not have it, contact Dolly @ dollyp@hawaii.rr.com.

II. Purpose of UPMC Funding to UH

- A. Planning for DOD-CIV ECMO Center in Hawaii. Dollars are part of UPMC's Congressionally funded IMITS program and the expansion of this advanced health care and telemedicine program into the Pacific Rim. One aspect of this is to plan for the ECMO Center that is being conducted in conjunction with the Telehealth Research Institute, UH-JABSOM (Dr. Burgess).
- B. Planning will lead to more rapid implementation of FY05 dollars. It is unclear how FY05 monies will be routed and contracted. As with other DOD health care congressional funding lines in Hawaii, it is likely to be through the Pacific Telehealth and Technology Hui, directed by Stanley M. Saiki, MD. As this is an operational program, the Tripler Army Medical Center Command will likely have a significant role in the direction of the program.
- C. Primary concern of planning on DOD-CIV issues, as this is a DOD-CIV Center; secondary concern CIV-CIV issues as patients are needed to support the Center with critical mass of cases and personnel.

III. FY05 Funding “Probabilities” to Consider in Planning

Cannot determine exactly how FY05 dollars would be expended. The current FY04 dollars focus on the planning process only. Initial funding will probably be for 1-3 years, then maintenance funding approximating \$1 Million a year. Final maintenance costs will be based on the business model discussed in IV.D. Based on preliminary discussions from apparent key stakeholders, it appears probable that funding will include:

- A. Perfusion including personnel, education and training.
- B. Equipment and supplies.
- C. Clinical and Administrative support personnel and supplies.

IV. Main Focus Areas (see also ECMO Project List for more specifics)

- A. Clinical – Largely completed based on pre-existing consortium as to NICU, PICU, and perfusion needs. In this model, NICU and PICU support must be well developed and maintained. Perfusion support is contracted for.
 - (1) Education and training will be necessary on an ongoing basis.
- B. Location of Center - Best Option is Kapiolani, and this is supported by all in the working group.
 - (1) Critical element is both NICU and PICU support. All pediatric centers in Hawaii have NICU support. However, only Kapiolani has higher acuity

Attachment 1

PICU support and dedicated space, combined with a consistent and established nursing and intensivist staffing model.

- (2) Virtual Center alternative-team delivers care in various hospitals. This can work for perfusionists, but would be difficult for nursing and intensivist staff to adapt to different environments. With the average ECMO run lasting 7 days, without the backdrop of a well-staffed PICU, this would be difficult to implement from both an intensivist and nursing staff perspective.
- (3) Center at Tripler alternative-all civilian and military cases go to Tripler. Initial core dollars will build infrastructure including nursing and intensivist staff, and cases would be transferred there. This is possible initially, with initial larger funding going towards the staffing of such a model. However, this funding is not sustainable and maintenance funding would not be able to staff the PICU. There is also a lack of qualified nurses in Hawaii, and probably not enough to fully staff two PICUs (Kapiolani and Tripler) in Hawaii. Kapiolani's will remain due to its established history and the larger population it serves. The intensivists are also part of this established staffing model at Kapiolani, and this would be leveraged appropriately when adding ECMO to the PICU's capability.

C. Perfusion

- (1) Requirements. Perfusion support would be accomplished on a contract basis per case per length of run. Perfusionists are paid directly by the hospital, with the hospital receiving the DRG payment.
- (2) Education and training-will be required for perfusionists on an ongoing basis.
- (3) Consumable supplies-initially will be paid for by Center, and potentially later during maintenance period, otherwise would be part of DRG reimbursement.
- (4) Equipment will be purchased-3 pumps. It is anticipated that 3 pumps will be needed: 1 for main, 1 for concurrent case or backup, 1 for backup or for transport.

D. Administrative Issues

Administrative issues loom as the most difficult to address. A well-defined business plan is necessary to: inform decision makers prior to constructing operating agreements, coordinate referral, coordinate payment, and receive appropriate reimbursement for services. Without these aspects, operating agreements between participating organizations will be difficult to draft, and reimbursement will not be adequate to sustain the Center after the initial startup period.

Attachment 1

Kapiolani administrative staff with Willow Morton is engaging on many of these issues. Tripler AMC will need to provide an individual from contracting and/or patient administration to participate in the working group.

- (1) Cost sharing between DOD-CIV.
- (2) Cost sharing CIV-CIV.
- (3) Budgetary: Administrative and Clinical Staffing models needed to determine maintenance costs.
- (4) Reimbursement from HMSA, Medicaid, TRICARE. Reimbursement does not come close to covering costs, but third party payors must be approached, as they are saving significant dollars in transporting patients to CONUS, so some of these savings need to be returned to the center.
- (5) Belong to national ECMO center working group, to share data.
- (6) Malpractice coverage while on DOD transport aircraft.
- (7) Cost data for typical hospitalization.
- (8) Staffing requirements for typical hospitalization.

E. Patient Transport

Numerous issues about air transport were discussed. With the intent for the Center to be a resource for the Pacific Rim, transport capability must be available.

- (1) On-island-Kapiolani transport team.
- (2) Inter-island - Rarely necessary, would seek Air Force support.
- (3) Trans-Pacific to HI- Air Force and support team. For transport from DOD sites and for transport from Civilian sites. This would be good for patient care, but indigent care could severely impact the Center if there is no accompanying reimbursement. If accomplished on a select basis, would consider utilizing a percentage of funds to cover civilians from Compact States or other Pacific Rim Countries. This would be good on several fronts, but funding will be needed. These additional cases could also help to provide the necessary critical mass for the Center to maintain the skills of the providers.
- (4) Malpractice coverage of civilians on DOD aircraft: Kapiolani and Kaiser physicians OK, nursing staff as well? DOD civilians should be covered. Contractors working in DOD hospitals may or may not be covered depending on how the contract is written. Civilian perfusionists may not be covered.

F. On-going Education and Training – Necessary for all providers.

V. Retreat I – October 29-31, 2004, Kauai Marriott.
Retreat II – To be determined.

VI. Monthly Planning Meeting: Next meeting October 2, 2004, 5-7 PM, Pacific Club

Attachment 1

AGENDA PEDIATRIC DOD-CIVILIAN ECMO CENTER – October 5, 2004

I. Introductions, Review of Contact Information

II. Update on UPMC Visit, 22-24 September 2004

D. Administration-

- (2) UPMC-Children's Hospital mobilizing admin team to assist with staffing models, reimbursement issues. They perform 30 per year at Children's Hospital.

- i. *Discussion: Kapiolani administrative staff very interested in pursuing both a short and long-term relationship in this arena, to better understand the nuances of staffing models, coding, third party reimbursement, and contracts so that the program is sustainable. In addition, it is equally important to develop the financial aspects of this business model, so that the congressional budget for sustainment can be properly determined.*

- (3) Should do a conference call with Kapiolani and other HI partners prior to retreat.

- i. *Discussion: In a follow-up conversation after the meeting with Cathy Poole of UPMC, they are mobilizing the team to attempt to due a conference call during the week of 11-15 October. This is vital so face-to-face contact can be made between POCs on both sides, and important data can be shared with the Hawaii team during the retreat. This will help to jumpstart the formation of the business plan.*

E. Reimbursement-

- (2) Similar reimbursement paradigms for 3rd party as in Hawaii, 55-60%.
- (3) Net additional 30% with Gateway and Med-plus contracts.
- (4) However, will gain additional dollars for follow-on procedure like transplant, heart operation.

- i. *Discussion: This data, provided by Jack McEwen, will be part of the discussion surrounding development of the business plan as discussed in I.A.a & b.*

F. Perfusion -

- (2) Supplementing Service - Contract, if won by UPMC's Biotronics, would preferably contract with local perfusionists to deliver the service. They CLEARLY do not desire to displace any perfusionist conducting the service. Their perfusionists would be available to supplement services on an as needed basis (e.g., 2 runs are occurring or it is a long run, and

Attachment 1

simultaneously a perfusionist is ill or on vacation.) Biotronics currently has 6 on-call perfusionists to provide 24/7 coverage anywhere in the US, so this could be beneficial to the Hawaii Center should the need arise.

- (3) Education and Training - They are interested in providing long-term education, training, and QI activities.
- (4) Patient Transport - They use their on-call perfusionists for both in-house transport and management, and to perform patient transport (both PEDS and adults) for other health systems, not involving UPMC.

- i. *Discussion: UPMC through Biotronics has significant expertise in this arena. The contracting issue is a separate activity from this planning exercise, and is beyond the control of the planning group. However, the planning phase and funding is designed to work closely with UPMC and Biotronics to learn from their expertise, and to clearly outline the specifics or “specs” that we should design this center around for the following perfusion perspectives: equipment and maintenance, perfusionist support for ECMO cases, perfusionist support for transport of ECMO cases, and education and training for perfusionists and the ECMO allied health team. These specs will be critical to the Center’s leadership in defining and contracting for the support that will be required when the time comes.*

G. Clinical-PEDS Intensivist

- (2) Cody Henderson, MD, Director of Wilford Hall ECMO Center attending.
- (3) Intensivist from Pittsburgh Children’s Hospital will attend.

- i. *Discussion – Since Cody is a Neonatal Intensivist, it would be preferential for UPMC-Children’s to send a Pediatric Intensivist.*

III. Retreat

- A. Attendance List – Review, confirm, modify.
 - a. Other perfusionists coming, or can meet in Honolulu?
- B. Agenda for Retreat -
- C. Follow-on meetings at Kapiolani, Tour, Tuesday, 0900-1300
 - a. Need to schedule with Kapiolani
- D. After hours meeting for those who would like to meet members of UPMC team?

-Discussion: Pete May will represent the perfusionists. Ancillary meetings other than the Kapiolani visit will not be arranged en masse. Many of the UPMC personnel will be available on a one-on-one or small group perspective as needed during the follow-on week in Hawaii. Others who will not be at the retreat are

Attachment 1

encouraged to attend the Kapiolani visit and tour, that is being arranged by Willow Morton and her administrative staff.

IV. Updates-Issues

- A. Clinical
- B. Administrative
- C. Patient Transportation
- D. Perfusion

- Discussion: See discussions in Sections II and III regarding these areas. Essentially, the group is looking forward to the information that will be shared at the retreat from UPMC.

Attachment 2

ECMO FLOWSHEET

(ECMO FY04 IMITS)

Daily Target values for:	
Wt:	Pt. sticker here
Age:	
Diagnosis:	
VA or VV	
ECMO Day:	
ACT	Pt. Temp
Flow	Blood Pressure
SvO2	Post mem. Pressure
Hct	
PaO2	
PaCO2	

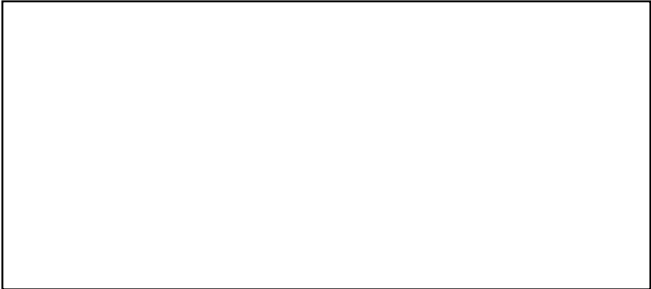
Date: _____ Page: ____ of ____

[illegible]

Attachment 2

Oxygen Challenge

Time	Pre venous O ₂	Post venous O ₂	Pre O ₂ sat	Post O ₂ sat



Addressograph

Attachment 2

Assessments

Time	08	12	16	20	00	04		08	12	16	20	00	04
Initials							Initials						
Every 4 hours							Oxygenator type & size						
Pre-membrane pressures							Condensation present & clear						

[illegible]

Attachment 2

Post membrane pressures						Condensation present & pink						
Bladder pressures						Clot free						
Heater set point						Clots @ bottom, non-occlusive						
Water temp						Clots @ top, non-occlusive						
Patient temp						Air bubbles present, removed						
CO ₂ psi						Other						
SVO ₂ monitor calibrated						Heat exchanger: ¼ “/ integral						
Every 8 hours						Air bubbles present, removed						
Zero alarm transducers						Other						
Flush transducers						Bubble trap/ clot free?						
Check supplies						Serum separation						
Hemochron QI (values)	Nl / Abn	Nl / Abn	Nl / Abn			Air bubbles present, removed						
Flush unused pigtails						Clots present @ top						
Heparin drip verified						Clots present @ sides						
Circuit Assess (Every 4)						Clots present at bottom						
Tie-bands at connections						Bladder						
Bubble detector fxning & on						Pressures within 20mmHg						
Tubing secured to bed						Clots present, removed						
Stopcocks off & dead ended						Air bubbles present, removed						
HL20 plugged into red outlet						Cannula site #1 location						
Voltage @ 27.4						Dsg dry & intact						
Temp probe to oxygenator						Open wound						
Hemofilter in line?						Sutures intact						
(Clot free?/Air free?/UF clear)						Drainage present						
Other						Cannula site #2 location						
Raceway size____ Walked @						Dsg dry & intact						
Turning smoothly?/ wear noted						Open wound						
Tubing						Sutures intact						
Clot free/non-occlusive clots at						Every 12 hours or prn						
Fibrin strands at connectors						Flush stopcock bridge						

ECMO Specialist

Name	Initials	Time in	Time out	Pager #

Attachment 2

[illegible]

Notes

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

Attachment 2

ECMO Record

Date:_____ Page ____ of _____ Adressograph

Hospital:_____ VA or VV ECMO : _____

Perfusionist:_____ Neonatologist:_____

Surgeon:_____ Other: _____

Patient Information:

Name:_____ ID # : _____ Sex: ____ Birth date:_____

Weight: _____ Height: _____ BSA: _____ VA max flow (120 cc/kg/min): _____

Allergies:_____ Blood type: _____ VV max flow (150 cc/kg/min): _____

History (include meds):_____

Diagnosis: _____

Pre-op Labs

HGB/ HCT: _____ PLT: _____ PT: _____ PTT: _____ Na: _____ K: _____ Glu: _____ iCa: _____

PH: _____ pCO₂: _____ pO₂: _____ HCO₃: _____ BE: _____ %SAT: _____

Equipment & Disposables:

Prime components:

Item	Manufacturer	Product #	Lot/Serial #	Exp. Date
Oxygenator				
Tubing pack				
B. Bladder				
Rotaflow				
Heat Xchang				
Bubble trap				
Art. Cannula				
Ven.Cannula				
UF device				
Art. Pump				
Heater/cooler				
Art. Cann.				
Ven. Cann				

PRBC unit # Or other	Vol.(cc)	Added to each unit
_____ _____ unit		____ Tham (50 cc if Hct > 42) or ____ bicarb (15 mEq if Hct < 42) ____ cc 25% albumin (40) ____ units heparin (100) ____ mg CaGluconate (300)
Hct _____ _____ unit		____ Tham (50 cc if Hct > 42) or ____ bicarb (15 mEq if Hct < 42) ____ cc 25% albumin (40) ____ units heparin (100) ____ mg CaGluconate (300)

Hct

Ecmo specialist(s): _____

Prime gas: pH: ____ pCO₂: ____ pO₂: ____ BE/HCO₃: _____

Attachment 2

Date: _____

HCT/HGB: _____ NA: _____ K: _____ iCa: _____ Glu: _____



BioTronics, Inc.

Memo

To: Ralph Caputo

From: Melissa Mattes

Date: 10/5/2007

Re: The BioTronics perfusion team conducted a pilot study to examine the feasibility of a long term study that would examine the Jostra Rotaflow and its applicability to extracorporeal membrane oxygenation (ECMO). The rest of this memo is a summary of the study, the background leading into the study, and the results of the study. Formal reference citations can be provided upon request.

Purpose of the Study:

The goal of the study was to evaluate the latest generation centrifugal pump, the Jostra Rotaflow (Jostra Medizintechnik AG, Hirrlingen, Germany), to determine whether it can be used for neonatal ECMO and whether it might deliver a superior result with greater safety and improved outcomes than either the roller head or the earlier generation of centrifugal pumps provided. Our study was designed to look at hemolysis using this device and compare it against the hemolysis rate of a traditional roller head (Sarns 8000), and the Medtronic Biomedicus BP-50. The first phase of the study is a feasibility study to see if trends can be identified and to find any problems in the materials and methods before investing large amounts of funding. We will use plasma free hemoglobin generation as the indicator for hemolysis.

Background:

Extracorporeal Membrane Oxygenation, or ECMO, is a treatment modality for critically ill patients who have clinically reversible conditions but require support of their heart and/or lungs until the condition can be reversed. ECMO grew out of the discipline of perfusion in which the heart lung machine is used to support a patient during cardiac surgery. Patient selection and appropriate use of ECMO are major concerns. Another important concern is the appropriate use of new technologies.

The main components of the ECMO circuit are the pump and the oxygenator, which are connected with tubing and then connected to the patient's circulation system using cannulas. Throughout the years, the components have been changed and improved, safety devices have been added, and methods of monitoring have been refined.

The current gold standard for neonatal ECMO is the use of a roller pump as the propulsion device because it is simple, inexpensive, and familiar to most ecmologists. The roller pump, however, has many drawbacks. Occlusion of the outflow can result in high pressures, separation of the tubing, and catastrophic blood loss. Due to the extreme negative pressure that the roller pump exerts on the heart, a "bladder box" is needed to smooth the pressures out. Often

Attachment 3

these “bladder boxes” have areas of stagnation that produce clots risking the introduction of foreign particles to the circuit and the need to change the circuit. The roller heads are cumbersome and cannot be maneuvered in close to the patient necessitating long tubing, and thus greater foreign surface contact. As the foreign surface area that the blood contacts increases, so does the possibility of thrombus creation, platelet damage, and complement activation, which then increases the blood requirements. During extended use, the constant rubbing of the roller on the tubing can cause spallation, or damage to the inside of the tubing. If this occurs, it may introduce foreign particles to the blood path, or risk tubing rupture, which in turn may result in catastrophic blood loss and air embolus introduction to the circuit. The early pioneers of the discipline discovered many of these pitfalls and began looking for ways to overcome them and safety devices that would alert them to impending problems. Pressure monitors on the arterial line were added to identify high pressures. Later improvements connected these pressure monitors to the roller heads to automatically stop the forward flow of blood if the pressure climbed too high. New generations of “bladder boxes” are being developed that minimize stagnation. Procedures have been developed, such as shifting the tubing in the head to insure that the pressure is not always on the same piece of tubing and eliminate the spallation effect. In addition to these changes in methodology, other changes were needed, most importantly, improvements in the equipment available for purchase.

Industry partners have worked with the clinicians to improve the equipment available, adding the requested safety devices to the equipment and developing high tech coatings for the inner surfaces of the components in order to minimize the impact of the foreign surface area on the blood components. Through out the years much effort has gone into developing a better pump. In the 1970s, centrifugal pumps were developed that utilized a variety of methods to impart kinetic energy to the blood that was then propelled from the centrifugal head through the circuit. In 1973, Medtronic (Medtronic Biomedicus, Inc. Eden Prairie, MN.) produced a disposable centrifugal head which allowed the new technology to be used for clinical procedures. This centrifugal pump consists of a series of concentric cones that spin when placed on the console due to its electromagnetic coupling. This spinning creates a negative force at the inflow which brings the blood into the cone. Once there, the cones impart the kinetic energy into the blood path and send the blood through the outflow of the cone. This method of blood propulsion was a benefit because it was afterload sensitive and occlusion of the outflow merely stops the flow rather than causes high pressure and all the resulting sequelae. No bladder box was deemed necessary with this generation of pump and it could be moved closer to the patient resulting in shorter lines, reduced foreign surface area, and reduced priming volume. However, the Biomedicus solved some problems and introduced others. Hemolysis generation is the primary concern when using this pump. The hemolysis is attributed to a variety of reasons including: the negative pressure generated at the inflow, length of time the blood spends in the cone, and heat generation from the electromagnetic coupling. Regardless of the reasoning behind it, it is common to change out the biohead while on ECMO every 4 days to minimize the hemolysis. Other concerns include inconsistent flow problems requiring a separate monitoring device, and a concern that the centrifugal pumps are not well paired with the Scimed (Medtronic Biomedicus, Inc. Eden Prairie, MN.) oxygenator which is the traditional ECMO oxygenator. The compatibility is a concern because of the high pressure requirements of the oxygenator, which is caused by its inherent resistance.

Now the next generation of centrifugal pumps is available. The Jostra Rotaflow (Jostra Medizintechnik AG, Hirrlingen, Germany) is one of the new generation. In this pump, the kinetic energy is created by a spinning rotor containing flow channels that direct the blood through the head and propel it through the circuit. With a single, non metal bearing for the rotor to rotate around, and a small priming volume, its product information reports that it has no areas of stagnation, less heat generation, and improved flow characteristics. Theoretically, these characteristics should have eliminated many of the disadvantages of the centrifugal pump; however, questions about the hemolytic properties of the early versions still persist. This is a grave concern because hemolysis, and its associated effects, remains one of the most common complications occurring in neonates undergoing ECMO. The Extracorporeal Life Support Organization's (ELSO) 2003 July Summary reports an incidence of hemolysis (as indicated by an elevated plasma-free hemoglobin >0.5 g/dL) to be in the order of 9.3% of all ECMO patients.

Attachment 3

Most authors have identified the method of blood propulsion as a major contributor to this hemolysis.

Previous Research:

Previous investigators have compared the roller pump to the Biomedicus pump and Jostra Rotaflow, the most notable among these being Duke Medical Center Lawson et al and Royal Children's Hospital Bennett et al. However, no one has looked at the neonatal ECMO scenario. The neonatal ECMO scenario is unique because it requires a low flow (1.5 liters per minute or less) that must pass through a high-pressure system (non-porous oxygenator) or through a low-pressure system (porous oxygenator). This lack of study has held back what could potentially be a quantum leap in both patient care and patient safety in the neonatal ECMO arena.

Study methods and materials:

Each run of the study was conducted on three separate circuits that each contained a different pump: the roller pump, the Biomedicus BP-50, or the Jostra Rotaflow. Each of the pumps was run in a circuit, constructed to closely mimic a high pressure clinical neonatal ECMO circuit, with a Scimed oxygenator (Avecor) and the ECMOtherm II heat exchanger (Medtronic) in line. The Scimed oxygenator is currently the only FDA approved oxygenator for ECMO. The tubing used was ¼ by 3/32 tubing. The circuit loop re-circulated through a one-liter bag. The circuit was primed with a unit of bovine blood, adding Plasmalyte to achieve a normal hematocrit and titrated with Sodium Bicarbonate to achieve a normal pH.

The three circuits are as follows: Circuit 1: The roller pump circuit is comprised of tubing that passes through a Sarns 8000 roller pump, and connects a 1500 Sci-med oxygenator, a heat exchanger, arterial pressure monitoring, sampling site, and a bag acting as a reservoir. Circuit 2: The Rotaflow circuit is comprised of tubing, the Rotaflow, a 1500 Sci-med oxygenator, a heat exchanger, arterial pressure monitoring, sampling site, and a bag acting as a reservoir. Circuit 3: The Biomedicus circuit is comprised of tubing, the Medtronic Biomedicus BP-50, a 1500 Sci-med oxygenator, a heat exchanger, arterial pressure monitoring, sampling site, and a bag acting as a reservoir.

These 3 separate circuits had simulated ECMO runs of six (6) hours apiece with each circuit, being run simultaneously with the same unit of blood. The trial was repeated three (3) times during this pilot study. These were labeled as run 1, run 2, and run 3. The occlusion on the roller pump was set using the gravity method. The circuits were primed with crystalloid and then with bovine blood. The target hematocrit was 30%. The blood was buffered with sodium bicarbonate to achieve the target blood gas. During the study, the blood was maintained at 37 degrees, Celsius. The blood gas parameters were as follows: pH of 7.30-7.45; pCO₂ of 35-45; and PaO₂ of 150-200. The flow was maintained during the 6 hour run at a rate of 300 ml /minute. A partial occluding clamp was applied to the arterial line to achieve a pressure of 300 Tor. All samples were taken from a stopcock after the dead space had been cleared and put into the green top tube required for plasma free hemoglobin testing. The plasma-free hemoglobin samples were collected at the same time on each of the three circuits for each run at the following time intervals: 10 minutes, 30 minutes, 60 minutes, 120 minutes, 180 minutes, 240 minutes, 300 minutes, and 360 minutes. The raw data was tabulated and analyzed with statistical software.

Results

Data for Run 1: Plasma free hemoglobin generated by each pump at specific time periods.

Time	Roller1	Jostra1	Bio1	Static1
10	55.5	234.7	524.6	19
30	178.4	361	759	17.9
60	254.8	428.9	899.3	18.3
120	373.3	543.9	1147	22.6
180	431.3	687.1	1263	19.4
240	520.2	780	1305	31.8

Attachment 3

300	543	843.8	1338	36.2
360	584.5	917	1435	33.6

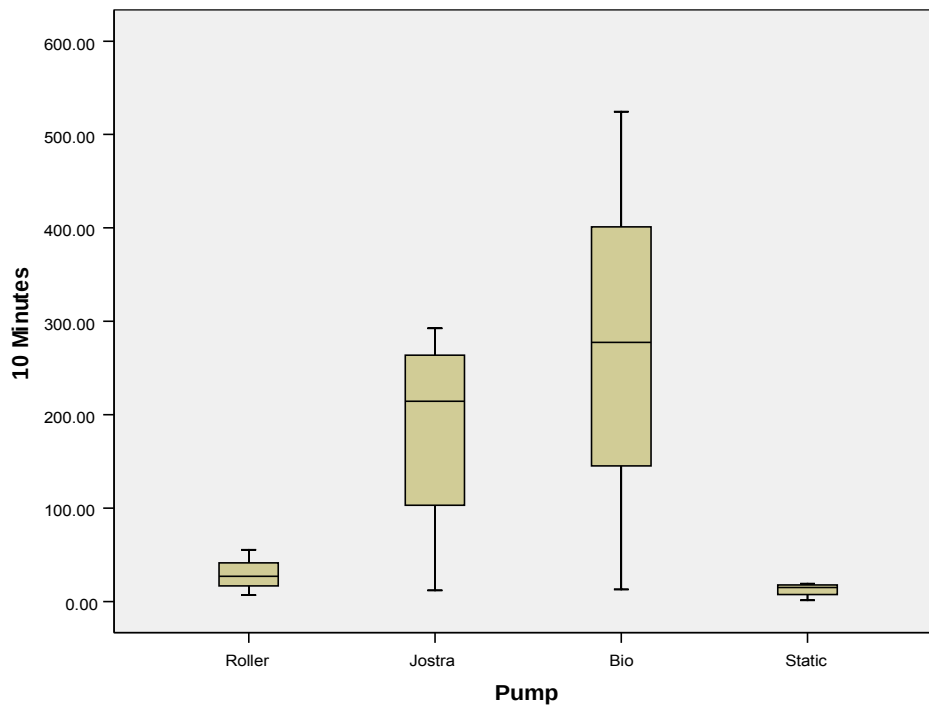
Data for Run 2: Plasma free hemoglobin generated by each pump at specific time periods.

Time	Roller2	Jostra2	Bio2	Static2
10	27.3	193.8	281.6	16
30	50.9	345.2	365.8	14.4
60	97.4	486.1	438.1	17.8
120	219.8	679.6	615.2	22.1
180	351.6	838.5		22.3
240	462.8	930.8	862.7	18.2
300	532	970.5	1003	22.6
360	662.5	1057	1089	18.4

Data for Run 3: Plasma free hemoglobin generated by each pump at specific time periods.

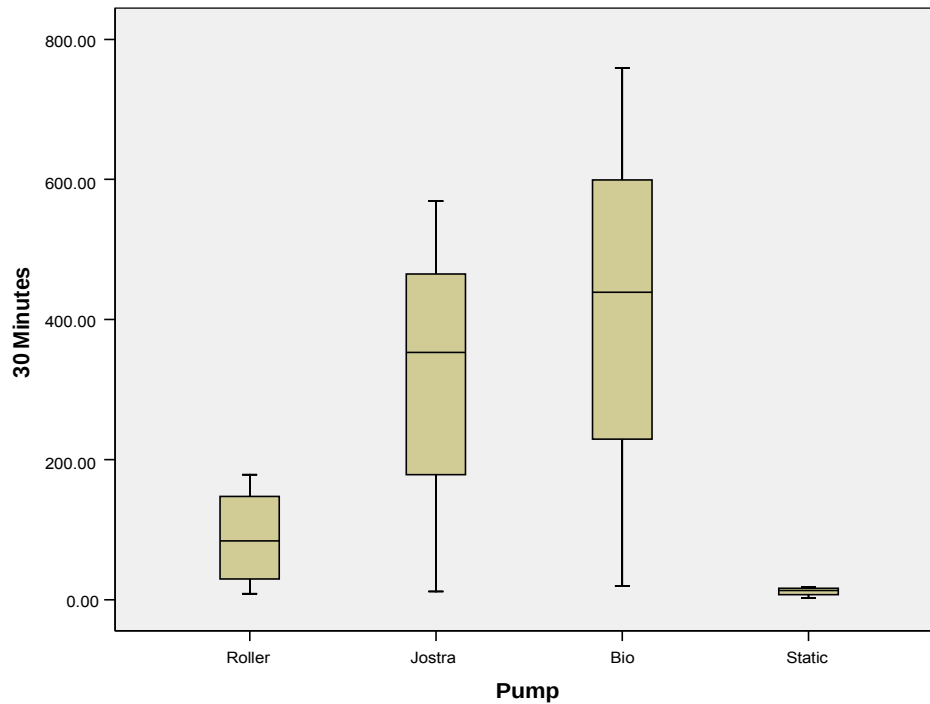
Time	Roller3	Jostra3	Bio3	Static3
10	26.5	292.6	277.3	13.7
30	116.5	569.2	439.1	11.7
60	472.2	754.6	602.1	20.2
120	1398	1009	769.7	14.6
180	2163	1203	927.9	22.7
240	2759	1264	1025	19.6
300	3100	1407	1008	18.9
360	3337	1532	1134	19.4

Graph 1: Mean plasma free hemoglobin produced by each of 3 pumps and the static sample at time 10 minutes. Displayed with variance.

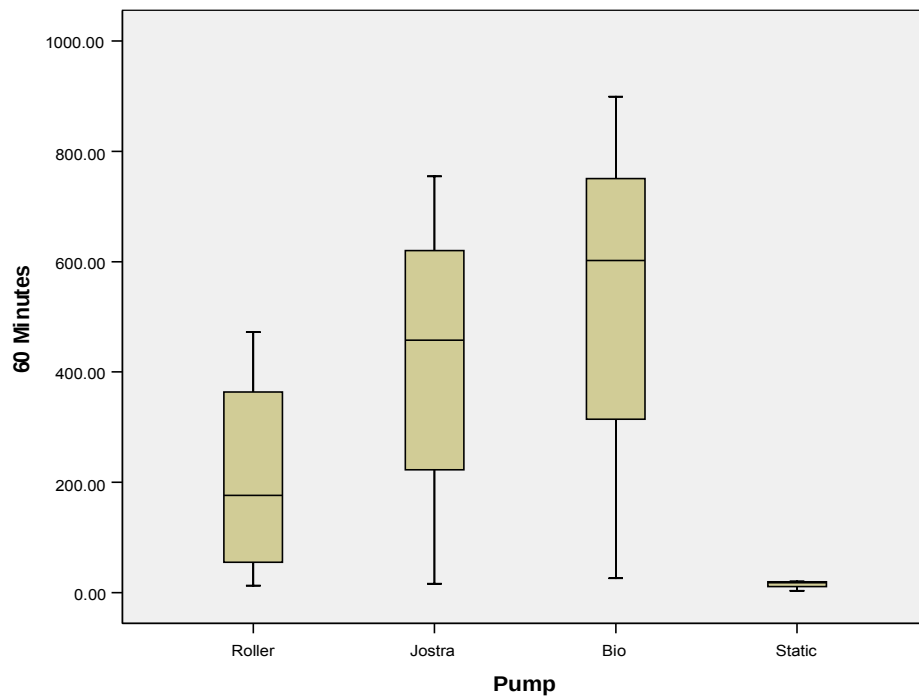


Attachment 3

Graph 2: Mean plasma free hemoglobin produced by each of 3 pumps and the static sample at time 30 minutes. Displayed with variance.

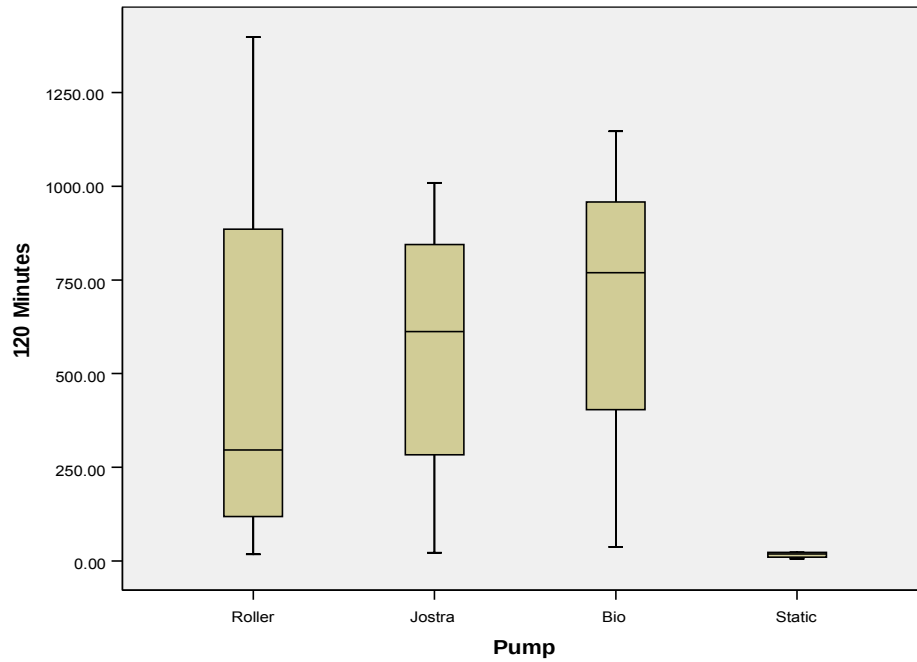


Graph 3: Mean plasma free hemoglobin produced by each of 3 pumps and the static sample at time 60 minutes. Displayed with variance.

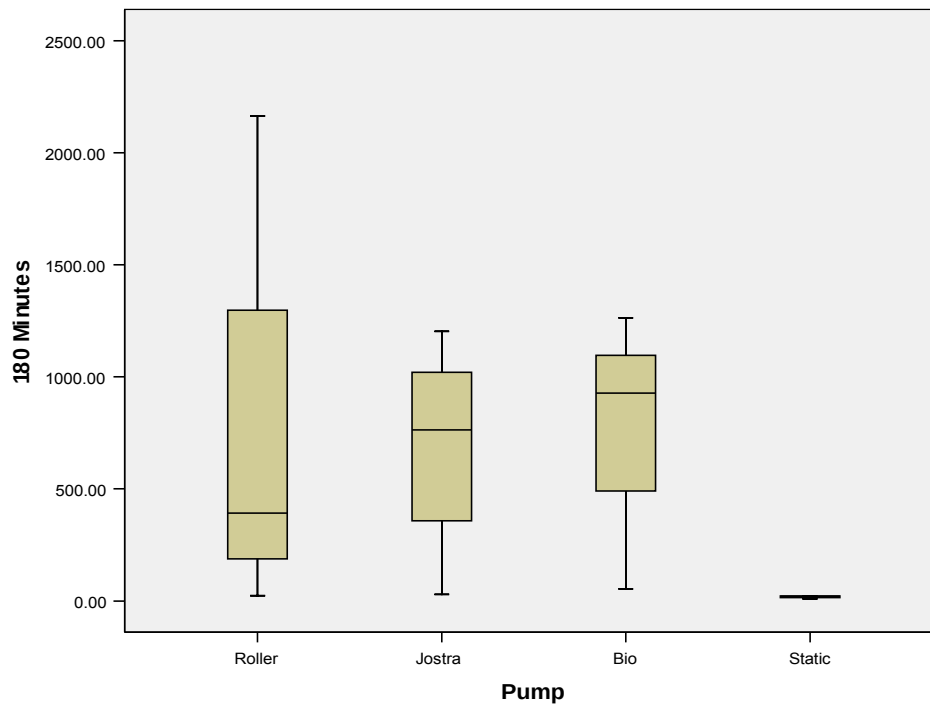


Attachment 3

Graph 4: Mean plasma free hemoglobin produced by each of 3 pumps and the static sample at time 120 minutes. Displayed with variance.

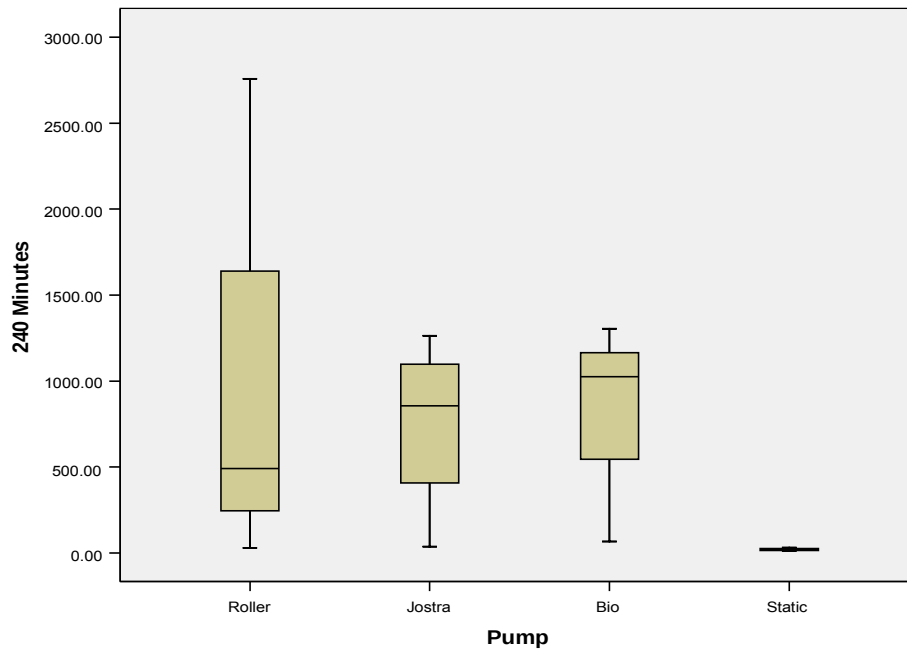


Graph 5: Mean plasma free hemoglobin produced by each of 3 pumps and the static sample at time 180 minutes. Displayed with variance.

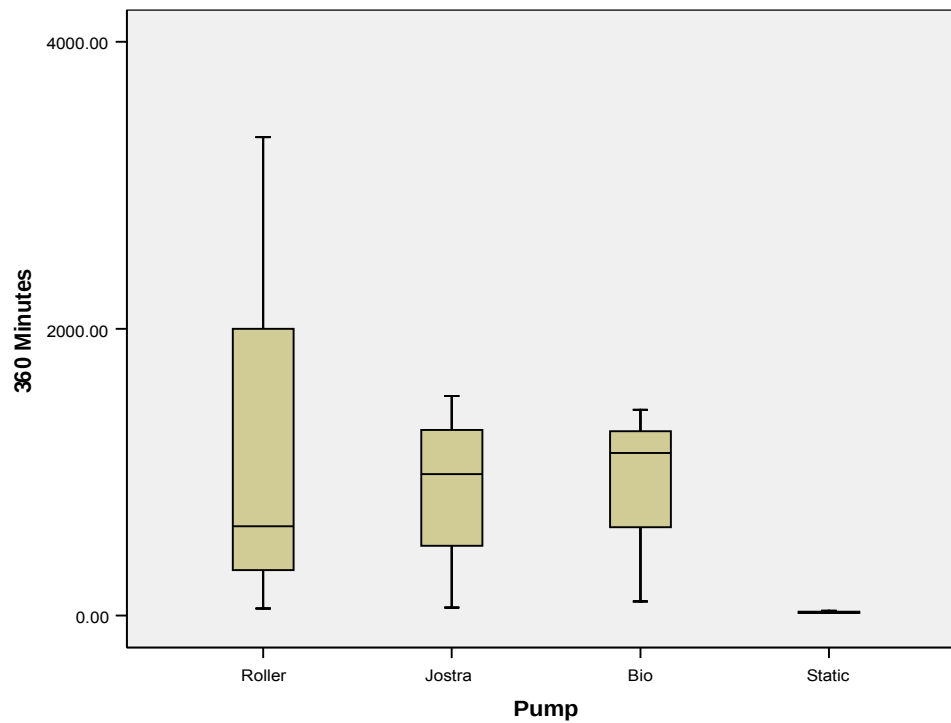


Attachment 3

Graph 6: Mean plasma free hemoglobin produced by each of 3 pumps and the static sample at time 240 minutes. Displayed with variance.



Graph 7: Mean plasma free hemoglobin produced by each of 3 pumps and the static sample at time 300 minutes. Displayed with variance.



Attachment 3

Discussion

Since ECMO is a therapy that serves a small population of critically ill patients, there is high morbidity and mortality associated with the procedure. As such, it is incumbent upon the caregivers to explore new equipment and procedures to identify components and methods that may improve the outcomes of their patients. We believe that the latest generation centrifugal pump, Jostra Rotaflow (Jostra Medizintechnik AG, Hirrlingen, Germany), can be used for neonatal ECMO and will deliver a superior result with greater safety than either of the two pumps that are currently employed most frequently for ECMO in the United States of America.

In our study we looked at the hemolysis of the Jostra Rotaflow compared to the hemolysis of a traditional roller head (Sarns 8000) and the Medtronic Biomedicus BP-50. We selected to start with a pilot study due to the expense of the equipment. We wanted to know whether the methods employed in this equipment study were feasible. However, due to the limited data set, the results must be examined with caution. Our interpretation was further complicated by large variance, particularly in the third run. We suspect this variance was due to the nature of the blood sample used in that run. A larger study would allow a run of this nature to be identified as the result of an unexpected trend, or as an outlier. With the size of the study, we are unable to identify these points as outliers with any certainty.

Although the limited data set and the variance do not allow for a statistically significant comparison, it is useful to note that the order of the means is consistent across all time periods, as demonstrated by graphs 1 – 7, and is in the direction that was anticipated with the roller head producing the smallest amount of hemolysis, the Rotaflow the next lowest level, and the Biomedicus pump producing the greatest hemolysis. These results are promising and suggest that the subject should be subjected to a more rigorous examination.

If continued study bears out these trends, it would be our suggestion that the Jostra Rotaflow would be appropriate for all ECMO patients except for the following cases:

1. Patients who have Congenital Diaphragmatic Hernias and will require a prolonged ECMO run.
2. Patients who have Pulmonary Hypoplasia and will require a prolonged ECMO run
3. Patients between 5 & 10 kg
4. Other patients for whom the ECMO run is presumed to last more than a week as determined by the attending ECMO physician.

These four types of cases would be conducted on a roller pump that at this point appears to have the lowest generation rate of plasma free hemoglobin.

Moving all other cases to utilizing the Jostra Rotaflow allows for the prime of the circuit to be minimized, thus minimizing the impact of foreign surface area on the blood components, and minimizing the patient's exposure to blood products. It also provides improved safety, and would facilitate transportation of a patient on ECMO.

Regarding the feasibility of the methods of the study, we found that the circuits and methods were acceptable and would suggest using them in a larger study. However, before undertaking a study that would provide larger numbers and incur greater expenses, a fresh, locally available blood source would need to be identified and procured.

Future studies

In October, the FDA approved a new generation of membrane oxygenator, specifically Jostra's Quadrox D, for use in the United States. In the educational material that accompanies the product, the manufacturer explains that the Quadrox D is comprised of two membranes, the first of which contains both a sheet of heat exchanger fibers and a sheet of diffusion oxygenation fibers. The second membrane is entirely oxygenation fibers. The oxygenation fiber being used is a true diffusion membrane that only allows diffusion of the gas molecules across the membrane in the direction of the concentration gradient. As such, it acts as a solid barrier, and plasma leaks will not occur. These characteristics will make the Quadrox D ideal for ECMO. It also has lower pressure requirements that the Scimed oxygenator and will be more compatible with the Rotaflow.

Future studies should investigate the plasma free hemoglobin generation of the three pumps, the roller head, the Jostra Rotaflow, and the Biomedicus BP-50 in combination with the

Attachment 3

newly released Quadrox D oxygenator to compare their hemolytic properties. This would provide research based evidence to back up the anecdotal evidence coming from international ECMO institutions that indicates that the pairing of the Rotaflow with the new generation of oxygenator will produce a sophisticated system which can improve the patient outcomes for ECMO.

Attachment 4

FY04 Integrated Medical Information Technology Systems (IMITS) Extra Corporeal Membrane Oxygenation (ECMO)

Strategic Plan for Short and Long-Term Implementation of Operational Plan By Dr. Larry Burgess, Principal Investigator April 2006

The Strategic Plan for Implementation of the IMITS ECMO program is outlined as follows:

Week 0 - 4	1. Identify military and civilian experts in Honolulu, who will participate in the planning process. 2. Identify UPMC and Air Force (local and WHMC) subject matter experts.
Week 5 - 20	1. Conduct planning sessions with subject matter experts to: a. Identify short and long-term equipment and personnel requirements for the Center. b. Identify the location(s) for the Center in Honolulu. c. Identify short and long-term equipment and personnel needs for the transport team d. Identify contracting requirements, memorandums of understanding between organizations. e. Develop a budget for implementation.
Week 21 - 40	1. On-going planning. 2. Conduct a retreat with subject matter experts to finalize the planning effort and preparation of documents for additional funding.
Week 41 - 52	1. Develop language for future contracts between organizations, which will lay the groundwork for legal documents. 2. Finalize budgets. 3. Submit proposals for additional funding. 4. Transition to implementation funding source.

Contact Information

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Attachment 5

FY04 IMITS Extra Corporeal Membrane Oxygenation (ECMO)

ECMO TRAINING

Prepared by Melissa Mattes, Clinical Director Perfusion Hawaii

I. ECMO Training - Completed

Mon, Dec. 12	Pump uncrating & setup
Tues, Dec. 13	Overview of new system Administrative overview
Wed, Dec. 14	Jostra Pump theory & practical
Thurs, Dec. 15	Jocap theory & practical
Fri, Dec. 16	Jocap administrative session
Tues, Jan. 3	Wet lab training Setting up the ECMO Alarms
Mon, Jan. 23	Wet lab training Emergency situations More on alarms & interactions with machines
Thurs, Feb. 2	ECMO Training Differences between neonatal & pediatric ECMO

II. Didactic Training

- ECMO books have been provided to the perfusionists for self guided study
- Pretests were given to the perfusionists for identification of areas of concentration for individual target.

Attachment 6

FY04 IMITS Extra Corporeal Membrane Oxygenation (ECMO) ECMO Research Lab Protocol Prepared by Melissa Mattes, Clinical Director Perfusion Hawaii

Preparing for an ECMO

Pump should be stored plugged in and Main (Circle with dot in it) should be on. Everything else is off. (This ensures you always have a fully charged pump– 27.4 V)

Call blood bank (X-) for ACT machine, disposables, and QC materials.

Setting up dry

- 1. Put the pump that you want to use on the console before turning P1 on.**
2. Turn on P1 (pump power)
3. Turn on M (monitor). Wait for self tests.
4. Silence alarms
5. Override alarms on monitor:
 - a. 4 pressures
 - b. Bubble detector
 - c. Level is not used
6. Fill heater cooler with 2 bottles of sterile water. Save 1 empty bottle for use in priming
7. Put oxygenator & heat exchanger (if using Sci-med) on brackets. Attach water lines, set water temp, and water leak test.
8. Put transducers in holders & connect to cables
9. Check limits on pressure module (Push limit button & adjust with turning knob. If you need to go from positive to negative, dial to zero & then use the dogear button to toggle to the other side of zero.)
10. To each pressure transducer, add a pigtail with stopcock to the other side of the transducer. Put a 10 cc syringe on the stopcock.
- 11.

	Pressure 1 Air chamber of better bladder	Pressure 2 Venous line pressure	Pressure 3 Pre-membrane Art. Pressure	Pressure 4 Post-membrane Art. Pressure
High limit	50	50	400	400
Low limit	-40	-20	0	0

12. Zero each pressures (Dog ear button and -0- button) for each pressure.
13. Put Better Bladder in it's holder.
14. **Test Better Bladder seals** as follows:
 - a. Isolate the BB from the rest of the circuit by clamping its inlet and outlet tubing.
 - b. Turn the stopcock connected to the air chamber (S1) to connect all three ports, pull on the 10 cc syringe until the pressure monitor indicates a negative pressure of approximately -100mmHg.

Attachment 6

- c. Turn the stopcock off to the syringe but open between the BB and the transducer. Maintain that negative pressure for at least 1 minute. Observe the pressure indicator to assure its reading does not drift upward (from a negative value towards atmosphere) from its initial pressure reading.
- d. A change in pressure indicates that air is leaking into the housing (not the blood path) of the BB. A slight initial increase in pressure may occur due to contraction of the components. If the pressure continues to drift upward, you have a leak.
- e. Ensure that all gas connections are tight and retest. If a leak persists, close the stopcock to the pressure transducer. If the pressure continues to increase, then replace the stopcocks or transducer.
- f. If there is no pressure loss, then one of the seals of the BB may be leaking. The BB must be replaced, and step 4 repeated.
- g. Remove the tubing clamps.
- h. Turn S1 to connect all its ports and, using the 10cc syringe, adjust the volume in the housing to assure that the bladder is full and the pressure is slightly negative (e.g. - 5mmHg). Close S1 to atmosphere but open between the pressure transducer and BB pressure port.

15. If using Rotaflow:

- a. Turn Rotaflow pump on.
- b. Push valve clamp off (verifies that there is a method of preventing retrograde flow)
- c. Check that mode switch is set to arterial.
 - i. Press “set” button until “mode” appears.
 - ii. Press “select” button until “art” appears.
 - iii. Press “set” button to select it.
- d. Check that the soft alarms are on. (This allows for servo-regulation of pump with pressures.)
- e. Calibrate flow: Turn flow dial to “0”. Push Zero button and hold for 3 seconds.
- f. If using the RotaFlow Drive Unit, turn off the Rotaflow console before attaching the Rotaflow drive unit cable to the RFD Master socket.
- g. **Note: Do not turn on RotaFlow if not primed. It can damage the ball bearing.**
- h. **Note: If using in stand-alone mode: Turn the Mains circuit-breaker (on the back of pump) to “on” position. Otherwise it will run off battery and then will stop when battery is drained.**

16. If using a roller head:

- a. Make sure P1 is off. Remove Rotaflow pump and put roller head on console.
- b. Check that mode switch is set to arterial.
 - i. Press “set” button until “mode” appears.
 - ii. Press “select” button until “art” appears.
 - iii. Press “set” button to select it.
- c. Set the tube size (in same manner as setting the mode)
- d. Check that the soft alarms are on. (This allows for servo-regulation of pump with pressures.)

- 17. Assemble circuit dry using schematic. Connect the bridge, but leave it open to air (off to the arterial side of the circuit).

Attachment 6

18. If using a roller pump & Sci-med. Leave the line out of the pump head until after CO₂ flushing.

CO₂ priming

19. Clamp the spike lines and below the bubble trap and make sure the venous side of the bridge is closed and the arterial side of the bridge is open to air and closed to the arterial side so that there is a place for the CO₂ to vent.
20. Attach the CO₂ to the top of the bubble trap and flush the circuit. Briefly open the venous clamp so the blood filter is flushed. Move the clamp from the outlet of the bubble trap to the inlet so the arterial line can flush too.
21. When the circuit is flushed, turn off the CO₂, close the port and move the clamp from the inlet of the bubble trap to the outlet of the rotaflow. Turn the stopcocks on the bridge off.

Crystalloid priming

22. If using a roller head, put the arterial boot in the rollers. Leave excess line on the arterial side so there is room for walking. **If pump alarms when loading tubing, turn off P1, finish tubing loading, close shims & head & turn back pump back on. Continue to look for the reason for failure. If failure continues please notify Mfg Field Service Representative.**
23. Spike the saline with the venous spike. Retrograde prime the blood filter & “Y” and clamp out.
24. For the rotaflow:
 - a. Raise the biohead above prime bag. Use opening the clamp & slowly lowering the biohead to prime the circuit in a smooth & slow manner.
 - b. Once past the biohead, clamp the line. Put a strip of gel (the nivea cream like gel) along the bottom of the outlet of the rotaflow. Put the rotaflow in it's holder & snap it closed.
25. For the roller head:
 - a. When priming the better bladder, turn upside down to facilitate air removal.
 - b. Lower the bag of prime, open up the last stopcock on the venous side proximal to the pump head. Using a clamp & raising the bag, slowly prime the circuit to this point. Close the stopcock.
26. Purge the venous line stopcocks
27. Fill the bridge from the venous side & close again.
28. Use the 10 cc syringes on top of the venous pressure transducers to fill the transducer lines.
29. Put the CDI line off the top of the bubble trap into the empty sterile water bottle. Open the stopcock.
30. Move the clamp to under the bubble trap and continue to prime.
31. For the rotaflow:
 - a. Use the stopcock on top of the bubble trap to control the speed and continue to prime with gravity.
 - b. As soon as the prime is past pressure transducer 3, use the syringe on top of the transducer to prime the line.
32. For the roller head:

Attachment 6

- a. Make sure the top of the bubble trap is open and then pump through the head and set the occlusion on both rollers. Use the lever on the side of the central pivot of the rollerhead to allow the occlusion to be set. Press down & forward to unlock. Press back & up to lock back in place.
 - b. As soon as the prime is past pressure transducer 3, use the syringe on top of the transducer to prime the line.
 - c. Pump slowly through the oxygenator. Opening and closing the stopcock on top of the bubble trap to maintain a pressure in the arterial line of 200 mm Hg.
 - d. When using the Sci-med & heat exchanger, turn the heat exchanger upside down to facilitate priming. Once the air is past it should be returned to the position of inflow at the top, and outflow from the bottom that makes it function as a bubble trap.
33. Open stopcocks on the oxygenator to purge air.
 34. Turn off the CDI line & connect to the venous side.
 35. Release the clamp on the line below the bubble trap, unclamp and open the arterial spike & prime the arterial line.
 36. Spike the arterial line into another opening of the priming bag and recirculate.
 37. Purge air from the arterial stopcocks.
 38. Recirculate & de-air the system.
 39. Add 10 cc of 25% albumin & recirculate.

Blood Prime

40. Run a blood gas on the unit of cells to determine the hematocrit.
41. If the hematocrit is less than 42 add to each bag of cells (in this order):
 - a. 100 units heparin diluted in Normal saline to 1cc
 - b. 40 cc 25% albumin
 - c. 15 mEq of sodium bicarbonate
 - d. 300 mg of Calcium gluconate (**making sure that you add the heparin before the calcium.**)
42. If the hematocrit is 42 or greater, add to the bag of cells:
 - a. 100 units heparin diluted in Normal saline to 1cc
 - b. 40 cc 25% albumin
 - c. 50 cc Tham
 - d. 300 mg of Calcium gluconate (**making sure that you add the heparin before the calcium.**)
43. Spike the first packed cell with the venous line that has the filter in it. Clamp the other one out.
44. Turn on the pump & fill the circuit with blood, chasing the crystalloid into the original priming bag. Watch your blood so that you don't introduce air into the blood filter. Change to the second bag of cells when the first is nearly empty.
45. When all of the crystalloid has been chased into the crystalloid bag (plus the light pink mix - - to optimize hematocrit), clamp the arterial spike in the crystalloid bag & put the second arterial spike into the blood bag. Recirculate just a few seconds until all the blood has gone through the filter once. Then change the venous spikes so that the prime is not being recirculated through the blood filter.

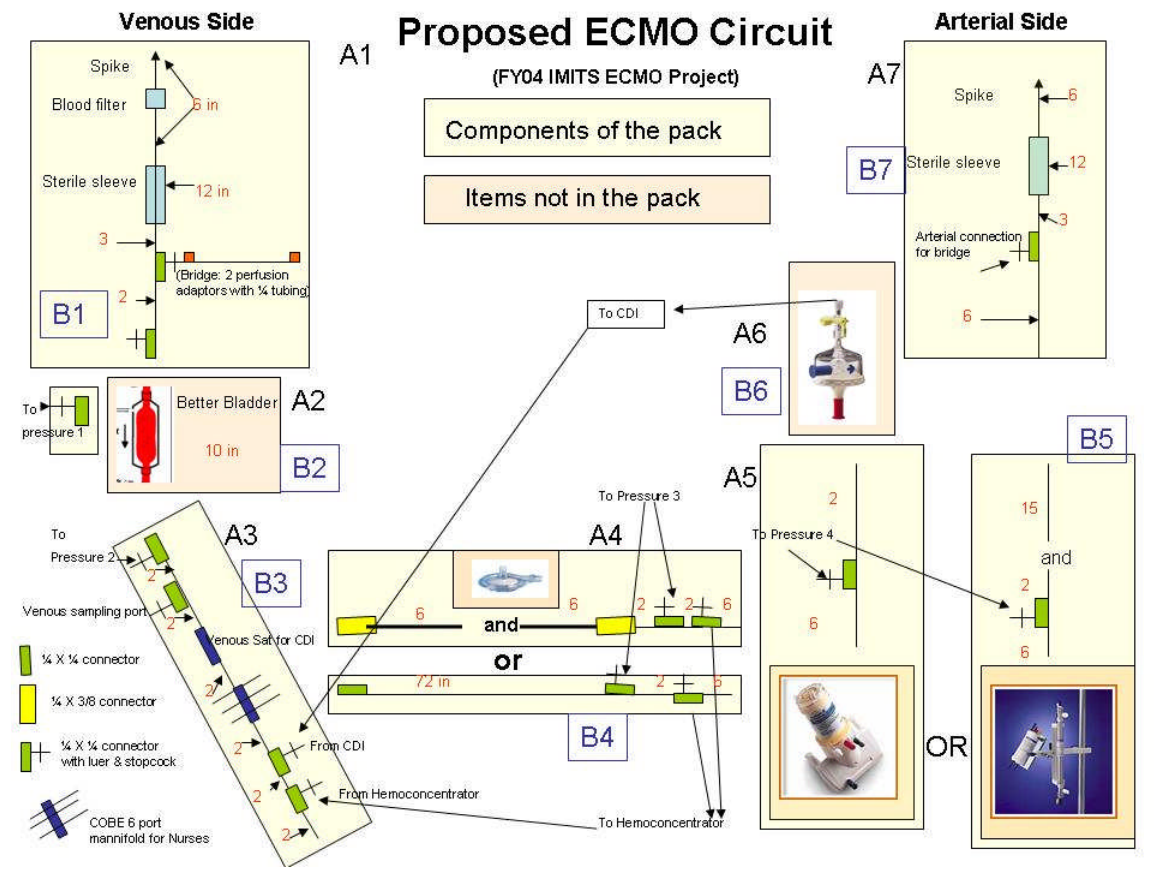
Attachment 6

46. Recirculate. Blow off extra CO₂ by turning on the sweep to 0.5 L and turning the FiO₂ to 0.21. Recirculate with the gas on for 5 minutes. Turn off the gas and check the prime blood gas.
47. Look at the baby's last gas.
48. Check with the attending neonatologist regarding what he/she would like the prime gas to look like. If there is no guidance,
 - a. Prime gas should be: pH: 7.40 – 7.60 pCO₂: 25 – 45 pO₂: 250 – 350
 - b. CO₂ with in this range, but matched as closely as possible to the baby's CO₂.
49. Manipulate the blood gas by:
 - a. Adding 8.4% bicarb to adjust base deficit & pH of prime.
 - b. Recirculating with a sweep of 0.5 L and FiO₂ of 0.21 (with or without CO₂ as needed) to adjust the pCO₂ until the blood gas meets the assigned criteria.
50. To add pressure, recirculate through the bridge with the bags clamped out. Open the clamp on the venous line & push in as much blood as it takes to attain the pressure that is wanted. Check with neonatologist about pressure. 10 mm above the patient's pressure should keep the baby from dropping after initiation.
51. Clamp above the sterile sleeves and below (just on the patient side of the bridge). Assist the surgical team in cutting the lines making sure they cut on the end toward the priming bag.
52. Have someone draw up excess blood in priming bags to have ready to add to circuit if volume is needed.
53. When connected open arterial and venous lines, make sure bridge is closed.

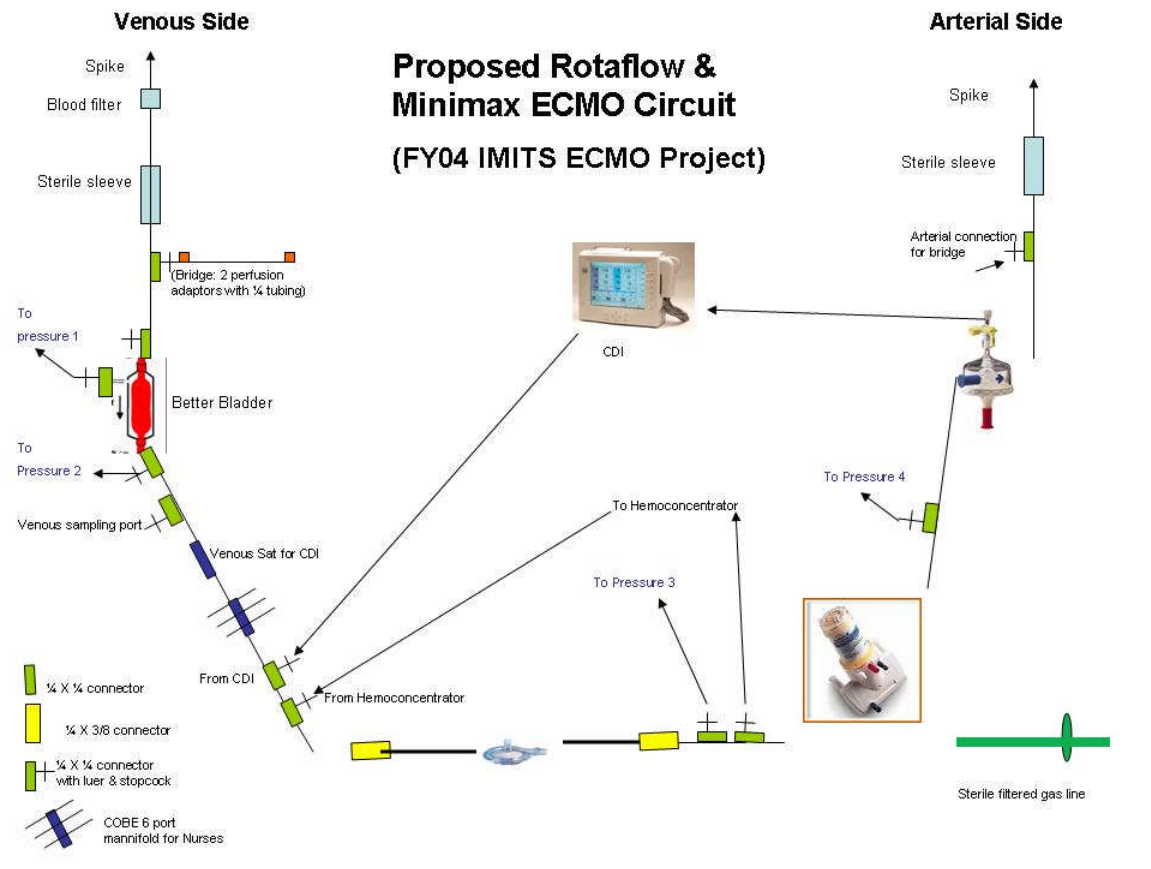
Initiation of ECMO

54. Verify heparin has been given.
 - a. Initial dose: 40 units/kg to achieve an ACT>300
 - b. Maintenance Dose: 25 units/kg/hr to achieve ACT between 180 – 200
 - c. Get ACT running
55. Gas Flow at 0.5 LPM with FiO₂ @ 0.7 – 0.8
56. Blend in 0.02 LPM of CO₂ (Range on ECMO is 0.01 – 0.04)
57. Start blood flow at 20 cc/kg/min
58. Increase flow slowly to max flow
 - a. VV = 150 cc/kg/min
 - b. VA = 120 cc/kg/min
 - c. VA cardiac = Discuss with neonatologist

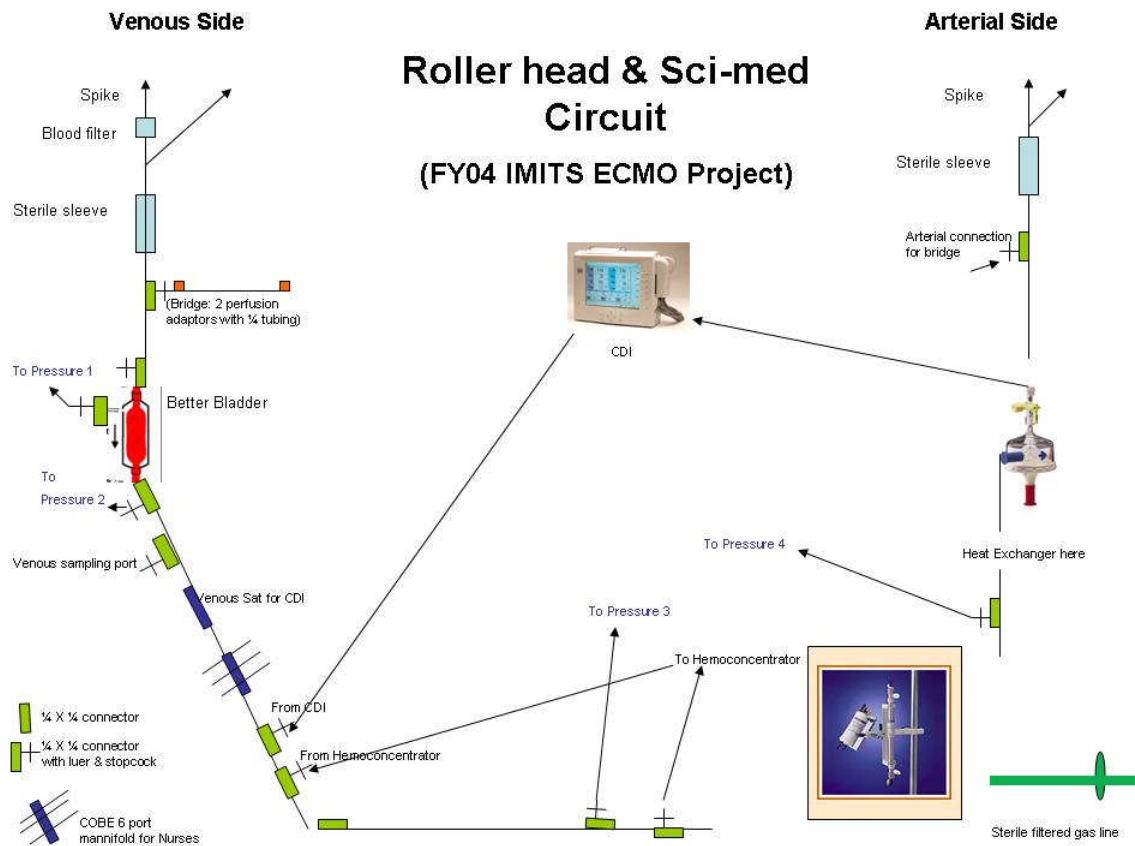
Attachment 7



Attachment 8



Attachment 9



Appendix 3



IMITS Center

To: John W. Marsh, Maj, USAF, MSC, FACHE
Deputy Chief, Management and Program Support Division, AF/SGRM
Office of the Assistant Surgeon General, Modernization
5201 Leesburg Pike
Falls Church VA 22041

From: Jeananne Nicholls
Associate Director of Operations
University of Pittsburgh Medical Center
200 Lothrop Street
Quantum 1 Building, Suite 079.1
Pittsburgh, Pa 15232

Date: May 30, 2007

Re: FY04 IMITS – Advanced Simulation for Medical Education and Training in the Pacific Rim Project (Cooperative Agreement DAMD1703-2-0017)

Major Marsh,

A detailed evaluation of the University of Hawaii's (UH) simulation requirements was conducted by members of the UH, UPMC, and University of Pittsburgh WISER Simulation Institute. The project team was able to develop a collaborative model to assist in the development of the UH simulation center. The collaborative team developed Memorandum of Agreements (MOAs) and licensing agreements to share curriculum and technologies. This collaborative process assisted in the design of the UH simulation center's hardware and software remotely hosted solution at the WISER Institute. The project team was able to use the WISER Institute's SIMS application to effectively create a solution to deliver Internet based simulation and non-simulation training to UH educators and students. This solution is also compatible with the programs currently developed at the University of Pittsburgh WISER Simulation Institute. Upon completion of the solution, UH was able to requisition the required simulator equipment to complete the project. The simulation center was initially implemented/opened in October 2006. The results of the October implementation as well as the courses available at UH are outlined in Attachments 5-7.

During this collaborative process, the WISER Simulation Institute's members were able to identify existing partnerships between Asia and UH in order to increase the exposure of the WISER Institute, medical simulation, and medical simulation usage in the military to these regions. UPMC and University of Pittsburgh WISER Simulation Institute are continuing to develop these partnerships to increase the UPMC WISER Institute exposure in Asia. Several members of the UPMC and University of Pittsburgh WISER Simulation Institute are continually invited to participate and present in the Annual Asia Pacific Military Medicine Conferences held in the PACIFIC RIM every May.

Key research accomplishments:

- Assist and developing course goals, objectives, curriculum, and education tools with the University of Hawaii for simulation education
- Establish contacts to conduct an outreach program for Asia and the Pacific Rim



- Attend several Asia-Pacific Military Medicine Conference (APMMC) conferences
- Establish a simulation center at the University of Hawaii (SimTiki)
- Integrate the WISER Institute's SIMS application with the SimTiki simulation center
- Integrate several University of Hawaii medical course onto the SIMS delivery platform
- Completed the final report for submission to SGR

At this time, UPMC has accomplished all required deliverables for the FY04 IMITS – Advanced Simulation for Medical Education and Training in the Pacific Rim Project (Cooperative Agreement DAMD1703-2-0017). All of the attached documents fulfill the remaining deliverable requirements for this project.

The following deliverables have been provided:

1. Simulation Information Management System (SIMS) User Guide.
2. The agenda for the APMMC conference where WISER initiated exposure to the Asian-Pacific Rim military and civilian healthcare systems.
3. The completed SimTiki set-up information template required to integrate the SimTiki requirements into the SIMS application.
4. A completed SimTiki course development template required to integrate the specific course into the SIMS application.
5. SimTiki course listing effective the “unofficial” opening in October 2006. Additional courses have been added since October 2006 and the “official” SimTiki opening in April 2007. Additional courses are outline in Attachment 6.
6. Screenshots from the SimTiki (SIMS) Website.
7. The SimTiki October 2006 go-live trip report.

UPMC would like to request the official closure of this project. It was recommended that you be informed and approve this decision. Please indicate your concurrence with completion of these deliverables.

Feel free to contact me as needed.

Sincerely,

Jeananne Nicholls
Associate Director of Operations

Attachments

- (1) - SIMS User Guide
- (2) - Agenda APMMC PACRIM Outreach
- (3) - SimTiki Set-Up Information
- (4) - SimTiki Course Development Information
- (5) - SimTiki Course List
- (6) - SimTiki Website Pictures
- (7) - SimTiki Go-Live Trip Report

cc:

Tess Ellis

Aaron Yanuzo

Attachment 1

SIMS

User Guide

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Introduction to SIMS

The Simulation Information Management System (SIMS) is a software tool built specifically to help Health Care Simulation Centers efficiently manage their daily operations. Operational tasks performed using SIMS include:

- creating and maintaining user accounts
- maintaining the course calendar
- reviewing course materials
- requesting permission to take a course
- granting access to a course
- scheduling classes
- enrolling participants in classes
- activating quizzes during a class session
- participating in courses
- completing quizzes, surveys, and evaluations
- reviewing course participant progress
- uploading simulation session results

- reviewing evaluations about the facilitator, the course, and the Participant
- reviewing statistical reports

The software's foundation is based on best practices in the simulation-based education field over the last decade. Some of the SIMS courses integrate with simulation software and products engineered by Laerdal Medical Corporation, the manufacturer of SimMan™, AirMan™, Resusci® Anne and other simulation-based training manikins.

SIMS employs defined roles and responsibilities to control various administrative processes. These roles provide data security, division of responsibility, process workflows, and ensure that no tasks are left undone. Identify your role in SIMS by reading the descriptions in ***SIMS User Roles*** on page 3.

SIMS users can access the tool from any computer with an Internet connection either in the center, in their office, or in their home. The computer being used to access SIMS must have Internet Explorer version 6 (IE6) loaded.

SIMS automated alert capabilities send email messages

- when classes are scheduled or tasks are incomplete.
- when access to a course is requested.
- with a request to add a class to the schedule.

In addition to the descriptions of the roles and responsibilities, this chapter contains instructions to get you started using SIMS including how to obtain a user account, how to login to SIMS, and how to review the course descriptions.

SIMS User Roles

Any visitor to the Health Care Simulation Center may browse the SIMS course catalog and review descriptions of the courses offered by the center. The center employees and those wishing to take classes at the center must create SIMS user accounts.

Various users perform tasks with SIMS according to the role that they hold in the Health Care Simulation Center. The roles interact to enable courses to be scheduled and taught and session results to be captured.

The following sections describe the SIMS user roles. Find instructions to perform the tasks for each role in the chapter dedicated to that role.

Participant

The Participant is a nurse, medical student, paramedic, emergency medical technician (EMT), emergency room doctor, or other health care professional who enrolls in courses in the Health Care Simulation Center. This person gains access to the course materials by completing a request form that is sent to the Course Director.

The Participant receives a course confirmation message when added to the course and is then able to review course materials. If the Participant has also been enrolled in a class, the class materials (quizzes, surveys, and evaluations) are available as well. Otherwise, the Participant completes a request form for class enrollment, which is also sent to the Course Director. Optionally, the Participant can send an enrollment request to the Facilitator.

SIMS tracks the Participant's progress and visually identifies what tasks need to be accomplished for each class to be considered complete. On a preset time schedule, SIMS also generates an email message to remind the Participant, if necessary, to complete outstanding tasks for a class.

Participants can view the course materials for each class that they are enrolled in — even those classes that are complete.

Facilitator

The Facilitator teaches classes for courses that are offered with SIMS. Facilitators are assigned to courses by the Course Director. Sometimes, the Course Director also assigns the Facilitator to teach a specific class. The Facilitator can also request a new class be added to the course schedule.

The Facilitator manages the Participants in the class by checking class enrollment, adding a Participant to a class (if required), switching participants between classes to balance the class load, and reviewing the Participant's progress in the class.

Course Director and Director Proxy

The Course Director manages the courses in the simulation center. The Course Director can also identify how many classes should be offered, how often classes should be scheduled for the course, and request that classes be added to the course schedule.

Requests from Participants and Facilitators who wish to review the course materials are sent to the Course Director who approves the request and provides the requestor access to the course. The Course Director determines which Facilitators should teach each class and assigns the Facilitator to the class. In addition, the Course Director can enroll Participants who have requested access to the course in a class or the Course Director can request that the Facilitator provide class enrollments.

The Course Director also reviews course evaluations completed by the Participant as well as the results of the Participant's simulation session (if included in the course).

The Course Director Proxy performs all tasks identified above at the direction of the Course Director and has all of the same SIMS privileges.

Site Director and Director Proxy

The Site Director manages the day-to-day workings of the simulation center. This includes identifying which courses should be taught and either acquiring or developing the courses. The Site Director assigns one or more Course Directors to manage the courses once they are a part of the center's core curriculum.

The Site Director can perform all tasks identified for the Course Director. SIMS provides special reports available only to the Site Director.

The Site Director Proxy performs all tasks identified above at the direction of the Site Director and has all of the same SIMS privileges.

Class Maintainer

The Class Maintainer performs class scheduling and class administrative functions. The Class Maintainer receives requests from the Course Director or the Facilitator to add classes to the course schedule. The Class Maintainer also manages the Participant check-in list for the class.

Account Maintainer

The Account Maintainer administers the SIMS user accounts. Some of the tasks performed by the Account Maintainer are automated in SIMS, such as creating an account, resetting a password, or changing non-system-critical account information.

How Roles Interact

The following process flows depict the interaction between the SIMS user roles. In the first example, once a course is added to the center curriculum, the Site Director assigns a Course Director to manage the course. It is the responsibility of the Course Director to identify Facilitators, and enroll Participants.

When a new SIMS user account is created, the Account Maintainer sets the access privileges for the user according to the role the user fulfills.

SIMS Support Roles

The roles identified in this section are required by SIMS and are performed in support of the SIMS software tool.

Course Author

The Course Author is the person who creates the course and authors the course materials. This person is generally a specialist in the area of medicine being taught in the course.

The Course Author works with the Course Maintainer to have course materials added to SIMS and made available to the Facilitators and Participants.

Site Technology Team

The Site Technology Team acts as Tier 1 support for all users in the Health Care Simulation Center. They field questions and resolve simple issues. They have Account Maintainer and Class Maintainer access to the tasks performed by those roles. Unresolved issues are escalated to the SimMedical Technology Team.

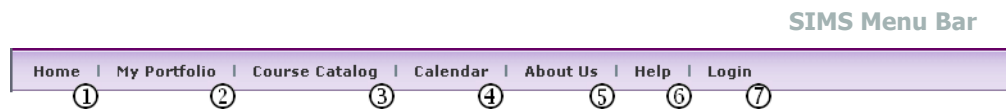
SIMS Guided Tour

Any visitor to the Health Care Simulation Center can browse the SIMS course offerings and review the current course calendar. You will view several different screens to locate the information. Find instructions to use SIMS to view course information in the following sections.

About the SIMS Interface

The Simulation Information Management System (SIMS) is a web-based tool. You access SIMS using the Internet Explorer browser and the web address provided by your Health Care Center.

The SIMS Home page contains information about the Health Care Simulation Center. You access course information and the course calendar using the SIMS menu bar as depicted in the following graphic.



Select a menu to perform the following actions:

	Menu	Action
①	Home	Returns to the Health Care Simulation Center information page from any SIMS page.
②	My Portfolio	Opens the My Portfolio page for those who have a SIMS account or displays the login screen if you have not yet logged into SIMS. Find instructions to use the My Portfolio page in <i>How to View My Courses and Access the Class Portfolio Page</i> on page 28.
③	Curriculum	Opens the Course Catalog page.
④	Calendar	Opens the Course Calendar page.

	Menu	Action
⑤	About Us	Opens additional informational pages that are specific to the Health Care Simulation Center.
⑥	Help	Opens an online help pages containing information about using SIMS.
⑦	Login	Displays the SIMS login page. You can also request an account from this page. Find login instructions in <i>How to Login to SIMS</i> on page 19.

How to Use the Course Calendar

The course calendar displays all classes for each course taught in the Health Care Simulation Center. You can choose to view a list of all classes for one day, one week, or one month as well as see the details of any course.

Viewing the descriptions of courses offered in the Simulation Center does not required you to have a SIMS user account. However, if you wish to view the course materials, you will need to request an account.

Complete the following steps to view the course calendar...

Procedure

- 1 Select the Calendar menu.

The Calendar page opens.

Calendar Page

Home My Portfolio Course Catalog Calendar About Us Help Login						
Calendar						
Today		Show Sessions	T-C	<< < June 2005 > >>		Day Week 2 Weeks Month
MON	TUE	WED	THU	FRI	SAT	SUN
6 STRATUS CTT 9:00- 10:00 STRATUS- 1	7 STRATUS DAM ANES FAC 6:00- 7:00 STRATUS-1 STRATUS CTT 6:00- 7:00 STRATUS-2	8 STRATUS CTT 8:00- 8:00- 8:00 STRATUS-2 STRATUS DAM ANES FAC 11:00- 12:00 STRATUS- 2	9 STRATUS CTT 6:00- 7:00 STRATUS-2	10 STRATUS DAM ANES FAC 1:00- 5:00 STRATUS-1	11	12

- 2** Change the information shown on the Calendar page.

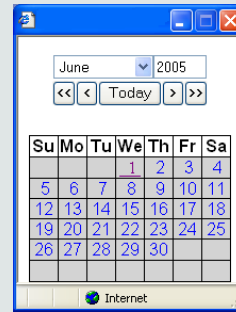
Use the links above the calendar to select different calendar views, including:

Link	Action
Today	Displays all course offerings for the current date.
Show Sessions	Displays all meeting and conference rooms used for each class.
T-C	Determines the order that course information is displayed in the calendar. When the link is shown as T-C, the classes are displayed using the time and then the course name. The opposite is C-T, which is course name and then time. The inverse setting is shown in the menu.
<<	Changes the calendar display to show other timeframes. The increment changes according to what is in view as follows: If the calendar shows one day, selecting this command will display the same week day, one week earlier. If the calendar shows one week or two weeks, selecting this command will display the same week(s) one month earlier. If the calendar shows one month, selecting this command will display the same month one year earlier.
<	Changes the calendar display to show other previous timeframes. The increment changes according to what is in view as follows: If the calendar shows one day, selecting this command will display one day earlier. If the calendar shows one week or two weeks, selecting this command will display the same week(s) two weeks earlier. If the calendar shows one month, selecting this command will display one month earlier.

Link	Action
Month Year	Changes the calendar display to the Month and Year selected in the menu. The menu contains one calendar year of choices.
>	Changes the calendar display to show other previous timeframes. The increment changes according to what is in view as follows: If the calendar shows one day, selecting this command will display the same week day one day ahead. If the calendar shows one week or two weeks, selecting this command will display the same week(s) two weeks ahead. If the calendar shows one month, selecting this command will display one month ahead.
>>	Changes the calendar display to show other timeframes. The increment changes according to what is in view as follows: If the calendar shows one day, selecting this command will display the same week day ahead one week. If the calendar shows one week or two weeks, selecting this command will display the same week(s) ahead one month. If the calendar shows one month, selecting this command will display the same month one year ahead.
Day	Displays courses scheduled for the current date, or the date selected in the popup calendar.
Week	Displays courses for the week containing the current date.
2-Week	Displays courses for two weeks. One week contains the current date.

Link	Action
Month	Displays courses for one calendar month.
Calendar icon	Opens a window containing an interactive calendar. Select a date in the calendar to be used to the focus date for courses in the main window calendar.

Calendar Popup



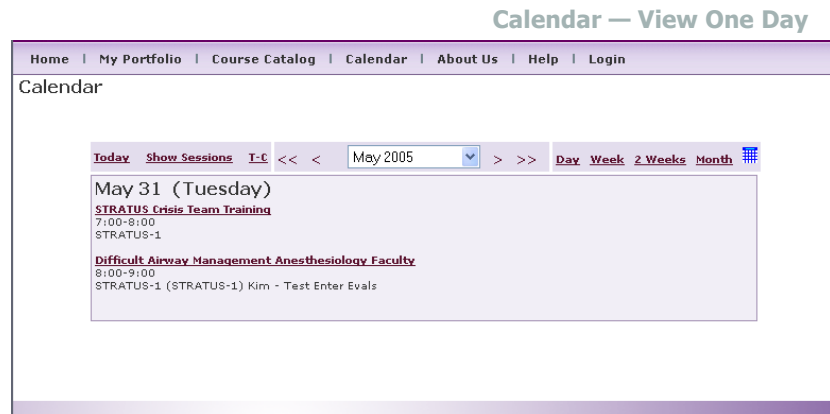
- 3 Select a course name on the calendar.

The View Class page opens and provides additional details about the class including a link to the course description, comments about the course, and a list of all rooms to be used for the course.

View Class Page

Home	My Portfolio	Course Catalog	Calendar	About Us	Help	Login
View Class						
Course: Difficult Airway Management Anesthesiology Faculty						
Class Date: 5/31/2005						
Initial Meeting Room: STRATUS Test Room 1						
Time: 08:00 AM - 09:00 AM						
Comments: Kim - Test Enter Evals						
Session Rooms: STRATUS-1						

You can select the course date to open a page to view all courses offered on that date, as depicted in the following graphic.



Next Steps

After you review the course dates, you may choose to take classes. You must first create a SIMS user account. The SIMS account logs the results of your activities using SIMS for simulation-based education.

Once your account is created, you can request access to a course or request to be enrolled in a class. Participants will find instructions to request course access in ***How to Request Course Access*** on page 25 and will find instructions to complete the Request Class Assignment form in ***How to Request Class Assignments*** on page 30. Facilitator instructions to request course access are in ***How to Request Course Access*** on page 42.

How to View Course Descriptions

SIMS allows visitors to the Health Care Simulation Center to view information about the various course offerings. The Course Catalog displays a list of all courses. From the Course Catalog, you can open a page to read a brief description of the course.

Complete the following steps to view course information...

Procedure

- 1 Select the Curriculum menu.

The Course Catalog page opens.

Course Catalog Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Course Catalog

These are the courses offered by STRATUS. They are listed in alphabetical order. Click on a course name below to find more information on that course. You can search for specific classes which will match the course name, abbreviation or description. You can also sort by specific criteria such as sponsoring department or type of students in the course by selecting one of the links to the left.

TOOLS	COURSES
Search for Course	Difficult Airway Management Anesthesiology Faculty
All Courses	Difficult Airway Management Anesthesiology Residents
Course by [Dept.]	Moderate Sedation for Non-Anesthesia Care Givers - Adult
Course by [Student]	STRATUS Central Venous Cannulation Training
CME Courses	STRATUS Crisis Team Training

You can choose which courses are displayed in the Course Catalog using the links in the Tools group. The following links are available:

- Search for Course — opens a page containing a search field. Enter keywords in this field to be used to find courses by name or by description.
- All Courses — displays all courses listed in alphabetical order.
- Course by Department — displays all courses for one department (for example, Anesthesiology).
- Course by Student — displays all courses according to the student profile (for example, Residents).
- CME Courses — displays accredited courses that can be taken for continuing medical education (CME).

- 2** Select the course by clicking on the course name.

The View a Course page opens.

View a Course Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Name: Air Medical Crew Training
 Abbreviation: MED CREW TRAIN
 Director: Test Director,
 Description: This course is designed to train air flight crews in difficult airway management and aspects of medical decision making in-flight. In part one of this course, participants gain competencies in difficult airway management techniques and devices. In the second part of this course, medical emergencies are reviewed and participants practice identifying and treating these emergencies using the evidence based guidelines and simulation.
 Facilitators: Test Facilitator;

Participants: [Click here](#) to access, or request access to, the participant course material for this course.
 Facilitators: [Click here](#) to access, or request access to, the facilitator course material for this course.

Note: You must be logged into STRATUS to access a course. When you select one of the links above, if you do not have a STRATUS user account, you will be presented with a Create Account form. You can request access to the course materials after the form is completed.

The View a Course page contains:

- the course description
- the Course Director's name
- the Facilitator's name
- a link to view the course material for Participants
- a link to view the course material for Facilitators.

- 3** Request access to the course materials.

This is the first step to perform to take a class using SIMS. Participants or Facilitators can request access to the course materials by selecting the appropriate "Click here to access, or request access to, the [---] materials for this course." link. When you select a link, SIMS presents the SIMS Login page.

- If you have a SIMS account and have been granted permission to access the course, enter your username and password in the appropriate fields. SIMS displays the course materials.
- If you have a SIMS account, but have not been given permission to view the course materials, SIMS presents the Request Course Access page. Participants will find instructions to complete this form in **How to Request Course Access** on page 25. Facilitators' instructions are in **How to Request Course Access** on page 42.

- If you do not have a SIMS account, select the Request an Account link and follow the instructions in **How to Create An Account** on page 17 to create an account.

Note After you have created an account, you must be given permission to access the course materials. SIMS displays the Request Course Access form for you to complete. You will receive an email after permission has been granted that contains a link to the course materials.

Next Steps

After you have reviewed all course descriptions, create an account to enable you to view the course materials and to request access to a course. Find instructions to create an account in the following section.

How to Create An Account

You must create a SIMS account to perform tasks with SIMS beyond viewing the classes available in the Health Care Simulation Center. The tasks you are able to perform using SIMS are detailed in each of the following chapters according to the role that you perform.

Complete the following steps to create a SIMS user account...

Procedure

- 1 From the SIMS Menu, select either the My Portfolio or Login menu items.

SIMS displays the Login page.

SIMS Login Page

The screenshot displays the SIMS Login Page. At the top is a navigation bar with links: Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login. The main content area is divided into two columns. The left column, titled 'Educational Portfolio LOGIN SCREEN', contains a login form with fields for 'Enter your username (login id)' and 'Enter your password (case sensitive)', a 'Login' button, and a 'Privacy Policy' link. Below the form is a link for 'Lost or Forgotten Username or Password?' with a note and a 'click here' link. The right column, titled 'Create a New Educational Portfolio ACCOUNT REQUEST OVERVIEW', contains text explaining the account requirement and a list of information needed for a new account: Name, Date of birth, Social Security number, Health System login name, and current email address. A red note at the bottom right states: 'You will receive a confirmation email when your account has been set up. Please note: this account is separate from your Health Care System user account.'

- 2 Select the Request an Account link.

The Request an Account link is located in the explanatory text beneath the Create a New Educational Portfolio heading on the Login page.

SIMS displays the Create Account page.

Create Account Page

[Home](#) | [My Portfolio](#) | [Course Catalog](#) | [Calendar](#) | [About Us](#) | [Help](#) | [Login](#)

Create Account

All information below is required, unless otherwise indicated.
Please complete the form and click Create Account at the bottom of the page.

CONTACT INFORMATION

First Name:

Middle Name: (Optional)

Last Name:

Email Address:

Confirm Email Address:

Telephone Number:

ACCOUNT INFORMATION

Desired Login Name: [CHECK AVAILABILITY](#)

Password: (minimum length of 6 characters)

Confirm Password:

Last Five Digits Of SSN (Social Security Number): [More Information](#)

Date Of Birth: (MM/DD/YYYY)

Create Account

- 3 Enter your personal information in the fields on this form.

Complete the Create Account form as follows:

Field	Description
First Name:	Enter your first name as you wish for it to be displayed in registration materials, reports, etc. generated by SIMS
Middle Name:	Optionally, enter your middle name.
Last Name:	Enter your last name.
Email Address:	Enter the email address to be used by SIMS to send confirmations and notifications.
Confirm Email Address:	Retype the email address entered previously.
Telephone Number:	Enter a telephone number where you can be reached during business hours.
Desired Login Name:	Enter the name you will use to login to SIMS. This account is different from your Health Care account.
Password:	Enter a password for the user account. The password must be a minimum of six characters.

Field	Description
Confirm Password:	Retype the password entered previously.
Last Five Digits of SSN:	Enter the last five digits of your social security name. These numbers will be used if you forget your password.
Date of Birth:	Enter your date of birth in MM/DD/YYYY format.

- 4** Verify the availability of your desired user name.

Select the Check Availability link to verify that the name you have entered is not being used by anyone else. SIMS prompts you to change the name if a conflict is found.

- 5** Read about the reason for entering your partial Social Security number.

Select the More Information link to open a window containing usage information for your Social Security number.

Next Steps

After you have created an account, Participants and Facilitators can login to SIMS and perform other tasks such as requesting access to a course, viewing course materials, and taking classes.

Other users can perform tasks for the roles identified in the chapters that follow.

How to Login to SIMS

SIMS displays the Login page when you select any link requiring you to have an account. Enter the user name and password you identified when you created your SIMS account.

Complete the following steps to login to SIMS...

Procedure

- 1 From the Main menu, select My Portfolio or Login.

SIMS displays the Login page.

SIMS Login Page

- 2 Enter your user name and password.
- 3 Select the Login button.

Enter the login name and password you identified in the Create Account form.

SIMS opens the My Portfolio page. From this page, you can access all tasks for your user role.

My Portfolio Page

Note If you enter a wrong username or password, SIMS displays a LOGIN FAILURE message next to the username entry box.

Next Steps

Review the chapter in this User Guide that applies to your role in the Health Care Simulation Center. The roles are identified in **SIMS User Roles** on page 3.

How to Edit Your Account

Once you have created your account, you can edit the account information to correct typographical errors, enter a new email address or change your password. You use the Edit an Account page to accomplish these tasks.

Complete the following steps to edit a user account:

Procedure

- 1 From the My Portfolio page, select Account Information.

The Edit Account Information page opens.

- 2 Edit your personal information in the fields on this form.

You will notice that the username and birthdate fields cannot be edited and your Social Security number digits are not shown. These fields are used to secure your account and can only be modified by an Account Maintainer.

Edit the remaining fields as follows:

Field	Description
First Name:	Enter your first name as you wish for it to be displayed in registration materials, reports, etc. generated by SIMS
Middle Name:	Optionally, enter your middle name.
Last Name:	Enter your last name.

Field	Description
Email Address:	Enter a new or correct the existing email address to be used by SIMS to send confirmations and notifications.
Confirm Email Address:	Retype the email address entered previously.
Telephone Number:	Enter a telephone number where you can be reached during business hours.
New Password:	Enter a new password for the user account. The password must be a minimum of six characters.
Confirm New Password:	Retype the password entered previously.

- 3 Enter existing password.
- 4 Select the Update Account button.
- 5 Select My Portfolio on the menu bar to return to the My Portfolio page.

SIMS requires you enter your existing password to complete the account modification activity.

SIMS updates your user account with the new information you have provided and displays an Update Successful message on the Edit Account Information page.

2 Tasks for the Participant

Participants use SIMS to view course materials and perform course-related tasks as you participate in classes. SIMS stores the results of your participation in every class that you have permission to attend.

You may take more than one class for each course. This allows you to keep your skills honed for procedures that you infrequently perform or to stay current with best medical practice.

You gain access to the course using the commands under the General Utilities section of the My Portfolio page. The commands are shown in the following graphic.

My Portfolio: Participant

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

My Portfolio

ACCOUNT: MARIA STEVENS

TIMEFRAME

« June 2005 »

Su	Mo	Tu	We	Th	Fr	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

« June 2005 »

Preset Timeframes:

Today

This Week

This Month

This Academic Year

All

Search

MY PORTFOLIO

MY COURSES

Welcome to the Simulation Information Management System (SIMS). The My Portfolio pages provide personalized access to all other activities within the system.

Use the calendar to identify the time range to be used to view the courses you are taking. You can choose daily, weekly, monthly, or academic year timeframes. When you select the Search button, the course list is displayed on the My Courses tab. You will receive a message if you have not requested course access.

Use the Utilities links to perform course-related and account-related activities with SimMedical.

Participants can request class access, view course materials, complete evaluations and review their course status.

GENERAL UTILITIES

Account Information

Request Course Access

This chapter divides the Participant tasks into two groups: requesting access to a course or class and taking classes.

24

SimMedical

Obtain Course and Class Access

As a Participant taking classes, you can view information about the courses offered, request access to a course, and participate in a class for that course. During your participation, you will review presentation slides and may also take quizzes, complete surveys and evaluations, and perform scenarios using the Laerdal™ simulator.

This section describes how to obtain access to a course, how to request assignment to a class, and how to navigate SIMS to view the course material. Find instructions to use SIMS to take a class in **Take Classes** on page 32.

How to Request Course Access

Before you can take a class, you must be granted access to the course. Access to a course is requested using the Request Course Access form and granted by the Course Director. Usually, the Course Director assigns you to a class at the same time.

Once you have course access, SIMS displays the course name and a link to the class session (if you have been assigned to a class) on the My Courses page. In addition, all materials for that course become available for review.

Before You Begin

You must have a valid user account for SIMS. Find instructions to create an account in **Chapter 1: Introduction to SIMS**.

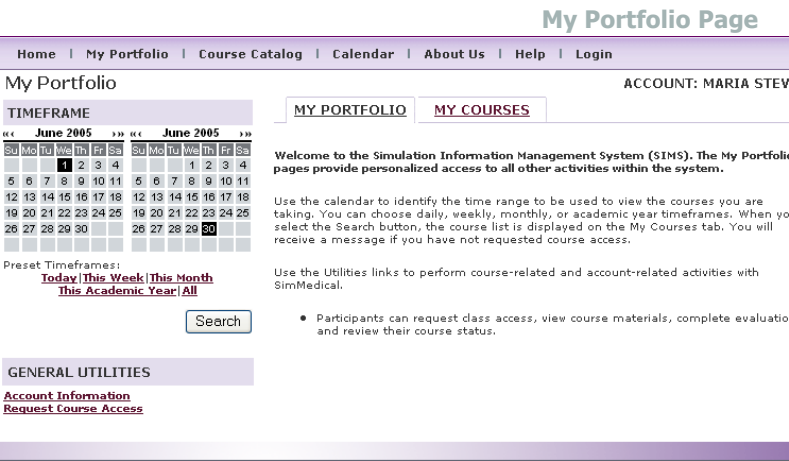
Complete the following steps to request access to a course...

Procedure

- 1 Select My Portfolio on the SIMS menu bar.

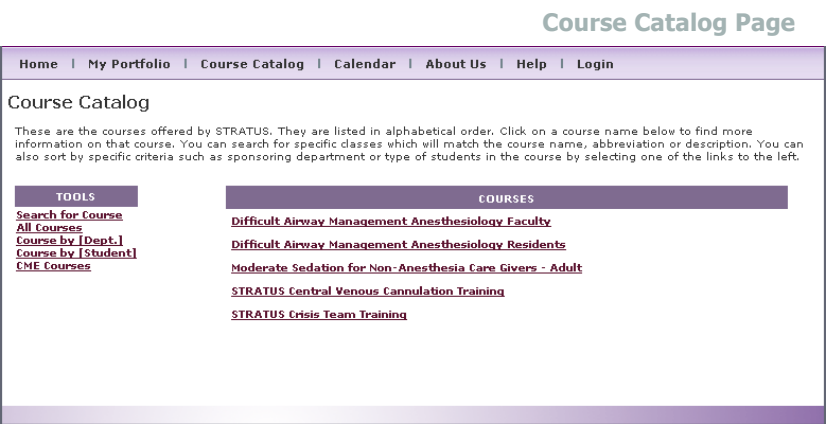
If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.

If you have logged into SIMS, the My Portfolio page is shown.



- 2 Under the General Utilities group, select Request Course Access.

SIMS displays the Course Catalog page. The Course Catalog contains links to all courses offered by SIMS.



You can choose which courses are displayed in the Course Catalog using the links in the Tools group. The following links are available:

- Search for Course — opens a page containing a search field. Enter keywords in this field to be used to find courses by name or by description.
- All Courses — displays all courses listed in alphabetical order.
- Course by Department — displays all courses for one department (for example, Anesthesiology).
- Course by Student — displays all courses according to the student profile (for example, Residents).

- 3 Select a course from the Courses list.

- CME Courses — displays accredited courses that can be taken for continuing medical education (CME).

SIMS displays the View a Course page containing information about the course including:

- the course description
- the Course Director's name
- the Facilitator's name
- a link to view the course material for Participants
- a link to view the course material for Facilitators.

Note The View a Course page is also available to those who are researching the course offerings, but have not yet completed the Create Account form. If you do not have an account, SIMS opens the Login page when you select either link to view course materials.

- 4 Select the link: "Click here to access, or request access to, the Participant course material for this course."

If you do not have access to the course, SIMS displays the Request Course Access page depicted in the following graphic.

Request Course Access Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Request Course Access

ACCOUNT: MARIA STEVENS

Use this form to request participant access to the STRATUS Crisis Team Training course. When you select the Submit Request button, your request will be sent via email to the course directors: **Test Director**

REQUEST FORM:

Account Name: Maria Stevens
Course: STRATUS Crisis Team Training
Access Level: Participant
Note:

If you have already been granted access to the course, and you are already logged into SIMS, SIMS displays the course materials. Otherwise, SIMS presents the login page before displaying the course materials. Find more information about viewing the course materials in **How to View Course Materials** on page 32.

- 5 Optionally, enter a note in the Note field.

You can request to attend a specific class or may need to identify special needs regarding your participation in the class. Enter any special requests here.

- 6 Select the Submit Request button.

SIMS sends an email message to the Course Director containing your course access request. The Course Director grants access and, optionally, assigns you to a specific class.

Note When the Course Director adds you to a course, SIMS automatically sends you an email message to confirm you were added. The email message contains a link to the course materials.

Next Steps

If you were given course access, but not assigned to a class, you should request to be assigned to a class. Find instructions in ***How to Request Class Assignments*** on page 30.

How to View My Courses and Access the Class Portfolio Page

You must have been given access to one or more courses before the courses are shown on the My Courses page. This page displays both the courses for which you have access and the class assignment for each course.

You may be assigned to more than one class for any given course. The course might be taken yearly to maintain your certification or to ensure you stay current on practices and procedures. Or, you may be requested to take the course if a new procedure is adopted.

Complete the following steps to view your courses...

Procedure

- 1 Select My Portfolio on the SIMS menu bar.
- 2 Use the calendar to identify the course timeframe.

If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.

If you have logged into SIMS, the My Portfolio page is shown.

You choose a start date and end date by selecting specific days on the calendar, or you can choose predefined timeframes to be used to search for available classes. The predefined timeframes include:

- Today

- This Week — sets the start and end dates to the first and last day of the current week.
- This Month — sets the start and end dates to the first and last day of the current month.
- This Academic Year — sets the start and end dates to a July 1 to June 30 calendar year.
- All — sets the start and end dates to a predefined date range.

The calendar updates to show the appropriate start date and end date when you select one of the predefined timeframes.

SIMS finds all classes you have permission to access that occur within the defined timeframe.

3 Select the Search button.

Tip Select the Search button when you change the time frame in the Calendar to update the courses list displayed on the My Courses page.

4 Select the My Courses tab.

SIMS displays all classes you are assigned to that fall within the selected timeframe. Scroll the window to see all available courses.

If you have been assigned to a class for a course, you will see the name of the course along with a link identifying the class date, time, and location (as depicted by the last course shown in the following graphic).

My Courses Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

My Courses ACCOUNT: MARIA STEVENS

TIMEFRAME

« May 2005 » « June 2005 »

1	2	3	4	5	6	7	1	2	3	4			
8	9	10	11	12	13	14	5	6	7	8	9	10	11
15	16	17	18	19	20	21	12	13	14	15	16	17	18
22	23	24	25	26	27	28	19	20	21	22	23	24	25
29	30	31					26	27	28	29	30		

Preset Timeframes:
[Today](#) | [This Week](#) | [This Month](#)
[This Academic Year](#) | [All](#)

GENERAL UTILITIES
[Account Information](#)
[Request Course Access](#)

MY PORTFOLIO **MY COURSES**

DIFFICULT AIRWAY MANAGEMENT ANESTHESIOLOGY FACULTY
 You are not scheduled for any classes in the defined time frame (5/1/2005 - 6/1/2005).
[Click here](#) to access the course material.

STRATUS CENTRAL VENOUS CANNULATION TRAINING
 You are not assigned to any classes in this course.
 To receive access as a Participant to a class, [click here](#) to complete the Class Access Request form.
 To receive access as a Facilitator to a class, [click here](#) to complete the Class Access Request form.
[Click here](#) to access the course material.

STRATUS CRISIS TEAM TRAINING
05/31/05 07:00 A.M. STRATUS Test Room 1 (P)

If you have access to the course but not to a specific class within the selected timeframe, you will see the course name listed along with the message “You are not scheduled for

any classes in the defined time frame (05/01/2005 - 06/01/2005)".

Tip

If the "time frame" message is displayed, increase the time frame on the calendar that is used to search for classes and search again.

If you have access to the course but have not been assigned to a class, you will see the course name listed along with the message "You are not assigned to any classes in this course". Find instructions in **How to Request Class Assignments** on page 30 to request to be assigned to a class.

- 5 Select the class link for the course.

SIMS displays the Class Portfolio page, as depicted in the following screen. The Class Portfolio page provides links to all course materials that you will use during the class.

Class Portfolio Page

Home My Portfolio Course Catalog Calendar About Us Help Login	
Course: DAM ANES FAC	
ACCOUNT: MARIA STEVENS	
COURSE CONTACT MY PORTFOLIO MY COURSES	
DIRECTORS: Test Director	
CLASS INFORMATION	
DATE: 6/9/2005	ANNOUNCEMENTS PRE CLASS COURSE MATERIAL DURING CLASS POST CLASS
TIME: 12:00 PM - 04:00 PM	DIFFICULT AIRWAY MANAGEMENT ANESTHESIOLOGY FACULTY The objective of this course is for the trainees to obtain a working knowledge and proficiency of the American Society of Anesthesiologists Difficult Airway Management Guidelines and its associated airway management techniques. Didactic training focuses on evaluation of the airway and the ASA Difficult Airway Management Guidelines. Simulator training focuses on psychomotor skill sets for various airway management techniques and devices including: retrograde intubation, lighted stylet, ventilating tube exchanger, laryngeal mask airway, Combitube, transtracheal jet ventilation, and cricothyrotomy. After skill set training, trainees are presented with a range of difficult airway scenarios on the simulator, which they manage in real-time with individualized feedback to gain experience and confidence in their skills. Formative and summative assessment of simulation based performance is provided pre- and post- training. Author: Joe Somebody
MEETING ROOM: STRATUS Test Room 1	View Participant Material
FACILITATOR: Test Facilitator	
SESSION ROOM(S): STRATUS-1	

Find instructions to work with the Class Portfolio page in **Take Classes** on page 32.

How to Request Class Assignments

When you request course access, the Course Director may or may not assign you to a specific class for the course. If you are not assigned, complete the Request Class Assignment form. In the Notes field, you can request a specific class date from those shown on the Calendar. SIMS sends this request to the

Before You Begin

Course Director, who assigns you to a class. SIMS then sends you an email message confirming your assignment.

You must request access to a course before you can request to be assigned to a class. Find instructions to be added to a course beginning in **How to Request Course Access** on page 25.

Complete the following steps to request a class assignment...

Procedure

- 1 Select My Portfolio on the SIMS menu bar.
- 2 Select the My Courses page.
- 3 Select the “To receive access as a Participant to a class, click here to complete the Class Access Request form.” link.

If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.

If you have logged into SIMS, the My Portfolio page is shown.

All courses that you have permission to access are shown. Find the course containing the message “You are not assigned to any classes in this course.”

The Request Class Assignment page opens.

Request Class Assignment Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Request Class Assignment ACCOUNT: MARIA STEVENS

To request assignment to a class please complete the form below.
This form will send a request via email to the course directors: **Test Director**

REQUEST FORM:

Course: STRATUS Central Venous Cannulation Training
Role: Participant

Note:

- 4 Optionally, enter a comment in the Note field.
- 5 Select the Submit Request button.

You may want to request to attend a specific class or may need to identify special needs regarding your participation in the class. Enter any special requests here.

SIMS sends an email message containing the class assignment request to the Course Director. The Course Director assigns you to the class. You are sent an email message confirming the class date, time, and location.

Take Classes

The Class Portfolio page provides access to all information required to participate in a class. When the Class Portfolio page opens, the Course Materials link is selected by default. From this page, you can view the course slides, find contact information for the Facilitator(s), and locate the class rooms and meeting rooms to be used for the class.

Additional materials may be provided for use during the class. These materials include surveys, quizzes, and evaluations. The Facilitator provides access to these materials when appropriate during the class session.

This section describes how to use SIMS to access the course materials during a class session.

How to View Course Materials

After you have been granted access to a course, you can access the course materials from the Class Portfolio page. The Participant materials include the course slides, quizzes, surveys, and evaluations used during the presentation. Prior to being assigned to a class, you can view the course slides only. After you have been assigned to a class, you are able to access all course materials.

Complete the following steps to view course materials...

Procedure

- 1 Open the Class Portfolio page.

If you need assistance getting to this page, follow the steps in ***How to View My Courses and Access the Class Portfolio Page*** on page 28.

Class Portfolio Page -- Course Material link

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Course: DAM ANES FAC ACCOUNT: MARIA STEVENS

COURSE CONTACT MY PORTFOLIO MY COURSES

DIRECTORS:
[Test Director](#)

CLASS INFORMATION

DATE:
6/9/2005

TIME:
12:00 PM - 04:00 PM

MEETING ROOM:
STRATUS Test Room 1

FACILITATOR:
[Test Facilitator](#)

SESSION ROOM(S):
STRATUS-1

ANNOUNCEMENTS | **PRE CLASS** | **COURSE MATERIAL** | **DURING CLASS** | **POST CLASS**

DIFFICULT AIRWAY MANAGEMENT ANESTHESIOLOGY FACULTY
The objective of this course is for the trainees to obtain a working knowledge and proficiency of the American Society of Anesthesiologists Difficult Airway Management Guidelines and its associated airway management techniques. Didactic training focuses on evaluation of the airway and the ASA Difficult Airway Management Guidelines. Simulator training focuses on psychomotor skill sets for various airway management techniques and devices including: retrograde intubation, lighted stylet, ventilating tube exchanger, laryngeal mask airway, Combitube, transtracheal jet ventilation, and cricothyrotomy. After skill set training, trainees are presented with a range of difficult airway scenarios on the simulator, which they manage in real-time with individualized feedback to gain experience and confidence in their skills. Formative and summative assessment of simulation based performance is provided pre- and post- training.
Author: Joe Somebody

[View Participant Material](#)

- 2** Use the links on the Class Portfolio page to view class material.

Use the links on the Class Portfolio page as follows:

Link	Action
Course Director(s) name	Opens a message window for your default email software and places the Course Director's email address in the To: line. Use this window to send a message to the Course Director(s).
Facilitator(s) name	Opens a message window for your default email software and places the Facilitator's email address in the To: line. Use this window to send a message to the Facilitator(s).
My Portfolio	Opens the My Portfolio page.
My Courses	Opens the My Courses page.
Announcements	Opens a page containing announcements regarding the course or the class you are taking.
Pre Class	Opens a page containing links to surveys or quizzes to be taken prior to the class instruction.
Course Material	Opens a page containing a short description of the course and a link to the course slides.

Link	Action
During Class	Opens a page containing links to quizzes to be taken during the class session.
Post Class	Opens a page containing links to quizzes and evaluations to be completed at the end of the class session. Also contains a link to view the results of your Laerdal™ simulation session (if applicable to the course).

- 3

Select the Course Material link.

This page contains a description of the course along with a link to view the Participant course slides.
- 4

From the Course Material page, select the View Participant Materials link.

SIMS displays the Participant course slides for the active course. Use the navigation available on the course slide pages to view the content.

Note Generally, each course’s navigation commands are located at the bottom of the course materials. The course materials may differ in composition per course. Contact the Facilitator for assistance with using the course materials.

Tip When you are finished browsing the course slides, select the My Courses link to return to the My Courses page. From the My Courses page, select the class to return to the Class Portfolio page.

How to Access and Complete Quizzes, Surveys, and Evaluations

Courses may utilize quizzes to verify Participants’ mastery of the course materials or include surveys and evaluations to be used by the Facilitator to understand the educational level of the Participants or obtain feedback on the course. Sometimes the materials, such as pre-class surveys and assessments, are available when you are assigned to a class. Sometimes the

Facilitator will instruct you to visit a page and complete a quiz, evaluation or survey.

Tip Check the Task column on the Pre Class, During Class, and Post Class pages for the presence of links to quizzes, surveys, or evaluations. The status column identifies your need to complete the task.

Before You Begin

You must be assigned to a class before you are able to access the class materials. Find instructions to request a class assignment in ***How to Request Class Assignments*** on page 30.

Complete the following steps to access the quizzes, surveys, or evaluations...

Procedure

- 1** From the My Courses page, select a link for a class.
- 2** Select the Pre Class link.

The Class Portfolio page opens. This page shows the information about the course and a link to the class materials.

The Pre Class page opens. Any pre-class surveys or quizzes to be taken are displayed in the Task column on this page. Also shown on this page are messages from the Facilitator giving special instructions about the class (for example, a reminder to bring a stethoscope).

Class Portfolio Page - Pre Class page

Home My Portfolio Course Catalog Calendar About Us Help Login												
Course: DAM ANES FAC		ACCOUNT: MARIA STEVENS										
COURSE CONTACT MY PORTFOLIO MY COURSES												
DIRECTOR: Test Director												
ANNOUNCEMENTS PRE CLASS COURSE MATERIAL DURING CLASS POST CLASS												
CLASS INFORMATION DATE: 6/2/2005 TIME: 01:00 PM - 02:00 PM MEETING ROOM: STRATUS Test Room 2 FACILITATOR: Test Facilitator SESSION ROOM(S): STRATUS-1												
<table border="1"> <thead> <tr> <th>TASK</th> <th>STATUS</th> </tr> </thead> <tbody> <tr> <td>Please complete the pre survey before the class session.</td> <td>NA</td> </tr> <tr> <td>Remember to bring your stethoscope.</td> <td>NA</td> </tr> <tr> <td>Pre Class Survey</td> <td>COMPLETE</td> </tr> <tr> <td>SAMPLE PRE-QUIZ (You can take this multiple times)</td> <td>NEEDED</td> </tr> </tbody> </table>			TASK	STATUS	Please complete the pre survey before the class session.	NA	Remember to bring your stethoscope.	NA	Pre Class Survey	COMPLETE	SAMPLE PRE-QUIZ (You can take this multiple times)	NEEDED
TASK	STATUS											
Please complete the pre survey before the class session.	NA											
Remember to bring your stethoscope.	NA											
Pre Class Survey	COMPLETE											
SAMPLE PRE-QUIZ (You can take this multiple times)	NEEDED											

Any task entered on this page has one of three statuses:

- Needed — you are required to complete this task during the course.
- Complete — this task is finished. You are not able to perform this task again during this class session.
- NA — this task does not require you to perform an action using the SIMS software.

The statuses change as you complete each task.

Note You may find quizzes to complete on the During Class and Post Class pages also. If any of the Class pages do not contain tasks, check back often during the class. The Facilitator may give you access to quizzes during the various class segments.

3 Select a link in the Task list.

SIMS opens a new page and displays the quiz or survey contents. Follow the instructions on the page to complete the task.

Note Contact the Facilitator if you have questions or need assistance to complete the task.

4 Select the Post Class link.

The Post Class page opens. Generally, you will find all wrap-up evaluations and surveys posted on this page as well as any final exams.

Class Portfolio Page - Post Class link

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Course: DAM ANES FACACCOUNT: MARIA STEVENS

COURSE CONTACT

MY PORTFOLIO | MY COURSES

DIRECTORS:
Test Director

ANNOUNCEMENTS | PRE CLASS | COURSE MATERIAL | DURING CLASS | POST CLASS

CLASS INFORMATION

DATE:
6/2/2005

TIME:
01:00 PM - 02:00 PM

MEETING ROOM:
STRATUS Test Room 2

FACILITATOR:
Test Facilitator

SESSION ROOM(S):
STRATUS-1

TASK

STATUS

Please complete the Facilitator evaluation.
Remember to take your stethoscope home with you.
Post Class Facilitator Evaluation
Review Sessions

NA
NA
COMPLETE
NA

You access each task by selecting the link, as before. When you have completed the task, the status changes appropriately.

How to Review Session Results

Some courses use a Laerdal™ simulator as part of the course curriculum. For those using this simulator, each participant can review the results of their simulation session as soon as the Facilitator completes the session evaluation.

Complete the following steps to review session results...

Procedure

- 1 From the Class Portfolio page, select the Post Class tab.
- 2 Select the Review Session link.

The Post Class page opens.

The Competency Evaluation Summary report opens. This report shows the results of each simulation scenario performed for one class session.

Competency Evaluation Summary Page

- 3 Select the course date and assessment period.

Enter information on this form as follows:

Field	Description
Detailed Score and Feedback for class on:	Select the class date from the drop down menu. Only those classes that you have participated in are shown in the list.
Class Assessment period:	The assessment period may change according to the class taken. The periods might include Pre Class, Post Class, Retesting, and others. The assessment periods are specific to the course.

SIMS updates the report using the values you select for the fields in the previous table. Session results are shown using a Pass/Fail grading system.

SIMS stores the results of each simulation session that you take along with the Pass/Fail grade in your user account. You can review this report at any time.

Tip Use the Internet Explorer Print command to print a copy of this report.

Next Steps

Participants are required to retake any simulation scenario that they did not pass.

3 Tasks for the Facilitator

SIMS provides a special set of utilities for the Facilitator. To access these utilities, the Facilitator must be setup in SIMS in the Facilitator group and must be given access to one or more courses.

You gain access to the course using the commands under the Facilitator Utilities section of the My Portfolio page. The commands are shown in the following graphic.

My Portfolio: Facilitator

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

My Portfolio ACCOUNT: TEST FACILITATOR

TIMEFRAME

« June 2005 » June 2005 »»

Su	Mo	Tu	We	Th	Fr	Sa	Su	Mo	Tu	We	Th	Fr	Sa
			1	2	3	4				1	2	3	4
5	6	7	8	9	10	11	5	6	7	8	9	10	11
12	13	14	15	16	17	18	12	13	14	15	16	17	18
19	20	21	22	23	24	25	19	20	21	22	23	24	25
26	27	28	29	30			26	27	28	29	30		

Preset Timeframes:
[Today](#) | [This Week](#) | [This Month](#)
[This Academic Year](#) | [All](#)

MY PORTFOLIO **MY COURSES**

Welcome to the Simulation Information Management System (SIMS). The My Portfolio pages provide personalized access to all other activities within the system.

Use the calendar to identify the time range to be used to view the courses you are taking. You can choose daily, weekly, monthly, or academic year timeframes. When you select the Search button, the course list is displayed on the My Courses tab. You will receive a message if you have not requested course access.

Use the Utilities links to perform course-related and account-related activities with SimMedical.

- Facilitators can view information about participants in courses, view all classes for one course, view the course materials, and request new classes be scheduled.

FACILITATOR UTILITIES

[View Course Participant Status](#)
[View Course Participant List](#)
[View Classes](#)
[Modify User Access](#)
[Request New Class](#)
[View My Evaluations](#)

GENERAL UTILITIES

[Account Information](#)
[Request Course Access](#)

Generally, the Course Director assigns Facilitators to one or more courses and also to one or more classes for that course. You gain access to the Facilitator Utilities after course access is provided.

This chapter divides the Facilitator tasks into three groups. The first group includes tasks performed when requesting access to a course or a class. These tasks include:

- requesting access to a course.
- reviewing the course list.
- requesting a class be added for a course.
- reviewing course materials.

The second group of tasks are performed to administer a class. They include:

- viewing assigned classes.
- verifying Participants assigned to a class.
- providing a class assignment for a Participant.
- creating messages for the Participants that are displayed on the SIMS screen.

Finally, the last group of tasks are those performed when managing classes. They include:

- ensuring Participants complete all course materials.

- activating and reviewing the course quizzes and evaluations completed by the Participants.
- storing recorded simulation sessions along with the Participant performance evaluation.

Find instructions to perform these tasks in the following sections.

Obtain Course and Class Access

As the Facilitator, you have the ability to view information about the classes you have been assigned to teach. This information includes the class dates, times, and locations as well as the presentation slides, quizzes, and evaluations that are used by the Participant. To obtain access to this information, you must first have access to a course and a class.

This section discusses how to obtain course access, how to view courses and the Class Portfolio page, how to request a class be scheduled for a course, and how to view course materials.

How to Request Course Access

Before you can facilitate a class, you must obtain access to the course. Access to a course is requested using the Request Course Access form and granted by the Course Director. Once the Facilitator has course access, SIMS displays the course name and a link to the class session (if you have been assigned to a class) on the My Courses page. In addition, all materials for that course become available for review.

Before You Begin

You must have a valid user account for SIMS. Find instructions to create an account in **Chapter 1: Introduction to SIMS**.

Complete the following steps to request access to a course...

Procedure

- 1 Select My Portfolio on the SIMS menu bar.

If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.

If you have logged into SIMS, the My Portfolio page is shown.

- 2 Under the General Utilities group, select Request Course Access.

SIMS displays the Course Catalog page. The Course Catalog contains links to all courses offered by SIMS.

Course Catalog Page

The screenshot shows the 'Course Catalog Page' with a navigation bar at the top containing links: Home, My Portfolio, Course Catalog, Calendar, About Us, Help, and Login. Below the navigation bar is the 'Course Catalog' section. It includes a paragraph explaining that courses are listed alphabetically and can be searched or sorted by criteria like department or student type. To the left is a 'TOOLS' group with links: Search for Course, All Courses, Course by [Dept.], Course by [Student], and CME Courses. To the right is a 'COURSES' group listing: Difficult Airway Management Anesthesiology Faculty, Difficult Airway Management Anesthesiology Residents, Moderate Sedation for Non-Anesthesia Care Givers - Adult, STRATUS Central Venous Cannulation Training, and STRATUS Crisis Team Training.

You can choose which courses are displayed in the Course Catalog using the links in the Tools group. The following links are available:

- Search for Course — opens a page containing a search field. Enter keywords in this field to be used to find courses by name or by description.
- All Courses — displays all courses listed in alphabetical order.
- Course by Department — displays all courses for one department (for example, Anesthesiology).
- Course by Student — displays all courses according to the student profile (for example, Residents).
- CME Courses — displays accredited courses that can be taken for continuing medical education.

- 3 Select a course from the Courses list.

SIMS displays the View a Course page containing information about the course including:

- the course description
- the Course Director's name
- the Facilitator's name
- a link to view the course material for Participants
- a link to view the course material for Facilitators.

Note The View a Course page is also available to those who are researching the course offerings, but have not yet completed the Create Account form. If you do not have an account, SIMS redirects you to the Create Account form when you select either link to view course materials.

- 4 Select the link: “Click here to access, or request access to, the facilitator course materials.”

If you do not have access to the course, SIMS displays the Request Course Access page depicted in the following graphic.

Request Course Access Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Request Course Access

Use this form to request participant access to the STRATUS Crisis Team Training course. When you select the Submit Request button, your request will be sent via email to the course directors:

REQUEST FORM:

Account Name: _____

Course: STRATUS Crisis Team Training

Access Level: Participant

Note:

If you have already been granted access to the course, and you are already logged into SIMS, SIMS displays the course materials. Otherwise, SIMS presents the login page before displaying the course materials. Find more information about viewing the course materials in **How to View Course Materials** on page 49.

- 5 Optionally, enter a note in the Note field.
- 6 Select the Submit Request button.

You may want to request to be signed up for a specific class or may need to identify special needs regarding your participation in the class. Enter any special requests here.

SIMS sends an email message to the Course Director containing your course access request. The Course Director grants access and, optionally, assigns you to a specific class.

Note When the Course Director adds you to a course, SIMS automatically send you an email message to confirm you were added.

Next Steps

After you have been given access to a course, if you have not been assigned to a class by the Course Director, you can request a new class be added for that course. Find instructions to request a new class in **How to Request a New Class** on page 47.

How to View My Courses and Access the Class Portfolio Page

You must have been given access to one or more courses before the courses are shown on the My Courses page. A Facilitator may teach more than one class for one single course. This page displays both the courses for which you have access and the courses for which you have been assigned to facilitate or participate in the class.

Complete the following steps to view your courses...

Procedure

- 1 Select My Portfolio on the SIMS menu bar.

If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.

If you have logged into SIMS, the My Portfolio page is shown.

- 2 Use the calendar to identify the course timeframe.

You choose a start date and end date by selecting specific days on the calendar, or you can choose predefined timeframes to be used to search for available classes. The predefined timeframes include:

- Today
- This Week — sets the start and end dates to the first and last day of the current week.
- This Month — sets the start and end dates to the first and last day of the current month.
- This Academic Year — sets the start and end dates to a July 1 to June 30 calendar year.
- All — sets the start and end dates to a predefined date range.

The calendar updates to show the appropriate start date and end date when you select one of the predefined timeframes.

- 3 Select the Search button.

SIMS finds all classes you have been granted access to that occur within the defined timeframe.

Tip

Select the Search button when you change the time frame in the Calendar to update the courses list displayed on the My Courses page.

4 Select the My Courses tab.

SIMS displays all classes you have been granted access to that fall within the selected timeframe. Scroll the window to see all available courses.

If you have been assigned to a class for a course, you will see the name of the course along with a link identifying the class date, time, and location (as depicted by the first course shown in the following graphic).

My Courses Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

My Courses ACCOUNT: TEST FACILITATOR

TIMEFRAME

May 2005 June 2005

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

Preset Timeframes:
[Today](#) [This Week](#) [This Month](#)
[This Academic Year](#) [All](#)

FACILITATOR UTILITIES
[View Course Participant Status](#)
[View Course Participant List](#)
[View Classes](#)
[Modify User Access](#)
[Request New Class](#)
[View My Evaluations](#)

GENERAL UTILITIES
[Account Information](#)
[Request Course Access](#)

MY COURSES

DIFFICULT AIRWAY MANAGEMENT ANESTHESIOLOGY FACULTY
 06/01/05 08:00 A.M. STRATUS Test Room 1 (F)

STRATUS CENTRAL VENOUS CANNULATION TRAINING
 You are not assigned to any classes in this course.
 To receive access as a Participant to a class, [click here](#) to complete the Class Access Request form.
 To receive access as a Facilitator to a class, [click here](#) to complete the Class Access Request form.
[click here](#) to access the course material.

STRATUS CRISIS TEAM TRAINING
 You are not scheduled for any classes in the defined time frame (5/1/2005 - 6/1/2005).
[click here](#) to access the course material.

If you have access to the course but have not been assigned to a class, you will see the course name listed along with the message “You are not assigned to any classes in this course”. Immediately following this message are links to be selected to request class access or to view the course materials. Facilitators can request to be added to the class as a Participant or as a Facilitator.

If you have access to the course but not to a specific class within the selected timeframe, you will see the course name listed along with the message “You are not scheduled for any classes in the defined time frame (05/01/2005 - 06/01/2005)”. Immediately following this message is a link to be selected to request class access or to view the course materials.

Tip

If the “timeframe” message is displayed, increase the timeframe on the calendar that is used to search for classes and select the Search button again.

- 5 Select the class link for the course.

SIMS displays the Class Portfolio page, as depicted in the following screen. The Class Portfolio page provides links to all course materials that you will use to facilitate the class.

Class Portfolio Page

Home My Portfolio Course Catalog Calendar About Us Help Login	
Course: DAM ANES FAC ACCOUNT: TEST FACILITATOR	
COURSE CONTACT MY PORTFOLIO MY COURSES	
DIRECTORS: Test Director	
CLASS INFORMATION ANNOUNCEMENTS PRE CLASS COURSE MATERIAL DURING CLASS POST CLASS 	
DATE: 6/1/2005 TIME: 08:00 AM - 09:00 AM MEETING ROOM: STRATUS Test Room 1 FACILITATOR: Test Facilitator SESSION ROOM(S): STRATUS-1	
The objective of this course is for the trainees to obtain a working knowledge and proficiency of the American Society of Anesthesiologists Difficult Airway Management Guidelines and its associated airway management techniques. Didactic training focuses on evaluation of the airway and the ASA Difficult Airway Management Guidelines. Simulator training focuses on psychomotor skill sets for various airway management techniques and devices including: retrograde intubation, lighted stylet, ventilating tube exchanger, laryngeal mask airway, Combitube, transtracheal jet ventilation, and cricothyrotomy. After skill set training, trainees are presented with a range of difficult airway scenarios on the simulator, which they manage in real-time with individualized feedback to gain experience and confidence in their skills. Formative and summative assessment of simulation based performance is provided pre- and post-training. Author: Joe Somebody	
View Facilitator Material View Participant Material	

Find instructions to work with the Class Portfolio page in **Manage Classes** on page 62.

How to Request a New Class

Generally, Facilitators are assigned to teach a class by the Course Director. You can optionally submit a request for classes to be added to the calendar. Facilitators can teach one or more class sessions for one course.

Before You Begin

You must have access to the course before you can submit a request to add classes. If you do not have course access, first follow the instructions to obtain course access in **How to Request Course Access** on page 42, then perform the following instructions.

Complete the following steps to request a new class...

Procedure

- 1 Select My Portfolio on the SIMS menu bar.

If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.

If you have logged into SIMS, the My Portfolio page is shown.

- 2 Under the Facilitator Utilities group, select Request New Class.

The Request New Class page opens and contains a form to be completed.

Request New Class Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Request New Class

ACCOUNT: TEST FACILITATOR

Please fill out the form below to request a class. Fields with a red asterisk (*) are required.

Course Coordinator:

Facilitator, Test

*

Course Title:

Select a Course

*

Date Of Class Request:

<

>

*

Start Time:

-

:

-

*

Stop Time:

-

:

-

*

Number Of Rooms:

1

*

Number Of People:

Select # of People

*

Special Requests Or Notes:

Submit

- 3 Use the drop-down menus to select the appropriate values for each field on the form.

Enter information in this form as follows:

Field	Description
Course Coordinator:	Identify a SIMS user who should receive email notification of the scheduled class. Both the Course Coordinator and the person requesting the class will receive the email message.
Course Title:	Select the course name.
Date of Class Request:	Select the calendar icon to choose the class date or, optionally, type in the date in MM/DD/YYYY format.
Start Time:	Enter the time (in hours and minutes) when the class will begin.
Stop Time:	Enter the time (in hours and minutes) when the class will end.
Number of Rooms:	Select the number of rooms to be used for the class. Include class rooms, meeting rooms, and simulator rooms in this count.

Field	Description
Number of People:	Select the range that represents the expected number of Participants for the class.
Special Requests or Notes:	Enter information detailing special needs for the class, such as specialized equipment requirements, number of simulators required, or dates to be avoided when scheduling the class.

- 4** Select the Submit button.

SIMS sends an email message to the Class Maintainer requesting to have a class added to the course schedule.

Note When the class is scheduled, the Class Maintainer sends an email message confirming the class date, time, and location. The Class Maintainer also sends an email message if any scheduling conflicts arise.

Next Steps

Now that you have both course and class access, you can view course materials and Participant lists, add Participants to classes, view Participant status for the Participants who take the class you are facilitating, and perform class management tasks. These tasks are described in the remainder of this chapter.

How to View Course Materials

SIMS stores course materials for both the Participant and the Facilitator. The Facilitator has access to both sets of materials from the Class Portfolio page.

- The Participant materials include the course slides, quizzes, surveys, and evaluations used during the presentation.
- The Facilitator materials include course slides for the Facilitator as well as tools to manage the quizzes, surveys and evaluations.

This section describes how to review the course slides. Find the instructions to perform other class management tasks in later sections of this chapter.

Complete the following steps to view course materials...

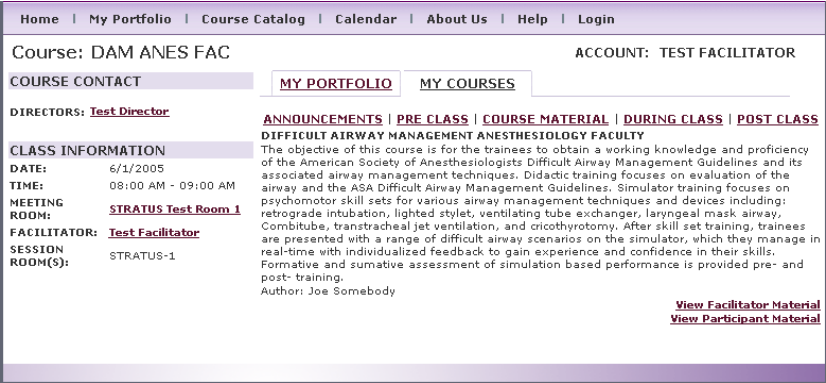
Procedure

- 1 Open the Class Portfolio page.

If you need assistance getting to this page, follow the steps in *How to View My Courses and Access the Class Portfolio Page* on page 45.

The Class Portfolio page shows the information about the course and a link to the class materials.

Class Portfolio Page -- Course Material link



- 2 Select the View Facilitator Materials link.

If the course information is not visible, select the Course Material link to bring this information into view.

SIMS displays the Facilitator course materials for the active course. Use the navigation available on the course materials pages to view the materials.

Note When finished reviewing the Facilitator materials, select the My Courses tab and perform all steps to return to the Class Portfolio page.

- 3 From the Course Material page, select the View Participant Materials link.

SIMS displays the Participant course materials for the active course. Use the navigation available on the course materials pages to view the materials.

Note Generally, each course's navigation commands are located at the bottom of the course slides. The course slides may differ in composition per course. Facilitators should contact the Course Director for assistance with using the course materials.

Administer Classes

Part of facilitating a class includes performing administrative tasks. You can review Participant lists, add Participants to classes, and include notes and messages for the Participants.

This section describes how to perform these tasks.

How to View Assigned Classes

Facilitators are assigned to teach classes by the Course Director. You receive an email message providing the class date, time and location when the class is scheduled. Use SIMS to view all classes you have been assigned to teach.

Complete the following steps to view assigned classes...

Procedure

- 1 Select My Portfolio on the SIMS menu bar.

If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.

If you have logged into SIMS, the My Portfolio page is shown.

- 2 Under the Facilitator Utilities group, select View Classes.

The View Classes page opens. Initially, this page shows all classes scheduled for all courses that you have permission to access.

You can choose to display classes within a specific time period, for one class, or only classes assigned to you.

View Classes Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

View Classes

ACCOUNT: TEST FACILITATOR

Start Date: 05/20/2005 < > Friday

End Date: 07/03/2005 < > Sunday

Course: DAM ANES FAC (Don't select a course to get all courses)

Search:

View Classes

Click the date to view information about that class

DATE	COURSE	INITIAL MEETING ROOM	COMMENTS
05/25/2005 08:00 am - 09:00 am (Wed)	STRATUS DAM ANES FAC	STRATUS-1	
05/26/2005 08:00 am - 09:00 am (Thu)	STRATUS DAM ANES FAC	STRATUS-1	
05/27/2005 08:00 am - 09:00 am (Fri)	STRATUS DAM ANES FAC	STRATUS-1	
05/28/2005 08:00 am - 09:00 am (Sat)	STRATUS DAM ANES FAC	STRATUS-1	
05/30/2005 08:00 am - 11:00 am (Mon)	STRATUS DAM ANES FAC	STRATUS-1	
05/31/2005 08:00 am - 09:00 am (Tue)	STRATUS DAM ANES FAC	STRATUS-1	
06/01/2005 08:00 am - 09:00 am (Wed)	STRATUS DAM ANES FAC	STRATUS-1	Test class that should display post tasks for part
06/02/2005 01:00 pm - 02:00 pm (Thu)	STRATUS DAM ANES FAC	STRATUS-2	Test
06/08/2005 11:00 am - 12:00 pm (Wed)	STRATUS DAM ANES FAC	STRATUS-2	
06/10/2005 09:00 am - 10:00 am (Fri)	STRATUS DAM ANES FAC	STRATUS-2	

3 Enter information or use the drop-down menus to select appropriate values for each field on the form.

Enter information in this form as follows:

Field	Description
Start Date:	Enter the first date, in MM/DD/YYYY format, to be used to limit the classes shown. Optionally, select the calendar icon to select a start date on a popup calendar.
End Date:	Enter the last date, in MM/DD/YYYY format, to be used to limit the classes shown. Optionally, select the calendar icon to select an end date on a popup calendar.
Course:	Select the course name. If a course name is not chosen, all classes for all courses that you have permission to access are shown.
Search:	Enter a value, for example the Facilitator's name, to be used to reduce the number of classes shown.

4 Select the View Classes button.

SIMS displays all classes in the list that match the values entered in the form fields. You can optionally select a date link to view information specific to that class, or select a course link to view information about the course.

- 5** Optionally, select the course name.
SIMS displays the View a Course page containing a description of the course and links to access the course materials.
- 6** Optionally, select the course date.
SIMS displays the View Class page providing links to edit the class and view the class participant's status.

How to View Class Enrollment

You can view the list of Participants in all class that are scheduled for all courses in the facility. Use this list to verify a Participant is assigned to a class, to see which Participants are scheduled to attend, or to balance the load of Participants in a class.

You can also use this report to view all activities taking place within the facility that require the use of a room.

Complete the following steps to view class enrollments...

Procedure

- 1** Select My Portfolio on the SIMS menu bar.
If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.
If you have logged into SIMS, the My Portfolio page is shown.
- 2** Under the Facilitator Utilities group, select View Course Participant List.
The Class Facilitator and Participant Listing page opens.

Class Facilitator and Participant Listing Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Class Facilitator And Participant Listing ACCOUNT: TEST FACILITATOR

Start Date: 06/01/2005 < > Wednesday

End Date: 06/17/2005 < > Friday

Courses: DAM ANES FAC (Don't select a course to get all courses)

Show Facilitators: ☒

Show Participants: ☒

Show Non-Instructional: ☐

Generate Report

- 3 Use the drop-down menus to select appropriate values for each field on the form.

Enter information in this form as follows:

Field	Description
Start Date:	Enter the first date, in MM/DD/YYYY format, to be used when searching for class information. Optionally, select the calendar icon to select a start date on a popup calendar.
End Date:	Enter the last date, in MM/DD/YYYY format, to be used when searching for class information. Optionally, select the calendar icon to select an end date on a popup calendar.
Courses:	Select the course name. If a course name is not chosen, all classes for all courses that you have permission to access will be shown.
Show Facilitators:	Select this checkbox to include the name of the Facilitator assigned to the class in the report.
Show Participants:	Select this checkbox to include the Participant list in the report.
Show Non-Instructional:	Select this checkbox to view all events occurring at the facility, which are non-class related, but which require a room to be reserved (for example, a facility tour).

- 4 Select the Generate Report button.

SIMS gathers information about each class scheduled for the selected course (or all courses that you have permission to access) and displays that information on the page (as depicted in the following graphic).

Expanded View Participant List Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Class Facilitator And Participant Listing ACCOUNT: TEST FACILITATOR

Start Date: 06/01/2005 < [Calendar Icon] > Wednesday
 End Date: 06/17/2005 < [Calendar Icon] > Friday
 Courses: DAM ANES FAC (Don't select a course to get all courses)
 Show Facilitators: ☒
 Show Participants: ☒
 Show Non-Instructional: ☐

Click on the class date to view and edit that class

6/1/2005 (08:00 : 09:00) Difficult Airway Management Anesthesiology Faculty	
FACILITATORS Facilitator, Test	PARTICIPANTS User, Test
6/2/2005 (13:00 : 14:00) Difficult Airway Management Anesthesiology Faculty	
FACILITATORS Facilitator, Test	PARTICIPANTS User, Test User, Test
6/8/2005 (11:00 : 12:00) Difficult Airway Management Anesthesiology Faculty	
FACILITATORS	PARTICIPANTS
6/10/2005 (09:00 : 10:00) Difficult Airway Management Anesthesiology Faculty	
FACILITATORS Facilitator, Test	PARTICIPANTS User, Test User, Test

- 5** Optionally, select the course date link.

SIMS opens the View Class page showing information about the class and providing links to edit the class and view the course participant's status.

Next Steps

Use the Modify User Access page to adjust the number of Participants assigned to each class.

How to Add Participants to a Class

Generally, Participants are added to classes by the Course Director when the Participant requests course access. Sometimes, however, a Participant may arrive expecting to take a class and may not be on the class list. If this occurs, you may add the Participant to the class that you are facilitating.

Note A Participant must be included in the class list to enable them to access the class materials (for example, the quizzes, tests, and evaluations).

Before You Begin

Before you add a Participant to a class, you should view the Participant list for other classes to verify that the Participant was not assigned to another class. Find instructions to view the class enrollment beginning in *How to View Assigned Classes* on page 51.

Complete the following steps to add a Participant to a class...

Procedure

- 1 Select My Portfolio on the SIMS menu bar.
- 2 Under the Facilitator Utilities group, select Modify User Access.

If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.

If you have logged into SIMS, the My Portfolio page is shown.

The Modify User Access page opens.

Modify User Access Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Modify User Access

ACCOUNT: TEST FACILITATOR

If participants are missing from the No Access list, have them go to the [Account Request](#) page to request a user account.

STEP 1:

Selected Group: Participant
Group Description: STRATUS Participants - Difficult Airway Management Anesthesia Faculty

GROUP TO EDIT

Participant

COURSE NAME

STRATUS DAMANES FAC

CLASS DATE

Select a Class Date

NO ACCESS

Select from list or use text search boxes

Director, Test (testdirector)
Director Proxy, Test (testdirectorproxy)
Facilitator, Test (testfacilitator)
Maintainer, Account (acctmain)
Maintainer, Class (classmain)
Maintainer, Course (coursemain)
Site Director, Test (testsitedir)
Site Director Proxy, Test (testsitedirproxy)

COURSE MATERIAL ACCESS ONLY

Select from list or use text search boxes

Demo, Sims (simsdemo)
User, Test (testuser)

COURSE AND CLASS ACCESS

Select from list or use text search boxes

STEP 2:

MOVE

TO "NO ACCESS"

MOVE

TO "COURSE MATERIAL ACCESS ONLY"

MOVE

TO "COURSE AND CLASS ACCESS"

Note You can also access the Modify User Access page from the Class Portfolio. Use the Add Participants link on the Pre Class page. Find information on this page in *Manage Classes* on page 62.

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SimMedical

- 3** Use the drop-down menu to select the course name.

When the course name is selected, SIMS changes the form as follows:

- shows the selected course name in the drop down field.
- enters the course name after the Group Description: label
- identifies all users who have been given access to the course in the Course Material Access Only list.
- gathers all available class dates for the course

- 4** Use the drop-down menu to select the class date in which the Participant is to be added.

When the class date is selected, SIMS changes the form as follows:

- displays the selected date in the drop down field.
- identifies all users who have been given access to the class in the Course and Class Access list.

Note Only the classes that you are facilitating are shown in the Class Date list.

- 5** Complete the following steps to add a user to the Participant list for a class.

- a** Select the user name in the No Access list or the Course Material Access Only list.

SIMS highlights the user name in the list.

- If the Participant's name is in the No Access list, they have not yet been given access to the course.
- If the Participant's name is in the Course Material Access Only list, they have access to the course, but not to the class.

Note If the Participant's name is not shown in the No Access list or the Course Material Access Only list, then the Participant does not have a SIMS user account. The Participant will need to complete and submit the Create Account form before you can add them to the class.

- b** Select the Move button for "Course and Class Access"

SIMS moves the user name from the original list to the Course and Class Access list. This action gives the user class access.

SIMS also sends an email confirmation to the Participant providing the class date, time, and location.

How to Edit Class Instructions

You may edit the information displayed for any class that you have been assigned to facilitate. The information you can change includes:

- Comments that are displayed on the general Course Calendar.
- Instructions to be displayed on the Pre Class page or Post Class page for the Participants or other Facilitators.
- Names of Participants who are assigned to the class.

Note Participants must have been granted access to the course, and optionally to the class, before you can change their class participation.

Tip Contact the Class Maintainer to coordinate any changes that may be required for the class date or time.

Complete the following steps to edit class information...

Procedure

- 1

Open the Class Portfolio page.
- 2

Select the Pre Class link.

If you need assistance getting to this page, follow the steps in *How to View My Courses and Access the Class Portfolio Page* on page 45.

The Pre Class Activities for the Facilitator are shown on this page. The Edit Class link is first in the list.

Class Portfolio - Pre Class Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Course: DAM ANES FAC

ACCOUNT: TEST FACILITATOR

COURSE CONTACT

DIRECTORS:
Test Director

MY PORTFOLIO

MY COURSES

CLASS INFORMATION

DATE:
6/3/2005

TIME:
08:00 AM - 09:00 AM

MEETING ROOM:
Test Room 1

FACILITATOR:
Test Facilitator

SESSION ROOM(S):
STRATUS-1

ANNOUNCEMENTS

PRE CLASS

COURSE MATERIAL

DURING CLASS

POST CLASS

TASK

STATUS

This is where SIMS displays the Facilitator pre-instructions.

NA

Edit Class

NA

Manage Quizzes

NA

Manage Evaluations

NA

Add Participants

NA

Get Class Status

NA

- 3

Select the Edit Class link.
- The Edit Class Information page opens.

Edit Class Information Page (Top)

- 4 Optionally, enter a comment in the Comment field and select the Update Class button.
- 5 Select the “Click here to add instructions.” link to display the fields used to enter instructions.

SIMS displays the comment on the Course Calendar page. The comment is visible to all who review the class schedule using the Calendar.

When the “Click here to add instructions” link is selected, the page expands to show the entry fields for class instructions.

Edit Class Information (Middle)

- 6 Optionally, enter instructions and select the Update Class button.

Enter information in this form as follows:

Field	Description
Facilitator Pre Instructions:	Enter instructions to be displayed on the Pre Class page to all Facilitators assigned to teach this class.
Facilitator Post Instructions:	Enter instructions to be displayed on the Post Class page to all Facilitators assigned to teach this class.
Participant Pre Instructions:	Enter instructions to be displayed on the Pre Class page to all Participants assigned to take this class.
Participant Post Instructions:	Enter instructions to be displayed on the Post Class page to all Participants assigned to take this class.

- 7 Review the Facilitators and Participants assigned to the class.

The names of the Facilitators and Participants are displayed in the Update the people in this class section of the form.

Edit Class Information Page (Bottom)

Update the people in this class

FACILITATORS	
Potential Facilitator, Test (testfacilitator) Add or remove people from this facilitator group.	This Class Facilitator, Test (testfacilitator)

Navigation buttons: --> and <--

PARTICIPANTS	
Potential New, Test (testnew) User, Test (testuser) Add or remove people from this participant group.	This Class

Navigation buttons: --> and <--

LIST OF PARTICIPANTS IN THIS CLASS	EMAIL THE PARTICIPANTS IN THE CLASS

Note Only Facilitators and Participants who have access to the course are included in the Potential list.

- 8 Optionally, add or delete one or more Facilitators or Participants from the class.

For both the Facilitators and Participants lists, the Potential list includes all account holders who have access to the course; the This Class list indicates they have been added to the class.

- To add a Facilitator or Participant to the class, select the name in the Potential list and select the right arrow button. SIMS adds the Facilitator or Participant name to the This Class list, displays the Participant name and email address in the List of Participants in This Class region, and sends an email to the Facilitator or Participant who was added to the class identifying the class name, date, time, and location.

- To remove a Facilitator or Participant from the class, select the name in the This Class list and select the left arrow button.

SIMS removes the sends an email confirmation to the Facilitator or Participant who has been deleted from a class

Manage Classes

You perform tasks during the actual class session that are important to the success of the class. These tasks include ensuring the Participants complete all required course materials, activating and reviewing quizzes and evaluations to be completed by the Participant, and recording and evaluating simulation sessions (if you are using the Laerdal™ simulator).

These tasks are described in this section.

How to View Participant Progress

Participants may be required to complete evaluations, surveys, quizzes, and tests during the class. You can check the status of these class materials to see whether the Participant has completed the required materials.

You can see the Participant progress for the classes you are assigned to teach, but not for all classes on the schedule.

Complete the following steps to view the Participant's progress...

Procedure

- 1 Select My Portfolio on the SIMS menu bar.

If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.

If you have logged into SIMS, the My Portfolio page is shown.

- 2 Under the Facilitator Utilities group, select View Course Participant Status.

The View Course Participant Status page opens. This page contains the names of each Participant who is scheduled for each class for one or more courses.

Note You can also access the View Course Participant Status page from the Class Portfolio. Use the Get Class Status link on the Pre Class, During Class, or Post Class pages. Find information on these pages in this section.

View Course Participant Status Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

View Course Participant Status ACCOUNT: TEST FACILITATOR

Start Date: 06/06/2005 < > Monday
 End Date: 06/10/2005 < > Friday
 Courses: STRATUS DAMANES FAC (Don't select a course to get all courses)
 Send Emails: ☐
 Generate Report

KEY
 = complete
 = not complete
 = not active/available
Participant = has signed in

Click on the class date to view and edit that class. Click on the 'Participants' header in the 1st column to view and edit the people in that class.

Participants [click to edit]	During Course	Pre Survey	Post Facilitator	SAMPLE INTER-CLASS QUIZ	SAMPLE PRE-QUIZ
06/07/2005 (06:00 : 07:00) Difficult Airway Management Anesthesiology Faculty					
Participant, Test					
User, Test					
06/08/2005 (11:00 : 12:00) Difficult Airway Management Anesthesiology Faculty					
06/09/2005 (12:00 : 16:00) Difficult Airway Management Anesthesiology Faculty					
Participant, Test					
Stevens, Maria					
User, Test					
06/10/2005 (13:00 : 17:00) Difficult Airway Management Anesthesiology Faculty					

- 3 Use the drop-down menus and calendar pop-ups to select appropriate values for each field on the form.

Enter information in this form as follows:

Field	Description
Start Date:	Enter the first date, in MM/DD/YYYY format, to be used to search for class information. Optionally, select the calendar icon to select a start date on a popup calendar.
End Date:	Enter the end date, in MM/DD/YYYY format, to be used to search for class information. Optionally, select the calendar icon to select a start date on a popup calendar.
Courses:	Select the course name. All classes for all courses will be shown if a course name is not chosen.
Send Emails:	Select this checkbox to have SIMS send an email to each Participant who has not completed all of the requirements for the class to encourage the Participant to finish the incomplete tasks. SIMS automatically generates these reminder emails on a periodic basis. Participants who have completed all course materials will not receive an email message.

- 4 Select the Generate Report button.

SIMS searches for all classes which match the information entered in the page and displays the Participant status for each class grouped by the class.

How to Activate and Review Quizzes

SIMS displays all quizzes associated with a course on the Manage Quizzes page. The Facilitator can review:

- the “blank” quiz (without any responses)
- quizzes with response statistics (percentage of Participants selecting each response)
- Participant results (number of correct responses)

The Facilitator can also activate quizzes to allow the Participant to access the quiz at a specific time during the class.

Complete the following steps to manage quizzes...

Procedure

- 1 Open the Class Portfolio page.

If you need assistance getting to this page, follow the steps in ***How to View My Courses and Access the Class Portfolio Page*** on page 45.

- 2 Select the Pre Class link.

The Pre Class Activities for the Facilitator are shown on this page. The Manage Quizzes link is second in the list.

Note The Manage Quizzes link is also available from the During Class and Post Class pages.

- 3 Select the Manage Quizzes link.

The Manage Quizzes page opens. All quizzes (pre, during, or post) that are included with the course are shown on this page. The type and number of quizzes vary by course.

Manage Quizzes Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Manage Quizzes ACCOUNT: TEST FACILITATOR

DIFFICULT AIRWAY MANAGEMENT ANESTHESIOLOGY FACULTY 6/7/2005 (06:00 AM - 07:00 AM)

SAMPLE PRE-QUIZ ([view sample quiz](#))

ALWAYS AVAILABLE Completion: 0/2 (0%) Avg: 0% (0%) View entire class results: [all questions](#) or [individual](#) [Show/Hide Results by Student](#)

NAME	NUMBER CORRECT	SCORE
Participant, Test (testpart)	Has not taken quiz	
User, Test (testuser)	Has not taken quiz	

SAMPLE INTER-CLASS QUIZ ([view sample quiz](#))

UNAVAILABLE [ACTIVATE](#) Completion: 0/2 (0%) Avg: 0% (0%) View entire class results: [all questions](#) or [individual](#) [Show/Hide Results by Student](#)

Quizzes are displayed in the Manage Quizzes page with one of three statuses:

- **Always Available** — the Participant can access the quiz at any time during the class session.
- **Unavailable** — the quiz is currently hidden from the view of the Participant.
- **Available** — the Facilitator has activated the quiz, which can now be seen by the Participant.

Tip

Use the Internet Explorer's Back button to return to the Manage Quizzes page after you review the quiz details described in the following steps.

- 4 Select the link following the quiz name to view the quiz.
- 5 Select the link to view the class results either by all questions or by individual.
- 6 Select the Show/Hide Results by Student link.

SIMS opens a page containing the quiz (both questions and answers) that is presented to the Participant.

SIMS opens a page containing the quiz questions and answers along with results statistics. The correct answer is identified as well.

- If you choose the "all questions" link, all questions, answers and results are displayed in a scrolling page.
- If you choose the "individual" link, only one question along with its possible answers and results is displayed at one time. Select the Go to the next question button to advance through the entire quiz.

SIMS displays a table containing each Participant's name and their individual results. A note is shown if the Participant has not taken the quiz. The table is hidden from view when

the Manage Quizzes page opens. The table is shown in the Manage Quizzes Page graphic on the previous page.

Note SIMS displays the Participant results for class that you facilitate and only for the Participants in that class.

- 7 Select the Activate link to enable a quiz during a class.

Sometimes, quizzes are hidden from the view of the Participant until it is time during the class for the quiz to be taken. Use the Activate link to enable the Participant to access the quiz during the class.

After selected, the link on the Manage Quizzes page is changed to Deactivate and the quiz status is changed to Available.

How to Activate and Review Evaluations

SIMS displays all evaluations associated with a course on the Manage Evaluations page. The Facilitator can review:

- the “blank” evaluation or survey (without any responses)
- evaluations or surveys with response statistics (percentage of Participants selecting each response)

The Facilitator can also activate evaluations or surveys to allow the Participant to access the evaluation or survey at a specific time during the class.

Complete the following steps to manage evaluations...

Procedure

- 1 Open the Class Portfolio page.

If you need assistance getting to this page, follow the steps in ***How to View My Courses and Access the Class Portfolio Page*** on page 45.

- 2 Select the Pre Class link.

The Pre Class Activities for the Facilitator are shown on this page. The Manage Evaluations link is third in the list.

Note The Manage Evaluations link is also available from the During Class and Post Class pages.

- 3 Select the Manage Evaluations link.

The Manage Evaluations page opens. All evaluations and class surveys (the pre class survey, the course evaluation,

and the Facilitator evaluation) that are included with the course are shown on this page.

Manage Evaluations Page

Home My Portfolio Course Catalog Calendar About Us Help Login		
Manage Evaluations		ACCOUNT: TEST FACILITATOR
Difficult Airway Management Anesthesiology Faculty 6/7/2005 (06:00 AM - 07:00 AM)		
Course Evaluation (view sample evaluation/survey)		
Unavailable activate	0/2 (0%)	Show Evaluation Report
Pre Class Survey (view sample evaluation/survey)		
Always Available	0/2 (0%)	Show Evaluation Report
Post Class Facilitator Evaluation (view sample evaluation/survey)		
Always Available	0/2 (0%)	Show Evaluation Report

Evaluations and surveys are displayed in the Manage Evaluations page with one of three statuses:

- Always Available — the Participant can access the evaluation or survey at any time during the class session.
- Unavailable — the evaluation or survey is currently hidden from the view of the Participant.
- Available — the Facilitator has activated the evaluation or survey, which can now be seen by the Participant.

Tip

Use the Internet Explorer's Back button to return to the Manage Evaluations page after you review the evaluation or survey details described in the following steps.

- 4 Select the link following the evaluation type to view the evaluation/survey.
 - 5 Select the Show Evaluation Report link.
- a Select the course name and select the Next button.

SIMS opens a page containing an evaluation as displayed to the Participant.

SIMS displays the first of three screens. SIMS gathers the information and builds a report showing the evaluation or survey results using the selections you make in these screens.

Select the course name from the drop down menu. When you select the Next button, the page displays the Select Date Range form.

- b** Select the class date range and select the Next button.

You need to identify a Start Date and an End Date for the search. Use the calendar popup or enter the date value in MM/DD/YYYY format.

When you select the Next button, SIMS gathers all results for all classes within the selected timeframe and uses those results to build the evaluation report. The page changes to display the Select Evaluation Type/Survey form.

- c** Select the survey or evaluation to be displayed and select the Next button.

SIMS provides a list of all available surveys and evaluations in a drop down menu. When you select the Next button, the report displays.

The Evaluation Report includes all responses for the timeframe selected in Step 5b as compared to all Participant responses to date.

Note Ten or more Participants must have completed the survey or evaluation before the Evaluation Report can be created. SIMS displays a message suggesting you expand your search timeframe to generate the report if this condition exists.

- d** Optionally, use your Internet browser's Print command to print a copy of the report.

- 6** Select the Activate link.

Sometimes, surveys and evaluations are hidden from the view of the Participant until it is time during the class for the survey or evaluation to be completed. Use the Activate link to enable the Participant to access the survey or evaluation during the class

How to Record a Simulation Session

SIMS stores results from a Laerdal™ simulation session along with comments from the Facilitator about the Participant's performance of a procedure using the simulator. This section describes:

- How to upload the simulation session file.
- How to include an evaluation of the Participant's performance using the simulator.
- How to view the session performance status for one Participant in one class.

- How to view the session performance status for all Participants in one class.

Complete the following steps to record a session...

Procedure

- 1 Open the Class Portfolio page.

If you need assistance getting to this page, follow the steps in ***How to View My Courses and Access the Class Portfolio Page*** on page 45.

- 2 Select the During Class link.

The During Class Activities for the Facilitator are shown on this page. The Record Session link is last in the list.

Class Portfolio - During Class Page

Home My Portfolio Course Catalog Calendar About Us Help Login	
Course: DAM ANES FAC	
ACCOUNT: TEST FACILITATOR	
COURSE CONTACT	MY PORTFOLIO MY COURSES
DIRECTOR: Test Director	ANNOUNCEMENTS PRE CLASS COURSE MATERIAL DURING CLASS POST CLASS
CLASS INFORMATION	TASK STATUS
DATE: 6/3/2005	Manage Quizzes NA
TIME: 08:00 AM - 09:00 AM	Manage Evaluations NA
MEETING ROOM: STRATUS Test Room 1	Get Class Status NA
FACILITATOR: Test Facilitator	Record Session NA
SESSION ROOM(S): STRATUS-1	

- 3 Select the Record Session link.

The Record a Simulation Session page opens. This is the first of five pages presented by SIMS to enable you to record a session for a Participant.

- 4 Select the Participant name from the drop down menu and select the Next button.

Only those Participants assigned to the selected class are included in the drop down menu. When training in a team scenario, select the Participant who is the team leader.

- 5 Select the Scenario name from the drop down menu.

The Select a Scenario page identifies the scenarios to be performed during this class. SIMS uses color coding to indicate the order of performance or optional scenarios as follows:

- Scenarios that have been performed are indicated in grey and show the scenario name and scenario ID code.
- Scenarios indicated in yellow are the next required scenario to be performed in the sequence.

- Scenarios indicated in green are required and are activated in the order in which they should be performed. When a green scenario is activated, it becomes yellow.
- Scenarios indicated in blue are optional.

SIMS advances to the next page automatically after the scenario is chosen.

- 6
- Select a Session Room and select the Next button.
- 7
- Follow the instructions for recording a session using the Laerdal™ software and select the Next button when complete.

The available session rooms are identified in a drop down menu. SIMS connects to the server in the room when the Next button is selected.

SIMS opens the Post Session Data page.
Use this page to enter your evaluation of the Participant.

Record Session - Post Session Data Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Record a Simulation Session

ACCOUNT: TEST FACILITATOR

Click here to hide/show session information

Course: Difficult Airway Management Anesthesiology Faculty

Criteria: POST

Scenario: IVA CNV/CNI - Non-surg

STEP 7 OF 7: POST SESSION DATA

UPDATE SUCCESSFUL!

Pass/Fail:

Pass

Participant exhibits mastery of procedure.

Comments:

Additional Participants: (if needed)

In Class

Test Participant (testpart)

In this session

Test User (testuser)

Load SimMan Log: ☐

Update Session

[Enter the Next Session for this Class](#)

[List the sessions for Test User](#)

[List the sessions for this class](#)

- 8
- Complete the evaluation form.

Enter information in this form as follows:

Field	Description
Pass/Fail:	Select Pass if the Participant successfully performed the scenario. Select Fail if the Participant needs to repeat this test.
Comments:	Enter your comments regarding the Participant's performance of the procedure.

Field	Description
Additional Participants:	If this session was used for team training, use these fields to identify the other Participants who were in the room during the session. Select the Participant name in the In Class list and select the right arrow button to move the Participant name to the In this session list.
Load SimMan Log:	Select this checkbox if the record session log file generated as a result of the simulation should be stored with this evaluation.

- 9** Select the Update Session button.

SIMS stores the information entered in the form and displays

- an Update Successful! message.
- a green bar if the Participant passed; a red bar if the Participant failed.
- an Enter the Next Session for this Class link to be used to perform the next scenario and record the session.

- 10** Optionally, select the link to view all sessions stored for the Participant.

Use this page to review the status for one Participant in the class. From this page, you can review the results of the simulation session to provide feedback to the Participant.

View Sessions - Participant Page

[Home](#)
[My Portfolio](#)
[Course Catalog](#)
[Calendar](#)
[About Us](#)
[Help](#)
[Login](#)

List Sessions for Test User

ACCOUNT: TEST FACILITATOR

DIFFICULT AIRWAY MANAGEMENT ANESTHESIOLOGY FACULTY 6/7/2005 (06:00 AM - 07:00 AM)

#	SESSION ID #	SCENARIO	CRITERIA	PASS/FAIL	PARTICIPANT(S)	COMMENTS	VIDEO FILE	SIMMAN LOG
STRATUS-1 - # 4	211	CNV/CNT - Surg.	PRE		Test User (testuser)			

[VIEW THIS CLASS](#)
[GET PASS FAIL STATISTICS FOR DIFFICULT AIRWAY MANAGEMENT ANESTHESIOLOGY FACULTY](#)
[LIST ALL THE SESSIONS FOR THIS CLASS](#)

11 Optionally, select the link to view all sessions stored for the entire class.

Use this page to review the status of all Participants in one class.

View Sessions - Class Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

List Sessions for Class

ACCOUNT: TEST FACILITATOR

DIFFICULT AIRWAY MANAGEMENT ANESTHESIOLOGY FACULTY 6/7/2005 (06:00 AM - 07:00 AM)

#	SESSION ID #	SCENARIO	CRITERIA	PASS/FAIL	PARTICIPANT(S)	COMMENTS	VIDEO FILE	SIMMAN LOG
STRATUS-1 - #1	202	CNV/CNI - Surg.	PRE		KimTest Participant (kimtestpart)			
STRATUS-1 - #2	205	CW/CNI	POST		KimTest Participant (kimtestpart)			SimMan Log
STRATUS-1 - #3	208	AWAKE	POST		KimTest Participant (kimtestpart)			SimMan Log
STRATUS-1 - #4	211	CNV/CNI - Surg.	PRE		Test User (testuser)			

[VIEW THIS CLASS](#)

[GET PASS FAIL STATISTICS FOR DIFFICULT AIRWAY MANAGEMENT ANESTHESIOLOGY FACULTY](#)

How to Review Sessions

A Participant can perform one or more scenarios during a class session. As the sessions are performed, a recording is made and eventually stored with an evaluation of the Participant's performance. The evaluation indicates whether the Participant has passed or failed the scenario and determines whether the Participant must retake the class when all scenarios are complete.

The Review Session page details the status of each scenario performed by one or more Participants and provides links to edit or delete the session from SIMS. This page can be used in lieu of the List Sessions pages described in the previous section.

Complete the following steps to review sessions...

Procedure

1 Open the Class Portfolio page.

If you need assistance getting to this page, follow the steps in *How to View My Courses and Access the Class Portfolio Page* on page 45.

2 Select the Post Class link.

The Post Class Activities for the Facilitator are shown on this page. The Review Session link is last in the list.

Class Portfolio - Post Class Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Course: DAM ANES FAC ACCOUNT: TEST FACILITATOR

COURSE CONTACT MY PORTFOLIO MY COURSES

DIRECTORS:
[Test Director](#)

CLASS INFORMATION

DATE:
6/3/2005

TIME:
08:00 AM - 09:00 AM

MEETING ROOM:
STRATUS Test Room 1

FACILITATOR:
[Test Facilitator](#)

SESSION ROOM(S):
STRATUS-1

ANNOUNCEMENTS | **PRE CLASS** | **COURSE MATERIAL** | **DURING CLASS** | **POST CLASS**

TASK	STATUS
This is where SIMS displays the Facilitator post-instructions.	NA
Manage Quizzes	NA
Manage Evaluations	NA
Get Class Status	NA
Review Sessions	NA

- 3 Select the Review Sessions link.

The Review a Simulation Session page opens. This is the first of five pages presented by SIMS to enable you to record a session for a Participant.

Review Session Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Review a Simulation Session ACCOUNT: TEST FACILITATOR

Course: [Difficult Airway Management Anesthesiology Faculty](#)

Class: 6/7/2005 06:00 AM to 07:00 AM - STRATUS Test Room 1 (STRATUS-1, STRATUS-2) - demo class for sessions - DO NOT DELETE

Participant: (Don't select a name to get all participants.)

Test User (click name for summary)

PRE: (Minimum of 1) [CNV/CNI - Surg.](#) [\[EDIT\]](#) [\[DELETE\]](#)

RETEST: (Minimum of 0)

POST: (Minimum of 4) [CNV/CNI - Non-surg](#) [\[EDIT\]](#) [\[DELETE\]](#) [CV/CNI](#) [\[EDIT\]](#) [\[DELETE\]](#)

KEY

- = passed
- = failed
- = not determined

- 4 Complete the fields in the form to view the Participants' status.

Enter information in the form as follows:

Field	Description
Participant:	Select the name of a Participant from the drop down list to create a report for one Participant. Otherwise, all Participants will be shown.

- 5 Select the Submit button.

SIMS updates the form to show the Participants' status. The scenarios are color-coded as follows:

- Green indicates the Participant passed this scenario.
- Red indicates the Participant failed the scenario.

6 Optionally, select the [EDIT] link to update the facilitator comments for this scenario.

7 Optionally, select the [DELETE] link to remove this scenario from the class list.

- Grey indicates the scenario has been recorded, but the Facilitator has yet to apply comments.

SIMS opens an Edit Session page. Update the fields on this page and select the Update Session button to save your changes.

SIMS deletes the scenario comments and Laerdal™ simulation session file, if attached.

4 Tasks for the Directors

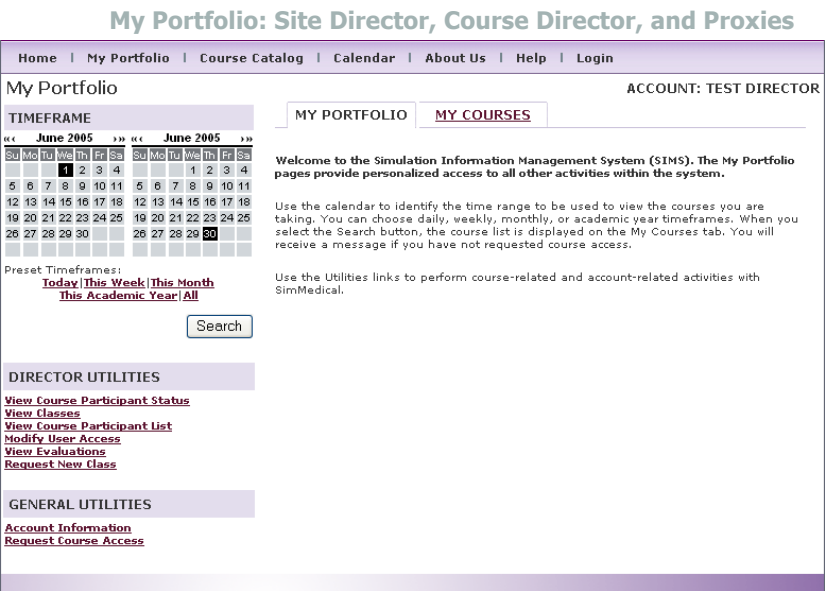
Two levels of Directors may work in a Simulation Center — a Site Director, who oversees all workings of the center, and a Course Director, who is appointed by the Site Director to manage one or more course offerings. SIMS provides a variety of reports and utilities to allow the Director to effectively perform administrative and managerial tasks.

Using SIMS, a Director can:

- schedule classes
- assign Facilitators and optionally, enroll Participants in classes
- balance class loads
- review Participant course progress
- review comments and responses from the Participants about the course and the Facilitators
- generate statistical reports

Directors may also assign Proxies, who are persons within the Simulation Center that perform administrative tasks at the direction of the Director. Both the Site Director and Course Director can assign a Proxy to assist them with their tasks.

You gain access to the course using the commands under the Director Utilities section of the My Portfolio page. The commands are shown in the following graphic.



This chapter describes all tasks to be completed by the Site Director, Course Director, or the Proxy.

Administer Classes

The course administration tasks for a Course Director includes requesting classes be added to the course schedule, assigning Facilitators to teach the course, and enrolling Participants in a class when requested or when needed to complete program or certification requirements. SIMS also provides tools to view the courses you have access to and the number of participants in each class.

The Course Director Proxy has the same privileges in SIMS as the Course Director. Often, the Course Director Proxy administers classes at the direction of the Course Director.

The Site Director uses the same tools when needed to perform administrative tasks. Most often, the Site Director is interested in a broad view of the classes scheduled in the Simulation Center and the volume of Participants who take the classes. Occasionally, the Site Director may request a class be scheduled or add Participants to classes.

The Site Director Proxy has the same privileges in SIMS as the Site Director.

This section contains instructions to perform class administrative tasks.

How to Request a New Class

The Course Director understands the educational needs of the Participants and schedules classes to meet these needs. The Course Director completes the Request New Class form identifying all the requirements for the class. SIMS sends this request to the Class Maintainer. Classes are added to the course schedule by the Class Maintainer upon receipt of the request.

Before You Begin

You must have access to the course before you can submit a request to add classes. Generally, the Site Director assigns a Course Director to manage one or more courses, and, in doing so, grants course access for the Course Director. The Site Director might also grant course access for the Course Director Proxy.

Complete the following steps to request a new class...

Procedure

- 1 Select My Portfolio on the SIMS menu bar.

If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.

If you have logged into SIMS, the My Portfolio page is shown.

My Portfolio Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

My Portfolio

ACCOUNT: TEST DIRECTOR

TIMEFRAME

« June 2005 »» « June 2005 »»

Su	Mo	Tu	We	Th	Fr	Sa	Su	Mo	Tu	We	Th	Fr	Sa
							1	2	3	4			
5	6	7	8	9	10	11	5	6	7	8	9	10	11
12	13	14	15	16	17	18	12	13	14	15	16	17	18
19	20	21	22	23	24	25	19	20	21	22	23	24	25
26	27	28	29	30			26	27	28	29	30		

Preset Timeframes:

Today | This Week | This Month | This Academic Year | All

Search

MY PORTFOLIO

MY COURSES

Welcome to the Simulation Information Management System (SIMS). The My Portfolio pages provide personalized access to all other activities within the system.

Use the calendar to identify the time range to be used to view the courses you are taking. You can choose daily, weekly, monthly, or academic year timeframes. When you select the Search button, the course list is displayed on the My Courses tab. You will receive a message if you have not requested course access.

Use the Utilities links to perform course-related and account-related activities with SimMedical.

DIRECTOR UTILITIES

View Course Participant Status

View Classes

View Course Participant List

Modify User Access

View Evaluations

Request New Class

GENERAL UTILITIES

Account Information

Request Course Access

- 2 Under the Director Utilities group, select Request New Class.

The Request New Class page opens and contains a form to be completed.

Request New Class Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Request New Class

ACCOUNT: TEST DIRECTOR

Please fill out the form below to request a class. Fields with a red asterisk (*) are required.

Course Coordinator:

Director, Test

*

Course Title:

Select a Course

*

Date Of Class Request:

< >

*

Start Time:

-

 :

-

 *

Stop Time:

-

 :

-

 *

Number Of Rooms:

1

 *

Number Of People:

Select # of People

 *

Special Requests Or Notes:

Submit

- 3** Use the drop-down menus to select the appropriate values for each field on the form.

Enter information in this form as follows:

Field	Description
Course Coordinator:	Identify a SIMS user who should receive email notification of the scheduled class. Both the Course Coordinator and the person requesting the class will receive the email message.
Course Title:	Select the course name.
Date of Class Request:	Select the calendar icon to choose the class date or, optionally, type in the date in MM/DD/YYYY format.
Start Time:	Enter the time (in hours and minutes) when the class will begin.
Stop Time:	Enter the time (in hours and minutes) when the class will end.
Number of Rooms:	Select the number of rooms to be used for the class. Include class rooms, meeting rooms, and simulator rooms in this count.
Number of People:	Select the range that represents the expected number of Participants for the class.
Special Requests or Notes:	Enter information detailing special needs for the class, such as specialized equipment requirements, number of simulators required, or dates to be avoided when scheduling the class.

All fields indicated with an asterisk are required. SIMS prompts you to enter a value for each of these fields.

- 4** Select the Submit button.

SIMS sends an email message to the Class Maintainer requesting to have a class added to the course schedule.

Note When the class is scheduled, the Class Maintainer sends an email message confirming the class date, time, and location. The Class Maintainer also sends an email message if any scheduling conflicts arise.

Next Steps

As soon as the class is scheduled, Directors can assign Facilitators to teach the class, and optionally, enroll Participants

in the class. The Course Director can grant permission to access the class to the Course Director Proxy. The Site Director can grant permission to access the class to the Site Director Proxy.

How to View Assigned Classes

The Course Director can view all classes for the courses that you are assigned to manage. The report includes the course name, class date, initial meeting room, and any notes about the course that were entered when the class was scheduled.

The Site Director can view all classes for all courses being conducted in the Simulation Center.

Complete the following steps to view classes...

Procedure

- 1 Select My Portfolio on the SIMS menu bar.

If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.

If you have logged into SIMS, the My Portfolio page is shown.

- 2 Under the Director Utilities group, select View Classes.

The View Classes page opens. Initially, this page shows all classes scheduled for all courses that you have permission to access.

You can choose to display classes within a specific time period or all classes for one course.

View Classes Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

View Classes ACCOUNT: TEST DIRECTOR

Start Date: 05/20/2005 < > Friday
 End Date: 07/03/2005 < > Sunday
 Course: DAM ANES FAC
 Search:

Click the date to view information about that class

DATE	COURSE	INITIAL MEETING ROOM	COMMENTS
05/26/2005 08:00 am - 09:00 am (Thu)	STRATUS DAM ANES FAC	STRATUS-1	
05/28/2005 08:00 am - 09:00 am (Sat)	STRATUS DAM ANES FAC	STRATUS-1	
05/30/2005 08:00 am - 11:00 am (Mon)	STRATUS DAM ANES FAC	STRATUS-1	
05/31/2005 08:00 am - 09:00 am (Tue)	STRATUS DAM ANES FAC	STRATUS-1	
06/01/2005 08:00 am - 09:00 am (Wed)	STRATUS DAM ANES FAC	STRATUS-1	Test class that should display post tasks for part
06/02/2005 01:00 pm - 02:00 pm (Thu)	STRATUS DAM ANES FAC	STRATUS-2	
06/07/2005 06:00 am - 07:00 am (Tue)	STRATUS DAM ANES FAC	STRATUS-1	demo class for sessions - DO NOT DELETE
06/08/2005 11:00 am - 12:00 pm (Wed)	STRATUS DAM ANES FAC	STRATUS-2	
06/09/2005 12:00 pm - 04:00 pm (Thu)	STRATUS DAM ANES FAC	STRATUS-1	
06/10/2005 01:00 pm - 05:00 pm (Fri)	STRATUS DAM ANES FAC	STRATUS-1	
06/14/2005 07:00 am - 10:00 am (Tue)	STRATUS DAM ANES FAC	STRATUS-2	
06/16/2005 07:00 am - 10:00 am (Thu)	STRATUS DAM ANES FAC	STRATUS-1	
06/22/2005 06:00 am - 05:00 pm (Wed)	STRATUS DAM ANES FAC	STRATUS-1	
06/27/2005 01:00 pm - 02:30 pm (Mon)	STRATUS DAM ANES FAC	STRATUS-1	
06/27/2005 02:30 pm - 04:00 pm (Mon)	STRATUS DAM ANES FAC	STRATUS-1	
06/27/2005 09:00 am - 10:30 am (Mon)	STRATUS DAM ANES FAC	STRATUS-1	
06/27/2005 10:30 am - 12:00 pm (Mon)	STRATUS DAM ANES FAC	STRATUS-1	

- 3** Enter information or use the drop-down menus to select appropriate values for each field on the form.

Enter information in this form as follows:

Field	Description
Start Date:	Enter the first date, in MM/DD/YYYY format, to be used to limit the classes shown. Optionally, select the calendar icon to select a start date on a popup calendar.
End Date:	Enter the last date, in MM/DD/YYYY format, to be used to limit the classes shown. Optionally, select the calendar icon to select an end date on a popup calendar.
Course:	Select the course name. If a course name is not chosen, all classes for all courses that you have permission to access are shown.
Search:	Enter a value, for example the Facilitator's name, to be used to reduce the number of classes shown.

- 4** Select the View Classes button.

SIMS displays all classes in the list that match the values entered in the form fields. You can optionally select a date

- 5

Optionally, select the course name.

link to view information specific to that class, or select a course link to view information about the course.
- 6

Optionally, select the course date.

SIMS displays the View a Course page containing a description of the course and links to access the course materials.
- SIMS displays the View Class page providing links to edit the class and view the class participant's status.

Next Steps

Use the Modify User Access page to adjust the number of Facilitators or Participants assigned to each class.

How to View Class Enrollment

You can view the list of Participants in all classes that are scheduled for all courses in the facility. Directors use this list to verify a Participant is assigned to a class, to see which Participants are scheduled to attend, or to balance the load of Participants in a class.

Note Course Directors can view only those courses that they has been granted access. The Site Director can view all classes for all courses.

You can also use this report to view all activities taking place within the facility that require the use of a room.

Complete the following steps to grant access to a class...

Procedure

- 1

Select My Portfolio on the SIMS menu bar.

If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.
- If you have logged into SIMS, the My Portfolio page is shown.
- 2

Under the Director Utilities group, select View Course Participant List.

The Class Facilitator and Participant Listing page opens.

Class Facilitator and Participant Listing Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Class Facilitator And Participant Listing ACCOUNT: TEST DIRECTOR

Start Date: 06/09/2005 < > Thursday

End Date: 06/10/2005 < > Friday

Courses: DAMANES FAC (Don't select a course to get all courses)

Show Facilitators: ☒

Show Participants: ☒

Show Non-Instructional: ☐

- 3** Use the drop-down menus to select appropriate values for each field on the form.

Enter information in this form as follows:

Field	Description
Start Date:	Enter the first date, in MM/DD/YYYY format, to be used when searching for class information. Optionally, select the calendar icon to select a start date on a popup calendar.
End Date:	Enter the last date, in MM/DD/YYYY format, to be used when searching for class information. Optionally, select the calendar icon to select an end date on a popup calendar.
Courses:	Select the course name. If a course name is not chosen, all classes for all courses that you have permission to access will be shown.
Show Facilitators:	Select this checkbox to include the name of the Facilitator assigned to the class in the report.
Show Participants:	Select this checkbox to include the Participant list in the report.
Show Non-Instructional:	Select this checkbox to view all events occurring at the facility, which are non-class related, but which require a room to be reserved (for example, a facility tour).

- 4** Select the Generate Report button.

SIMS gathers information about each class scheduled for the selected course (or all courses that you have permission to access) and displays that information on the page (as depicted in the following graphic).

Expanded View Participant List Page

[Home](#) | [My Portfolio](#) | [Course Catalog](#) | [Calendar](#) | [About Us](#) | [Help](#) | [Login](#)

Class Facilitator And Participant Listing

ACCOUNT: TEST DIRECTOR

Start Date: 06/09/2005 < > Thursday

End Date: 06/10/2005 < > Friday

Courses: DAMANES FAC (Don't select a course to get all courses)

Show Facilitators: ☒

Show Participants: ☒

Show Non-Instructional: ☐

Generate Report

Click on the class date to view and edit that class

6/9/2005 (12:00 : 16:00) Difficult Airway Management Anesthesiology Faculty
FACILITATORS Facilitator, Test PARTICIPANTS Participant, Test Stevens, Maria User, Test
6/10/2005 (13:00 : 17:00) Difficult Airway Management Anesthesiology Faculty
FACILITATORS Facilitator, Test PARTICIPANTS

5 Optionally, select the course date link.

SIMS opens the View Class page showing information about the class and providing links to edit the class and view the course participant's status.

Next Steps

Use the Modify User Access page to adjust the number of Facilitators or Participants assigned to each class.

How to Add Participants to a Class

The Course Director receives requests for access to courses offered in the Simulation Center from Participants and sometimes from Facilitators. When granting access to the course, you can also grant access to a specific class.

- A Participant must be included in the class list to enable them to access the class materials (for example, the quizzes, tests, and evaluations).
- A Facilitator must have access to the class to activate quizzes, review scenario session results (if applicable), apply grades, and view evaluations.
- A Course Director Proxy must have access to the class to perform administrative duties at the direction of the Course Director. Either a Course Director, Site Director, or Site Director Proxy can provide access at this level.

- A Site Director Proxy must have access to a class to perform administrative duties at the direction of the Site Director. Only a Site Director has permission to provide access at this level.

Before You Begin

You may wish to check the enrollment for each scheduled class to ensure the classes are adequately balanced prior to enrolling a Participant in a class. Find instructions to view the class enrollment in ***How to View Assigned Classes*** on page 80.

Complete the following steps to add a Participant, Facilitator, Course Director Proxy, or Site Director Proxy to a class...

Procedure

- 1 Select My Portfolio on the SIMS menu bar.
- 2 Under the Director Utilities group, select Modify User Access.

If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.

If you have logged into SIMS, the My Portfolio page is shown.

The Modify User Access page opens.

Modify User Access Page

Home My Portfolio Course Catalog Calendar About Us Help Login		
Modify User Access		ACCOUNT: TEST DIRECTOR
If participants are missing from the No Access list, have them go to the Account Request page to request a user account.		
STEP 1:		
Selected Group: Facilitator Group Description: Facilitators - Difficult Airway Management Anesthesia Faculty		
GROUP TO EDIT	COURSE NAME	CLASS DATE
Facilitator	DAM ANES FAC	Select a Class Date
NO ACCESS	COURSE MATERIAL ACCESS ONLY	COURSE AND CLASS ACCESS
Select from list or use text search boxes	Select from list or use text search boxes	Select from list or use text search boxes
 Director, Test (testdirector) Director Proxy, Test (testdirectorproxy) Maintainer, Account (acctmain) Maintainer, Class (classmain) Maintainer, Course (coursemain) Site Director, Test (testsitedir) Site Director Proxy, Test (testsitedirproxy)	 Facilitator, Test (testfacilitator)	
STEP 2:		
MOVE TO "NO ACCESS" MOVE TO "COURSE MATERIAL ACCESS ONLY" MOVE TO "COURSE AND CLASS ACCESS"		

- 3** Use the drop-down menu to select the Group to Edit.

The Group to Edit menu contains the roles for whom you have permission to grant course and class access.

- A Site Director or Site Director Proxy can grant access to all roles.
- A Course Director or Course Director Proxy can grant access to Facilitators and Participants.

When the role is selected, SIMS displays only the names of the SIMS accounts who are in that role's group. For example, only Facilitators names are displayed when Facilitators is selected in the drop-down menu.

- 4** Use the drop-down menu to select the course name.

When the course name is selected, SIMS changes the form as follows:

- shows the selected course name in the drop down field.
- enters the course name after the Group Description: label
- identifies all users who have been given access to the course in the Course Material Access Only list.
- gathers all available class dates for the course

Note The Site Director and Site Director Proxy can choose from all courses. The Course Director and Course Director Proxy can choose from only those classes that they have been granted access.

- 5** Use the drop-down menu to select the class date in which the Participant is to be added.

When the class date is selected, SIMS changes the form as follows:

- displays the selected date in the drop down field.
- identifies all users who have been given access to the class in the Course and Class Access list.

Note SIMS displays all classes for the selected course in the Class Date list.

- 6** Complete the following steps to grant a user access to a class.
- a** Select the user name in the No Access list or the Course Material Access Only list.

SIMS highlights the user name in the list.

- If the user's name is in the No Access list, they have not yet been given access to the course.

- If the user's name is in the Course Material Access Only list, they have access to the course, but not to the class.

Note If the name of the person to be added to the class is not shown in the No Access list or the Course Material Access Only list, then that person does not have a SIMS user account. Ask the person to complete and submit the Create Account form to allow you to add them to the class.

- b** Select the Move button for
"Course and Class Access"

SIMS moves the user name from the original list to the Course and Class Access list. This action gives the user class access.

SIMS also sends an email confirmation to the user providing the class date, time, and location.

Manage Classes

Site Directors and Course Directors are often concerned with the progress made by Participants and the effectiveness of the Facilitator. SIMS provides two utilities for use by the Directors for this purpose.

- The View Course Participant Status page provides a snapshot of the Participant's progress. It shows all Participants for each course and what tasks they have or have not completed.
- The Evaluation/Survey Report page provides a graphical view of the class Participants' evaluation of the Facilitator.

How to View Participant Progress

Participants may be required to complete evaluations, surveys, quizzes, and tests during the class. You can check the status of these class materials to see whether the Participant has completed the required materials.

Course Directors and Proxies can **only** see the Participant progress for the courses they are assigned to manage.

Site Directors and Proxies can see the Participant progress for **all** courses offered in the Simulation Center.

Complete the following steps to view the Participant's progress...

Procedure

- 1** Select My Portfolio on the SIMS menu bar.

If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.

If you have logged into SIMS, the My Portfolio page is shown.

- 2** Under the Director Utilities group, select View Course Participant Status.

The View Course Participant Status page opens. This page contains the names of each Participant who is scheduled for each class for one or more courses.

View Course Participant Status Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

View Course Participant Status ACCOUNT: TEST DIRECTOR

Start Date: < > Monday

End Date: < > Friday

Courses: (Don't select a course to get all courses)

Send Emails: ☐

KEY

- = complete
- = not complete
- = not active/available
- Participant** = has signed in

Click on the class date to view and edit that class. Click on the 'Participants' header in the 1st column to view and edit the people in that class.

Participants	During Course	Pre Survey	Post Facilitator	SAMPLE INTER-CLASS QUIZ	SAMPLE PRE-QUIZ
05/30/2005 (08:00 : 11:00) Difficult Airway Management Anesthesiology Faculty					
Participant, KimTest					
05/31/2005 (08:00 : 09:00) Difficult Airway Management Anesthesiology Faculty					
Participant, KimTest					
06/01/2005 (08:00 : 09:00) Difficult Airway Management Anesthesiology Faculty					
User, TashTest					
06/02/2005 (13:00 : 14:00) Difficult Airway Management Anesthesiology Faculty					
Stevens, Maria					
User, TashTest					

- 3** Use the drop-down menus and calendar pop-ups to select appropriate values for each field on the form.

Enter information in this form as follows:

Field	Description
Start Date:	Enter the first date, in MM/DD/YYYY format, to be used to search for class information. Optionally, select the calendar icon to select a start date on a popup calendar.
End Date:	Enter the end date, in MM/DD/YYYY format, to be used to search for class information. Optionally, select the calendar icon to select a start date on a popup calendar.

Field	Description
Courses:	Select the course name. All classes for all courses will be shown if a course name is not chosen. The Course Director will see classes only for those courses being managed by the Director.
Send Emails:	Select this checkbox to have SIMS send an email to each Participant who has not completed all of the requirements for the class to encourage the Participant to finish the incomplete tasks. SIMS automatically generates these reminder emails on a periodic basis [HOW OFTEN?] . Participants who have completed all course materials will not receive an email message.

- 4 Select the Generate Report button.

SIMS searches for all classes which match the information entered in the page and displays the Participant status for each class grouped by the class.

How to Review Evaluations

Site Directors and Course Directors can review a summary report, in the form of a bar graph, which contains the Participant's evaluation of a course Facilitator. Course Directors and Proxies can review the evaluations only for those courses that they manage. Site Directors and Proxies can review the evaluations for all courses.

Complete the following steps to manage evaluations...

Procedure

- 1 Select My Portfolio from the SIMS menu bar.

If you have not yet logged into the system, SIMS displays the login screen. Enter your username and password to access the My Portfolio pages.

If you have logged into SIMS, the My Portfolio page is shown.

- 2** From the Director Utilities group, select the View Evaluations link.

- a** Select the course name and select the Next button.

SIMS displays the first of three screens for the Evaluation / Survey Report. SIMS gathers the information and builds a report showing the evaluation or survey results using the selections you make in these screens.

Select the course name from the drop down menu. When you select the Next button, the page displays the Select Date Range form.

Note Site Directors can choose from all courses. Course Directors can choose only those courses that they have been assigned to manage.

- b** Select the class date range and select the Next button.

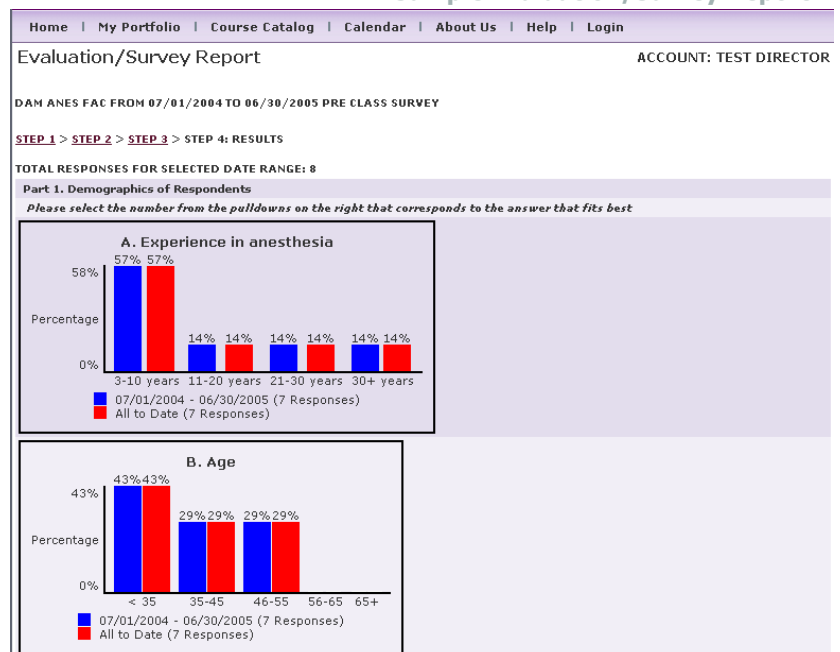
You need to identify a Start Date and an End Date for the search. Use the calendar popup or enter the date value in MM/DD/YYYY format.

When you select the Next button, SIMS gathers all results for all classes within the selected timeframe and uses those results to build the evaluation report. The page changes to display the Select Evaluation Type/Survey form.

- c** Select the survey or evaluation to be displayed and select the Next button.

SIMS provides a list of all available surveys and evaluations in a drop down menu. When you select the Next button, the report displays.

Sample Evaluation/Survey Report



The Evaluation Report includes all responses for the timeframe selected in Step 2b as compared to all Participant responses to date.

Note Several Participants must have completed the survey or evaluation before the Evaluation Report can be created. SIMS displays a message suggesting you expand your search timeframe to generate the report if this condition exists.

Note Site Directors can review all evaluations for all Facilitators for all courses. Course Directors can review Facilitator evaluations only for the courses that they manage.

- d Optionally, use your Internet browser's Print command to print a copy of the report.

5 Tasks for the Class Maintainer

The Class Maintainer is responsible for adding classes to the Course Calendar, updating and maintaining the class information, and ensuring the class attendees sign in on the day of the class.

SIMS provides utilities to be used to perform each of these tasks as well as access to reports to help the Class Maintainer understand the current class loads. The links to access these utilities are available on the My Portfolio page as depicted in the following graphic.

My Portfolio: Class Maintainer

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

My Portfolio

ACCOUNT: CLASS MAINTAINER

TIMEFRAME

« July 2005 »»

« July 2005 »»

Su	Mo	Tu	We	Th	Fr	Sa	Su	Mo	Tu	We	Th	Fr	Sa
					1	2						1	2
3	4	5	6	7	8	9	3	4	5	6	7	8	9
10	11	12	13	14	15	16	10	11	12	13	14	15	16
17	18	19	20	21	22	23	17	18	19	20	21	22	23
24	25	26	27	28	29	30	24	25	26	27	28	29	30
31							31						

Preset Timeframes:

Today

This Week

This Month

This Academic Year

All

Search

CLASS MAINTAINER UTILITIES

Add a Class

View Classes

View Class Facilitators and Participants

View Course Participant Status

Electronic Class Signin

GENERAL UTILITIES

Account Information

Request Course Access

MY PORTFOLIO

MY COURSES

Welcome to the Simulation Information Management System (SIMS). The My Portfolio pages provide personalized access to all other activities within the system.

Use the calendar to identify the time range to be used to view the courses you are taking. You can choose daily, weekly, monthly, or academic year timeframes. When you select the Search button, the course list is displayed on the My Courses tab. You will receive a message if you have not requested course access.

Use the Utilities links to perform course-related and account-related activities with SimMedical.

• Class Maintainers can schedule and manage classes, view information about participants in courses, and open a class sign-in page.

This chapter contains instructions for the following tasks:

- add a class to the Course Schedule
- edit the class information
- view a report showing Facilitators and Participants assigned to the class
- view a report showing the Participant's progress in a class
- open an electronic sign in page to be used by Facilitators and Participants to acknowledge their attendance in the class.

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SimMedical

Add and Update Classes

The Class Maintainer's primary responsibilities are to schedule and maintain scheduled classes. When scheduling a class, you identify the date and time the class will be held, the course that will be taught during the class time, the meeting room where the class will gather initially, and the list of people who require access to the course. You can optionally add messages to the Facilitators and Participants to assist with taking the class as well as any secondary rooms to be reserved.

Scheduled classes might need to be updated due to conflicts in the Simulation Center, with the Facilitator, or class loads. You can edit class dates, times, rooms, and participants. Or, you may need to present new messages to the class participants.

This section describes how to add classes to the Course Calendar and how to update classes that have been already been scheduled.

Add Classes to the Course Calendar

The Class Maintainer schedules classes when requested by the Site Director or Proxy, the Course Director or Proxy, or the Facilitator. When adding a class to the schedule, you can include messages to the participants such as reminders to bring personal medical equipment to be used or identification of pre-reading assignments.

Complete the following steps to add a class...

Procedure

- 1 From the My Portfolio page, select the Add a Class link.

The Add a Class page opens.

Add a Class Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Add a Class

ACCOUNT: CLASS MAINTAINER

Course:STRATUS DAMANES RES*

Class Date:07/18/2005< > Monday*

Start Time:8 (am):30*

Stop Time:12 (pm):00*

Initial Meeting Room:Classroom*

Comments:

Internal Comments:
(Class Maintainer's Only)

Facilitator Pre Instructions:

Facilitator Post Instructions:

Participant Pre Instructions:

Participant Post Instructions:

Class Announcements:

Session Room(S):

Classroom
Conf. Rm
HPS A
HPS B
Micro Sim

Hold down the CTRL key to select multiple rooms

Recurrence:☐ To add multiple classes at the same time, select this check box and complete recurrence pattern and dates below.

* indicates a required field

Create Class

View Classes

- 2 Use the drop down menus and other input regions to select appropriate values for each field on the form.

Complete the required fields in the Add a Class form as follows:

Field	Description
Course	Select the course name.
Class Date:	Enter the class date in MM/DD/YYYY format. Optionally, select the calendar icon to select the class date in a popup calendar.
Start Time:	Use the drop down menus to select the class start time. The time is entered in hours and minutes.
Stop Time:	Use the drop down menus to select the class stop time. The time is entered in hours and minutes.
Initial Meeting Room:	Use the drop down menu to select the room to be used as the initial meeting place for the class.

- 3** Optionally, enter comments and instructions about the class.

Add values to the comments and instructions fields as follows:

Field	Description
Comments:	Enter comments about the class to be displayed on the course calendar.
Internal Comments:	Enter notes to be seen by Class Maintainers only that pertain to this specific class.
Facilitator Pre Instructions:	Enter instructions to be displayed on the Pre Class page to all Facilitators assigned to teach this class.
Facilitator Post Instructions:	Enter instructions to be displayed on the Post Class page to all Facilitators assigned to teach this class.
Participant Pre Instructions:	Enter instructions to be displayed on the Pre Class page to all Participants assigned to take this class.
Participant Post Instructions:	Enter instructions to be displayed on the Post Class page to all Participants assigned to take this class.
Class Announcements:	Enter announcements to be displayed on the Announcements page to all Facilitators and Participants assigned to take this class.

- 4** Optionally, select additional rooms to be used for the class.
- 5** Optionally, select the Recurrence check box to schedule this as a regular repeating class.

All rooms to be used for the class need to be scheduled when the class is added. Hold down the Control key to select multiple rooms.

SIMS expands the form to reveal fields to be used to schedule repeating classes.

Expanded Add a Class Page

Recurrence: ☒ To add multiple classes at the same time, select this check box and complete recurrence pattern and dates below.

☐ Weekly: ☐ Mon ☐ Tue ☐ Wed ☐ Thu ☐ Fri ☐ Sat ☐ Sun
☐ Monthly: Every

Between: < And <

* Indicates a required field

- If classes repeat weekly on the same day of the week, select the box next to the appropriate week day.
- If the class repeat once a month on the same day of the month, select which day and the day of the week from the drop down menu. Also, select a start and end date for the class.

SIMS highlights the button next to the Weekly label and places an X in the selected check box.

The values in the drop down next to the Every: label are first, second, third, or fourth.

The values in the drop down to the right are the days of the week.

Use the calendar icon to select a date from the popup calendar or enter the value in MM/DD/YYYY format.

So, in the example depicted in the previous graphic, the class will be scheduled for reoccurrence on the first Monday of every month.

6 Select the Create Class button.

SIMS creates the class, adds the class to the Course Calendar, and sends an email notification that the class was created.

SIMS also displays the list of all Facilitators and Participants who can be added to the class.

Add a Class: Facilitators and Participants

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Add a ClassACCOUNT: CLASS MAINTAINER

CLASS ADDED SUCCESSFULLY!

ADD PARTICIPANTS TO THE DIFFICULT AIRWAY MANAGEMENT ANESTHESIOLOGY FACULTY CLASS ON 7/7/2005 FROM 02:30 PM TO 05:00 PM BELOW

[View](#) your classes [Add](#) another class to this course.

UPDATE THE PEOPLE IN THIS CLASS

FACILITATORS

Potential

Facilitator, Test

Add or remove people from this **facilitator** group.

This Class

->>

<<-

PARTICIPANTS

Potential

Demo, Sims
Participant, Test
User, Test

Add or remove people from this **participant** group.

This Class

->>

<<-

LIST OF PARTICIPANTS IN THIS CLASS

EMAIL THE PARTICIPANTS IN THE CLASS

7 Use the Facilitators region to add class Facilitators.

- a Select one or more Facilitator names in the Potential list.

SIMS highlights the selected Facilitator name. Hold down the Control key to select more than one name.

- b** Select the right arrow to move the Facilitator name to the This Class list.
- 8** Use the Participants region to add class Participants.
 - a** Select one or more Participant names in the Potential list.
 - b** Select the right arrow to move the Participant name to the This Class list.

SIMS adds the name to the This Class list.

SIMS highlights the selected Participant name. Hold down the Control key to select more than one name. SIMS adds the name to the This Class list and displays the Participant name and email address in the List of Participants in this Class region and the Email the Participants in this Class region.

Note When SIMS moves the name from the Potential list to the This Class list, the user is automatically given access to all course materials for that class.

View and Edit Scheduled Classes

When scheduling classes, you should review the current class list to ensure you do not create a conflict with another course being offered in the Health Care Simulation Center. SIMS provides the View Classes page for this use.

Use this page to:

- view all scheduled classes
- view detailed information for one class
- edit the information for one class
- group class sessions
- view the course description
- delete classes from the schedule

Complete the following steps to view class information...

Procedure

- 1 From the My Portfolio page, select the View Classes link.

The View Classes page opens.

View Classes Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

View Classes

ACCOUNT: CLASS MAINTAINER

Start Date: 06/23/2005 < [Calendar Icon] > Thursday

End Date: 08/07/2005 < [Calendar Icon] > Sunday

Course: Select a Course

Search:

View Classes

Click the date to view information about that class

DATE	EDIT CLASS	GROUP MEMBERS	GROUP CLASSES	COURSE	INITIAL MEETING ROOM	COMMENTS	DELETE CLASS
06/23/2005 12:00 pm - 04:00 pm (Thu)	[Edit]	not part of group	☐	SimMed STRATUS CTT	Conf. Rm		[Delete]
06/27/2005 01:00 pm - 02:30 pm (Mon)	[Edit]	not part of group	☐	STRATUS DAM ANES FAC	Conf. Rm		[Delete]
06/27/2005 02:30 pm - 04:00 pm (Mon)	[Edit]	not part of group	☐	STRATUS DAM ANES FAC	Conf. Rm		[Delete]
06/27/2005 10:30 am - 12:00 pm (Mon)	[Edit]	not part of group	☐	STRATUS DAM ANES FAC	Conf. Rm		[Delete]
06/29/2005 09:00 am - 10:30 am (Wed)	[Edit]	not part of group	☐	STRATUS DAM ANES FAC	Conf. Rm		[Delete]

Merge class people? ☐ Create Group

Note When the View Classes page opens, only the fields above the View Classes button are displayed. Perform steps 2 and 3 to bring the classes into view.

- 2 Use the drop down menus to select the start and end dates and the course.

Complete the fields in the View Classes page as follows:

Field	Description
Start Date:	Enter the start date in MM/DD/YYYY format. Optionally, select the calendar icon to select the class date in a popup calendar.
End Date:	Enter the end date in MM/DD/YYYY format. Optionally, select the calendar icon to select the class date in a popup calendar.
Course:	Select a course from the drop down menu. If you leave this region blank, SIMS displays all classes for all courses.
Search:	Enter a search string to be used to find a specific class.

- 3 Select the View Classes button.

SIMS displays all classes matching the search criteria. The read-only information displayed for each class includes:

- Group Members — the list of classes that have been grouped together to allow one course to span multiple class times.
- Initial Meeting Room — the name of the room where Participants should report for the class.
- Comments — information about the course for the Class Maintainers.

- 4 Optionally, select the Date link to open the View Class page.

SIMS displays information for one class in the View Class page.

View Class: Detailed Class Information

Home My Portfolio Course Catalog Calendar About Us Help Login	
View Class	ACCOUNT: CLASS MAINTAINER
Course: Difficult Airway Management Anesthesiology Faculty Class Date: 6/27/2005 Edit Class Delete Class View Classes Get Status Initial Meeting Room: Conference Room Time: 01:00 PM - 02:30 PM Comments: Session Rooms: Conf. Rm	

- Select the course name to view the detailed description of the course.
- Select the date to view the course calendar for that date.
- Select the Edit Class link to open the Edit a Class page.
- Select the Delete Class link to remove the class from the course schedule.
- Select the View Classes link to return to the View Classes page.
- Select the Get Status link to view the progress of all class participants.
- Select the link for the meeting room.

Find instructions to use this page in step 5.

SIMS displays a confirmation page allowing you to confirm the deletion of the class or cancel the action.

Find instructions to use this page in **How to View Participant Progress** on page 108.

SIMS displays instructions to find the room in the facility.

- 5 Optionally, select the Edit link from the View Classes page to edit the class information.

SIMS opens the Edit Class Information page.

Edit Class Information Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Edit Class InformationACCOUNT: CLASS MAINTAINER

Course:SIMMED STRATUS CTT

Date:06/23/2005< > Thursday

View Classes

Start Time:12 (pm):00

Stop Time:4 (pm):00

View Course Participant Status

Initial Meeting Room:Conf. Rm

Session Room(s):

☐ Classroom

☒ Conf. Rm

☐ HPS A

☐ HPS B

☐ Micro Sim

☐ Partial Task

CAUTION! Deleting a session room also deletes any associated session data such as session participants.

Comments:

Internal Comments:
(Class Maintainers Only)

Click here to add instructions.

Facilitator Pre Instructions:

Facilitator Post Instructions:

Participant Pre Instructions:

Participant Post Instructions:

Class Announcements:

Update Class

- a Edit the existing information about the class, if required.

Use the drop down menus to change the field values as follows:

Field	Description
Class Date:	Modify the class date using MM/DD/YYYY format. Optionally, select the calendar icon to select the class date in a popup calendar.
Start Time:	Use the drop down menus to select a new class start time. Enter the time in hours and minutes.
Stop Time:	Use the drop down menus to select a new class stop time. Enter the time in hours and minutes.
Initial Meeting Room:	Use the drop down menu to change the room to be used as the initial meeting place for the class.
Session Room(s):	Select the checkbox next to the room name to add the room to the list of required rooms. SIMS places an X in the box.

Field	Description
Comments:	Add or modify comments to be displayed on the Course Calendar.
Internal Comments:	Add or modify comments to be seen by all Class Maintainers.

- b** Include instructions for class Facilitators and Participants.

Note The Instructions and Comments regions depicted on the graphic are hidden from view when the page opens. Select the Click here link above these fields to display them.

Complete the fields as described in the following table:

Field	Description
Facilitator Pre Instructions:	Enter or modify the instructions to be displayed on the Pre Class page to all Facilitators assigned to teach this class.
Facilitator Post Instructions:	Enter or modify the instructions to be displayed on the Post Class page to all Facilitators assigned to teach this class.
Participant Pre Instructions:	Enter or modify the instructions to be displayed on the Pre Class page to all Participants assigned to take this class.
Participant Post Instructions:	Enter or modify the instructions to be displayed on the Post Class page to all Participants assigned to take this class.
Class Announcements:	Enter or modify the announcements to be displayed on the Announcements page to all Facilitators and Participants assigned to take this class.

- c** Select the Update Class button.
- d** In the Facilitators or Participants region, use the arrow keys to move people into or out of a class.

SIMS saves the changes made in all fields modified in steps a and b, and updates all views for this class.

SIMS displays Facilitators and Participants assigned to the class in the lower portion of the View Classes page.

Edit Class Information: Facilitators and Participants

Update the people in this class

FACILITATORS	
 Potential Facilitator, Test (testfacilitator) Add or remove people from this facilitator group.	 This Class ->> <<-

PARTICIPANTS	
 Potential User, Test (testuser) Add or remove people from this participant group.	 This Class ->> <<-

LIST OF PARTICIPANTS IN THIS CLASS	EMAIL THE PARTICIPANTS IN THE CLASS
Empty rows representing the content area	

- Select one or more names in the Potential or This Class regions.
- Select an arrow button to move the selected name(s) from one list to the other.

Hold down the Control key to select more than one name.

When a name is added to the This Class list in the Participants region, the name and respective email address are added to the List of Participants in This Class and Email the Participants in This Class regions at the bottom of the page.

- e Select the View Classes button to return to the View Classes page.
- f Select the View Course Participant Status button to view Participant progress.

- 6 Optionally, create a class group.

Find instructions to use this page in **How to View Participant Progress** on page 108.

Classes that span multiple days can be grouped together and identified to SIMS as one class. This is useful for situations where evaluations and quizzes should only be

a In the View Classes page, select the box in the Group Classes column for all classes to be grouped. b To ensure all Participants are assigned to each class, select the Merge class people? check box. c Select the Create Group button.	presented to the Participant once for the entire class, not for each segment of the class. SIMS places an X in the check box.
7 Optionally, select the course name from the View Classes page to view course descriptive information.	SIMS places an X in the check box. SIMS lists the classes that have been grouped together in the Group Members column. If you selected the Merge class people check box, all Participants assigned to any class in the group should now be assigned to all classes.
8 Optionally, select the Delete link for the class to delete the class from the Site Calendar.	SIMS displays a confirmation page allowing you to confirm the deletion of the class or cancel the action.

View Reports

SIMS allows you to view the enrollment for classes using two different reports. The Class Facilitator and Participant Listing report shows both the Facilitators assigned to teach each class as well as the Participants who have enrolled in the class. The View Course Participant Status report shows the Participants enrolled in the class and the progress they have made to complete all required class materials.

Both of these reports are helpful for maintaining an appropriate balance of classes in the Simulation Center.

How to View Class Enrollment

You can view the list of Participants in all class that are scheduled for all courses in the facility. Use this list to verify a Participant is assigned to a class, to see which Participants are scheduled to attend, or to balance the load of Participants in a class.

You can also use this report to view all activities taking place within the facility that require the use of a room.

Complete the following steps to view class enrollments...

Procedure

- 1 From the My Portfolio page, select the View Class Facilitators and Participants link.

The Class Facilitator and Participant Listing page opens.

Class Facilitator and Participant Listing Page

[Home](#) | [My Portfolio](#) | [Course Catalog](#) | [Calendar](#) | [About Us](#) | [Help](#) | [Login](#)

Class Facilitator And Participant Listing

ACCOUNT: CLASS MAINTAINER

Start Date: 06/01/2005 < > Wednesday

End Date: 06/17/2005 < > Friday

Courses: DAM ANES FAC (Don't select a course to get all courses)

Show Facilitators: ☒

Show Participants: ☒

Show Non-Instructional: ☐

Generate Report

- 2** Use the drop-down menus to select appropriate values for each field on the form.

Enter information in this form as follows:

Field	Description
Start Date:	Enter the first date, in MM/DD/YYYY format, to be used when searching for class information. Optionally, select the calendar icon to select a start date on a popup calendar.
End Date:	Enter the last date, in MM/DD/YYYY format, to be used when searching for class information. Optionally, select the calendar icon to select an end date on a popup calendar.
Courses:	Select the course name. If a course name is not chosen, all classes for all courses that you have permission to access will be shown.
Show Facilitators:	Select this checkbox to include the name of the Facilitator assigned to the class in the report.
Show Participants:	Select this checkbox to include the Participant list in the report.
Show Non-Instructional:	Select this checkbox to view all events occurring at the facility, which are non-class related, but which require a room to be reserved (for example, a facility tour).

- 3** Select the Generate Report button.

SIMS gathers information about each class scheduled for the selected course (or all courses that you have permission to access) and displays that information on the page (as depicted in the following graphic).

Expanded View Participant List Page

[Home](#) | [My Portfolio](#) | [Course Catalog](#) | [Calendar](#) | [About Us](#) | [Help](#) | [Login](#)

Class Facilitator And Participant Listing ACCOUNT: CLASS MAINTAINER

Start Date: 06/01/2005 < > Wednesday

End Date: 06/17/2005 < > Friday

Courses: DAM ANES FAC (Don't select a course to get all courses)

Show Facilitators: ☒

Show Participants: ☒

Show Non-Instructional: ☐

Generate Report

Click on the class date to view and edit that class

6/1/2005 (08:00 : 09:00) Difficult Airway Management Anesthesiology Faculty	
FACILITATORS Facilitator, Test	PARTICIPANTS User, Test
6/2/2005 (13:00 : 14:00) Difficult Airway Management Anesthesiology Faculty	
FACILITATORS Facilitator, Test	PARTICIPANTS User, Test User, Test
6/8/2005 (11:00 : 12:00) Difficult Airway Management Anesthesiology Faculty	
FACILITATORS	PARTICIPANTS
6/10/2005 (09:00 : 10:00) Difficult Airway Management Anesthesiology Faculty	
FACILITATORS Facilitator, Test	PARTICIPANTS User, Test User, Test

- 4 Optionally, select the course date link.

SIMS opens the View Class page showing information about the class and providing links to edit the class and view the course participant’s status.

How to View Participant Progress

Participants may be required to complete evaluations, surveys, quizzes, and tests during the class. You can check to see if the Participant has completed the required materials.

Complete the following steps to view the Participant’s progress...

Procedure

- 1 From the My Portfolio page, select View Course Participant Status.

The View Course Participant Status page opens. This page contains the names of each Participant who is scheduled for each class for one or more courses.

View Course Participant Status Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

View Course Participant Status ACCOUNT: CLASS MAINTAINER

Start Date: 06/06/2005 < > Monday
 End Date: 06/10/2005 < > Friday
 Courses: STRATUS DAM ANES FAC (Don't select a course to get all courses)
 Send Emails: ☐
 Generate Report

KEY
 = complete
 = not complete
 = not active/available
Participant = has signed in

Click on the class date to view and edit that class. Click on the 'Participants' header in the 1st column to view and edit the people in that class.

Participants [click to edit]	During Course	Pre Survey	Post Facilitator	SAMPLE INTER-CLASS QUIZ	SAMPLE PRE-QUIZ
06/07/2005 (06:00 : 07:00) Difficult Airway Management Anesthesiology Faculty					
Participant, Test					
User, Test					
06/08/2005 (11:00 : 12:00) Difficult Airway Management Anesthesiology Faculty					
06/09/2005 (12:00 : 16:00) Difficult Airway Management Anesthesiology Faculty					
Participant, Test					
Stevens, Maria					
User, Test					
06/10/2005 (13:00 : 17:00) Difficult Airway Management Anesthesiology Faculty					

- 2** Use the drop-down menus and calendar pop-ups to select appropriate values for each field on the form.

Enter information in this form as follows:

Field	Description
Start Date:	Enter the first date, in MM/DD/YYYY format, to be used to search for class information. Optionally, select the calendar icon to select a start date on a popup calendar.
End Date:	Enter the end date, in MM/DD/YYYY format, to be used to search for class information. Optionally, select the calendar icon to select a start date on a popup calendar.
Courses:	Select the course name. All classes for all courses will be shown if a course name is not chosen.
Send Emails:	Select this checkbox to have SIMS send an email to each Participant who has not completed all of the requirements for the class to encourage the Participant to finish the incomplete tasks. SIMS automatically generates these reminder emails on a periodic basis. Participants who have completed all course materials will not receive an email message.

3 Select the Generate Report button.	SIMS searches for all classes which match the information entered in the page and displays the Participant status for each class grouped by the class.
4 Optionally, select the class date to view information about the class.	SIMS opens the View Class page. Find instructions to use this page in step 4 on page 101.
5 Optionally, select the Participants link to edit the participant list.	SIMS opens the Edit Class page. Find instructions to use this page in step 5 on page 102.

Administer the Class

One important task performed by the Class Maintainer is to verify who actually attends the class. SIMS allows you to gather the class roll without ever being in the classroom. This is done using the Electronic Sign In page.

Find the instructions to use this page in this section.

How to Activate the Electronic Sign In Page

The Electronic Sign In page allows Facilitators and Participants to sign themselves into a class. The Class Maintainer activates the sign in page on a computer sitting in or near the classroom. Each person verifies their participation in the class by selecting their name in the class list and acknowledging their participation.

The Electronic Sign In page is controlled by an auto timer. After a user has signed in and verified attendance in the class, SIMS displays the current day's course list automatically after a five second delay.

The Electronic Sign In page remains open, showing the class list, until someone signs in.

Complete the following steps to activate the sign in page...

Procedure

1 Login to SIMS using a computer located in or near the classroom.	Use your username and password to login.

- 2 From the My Portfolio page, select the Electronic Class Sign In link.

The Electronic Sign In page opens.

Electronic Sign In Page

[Home](#) | [My Portfolio](#) | [Course Catalog](#) | [Calendar](#) | [About Us](#) | [Help](#) | [Login](#)

STRATUS Electronic Sign In

ACCOUNT: CLASS MAINTAINER

CLICK ON YOUR COURSE

[Difficult Airway Management Anesthesiology Faculty — 02:30 PM to 05:00 PM in Conference Room](#)

All classes scheduled for the Health Care Simulation Center for the current date are displayed on the page.

- 3 Select the course name and class time.

SIMS updates the Electronic Sign In page to show the list of people scheduled to be part of the selected class. The list includes both Facilitators and Participants.

Electronic Sign In: Class Page

[Home](#) | [My Portfolio](#) | [Course Catalog](#) | [Calendar](#) | [About Us](#) | [Help](#) | [Login](#)

STRATUS Electronic Sign In

ACCOUNT: CLASS MAINTAINER

DIFFICULT AIRWAY MANAGEMENT ANESTHESIOLOGY FACULTY

A. CLICK YOUR NAME IN THE LIST BELOW TO SIGN IN

[Facilitator, Test](#)
[Stevens, Maria](#)
[User, Test](#)

PEOPLE WHO HAVE SIGNED IN

OR

B. IF YOUR NAME IS NOT LISTED, START TYPING YOUR LAST NAME

If you made a mistake
[CLICK HERE](#)

- 4 Instruct the people scheduled to be in the class to select their name from the list.

SIMS opens a page asking the person to verify their attendance in the class.

Electronic Sign In: Verification Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

STRATUS Electronic Sign In ACCOUNT: CLASS MAINTAINER

Test Facilitator, are you sure you are taking this class today: **Difficult Airway Management Anesthesiology Faculty** ?

[YES](#) [NO](#)

If you made a mistake
[CLICK HERE](#)

- 5** Optionally, instruct a person with a user account who is not on the attendance list to sign in by entering their username.

- If the user selects Yes, SIMS checks the person into the class and displays the user name in the People Who Have Signed In region.
- If the user selects No, SIMS returns to the Electronic Sign In “home” page.

SIMS searches for the matching user account and displays the username in the drop down menu. Select the Submit button to add the user name to the attendee list.

6 Tasks for Account Maintainers

The Account Maintainer is responsible for ensuring that all users are able to successfully access the required SIMS functionality. You provide troubleshooting for users who are unable to login or are unable to see the appropriate utilities.

SIMS displays utilities according to the group that the user belongs to. The Account Maintainer assigns users to groups when the user creates a SIMS account. The Account Maintainer can also create user accounts and add the account to a group at the same time.

Each user must also be given access to a site. A site is equivalent to a Health Care Simulation Center. One user may take classes at one or more Simulation Centers and must have access to the courses at each of these centers.

You can find all utilities for the Account Maintainer on the My Portfolio page.

My Portfolio Page: Account Maintainer

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

My Portfolio

ACCOUNT: ACCOUNT MAINTAINER

TIMEFRAME

July 2005

July 2005

30	Mo	Tu	We	Th	Fr	Sa	30	Mo	Tu	We	Th	Fr	Sa
3	4	5	6	7	8	9	3	4	5	6	7	8	9
10	11	12	13	14	15	16	10	11	12	13	14	15	16
17	18	19	20	21	22	23	17	18	19	20	21	22	23
24	25	26	27	28	29	30	24	25	26	27	28	29	30
31							31						

Preset Timeframes:
[Today](#) | [This Week](#) | [This Month](#)
[This Academic Year](#) | [All](#)

Search

Welcome to the Simulation Information Management System (SIMS). The My Portfolio pages provide personalized access to all other activities within the system.

Use the calendar to identify the time range to be used to view the courses you are taking. You can choose daily, weekly, monthly, or academic year timeframes. When you select the Search button, the course list is displayed on the My Courses tab. You will receive a message if you have not requested course access.

Use the Utilities links to perform course-related and account-related activities with SimMedical.

- Account Maintainers can manage user accounts and user groups.

ACCOUNT MAINTAINER UTILITIES

[Add a User](#)
[Edit Users in One Group](#)
[Reset Account Password](#)
[Find and Manage User Accounts](#)
[Case Name Check](#)
[View Group Definitions](#)
[Edit Groups for One User](#)
[View User Activity](#)

GENERAL UTILITIES

[Account Information](#)
[Request Course Access](#)

This chapter includes instructions to perform the following tasks:

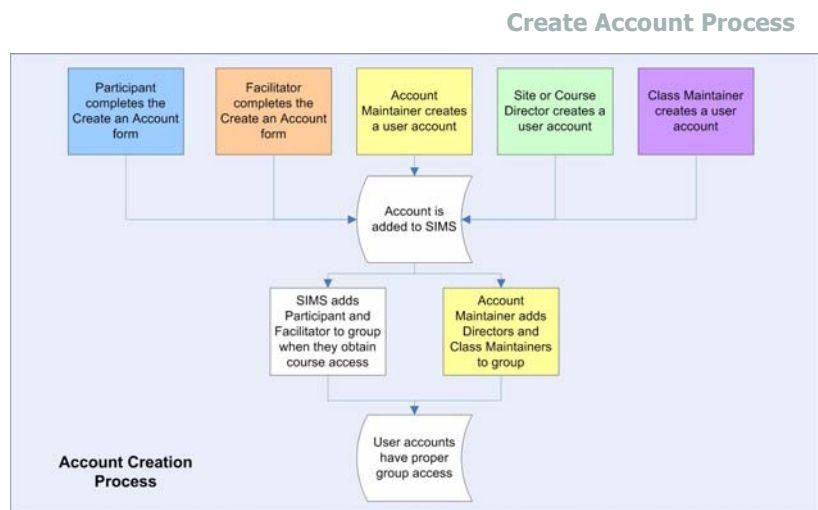
- Create a user account.
- Add one user to one or more groups.
- Add one or more users to one group.
- Edit user account information.
- Reset user account password.
- Check user login activity.
- Correct user name entries.

These activities have been divided into two sections within this chapter: activities to set up user accounts and activities to manage user accounts.

Setup User Accounts

All users must have an account to access the utilities that are available from the My Portfolio page. You can create an account for a user or the user can create the account by completing the Create an Account form and submitting it. Once the account has been created, the account must be added to a group.

Account Maintainers assign users to groups (or roles) in SIMS. If you create the user account, you add the user to a group when the account is being created. Users are added to the Participant group when they are granted access to a course. The Account Maintainer will specifically identify groups for higher level users: Site Director, Site Director Proxy, Course Director and Course Director Proxy.



This section contains the instructions for both of these scenarios.

Create One or More User Accounts

Users create their own accounts by selecting the link from the Login page and completing the Create an Account form. Find the instructions for a user to create an account in ***How to Create An Account*** on page 17. Sometimes, the Account

Maintainer might be asked to add one or more users to SIMS. Use the Add a User form for this purpose.

Before You Begin

Use the Find and Manage User Accounts page to ensure the user does not already have a user account. The Add a User page is used only to create new user accounts.

Complete the following steps to add one or more users...

Procedure

- 1 From the My Portfolio page, select the Add a User link.

The Add a User page opens.

Add a User Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Add a User

ACCOUNT: ACCOUNT MAINTAINER

First Name: *

Middle Name:

Last Name: *

Login Name: *

This should match the Network ID when possible.

Email: *

Birth Date: < [icon] > *

Click the icon to pop up a calendar

PIN: *

Last 5 digits of the Social Security #

* indicates a required field

ADD TO GROUPS

STRATUS ALL ACCESS

STRATUS Acct. Maintainers

STRATUS CTT Director Proxy

STRATUS CTT Directors

STRATUS CTT FacI.

STRATUS CTT Part

STRATUS CVCT Director Proxy

STRATUS CVCT Directors

Hold down the CTRL key to select multiple groups

ADD TO SITES

STRATUS

SimMed

WISER

Hold down the CTRL key to select multiple groups

<< Back

Add User

- 2 Enter user information in the form.

Complete the fields of the form as follows:

Field	Description
First Name:	Enter the user's first name.
Middle Name:	Enter the user's middle name. This field is optional.
Last Name:	Enter the user's surname.
Login Name:	Enter a name to be used to login to SIMS. This name should match their Health Care System login name, if possible.
Email:	Enter the user's email address. This address is used to send all communications from SIMS to the user. It should be an email address that the user checks frequently.

Field	Description
Birth Date:	Enter the user's birth date in MM/DD/YYYY format. Optionally, select the calendar icon to open a window. Select the birth date from the calendar in the window.
Last 5 Digits of SSN:	This is a personal information number to be used to reset the password should the user forget it. This number should be equivalent to the last five digits of the user's Social Security number.

- 3** In the Add to Groups region, select one or more group names to add the user to a group.

Each SIMS user must be assigned to a role to enable the user to interact with SIMS appropriately. All user groups are shown in the Add to Groups: region. Hold the Control key down to select multiple groups.

Note User accounts can also be added to groups from the Edit Users in One Group form or the Edit Groups for One User form. Use these forms to add the user account to a group when the user has created their own account . Select either of these links from the My Portfolio page.

- 4** In the Add to Sites region, select one or more site names to add the user to a site.

SIMS maintains all users for all sites that are using SIMS. One user may participate in classes at multiple sites. Each site using SIMS is shown in the Add to Sites: region. Hold the Control key down to select multiple sites (if required).

Tip All users must be assigned to a Site to enable them to access the information stored in the SIMS database for that site.

- 5** Select the Add User button.
- 6** Repeat steps 2-5 to create additional user accounts.
- 7** Select the Back button to return to the My Portfolio page.

SIMS creates a new account for this user and adds the user account to the group and the site identified on the form.

Selecting the My Portfolio menu located in the menu bar also performs the same action.

Add a User Account to a Group

Users create their own accounts using the Create an Account form. SIMS sends an email notification to the user and to the Account Maintainer that the account was created.

Once the account is created, the account must be added to a group to enable the user to access the appropriate SIMS functionality. The Account Maintainer is responsible for adding user accounts to groups. The groups equate with the roles identified in **Chapter 1: Introduction to SIMS**.

Users with existing accounts may need to be added to other groups if their role changes within the Health Care Simulation Center.

You can use the Find and Manage User's Groups form to add one user to one or more groups. You can optionally use the Edit Groups form to add one or more users to one single group. Both procedures are described in this section.

Before You Begin

Check with the Course Director or Site Director if you are unsure which group a user account should be assigned to.

Complete the following steps to add user accounts to a group...

Procedure (add one user to one or more groups)

- 1 From the My Portfolio page, select the Edit Groups for One User link.

The Edit Groups for One User page opens.

Edit Groups for One User Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Edit Groups for One User ACCOUNT: ACCOUNT MAINTAINER

USER'S NAME

Select from list or use free-text search

▼

☒ Show Active Users Only

OUT

Select from list or use free-text search

▲

▼

STRATUS ALL ACCESS
 STRATUS Acct. Maintainers
 STRATUS CTT Director Proxy
 STRATUS CTT Directors
 STRATUS CTT Fac.
 STRATUS CTT Part.
 STRATUS CVCT Director Proxy
 STRATUS CVCT Directors
 STRATUS CVCT Fac.
 STRATUS Class Maintainers
 STRATUS Course Director Proxies
 STRATUS Course Directors
 STRATUS Course Facilitators
 STRATUS Course Maintainers
 STRATUS DAM ANES FAC Director Proxy
 STRATUS DAM ANES FAC Directors
 STRATUS DAM ANES FAC Fac.
 STRATUS DAM ANES RES Director Proxy
 STRATUS DAM ANES RES Directors
 STRATUS DAM ANES RES Fac.
 STRATUS DAM ANES RES Part.
 STRATUS MOD SED - ADULT Director Proxy
 STRATUS MOD SED - ADULT Directors
 STRATUS MOD SED - ADULT Fac.
 STRATUS MOD SED - ADULT Part.

IN

Select from list or use free-text search

▲

▼

STRATUS CVCT Part.
 STRATUS DAM ANES FAC Part.
 SimMed STRATUS CTT Part.

<->

2 Select a user from the drop down menu.

SIMS displays all groups that the user account has been added to along with the list of all groups in the system.

3 Select the group name in the Out region.

SIMS highlights the group name.

Tip Hold down the Control key to select more than one group in the list.

4 Select the arrow button.

SIMS moves the selected group name from the Out region to the In region. The user account now belongs to that group.

5 Repeat steps 3 and 4 to add the user to multiple groups.

Some users may need to be members of multiple groups. For example, a Facilitator might teach one course, and may be a Participant in another. This user will be assigned to both the Facilitator group and the Participant group.

Note You can delete the user from the group by selecting the user's name in the In region and selecting the arrow button to move the name to the Out region.

Procedure (add one or more users to one group)

- 1

From the My Portfolio page, select the Edit Users in One Group link.
- The Edit Users in One Group page opens.

Edit Users in One Group Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Edit Users in One Group

ACCOUNT: ACCOUNT MAINTAINER

GROUPS

Select from list or use free-text search

STRATUS Course Facilitators

☒ Show Active Users Only

OUT

Select from list or use free-text search

Director, Test (testdirector)

Director Proxy, Test (testdirectorproxy)

Maintainer, Account (acctmain)

Maintainer, Class (classmain)

Maintainer, Course (coursemain)

NewUserEmail, Test (newuseremail)

Site Director, Test (testsitedir)

Site Director Proxy, Test (testsitedirproxy)

User, Test (testuser)

IN

Select from list or use free-text search

Facilitator, Test (testfacilitator)

<->

List for copying & pasting:
Facilitator, Test

Email list for copying & pasting:
test2.facilitator@gmail.com; test.facilitator@gmail.com;

2

Select a group in the drop down menu.

SIMS displays all users who have been assigned to that group along with the list of all registered users.

3

Select the user's name in the Out region.

SIMS highlights the user's name.

4

Select the arrow button.

SIMS moves the user's name from the Out region to the In region.

5

Repeat steps 3 and 4 to add multiple users to the group.

Use this functionality when multiple users have created accounts and all need to be added to the same group.

Tip

Hold down the Control key to select more than one user names in the list.

Note

You can delete the user from the group by selecting the user's name in the In region and selecting the arrow button to move the name to the Out region.

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SimMedical

Manage Accounts

As the Account Maintainer, you often are requested to troubleshoot problems with user accounts. SIMS provides a variety of utilities to assist you with this job.

Access problems are most likely caused by the account not belonging to the appropriate group. You can learn which groups an account belongs to and add the account to a group if required.

Users forgetting their password is another common problem. You are able to reset a user's password to the last five digits of the Social Security number that was provided when their account was created.

Other utilities available to you provide views into which groups are available. All utilities which help you manage accounts are described in this section.

Lookup User Account Information

The Find and Manage User Accounts page encapsulates account lookup information and provides access to other pages that are used to manage the SIMS settings for the user account. Each piece of information on this page is available from other SIMS pages.

Complete the following steps to lookup account information...

Procedure

- 1 From the My Portfolio page, select the Find and Manage User Accounts link.

The Find and Manage User Accounts page opens.

Find and Manage User Accounts Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Find and Manage User AccountsACCOUNT: ACCOUNT MAINTAINER

ID	NAME	EDIT	GROUPS	LAST LOGIN	PASSWORD	EMAIL
4	Director, Test	testdirector	View / Edit	6/29/2005 8:29:23 AM	Reset	Resend
153	Director Proxy, Test	testdirectorproxy	View / Edit	6/22/2005 2:51:24 PM	Reset	Resend
165	Site Director, Test	testsiteidir	View / Edit	6/22/2005 1:23:08 PM	Reset	Resend
166	Site Director Proxy, Test	testsiteidirproxy	View / Edit	6/7/2005 2:11:38 PM	Reset	Resend

2 Enter the user name and select the Search button.

3 Review user information in the form that is shown.

4 Optionally, from the Edit column, select the user account name to edit the user information.

You can enter all or a portion of the user's name or the SIMS account name in the entry box. SIMS displays all user accounts that match the name you have entered.

SIMS displays read-only information in this form including:

- a user ID that is used by SIMS internally to identify the user.
- the user's full name as entered in the Create an Account form.
- the date and time when the user last logged into SIMS.

The Edit a User page opens.

Edit a User Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Edit a UserACCOUNT: ACCOUNT MAINTAINER

First Name: *

Middle Name:

Last Name: *

Login Name: *

This should match the Network ID when possible.

Email: *

Birth Date: < > Friday *

Click the icon to pop up a calendar

PIN: *

Last 5 digits of the Social Security #

* indicates a required field

ADD TO GROUPS

STRATUS ALL ACCESS

STRATUS Acct. Maintainers

STRATUS CTT Director Proxy

STRATUS CTT Directors

STRATUS CTT Facd.

STRATUS CTT Part

STRATUS CVCT Director Proxy

STRATUS CVCT Directors

Hold down the CTRL key to select multiple groups

ADD TO SITES

STRATUS

SimMed

WISER

Hold down the CTRL key to select multiple groups

a Make changes or corrections to the user account information on the left side of the page.

Note This is the only form that allows you to change the user's Social Security number.

- b** In the Add to Groups region, add the user to one or more groups.
- c** In the Add to Sites region, add the user to one or more sites.

Tip

Hold the Control key to select one or more Groups or Sites for the user.

- 5** Optionally, use the fields on the form to perform activities with the user account.

Perform the actions as described below:

Field	Description
List Groups	Select the View / Edit link to open the Edit Groups for One User page. Use this page to review the groups that the user account has been assigned to and to add the user to additional groups. Find additional information to edit groups in Add a User Account to a Group on page 120.
Reset Password	Select the Reset link to reset the user account password to the last five digits of the user's Social Security number.
Resend Email	Select the Resend link to have SIMS resend the New Account email message to the user. The Resend Email function is available from this page only.

Reset User Password

If a user has difficulty accessing SIMS, you may wish to reset their password to verify that this is not the problem. You will also use this command if the user has forgotten their password. SIMS resets the password to the last five digits of the user's Social Security number or another five digit number of the user's choice.

Complete the following steps to reset the user's password...

Procedure

- 1 From the My Portfolio page, select the Reset Account Password link.

The Reset Account Password page opens.

Reset Account Password Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Reset Account Password

ACCOUNT: ACCOUNT MAINTAINER

This will reset the selected user password to the last 5 digits of their SSN (the PIN entry in their database listing).

User, Test (testuser)

Just start typing the last name.

User, Test (testuser)

Reset User Password

- 2 Enter the user's last name in the entry box.
- 3 If more than one name matches, select the desired user name in the drop down menu.
- 4 Select the Reset User Password button.

As you type, SIMS displays all user names that match the name you enter.

SIMS highlights the name in the list.

SIMS displays the "Password has been reset!" message and sets the user password to the last five digits of the user's Social Security number. SIMS also generates an email message to both you and the user confirming that the password has been changed.

View User's Last Login

You can verify the last date and time that a user logged into SIMS. This feature is useful if the SIMS user is having difficulty with accessing the account information. You can pass this information along to the second level of support if resetting the password doesn't solve the problem.

Complete the following steps to view the last login...

Procedure

- 1 From the My Portfolio page, select the View User Activity link.

The View User Activity page opens.

View User Activity Page

[Home](#) | [My Portfolio](#) | [Course Catalog](#) | [Calendar](#) | [About Us](#) | [Help](#) | [Login](#)

View User ActivityACCOUNT: ACCOUNT MAINTAINER

USERNAME	LAST LOGIN FOR SITE
testdirector	6/29/2005 8:29:23 AM
testdirectorproxy	6/22/2005 2:51:24 PM
testsitedir	6/22/2005 1:23:08 PM
testsitedirproxy	6/7/2005 2:11:38 PM

4 user logins.

- 2 Enter the user's last name in the entry box.
- 3 Select the Search button.

You can enter all or a portion of the user's name or the SIMS account name in the entry box.

SIMS displays the user's username along with the date and time that the user last logged into SIMS.

Find Group Descriptions

SIMS groups provide system access to users. The Site Director, Site Director Proxy, Class Maintainer and Account Maintainer groups are not related to any one course, but members of those groups can access course materials. Participants and Facilitators must be part of those groups to access course materials.

Each course has several groups for the various users who need access to that course. For example, one course will have individual groups for the Course Director, Course Director Proxy, Facilitator, and Participant. These groups provide different levels of access to the course materials based upon the user's role.

You can view the entire list of groups for your site and a description of each group from the View Group Definitions page.

Complete the following steps to view the list of groups...

Procedure

- 1 From the My Portfolio page, select the View Group Definitions link.

The View Group Definitions page opens.

View Group Definitions Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

View Group Definitions

ACCOUNT: ACCOUNT MAINTAINER

Search:

ID	GROUP	DESCRIPTION
3	WISER Course Facilitators	WISER Course Facilitators - They teach the individual classes
6	WISER DAM ANES RES FacL	WISER Facilitators - Difficult Airway Management Anesthesia Residents
10	WISER DAM ANES FAC FacL	WISER Facilitators - Difficult Airway Management Anesthesia Faculty
11	WISER DAM ANES FAC Part.	WISER Participants - Difficult Airway Management Anesthesia Faculty
13	STRATUS Course Facilitators	STRATUS Course Facilitators - teach the individual classes
17	STRATUS DAM ANES FAC FacL	STRATUS Facilitators - Difficult Airway Management Anesthesia Faculty
18	STRATUS DAM ANES FAC Part.	STRATUS Participants - Difficult Airway Management Anesthesia Faculty
19	STRATUS DAM ANES RES FacL	STRATUS Facilitators - Difficult Airway Management Anesthesia Residents
22	WISER MOD SED - ADULT FacL	WISER Facilitators - Moderate Sedation for Non-Anesthesia Care Givers - Adult
24	STRATUS MOD SED - ADULT FacL	STRATUS Facilitators - Moderate Sedation for Non-Anesthesia Care Givers - Adult
25	WISER CVCT FacL	WISER Facilitators - Central Venous Cannulation Training
30	WISER DAM ANES FAC Directors	WISER Directors - Difficult Airway Management Anesthesia Faculty
32	WISER DAM ANES FAC Director Proxy	WISER Proxies - Difficult Airway Management Anesthesia Faculty
46	STRATUS CVCT FacL	STRATUS Facilitators - Central Venous Cannulation Training
50	STRATUS DAM ANES FAC Director Proxy	STRATUS Proxies - Difficult Airway Management Anesthesia Faculty
51	STRATUS DAM ANES FAC Directors	STRATUS Directors - Difficult Airway Management Anesthesia Faculty
52	WISER CTT FacL	WISER Facilitators - Crisis Team Training
56	SimMed STRATUS CTT FacL	SimMed STRATUS Facilitators - Crisis Team Training
63	SimMed Course Facilitators	SimMed Course Facilitators - They teach the individual classes
74	SimMed CTT FacL	SimMed Facilitators - Crisis Team Training
78	STRATUS CTT FacL	STRATUS Facilitators - Code Team Training

- 2 Optionally, enter one or more words to be used to search for a group and select the Search button.
- 3 Optionally, select the group name.

SIMS displays only those groups that match the words entered in the Search box.

The Edit Groups page opens. Find instructions to use this page in **Add a User Account to a Group** on page 120.

Find User Name Typographical Errors

Sometimes, when user information is entered into the Create an Account form, it may contain typographical errors. In particular, this page finds user names which have the incorrect use of upper and lower case letters.

Complete the following steps to find typographical problems with user names...

Procedure

- 1 From the My Portfolio page, select the Case Name Check link.

The Case Name Check page opens.

Case Name Check Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Case Name Check ACCOUNT: ACCOUNT MAINTAINER

ACCOUNTS WITH A FIRST OR LAST NAME IN ALL UPPER OR LOWER CASE

Click the account name to edit the name

FIRST	LAST	ACCOUNT NAME
TESTAIMEE	TEST	testaimed1
TESTAIMEE	TEST	testaimed3

[Refresh](#)

- 2 Select the Account Name link.

The Edit a User page opens.

Edit a User Page

Home | My Portfolio | Course Catalog | Calendar | About Us | Help | Login

Edit a User ACCOUNT: ACCOUNT MAINTAINER

First Name: *

Middle Name:

Last Name: *

Login Name: *

This should match the Network ID when possible.

Email: *

Birth Date: < > Friday *

Click the icon to pop up a calendar

PIN: *

Last 5 digits of the Social Security #

* indicates a required field

ADD TO GROUPS

- STRATUS ALL ACCESS
- STRATUS Acct. Maintainers
- STRATUS CTT Director Proxy
- STRATUS CTT Directors
- STRATUS CTT Faci.
- STRATUS CTT Part.
- STRATUS CVCT Director Proxy
- STRATUS CVCT Directors

Hold down the CTRL key to select multiple groups

ADD TO SITES

- STRATUS
- SimMed
- WISER

Hold down the CTRL key to select multiple groups

[<< Back](#) [Edit User](#)

- 3 Select the Refresh button.

Make your corrections on this page and select the Edit User button. Find instructions to use the Edit a User page in step 4 on page 124.

SIMS displays all accounts having either the first name or last name entered in all upper case letters. The user account that you corrected in step 2 should no longer be displayed in this list.

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Attachment 2

Agenda - Simulation Training in Military Medicine
May 9-11, 2005
APMMC, Hanoi, Vietnam

Day 1: Simulation and Training 1, Monday, May 9th, 90 minutes
Lawrence Burgess, MD, Moderator

<i>Simulation Training Overview</i>	<i>Lawrence Burgess, MD</i>	15 min
	<i>Q&A</i>	5 min

Training landscape and problems: no dollars, personnel, must build curriculum, etc.,
Proposed solutions: local approaches; enterprise approaches
Reviews types of training: (mannequins: part vs. full task trainers, immersive virtual reality.
Difference between cognitive vs. procedural (gross motor and/or fine motor) vs. integrated types like mannequin for gross motor or immersive virtual reality for fine motor
Intro: Actual training is 70%, but must have curriculum and back-end for data collection of training results.

<i>Overview of Tools for Training: Cognitive and Integrative Training with MicroSim and SimMan</i>	<i>Alan Morgan, MD</i>	30 min
	<i>Q&A</i>	5 min

- Cognitive training through MicroSim
- Integrated training through SimMan

<i>Overview: WISER Approach to Simulation Training</i>	<i>John Schaefer, MD</i>	30 min
	<i>Q&A</i>	5 min

- Center approach to training students, workforce
- Developing champions in your faculty (course directors and facilitators)
- Funding for Center
- Web-based curriculum for pre-training and bedside (mannequin-side) teaching
- Scheduling system, automated data collection to monitor training results

Day 2: Simulation and Training CI, Tuesday, May 90 minutes
Lawrence Burgess, MD, Moderator

<i>Military Medical Integrative Training</i>	<i>Alan Morgan, MD</i>	30 min
	<i>Q&A</i>	5 min

- MicroSim and SimMan in US military medical training
- Training possible for a wide range of military health care providers from medics to nurses to physicians.

	Q&A	5 min
	On-line curriculum	
	Pretest	
	Training	
	Immediate feedback, automated data gathering	
SimMan DEMO -	John Schaefer, MD	15 min
	Q&A	10 min
LUNCH - Military Medicine Simulation Working Group		
(Open session, bring buffet lunch into designated conference room)		
	Alan Morgan, MD	75 min
Day 3 Simulation and Training III, Wednesday, May^{11th}, 4.5 hours		
Lawrence Burgess, MD, Moderator		
Continental Breakfast		0700-0730
Opening Remarks	Lawrence Burgess, MD	0730-0745
Separation into 4 groups, 4 rooms		
Scenarios 1-4 divided in groups of 10, rotating between 4 stations in 4 different rooms (including computer room).		
-MicroSim (print certificates)	John Rodgers, Phil White	
-Pre-hospital	Lawrence Burgess, MD	
-ATLS type scenario	Alan Morgan, MD	
-ACLS type scenario	John Schaefer, MD	
Scenario 1		0745-0900
15-minute introduction to scenario and training goals		
1 hour of multiple sessions with individuals rotating		
Scenario 2		0900-1015
Break		1015-1030
Scenario 3		1030-1145
Scenario 4		1145-1300
Conclusion, Certificates		1300
WISER System for Simulation and Training	John Schaefer, MD	30 min

Attachment 3



Date: December 15, 2007

Re: FY04 IMITS – Advanced Simulation for Medical Education and Training in the Pacific Rim Project (SimTiki Simulation Set-up Information)

I. General Simulation Center Information

If you have any questions about completing this form, please email help@simmedical.com.

Please enter the following general information about your simulation center.

SEE BELOW

Field Name	Your Data	Example/Description
Website Address:	http://tri.hawaii.edu/SimTiki/	www.wiser.pitt.edu
Simulation Center Name (long):	John A Burns School of Medicine Telehealth Research Institute SimTiki Simulation Center	<i>Peter M. Winter Institute for Simulation, Education and Research</i>
Simulation Center Abbreviation/Acronym:	SimTIKI	<i>WISER</i>
Help Desk Email Address	help@simtiki.org	<i>The email address you would like users to address technical questions to.</i>
From Email Address	help@simtiki.org	<i>The address that emails automatically generated from the SIMS application should be sent from. This may be the same address as your help desk email address.</i>
Help Desk Phone Number	808-692-1080	
IP Address Range	TO FOLLOW	<i>This is used for security purposes so that session data may only be uploaded from specified computers in your simulation center. List the IP address of each PC that controls the SimMen in your center. If the IP addresses are dynamic (DNS), list the first two segments of your IP address range.</i>

II. Locations and Rooms

Locations - enter a short abbreviation and a long description for each location/building at your simulation center. You must have at least one location listed. Add additional rows as needed.

SEE BELOW

	Abbrev.	Description
	JABSOM - MEB	<i>John A Burns School of Medicine. Medical Education Building, Honolulu HI</i>
	JABSOM - TRI	<i>John A Burns School of Medicine. Telehealth Research Institute, Honolulu HI</i>
	TAMC	<i>Tripler Army Medical Center, Honolulu HI</i>
	SimTiki	<i>Telehealth Research Institute-SimTiki Simulation Center</i>
	NHG	<i>Naval Hospital Guam, Guam USA</i>
	121GH	<i>121st General Hospital, Seoul Korea</i>
	HMC	<i>Hilo Medical Center, Hilo HI</i>
	MCC	<i>Maui Community College, Kahului HI</i>



Rooms - enter a short abbreviation and a long description for all rooms in which classes or meetings will be scheduled for each of the above locations. Place the location abbreviation in the first column so we know where each room is located. Include any room that you may need to schedule, including conference and class rooms. Add additional rows as needed.

SEE BELOW

	Location Abbrev.	Room Abbrev.	Description
	JABSOM TRI	S1	Simulation Suite 1
	JABSOM TRI	S2	Simulation Suite 2
	JABSOM TRI	CS	Clinical Skills Rooms
	JABSOM TRI	DB 1	Debriefing Room 1
	JABSOM TRI	DB 2	Debriefing Room 2
	JABSOM TRI	DB	Control room
	JABSOM TRI	AG	Access Grid Conference Room
	JABSOM - MEB	314-5	JABSOM Conference room 314-315 (3 rd Floor Medical Education Building)
	JABSOM- MEB	316	JABSOM Lecture Hall (3 rd Floor Medical Education Building)
	121GH	Conf Room	Clinical Conference room
	NHG	Aud	Main Auditorium – 3 rd deck

III. Simulation Center Forms (optional)

You will have the ability to present new users with forms the first time they login. These forms might include items such as a confidentiality statement or a release for still photographs and video recordings. Users are only prompted to answer each form one time. New forms can be added at any time and all users will be prompted to answer the next time they login. The user's response is recorded in the database. Each form can be setup with one of three different response types:

- 1) "I acknowledge that I have read and agree to the above."
- 2) "I have read and accept the above."
- 3) Yes or No

Please list any site forms you would like to have below. If the forms already exist in some other electronic format, such as a Microsoft Word document, you may also send them to us as an attachment.

NONE FOR NOW

	Heading	Text	Response Type



IV. User Profile Questions

SIMS collects profile information from each user. This information is included in course/class access request emails and is intended to help the course director or facilitator identify who the person is and why they are requesting access. This information may also be valuable for simulation center reporting, statistics and research. If you have any questions about this, please email help@simmedical.com.

Following is an example form:

New User Profile
ACCOUNT: MITCKS

Please provide answers to the following questions. This information will help us assign you to the correct classes and provide access to the materials you will need.

- All answers are required.
- You will only need to complete this form once.
- If your information changes in the future you can update it under Account Information.

Institution: Other

Describe: Test

School/Department: Anesthesiology

Profile Role: Faculty 10 Years Experience

Submit

The user profile form can contain up to three main questions. Typically these “parent” questions are: Institution, School/Department and Profile Role. However, you can customize the labels of these three questions to meet your center’s needs. Please list your three question labels below.

SEE BELOW

Question Number	Parent Question Label
1	Institution
2	Professional Status
3	Course Role

Each parent question will have a drop down list of possible answers. Please provide us with a list of your possible answers for each question, add rows as needed:

SEE BELOW

Question Number	Possible Parent Question Answer
1	JABSOM
1	Tripler Army Medical Center
1	Hilo Hospital
1	Kona Hospital
1	Maui Memorial Hospital
1	Wilcox Hospital
1	Queens Medical Center
1	Maui Community College
1	Kapiolani Community College
1	UH Manoa – School of Nursing
1	City and County of Honolulu
1	Hawaii Department of Health
1	Other
2	Physician
2	Resident Physician



2	Medical Student
2	Nurse
2	Nurse Practitioner
2	Nursing Student
2	Physician Assistant
2	Paramedic
2	EMT
2	Other
3	Student
3	Instructor
3	Instructor Candidate
3	Simulation Specialist-Facilitator

Each question answer may also have “child” answers. For example, when Faculty is selected as a role, you may want the user to then enter “years experience”. If any of the answers above have “children”, please list the possible child answers below.

Parent Question Answer	Possible Child Answers
Physician	UH Faculty
	UH Clinical Faculty
Physician	Specialty_(please specify)
Resident Physician	UH Residency
	TAMC Residency
Medical Student	Year 1
	Year 2
	Year 3
	Year 4

Attachment 4



Date: December 15, 2005

Re: FY04 IMITS – Advanced Simulation for Medical Education and Training in the Pacific Rim Project (Course Development Process Sample)

Packets of material will be delivered to the IT team at the indicated intervals during a courses development process. At that time the IT team will give an approximate timeline for having the material up on the testing server. After the material has been deployed onto the testing server, the Course QA group will be notified, as well as the course author. The course author will notify the IT team within one week of getting access to the material of any changes that need to be made. The IT team will make the changes within one week of the notification.

Packet 1:

Delivery schedule: at **start of course development**.

1. Full course name: [Fundamental of Critical Care Support](#)
2. Abbreviated name: [FCCS](#)
 - a. Suitable for calendars, etc.
 - b. Must be unique to WISER/SimMedical
3. Course description of 1-2 paragraphs stating goals and objectives

[Course Purpose](#)

- [To better prepare the non-intensivist for the first 24 hours of management of the critically ill and injured patient until transfer or appropriate critical care consultation can be arranged.](#)
- [To assist the non-intensivist in dealing with sudden deterioration of the critically ill and injured patient.](#)
- [To prepare house staff for ICU coverage.](#)
- [To prepare nurses and other critical care practitioners to deal with acute deterioration in the critically ill and injured patient.](#)

[Course Objectives](#)

- [Prioritize assessment needs for the critically ill and injured patient.](#)
- [Select appropriate diagnostic tests.](#)
- [Identify and respond to significant changes in the unstable patient.](#)
- [Recognize and initiate management of acute life-threatening conditions.](#)
- [Determine the need for expert consultation and/or patient transfer and prepare the practitioner for optimally accomplishing transfer](#)

4. Course Author Name [Benjamin W Berg MD](#)



5. Course Author Email bwberg@hawaii.edu
6. Course Author Office Phone Number. [808-692-1080](tel:808-692-1080)
7. Course Author Pager/Cell Phone Number. [808-779-5651](tel:808-779-5651)
8. Description of what format the content will be in and the expected amount. I.e. “Approximately 35 word pages”, “45 PowerPoint slides”, “10 videos of approximately 5 minutes each”.

This is a two day course with 17 didactic presentation accompanied by 17 Power point presentations. Skills stations are also included with simulation training on partial task trainers. Some of the power point presentations have imbedded video files

Packet 2:

Delivery schedule: at approximately **50% completion**.

1. Initial set of content. This content should help frame what the course will contain.

[ATTACHED IS THE COURSE SCHEDULE](#)

[Will also require pre-test/post-test/course evaluation](#)

Packet 3:

Delivery schedule: at approximately **75% completion**.

1. Second set of content. This should include nearly all of the content at this point.
2. Surveys
 - a. Pre-class
 - b. Post-class
3. Evaluations
 - a. Post – Course
 - b. Post – Facilitator
4. Quizzes
 - a. Pre-class
 - b. During class
 - c. Post-class
5. Scenario and criteria descriptions and structure. These need describe how the scenarios are grouped and exclude each other, similarly to the DAM I-IV, A-D, Pre, Post model.

Packet 4:

Delivery schedule: at **100% completion**.

1. Final set of content. This should include all content and changes that need to be made.
2. A description of what constitutes the passing or completion of a course.

Attachment 5



Date: October 9-12, 2007

Re: FY04 IMITS – Advanced Simulation for Medical Education and Training in the Pacific Rim Project
(Courses on the SimTiki Website)

Fundamental of Critical Care Support:

This is a two day course which begins on the date(s) identified above.

Course Purpose

- To better prepare the non-intensivist for the first 24 hours of management of the critically ill and injured patient until transfer or appropriate critical care consultation can be arranged.
- To assist the non-intensivist in dealing with sudden deterioration of the critically ill and injured patient.
- To prepare house staff for ICU coverage.
- To prepare nurses and other critical care practitioners to deal with acute deterioration in the critically ill and injured patient.

Course Objectives

- Prioritize assessment needs for the critically ill and injured patient.
- Select appropriate diagnostic tests.
- Identify and respond to significant changes in the unstable patient.
- Recognize and initiate management of acute life-threatening conditions.
- Determine the need for expert consultation and/or patient transfer and prepare the practitioner for optimally accomplishing transfer

JABSOM - Airway Management Course I:

This course will introduce student to basic and advanced concepts of airway management utilizing didactic and simulation based practical experience with a variety of airway devices and techniques. Advanced material includes the following focus areas:

- Airway management in mass casualty
- Obstetric airway management
- Pediatric Airway management
- Supraglottic airway management
- Airway management complications
- Airway in trauma
- Difficult airway evaluation
- Advanced airway techniques I & II
- Airway in the ICU
- Out of operating room airway management
- Advanced masking techniques
- Flexible fiberoptic intubation

JABSOM MS3 - Surgery Trauma Program I:

Course Purpose

- To provide an introduction to basic principles of trauma management
- To augment the American College of Surgeons core medical student TEAM Curriculum with high fidelity manikin based curriculum.



- To support the research project: Outcomes Assessment in a Simulator-Based Trauma Curriculum: Use of Scenario Development.

Course Objectives

- Prioritize assessment and management strategies for trauma patients using the ABCDE approach
- Demonstrate knowledge of basic principles through manikin trauma scenario management.
- Complete one scenario development exercise

JABSOM MS3 - Surgery Trauma Program II:

Course Purpose

Session II of the MS3 JABSOM Surgery trauma Curriculum

- To provide an introduction to basic principles of trauma management
- To augment the American College of Surgeons core medical student TEAM Curriculum with high fidelity manikin based curriculum.
- To support the research project: Outcomes Assessment in a Simulator-Based Trauma Curriculum: Use of Scenario Development.

Course Objectives

- Prioritize assessment and management strategies for trauma patients using the ABCDE approach
- Demonstrate knowledge of basic principles through manikin trauma scenario management.
- Complete one scenario development exercise

JABSOM MS4 - Emergency Medicine Skills Lab I:

This course is a required element of the JABSOM MS4 Emergency Medicine rotation. The session will utilize manikin based simulation techniques and didactic lectures for instruction in the following focus areas:

- Introduction to Emergency Medicine
- Airway Management
- Respiratory emergencies
- Chest pain evaluation and management
- 12 Lead EKG Interpretation

JABSOM MS4 - Emergency Medicine Skills Lab II:

This course is a required element of the JABSOM MS4 Emergency Medicine rotation. The session will utilize manikin based simulation techniques and didactic lectures for instruction in the following focus areas:

- Altered Mental Status
- Toxicology
- Shock
- Trauma

There are also plans to have the CTT course that is taught at WISER to be rolled out to SimTiki ASAP.

Attachment 6



SimTiki

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MISSION STATEMENT

SimTiki is the educational simulation center at the University of Hawaii John A Burns School of Medicine Telehealth Research Institute. The center is a community resource facilitating integration and development of simulation techniques into new and existing healthcare education initiatives. SimTiki focus areas include 3-D screen based, high fidelity manikin, virtual reality, and haptics enhanced simulation techniques. We seek to facilitate and study technology enhanced learning strategies within University based and extramural educational programs through strategic partnerships and academic excellence.



SIMTIKI

tiki. origin. Marquesan. A Polynesian figure in simplified human shape.

tiki. origin. Maori. In Polynesian mythology, the first man.

tiki. A prehistoric chieftain who led his people to colonize Polynesia [ref. Thor Heyerdahl and Kon-Tiki]

Sources: [Wikipedia](#) and [answers.com](#)

SimTiki. A model of a human used to disseminate medical education in Hawaii and the Pacific.

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Director



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Associate Dean of Clinical Affairs
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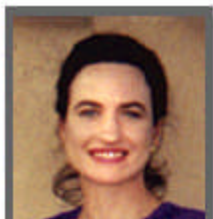
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 Search**GROUPING OPTIONS**

All Courses



Courses by Department



Courses by Participant Type



CME Courses

ALL COURSES[AirMed Difficult Airway Simulations](#)[AirMed High Risk OB/Fetal Heart Monitoring](#)[Fundamental of Critical Care Support](#)[JABSOM - Airway Management Course I](#)[JABSOM MS1 - Unit 2 Simulation](#)[JABSOM MS2 - BioMed 555 Simulation Laboratory](#)[JABSOM MS3 - Surgery Trauma Program I](#)[JABSOM MS3 - Surgery Trauma Program II](#)[JABSOM MS3 Internal Medicine: Introduction to Medical Emergencies](#)[JABSOM MS4 - Emergency Medicine Skills Lab I](#)[JABSOM MS4 - Emergency Medicine Skills Lab II](#)[JABSOM PBL - Manikin Simulation Lab](#)[JABSOM PBL - Virtual Simulation: Bronchoscopy](#)[Medical Educator Orientation Program](#)[ObGyn Residents 1 Resuscitation](#)[SimTiki Tour - Health care provider](#)[Simulation Laboratory for Pediatric Residents](#)[TAMC ENT Airway Simulation I](#)[TAMC Surgery Simulation Lab Series I](#)[Tripler General Surgery - Manikin Sim Lab](#)[Tripler General Surgery - Virtual Sim Lab](#)

Attachment 7



Date: October 9-12, 2007

Re: FY04 IMITS – Advanced Simulation for Medical Education and Training in the Pacific Rim Project
(Trip Report - WISER SimTiki Site Visit)

WISER faculty Paul Phrampus and John Lutz visited the University of Hawaii simulation center, SimTiki from October 9 through 12, 2006. During that time, they conducted a site review and identified numerous collaborative projects to work on in the future. This report reviews the visit.

SimTiki facility

SimTiki is located on the second floor of the Medical Education Building at the University of Hawaii (UH) John A. Burns School of Medicine. There is 1 large simulation room with 2 Laerdal SimMan & 1 METI Human Patient Simulator. This room is outfitted with video cameras and microphones to record simulation sessions onto video tape. There is another room that contains an Immersion Endoscopy Accutouch simulator, an Immersion Laparoscopic Surgical Workstation, a laparoscopic simulator that was developed in-house, and a virtual reality (VR) simulator, utilizing goggles, headphones and VR gloves. The VR simulator was also developed in-house. There is a control room between the two simulation rooms with one-way mirrored windows between the simulation rooms and the control room. The control room houses the audio and visual components.

UH also has a large teleconference room on the same floor that utilizes Access Grid software. This software allows multiple simultaneous high speed video conferences utilizing the Internet2 network. The Pittsburgh Supercomputing Center also has an Access Grid node, so this will be explored as a possible collaborative project (see below).

There are multiple conference rooms throughout the office space. There are also numerous empty offices and cubicles that the Telehealth Research Institute (TRI) program (under which SimTiki sits) hopes to utilize with collaborative entities.

Collocated on the second floor is the Objective Structured Clinical Examination (OSCE) Center for the UH School of Medicine. While SimTiki is not directly involved in the OSCE program at the UH, there is possible future collaborations here. There are approximately 10 patient exam rooms with audio and video recording equipment. Patient interactions can be viewed live or recorded on PCs in a central review room.

Collaborative Projects

The following is a list of projects that were discussed and seem to provide excellent collaborative possibilities.

- o Ft. Sam / Ft. Irwin
Discussed the next steps to move the Ft. Sam / Ft. Irwin project forward
- o Crisis Team Training – Rapid Response Course
There is significant interest in having the CTT course run at SimTiki. Paul will discuss with Mike Devita to get this moving forward
- o SimTiki grand opening in February
SimTiki will hold a conference in February to mark its official opening. There will be presentations, etc. John & Paul plan on going. Funding will be available to pay for the trip.



- o APPMC in Manila. The Asia Pacific Military Medicine Conference will be held in Manila this year. Paul & John will present in a similar manner to what they did in New Delhi this year. Funding will be available to pay for this trip as well.
- o Audience Response System
Ben & Dale have been utilizing the TurningPoint (TP) audience response system (<http://www.turningtechnologies.com>). We have identified a number of projects to use this system. There are three research projects that will utilize this system: Vital Sign reliability, Transcutaneous pacing, and task distribution with novices. Essentially each project will involve a group watching a live simulation or video presentation and using the (TP) keypad to respond to prompts. The exact protocols for each of the projects will be developed in the near future.

Another project is integrating the TP system into SIMS. We have purchased the TP system at WISER and are currently integrating the two together.
- o Video Laryngoscope
Ben & Dale have been using the Video Laryngoscope (VL), developed by the Karl Storz company, and in collaboration with Ben Boedeker from the University of Nebraska. Ben Boedeker has developed curriculum for the VL, which will be deployed via SIMS on the Medical Education Consortium Center for Advanced Technology web site (www.medccat.org).
- o ECMO
We met on the ECMO project. Larry outlined the funding for this project and started to develop tasks and who would work on them. We also met with Anne Naclerio, who is developing nursing critical care curriculum as part of this project.
- o MET integration into SIMS
SimTiki utilizes at METI HPS simulator. We will work to download data from the simulator into SIMS in a fashion similar to what we do with SimMan now.
- o Access Grid
We will look at opportunities to utilize the Access Grid in for remote training. The Pittsburgh Supercomputing Center has an Access Grid center on South Craig St. John has contacted them to see if we can utilize that system.

Appendix 4



IMITS Center

To: John W. Marsh, Maj, USAF, MSC, FACHE
Deputy Chief, Management and Program Support Division, AF/SGRM
Office of the Assistant Surgeon General, Modernization
5201 Leesburg Pike
Falls Church VA 22041

From: Jeananne Nicholls
Associate Director of Operations
University of Pittsburgh Medical Center
200 Lothrop Street
Quantum 1 Building, Suite 079.1
Pittsburgh, Pa 15232

Date: April 10, 2007

Re: FY04 IMITS – Patient Transfer Simulation Training Course Project (Cooperative Agreement DAMD1703-2-0017)

Major Marsh,

A detailed evaluation of the UPMC Nursing's current training methods for the prevention of back-related injuries was conducted by members of the UMPC, the Beckwith Institute, and the University of Pittsburgh WISER Simulation Institute. The project team was able to obtain relevant information pertaining to the specific programs/training and the support structure required in preventing back-related injuries. From this evaluation, the project team was able to develop the course goals, objectives, curriculum, and educational tools. The course and the curriculum were incorporated into the University of Pittsburgh WISER Institute's SIMS application for both traditional and online training delivery methods. The course was designed for integration with high fidelity patient simulators and other mannequins designed for bio-mechanic and "patient" move simulations. Several evaluation and feedback methods were incorporated into the course materials. Evaluation methods such as pre and post patient transfer observations, trainee performance assessment tools, learning system effectiveness methods, programs leadership and support evaluations, instructor evaluations, and satisfaction surveys were be used.

Upon completion of the course design, a research study protocol was developed to accurately observe the effects of the course on the nursing participants. The protocol outlined a control group and a treatment group. The control group consists of one nursing unit that will only be supplied with traditional back injury prevention training through the Internet. The treatment group consists of two nursing units that receive the new course material. This protocol was approved by the University of Pittsburgh Institutional Review Board (IRB) in January 2006. This protocol was submitted to the US Army Human Subject Review Board (HSRRB) as an expedited study, for second level review. HSRRB deferred their second level review requirement to SGR. The final second level letter from SGR, is pending submission to UPMC.



The project team has completed all the evaluation observations listed: pre and post patient transfer observations, trainee performance assessment tools, learning system effectiveness methods, programs leadership and support evaluations, instructor evaluations, and satisfaction surveys. Preliminary and final results were presented at several national conferences, listed in the key research accomplishments below.

Key research accomplishments:

- Developed course goals, objectives, curriculum, and education tools.
- Developed evaluation and feedback methods.
- Developed research study protocol.
- Received University of Pittsburgh IRB approval for the study protocol.
- Pending final Second Level Protocol Approval from USAF.
- Completed all pre-training observations.
- Complete both the control and treatment groups' participation in the nursing training on the new curriculum.
- Completed all post-training observations.
- Completed statistical analysis of all training observations.
- Completed the final report for submission to SGR
- Project featured in UPMC/IMITS Exhibit Booth at 2006 American Telemedicine Association (ATA) Annual Conference, San Diego, CA.
- Project featured in 2006 American Organization of Nurse Executives (AONE) Annual Conference, Atlanta, GA.
- Project featured in 2006 Institute for Healthcare Improvement (IHI) Annual Conference, Atlanta, GA.
- Project featured in 2006 American Association of Nurse Anesthetists poster presentation.
- Project featured in 2007 Society for Simulation in Healthcare (IMSH) Annual Conference, Orlando, FL.

At this time, UPMC has accomplished all required deliverables for the FY04 IMITS – Patient Transfer Simulation Training Course Project (Cooperative Agreement DAMD1703-2-0017). All of the attached documents fulfill the remaining deliverable requirements for this project.

The following deliverables have been provided:

1. Copy of the approved IRB protocol was provided to SGR in 2005 (Attachment 1)
2. The project team submitted the protocol to University of Pittsburgh for a scientific review. The scientific review was favorably completed by the School of Nursing, and the review letter was provided to SGR in 2006. (Attachment 2)
3. As a result of human subject involvement in this protocol, the project team submitted the protocol to University of Pittsburgh for IRB approval. The protocol was approved as an expedited research protocol, and the approval letter was provided to SGR in 2006. (Attachment 3)
4. A final report of the findings of the Nursing Back Injury Prevention Project (N-BIPP) protocol has been finalized for submission to SGR. (Attachment 4)



5. A copy of the Nursing Back Injury Prevention Project (N-BIPP) Poster summarizing the protocol and the results has been finalized for submission to SGR. (Attachment 5)

UPMC would like to request the official closure of this project. It was recommended that you be informed and approve this decision. Please indicate your concurrence with completion of these deliverables.

Feel free to contact me as needed.
Sincerely,

Jeananne Nicholls
Associate Director of Operations

Attachments

- (1) - Nursing Back Injury Prevention Project (N-BIPP) Protocol
- (2) - Nursing Back Injury Prevention Project (N-BIPP) University of Pittsburgh Scientific Review
- (3) - Nursing Back Injury Prevention Project (N-BIPP) University of Pittsburgh IRB Approval
- (4) - Report: Final Report/Findings Nursing Back Injury Prevention Project (N-BIPP)
- (5) - Nursing Back Injury Prevention Project (N-BIPP) Poster

cc:

Tess Ellis
James Mason
Aaron Yanuzo
Judy Bradle
John O'Donnell

Attachment 1

Title: The Nursing Back Injury Prevention Project (N-BIPP) – A Pilot Study: Implementation of an Innovative and Comprehensive Training Program Using Simulation Education and an Internet Based Curriculum to Improve Provider Knowledge in Patient Transfer and Provider Adherence to a 10 Point Patient Transfer Protocol

1.0 Objective and Specific Aims

This pilot study is intended to evaluate the efficacy of an internet-supported, comprehensive, ergonomics training program for development of safer patient transfer skills among direct care personnel. The program will utilize survey and assessment tools, a 10-point move protocol, integrated audiovisual systems, ergonomic expert oversight, and simulated patient transfers using transfer mannequins. Pre and post training observation of provider teams and their use of the steps of the 10 point protocol will be conducted through observation on three clinical units at UPMC.

The primary aim of the program is to improve direct patient care personnel skills and adherence in ergonomically sound patient transfer behaviors according to a 10 point protocol. The 10 point protocol was developed based on the available literature and reviewed by ergonomic experts. Secondary aims include increasing provider knowledge about safe patient transfer, evaluating attitudes toward educational interventions using human simulation mannequins and assessing provider communication skills during transfer events.

2.0. Background and Significance

2.1 Background

The national emergence of nursing as the number one profession in workforce demand has forced hospitals to scrutinize how they are providing nurses and nursing assistants with the education and tools for preventing back injury and other musculoskeletal injuries. The costs to our health care system are very high and include, but are not limited to, financial losses from workers compensation claims, stresses to staffing levels from loss of personnel and lost wages for the injured party. As an example of the potential system-wide impact, a single UPMC nursing unit (Unit 5 West at UPMC Shadyside) recorded 13 workers compensation claims during Fiscal Year 2003¹. Anecdotal observation of 40 patient transfers performed at UPMC Presbyterian and UPMC Shadyside in October 2003 reinforced our hypothesis that UPMC direct care providers (nurses and nursing assistants) are consistently exposing themselves to potential back and musculoskeletal strains and sprains due to incorrect patient transfer techniques and/or incorrect body mechanics. It was also noted that as nursing staff became more task saturated they did not inquire about the patient's ability to participate in his/her own transfer nor did they consistently attempt to involve the patient in his/her own transfer. This is a critical point as patient involvement is known to decrease the likelihood of an employee sprain and/or strain injury occurring, and as well can benefit the patient's recovery process. It was noted that patient transfers were frequently inefficient in terms of resource utilization and not based on equipment use standards or patient weight-based standards. Often, all available staff in the area were called for each transfer in a process they referred to as 'swoop and scoop'. This occurred even when the level of personnel utilization was clearly inappropriate.

The use of simulation as a training tool offers significant potential in healthcare²⁻²². There is widespread perception of the utility and value of simulation education for healthcare professionals, with an accompanying global proliferation of health science oriented simulation facilities and approaches. Despite this, studies that have convincingly demonstrated transference of skills gained during simulation to a clinical setting are only recently emerging with measurement of direct outcome an ongoing challenge^{2, 12, 16, 21, 23-26}

The prospect of health care providers being able to learn and practice in the simulated environment as opposed to "on the job" with living patients is intuitively and ethically superior to most traditional models^{9, 27}. Simulation education occurs on a spectrum of simple to complex. 'Part-task' (PT) training involves learning specific parts or components of techniques for manual or hands on skills in a context which does not fully duplicate the entire task or clinical setting^{9, 16, 18, 21, 23, 27-29}. A few common examples of PT training include skill attainment in CPR (chest compression and ventilation), IV catheter insertion (latex arm with tubing), and endotracheal intubation (intubating head or head with torso).

The other end of the simulation-training spectrum can be called 'full-task' (FT) and often encompasses the use of High Fidelity Human Simulators (HFHS) employed in realistic environments where instructors and trainees participate in assigned roles^{14, 18, 20}. Immersed in scripted, realistic scenarios, trainees have the opportunity to participate in a wide variety of events from mundane to crisis situations and from common to very rare or high risk situations. The goal of such scenarios is to practice or demonstrate key interventional skills, develop critical thinking, refine communication ability, and practice management of resources. The genesis for this approach has as its roots similar training in industry, particularly in the military as well as in aviation and nuclear power^{6, 9, 16, 20, 21}. Our pilot project has both PT and FT components. The setting will be full context, but the mannequins will be lower fidelity. This blend of part and full task training is often seen with clinical simulations.

2.2 Significance

Nursing back and musculoskeletal injury is epidemic in the United States and across the world³⁰⁻⁴⁰. While the financial cost to the healthcare system alone is staggering, the impact of ongoing nursing injury rates in a period of critical nursing shortages cannot be underestimated.³² 'No lift' policies have been in place in Australia and England since 1996 and 1998 respectively³². These policies call for minimal nursing exertion during lift maneuvers and the use of lift devices where possible. Perhaps a better term for these policies would be 'safe-lift' instead of 'no-lift' as the latter description implies that nurses will not be involved in any patient transfers. The use of back support devices and lift training alone have been demonstrated as ineffective deterrents to injury among direct patient care personnel⁴¹ while a comprehensive program incorporating a lift algorithm, ergonomic expert input, lift device training, staff support, and ongoing data collection has been demonstrated to be effective⁴¹. The incidence of back injury and other musculoskeletal strains or sprains among direct care personnel at the University of Pittsburgh Medical Center remains significant. Between UPMC Presbyterian and UPMC Shadyside Hospitals a total of 171 musculoskeletal sprains and strains occurred in Fiscal Year (FY) 2005¹. There are ~ 2500 direct care personnel in these two facilities. Including indirect costs such as legal fees and lost work time (but excluding replacement personnel), musculoskeletal injury accounted for approximately \$5.8 M from July 2003 through June 2005 in just these two hospitals and over \$15.9 M for the 19 hospital system.¹

Specific Aim 1

Improve direct patient care personnel skills and adherence in ergonomically sound patient transfer behaviors according to a 10 point protocol (Appendix B).

Long-term impact of Specific Aim 1

Many variables account for development and incidence of caregiver back and musculoskeletal injury^{31-34, 38, 39}. Injury prevention programs which appear to show promise incorporate education, administrative policy, and focused training^{31-34, 38, 39}. 'No lift' policies exist in the United Kingdom and are becoming part of the legislative landscape in the US. However, no-lift does not signify 'no-transfer' and the ongoing incidence of injuries among direct care personnel points to the need for innovative approaches. The current training method in back injury prevention at UPMC consists of verification that each provider watches a back injury prevention video. The use of hands on simulation to practice transfers under the guidance of ergonomic experts and according to a 10 point move protocol is an innovative approach that we hope will result in adherence to the 10 point protocol in actual patient transfers. This pilot will verify our ability to effectively train a small cohort of direct care providers and assess their adherence to the 10 point patient transfer protocol. If successful, the program will be offered to new hires as well as existing nurses in the UPMC system. Follow-up study across the health system will have sufficient power to detect change in back and musculoskeletal injury incidence rates upon widespread implementation of the training protocol.

Specific Aim 2

Increase provider knowledge about safety in patient transfer events relative to the 10 point move protocol.

Long-term impact of Specific Aim 2

It is our hope that the continual reinforcement of the 10 steps of the move protocol will result in an increase of direct care provider knowledge with respect to patient transfer safety. We have test items referenced to each step of the 10 point move protocol and also referenced to recent literature and regulation on safe patient transfer. We believe that an increase in knowledge with reinforcement of the safety elements will lead to greater compliance with the protocol and less risk of provider injury during transfer events.

Specific Aim 3

Evaluation of provider attitudes toward educational interventions using human simulation mannequins.

Long-term impact of Specific Aim 3

Simulation educational approaches are increasingly used in medical education, but have not been employed in patient transfer training. This 'hands-on' approach is well received for many areas of nursing education^{10, 12, 27}, but provider attitudes toward simulation educational approaches in developing patient transfer skills is unknown. Through evaluation of provider attitudes, we can modify and improve subsequent ergonomic training initiatives.

Specific Aim 4

Assess provider communication skills during transfer events.

Long-term impact of Specific Aim 4:

Multiple steps of the 10 point patient transfer protocol require effective communication with two steps specifically addressing this skill. The 2006 JCAHO National Patient Safety Goals (NPSGs) focus on communication with NPSG # 2 *Improve the effectiveness of communication among caregivers* being directly relevant.⁴² We will evaluate effectiveness of communication throughout transfer training at WISER and provide feedback to all subjects with respect to mechanisms for improvement (closing loops, specific direction, use of names, avoiding cross talk etc.)

3.0 Research Design and Methods

3.1 Drug/Device Information:

The Tuff-Kelly lift mannequin (Laerdal Inc, Gatesville TX) will be used for the study as well as the Laerdal SimMan Human Simulator (Laerdal Inc, Gatesville TX). The Tuff Kelly mannequins are designed for use in patient transfers. They are the approximate height of an average male (67 inches) and can be weighted in a range from 70 - 300 lbs. Max weight that will be used for training in this study will be 100 lbs. The SimMan mannequin also will be used. The dimensions are similar with the total weight of 75 lbs representing electronic components. When scenarios call for higher patient weight- we will simulate the higher weight by dressing the mannequin in a color coded t-shirt with the 'simulated' weight printed on the front (ie red t shirt 300 lb, green t shirt 250 lb, purple t shirt 200 lb, blue t shirt 150 lb).

The Laerdal SimMan™ software has been programmed with the 10 point move protocol so that immediate feedback and formative evaluation can be given during practice transfers and also for summative evaluation at the end of the training session.

HP IPAQ h4350 pocket PC's have been programmed with the 10 point move protocol. They will be used to record adherence to educational interventions during actual lift events on the targeted nursing units. Up to 100 actual patient transfer events will be scored and recorded before training and up to 300 actual patient transfer events will be scored and recorded after WISER training has been completed.

3.2 Research Design and Methods

The proposed pilot study will be conducted as a quasi-experimental educational intervention. Due to the nature of the proposal, it will not be possible to mask the investigators, trainers and participants from each other.

Subjects will be enrolled from up to six patient care units at UPMC. This convenience sample of Units was selected on the basis of having high census and thus opportunity for many transfer observations. Units 9D and 10D PUH and Unit 5 Main Shadyside have primarily ambulatory patients and do not perform many actual patient transfers to provide an adequate observation sample within a reasonable time frame. The nurses from units 10D and 5 Main will receive the educational training intervention at WISER as planned. PUH Unit 9D will no longer be used for the study. Four additional units have been identified having a high census and multiple daily patient transfers by direct care providers. They are spinal cord rehabilitation units within the UPMC system (Rehab Unit 4A at UPMC St Margaret and Rehab Units 4A, 5A and 5B at UPMC South Side). Unit 4A at UPMC St. Margaret will serve as the control unit with Southside units 4A, 5A, and 5B receiving the intervention. The nurses on these high census units perform many actual patient transfers due to their population. Up to 160 total subjects will be enrolled with up to 120 receiving training at WISER according to the 10 point move protocol. The control unit will receive no training but researchers will record move events on this unit in the pre and post training periods.

The research script will be distributed prior to collection of move events on the units. Scripts will be placed in each provider mailbox, and also will be available from the Unit Managers and data collectors.

Prior to implementation of WISER training, a 10 point move protocol will be used to assess team performance on actual patient units in a sample of up to 132 actual patient moves (up to 33/unit in the control unit St. Margaret 4A as well as Units 4A, 5A and 5B at UPMC Southside). All data will be aggregate group performance data with no individual provider or patient identification. The patient transfer observations will be recorded on the HP IPAQ units which are programmed with the 10 point protocol (Appendix B). Each step will be coded as completed, not completed, or N/A. Coding will be completed by ergonomics experts and by research team members trained for at least 4 hours in correct coding by ergonomics experts. The UPMC Department of Nursing and the Unit Managers have given consent for researcher observation of transfers. Should an individual nurse, patient, or provider object to having the transfer observed, researchers will not record data and will move on to the next transfer observation.

On the day of WISER training, subjects will be asked to sign the informed consent. They will then register for the course via the WISER online course registration system. Each potential subject will be assigned an anonymous but unique alpha-numeric identifier. They will then complete pre-course assessment instruments which will be collected via the WISER Simulation Information Management System (SIMS).

- Pre-course assessment instruments include:
 1. Demographic data collection form (Appendix C)
 2. Pre-course didactic knowledge assessment (Appendix D)
 3. Pre-course attitudinal survey with respect to simulation training (Appendix E)
- Following completion of the assessment instruments the subjects will be directed to WISER training rooms and will be asked to perform 2 'cold' simulated transfer events (lifts/transfers prior to any didactic or ergonomics training). Each move will be scored within the SimMan software. A scoring log will be generated that includes specific feedback that will be shared with the team members after the second of the 'cold' transfers.
- The subjects will then receive didactic training and ergonomics training specific to the 10 point move protocol.
- Teams will then perform 2 post-training simulated transfer events which will receive summative scoring with each group of providers being given a team score.

- A total of 4 patient transfer events have been designed for use during training. The 10 point move protocol has been programmed into the Laerdal SimMan™ software as well as IPAQ pocket PC units.
- Raters will use the programmed 10 point protocol to code correct vs. incorrect performance by teams of care providers for each transfer (both real and simulated).
- The move training at WISER will include teams of up to 5 direct patient care providers who will perform 4 patient transfers over a 4 hour time period. Each transfer will be evaluated and will include feedback. The transfers include:
 1. Pulling a patient up in bed
 2. Transfer from gurney to bed
 3. Repositioning of patient from side to side within the bed
 4. Transfer from bed to gurney
- The Laerdal software automatically prints a performance log for each transfer event. Since the protocol is programmed into the software, the log will immediately show correct performance (in green) vs. incorrect performance (in red) with total score automatically tabulated against the programmed 10 point move protocol.
- Teams will perform the first 2 transfers without instruction ('cold') and at the end of the second 'cold' transfer will receive formative feedback. Each transfer will be scored within the software with a log immediately generated that includes specific feedback.
- The last 2 transfer events will occur after receiving the didactic and ergonomics elements on the 10 point protocol with these transfers receiving summative scoring and each group of providers being given a team score.
- Final outcome criteria for the WISER training will be completion of all 4 transfer events with correct performance scores of at least 80% on the last two transfers.
- Ergonomic experts will observe all transfer events and will halt any provider move behaviors having potential to cause injury.
- Groups that do not score at least 80% in the last 2 transfer events will be offered a remediation exercise at WISER as time permits. Focus for the remediation training will be on those areas assessed by the ergonomic experts as non-compliant with the 10 point move protocol. If time does not permit, the team will return for the remediation training event at a later time.
- After training, subjects will be asked to complete post-course assessment instruments which will again be collected via the WISER Simulated Information Management System (SIMS) using the same anonymous alpha-numeric identifier.
- Post-course assessment tools include:
 1. A post-course didactic assessment (Appendix F)
 2. A post-course attitudinal survey with respect to simulation training (Appendix G)
 3. A four week post course satisfaction survey (Appendix J)
- Following completion of WISER training by all direct care personnel, the 10 point move protocol will again be used to assess team performance in a follow-up sample of up to 396 actual patient moves (up to 33/unit in the control unit St. Margaret 4A as well as Units 4A, 5A and 5B at UPMC Southside) at 4, 8, and 12 weeks post-training.

3.3 Data Collection and Statistical Considerations

Data will be collected at multiple points and from multiple sources during the study.

The three main sources include data entered by subjects into the WISER website (quizzes and surveys) as well as data entered by researchers into the HP IPAQ 10 point move scoring devices and data entered by researchers using the SimMan software scoring system.

Subject surveys and quizzes will be administered via the WISER site and results will be de-identified before release to researchers. All data collected by researchers via the IPAQ units and the SimMan software is observational data based on the 10 point move protocol.

All data will be entered into SPSS 13.0 or Excel 2003.

10 point move protocol compliance rates will be compared pre- and post-training (pre, 4, 8, 12 wks) across all units. Appropriate statistical tests will be chosen to analyze data according to data level (nominal, ordinal, interval) as well as the resultant data distribution (parametric vs. non-parametric).

4.0 Human Subjects

4.1 General Characteristics - Minority Inclusion and Non-Discriminatory Statements

Subjects will be enrolled from nursing units in the University of Pittsburgh Medical Center. All subjects will be adults > 18 years of age. No subjects will be excluded or discriminated against on the basis of race, gender, ethnicity, or veteran status.

4.2 Inclusion of Children in Research: N/A

This protocol does not involve research with children or minors.

4.3 Inclusion/Exclusion Criteria - Pregnancy and Birth Control Statements

Females of childbearing potential will be included in the study. This protocol does not present any known reproductive risks to either a participant or fetus. There are no interventions (drugs or devices) that will be used on any participant. Personnel who are on restricted duty or who are not currently required to participate in patient transfers on their nursing units will be excluded from the study. Individuals < 18 years of age will be excluded.

4.4 Recruitment Procedures

Subjects on up to six nursing units will be informed initially by their nurse managers to announce the program. A recruitment script will be posted on the units and distributed to each unit member explaining the purpose and requirements of the study. (Appendix H- Recruitment Script).

- Written informed consent will be obtained prior to course registration and anonymous assessment (Appendix I- Informed Consent).
- In the consent, the entire research protocol will be described, including risks and potential benefits of study participation and their rights as a research subject prior to obtaining their signature.
- The informed consent will explicitly state that participation in the protocol is voluntary, is not considered integral to their employment, and that participation/non-participation in the protocol will have no impact on the participants job status or employment evaluation.
- The proposed study does not require the collection of private information about participant family members and no family members of the participants will be contacted or questioned.
- Personnel who are on restricted duty or who are not currently required to participate in patient transfers on their nursing units will be excluded from the study.
- Personnel < 18 years of age will be excluded.
- No other special screening is required for participation in the study.

4.5 Risk/Benefit Ratio

The risks of participation in the study are minimal. Each of the subjects will be a direct patient care provider who already performs patient transfers as a component of daily work requirements. During the WISER patient transfer practice sessions, there is a small risk of musculoskeletal injury. This risk has been minimized by limitation of mannequin weight to approximately 100 pounds. In addition, ergonomic expert oversight will occur throughout all patient transfer simulations. Any subject behaviors deemed to be unsafe by these experts will be halted and corrected at time of occurrence. Breach of confidentiality of subjects and their performance is a possible risk of the study. Substantial steps have been taken to reduce this risk including a Data Safety and Monitoring Plan. Other mechanisms to assure confidentiality include that researchers will not have access to the data entered via the WISER site until the data has had personal identifiers removed and an anonymous but unique alpha numeric code has been assigned. Once this data is released to investigators it will be secured in

the offices of the PI in physically or electronically secured files in accordance with IRB requirements. Coding of move event data will occur via the IPAQ units and SimMan software according to the steps of the 10 point protocol. This is group not individual data. Once entered, the data will be transferred to Excel files. This data will also be kept in locked or electronically secured files in the office of the PI.

There are multiple potential benefits although none are guaranteed. These include:

- Improved knowledge and skill in the area of safe patient transfer behaviors.
- Improved communication skills
- Potential reduction in back and musculoskeletal injury among the workforce
- Potential reduced risk of patient injury due to improper or incorrect patient transfer approaches
- Increased confidence of providers in assembling effective teams and performing group interventions.

Data and Safety Monitoring Plan

A data and safety monitoring plan will be implemented by the Principal Investigator to ensure that there are no changes in the risk/benefit ratio during the course of the study and that confidentiality of research data is maintained. Each member of the study team will meet with the PI and review confidentiality issues and complete a confidentiality agreement, prior to having contact with research subjects. Investigators and study personnel will meet monthly to discuss the study (e.g., study goals and modifications of those goals; subject recruitment and retention; progress in data coding and analysis; documentation, identification of adverse events or research subject complaints; violations of confidentiality) and address any issues or concerns at that time. Minutes will be kept for these meetings and will be maintained in the study regulatory binder. Any instances of adverse events will be reported immediately the University of Pittsburgh IRB using the standard forms and/or procedures that have been established by the IRB. The yearly IRB renewal for this study will include a summary report of the Data and Safety Monitoring Plan findings from the prior year.

5.0 Costs and Payments

5.1 Research Study Costs

There will be no charges to either the study participants or any insurance providers with respect to this protocol.

5.2 Research Study Payments

Participation in this protocol will be voluntary with no direct payment to subjects for participation.

6.0 Appendices:

Appendix A: Investigator Qualifications

Principal Investigator:

John O'Donnell, MSN, CRNA

John O'Donnell has been involved with High Fidelity Human Simulation education for the last 10 years. He is recognized nationally for his expertise in this area and has published as well as spoken to multiple national, state and local groups. He was named Assistant Director for Nursing Simulation at the WISER Institute in 2004 and is Co-Chair of the Simulation Efforts in Graduate and Undergraduate Education at the University of Pittsburgh School of Nursing. He has 22 years experience as professional nurse and has been Director of the University of Pittsburgh School of Nursing, Nurse Anesthesia Program since 1994. In this role he has directed, participated in and assisted in evaluation of over 200 simulation courses at the School of Nursing and at the WISER Institute.

Co-Investigators:

Judith Bradle, Director Beckwith Institute

Judith Bradle is currently the Director of the Beckwith Institute for Innovation in Patient Care at The University of Pittsburgh Medical Center in Pittsburgh, Pennsylvania. The Institute fosters creative solutions to contemporary problems in clinical practice and leadership development, and contributes new knowledge through the generation and application of research. Ms. Bradle's work focuses on program development in the areas of leadership and organizational development, organizational assessment, leading change, and building an innovation culture in healthcare. As the Program Director and a faculty member and mentor for the national level Health Care Leadership Academy, she has developed leaders at all levels with proven results. She has spoken nationally and internationally, has been published on leadership development strategies and other issues in health care, and acts as a consultant for the *Institute on the Transformational Model for Professional Practice* for organizations around the country

Gail Wolf, RN, DNS, FAAN is currently the Chief Nursing Officer for the University of Pittsburgh Medical Center in Pittsburgh, Pennsylvania. UPMC is an integrated care delivery system comprised of 19 hospitals throughout Western Pennsylvania. The system employs approximately 37,000 employees, including more than 5,000 nurses, and has an annual revenue exceeding 5 billion dollars. Dr. Wolf received her Baccalaureate in Nursing from West Virginia University, her Masters in Nursing from the University of Kentucky, and her Doctorate in Nursing Administration and Organizational Psychology from Indiana University in Indianapolis, Indiana. She is a Wharton Fellow, has served as President of the American Organization of Nurse Executives and as a member of the Magnet Commission. She has published and lectured extensively throughout the United States, Australia, Italy, Japan, Canada, and Finland on issues relating to leadership of patient care. In 1989, Dr. Wolf founded the Beckwith Institute for Innovation in Patient Care and presently serves as the Executive Director. This institute was established to foster creative solutions to contemporary problems in clinical practice and leadership development, and to contribute new knowledge through the generation and application of research. Through the Institute for Innovation, Dr. Wolf and two of her colleagues have developed a model entitled A Transformational Model for the Practice of Professional Nursing, and has also developed the Beckwith Leadership Academy, a level-program designed to prepare future health care leaders.

Joseph S. Goode, Jr., MSN, CRNA

Joseph Goode has been involved with High Fidelity Human Simulation education since 2000. He has served as Adjunct Faculty with the University of Pittsburgh School of Nursing, Nurse Anesthesia Program and as a staff CRNA at UPMC-Presbyterian since 2001. He has worked in the areas of anesthesia, critical care and emergency medicine research since 1985. Mr. Goode has published and spoken on a broad range of topics including the use of High Frequency Jet Ventilation, artificial organ development and the use of computer systems in health care and medical research. He most recently was involved as co-investigator on a funded project to develop virtual reality training methodologies for the implementation of hypothermic suspended animation in the field.

Edward Cook, OTR/L, CEAS

Mr. Cook obtained a masters degree in occupational therapy from the University of Pittsburgh in 2004, and a Bachelor's degree in athletic training from California University of Pennsylvania in 2000. Mr. Cook is also a certified ergonomic assessment specialist. He is currently employed as an occupational therapist with Centers for Rehab Services and specializes in industrial rehabilitation, hand therapy, and ergonomic evaluation of work sites.

Appendix B: N-BIPP 10 Point Move Protocol

Step-1: Identify Patient & Move Requirement

- Proper identification of the patient using two identifiers (i.e. Name and medical record number)
- Assessment of the proposed move and what it will optimally require (i.e. Show patient with chest tubes or orthopedic devices)

Step-2: Assess The Patient

- Physical assessment of the patient's ability to assist with the move (show several specific examples of patients either able or unable to move)
- Assessment of patient specific requirements for the move (i.e. drains, orthopedic devices, etc.)
- Determination of the patient's current level of pain and the potential impact of the proposed move on the level of pain, including preemptive interventions to minimize this impact

Step-3: Enlist The Appropriate Number & Type Of Personnel

- Use of references for or unit manual for workplace moves
- Video clip of provider identifying devices required for specific patient needs
- Identifying standards for use of specific devices (i.e. need for minimum number of personnel when using a particular device or move protocol, Etc.)

Step-4: Gather Appropriate Equipment

- Providers gathering equipment
- Examining equipment integrity
- How to identify and red-tag defective equipment so that others won't use it.

Step-5: Prepare The Environment

- Arranging room furnishings and positioning necessary equipment
- Instructing and positioning required personnel
- Surface to surface matching
- Monitor and provide for support and/or free movement of all devices attached to the patient

Step-6: Communicate To The Patient

- Provider explaining the need for the move to the patient: why and where (i.e. transport to testing, or, etc)
- Provider explaining expectations and the patient's role (passive or active, based on assessment in step #2)

Step-7: Communicate Intention Of Move To Personnel

- Provider explaining the steps of the move and the role of all personnel involved
- Provider including the patient in the explanation, both reassuring and empowering the patient

Step-8: Perform The Move

- Locking of all devices into position
- Performing the actual move, including the count
- Demonstrating correct position, alignment, ergonomics
- Close-up shots of key assistive equipment functioning and of body mechanics and positioning

Step-9: Reassess The Patient

- Provider will reassess in key areas of injury, pain, lines/disconnections and other potential patient needs

Step-10: Reset The Environment

- Returning room furnishings to original position
- Inspecting, cleaning, properly storing equipment
- Being sure that patient is left in an optimal position and that the call-bell is within reach if applicable

Appendix C: NBIPP Demographics Data

Confidentiality Statement: The following survey information will be kept confidential in that all individual identifying information will be removed by an “honest broker” prior to release of the information to researchers.

Age _____

Male _____ Female _____

Height _____ Weight _____

Left or right handed _____

Job Title: _____

Nursing unit: _____

Total number of years providing direct patient care: _____

Lifetime musculoskeletal injuries (work related and non-work related) _____

Work related musculoskeletal injuries (estimate): _____

Musculoskeletal injuries for which medical care was sought: _____

Ill days taken due to MS injury (estimate) during career: _____

Have you ever received workmans comp for a MS injury? _____

What type of health insurance (if any) do you have? _____

Does your health insurance allow chiropractic care? _____

What type of healthcare provider have you accessed for musculoskeletal injury and indicate the number of times you have obtained treatment. Fill in as many as are applicable:

MD (medical management) _____

MD (surgical management) _____

DO (medical management) _____

DO (surgical management) _____

DCM (doctor of chiropractic medicine) _____

Pain management physician/specialist _____

Nurse practitioner _____

Physical therapist _____

Occupational therapist _____

Non-Traditional Therapy (Acupuncture, Herbology, Massage Therapy, Reflexology, etc.)

Appendix D: NBIPP Pre Course Knowledge Assessment

1. In order to most effectively accomplish a patient transfer, which of the following is the correct sequence according to the 10 point protocol?
 - a. **Identify, Prepare, Communicate, Perform**
 - b. Communicate, Identify, Prepare, Assess
 - c. Prepare, Communicate Identify, Assess
 - d. Identify, Perform, Prepare, Communicate
2. Which of the following is not one of the key principles of body mechanics?
 - a. Establish a wide base of support in order to promote balance
 - b. Use both arms and or legs in an equal or symmetrical manner.
 - c. Maintain good posture with shoulders 'square' to the patient when possible
 - d. **Keep arms away from your body to promote correct alignment**
3. When performing a transfer, it is most important to:
 - a. Call the patient's family members if the patient is not oriented to time
 - b. Alert the attending physician in order to obtain an order for each transfer
 - c. **Communicate clearly with both the patient and personnel assisting with the transfer**
 - d. Have only an RN give the instructions (1,2,3- MOVE) as this is regulated under the nurse practice act.
4. According to JCAHO's National Patient Safety Goals 2006- Goal #1 is to improve the accuracy of patient identification by:
 - a. **Using at least 2 patient identifiers with neither being the room number**
 - b. Posting color digital pictures of each patient outside of the room with their patient ID number in the lower right hand corner
 - c. Asking the patient their name and room number
 - d. Developing better teamwork through team building exercises which improve communication.
5. Which of the following identifiers should NOT be used when performing patient identification?
 - a. Compare patient with digital photo placed on the patient record
 - b. Use patient ID number verified with patient and against ID band
 - c. **Use patient room number and bed space**
 - d. Use full patient name and middle initial verified with the patient or ID band
6. According to both NIOSH and OSHA, the maximum weight that a single provider should lift during a transfer event is _____ pounds.
 - a. 25
 - b. **50**
 - c. 75
 - d. 100
7. When transferring a 240 pound man from a bed to a gurney who can offer only *minimal* assistance you should:
 - a. Always use a sling transfer device or you are in violation of JCAHO guidelines
 - b. **Use a friction reducing device such as a slide board**
 - c. Use the top to bottom transfer strategy by first sliding a patient's upper body over and then their lower body
 - d. Position the strongest provider on the gurney side to maximize the efficiency of the team

8. What are the best body mechanics to use for a bed to gurney transfer?
 - a. A narrow stance which will enable further reach and leverage; head and shoulders upright; knees locked for stability; palms down grip
 - b. Feet staggered and shoulder width apart; head and shoulders upright; lumbar spine locked; palms up grip; knees unlocked**
 - c. Arms fully extended grasping sheet with palms down; feet staggered; lumbar curvature flat, knees bent, arms away from body
 - d. Head and shoulders upright; a staggered but narrow stance; elbows tucked and then moved to an extended position for improved upper body strength and better lumbar rotation
9. When boosting a 200 pound patient up in bed, the level of the bed should be adjusted:
 - a. To 48 inches- this height will allow both the shortest and tallest person performing the move to be comfortable
 - b. At the lowest possible setting to improve leverage
 - c. Unchanged because that is where it was at when you entered the room
 - d. To accommodate the shortest person performing the move**
10. The final step that should always be completed when you finish transferring a patient is:
 - a. Return equipment to the storage area**
 - b. Leave environment and equipment in position in order to most efficiently transfer the patient upon their return
 - c. Call housekeeping to clean the area vacated by the patient
 - d. Hand the patient the call bell and telephone

Appendix E: NBIPP Pre Course Attitude Assessment

Health Professional Simulation Education Assessment Tool (NBIPP -1)

Confidentiality Statement: The following survey information will be kept anonymous in that all individual identifying information will be re-transferred by an “honest broker” prior to compilation of the information

Use this rating scale to rate all questions below:

1=Strongly Disagree 2=Disagree 3=Neutral 4=Agree 5=Strongly Agree

	1	2	3	4	5
I anticipate that the objectives of the musculoskeletal (MS) injury prevention program will be met through participation in the transfer simulation modules					
I anticipate that the MS injury prevention program will improve my knowledge base of nursing back injuries and how to prevent them.					
I anticipate that the transfer simulation modules will improve my knowledge of equipment needed for transfers					
I anticipate that the transfer simulation modules will help me to understand the number of personnel needed for transfers by weight.					
I anticipate that the transfer scenarios will be realistic.					
I anticipate that the transfer scenarios will be similar to actual clinical situations					
I anticipate that I will gain specific MS injury prevention skills during the transfer simulation modules.					
I anticipate that the transfer simulation modules will improve my overall patient transfer skills					
I am confident that instructors will be able to form an accurate opinion of my patient transfer skills during the simulation modules.					
I am anxious about having my performance observed during the simulation modules.					
I anticipate that I will gain confidence in correct patient transfer approaches through the program.					
I anticipate that my communication with patients during transfers will be more effective based on the simulation modules.					
I anticipate that my communication with other providers will become more effective based on the simulation modules.					
I anticipate that the simulation modules will allow me to be a more effective team member during patient transfers.					
I anticipate that the simulation modules will allow me to more safely transfer patients.					

Appendix F: NBIPP Post Course Knowledge Tool

11. In order to most effectively accomplish a patient transfer, which of the following is the correct sequence according to the 10 point protocol?
 - a. **Identify, Prepare, Communicate, Perform**
 - b. Communicate, Identify, Prepare, Assess
 - c. Prepare, Communicate Identify, Assess
 - d. Identify, Perform, Prepare, Communicate
12. Which of the following is **not** one of the key principles of body mechanics?
 - a. Establish a wide base of support in order to promote balance
 - b. Use both arms and or legs in an equal or symmetrical manner.
 - c. Maintain good posture with shoulders 'square' to the patient when possible
 - d. **Keep arms away from your body to promote correct alignment**
13. When performing a transfer, it is most important to:
 - a. Call the patient's family members if the patient is not oriented to time
 - b. Alert the attending physician in order to obtain an order for each transfer
 - c. **Communicate clearly with both the patient and personnel assisting with the transfer**
 - d. Have only an RN give the instructions (1,2,3- MOVE) as this is regulated under the nurse practice act.
14. According to JCAHO's National Patient Safety Goals 2006- Goal #1 is to improve the accuracy of patient identification by:
 - a. **Using at least 2 patient identifiers with neither being the room number**
 - b. Posting color digital pictures of each patient outside of the room with their patient ID number in the lower right hand corner
 - c. Asking the patient their name and room number
 - d. Developing better teamwork through team building exercises which improve communication.
15. Which of the following identifiers should NOT be used when performing patient identification?
 - a. Compare patient with digital photo placed on the patient record
 - b. Use patient ID number verified with patient and against ID band
 - c. **Use patient room number and bed space**
 - d. Use full patient name and middle initial verified with the patient or ID band
16. According to both NIOSH and OSHA, the maximum weight that a single provider should lift during a transfer event is _____ pounds.
 - a. 25
 - b. **50**
 - c. 75
 - d. 100
17. When transferring a 240 pound man from a bed to a gurney who can offer only *minimal* assistance you should:
 - a. Always use a sling transfer device or you are in violation of JCAHO guidelines
 - b. **Use a friction reducing device such as a slide board**
 - c. Use the top to bottom transfer strategy by first sliding a patient's upper body over and then their lower body
 - d. Position the strongest provider on the gurney side to maximize the efficiency of the team

18. What are the best body mechanics to use for a bed to gurney transfer?
- a. A narrow stance which will enable further reach and leverage; head and shoulders upright; knees locked for stability; palms down grip
 - b. Feet staggered and shoulder width apart; head and shoulders upright; lumbar spine locked; palms up grip; knees unlocked**
 - c. Arms fully extended grasping sheet with palms down; feet staggered; lumbar curvature flat, knees bent, arms away from body
 - d. Head and shoulders upright; a staggered but narrow stance; elbows tucked and then moved to an extended position for improved upper body strength and better lumbar rotation
19. When boosting a 200 pound patient up in bed, the level of the bed should be adjusted:
- a. To 48 inches- this height will allow both the shortest and tallest person performing the move to be comfortable
 - b. At the lowest possible setting to improve leverage
 - c. Unchanged because that is where it was at when you entered the room
 - d. To accommodate the shortest person performing the move**
20. The final step that should always be completed when you finish transferring a patient is:
- a. Return equipment to the storage area**
 - b. Leave environment and equipment in position in order to most efficiently transfer the patient upon their return
 - c. Call housekeeping to clean the area vacated by the patient
 - d. Hand the patient the call bell and telephone

Appendix G: NBIPP Post Course Attitude Survey

Use this rating scale to rate all questions below:

1=Strongly Disagree 2=Disagree 3=Neutral 4=Agree 5=Strongly Agree

	1	2	3	4	5
The objectives of the musculoskeletal (MS) injury prevention program were met during my participation in the transfer simulation modules					
The MS injury prevention program improved my knowledge base of MS injuries and how to prevent them.					
The transfer simulation modules improved my knowledge of equipment needed for transfers					
The transfer simulation modules helped me to understand the number of personnel needed for transfers according to patient weight.					
The transfer simulation scenarios were realistic.					
The transfer simulation scenarios were similar to actual clinical situations					
I believe that I gained specific MS injury prevention skills during the transfer simulation modules.					
I believe that the simulation modules will improve my overall patient transfer skills					
I believe that the instructors formed an accurate opinion of my patient transfer skills during the transfer simulation modules.					
I remain anxious about having my performance observed during the transfer simulation modules.					
I gained confidence in correct patient transfer approaches through the program.					
I believe that my communication with patients during transfers will be more effective based on the program and modules.					
I believe that my communication with other providers will be more effective based on the program and modules.					
I believe that the transfer simulation modules will allow me to be a more effective team member in patient transfers.					
I believe that the transfer simulation modules will allow me to more safely transfer patients.					

Appendix H: NBIPP Recruitment Script

The purpose of this research study titled The Nursing Back Injury Prevention Project (N-BIPP) – A Pilot Study: Implementation of an Innovative and Comprehensive Training Program Using Simulation Education and an Internet Based Curriculum to Improve Provider Knowledge in Patient Transfer and Provider Adherence to a 10 Point Patient Transfer Protocol is to determine whether instruction in simulated patient transfers involving the use of simulation mannequins (Sim-Man™ or Tuff Kelly™) will improve adherence to an evidence based 10 point move protocol in actual practice. Knowledge acquisition, change in attitude toward simulation training, and communication skill will also be assessed. This study is being conducted by Mr. John O'Donnell, Mr. Joseph Goode, Ms. Judy Bradle, Dr. Gail Wolfe, and Mr. Edward Cook.

Subjects who consent to the study will receive 4 hours of patient transfer training at the Winter Institute for Simulation, Education, and Research (WISER). Human simulators are mannequins which can be programmed via an interactive software package to allow simulation of a variety of patient events. Some examples include blood pressure changes during moving, patient communication, actually moving patients, pain report, and a variety of other events encountered in clinical practice. Subjects will be participating in or watching a variety of different simulated transfer events during WISER training session.

Researchers will be observing actual patient transfers on nursing units before and after the WISER simulation training. They will document adherence to a 10 point protocol that has been developed for patient moves. Subjects will be asked to sign an informed consent form prior to participation in the WISER training component of the study. After signing the consent, subjects will register for the N-BIPP course on the WISER website. They will then be directed to take a brief quiz and complete a survey. Subjects will perform 2 'cold' simulated patient transfers (transfers prior to receiving didactic or ergonomics training). Subjects will then access educational materials on safe patient transfers and will review a 10 point patient transfer protocol. Subject teams will then participate in 2 'post-training' simulated patient transfer events under the direction of ergonomic experts. The teams will be scored according to the 10 point protocol. This data is observational and will be group not individual data. Immediately following training you will be asked to take a follow-up quiz and survey. These survey and quiz results will be submitted directly to the WISER website and any personally identifying information will be removed. Only data that has no personal identifiers will be released to the investigators. Four weeks after the course you will be asked to complete a course satisfaction survey on the WISER site.

There is a small risk of provider injury during the patient transfer practice sessions at WISER although they will take place under the direction of experts in ergonomics. Incorrect moving postures will be corrected immediately to prevent injury. Further, no mannequin will be weighted over 100 pounds. Thus the risks associated with your participation in this study are similar to risks assumed during your daily work. Potential benefits include knowledge and skill acquisition in the area of communication, musculoskeletal injury prevention, and patient transfers. There will be no impact on your employment or job evaluation related to your participation or non-participation in the study.

This research is funded by the Department of Defense. UPMC has been awarded these funds for research in the area of healthcare technology development.

Should you have further questions, please direct them to the Principal Investigator John O'Donnell at 412-980-5176 or jod01@pitt.edu.

Appendix I: NBIPP Informed Consent

Note:

Protocol pagination 19-22 = Consent form pagination 1-4.

Appendix J: NBIPP Post Course Satisfaction Survey

Use this rating scale to rate all questions below:

1=Strongly Disagree 2=Disagree 3=Neutral 4=Agree 5=Strongly Agree

	1	2	3	4	5
The course content was valuable.					
The course was well organized.					
The course material was coordinated in a logical sequence.					
The variety of educational activities in the course contributed to my learning.					
Instructors treated me with respect.					
Instructors treated me in a professional manner.					
Instructors gave directions that were easy to follow.					
Instructors gave clear and precise critiques.					
Instructors were readily available for assistance.					
Posting of course materials on the web site contributed to my learning.					
The WISER staff were helpful.					
Audiovisual material quality was good.					
The WISER website was easy to use					
The patient transfer demonstrations were helpful					
In room debriefings were helpful					
The quizzes were helpful in learning the material					
The quizzes should be used again in teaching this course.					
The facility (physical environment) was conducive to learning.					
The equipment available (lift mannequins & move devices) was conducive to my learning.					

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6.3 Multicenter Studies: N/A

6.4 Investigator-Sponsored Investigational New Drug (IND) or Investigational Device (IDE) Studies:
N/A

Attachment 2



University of Pittsburgh

School of Nursing

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Pittsburgh, PA 15261
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<http://cre.nursing.cit.edu>

PROPOSAL REVIEW VERIFICATION FORM

The attached proposal,

**TITLE: The Nursing Back Injury Prevention Project (N-BIPP) – A Pilot Study:
Implementation of an Innovative and Comprehensive Training Program
Using Simulation Education and an Internet Based Curriculum to Improve
Patient Transfers and Reduce Musculoskeletal Injury Rates in Direct
Patient Care Personnel**

PRINCIPAL INVESTIGATOR: John O'Donnell

has been scientifically reviewed and is approved for submission to the University of Pittsburgh
Institutional Review Board.

Susan M. Sereika, PhD
Director, Center for Research and Evaluation

Date 11/2/2005

Attachment 3



University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 393-1480
(412) 383-1509 (fax.)

MEMORANDUM

TO: John M. O'Donnell, MSN, CRNA

FROM: Christopher Ryan, PhD, Vice Chair

DATE: January 31, 2006

SUBJECT- IRB # 0511041: The Nursing Back Injury Prevention Project (N-BIPP) - A Pilot Study: Implementation of an Innovative and Comprehensive Training Program Using Simulation Education and an Interim Based Curriculum to Improve Provider Knowledge in Patient Transfer and Provider Adherence to a 10 Point Patient Transfer

The Institutional Review Board reviewed the recent modifications to your protocol and consent form(s) and find them acceptable for expedited review. These changes, noted in your submission of January 09, 2006, are approved,

Please include the following information in the upper right-hand corner of all pages of the consent form(s), if modifications were made to the consent form(s):

Current Approval Date-, December 5, 2005
Modification Approval Date: January 31, 2006
Renewal Date~ December 4, 2006
University of Pittsburgh
Institutional Review Board
IRB #0511041

The protocol and consent form(s) together with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FVVA00006735 (University of Pittsburgh Medical Center), FVVA00006600 (Children's Hospital of Pittsburgh).

If your research proposal involves an investigational drug, please forward a COPY Of this approval 448 along with a copy of the Cover Sheet, protocol, consent form(s) and drug brochure to Investigational Drug Service, PUH Pharmacy.

Please be advised that your research study may be audited periodically by the University of Pittsburgh **Research Conduct and Compliance Office**.

CR:kh

Attachment 4

Abstract

Introduction

Injury is the single biggest factor in workforce loss of nurses with rate of back and musculoskeletal injury epidemic. The public health implication is significant given the nursing shortage, aging population, and importance of nurse staffing levels to outcome. Human simulation educational methods have not been studied but could have advantages over traditional approaches. Our purpose was to implement a patient transfer simulation with web-supported curriculum, targeting team transfer skill (% success in adherence to a 10 point transfer protocol [TPP]) with evaluation of change in knowledge, attitude and satisfaction.

Methods

The TPP was developed through hierarchical task analysis and expert validation. Inter-rater reliability in coding observed transfers was established. Group measurement included observation of 'real-world' patient transfers at three time points (Pre-, 4, 12 weeks) as well as pre- and post-simulation intervention. Individual subject measures included demographics, knowledge, attitude, and satisfaction.

Results

Group level measures: Significant increase in TPP % success was found in the simulated environment ($n = 19$ teams, $t_{18, .05} = -14.76$, $p \leq 0.0004$) with mean simulated success post training at 86%. A 2 X 2 X 3 univariate ANOVA was significant ($p \leq 0.0004$) for differences in group (control vs. intervention units), move-type (chair moves vs. bed moves), time (pre, 4, 12 weeks) with significant group*time interaction. Main effects analysis indicated that 88% success on the TPP at 4 weeks (intervention unit) was significant ($t_{81, .05} = 7.447$, $p \leq 0.0004$). Success in *both* trained and untrained transfer events increased substantially at 4 weeks.

Individual level measures: Knowledge improvement was significant ($n = 67$ pairs, $t_{66, .05} = -11.21$, $p \leq 0.0004$). Attitude change was significant on 13/15 items ($p \leq 0.05$). Overall satisfaction was high across 19 items (mean 4.29 on 1-5 scale).

Conclusions

We successfully demonstrated transference of skills developed during simulation to performance in the clinical setting. Improvement on transfers **not trained** suggests the TPP is generalizable to events other than those which are specifically trained.

Introduction

The Problem

Nursing is the single largest healthcare group comprising almost 55% of the total healthcare workforce [1]. Back and musculoskeletal injury among nurses and other direct care personnel is epidemic with as many as 80% of nurses expected to experience at least 1 significant injury during their career [2-5]. Many hospitals continue to experience shortages and projections indicate that this is a longterm problem not only in the United States but internationally[1]. Back injury has been identified as the single largest contributor to the nursing workforce shortage with manual lifting identified as the primary culprit [2]. This situation has forced hospitals across the US to develop strategies aimed at retention of the workforce including interventions which promote health as well as to prevent work-related injury.

Existing Interventions

Single focus interventions such have been largely unsuccessful in reducing the burden of injury[4, 15-17]. For example, the use of back belts or other support devices and lift training alone have been demonstrated as ineffective deterrents to injury among direct patient care personnel[5, 18]. Conversely, a comprehensive program incorporating a lift algorithm, ergonomic expert input, lift device training, staff support, and ongoing data collection have demonstrated effectiveness in some settings [5].

The Potential of Simulation Educational Approaches

Traditional classroom training in back injury prevention as well as the use of videos and belts are ineffective: perhaps because the process of performing a patient transfer is more complex and includes psychomotor, affective and interactive skills which are absent from traditional formats. Simulation educational approaches contain diverse learning elements and have promise for use in a broad spectrum of education and research applications across simple to complex healthcare tasks [19-40]. There is widespread perception of the utility and value of simulation education for healthcare professionals, with an accompanying global proliferation of health science oriented simulation facilities and approaches[19, 29, 33, 38, 41-44]. Research and scholarly inquiry is now focusing on validating utility of simulation methods in specific domains or tasks and attempting to make the translational link from improved skill or knowledge during simulation to improvement in clinical practice [33, 45-53]. Several recent studies have demonstrated improvement in technical skills on specific tasks, improvement in non-technical skills, head to head superiority in comparison to other educational approaches and as an evaluative tool or replacement for traditional training preparation for clinical trials research in humans [41, 54-59].

The Nursing Back Injury Prevention Program (NBIPP)

Our program evaluated the impact of an internet-supported, simulation-based, comprehensive, ergonomics training program for development of safe patient transfer skills among direct care personnel. The primary aim of the program was to improve direct patient care skill in both ‘real world’ and simulation settings through measurement of success (adherence) in performance of a 10 point patient transfer protocol. The 10 point protocol was developed using hierarchical task analysis (HTA) methods applied to the patient transfer process and based on best evidence from the literature, review by nursing experts and validation by certified ergonomists. Secondary aims included evaluating provider knowledge, attitude toward educational interventions using human simulation techniques and satisfaction with the program.

Methods

Research design

The NBIPP project used a prospective longitudinal repeated measures design. The primary intervention was an internet-supported, simulation-based, patient transfer training program. The overall flow of the study is represented graphically in Figure XXX. The main data collection and intervention points included Pre-Course Observations (patient units), WISER Consent and Assessments (demographic, knowledge, attitude), ‘Cold’ Team Lifts (prior to training), Didactic and Lift Training, ‘Hot’ Team Lifts (after the training), Post-Course Assessments (knowledge, attitude, satisfaction), and Post-Course Observations (patient units at 4 and 12 weeks).



Figure XXX: Process map of the protocol (photo consents on file for all participants)

Population

Our population includes direct care workers within the nursing profession including registered nurses (RN), licensed practical nurses (LPN), nursing aides (NA) and patient care technicians (PCT). Our convenience sample was selected from employees at the Center for Rehabilitation and Research of the University of Pittsburgh Medical Center. The intervention group included subjects recruited from three connected rehabilitation units at one hospital site, while the control group was located in an entirely separate system hospital. These units were selected based on frequency of patient transfer events and a patient population with similar transfer needs.

Inclusion/exclusion criteria for the study

Inclusion criteria included employment as a direct patient caregiver within each hospital's department of nursing. For observational data, move events were recorded only when the individuals performing the transfer agreed to allow the observation to proceed. Providers who did not wish to have their move events recorded would indicate as much to the researchers and no observational data was collected.

Exclusion criteria for intervention subjects included age < 18 and > 65. Providers with known disability were excluded from participation in the simulated transfer aspects of the study, but were allowed to observe and receive the didactic components. Exclusion criteria for observation of 'real-world' move events included any patient transfer events in which the providers or patients objected to an observer on the grounds of maintaining patient dignity (e.g. transfers to a bedside commode or during personal hygiene).

IRB approval and consent

IRB approval for the study was obtained prior to beginning structured observation of the patient move attempts on the control and intervention units. A description of the research project was sent to unit administrators with the study description posted in public areas or in each employee mail slot. Subjects receiving the simulation intervention for which individual-level data was obtained were also asked to read and sign the IRB approved informed consent prior to enrollment.

Setting

'Real world' patient transfer observations were obtained on a total of 4 patient care units of the Center for Rehabilitation and Research of the University of Pittsburgh Medical Center. The simulation intervention was performed at the Winter Institute for Simulation, Education and Research (WISER) of the University

of Pittsburgh. WISER is a multidisciplinary, state of the art simulation facility housing a large number of both full task and part task simulators of varying levels of complexity and fidelity. Individual assessment data were collected and de-identified through WISER's proprietary Simulation Information Management System (SIMS) software. Identifiers were stripped and random alpha-numeric ID numbers were assigned to subjects through an honest broker data management system.

Hierarchical Task Analysis (HTA) Methodology and Protocol Development

The project was initiated in 2004 with identification of a high rate of nursing injury within the UPMC. Fellows from the Beckwith Institute for Innovation and Safety of UPMC anecdotally observed patient transfer events on UPMC patient care units. They were shocked to realize that in many transfers a 'swoop and scoop' process predominated with a group of providers rapidly assembling to move the patient. The patient would often not be actively involved in the transfer event, move counts were not conducted, positions were noted to be awkward and the team would leave immediately post move to continue with other responsibilities. No patient assessment or specific move requirements by patient type, condition, acuity, shape, weight or assistive ability were immediately available to these early observers. As a result a team of ergonomic experts, nursing experts, simulation experts and leadership academy fellows was constituted and went through a process of hierarchical task analysis (HTA) to define the steps of an 'idealized' patient move protocol for a future training program.

Using HTA methodology, our primary goal was development of a flexible and broadly applicable protocol for improvement of patient transfers according to optimal ergonomic principles and best evidence from the nursing injury and simulation literature. Additional live observations were conducted and the more complex process of a 'patient transfer' was dissected into component parts. Through an ongoing and iterative process, 10 clear sub-goals (steps) were described that should occur in every transfer event (Figure XXX). Each sub-goal was 'operationalized' by identifying all of its sub-goals required for completion. In actual coding, the steps were dichotomized with 'correct' indicating successful completion of all sub-goals and 'incorrect' indicating failure on any sub-goal.

10 Point Protocol
1. Identify Patient & Move Requirements
2. Assess Patient
3. Enlist Personnel
4. Gather Equipment
5. Prepare Environment
6. Communicate to Patient
7. Communicate to Personnel
8. Perform Move
9. Reassess Patient
10. Reset Environment

Figure XXX : 10 Point Transfer Protocol

Measurement Tools

A variety of tools were utilized in the study. The primary tool for measurement and assessment of both success of the transfer event and adherence to the training program was the 10 point patient transfer protocol (TPP). HP IPAQ™ handheld computers, running the Windows Mobile™ operating system, were programmed with embedded visual basic to create a graphic user interface (GUI) -based data collection system programmed with the TPP. This system provided the research team with a transportable, consistent data collection tool for assessment of group-level (transfer event) measures at all measurement points (pre-simulation intervention, during simulation training and at 4 and 12 weeks post-simulation training). In addition, the TPP steps were programmed into the Laerdal SimMan™ software system (version 2.3) allowing concurrent TPP coding for later comparison of SimMan™ output logs with IPAQ files. This allowed for immediate and robust debriefing of the scenario-based simulated transfer events as well as later calculation and analysis of inter-rater reliability statistics.

The individual-level study measures included a demographic collection instrument which obtained age, gender, years of work experience and job title. A 10 item knowledge assessment tool was used to measure baseline and post-intervention knowledge keyed to each TPP step. An assessment tool titled the ‘Health Professional Simulation Education Assessment Tool (HtSEAT)’ was used to collect subjective attitude and perception data pre- and post- intervention. A post-course satisfaction survey was used 4 weeks post-intervention with items drawn from items used by the Office of Measurement and Evaluation database at the University of Pittsburgh.

Simulation Tools and Props

The primary simulation tool used for the study was the Laerdal Tuff-Kelly™ (TK) Move Mannequin (Figure XXX) which was dressed in color-coded and weight labeled t-shirts to indicate the kilogram or pound weight of the patient within each scenario. Pounds were noted on the front of the shirt with kilograms on the reverse side allowing providers to rapidly determine the equipment and/or personnel needs for the transfer after determining the ability of the patient to assist.



Figure XXX: Laerdal TuffKelly™ Move Mannequin and Weight Indicator t-shirts

This adult sized mannequin is designed for practice of transfer events as well as for other purposes (eg extraction events by fire departments). TK can be weighted with lead shot placed via a removable chest plate to as much as 300 pounds. For the purposes of the study, all lead was removed and the actual mannequin weight was maintained at approximately 100 pounds to minimize risk of provider injury during training. Simulated transfer events used actual patient scenarios and descriptions requiring use of ancillary props (EKG, lines, dressings etc). Although the TK is a low fidelity simulator, vital signs were displayed via the Laerdal SimMan™ monitor system and the patient ‘voice’ was generated via a ceiling mounted intercom system enhancing the overall realism of the events. The TK mannequin lacks full articulation of joints and suffers from an inability to easily ‘lock’ the knees for use in a chair or standing transfer event. Because of the limitations of our ‘tool’ and our concern that attempts to use the TK mannequin for chair transfers could increase risk of injury, we trained bed-only simulated transfer events.

Transfer devices used in the study were primarily friction reducing devices (bed slides). These were chosen because they are the primary devices used by the rehabilitation units (although ceiling mounted and portable sling lifts are available on the clinical units). Importantly, the TPP ‘patient move’ step can include any transfer device or approach including devices used under ‘minimum’ and ‘no lift’ situations.

IRB Approval and Curricular Preparation

After IRB approval, permission for observation was obtained through the departments of nursing of the two UPMC facilities where the study was to be conducted. The research script and description was distributed to the nursing units prior to collection of move events. Scripts were posted or placed in each provider mailbox, and also were available from the Unit Managers who were asked to inform their staff of the protocol during unit meetings. Data collectors also distributed scripts upon request.

Prior to the simulation training, online curriculum and assessments were developed and posted on the WISER learning management system platform. Course objectives, the research script, short powerpoint lectures (musculoskeletal injury myths, review of body mechanics), a brief video demonstrating each step of the protocol, an overview of the importance of prevention in back injury and key references in full text pdf format were posted for participants (Figure XXX). Facilitator notes, the full IRB protocol, simulation scenarios and an introductory lecture on simulation education at the WISER center were developed and placed in the facilitator area of the course.

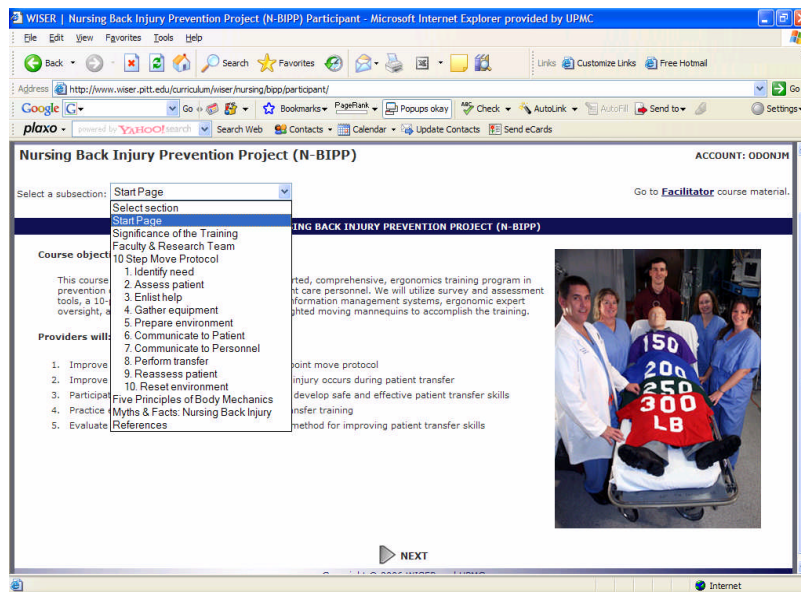


Figure XXX: Screenshot of course materials posted for participants. (photo permissions obtained)

Pre-Course Observations (patient units)

A total of 103 transfer events were observed on the intervention units (total of three connected units-one hospital) and 34 events were observed on the control unit (separate hospital). The TPP programmed into the HP IPAQ™ handheld personal computer (PC) was used for data collection.

Table XXX: Move Type and Code

Move Type	Coding key	Category	Trained at WISER
1. Side to Side in Bed	sts	bed	Yes
2. Up in Bed	uib	bed	Yes
3. Gurney to Bed	gtb	bed	Yes
4. Bed to Gurney	btg	bed	Yes
5. Bed to Chair	btc	chair	No
6. Chair to Chair	ctc	chair	No
7. Chair to Bed	ctb	chair	No
8. Chair to Standing Position	ctstd	chair	No
9. Up in Chair	uic	chair	No
10. Chair to Gurney	ctg	chair	No
11. Gurney to Chair	gtc	chair	No

A coding system was developed (Table XXX) for later identification of move types and locations. The

coding scheme used was: 'unit-move type-coder initials- nth move-hospital', with the IPAQ program automatically generating the date, step name, number of step, time stamp and coding score (Figure XXX)

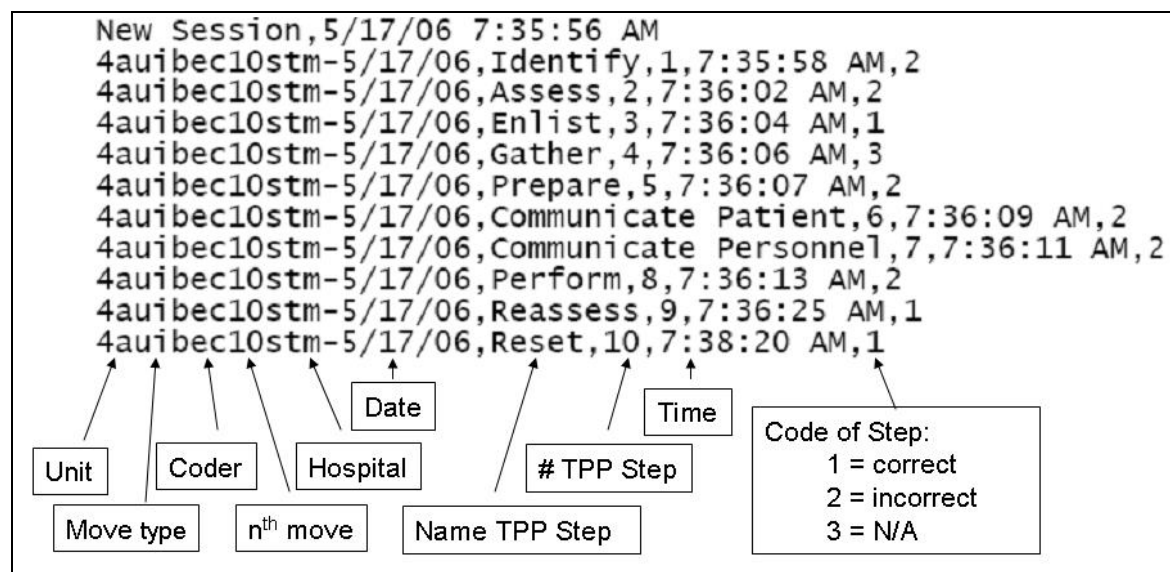


Figure XXX: HP IPAQ output text file of raw data extracted after transfer event was coded

WISER Consent and Pre-Course Assessments (demographic, knowledge, attitude)

All potential subjects were scheduled at the simulation center for a 4 hour block of time. Upon arrival, a brief tour was given and the informed consent was read with the group. Individuals interested in participating as subjects signed the consent and completed the assessments. Individuals who chose not to participate as subjects received payment for attendance, were offered all content and were allowed to observe and participate in all aspects of the course except for online assessments and the actual transfer simulations (n =4/75 or 5.3%). After signing the consent, subjects logged onto the WISER website via Toshiba TabletPC™ units and wirelessly registered for the course via the online course registration system. Subjects then completed assessments including the demographic data collection form, attitude survey and 10 item quiz. All assessments were available on the wireless tablet computers and upon submission of the assessment tools, trainees were assigned an anonymous but unique alpha-numeric identifier by the WISER information management system.

Cold' Team Lifts (prior to didactics and lift training)

Following completion of the assessment instruments the subjects were divided into teams of 3-5 and directed to WISER training rooms. Under the observation of certified ergonomists the teams were asked to perform 2 'cold' scenario based simulated transfer events (transfers prior to any didactic or ergonomics training). Each transfer was coded with both the IPAQ PC units and the Laerdal SimMan™ software (Figure XXX) which generated a log for each transfer event.

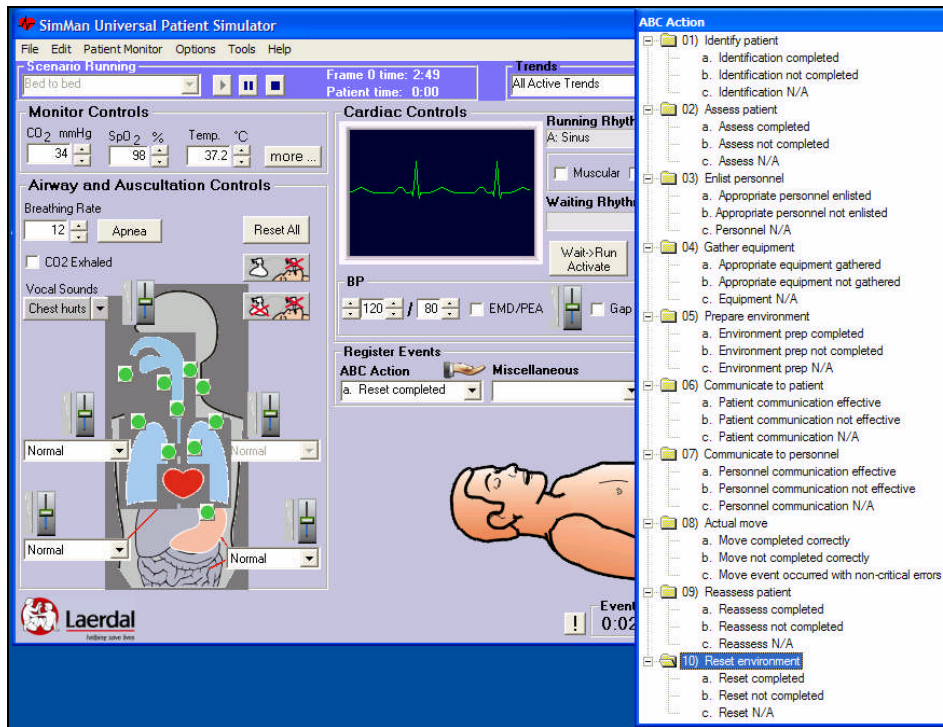


Figure XXX: Laerdal SimMan™ Universal Patient Simulator interface (version 2.3) with 10 point protocol programmed as an ABC Action handler.

Didactic and Lift Training

Debriefing of the SimMan logs from the 'cold' move events for each team initiated the intervention. SimLogs are the record generated by the SimMan software and each scenario was programmed to give step-specific feedback referenced to the literature or standards of care. The data from the logs is in .xml program language and an .xml style sheet allows feedback of correct and incorrect both in text and by color (correct = green, incorrect = red). (example Figure XXX)

SimMan Performance Evaluation		
Comments only version		
Date: 11.18.2006 Time: 17:37:58		
Time (hh:mm:ss)	Type	Status
00:00:06	Correct Step: a. Identification completed	Whenever a patient is receiving a med or undergoing any type of procedure, at least two identifiers should be used. This is often a component of the patient transfer. Room number may not be one of the ID elements. (Ref 2006 NPSG JCAHO)
00:00:08	Correct Step: a. Assess completed	Assessment prior to the transfer event should include: reason for the transfer, patient medical condition, patient ability to participate, patient's mental status and pain level, and any other patient specific needs important to the transfer or move (Nelson 2003, Move 2003)
00:00:09	Wrong Step: b. Appropriate personnel not selected	Communication to recruit appropriate personnel is key. Patient weight, ability to assist, type of transfer, and equipment available are all factors to be considered in this step. (OSHA 2005, 2006 JCAHO NPSG, Nelson 2003)
00:00:11	Correct Step: a. Appropriate equipment gathered	Equipment selection should be based on availability, training of providers, previous assessment of need (step 2), and available space for the move or transfer. Move algorithms can be used to guide these decisions. (OSHA 2005, Nelson 2003, Edlich 2005)
00:00:13	Wrong Step: b. Environment prep not completed	Environmental prep involves matching surface heights, freeing attached devices (IV's & drains), moving obstructions, and attaining the most suitable ergonomic position with height adjusted for the shortest provider. (OSHA 2005, Nelson 2003)

Figure XXX: Sim Man performance log of a bed to bed (btb) transfer event showing coding of steps 1-5.

Certified ergonomists conducted each debriefing and subjects then proceeded to the wireless classroom environment. Training videos for each protocol step were played for the entire group with instructor guidance over a 30 minute period. The next section of the training protocol required 45 minutes and is best described as an internet supported e-learning period. Subjects were encouraged to review the posted on-line content materials via their individual tablet PC units. A question and answer session followed allowing clarification of any points of confusion.

‘Hot’ Team Lifts (lift training post didactic content review)

After the content training was completed, the same teams of subjects were directed to the simulation training rooms. Two new scenario based transfer events were then performed and evaluated. Teams were required to attain an average score of at least 80% over these 2 transfer events and if they failed to do so were offered an immediate remediation scenario. Debriefing consisted of ergonomist review of performance logs in the training room immediately after each of these ‘hot’ training events.

WISER Post-Course Assessment (knowledge, attitude, satisfaction)

After the transfer training was completed, subjects completed post-course assessment instruments which again were entered via the WISER Simulated Information Management System (SIMS) with responses linked to the same anonymous alpha-numeric identifier. Knowledge and attitude assessment tools were completed during the transfer training day. From the end of training to four weeks post-training, the satisfaction survey was open on the WISER web site. Paper copies of the satisfaction survey were also distributed to the intervention units and returned in sealed envelopes directly to the investigators during the 4 week observations on the intervention units.

Post-Course Patient Transfer Observations (patient units at 4 and 12 weeks).

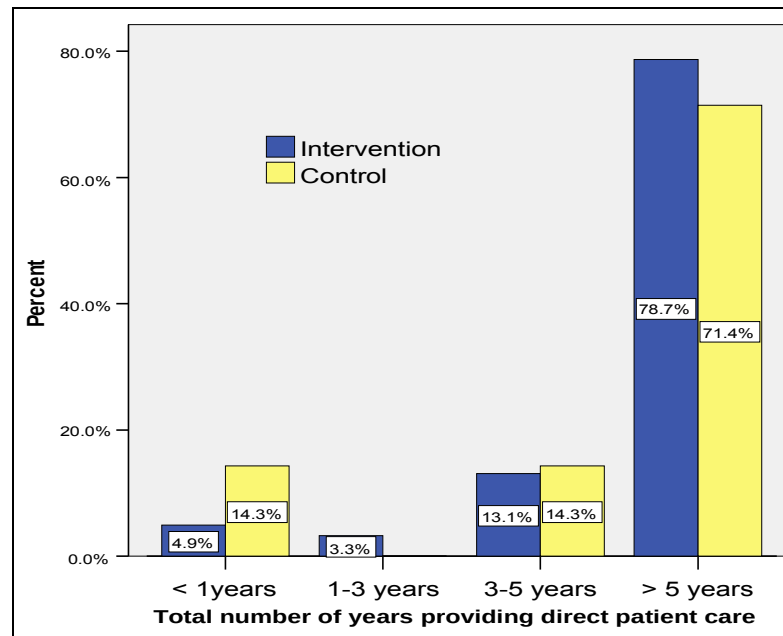
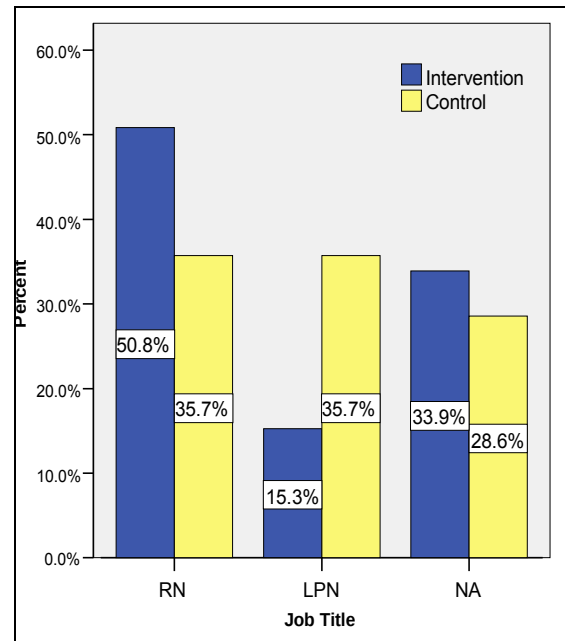
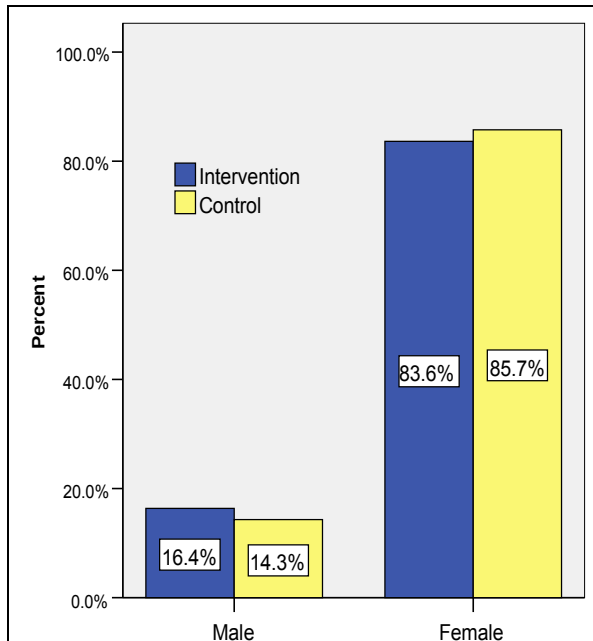
At the 4 week observation point, a total of 53 team transfer events were observed on the intervention units with 30 team transfer events observed on the control unit. At 12 weeks a total of 54 team transfer events were observed on the intervention units and 32 team transfer events on the control unit. The TPP programmed into the HP IPAQ™ handheld personal computer (PC) units was again used for data collection using the same coding system at each of these measurement points.

Results

The primary aim of the program was to improve patient transfer skill in both the ‘real world’ and simulation settings. Our approach was to measure transfer skill through measurement of performance on each step of a 10 point transfer protocol derived through HTA methods. Additional aims included evaluating provider knowledge change, evaluating change in attitude toward educational interventions using human simulation educational techniques and assessing subject satisfaction with the overall educational program.

Descriptive statistics

The intervention units employed a total of 81 providers at the time of IRB approval while the control unit employed a total of 14 providers. Demographic data for the intervention group was obtained with our survey tool. A total of 71/81 (88%) of the intervention unit providers enrolled as subjects, however only 61/81 (75%) completed the demographic tool. The demographic data available from the control units was a de-identified data set that included total number of employees, age, gender, years of experience and job title at the initiation point of the study. Mean age on the intervention unit was 44.4 and on the control unit 45.3. These age differences were not statistically significant (independent samples t-test, $p=0.953$). Figures X-Z portray the distribution of gender, years of experience and job title across the two groups with comparison of these factors revealing no statistical differences at baseline (Table XXX)



Figures XXX: Gender, job title and total number of years providing care between intervention and control units.

Table XXX: Comparison of key demographic variables- intervention vs. control groups

Intervention vs. Control Groups	Statistical Test	Sig (2 tailed)	Interpretation
Gender	χ^2^*	0.846	NS**
# Years Experience	χ^2	0.563	NS**
Job Title	χ^2	0.211	NS**

Legend: *Pearson's chi square , ** Non-significant

Group level measurement results:

Transfers in the Simulation Environment

A total of 19 teams of subjects completed a total of 76 transfer events (4 per team) in the simulated transfer component of the study. As previously described, the simulated transfer training events were restricted to 'bed' events due to the limitations of the mannequin. The transfer scenarios were side to side, bed to gurney, up in bed and gurney to bed.

A total of 38 transfer scenarios were completed prior to the educational intervention ('Cold') and 38 transfer scenarios were attempted after the training ('Hot'). All transfers were concurrently coded in both the SimMan software system as well as with the IPAQ units. The mean score for success in 'Cold' moves was 34% and the mean for 'Hot' success was 86%. Because the mean score for the final two moves was required to be 80% for each team, two teams underwent a final remediation move. This data was excluded from analysis. The increase in team success according to the TPP in the simulation setting was significant ($n = 19$ teams, $t_{18, .05} = -14.76$, $p \leq 0.0004$) (Figure XXX)

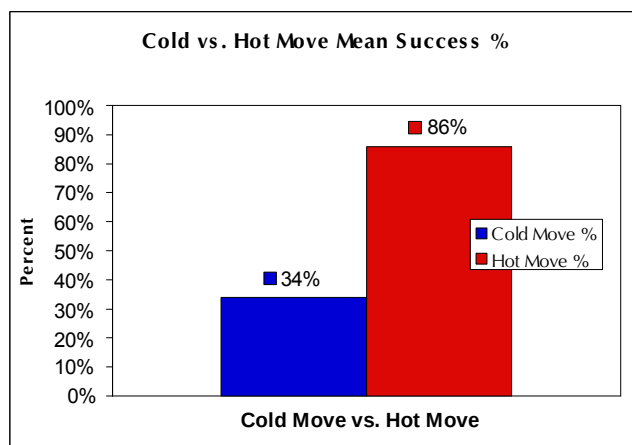


Figure XXX: 'Cold' (pre-training) move success vs. 'Hot' (post-training) move success ($p \leq 0.0004$)

Transfers in the clinical environment

A total of 306 transfer events were observed and coded at three time points: prior to the simulation intervention, 4 weeks post intervention and 12 weeks post intervention. All transfer events were gathered from 4 rehabilitation units at UPMC. Three units were located at the intervention hospital and 1 unit was located at the control hospital. The three intervention units worked closely together and staff moved freely between the units while the control unit was separated by a distance of almost 5 miles with staff interaction minimal between the facilities.

Percent success was calculated for each time point by aggregating the IPAQ files and calculating the mean success on transfers according to the TPP. A 2 X 2 X 3 univariate ANOVA was performed with three main-effects variables considered in the model. Differences between Group (control vs. intervention units), Move-type (chair moves vs. bed moves), and Time (measurement points pre-intervention, 4 weeks and 12 weeks) were compared. Significance was detected for all three of these variables ($p \leq 0.0004$). Interaction effects were then considered with the Group*Time interaction significant ($p \leq 0.0004$) (Table XXX) indicating that the change in % success at the 4 week measurement point should be further evaluated.

Table XXX: 2 X 2 X 3 Univariate ANOVA for Main Effects and Interaction

Tests of Between-Subjects Effects								
Dependent Variable: % success								
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power ^a
Corrected Model	3.471 ^b	11	.316	9.168	.000	.255	100.843	1.000
Intercept	97.260	1	97.260	2825.669	.000	.906	2825.669	1.000
Group	.541	1	.541	15.712	.000	.051	15.712	.977
MoveClass	.787	1	.787	22.869	.000	.072	22.869	.997
Time	.552	2	.276	8.020	.000	.052	16.040	.955
Group * MoveClass	.002	1	.002	.061	.806	.000	.061	.057
Group * Time	.759	2	.380	11.032	.000	.070	22.064	.991
MoveClass * Time	.131	2	.066	1.909	.150	.013	3.818	.395
Group * MoveClass * Time	.051	2	.026	.745	.476	.005	1.489	.176
Error	10.120	294	.034					
Total	163.062	306						
Corrected Total	13.591	305						

a. Computed using alpha = .05
b. R Squared = .255 (Adjusted R Squared = .228)

Further analysis of the data reveal that the increase in success to 88% on the TPP at 4 weeks post training on the intervention units was highly significant ($t_{81, .05} = 7.447, p \leq 0.0004$). No other pair-wise comparison of Time*Group was significant with this effect represented in Figure XXX.

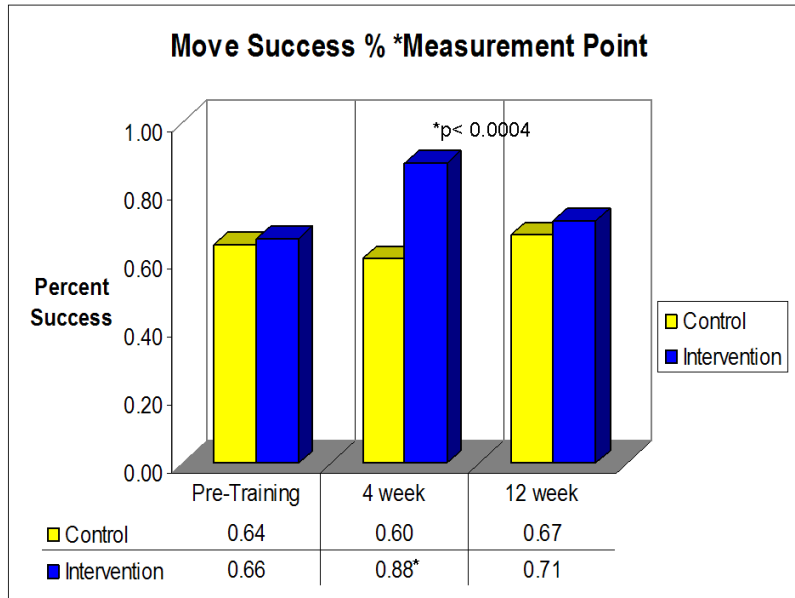


Figure XXX: Percent Success Group*Time at each measurement point with significance at 4 weeks in the intervention group ($p<0.0004$)

The significant ‘main effect’ difference associated with ‘type of transfer’ is also of note. A wide variety of transfer types were observed within the study. These move types were categorized according to transfers that were bed-based vs. those that were chair based (Table XXX Move Type and Code). Because the simulation course trained only bed-based transfers we stratified the bed vs. chair groups as trained vs. untrained (Figure XXX and Figure XXX). The events that were chair-based represented 66% of all moves collected but success was lower than success on bed moves at all measurement points except for at 4 weeks in the intervention group.

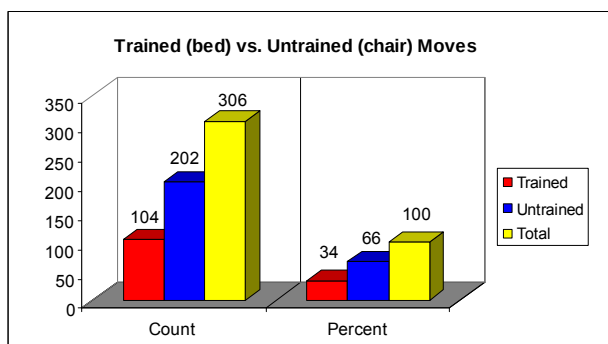


Figure XXX: Stratification of Observed Move Type : Trained (bed) vs Untrained (chair)

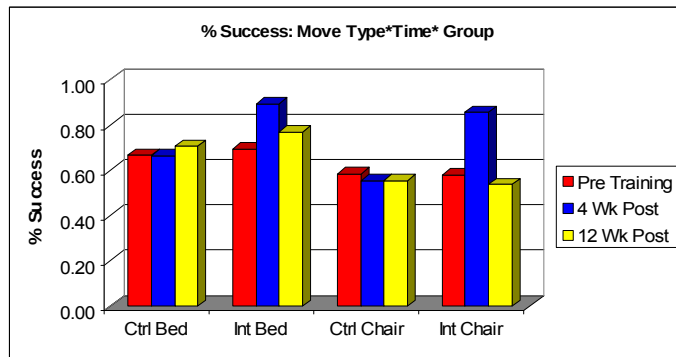


Figure XXX: Percent Success: Move Type (bed vs. chair)*Time Point (Pre, 4 wks, 12 wks)*Group (Control vs. Intervention)

TPP Protocol Steps Missed: Both Simulation and Live Observation

Because the TPP was used in evaluation across all measurement points, analysis of which steps were most commonly missed was conducted across the continuum of the study.

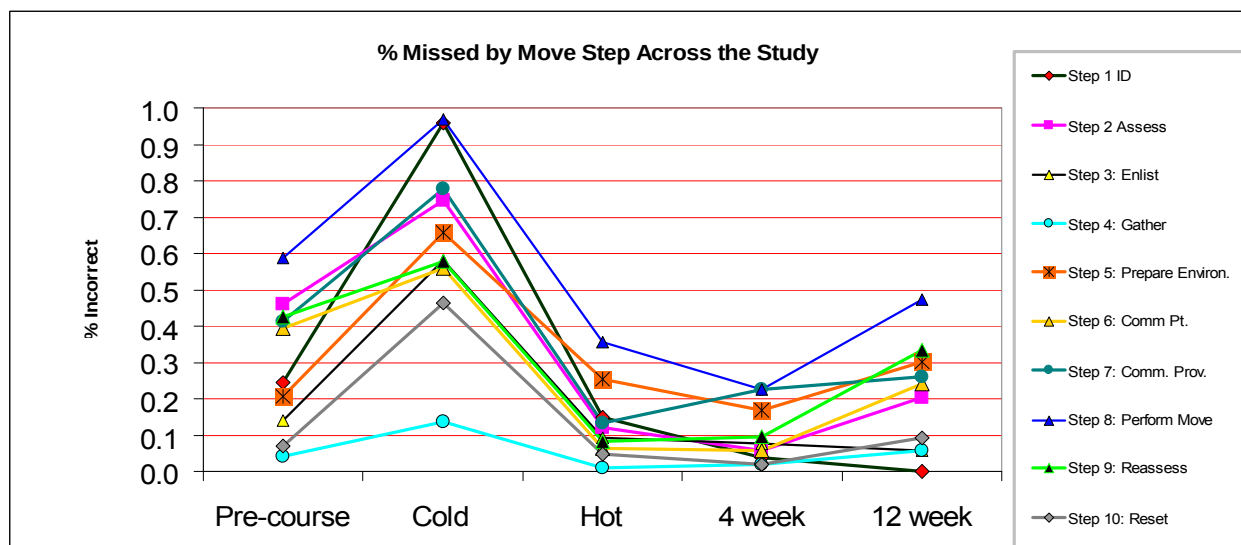


Figure XXX: % Missed by Move Step Across the Study

The mean percentage missed across the study by each TPP step was calculated and a distribution was developed. The least missed step (5 %) was 'gathering equipment' with the most frequently missed step (52%) being 'perform the move' reflecting the relative complexity of these two steps (Figure XXX)

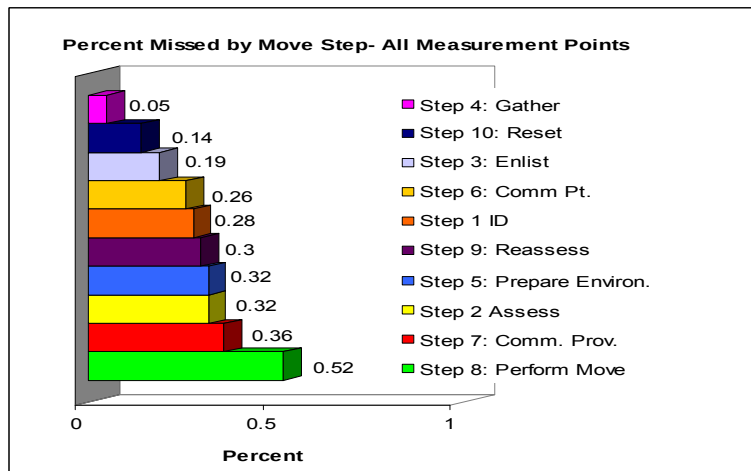


Figure XXX: % Missed by Move Step from Least to Most Frequently Missed

Individual-level measures

Knowledge

A 10 item multiple choice knowledge tool was employed as a classic pre-test/post test intervention. Each item was related to a specific TPP step. In addition items were constructed and referenced to best evidence or standards of patient care and cross referenced to content within the web-supported course material or within the debriefing feedback section of the SimMan™ log files. Knowledge improvement was significant across the intervention group ($n = 67$ valid pairs, $t_{66,05} = -11.21$, $p \leq 0.0004$) with an overall post-test mean score of 90% (Figure XXX)

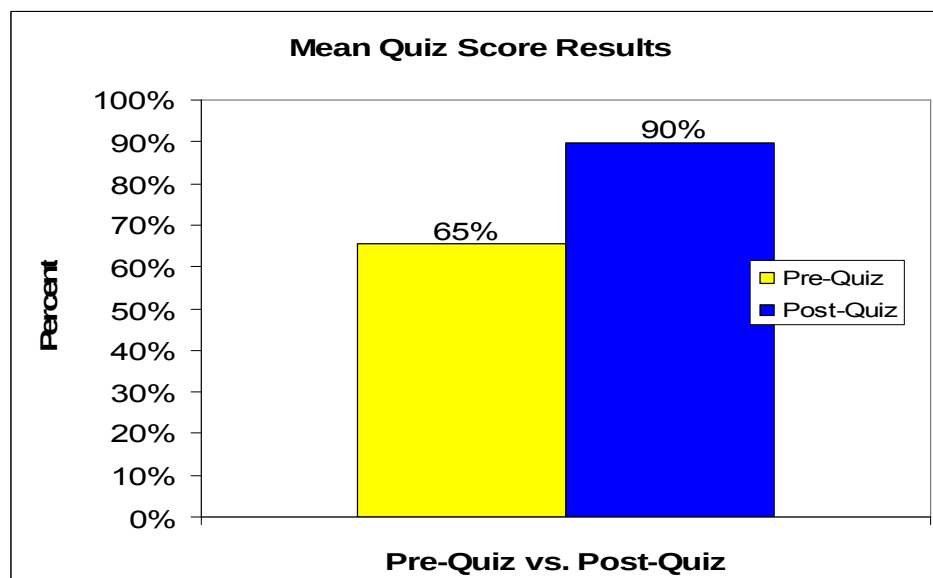


Figure XXX: Overall knowledge gain post simulation intervention.

Because individual knowledge items were catalogued by TPP step content, we analyzed by item to determine degree of difficulty as well as increase or decrease in item performance post intervention (Figure XXX). All items showed an increase in score with the exception of ‘Number of providers needed for a move’. Analysis of this item demonstrated low pre- and post course degree of difficulty (mean score pre- 98%, mean score post-94%). After analysis, no obvious course element can be identified that might lead to this result.

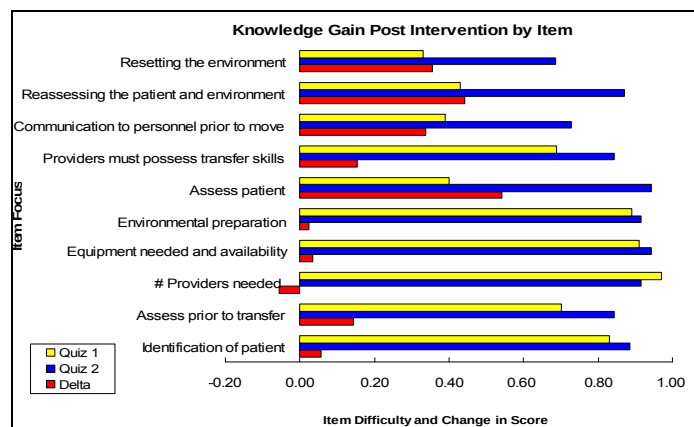


Figure XXX: Knowledge gain by quiz item referenced to each 10 point protocol step (N=67 pairs)

Attitude/Opinion

A total of 15 attitude/opinion items were developed to evaluate subject perception of the course, curriculum, simulation education, confidence, anxiety, communication, effectiveness, team performance and safety. These items were based on the ten point protocol and previous simulation-based protocols conducted at WISER. Table XXX demonstrates that subject responses on a 1-5 scale improved significantly on 13/15 items (paired samples t-test $p \leq 0.05$).

Items which improved included attainment of course objectives, knowledge of injury prevention, personnel needed for moves, realism of scenarios, similarity to clinical transfer events, gain in injury prevention skill, gain in patient transfer skill, confidence in instructor evaluation of performance, confidence during transfer, effectiveness of communication to patients, effectiveness of communication to providers, effectiveness as a team member and improvement of patient safety during transfer events.

Two items which did *not* improve were subject’s perception that the protocol improved knowledge of equipment needed for transfer and anxiety related to being observed during the transfer events. The first item is important as the focus of the intervention was not training on particular move devices but on the

TPP process. Also, no new transfer equipment was introduced- all equipment was similar to equipment available on the intervention units. Anxiety scores actually decreased pre- to post intervention confirming our intent to make the environment as non-threatening and comfortable for subjects as possible within the context of the research protocol.

Table XXX: Health Professional Simulation Education Assessment Tool (HtSEAT 1 & 2)

NBIPP Attitude Assessment: Pre vs. Post Intervention Scores (HtSEAT 1 & 2) Scale 1-5 (1=Strongly Disagree 2=Disagree 3=Neutral 4=Agree 5=Strongly Agree)							
		mean	sd	change	t-value	N	p
Met course objectives	Pre	4.19	0.93	0.48	-5.374	67	0.0004
	Post	4.67	0.76				
Knowledge base on back injury and prevention	Pre	4.32	1.00	0.27	-2.600	67	0.0115
	Post	4.59	0.79				
Knowledge of equipment needed for transfers	Pre	4.31	1.00	0.19	-1.540	66	0.1285
	Post	4.50	0.89				
Number of personnel need by patient weight	Pre	4.32	0.98	0.33	-3.645	67	0.0005
	Post	4.65	0.76				
Realism of simulation scenarios	Pre	4.13	0.97	0.24	-2.014	66	0.0481
	Post	4.38	0.97				
Similar to actual clinical transfer events	Pre	3.96	1.12	0.42	-3.072	66	0.0031
	Post	4.38	0.94				
Gain in injury prevention skills	Pre	4.21	0.99	0.37	-3.535	66	0.0008
	Post	4.58	0.81				
Gain in patient transfer skills	Pre	4.24	0.99	0.38	-3.760	65	0.0004
	Post	4.62	0.81				
Confidence in instructor evaluation of skill	Pre	4.25	0.97	0.26	-2.449	67	0.0170
	Post	4.51	0.95				
Anxiety related to observation of performance	Pre	3.25	1.33	-0.31	1.556	67	0.1243
	Post	2.94	1.51				
Gain in confidence during patient transfer	Pre	4.22	0.93	0.25	-2.715	65	0.0085
	Post	4.47	0.87				
More effective patient communication	Pre	4.12	1.04	0.40	-3.594	66	0.0006
	Post	4.51	0.86				
More effective provider communication	Pre	4.13	1.00	0.45	-4.317	66	0.0001
	Post	4.58	0.83				
More effective team member during transfer	Pre	4.26	0.96	0.34	-3.697	67	0.0004
	Post	4.61	0.81				
Improve patient safety during transfer	Pre	4.28	0.94	0.30	-3.656	67	0.0005
	Post	4.58	0.83				

Satisfaction

Post-course, subjects demonstrated a high degree of satisfaction with the intervention with responses indicating a desire for additional exposure to simulation training. 19 satisfaction items were administered and were stratified according to 4 categories: Instructors and Staff, Course and Materials, Assessment Tools and Infrastructure. The grand mean across all 19 items was 4.29 on a 5 point scale and an overall mean was calculated for each category area (Table XXX)

Table XXX: NBIPP Post-Course Satisfaction Survey Results.

NBIPP 4 Week Post Course Satisfaction Survey (Response rate 32/71 [45.1%]) Scale 1-5 (1=Strongly Disagree 2=Disagree 3=Neutral 4=Agree 5=Strongly Agree)	N	mean	sd
Instructors and Staff (overall mean 4.54)			
Instructors treated me with respect.	31	4.61	0.80
Instructors treated me in a professional manner.	32	4.59	0.80
Instructors gave directions that were easy to follow.	32	4.53	0.80
Instructors were readily available for assistance.	32	4.50	0.80
The WISER staff were helpful.	31	4.48	0.81
Instructors gave clear and precise critiques.	32	4.38	0.94
In room debriefings were helpful	32	4.34	0.83
The patient transfer demonstrations were helpful	31	4.23	1.06
Course and Material (overall mean 4.24)			
The course was well organized.	31	4.35	0.95
Audiovisual material quality was good.	32	4.31	0.86
The course material was coordinated in a logical sequence.	30	4.30	0.95
The variety of educational activities in the course contributed to my learning.	31	4.16	0.93
The course content was valuable.	31	4.06	1.06
Assessment (overall mean 4.15)			
The quizzes were helpful in learning the material	31	4.16	0.97
The quizzes should be used again in teaching this course.	30	4.13	1.04
Infrastructure: Equipment, Facility, Tools, Website (overall mean 4.09)			
The equipment available (lift mannequins & move devices) was conducive to my learning.	31	4.39	0.76
The facility (physical environment) was conducive to learning.	32	4.31	0.86
The WISER website was easy to use	31	3.94	1.03
Posting of course materials on WISER web site contributed to my learning.	31	3.71	1.07

Reliability of Measurement

Inter-rater reliability was assessed for each of the 10 point protocol steps. Coders were trained by certified ergonomists during the pre-course observation phase of the study. Training occurred for a minimum of 10 transfer observations and at least 4 hours of 1:1 training. Validation that coders were accurate was conducted during the simulation training sessions. Experts coded all of the team moves (n =76) on the Laerdal SimMan™ software during both ‘Cold’ and ‘Hot’ simulated move events. Concurrent coding on the HP IPAQ PC units by trained coders resulted in a total of 98 coded transfer observations (some moves

were coded by more than one trained coder) which were then paired with the expert coding. Cohen's kappa values were then calculated for each of the steps of the TPP with values ranging from 0.43- 0.83 (mean= 0.62) indicating substantial agreement between ergonomic experts and the trained coders and affording confidence in the reliability of real life coded observations (Table XXX)

Table XXX: Inter-rater reliability by protocol step

Inter-rater Reliability by 10 Point Protocol Step (Cohen's <i>kappa</i> range: .43-.83, mean 0.62)		<i>kappa</i> value	Asymp. Std. Error(a)	Approx. T(b)	Approx. Sig.
1	Identify the patient and move requirement	.833	.057	8.166	.0004
	N of Valid Cases	96			
2	Assess patient condition & pain level	.575	.084	5.659	.0004
	N of Valid Cases	97			
3	Enlist appropriate number of personnel	.778	.070	7.543	.0004
	N of Valid Cases	94			
4	Gather appropriate equipment	.588	.167	5.777	.0004
	N of Valid Cases	96			
5	Prepare environment	.445	.091	4.374	.0004
	N of Valid Cases	94			
6	Communicate with patient	.431	.100	4.269	.0004
	N of Valid Cases	98			
7	Communicate with personnel	.588	.084	5.676	.0004
	N of Valid Cases	93			
8	Perform the move/transfer	.666	.082	6.427	.0004
	N of Valid Cases	93			
9	Reassess patient pain level & condition	.621	.085	6.148	.0004
	N of Valid Cases	97			
10	Reset the environment	.633	.093	6.168	.0004
	N of Valid Cases	95			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Review of Literature and Discussion

Epidemiology of Nursing Injury

In the US population of working-age adults, the yearly prevalence of low-back symptoms is as high as 50% with 1 out of 7 primary care visits for musculoskeletal pain/dysfunction. In addition, low-back problems are the most common cause of disability for those under 45. Nursing back and musculoskeletal injury is at epidemic proportions the United States and across the world[2, 13, 14, 60-67] .

As many as 38% of nurses suffer from back pain severe enough to require time off and up to 12% leave the profession due to back pain. [68]. Employees in nursing and personal care homes suffer 200,000

injuries per year. Among female workers in the US, nursing aides, nursing assistants and orderlies suffer the highest prevalence (18.8%) and the largest number of cases of work related back pain (n=269,000). The National Institute of Occupational Safety and Health (NIOSH) reports a prevalence of back pain among nurses annually of 40% to 50% with a 35%-80% lifetime prevalence rate of back pain/injury[18]. Nurses and nursing aides have the highest rate of workers' compensation claims within healthcare and the 6th and 2nd highest rates respectively among all workers [60, 68, 69] (Table XXX)

Table XXX: Rank of At-Risk Occupations for Strains and Sprains 2000 with permission from de Castro 2004[69]

Table 1. Rank Of At-Risk Occupations For Strains And Sprains, 2000 (Bureau of Labor Statistics, April 2002)	
Rank	Occupation
1	Truck Drivers
2	Nursing Aids, Orderlies & Attendants
3	Laborers, Non-Construction
4	Assemblers
5	Janitors and Cleaners
6	Registered Nurses
7	Construction Laborers
8	Cashiers
9	Carpenters
10	Stock Handlers and Baggers

The reported incidence within the UPMC health system housing our experimental and control groups mirrors this global trend. There were approximately 2500 direct care personnel at just two of the nineteen UPMC facilities with 171 musculoskeletal strains and sprains among nursing personnel at these two sites in fiscal year 2005 alone.[70]

Etiology of Musculoskeletal Injury

Lifting or moving a patient has been identified as the leading source of injury across the injury literature. [13, 14, 16, 61-63, 66, 75]. Nurses are exposed to a variety of high stress situations on a daily basis and a variety of factors can contribute to development of injury including improper body mechanics, prior injury history, weight, age, fitness, obesity, genetics, and muscular strength[4, 5, 14, 61]. Manual lifting is not the sole culprit in development of musculoskeletal injury as a variety of patient transfer events and situations have been implicated as contributing to injury[2, 3, 14, 60, 66, 76-79]. Although widely

advocated as a solution, mechanical lift devices and even ‘no lift policies’ may simply shift the site of injury from the back to other areas of the body. [3, 78]. Some studies link injury to particular types of patient units/populations such as orthopedic patients and to frequency of patient transfers per shift. [14]. Lost-work time injury rates in home healthcare are 50% greater than in the institutional setting and 70% greater than the national population rate with back injury the most prevalent site of injury for home care in 1997. This may become an increasingly important issue as the burden of care is shifted from traditional settings to the home [71].

Financial Impact on the Healthcare System

The costs to our health care system are very high and include, but are not limited to, financial losses from workers compensation claims, stresses to staffing levels from loss of personnel and lost wages for the injured party. Direct costs are typically defined as medical expenditures and temporary to permanent disability payments. Indirect costs include loss of productivity and expenses associated with hiring and orientation of replacement staff. [71]. While the financial burden on the healthcare system alone is staggering, the impact of ongoing nursing injury rates in a period of critical nursing shortages cannot be underestimated.[2].

In the US the direct and indirect costs of back pain have been estimated to exceed 50 billion dollars per year, with 75% of that amount related to the 5% of people who are temporarily to permanently disabled [72]. More recent estimates specific to the healthcare industry indicate \$16 billion annual total cost with an estimated \$10 billion in indirect costs[60]. In our setting, indirect costs were calculated to include legal fees and lost work time, but excluding replacement personnel. Musculoskeletal injury accounted for approximately \$15.9 million dollars across this 19 hospital healthcare system in 2005[70].

The Nursing Shortage and Implications of High Injury Rates

The 2006 national vacancy rate of RN positions is on average 8.5% [73] with projections through 2020 indicating a total shortage of over 1,000,000 nurses (Figure XXX)

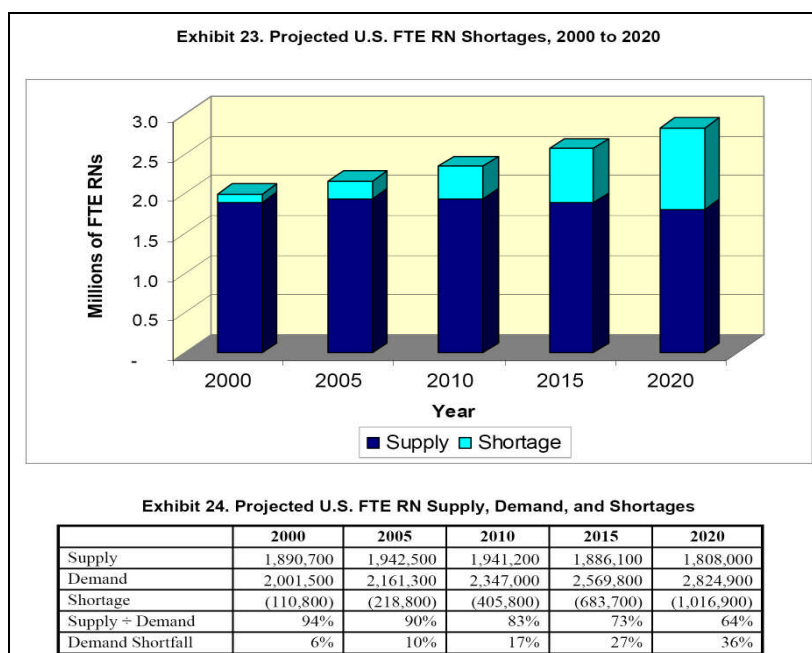


Figure XXX . Projected US FTE RN Supply, Demand, and Shortages 2000-2020 (BHPPr 2004) (with permission from BHPPr) [74]

The shortage of nurses in combination with high injury rates raises concern about future healthcare system capacity. Demand for full-time equivalent (FTE) RN's per thousand population will increase from 7 to 7.5 between 2000 to 2020 if healthcare consumption demands remain constant over time, based on the aging of the US population[74]. One solution might be to have individual nurses work longer hours, however working full time is associated with increased injury rates, with fewer health problems reported in nurses working ≤ 20 hours/week. [13, 14]. Finally, the loss of nursing personnel to injury can precipitate a self sustaining cycle of injury, as loss of direct care personnel results in increased pressure on the remaining workers, and elevates their risk profile with resulting occurrence of additional injuries. [60].

Available Nurses and Patient Outcomes

The public health implication of the ongoing loss of qualified nurses from our health care system is significant. Multiple indices of patient comfort, satisfaction and even survival are impacted by nurse levels[6-11]. In addition, shortages of nurses are often compensated for by increasing the work burden and length of hours worked in the remaining workers. These factors have been associated with increased risk of medical error[12], nurse burnout[7, 10] and injury [13, 14]

Political and Regulatory Action

A wave of educational and legislative initiatives focused on the issue of prevention of nursing back injury has occurred since the late 90's. 'No lift' policies have been in place in Australia and England since 1996 and 1998 respectively [2]. These policies call for minimal nursing exertion during lift maneuvers and the use of lift devices where possible. Perhaps a better term for these policies would be 'safe-lift' instead of 'no-lift' as the latter description implies that nurses will not be involved in any patient transfer events or situations- clearly an impractical absolute. The Australian Nursing Federation refers to the latest iteration of the program as the 'No lift, no injury' policy but acknowledges that lifts should occur only when a patient's life is threatened or only a small percentage of their weight is lifted [82]

In 2000, the Occupational Safety and Health Administration was poised to publish a final ergonomics rule (29 CFR Part 1910 Ergonomics Program; Final Rule) that would have defined parameters around patient transfer nationwide. This rule would have affected as many as 6 million employers and 93 million employees across the United States. Despite widespread support from the nursing and healthcare community, healthcare lobbyists garnered congressional support for a counter measure (S-J Res. 6) which repealed the rule [83]. "A condition of this repeal is that OSHA is barred from pursuing development of another ergonomics standard unless ordered so by Congress with agreement of the Executive Branch"[16].

In 2003, the American Nurses Association launched the 'Handle with Care®' campaign. The intent was to develop partnerships industry wide for education and training with the end goal being reduction and prevention of back and other musculoskeletal injuries within the nursing profession[16, 84]. The program also focused on pursuing federal and state level ergonomic legislation which would proscribe unsafe lifting practices within healthcare facilities[16].

Also in 2003 OSHA released guidelines for safe nursing home patient transfers ("Guidelines for Nursing Homes - Ergonomics for the Prevention of Musculoskeletal Disorders.") which were developed through collaboration with the PSCI and provide an algorithmic guideline for patient transfer in the nursing home setting [5]. However, these guidelines are not mandatory and have not been universally adopted.

In 2006, the National Institute for Occupational Safety and Health published a draft training protocol titled "Safe Patient Handling and Movement Principles" which is an algorithmic approach to patient lifts, mechanical device use and ergonomic management[18]. NIOSH worked closely with Dr. Audrey Nelson

Director of the Tampa Veterans Health Administration Patient Safety Center of Inquiry (PSCI) (www.patientsafetycenter.com).

Simulation Educational Approaches

The use of simulation as a training tool offers significant potential in healthcare [19-39]. There is widespread perception of the utility and value of simulation educational approaches for healthcare professionals, with an accompanying global proliferation of health science oriented simulation facilities and approaches. Despite this, studies that have convincingly demonstrated transference of skills gained during simulation to a clinical setting are only recently emerging with measurement of direct outcome an ongoing challenge [19, 29, 33, 38, 41-44]

The prospect of health care providers being able to learn and practice in the simulated environment as opposed to “on the job” with living patients is intuitively and ethically superior to most traditional models[26, 80]. Simulation education occurs on a spectrum of simple to complex. ‘Part-task’ (PT) training involves learning specific parts or components of techniques for manual or hands on skills in a context which does not fully duplicate the entire task or clinical setting[26, 33, 35, 38, 41, 59, 80, 81]. A few common examples of PT training include skill attainment in CPR (chest compression and ventilation), IV catheter insertion (latex arm with tubing), and endotracheal intubation (intubating head or head with torso).

The other end of the simulation-training spectrum can be called ‘full-task’ (FT) and often encompasses the use of High Fidelity Human Simulators (HFHS) employed in realistic environments where instructors and trainees participate in assigned roles[31, 35, 37]. Immersed in scripted, realistic scenarios, trainees have the opportunity to participate in a wide variety of events from mundane to crisis situations and from common to very rare or high risk situations. The goal of such scenarios is to practice or demonstrate key interventional skills, develop critical thinking, refine communication ability, and practice management of resources. The genesis for this approach has as its roots similar training in industry, particularly in the military as well as in aviation and nuclear power[23, 26, 33, 37, 38]

Strengths of the study

Effectiveness of the Protocol and Transference of Simulation Training to Clinical Skill Attainment

The significant improvement in 4 week performance demonstrated that the protocol was effective in modifying transfer behaviors among patient care providers on the intervention units. Providers were highly satisfied with feedback indicating that the instruction, curriculum, technology and protocol were

both realistic and effective. Trainees also benefited in the area of confidence and reported that their ability to provide care more safely was enhanced.

The % success demonstrated by subjects in the simulation center after the training closely paralleled their success in the clinical setting at 4 weeks. Given that the literature indicates that didactic training alone is not effective in changing lift behavior, we believe that our protocol incorporating simulation training with didactic support elements demonstrates direct transference of skills acquired in a simulation setting to the real world environment. This finding is highly significant for the field of human simulation education.

Generalizability of the Training Protocol

Our finding that caregivers at 4 weeks post intervention demonstrated nearly equal success on the untrained (chair) moves as they did on the trained (bed) moves (Figure XXX) suggests that the TPP process is generalizable to moves that were not specifically trained as a part of the protocol. This has broad implications for the utility and value of HTA methodology for development of training and evaluation protocols for other complex healthcare tasks. This also has value when planning implementation of training in other facilities that have different mix of patient transfers, equipment or specialized policies for patient transfers. Our emphasis on the process and *not* the specific move supports the insertion of nearly *any* move equipment or type into the move step.

Demonstration of the utility of the TPP and HP IPAQ™ Collection System

We were able to successfully demonstrate that through HTA methodology a complex task like ‘patient transfer’ could be analyzed, deconstructed and operationalized as a series of discrete and measurable steps. We also were able to show that with reasonable effort, non-expert coders could accurately capture real-time data as demonstrated by the inter-rater reliability analysis.

The HP IPAQ™ handheld PCs proved to be a critical component of the study. Empirical evaluation of the system has demonstrated key value attributes including flexibility, unobtrusiveness, ease of use, practicality, reliability and convenience of data retrieval and storage. These characteristics promise to support our ability to conduct future studies of similarly complex tasks..

Limitations of the study

Selection of subjects

Our goal was to demonstrate the effect of a concentrated educational intervention at the group and individual level. We were unable to randomize our sample to intervention and control arms on a single unit because maintaining groups within trained vs. untrained strata in a patient care situation were prohibit by practical logistics and available resources. Our use of a control unit for comparison of group level behaviors was designed to mitigate this issue and we were careful to select a unit with desired characteristics but minimal chance for contact with the intervention group.

Lack of literature and validated tools

Because the simulation literature is sparse in the area of demonstrated outcome studies showing transference, no clear model was available for modification. Standardized and validated measurement tools for this application are also unavailable and had to be created for the study. We attempted to handle this issue by using HTA methods and referencing all steps to best available evidence and standards of care. All survey tools and instruments underwent scientific review by nursing experts in the IRB submission process.

Refusal to allow observation

Providers who did not wish to have their move events recorded would indicate as much to the researchers with no observational data collected. This event occurred sporadically throughout the study but we did not collect incidence rates for later analysis. We are unable to determine the impact of this effect on our overall data set.

Dilution of Training Effect

Unanticipated changes in the composition of the care providers occurred on both the control and intervention units. The control unit experienced a net increase in employees of 1 (7.1%) and an overall change in staff by the end of the study of 33.3% (5/15) with none of the new employees (n=5) having received training.

The intervention units also underwent substantial change (Table XXX) with a total of 3 (untrained) employees leaving the units and a total of 13 new hires for a net change of 10 employees over the course of the study. Our results indicated regression of success % on the TPP on the intervention units at the 12 week measurement point. Because of the confounding influence of a large influx of untrained personnel between 4 and 12 weeks, we are unable to determine if the regression was the result of a fading

intervention effect, dilution or a combination. We did however correlate the % success across the measurement points with the % of trained personnel on the intervention units (Pearson product moment correlation, $r = 0.8317$) (Figure XXX).

Table XXX Change in employment demographics relative to NBIPP training

	Intervention Unit	Calculation
Baseline Total Employees	81	N/A
Baseline Trained (%) in NBIPP	71(87.7%)	71/81
Left Unit (%) 0-4 weeks	3 (3.7%)	3/81
New Hires (%) 0-4 weeks	2 (2.5%)	2/81
Change in Employees at 4 week	-1	81- 3 left + 2 new = -1 total
Total Employees 4 weeks	80	N/A
4 week trained in NBIPP	71 (88.8%)	71/80
Left Unit (%) 4-12 weeks	0 (0%)	0/80
New Hires (%) 4-12 weeks	11 (13.8%)	11/80
Net Change from Baseline 0-12 weeks (%)	10 (12.3%)	Total in= +13 Total out = -3 Net change = 10 % Net Change from baseline = 10/81

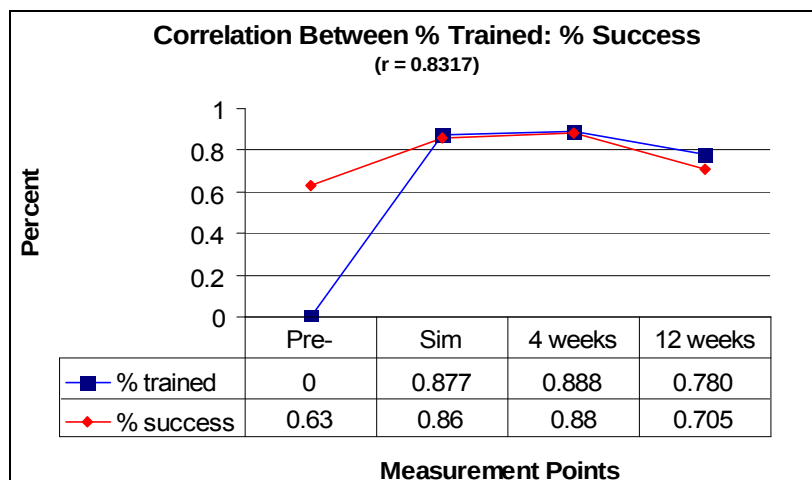


Figure XXX: Correlation between % Trained:% Success at Each Measurement Point

Conclusion

We successfully demonstrated transference of skills developed during simulation to performance in the clinical setting. This has been the key theoretical weakness of most simulation training. While philosophically and intuitively simulation training has been increasingly accepted as an effective health care training tool, acceptance as a true science can not take place without the ability to measure clinically relevant outcomes. Through this study we have developed and piloted an array of data collection and measurement tools that offer the ability to evaluate significant change in knowledge, attitude and skill with promise of future ability to make statements with respect to subject competence.

Improvement on transfer-types **not trained** is suggestive that the TPP is generalizable to events other than those which were specifically trained during the intervention. This finding is particularly important as it suggests potential for deploying this move protocol across a variety of healthcare settings and in situations with differing patient transfer needs. These results also suggest that, with modification, this conceptualization of the move process done through hierarchical task analysis could be adapted to transfer situations outside of the health care setting (i.e. industry or the military) where a variety of objects need to be manually or mechanically moved. In short, the move process model could serve as a fundamental conceptual foundation necessary to safely complete any type of transfer.

Our plan is to use this pilot data as the basis for a broad based program of provider training in patient transfers. We will initially train providers in a single system hospital and evaluate implementation and results. We also intend to integrate a fitness inventory and assessment that will allow targeted health coaching and intervention activities. This combination of a comprehensive training module with health and fitness consultation addresses the core issues associated with nursing injury and loss from the workforce. Outcomes in addition to those addressed in our study would include injury rates, satisfaction measures, fitness measures and longitudinal adherence to both the transfer protocol elements and the fitness components.

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Attachment 5

Development of a Simulation and Internet Based Pilot Intervention to Evaluate Adherence to a Patient Transfer Protocol in the Real World Environment

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INTRODUCTION

- Nursing back injury is epidemic:** The average age of nurses is > 45 with 80% expected to have at least 1 significant back or musculoskeletal injury during their career. Nursing personnel are # 2 behind truck drivers in work related musculoskeletal injury (Bureau of Labor Statistics 2002)
- Financial impact:** Nationally, the cost of nursing injury is estimated to be billions of dollars with 5% of patients responsible for up to 95% of overall expenditures
- Key barriers to safe and effective moves:** Inadequate orientation or lack of on-going training; perception of inadequate time, tools or people; physical fitness of staff; failure to assess patients' ability or engage them to help; lack of knowledge of true toll of injury
- Funding:** Project sponsored by funding from the USAF, administered by the US Army Medical Research Acquisition Activity, Ft. Detrick, MD (Award # DAMD 17-03-2-0017)

METHODS

- Primary Aim:** To improve direct patient care personnel skills and adherence according to a 10 point transfer protocol using an internet and simulation-based training program
- Design:** Prospective educational intervention conducted as a pilot study at the University of Pittsburgh and the University of Pittsburgh Medical Center (IRB# 0511041)
- Hierarchical Task Analysis:** Deconstructed transfer processes in consultation with certified ergonomic experts and direct care providers. Developed a universally applicable 10 point transfer protocol to be used as a primary measurement instrument
- Transfer Data:** Observed and scored transfers on four nursing units of the UPMC Institute for Rehabilitation and Research at UPMC South Side and UPMC St. Margaret and also during simulation training scenarios at WISER
- Data Collection:** Automated through use of HP IPAQ™ devices, Laerdal SimMan™ log files and through the WISER Simulation Information Management System (SIMS)

Key Program Elements

- 'Real-world' data collection pre- and post intervention
- Automated subject assessment using SIMS
- WISER supported internet based curriculum and instruction
- Ergonomic focused Simulation intervention
- Immediate feedback & correction
- Quantitatively measured transference of simulated to real-world skills

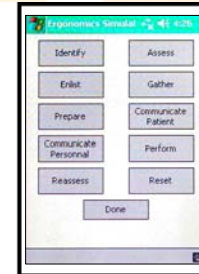
10 Point Protocol

1. Identify Patient & Move Requirements
2. Assess Patient
3. Enlist Personnel
4. Gather Equipment
5. Prepare Environment
6. Communicate to Patient
7. Communicate to Personnel
8. Perform Move
9. Reassess Patient
10. Reset Environment

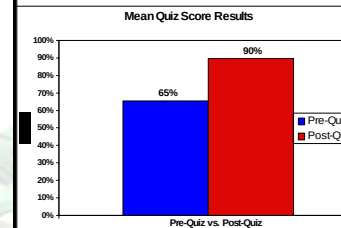
RESULTS

Development of Validity & Reliability

- Protocol steps were developed through expert consensus as well as referencing to practice standards or best evidence.
- Coders were trained by experts across 10 transfer events in the clinical environment
- Cohen's kappa was calculated for each of the 10 protocol steps with mean of 0.62 (range 0.43- 0.83) indicating substantial inter-rater agreement across the protocol

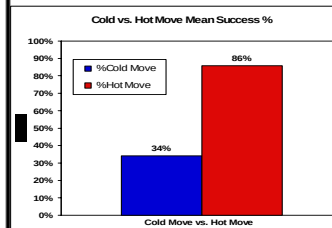


Improved Knowledge



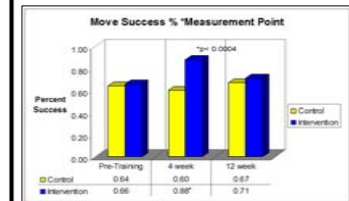
- Used a classic pre-test, post-test design
- 10 quiz items administered (pre & post)
- Paired t-test compared pre & post %
- N= 67 pairs, $t_{66,05} = -11.21$, $p \leq 0.0004$

Improved Simulated Skills



- 19 teams with each team performing 4 simulated moves (2 'cold' + 2 'hot')
- Paired t-test compared pre and post %
- N= 19 pairs, $t_{18,05} = -14.76$, $p \leq 0.0004$

Improved Real World Skills



- Observed real world patients transfers (n= 306) with observation at three time points (pre-intervention, 4 wk, 12 wk)
- Significant improvement in transfer skills observed at 4 week time point on intervention unit ($p \leq 0.0004$)

CONCLUSIONS

- Curricular Effectiveness:** Internet curriculum combined with hands on training using a low fidelity simulator (Laerdal TuffKelly Move Mannequin™) + structured protocol was effective for improvement of knowledge. Improved transfer skills were demonstrated across the protocol and in each 10 point transfer protocol step
- Satisfaction:** Subjects reacted positively and demonstrated a high level of satisfaction with the intervention both at the end of the simulation training and at the 4 week follow-up measurement point
- Retention:** Follow-up real world patient transfer observations at 4 weeks demonstrated significant improvement from baseline in adherence to the steps of the 10 point protocol. Observations at 12 weeks demonstrated regression toward baseline. However no definitive conclusions could be reached as unit personnel turnover closely paralleled reduction in adherence
- Tools:** Hand held computer units with data entry via a Graphic User Interface (GUI) allowed unobtrusive data collection in both the simulation laboratory and the clinical setting



Appendix 5

**A RANDOMIZED PROSPECTIVE MULTI-CENTERED, INVESTIGATOR-BLINDED TRIAL OF
PLATELET RICH PLASMA (PRP) GEL VERSUS CONTROL FOR THE TREATMENT OF
DIABETIC NEUROTROPHIC LEG ULCERS**

INVESTIGATIONAL PLAN

Sponsor:

**United States Air Force administered by the
U.S. Army Medical Research Acquisition
Activity, Fort Detrick, Maryland**

University of Pittsburgh Medical Center (UPMC)

Date Approved:

Statement of Confidentiality and Investigator Signatures

This document contains confidential and proprietary information. Access to this document is restricted to the following persons:

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2. Members of the reviewing IRB or Ethics Committee for the participating institution; and
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I understand that all information concerning this study supplied to me and not previously published is confidential information. This information includes the clinical protocol, case report forms and basic scientific data.

I hereby attest that I have read and understand the clinical protocol and agree to conduct the study as outlined. I will submit this protocol to the Ethics Committee, Institutional Review Board of my institution or to another appropriate committee and will not initiate this study without its prior approval.

 Principal Investigator signature	<u>01/15/07</u> Date signed	<u>David L. Steed, MD</u> Printed name
 Sub-Investigator signature	<u>01/15/07</u> Date signed	<u>Thomas E. Serena, MD</u> Printed name
 Sub-Investigator signature	 Date signed	 Printed name
 Sub-Investigator signature	 Date signed	 Printed name
 Sub-Investigator signature	 Date signed	 Printed name

Schedule of Required Study Procedures

Procedure	Patient Visit			
	Visit 1	Visit 2 ¹	Visit 3-13 ¹	Visits 14-16
Informed Consent	X			
Patient Characteristics	X			
Medical History	X			
Physical Exam	X	X	X	X
Vital Signs	X	X	X	
Body Mass Index	X			
Laboratory Tests ^{2, 3, 5} (SEE COMMENTS BELOW)	X		X	
Ankle Brachial index, TCPO ₂ , or Systolic Toe Pressure	X	X	X	
Debridement of Wound	X	X	X	
Wound Characteristics, Measurement and Digital Historical Photography	X	X	X	X
Wound Classification	X			
Wound Off-Loading		X	X	X
Adverse Events		X	X	X
Home glucose monitoring test (day before weekly visit)		X	X	X
PRPG and AT Production and Application ⁴		X	X	

1. Required assessments are performed weekly for 12 weeks or until wound is completely healed, whichever comes first.
2. Blood evaluations will include CBC, Serum chemistry, pre-albumin, platelet count, prothrombin time, partial thromboplastin time, serum pregnancy, Hbg-A1C, and urinalysis. This will be conducted on visit 1 and the end of treatment visit (wound completely healed or visit 13).
3. Growth factors characterization, WBC, and Platelet count of whole blood and PRP including; PDGF-Platelet derived growth factor-AB, TGF-Beta 1 -Transforming growth factor - Beta 1, and VEGF-Vascular endothelial growth factor will be performed on week one (visit two) of treatment. Platelet activation will be measured with P-Selectin level at week one (visit two) of treatment. Applies to subject in the treatment arm only.
4. Applies to subjects in the treatment arm only. PRPG is applied weekly for 12 weeks or until wound is completely healed, whichever comes first.
5. Hbg-A1c testing will be repeated at end of treatment (wound completely healed or visit 13) and final three-month visit.

Volume of Whole Blood Required for Study-Related Activities (ml)

	Patient Visit				
	Visit 1	Visit 2	Visit 3-13	Visit 13	Visits 14-16
Laboratory Tests ¹	20	10	0	20	0
Treatment Arm PRPG Production and Application	0	40	40	40	0
Total Whole Blood Drawn	20	40	40	60	0
ACD-A Anticoagulant Added	N/A	5	5	N/A	N/A
Total Anticoagulated Volume	N/A	40	40	N/A	N/A

1. Approximately 10 ml WB will be drawn for Growth Factor Characterization and P-selectin testing on visit 2, the first week of treatment from the treatment group only.

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A RANDOMIZED PROSPECTIVE MULTI-CENTERED, INVESTIGATOR-BLINDED TRIAL OF PLATELET RICH PLASMA (PRP) GEL VERSUS CONTROL FOR THE TREATMENT OF DIABETIC NEUROTROPHIC LEG ULCERS

I Introduction

Diabetic foot wounds are a significant health care problem in the United States, affecting 10-15 percent of 20 million patients with diabetes. Failure of these wounds to heal leads to amputation in 60,000-80,000 patients per year. The cost of care for a leg wound resulting in amputation is about \$70,000 per patient. At least half of these patients will lose the contra-lateral limb within five years.¹⁻³

Diabetic neurotrophic leg ulcers (DNLU) are a serious complication of diabetes. More than 20.8 million people in the US have diabetes, and 15% of them can be expected to develop a diabetic leg ulcer at some point in their lives. In general they include a combination of lower limb arterial insufficiency, lower limb diabetic neuropathy, and local trauma. About 20% of diabetic patients with leg ulcers will primarily have inadequate arterial blood flow, 50% will have diabetic neuropathy and 30% will be inflicted by both conditions. Inadequate arterial blood flow is usually treated by a variety of surgical techniques that will improve blood flow.

Diabetic neurotrophic leg ulcers present a more challenging problem in that there is no easy remedy. If arterial circulation is adequate for healing, then good care involves treatment of infection, off-loading, debridement, and proper dressing. There is no universally agreed upon cream, salve, or ointment for the treatment of DNLU. Successful treatment involves keeping the wound moist, often with saline or hydrogel. Other treatments include topical antibiotic creams and salves, hydro colloidal dressings, bio-occlusive dressings, enzymatic debriding agents and growth factors.

Recently the U.S. Food and Drug Administration approved several new treatments for patients with DNLU. These treatments represent two new treatment classes, growth factors and cell therapies, and are used in combination therapy with the above treatments. Even with the above products, success in treating DNLU is dismal. About 10-33% of the patients in the standard of care arm will heal in 12-20 weeks, whereas 30-50% of individuals receiving one of the new products will heal by 12-20 weeks of care.

Risk factors for developing DNLU are patient age, patient sex, duration of the wound, size of the wound, wound grade, number of wounds, prior care at the treatment center, and type of treatment center.

Platelets enter wounds to control hemorrhage. These platelets also bring growth factors, which are stored in their alpha granules. Growth factors are proteins that are present in small amounts yet exert a powerful influence over healing by acting as mitogens and chemoattractants.⁴ Growth factors can be extracted from the alpha granules of platelets, yielding a product known as a platelet releasate.⁵ Platelet releasates can be prepared from the patient's own platelets (an autologous product) or from pooled platelet donors (a homologous product).⁶ Platelet releasates have been tested in diabetic and venous stasis ulcers and a variety of other wounds, yet no homologous product has received FDA approval.⁷⁻¹² Autologous products, however, are frequently used and readily available under the name Procuren®.

A single growth factor can be made by recombinant DNA technology. Single growth factors, including Platelet-Derived Growth Factor (PDGF), Transforming Growth Factor-beta (TGF- β), Keratinocyte Growth Factor (KGF), Fibroblast Growth Factor (FGF), Insulin-like Growth Factor (IGF), Granulocyte Macrophage-Colony Stimulating Factor (GM-CSF), and Vascular Endothelial Growth Factor (VEGF) have been used in clinical trials of wound healing. As yet, only PDGF, also known as becaplermin or Regranex, is approved of use in the United States. Despite proof of benefit from PGDF in several randomized prospective double blind trials and widespread use of platelet releasate, the amputation rate remains the same.

Platelet rich plasma (PRP) gel can be prepared from several ounces of blood, if the platelet count and hemoglobin are normal. PRP gel contains at least 19 growth factors. In theory PRP gel offers greater benefit to healing than an isolated growth factor since it more closely mimics natural healing. Growth factor levels in wound fluids increase during the course of healing, and over time the spectrum of growth factors changes. Messenger RNA for growth factors is upregulated in the wound. It makes sense; therefore, that PRP gel harvested from a patient and reapplied as an autologous preparation would be of benefit in healing and offer an approach consistent with nature.

PRP gel (PRPG) can be made by adding autologous thrombin and calcium to a platelet pellet spun from a patient's own blood. The gel can be applied to a wound and left in place for up to one week. This autologous preparation offers minimal risk to the patient.

II Regulatory Compliance

This clinical pilot study, which will be conducted according to this protocol, is designed to meet the requirements of and will be conducted in accordance with the following:

- U.S. Code of Federal Regulations (CFR) 21 Part 812 "Investigational Device Exemptions", Part 50 "Protection of Human Subjects", & Part 56 "Institutional Review Boards"
- Declaration of Helsinki, October 2000

III Purpose

This clinical pilot study will be conducted to assess and evaluate the safety and efficacy of the use of autologous Platelet Rich Plasma Gel for the treatment of chronic (greater than 8 weeks in duration) diabetic neurotrophic leg ulcers.

An extract of activated platelets that is rich in platelet derived growth factors has been shown to enhance the healing of cutaneous ulcers and was previously commercialized under the name Procuren[®]. In addition, platelet derived growth factors as an isolated cytokine have been shown to enhance wound healing in several animal studies and non-healing wounds in humans.

IV Study Objectives

A. Primary Objective

The primary objective of this pilot study is to evaluate the safety and efficacy of PRP Gel and autologous thrombin in healing chronic diabetic neurotrophic leg ulcers as compared with standard care.

B. Secondary Objectives

1. To compare percent reduction in wound area between treatment groups, within a stratified population, at 12 weeks.
2. To compare time to wound closure (≤ 12 weeks) between treatment groups, within a stratified population.
3. To compare wound recurrence rates between treatment groups, within a stratified population, at any time between the end of treatment and the 3-month follow-up visit.
4. To compare incidence of infection of the study wound between treatment groups, within a stratified population, during the 12-week treatment period.
5. To compare the incidence of safety-related events between treatment groups, within a stratified population, during the 12-week treatment period.
6. Stratification by age of growth factor analysis in the treatment group.

C. Data Endpoints

Primary

Wound closure at 12-weeks post-treatment initiation.

Secondary

1. Time to wound closure (wound closure rate) (when ≤ 12 weeks).
2. Infection
3. Wound recurrence at any time between end of treatment and the 3-month follow-up visit.
4. Wound increase in size $\geq 30\%$.
5. Wound enlarges on two consecutive visits
6. Co-morbidities.
7. Patient compliance with treatment regimen (yes/no outcome) between completion of study treatment and the 3-month follow-up visit.
8. Adverse events
9. Develops an occurrence of an additional wound within 3 cm of the study wound
10. Study extremity requires revascularization or amputation
11. Patient no longer wish to participate in the study
12. PRPG cannot be applied to the study wound for 2 consecutive weeks
13. At the discretion of the physician for health reasons associated or not associated with the study the total number patients withdrawn.

D. Secondary Objectives and Secondary Endpoint Paring Analysis

<u>Secondary Objective</u>	<u>Secondary Endpoint</u>	<u>Affected Population Values</u> - Successful Treatment - Treatment Failure - Intent to Treat	<u>Calculations</u>	<u>Statistical Methods</u>
1	1, 4, 5, 9, 10, 11, and 12	▪ Number or weeks ▪ Percent Healing ▪ Percent Withdraw ▪ Percent Complete ▪ Percent Infection ▪ Type of AEs ▪ Number of AEs ▪ Percent of AEs	▪ Addition ▪ Percentage	▪ Kaplan Meier Survival Methodology ▪ Cox Proportional Hazards Model ▪ Student's t-test (Continuous) ▪ Chi-squared (Categorical)
2	1, 4, 5, 9, 10, 11, and 12	▪ Number or weeks ▪ Percent Healing ▪ Percent Withdraw ▪ Percent Complete ▪ Percent Infection ▪ Type of AEs ▪ Number of AEs ▪ Percent of AEs		
3	3, 7, and 9	▪ Percent Recurrence ▪ Percent Healing ▪ Percent Withdraw		
4	2	▪ Occurrence ▪ Percent Infection Rate ▪ Percent Healing ▪ Percent Withdraw		
5	6, 8, and 13	▪ Percent Withdraw ▪ Type of AEs ▪ Number of AEs ▪ Percent of AEs		
6	All (1-13)	▪ All		

V Device Description

One system, the FDA approved COBE Angel Whole Blood Separation System, will be used by all clinics for this study. The COBE Angel Whole Blood Separation System consists of a blood centrifugation device and two associated disposables: the Processing Set and the Whole Blood Access Kit. The system is designed to be used at the patient's point-of-care to sequester platelet rich plasma, platelet poor plasma and concentrated red blood cells from a sample of whole blood. These products are currently on the US market and will not be modified to support this study (reference 510(k)'s K042473 and BK050033).

The Processing Set contains a variable volume separation chamber that is capable of separating from 40 to 180 ml of ACD anti-coagulated autologous whole blood into red blood cells, platelet poor plasma, and platelet rich plasma. The Processing Set is provided sterile and is for single use only. Each disposable set will be used for one processing cycle. The Processing Set consists of the variable volume separation chamber as well as tubing, a platelet sensor/valve assembly, and a three-compartment reservoir bag to hold the whole blood, red blood cells, and platelet poor plasma. A luer lock syringe is provided to collect the platelet rich plasma.

The Whole Blood Access Kit is a convenience kit that contains pre-packaged, pre-sterilized devices for obtaining whole blood to be separated using the Angel System. The individual components are placed into a single box for the convenience of the user and are not re-packaged, re-sterilized, or otherwise altered. The kit contains an IV Site Kit for preparing the venipuncture site, one skin prep single swab (povidone iodine), one 17-gauge fistula needle for accessing the venipuncture site, one vial of ACD for use as an anticoagulant during blood collection, two 18-gauge needle for accessing the ACD from the vial, and two 60-ml syringes for collecting the blood. All components of the kit are labeled for single use only and are not to be re-used or re-sterilized by the user.

The Angel system performs blood component separation and will be used in this study to produce the autologous Platelet Rich Plasma Gel. "Autologous" relates to the use of products or components from the same individual. The Investigator will produce the Platelet Rich Plasma Gel at the point of care using separated blood products from the patient to be treated. The PRP will be used within 4 hours. The gel will be made from the combination of the patient's autologous platelet-rich-plasma (PRP), autologous thrombin, and 10% calcium chloride solution (USP). A commercially available FDA approved applicator will be used to mix the PRP, thrombin, and calcium chloride.

Because topical bovine thrombin has been linked to the development of antithrombin antibodies and resulting coagulopathies^{18,19} autologous thrombin will be used instead of bovine thrombin. It will be produced using an active autologous thrombin processing kit (activAT) manufactured by Cobe Cardiovascular, a Sorin Group Company. Pre-trial assessment of autologous thrombin potency has been documented. (Appendix L) The autologous thrombin will be used within 4 hours. During the trial, observation of firm gel and measurement of the selected growth factors (PDGF-Platelet derived growth factor-AB, TGF-Beta1-Transforming growth factor -Beta 1, VEGF-Vascular endothelial growth factor, and P-selectin) will be used as an indication of adequate activation.

VI Protocol

A. Study Design

This is a randomized, prospective, multi-centered, investigator blinded pilot study of platelet rich plasma gel and autologous thrombin versus control for the treatment of diabetic neurotrophic leg ulcers of 8 weeks or greater.

B. Anticipated Enrollment Period:

The total time from submission to the first Investigational Review Board (IRB) to completion of follow-up visits of last patient enrolled is projected to be 36 months

- **Timeline:**
 - 6-9 Months: Because this is a significant risk, multi-center, human trial involving Department of Defense Funding we will be submitting this protocol to two Investigational Review Boards (IRB); University of Pittsburgh Medical Center and Wilford-Hall Medical Center. This protocol must also receive second level approval from the office of the Surgeon General Office of the United States Air Force. In addition, we must first receive an Investigational Device Exemption (IDE) from the FDA. Since the FDA/IDE process takes 1-3 months and each IRB has a unique template to follow and both IRBs must approve before patients are enrolled we have allowed 6-9 months before the first patient is enrolled.
- 9-27 Months: During this phase we will begin recruitment of patients. The projected patient enrollment distribution is as follows; UPMC Comprehensive Foot and Ankle Center 25 total or ~2/month, UPMC North (Horizon, Shenango, and Greenville) 25 or ~2/month, and Wilford Hall 10 or ~1/month. Upon commencing enrollment we anticipate having all patients enrolled within 12 months, allowing for a three-month follow-up for a total trial period of 15 months. If projected enrollment target is not met we will expand recruitment efforts. If we continue to fall short we will contact the respective IRBs requesting an extension of recruitment period.
- 27-36 Months: Completion of records, collation of data, statistical analysis, preparation of manuscript, and submission to peer review journal for publication.
- Anticipated Study Completion: Three months after last patient completes treatment.

C. Investigational Site Participation

This pilot study will be conducted at these five investigational sites. All sites will follow the same protocol. Each site will seek approval from the IRB affiliated with its facility. The two affiliated IRBs are University of Pittsburgh Medical Center and Wilford Hall Hospital. In addition, the study will require second level DoD approval from the Surgeon General Office of the United States Air Force.

Current sites are:

- UPMC Comprehensive Foot and Ankle Center
- UPMC Horizon Greenville Center for Wound Treatment

- UPMC Horizon Shenango Valley Center for Wound Treatment
- UPMC Northwest Wound Clinic
- Wilford-Hall Medical Center Diabetes Clinic

D. Patient Population

This study will screen up to 100 patients and enroll up to 70 patients with diabetic neurotrophic leg ulcers; 30 patients per treatment arm, plus 10 additional patients due to an anticipated 10% withdraw rate and 7% withdraw rate as a result of infection. Patients will be randomized on a 1:1 basis to either standard treatment (standard of care group) or standard treatment with the replacement of Hydrogel with PRPG (treatment group).

Control Group			
Population Range	Number of Participants	GF Testing (3 GFs and P- selectin)	PRP GF Testing (3 GFs and P- selectin)
18-45	10	N/A	N/A
46-60	10	N/A	N/A
61-85	10	N/A	N/A
Total	30		

Treatment Group			
Population Range	Number of Participants	GF Testing, WBC, Platelet (3 GFs and P- selectin)	PRP GF Testing, WBC. Platelet (3 GFs and P- selectin)
18-45	10	1 @ wk 2	1 @ wk 2
46-60	10	1 @ wk 2	1 @ wk 2
61-85	10	1 @ wk 2	1 @ wk 2
Total	30		

E. Treatment Summary

“Standard Treatment” for the Standard of Care Group will consist of:

- Weekly visits
- Debridement of wound to necrosis free state, using sharp instrument. Debridement will be performed using a sharp instrument or mechanical lavage. Mechanical lavage debridement is defined as brisk lavage with sterile normal saline using a syringe and needle. We will not use enzymatic debridement.
- Application of Hydrogel
- Coverage of wound with Allevyn

Therapy for the “Treatment Group” will consist of:

- Standard treatment as described above, except that Platelet Rich Plasma Gel will be topically applied to the wound bed in place of Hydrogel.
- Phlebotomy will be performed in order to produce the Platelet Rich Plasma Gel and Autologous Thrombin

F. Patient Selection Criteria

1. Inclusion criteria

Patients must meet all the following inclusion criteria to be eligible for enrollment in the study:

- a. The patient must be 18 - 85 years of age
- b. Wound shows no clinical signs of infection
- c. No sign of Osteomyelitis
- d. Ulcers must be 0.5 to 12 cm² in area after debridement
- e. Wound debrided to necrosis free state
- f. HGB A-1C $\leq$ 9.0%
- g. The patient must have diabetes and neuropathy as determined by insensitivity to a 5.07 Semmes-Weinstein monofilament on the toes, metatarsal region or dorsum of the foot
- h. The patient must have full-thickness ulcers below the malleolous with no exposed bone, tendon or open joint after debridement
- i. Ulcers must be present for at least eight weeks without healing
- j. The patient must have adequate arterial circulation to the foot as documented by one of the following; ankle/brachial index (ABI) greater 0.7 but less than 1.3, TCPO₂ >30mmHg, or great toe systolic pressure >50mmHg.
- k. The patient must be able to understand the study protocol and provide written informed consent
- l. If patient is a woman of child-bearing age, the patient must not be pregnant and must use a method to prevent pregnancy during the study period
- m. Wound has not been present for longer than two years
- n. Wound does not decrease in size by 30% during the observation time
- o. Wound does not increase in size by 30% or enlarges by 30% on two consecutive visits
- p. Patient does not require systemic antibiotic therapy
- q. Patients with wounds that can be completely off-loaded
- r. Patients who are not pregnant and/or lactating
- s. Patients who are not on steroids, cytotoxic agents, or radiation therapy
- t. Non-Immunocompromised patients
- u. Patients with serum creatinine $\leq$ 2.5 mg/dl .
- v. Patient with liver function studies $\leq$ twice the upper limit of normal
- w. Patients that have not had cancer within the past five years.
- x. Patients not taking heparin, warfarin, clopidogrel, or ticlopidine
- y. Patients with serum albumin > 2 g/dl
- z. Patients with known hematocrit >32%
- aa. Patients with a platelet count >100,000/mm³
- bb. Patients without symptomatic congestive heart failure
- cc. Patients without connective tissue disorders or vasculitis

- dd. Patients willing and able to comply with study requirements
- ee. Patients who have not participated in another experimental drug or device trial within the past 30 days
- ff. Patients without known ethanol sensitivity
- gg. Patients with a Wagner Wound Classification Grade 1 or 2
- hh. Patients with multiple wounds must have a single wound > 3cm away from the nearest wound
- ii. Patients with a wound that does not contain Charcot areas

2. Exclusion criteria

The presence of any of the following will exclude a patient from study enrollment:

- a. The patient younger than 18 years of age
- b. Wound shows clinical signs of infection
- c. Osteomyelitis
- d. Ulcers < 0.5 and > 12 cm² in area after debridement
- e. Wound debrided is unable to produce necrosis free state
- f. HGB A-1C >9.0%
- g. The patient must have diabetes and neuropathy as determined by insensitivity to a 5.07 Semmes-Weinstein monofilament on the toes, metatarsal region or dorsum of the foot
- h. The patient does not have full-thickness ulcers below the malleolous with no exposed bone, tendon or open joint after debridement
- i. Ulcers have not been present for at least eight weeks without healing
- j. The patient does not have adequate arterial circulation to the foot as documented by one of the following; ankle/brachial index (ABI) less than 0.7, a TCPO₂ <30mmHg, or a great toe systolic blood pressure <50mmHg.
- k. The patient is unable to understand the study protocol and provide written informed consent
- l. If patient is a woman of child-bearing age, the patient is pregnant and is unable to use a method to prevent pregnancy during the study period
- m. Exposed bone at the base of the wound
- n. Wound present for longer than two years
- o. Clinical signs of infection
- p. Wound decreases in size by 30% during the observation time
- q. Wound increases in size by 30% or enlarges by 30% on two consecutive visits
- r. Patient requiring systemic antibiotic therapy
- s. Patients with wounds that cannot be completely off-loaded
- t. Patients who are pregnant and/or lactating
- u. Patients who are on steroids, cytotoxic agents, or radiation therapy
- v. Immunocompromised patients
- w. Patients with serum creatinine >2.5 mg/dl or patients on dialysis
- x. Patient with liver function studies > twice the upper limit of normal

- y. Patients with cancer within the past five years
- z. Patients taking heparin, warfarin, clopidogrel, or ticlopidine
- aa. Patients with serum albumin < 2 g/dl
- bb. Patients with known hematocrit <32%
- cc. Patients with a platelet count <100,000/mm³
- dd. Patients with symptomatic congestive heart failure
- ee. Patients with connective tissue disorders or vasculitis
- ff. Patients unwilling or unable to comply with study requirements
- gg. Patients who have participated in another experimental drug or device trial within the past 30 days
- hh. Patients with known ethanol sensitivity
- ii. Patients with a Wagner Wound Classification Grade 3, 4, and 5
- jj. Patients with multiple wounds do not have a single wound > 3cm away from the nearest wound
- kk. Patients with a wound that contains Charcot areas

G. Patient Randomization

A patient treatment randomization scheme will be computer generated at UPMC. UPMC Comprehensive Foot and Ankle Center will conduct the centralized randomization process. All patients, regardless of facility, will be randomization in a 1:1 ratio into the two arms, experimental and control. A blinded neutral observer, from UPMC Comprehensive Foot and Ankle Center, will keep the centralized randomization list. As patients are entered into the study, regardless of the facility, they will be consecutively assigned a study number from the list of subjects who are to receive PRP gel and standard care or standard care alone and based on that number assigned to one of the two treatment groups. The investigator will be blinded as to the treatment group of each patient. Blood will be drawn on patients in the treatment group after the investigator has examined the patient. A bandage will be applied to all patients before leaving the clinic. In the event of an emergency in which the patient's treatment group must be known in order to treat an adverse event or other medical problem, un-blinding may occur. This must be documented in the perceived un-blinding event log and reported to the medical monitor and the Investigator within 48 hours.

Patients, regardless of their facility, will be centrally randomized, at the UPMC Comprehensive Foot and Ankle Center facility, to either standard treatment (standard of care group) or standard treatment with the replacement of Hydrogel with PRPG (treatment group). Randomization will take place at the time of patient enrollment, after the following:

- Patient has given written informed consent
- All screening assessments have been completed
- The patient has met all eligibility criteria

H. Study Evaluation and Procedures

1. Informed Consent

The Investigator must inform the patient of the nature of the research, of the risks and potential adverse effects of the PRP Gel, the possible benefits of its use, and alternative modes of treatment. The Investigator is encouraged to use the study-specific **Informed Consent Form** (Appendix B). If an investigating center chooses to use an alternatively worded written consent document, the Institutional Review Board (IRB) at that center must also approve the consent.

Prior to participation in the study, the informed consent document will be reviewed with each patient who meets the eligibility criteria. If the patient chooses to participate, the patient will sign and date the study-specific informed consent document and will initial each page, if indicated. The Investigator or the person who conducts the informed consent discussion as well as a witness may also sign and date the document. The original signed informed consent is to be kept on file with the patient's study records and a signed copy is to be given to the patient.

2. Treatment Protocol

- For patients with multiple wounds, the treating physician will select only one wound for randomized treatment. The selection will be based on the wound meeting the size criterion of this study, ease of access, regular boundaries for more consistent measurement determination, and the selected wound must be at least three centimeters (3 cm) away from the nearest wound.
- Patients will receive standard group or treatment group wound care for 12 weeks unless the investigator observes one of the following attributes of the study wound: infection, increase in size by 30%, enlarges by 30% on two consecutive visits, or completely healed.

All patients will be evaluated in the wound clinic for two weeks prior to treatment in the study. Patients will then be seen in the clinic weekly until the patient has received 12 weeks of care, or until the investigator observes one of the study secondary data end points. At each weekly visit, wounds will be evaluated. The patient's medical status will be recorded, and adverse events will be noted and recorded. Wounds will be debrided as needed, measured, and two historical digital photographs will be taken by the principal investigator. The investigator will then leave the room and the research nurse will perform the following steps: record the wound measurement from the PI, store the historical digital photographs on a UPMC secure server, apply the appropriate gel based on the study group, and dress the wound. The same person (principal investigator) will perform the measurements and digital photographs for all of the patients' study wounds. Complete wound healing will be defined as a closed wound with mature epithelium, free of infection with no dressing required. Complete healing will be the judgment of the principal investigator. Patients who heal or have completed 12 weeks of care will then be seen **for a three month follow-up.**

3. Data Collection

Data collection for this study will use a Case Report Form (CRF) method (Appendix C). The Investigator is responsible for legibly recording the required study information into patient charts as the source documents for this study and for verifying that all entries in the source documents are complete and correct by signing and dating each chart page. The site is responsible for accurately entering the data onto study-specific CRFs.

a. Baseline Procedures: Visit 1 (Screening Visit)

To enter the trial, the patient must have a freshly surgically debrided ulcer. Baseline evaluations to be collected at this visit will be recorded on the Pre-Study Enrollment CRF. These data will include:

- Patient characteristics (date of birth, sex, height, weight)
- Medical history (including study ulcer duration) will be collected from the patient on the enrollment CRF. An attempt will be made to retrieve the patient's medical history from their primary care physician. If the patient's medical history is unavailable, at the time of the study, the patient's oral account of their medical history will be documented for the status and duration of the ulcer
- Physical examination (including examination of the affected extremity)
- Vital Signs
- Body mass index
- The patient will be phlebotomized to harvest the patient's whole blood.
- Laboratory tests (including CBC, Serum chemistry, pre-albumin, platelet count, prothrombin time, partial thromboplastin time, serum pregnancy, Hbg-A1C, and urinalysis)
- Ankle brachial index, TCPO2, or toe systolic blood pressure.
- Debridement of the chosen study wound to necrosis free state (note: debridement of the chosen study must remove all unhealthy tissue, debris, and excess exudates, leaving a clean moist and viable wound bed).
- Baseline measurement of the area of the chosen study wound using the Visitrak system and historical only digital photographs (taken at 6 in (15 cm) and 18 in (46 cm) from wound surface). (See Protocols #1 and #2)
- Wound Classification

b. Weekly Assessment Regimen: Visits 2-13

All patients will receive standard care. (Refer to SOP #7)

Information collected from these visits will be recorded on the Weekly Evaluation **CRF**. These data will include:

- Physical examination of the affected extremity
- Evaluation of the treatment wound with regard to the inclusion and exclusion criteria to ensure that the treatment wound still qualifies for participation in the study
- Vital signs
- Wound characteristics (e.g. erythema, amount and color of drainage)

- Debridement of the study wound to necrosis free state (note: debridement must remove all unhealthy tissue, debris, and excess exudates, leaving a clean, moist and viable wound bed). Documentation of whether debridement was performed and type (sharp instrument or mechanical). We will not use enzymatic debridement.
- Measurement of the wound area using the Visitrak system, including depth, and historical digital photographs will be collected by the investigator (taken at 6 in (15 cm) and 18 in (46 cm) from wound surface). The same person (investigator) will perform the measurement and digital photographs for all patients' study wounds. (Refer to SOP #1 and #2)
- Ankle brachial index, TPCO₂, or great toe systolic pressure.
- The patient will be phlebotomized to harvest the patient's whole blood.
- Growth Factor Characterization will be performed using whole blood obtain from patients in the treatment arm. (PDGF-Platelet derived growth factor-AB, TGF-Beta1-Transforming growth factor -Beta 1, VEGF-Vascular endothelial growth factor, and P-selectin) The whole blood harvested from all patients in the control arm will be used for standard testing only. (Laboratory tests including CBC, Serum chemistry, pre-albumin, platelet count, prothrombin time, partial thromboplastin time, serum pregnancy, Hbg-A1C, and urinalysis)
- Production and application of PRPG and autologous thrombin for all patients in the treatment arm.
- Growth Factor Characterization, WBC, and platelet count will be performed on the PRPG for all patients in the treatment arm (PDGF-Platelet derived growth factor-AB, TGF-Beta1-Transforming growth factor -Beta 1, VEGF-Vascular endothelial growth factor, and P-selectin).
- Wound Care (Refer to SOP #6)
- Wound dressing changes will be performed weekly. For patients in the standard of care group, these dressing changes will consist of application of Hydrogel agent to the wound bed, coverage of the wound with Allevyn, and application of multi layer gauze wrap. Patients in the Treatment Group will receive the same dressing changes, except the PRPG will be applied to the wound bed instead of Hydrogel agent. The PRPG will be applied with a standard spray applicator tip. An amount sufficient to completely cover the exposed tissue 2-4 mm in depth will be applied. Specific details on PRPG production are found on Appendix A.
- Under normal circumstances the patient is prohibited from removing the dressing between office visits. Reasonable care to avoid wetting and premature removal of the dressing will be instructed to the patient. However, if the dressing becomes saturated with drainage between visits, or if the dressing were to fall off or become dislodged, the patient may flush the wound with water and apply a hydrogel dressing. The patient should always change the dressing seven days after an office visit using hydrogel unless the patient has a study visit that day. The patient should report this event to the PI within 24 hours.
- Verify wound off-loading

All complications will be reported in detail on an **Adverse Event CRF**.

c. Post Treatment Study: Visits 14-16

Upon healing or completion of 12 weeks of treatment, patients will enter the post-treatment phase and will be seen **for three month follow-up**. At each monthly visit, the ulcer site will be photographed, for historical purposes, and measured by the Investigator. The same person will perform the measurement and digital photographs for all of the patients' study wounds. Persistent healing or recurrent ulceration will be documented by the Investigator.

The follow-up data listed below will be collected and recorded on the Three-Month Follow-up Visit CRF. These data will include:

- Status of wound at time of visit.
- Patient compliance with off-loading and wound care.
- Wound size.
- Historical digital photographs of wound (at 6 in (15 cm) and 18 in (46 cm)) will be taken.

All adverse events must be documented on the **Adverse Event CRF**.

4. End of Treatment

End of treatment will occur when at least one of the following events occur with the study wound:

- o Completely healed
- o Participation in the study for the entire 12 weeks
- o Infection
- o Wound increase in size $\geq 30\%$.
- o Wound enlarges on two consecutive visits
- o Co-morbidities
- o Adverse events
- o Develops an occurrence of an additional wound within 3 cm of the study wound
- o Study extremity requires revascularization or amputation

End of treatment will occur if one of the following events occurs:

- o Patient no longer wish to participate in the study
- o PRPG cannot be applied to the study wound for 2 consecutive weeks
- o At the discretion of the physician for health reasons associated or not associated with the study

If the wound completely heals during the treatment period (≤ 12 weeks), treatment will be discontinued with the exception of strict off-loading of wound, historical digital photography, and one subsequent three month follow-up visits

After 12 weeks of treatment, or when the ulcer has healed, wounds will be photographed for historical purposes; blood will be drawn for complete blood count,

serum chemistry, and serum pregnancy (if applicable). Urinalysis will be performed. Complete physical examination will be performed. Adverse events will be noted. The patient will be fit with diabetic shoes with insert. The patient will be instructed on care of the diabetic foot.

5. Treatment Failures

If the study wound experiences the following characteristics, the patient will be considered a treatment failure and will end participation in the study and resume normal treatment regimen. No additional follow up visits required. For statistical purposes, these patients will be considered in the intent to treat population.

- o Time to wound closure > 12 weeks
- o Infection
- o Wound recurrence at any time between end of treatment and the three-month follow-up visit.
- o Wound increase in size $\geq 30\%$.
- o If a blood vessel larger than 1 mm. is seen in wound the APG will not be applied
- o Wound enlarges on two consecutive visits
- o Co-morbidities
- o Develops an occurrence of an additional wound within 3 cm of the study wound
- o Study extremity requires revascularization or amputation
- o Patient no longer wish to participate in the study
- o PRPG cannot be applied to the study wound for 2 consecutive weeks
- o At the discretion of the physician for health reasons associated or not associated with the study

6. Follow-Up

Patients with a healed wound at or before 12 weeks will be seen for three-month follow-up appointment after completion of the study treatment to determine wound status at that time. Patients will be instructed to call investigational site personnel if the wound recurs prior to the three-month follow-up visit.

7. Failed Phlebotomy

If application of the Platelet Rich Plasma Gel cannot occur at a weekly visit due to problems phlebotomizing the patient or producing the PRPG, the problem will be noted on the associated weekly case report form. All other assessments/treatments will be done that week with the exception of applying the PRPG (the patient will not receive Bactroban or another anti-microbial ointment in place of the PRPG). If PRPG application does not occur for two consecutive weeks, the patient will be withdrawn from the study. All patients withdrawn from the study as a result of a failed phlebotomy or failure to produce PRPG will be included in the statistical intent to treat population.

8. Study Procedures

a. Historical Wound Photography

Historical digital photographs of the study wound will be taken at the pre-study evaluation, during each weekly visit, and the three-month follow-up visit by the investigator. The investigator will participate in the acquisition of the digital photographs of the study wound. Photographs will be taken using a digital camera, and will be taken looking straight down on the study wound. A measurement device (sterile ruler or equivalent) must be included in the photograph to allow quantification of the wound area. Two photographs of the wound will be taken, one at 6 in (15 cm) and one at 18 in (46 cm) from the surface of the wound. Each photograph from each session will be electronically transferred from the digital camera's SD memory card to a secure UPMC server, identified by the date the photographs were taken, the study number, and the subject study identification number. Separate directories will be created to store and organize the photographs from a single subject and a single weekly visit. The secure server will be backed up in accordance to the UPMC Information Services' Back-up and Disaster Recovery Plans.

(For a complete SOP on the digital wound photography specifications, requirements, and procedures, reference SOP #1.)

b. Ulcer Classification

Diabetic Neurotrophic leg ulcers are chronic wounds associated with long-standing diabetes of the lower extremities. During this study, chronic diabetes disease of the lower extremities will be categorized using the Wagner classification system: clinical manifestations, etiologic factors, anatomic involvement, and pathophysiologic features (reference Appendix D). A diabetic neurotrophic ulcer must meet the criteria for grade 1 or grade 2 in the Wagner Classification¹⁶⁻¹⁷ scale to qualify for inclusion in the study.

c. Wound Healing (Closure)

Complete wound healing (closure) is defined as full epithelialization of the wound and no drainage from the site.

9. Management of Subjects Who Develop Infection, Osteomyelitis, or Dermatitis During Trial Participation

Infection of the study wound, identified either through clinical observation (erythema, edema, induration, purulent drainage, foul odor, warmth at the wound site, or fever >37.8 degrees C, tenderness, and increasing pain at the wound site) or by a positive culture requires systemic antibiotics and appropriate local management as determined by the Investigator until the infection is resolved. If the study wound (or a non-study wound on the same extremity) becomes infected, study treatment will be discontinued to allow the infection to be treated. Once the infection has resolved, the subject will not be permitted to return to his/her treatment group. At this point, the treatment will be discontinued and considered a study failure. The patient will

then resume a normal treatment regimen. All patients withdrawn from the study as a result of an infection will be included in the statistical intent to treat population.

The presence of exposed bone will be presumptive evidence of Osteomyelitis. If this occurs, treatment will be interrupted and the exposed bone treated by the investigator as per their best judgment. Once the Osteomyelitis has been identified, the treatment will be discontinued and considered a study failure. The patient will then resume a normal treatment regimen to resolve the Osteomyelitis. All patients withdrawn from the study as a result of an Osteomyelitis will be included in the statistical intent to treat population.

Dermatitis at the study wound site will require determination of the cause and treatment as deemed appropriate by the wound care physician. If dermatitis is identified, the treatment will be discontinued and considered a study failure. The patient will then resume a normal treatment regimen to resolve the dermatitis. All patients withdrawn from the study as a result of dermatitis will be included in the statistical intent to treat population.

I. Adverse Events

An **adverse event** is **any untoward medical occurrence**, whether anticipated or unanticipated, in any patient during the course of the study. The Principal Investigator is required to **report all untoward medical events**. All adverse events will be reported on the **Adverse Event CRF** and may or may not be device related. Adverse events that are associated with the use of Platelet Rich Plasma Gel are cited in the **Risks** (Section VII).

1. Adverse Events

A **serious adverse event** is defined as any untoward medical event that

- results in a death
- is life-threatening (real risk of dying at the time of the event)
- requires hospitalization (initial or prolonged)
- results in disability (significant, persistent or permanent)
- requires intervention to prevent permanent impairment or damage

- A. Infection. The most common adverse event anticipated is infection. It is expected that the infection rate will be similar among groups. Wound culture and sensitivity must be performed. Infection is defined as three of the five clinical signs: erythema, edema or induration, warmth at the wound site or fever > 37.8 degrees C, tenderness, and increasing pain at the wound site. The presence of exposed bone will be presumptive evidence of osteomyelitis. If this occurs, treatment will be discontinued and the exposed bone treated by the investigator as per their best judgment. If clinical infection develops during the course of treatment, the patient will be dropped from the study and not allowed to re-enter. They will not resume treatment once the infection is cleared. All patients withdrawn from the study as a result of an infection will be included in the statistical intent to treat population.

- B. Wound size changes. If the wound decreased by 30% during the observation time, the patient will be excluded. If the wound worsen by 30% or enlarges on two consecutive visits, the patient will be withdrawn from the study and will be considered a study failure. All patients withdrawn from the study as a result of an the defined wound size changes will be included in the statistical intent to treat population
- C. Infrequent side effects occur in 1-10%, or 1-10 out of 100 people. Itching, hives, nausea, and vomiting may be expected in 1-2% of the individuals that receive Platelet Gel. These side effects are usually mild in severity. A rare side effect is local thrombosis of small foot blood vessels.
- D. You may experience bruising and soreness at the site where blood is drawn. There is also a slight possibility of infection at the site where the blood is drawn.
- E. Studies evaluating the capability of the medication under investigation to produce birth defects in an unborn child have not been completed/conducted.
- F. As a FEMALE OF CHILDBEARING POTENTIAL wishing to volunteer for this project, you must understand that the Platelet Gel might be harmful to (1) an unborn child if you are pregnant, or become pregnant; or (2) an infant if you are breastfeeding. Therefore, you may not be pregnant and will take a pregnancy test before and after you participate in this study. You must also agree to take precautions to prevent pregnancy during the course of this study due to the possible severe harm the drug/procedure may cause your unborn child. The only completely reliable methods of birth control are total abstinence or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm killing products are not totally effective in preventing pregnancy. Also, you may not breast-feed and participate in this study.
- G. If you become pregnant or feel you might be pregnant, contact your provider and the study investigator listed in the voluntary participation section.
- H. As a MALE who wishes to volunteer for this project, you must understand that this drug/procedure might be harmful to an unborn child if your partner(s) should become pregnant. Therefore, you must agree to ensure that precautions are taken to prevent pregnancy from occurring during the course of this study due to the possible severe harm the drug/procedure may cause the unborn child.

Investigator Adverse Event Reporting

The safety of all patients enrolled in this clinical trial will be monitored throughout the study. All serious adverse events occurring with any patient enrolled in this study will be assessed by the Principal Investigator and reported within 24 hours with a written report within 48 hours. A report will also be provided to the IRB(s) and the University of Pittsburgh Diabetes Institute within 10 working days after the Investigator first becomes aware of the event using the Adverse Event Report case report form provided. The nature and causes of the problem will be reported and any treatment that is administered due to the unanticipated effect will be described in detail.

It is the responsibility of the Principal Investigator to conduct an evaluation of each adverse event and, with respect to applicable regulations, to determine if it is an unanticipated adverse device effect. If the event is determined to be an unanticipated adverse device effect, all participating investigators, the FDA and all reviewing Institutional Review Boards will be notified. The Investigator may stop you the patient from taking part in the study at any time if the Investigator believe it is in the best interest of the patient; if the rules are not followed; or if the study is stopped.

J. Data Safety Monitoring Board

An Institutional Data and Safety Monitoring Board (IDSMB) will be created to review this study (Appendix J). The initial responsibility of the IDSMB will be to approve the initiation of this clinical trial. After this approval and at periodic intervals (to be determined by the subcommittee) during the course of the trial, the IDSMB responsibilities are to:

1. Review the research protocol, informed consent documents and plans for data and safety monitoring;
2. Evaluate the progress of the trial, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of the trial site, and other factors that can affect study outcome;
3. Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial;
4. Review clinical centers performance, make recommendations and assist in the resolution of problems reported by the PI;
5. Protect the safety of the study participants;
6. Report on the safety and progress of the trial;
7. Make recommendations to the PI, and if required, to the FDA concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the treatment under study;
8. If needed, conduct interim analysis to include evaluation of efficacy in accordance with stopping rules which are clearly defined in advance of data analysis and have the approval of the IDSMB;
9. Ensure the confidentiality of the trial data and the results of monitoring;
10. Assist the PI by commenting on any problems with study conduct, enrollment, sample size, and/or data collection.

The IDSMB will include experts in chronic wound patients, diabetic foot ulcers, clinical trials methodology, and biostatistics. Members will consist of persons affiliated with the University of Pittsburgh, the University of Pittsburgh Medical Center (UPMC) and Wilford Hall Medical Center (USAF), but independent of the investigators who have no financial, scientific, or other conflict of interest with the trial. Written documentation attesting to absence of conflict of interest will be required.

The University of Pittsburgh Office of Clinical Research, Health Sciences will provide the logistical management and support of the IDSMB. A safety officer (chairperson) will be identified at the first meeting. This person will be the contact person for serious adverse event reporting. Procedures for this will be discussed at the first meeting.

The first meeting will take place before initiation of the trial to discuss the protocol, approve the commencement of the trial, and to establish guidelines to monitor the study. The follow-up meeting frequency of the IDSMB will be determined during the first meeting. An emergency meeting of the IDSMB will be called at any time by the Chairperson should questions of patient safety arise. The principal investigator, co-investigators, and/or other study team members from each performance will be present for each meeting.

K. Patient Withdrawal or Discontinuation (Stopping Rules)

Subjects unable to comply with the requirements of the study such as the following will be withdrawn from the study:

- Treatment with immunosuppressive
- Cytotoxic
- Corticosteroids
- Anticoagulant agents such as Heparin, Plavix or Coumadin
- Needing radiation or chemotherapy
- Those who develop infection or dermatitis

If the study wound experiences the following characteristics, the patient will be considered a treatment failure and will end participation in the study and resume normal treatment regimen. No additional follow up visits required. For statistical purposes, these patients will be considered in the intent to treat population.

- Time to wound closure > 12 weeks
- Develops an infection that must be treated with antibiotics
- Wound recurrence at any time between end of treatment and the three-month follow-up visit.
- Wound increase in size $\geq 30\%$.
- Wound enlarges on two consecutive visits
- Co-morbidities
- Develops an occurrence of an additional wound within 3 cm of the study wound
- Study extremity requires revascularization or amputation

If one of the following events occur with the patient, the patient will also be considered a treatment failure and will end participation in the study and resume normal treatment regimen. No additional follow up visits required. For statistical purposes, these patients will be considered in the intent to treat population.

- Patient no longer wish to participate in the study
- PRPG cannot be applied to the study wound for 2 consecutive weeks
- At the discretion of the physician for health reasons associated or not associated with the study
- Adverse Event

Patients who discontinue study participation because of adverse experiences will be treated and followed according to established medical practice, and the outcome of such treatment will be recorded on the **Adverse Event CRF**.

L. Site Discontinuation

The Investigator has the right to discontinue enrollment and remove all treatment materials from the study site for the following reasons:

1. It becomes apparent that patient enrollment is unsatisfactory as to quality (violations of inclusion/exclusion criteria) and/or enrollment rate;
2. The completion of the CRFs is inaccurate, incomplete and/or considerably delinquent.
3. The Investigator believes that it is in the best interest of the patients, when the study rules are not followed appropriately, that the enrollment and or the study be stopped.

M. Data Analysis and Statistical Methods

All case report forms will be returned to the research nurse for entry into a study database. The data will be checked for consistency and completeness.

1. Sample Size

This study is designed to compare the incidence of wound closure between two treatment groups: standard therapy (standard of care) and standard therapy with the substitution of Platelet Rich Plasma Gel for the Hydrogel (treatment). The primary outcome is incidence of wound closure during the 12-week treatment period.

Published studies for diabetic neurotrophic leg ulcers have shown that standard care treatment results in wound closure rates of approximately 10-33%. It is hypothesized that the experimental treatment will improve on the stand care wound closure percentage. A sample size of 30 patients per group should provide the investigator with a significant scientific statistical analysis to support the hypothesis. To accommodate the potential of a 17% withdrawal and infection rate, a sample size of 35 patients per treatment group (a total potential enrollment of 70 patients) is planned.

2. Statistical Methods

Descriptive statistics will be used to summarize treatment group comparability for demographic variables, overall and by investigational site. Summaries will also be provided for primary and secondary outcomes, as well as adverse event experiences.

The primary outcome of incidence of wound closure at 12 weeks post-treatment initiation will be analyzed using a chi-square test for contingency tables. To assess the potential influence of co-factors such as investigational site effects, logistic regression will be used.

Secondary outcomes consisting of time-to-event data will be analyzed by Kaplan-Meier survival methodology. To assess the potential influence of co-factors, the Cox

proportional hazards model will be used. Continuous variables (e.g., percent reduction in wound area at 12 weeks post-treatment) will be compared between treatment groups using the Student's t-test. If the assumptions of the t-test are severely violated, a non-parametric alternative will be employed. Categorical variables (e.g., patient compliance at 3-month follow-up visit) will be compared between treatment groups using a chi-square test for contingency tables or a non-parametric alternative such as Mann-Whitney U test, as applicable.

The overall incidence of adverse events will be compared between treatment groups by the chi-square test for contingency tables.

Statistical significance is defined as $p < 0.05$. All analyses will be performed using the SAS software system.

A qualified statistician provided to the investigator(s) by the University of Pittsburgh Diabetes Institute Coordinating Center will perform all statistical analysis.

3. Population Definitions for Statistical Analysis

- a. Evaluation for Efficacy Population: The evaluation for efficacy population is defined as all randomized subjects who satisfy the study inclusion and exclusion criteria, does not become infected, receive a complete course of study medication as prescribed, complete all treatment visits according to schedule, and does not experience an adverse event that would lead to a withdraw from the study. This population will be used in the analysis of the protocol's primary endpoint, and will be included in the analysis of other efficacy and safety endpoints
- b. Intent to Treat Population: Efficacy analyses will be performed on this population in the same manner as for the Evaluation for Efficacy Population. Any subject, who is enrolled and randomized, whether or not he/she ultimately receives any study treatment, will be included in the intent to treat population. The following patient characteristics will qualify for the Intent to treat population:
 - o Time to wound closure > 12 weeks
 - o Patient no longer wish to participate in the study
 - o Failed phlebotomy or failure to apply PRPG to the study wound for 2 consecutive weeks
 - o Adverse Event leading to withdraw from the study
 - o Treatment with immunosuppressive
 - o Anticoagulant agents such as Heparin, Plavix or Coumadin
 - o Needing radiation or chemotherapy
 - o Those who develop infection, Osteomyelitis, or dermatitis
 - o At the discretion of the physician for health reasons associated or not associated with the study
 - o Wound recurrence at any time between end of treatment and the three-month follow-up visit.
 - o Wound increase in size $\geq 30\%$.
 - o Wound enlarges on two consecutive visits

- o Co-morbidities
 - o Develops an occurrence of an additional wound within 3 cm of the study wound
 - o Study extremity requires revascularization or amputation
- c. Evaluation for Safety Population: All subjects who receive at least one study treatment, partial or complete, (including subjects who experience an adverse event) will be evaluated for safety.

VII Risks and Benefit

In 2003, the Center for Medicare and Medicaid Services (CMS) conducted an extensive literature review seeking evidence for determining coverage for autologous PRP therapy. CMS concluded that, in the absence of reliable data, the evidence is not sufficient to approve coverage for the use of PRP in patients with chronic, non-healing wounds. The safety, efficacy, and effectiveness of platelet gel therapy in the diabetic patient population warrant further investigation in controlled clinical trials. This study will seek to build upon previous work in platelet derived growth factor therapy providing evidence sufficient to determine if technique modifications will measurably improve wound-healing outcomes in patients with chronic diabetic neurotrophic lower extremity wounds. There may be no direct benefit from participation in this study. The major risk is that the wound may not heal either with standard therapy or with PRP gel.

Autologous Platelet Gel (APG) involves steps that introduce risk to the patient; an approximate 40 ml. whole blood draw, combining the Platelet Rich Plasma (PRP) portion of the draw with autologous thrombin and calcium chloride in a 10:1 ratio, and topical application. When a phlebotomy is performed there is a risk of bruising, soreness, or rarely, infection. Infection occurs in 5-7% of patients with diabetic wounds present for more than one month. After the blood is separated the PRP is combined with calcified autologous thrombin and topically applied to the wound. During this process there is a 1-10% incidence of itching, hives, nausea, and vomiting. Rare occurrence of allergic reaction to the ethanol contained in the activAT processing syringe has been reported. Local thrombosis has occurred with the application of bovine thrombin.

The potential benefit is improved wound healing.

VIII Administrative Requirements

A. Study Monitor

While the Principal Investigator and the Data Safety Monitoring Board will have the overall study responsibility for the management and monitoring of this investigation.

C. Investigator and Staff Responsibilities

All investigators and researchers will be required to complete the governing IRB(s) research certification(s). These certifications will be attached to the study protocol and placed on file with the University of Pittsburgh Diabetes Center and the IDSMB.

1. Principal Investigator

The Principal Investigator is the person responsible for the conduct of the clinical pilot study at a study center. The responsibilities of the Principal Investigator include but are not limited to: obtaining patient informed consent, complying with the Investigational Plan and applicable FDA and other regulatory regulations, overseeing the administrative activities, study data collection, and the activities of the sub-investigators and other staff involved in conducting the study.

2. Sub-Investigator

A sub-investigator participates in the study (e.g., obtains patient informed consent, conducts patient examinations) under the direction of the Principal Investigator.

3. Research Coordinator

The research coordinator assists with clinical study activities as assigned under the direct supervision of the Principal Investigator. The duties of the research coordinator may include ensuring that the required tests and evaluations are done for each patient at the required intervals, completing the case report forms based on the medical records, assisting with administrative activities, and scheduling patient follow-up appointments.

D. Investigator Agreements

The **Investigator Agreements** (Appendix F) are written agreements to be signed by the Investigators that define their responsibilities.

D. Monitoring Procedures

Study Initiation: All personnel expected to be involved in the conduct of the study will undergo an orientation to include review of study protocol, instruction for record completion, and overall responsibilities.

E. Investigational Device Charge

The devices to be used in this clinical study will be loaned to the investigational sites by BioTronics, Inc. at no charge.

F. Laboratory Accreditation

Any laboratory facility to be used for analysis of routine clinical laboratory samples required by this protocol must provide evidence of adequate licensure or accreditation. Reference values and/or normal ranges for the test results used in conducting this protocol must be provided

G. Institutional Review Boards

This protocol, the proposed informed consent form, and any method used for patient recruitment must be reviewed and approved by the appropriate Institutional Review Board(s) (IRB(s)) prior to the start of the study. During the course of the study, the

Principal Investigator will make timely and accurate reports to the IRB(s) on the progress of the trial at intervals not exceeding one year, as well as satisfying any other local IRB(s) regulations regarding reporting. Furthermore, at the completion or early termination of the study, the Principal Investigator must make final report to the IRB(s) within the applicable IRB(s) time frames.

Any significant changes or revisions in the study protocol or any changes that may alter patient risk must be approved in writing by all appropriate IRB(s) prior to implementation. A protocol change intended to eliminate an apparent immediate hazard may be implemented immediately prior to and approval by the IRB(s).

Institutional Review Boards/Authorization Agencies

- University of Pittsburgh Medical Center
- Wilford Hall Medical Center
- Surgeon General of the United States Air Force (2nd level approval)

H. Informed Consent

The proposed informed Consent form, which must be in compliance with regulatory regulations, must contain all of these items:

- A complete explanation of the purpose and nature of the study.
- A description of the procedures.
- Possible advantages and risks.
- Alternate treatment options.
- A statement of confidentiality concerning patient study records.
- A statement regarding voluntary compensation and availability of treatment in the case of injury.
- An explanation of whom to contact about the research.
- The patient's rights.
- Notification that participation is voluntary and refusal will involve no penalty or loss of medical benefits.

These requirements are in accordance with the Federal Regulations as detailed in the 21 CFR 50.25 and the Declaration of Helsinki. The informed consent form should also indicate by signature that the patient, or where appropriate, legal guardian/representative, permits access to relevant medical records by representatives of the U.S. Food and Drug Administration (FDA) or other applicable regulatory agency and the Investigator and /or the Investigator's duly appointed agent, included the University of Pittsburgh Diabetes Institute Coordinating Center. The informed consent must be in the patient's primary language.

The investigator will be responsible for obtaining written informed consent from potential patients prior to any study specific screening and entry into the study. The investigator will retain the original. A copy of the signed document will be provided to the patient and a copy will be maintained with the patient's study documentation.

I. Records and Reports

1. Record Retention

The Investigator must maintain records of source documentation and all documents related to this investigation for at least 7 years after completion of the study. Additional information concerning record retention will be defined within the Data and Safety Monitoring Plan

2. Documentation

A log of all patients evaluated for this protocol must be maintained at each site. An explanation for any patients excluded from enrollment will be provided. Patients who sign an informed consent form and are enrolled under this protocol will be assigned a study subject identification number. This study subject identification number will be used to identify the subject on all case report forms, historical study photographs, and other study-related documentation.

For each individual treated under this protocol, the site Project Manager is required to prepare and maintain case histories in the patient chart that include all source documents needed to verify the accuracy of all observations and other data pertinent to the investigation. This will include all source documents needed to verify the accuracy of all observations and other data contained in the CRFs on each study patient.

The treating physician or his or her designee is required to retain the records related to the trial for at least 7 years after completion of the study. If no application is to be filed or if the application is not approved for such indication, the records must be retained until 2 years after the investigation is discontinued and the regulatory agencies are notified.

3. Principal Investigator's Final Report

Within 3 months following completion of the study, the Principal Investigator will be responsible for completing a final report containing a description of the outcomes of the study at his/her institution with respect to number of patients evaluated for the study, patient enrollment, serious adverse events, number of patients withdrawn, and reasons for withdrawal. This report will be made available to the Investigator, IRB'S, Surgeon Generals Office of the United States Air Force, and the University of Pittsburgh Diabetes Institute Coordinating Center.

4. Disclosure of Data

All information obtained as a result of this study or during the conduct of this study will be regarded as confidential. Disclosures (i.e., any release of information to any third party not noted herein) of any information not previously known to be public and/or results of the investigation for publication or by oral or poster presentation shall not be made earlier than thirty days after submission of the proposed material to the Investigator for inspection, unless the Investigator consents to earlier disclosure. The Investigator will take appropriate notice suggestions before

disclosure for publication or presentation consistent with protection of the Patient's right to its confidential data.

J. Patient Confidentiality

The Investigator will keep all data related to patient identification in strict confidence. Patient identity will not be revealed in any of the reports or publications resulting from this study.

L. Investigational Plan Modifications

Any changes to this protocol, that affect study objectives, study design, study procedures, patient population, or significant administrative procedures, will require a formal amendment to the protocol. Applicable regulatory agencies and the IRB must approve certain changes before implementation. Prior to implementation, an amendment must be agreed upon by the Principal Investigator, and approved by the applicable regulatory agencies and IRB. If the informed consent is affected by the changes, the investigator will be responsible for ensuring that all enrolled patients are notified and given the opportunity to sign a revised form

General administrative changes to the protocol are minor corrections and/or clarifications that do not affect the manner in which the study is to be conducted. Such administrative changes will be agreed upon by the Principal Investigator and will be documented in a memorandum. At the discretion of the Principal Investigator or his designee, the applicable IRB may be notified of administrative changes according to applicable IRB guidelines.

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Appendix 6



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

August 17, 2007

David L. Steed, M.D.
Professor of Surgery
University of Pittsburgh Medical Center
Comprehensive Foot and Ankle Center
2100 Jane St., Suite 7100
Pittsburgh, PA 15203

Re: BB-IDE 13374
Product: COBE-Angel Whole Blood Separation System
Dated: July 16, 2007
Received: July 19, 2007

Dear Dr. Steed:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application. You have corrected the deficiency(ies) cited in our June 5, 2007 conditional approval letter. Therefore, your supplement is approved and you may continue your investigation at the institution(s) enrolled in your investigation after you have obtained institutional review board (IRB) approval and submitted certification of IRB approval to FDA. Your investigation is limited to 5 (five) institutions and 70-100 subjects.

We note that the following non-conditional items from the June 5, 2007 letter were not adequately addressed. We strongly urge you to respond to the items and amend the investigational plan accordingly.

1. The method of evaluation of thrombin activity of the Activate autologous thrombin preparation used for the claim in the device labeling is not acceptable. In addition, the study entitled "Comparative study using Activate autologous thrombin and international standard for thrombin" does not define the thrombin activity in International or NIH Units. Please provide a detailed description of the study that was performed. In case the design is not acceptable, an additional study will need to be performed to evaluate the thrombin activity in the preparations. Lack of knowledge of well defined thrombin activity in the autologous thrombin preparations will make it difficult to monitor the quality of the preparations and to validate the results of the clinical trial in future. Please comment.
2. Regarding the statistical analysis section of the protocol,
 - a. It is unclear from the table on page 4 of the Investigational Plan how you plan to analyze the secondary endpoints. Although you do note the various tests to be applied to secondary endpoints, it is not evident which tests apply to the various secondary

Page 2 - Dr. Steed

endpoints. Therefore, please amend the protocol to describe in more detail (not a summary chart) the statistical analysis plan for each secondary endpoint.

- b. We previously recommended that you plan to analyze the possible impact of observed changes in HbA1c from baseline on efficacy outcomes. This is important to consider because changes in the HbA1c could confound wound healing. Please comment.
3. We note that the protocol specifies that subjects may withdraw from the study due to "at the discretion of the physician or health reasons associated or not associated with the study". Please clarify if you mean the number of subjects who withdraw prematurely for these reasons.
4. Any subject, who is enrolled and randomized, whether or not he/she ultimately receives study treatment, will be included in the intent-to-treat population. Please revise the protocol to specify that all subjects who withdraw will be treated as failures.
5. Please consider revising the photography standard operating procedures to better standardize photographs as follows:
 - a. Under "Digital Camera Specifications," we recommend you double check the accuracy of item 6, "Focal Length," which is listed as "Normal mode 23.6" - infinity." If correct, unless you use a macro setting, which we recommend, all photographs would be out of focus at the specified camera-subject shooting distances of 6 and 18 inches.
 - b. We recommend turning the on-camera flash off which will otherwise overexpose the image at the nearer subject-camera distance and will produce a flat image lacking depth.
 - c. We recommend digital zoom be switched off.
 - d. We recommend using a standard optical zoom position, such as fully extended to 3x (19.5 mm). If the optical zoom varies between shots, this changes the magnification factor of the images.
 - e. We recommend you use "program" rather than the "portrait" mode setting. In the Olympus Stylus 770 SW camera, which you stated during the teleconference held on August 15, 2007 you may use, manual setting of the ISO, which you stated you want to use, is not possible.
 - f. We recommend you employ a standard background for the lesion, such as a green surgical or gray towel whose tone approximates neutral (18%) gray.
 - g. We recommend you consider using a tripod, in which case using the lowest available ISO setting will produce the least noise and the best image quality.
 - h. In determining initial camera settings, we recommend evaluating test shots on a monitor, preferably with examination of the histogram, to verify exposure and to determine, with optical stabilization turned on if not using a tripod, whether adequate sharpness is obtained with a lower ISO setting.
 - i. Item 6, "Exposure - +/-2 EV steps in 1/3 EV steps" under "Photography Specifications" is not a photography specification [setting], but rather represents the range of possible exposure compensation settings. Depending on the skin tone of the subject, the tone of the background, the metering method, and the percent of the image area comprised by the subject, there may or may not be a need to change the Exposure [compensation] setting from zero. An in-camera evaluation of the histogram and of the photography review setting that makes overexposed highlights flash will aid in

Page 3 - Dr. Stead

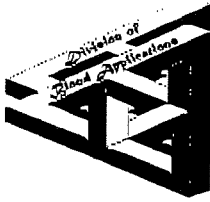
- determining proper exposure, as will examination of the image or a test shot and its histogram on a monitor (preferred method).
- j. Item 7 under "Photography Specifications:" When using a green surgical or neutral gray towel as the background we recommend setting "Backlight compensation" to "off."
 - k. Item 8 under "Photography Specifications:" "Light metering - Digital ESP Multi-Pattern, Spot Metering" is not a setting. These represent 2 different metering method settings. Depending on the experience level of the photographer in obtaining correct exposures, the ESP Multi-Pattern may be preferable. Spot metering is appropriate to base the exposure on the subject, allowing one to ignore the tone of the background, but requires experience in applying exposure compensation based on a modified zone system type of assessment of the tonality of the subject.
 - l. We recommend you specify that the rule be placed just next to and in the same plane perpendicular to the camera as the lesion.
 - m. If custom white balance is not available, we recommend an 18% gray card also be included in the image to permit appropriate color correction in post processing of the digital image. If you choose not to do this, the "fluorescent lamp 3" setting may provide more accurate color than using the "auto" color balance setting.
 - n. Any alterations to the images, such as removal of lens distortion, should be retrievable in a permanent electronic audit trail.
 - o. We recommend the same make and model of digital camera and lens be used at each study site.
 - p. We recommend you employ a 2nd SD card so that original JPEG images are not erased from the SD card until the copied image on the secure server has been backed up (i.e., delay erasing the image until the transferred copy and an additional backup copy of the image exist.

If you have any questions, please contact Heather Erdman at (301) 827-3524.

Sincerely yours,



Basil Golding, M.D.
Director
Division of Hematology
Office of Blood Research and Review
Center for Biologics
Evaluation and Research

**FACSIMILE TRANSMISSION RECORD****Division of Blood Applications**

1401 Rockville Pike, Suite 400N

Rockville, Maryland 20852-1448

FAX No. (301) 827-2857 TEL No. (301) 827-6182

To: Aaron Yanuzo/ c/o Dr. Steed**FAX No.** 412.432.7568**Telephone No.** 412.432.7226**Company:** University of Pittsburgh Medical Center**Message:**

Attached, please find the IDE 13374 approval letter.

Heather Erdman, RAC

Regulatory Project Manager

U.S. Food & Drug Administration

CBER/ OBRR/ DBA/RPMB

Direct Ph# 301.827.6182

Main RPMB Ph# 301.827.5307

Fax# 301.827.2857

Information provided by: H. Erdman .

Date: Thursday, Aug 21, 2007

Approved by _____ Date _____ Transmitted by *HE* Date *4 pages, incl. cover*

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Appendix 7



IMITS Center

To: John W. Marsh, Maj, USAF, MSC, FACHE
Program Element Monitor, AF/SGRM
Office of the Assistant Surgeon General, Modernization
5201 Leesburg Pike
Falls Church VA 22041

From: Jeananne Nicholls
Associate Director of Operations
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Date: October 5, 2007

Re: FY04 IMITS – Teleophthalmology Project
(Cooperative Agreement DAMD1703-2-0017)

Major Marsh,

The IMITS Teleophthalmology Project created software to support a simple, effective retinal screening process for people with diabetes. A design team, including project team members from the University of Pittsburgh Medical Center (UPMC) and The University of Pittsburgh assessed and determined requirements for effective and efficient retinal screenings. Technical experts developed a user interface for the importation of medical image files (JPG or DICOM) and the accompanying patients' metadata (unique identifiers). The process and software was developed - based on input of the project team members - to transfer the images from the non-mydiatic cameras to a server for consequent retrieval, examination, and grading by an ophthalmology specialist. Customizable software components enable 1) efficient acquisition of patient information (metadata), 2) packaging of metadata with digital retinal images, 3) packaging and transfer of metadata and retinal images to a designated server, 4) retrieval of images and metadata for grading by a specialist, and 5) tracking of follow-up care.

This flexible, modular, mobile prototype system was deployed in clinical and community settings. These settings provided the necessary environment to enable over 700 diabetic retinopathy screenings throughout the life of the project. Evaluation data gathered from community and clinical sites contributed to management decisions that guided continual refinements to software and workflow processes. The project effectively demonstrated that the designed software solution can be used to overcome challenges with retinal imaging. This was accomplished by providing adequate screening and diagnostic services for people with insufficient access to medical care.

Key research accomplishments:

- Designed, developed, and implemented a prototype image and metadata transfer system.
- Created screens and software components to support registration, imaging, grading, tracking, and reporting processes.



- Purchased equipment to support the technologies associated with acquisition, management, and archiving of image sets.
- Developed architecture with input from UPMC staff on site at Wilford Hall Medical Center (WHMC).
- Supported UPMC staff, on site at Wilford Hall Medical Center, assessment of retinal screening options for its Diabetes Outreach Clinic.
- Conducted an IRB approved research study designed to assess the feasibility and functionality of prototype system
- Adjusted clinical workflow processes and increased monthly patient enrollment figures by over 300%.
- Demonstrated the full functionality of the retinal screening software and workflow processes.
- Assessed feasibility of integrating system for integration into hospital enterprise (i.e., Stentor PACS).
- Provided recommendations for improvements of software and network configurations.
- Disseminated project accomplishments to audience of professionals through abstracts, presentations, posters, informational brochures, and demonstrations of equipment.

At this time, UPMC has accomplished all required deliverables for the FY04 IMITS Teleophthalmology Project (Cooperative Agreement DAMD1703-2-0017). The attached final project report and appendices fulfill the deliverables requirements for this project.

UPMC would like to request the official closure of this project. It was recommended that you be informed and approve this decision. Please indicate your concurrence with completion of these deliverables.

Feel free to contact me as needed.
Sincerely,

Jeananne Nicholls
Associate Director of Operations

Attachments

1. Final IMITS Teleophthalmology Project Report
2. Appendices for final report, including
 - a. Teleophthalmology – Software Schema
 - b. Teleophthalmology – Operations Manual with Software Screens
 - c. Teleophthalmology - Standard Screening Procedures
 - d. Camera and LAN Network Assembly Manual
 - e. Teleophthalmology - Sample Recruitment Flyer
 - f. Feasibility Study - Integration of Software with PACs
 - g. Evaluation Report Observation of Community Screening Events
 - h. Research Qualifications for Screening Participation
 - i. – s. Project Presentations

cc:
Tess Ellis
James Mason
Aaron Yanuzo
Leslie Anthony

AD _____
(Leave blank)

AWARD NUMBER: DAMD17-03-2-0017

TITLE: **Integrated Medical Information Technology System (IMITS)
FY 04 Teleophthalmology Project**

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REPORT DATE: July 2007

TYPE OF REPORT: Final Project Report

PREPARED FOR: U.S. Army Medical Research and Material Command
 Fort Detrick, Maryland 21702-5012

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IMITS 04 Teleophthalmology Project Final Project and Evaluation Report

INTRODUCTION

BACKGROUND

Through defense-spending appropriations, the University of Pittsburgh Medical Center (UPMC) and the Air Force Medical Service (AFMS) created a strategic partnership known as the Integrated Medical Information Technology System (IMITS). IMITS focuses on the implementation and evaluation of a variety of prototype telemedicine applications intended to provide widely available, flexible, clinically relevant services across multiple medical specialties on a secure, stable, low cost technology platform. These applications and processes were identified by the Air Force Medical Service (AFMS) as areas of interest due to personnel shortages and the desire to develop more cost effective means of health care delivery. The prototype technology systems created by IMITS may play a significant role in providing skilled medical care to active duty personnel and their families.

The IMITS Teleophthalmology Project created an image-capture and transfer system and workflow process for effectively screening individuals for diabetic retinopathy. Diabetic retinopathy, damage to the blood vessels in the retina, is the leading cause of blindness in adults 20 – 74 years of age. Nearly 300 million people worldwide have diabetes and nearly half of all people with diabetes will develop some degree of diabetic retinopathy during their lifetime. It has been estimated that blindness from diabetic retinopathy is preventable in at least 65% of cases, if detected early. The aim of the project was to develop a flexible, modular, mobile method for screening individuals that could be used effectively in a variety of medical and community settings.

The teleophthalmology system is designed to efficiently gather medical information, merge this information with digital images of the retina and transfer the merged sets to a specialist for follow-up examination. The system is basically comprised of five separate software components: registration, imaging, grading, tracking and reporting. Each component is modular and customizable to specific locations and needs. The registration component, a web page that is accessible from the central server, was designed for efficient registration of new patients including collection demographics and key medical information. The information collected is minimal, focused on diabetes and eye conditions.

The imaging component consists of customized software running on a computer attached to the camera that drives retinal image acquisition. From the registration data, a worklist is created of patients who are ready to be imaged. A patient is selected from the worklist and the imager takes photographs of up to three retinal images of each eye,

in any order. The imaging software includes areas for comments on any additional or unique attributes of the patient being imaged as well as any technical issues that may have been encountered during the imaging process. Once the images are captured, the entire study (i.e., retinal images and patient data) is 'packaged' together and transferred to a designated, central server.

The grading component allows the specialist to access the server, via the internet, to view a worklist of patients. The grader selects a patient, with either graded or ungraded images, and reviews patient specific data and images. For ungraded images, the specialist can use the grading software to manage the retinal images for examination. Based on analysis of the images, the level of retinopathy, maculopathy, quality of images and recommendations for follow-up eye care are recorded and saved in the database. For graded patients, results of a quality assurance review can also be saved.

The tracking component is used for tracking follow-up communications with the patient. Clinic staff can track information regarding graded and ungraded image sets. This information contributes to efficient follow-up communications with patients regarding their examination and compliance with recommendations for care. Finally, the reporting component is designed to generate customizable statistical reports for the screened populations.

Software components were developed using basic architectural decisions about middleware, security, timing, portability, and the organization of data. For portability, the core of the system is a laptop with adequate processing power and memory to act as a server with an SQL database. System functions are worklist driven, eliminating typing errors and improving productivity. A server-generated unique identifier tracks patient movement through the screening process, possibly non-sequentially depending on the setting and system-configured layout. Time for each participant to complete each component of the imaging process is tracked and enables assessment of the throughput of the system. Patient data is stored in the central server and customized reports can be created to support clinical processes and follow-up communications with patients.

An exempt IRB research study was approved by the University of Pittsburgh Investigational Review Board (IRB) to assess the capabilities and effectiveness of the technology and workflow process being created to support a teleophthalmology screening program for diabetic retinopathy. Throughout the project, research study observations and feedback contributed to improvements in the technology and workflow. To assess the impact of the teleophthalmology project on individuals with known diabetes, subjects were recruited for a research study conducted by the IMITS Diabetes Project. Results of the Teleophthalmology IRB Study are included in this final report under Deliverable 3.

UPMC served as a favorable test bed for determining the feasibility and scalability of large scale implementation of the teleophthalmology systems in a complex healthcare environment.

After prototype testing with approximately 500 patients, registration, imaging and grading components were refined and combined into a true Web application, with login verifications. The database was also redesigned to add integrity and some searching and reporting functions.

System software continues to be used by the IMITS Diabetes Project in UPMC clinics and at health fairs throughout the greater Pittsburgh area, with images and metadata transfers to the designated server. The system design, however, will easily enable transfer of data packages to an enterprise digital image archive system or alternative servers in the future. Full enterprise application is, however, a complex undertaking requiring the integration of information systems, image systems, image archives and specialized image viewing software.

Body

PURPOSE AND STRUCTURE OF DOCUMENT

The FY 2004 IMITS Teleophthalmology Project focused on three main tasks, described as deliverables.

- Deliverable 1: Image Reading Screens and Software
- Deliverable 2: Feasibility Study for the Integration Software with PACs
- Deliverable 3: Final Report on Development of Image and Metadata Transfer System and Outcome of Data Analysis

The purpose of this document is to describe the key research accomplishments associated with completion of each task in the approved statement of work, in the “Deliverables to Provide” column of UPMC’s FY04 IMITS Deliverables Report to the SGR. All user manuals and presentations included in this report as appendices were completed, in whole or in part, by UPMC Teleophthalmology Project staff during the course of this funding period.

DELIVERABLE 1: IMAGE READING SCREENS AND SOFTWARE

This project was designed to develop retinal screening system software and to demonstrate that it can be used reliably in a real world, clinical environment. Over the past two years, UPMC designed the software and conducted controlled clinical evaluation studies to assess the feasibility and functionality of using the retinal screening software to perform diabetic retinopathy screenings of the populace.

This deliverable consisted of five components:

- Component 1: Registration Screens and Software
- Component 2: Imaging Screens and Software
- Component 3: Grading Screens and Software
- Component 4: Tracking Screens and Software
- Component 5: Reporting Screens and Software

Status

Design, development, and applications testing are complete for all software components associated with this deliverable.

Research Accomplishments

UPMC and Wilford Hall Medical Center (WHMC) project teams worked collaboratively

on the design and refinements of the software screens and supportive workflow processes. Technical experts based software development on these designs. Observations, focus groups, and surveys were periodically conducted with project team members, screening staff, clinic staff, and patients throughout the duration of the study. These evolving findings contributed to further refinements to system software and workflow processes.

Registration and imaging components were initially field tested in August 2005 at a community healthcare event held in Pittsburgh, PA. Based on the initial success of the components at this event, the system/equipment continued to be transported to community healthcare events throughout western Pennsylvania and enabled retinal screenings for people in areas with poor access to eye care.

People at highest risk for diabetic retinopathy were targeted for retinal screenings through the placement of stationary equipment in two UPMC healthcare clinics. A stationary imaging workstation was deployed in UPMC's General Internal Medicine Clinic on November 16, 2006 where screenings continue to be offered. A second stationary workstation was deployed in UPMC's Center for Diabetes and Endocrinology, Falk Clinic. When the clinic moved into a temporary location, during construction of a new, larger facility; retinal imaging activities were discontinued. The new facility will be complete and retinal screenings will be offered again by the end of the third quarter CY2007.

Over the course of this project, over 700 individuals were screened for diabetic retinopathy across community and clinical settings. Demographic data and retinal screening outcomes were tracked and results are included in the attached evaluation report. The IMITS Diabetes Project continues to use the system at both UPMC clinics and at community healthcare events. Additional UPMC locations are being considered for expansion of the retinal screenings to other populations at risk.

A schema of the software design is included as Appendix A and screen shots of the software are included as Appendix B, an operations manual developed for system users.

Appendix A

Teleophthalmology Software Schema Diabetic Retinopathy Screening System IMITS Teleophthalmology Project

Appendix B

Teleophthalmology Operations Manual Diabetic Retinopathy Screening System IMITS Teleophthalmology Project

During the course of the project, observations reported by members of the University of Pittsburgh evaluation team resulted in improvements in retinal screening procedures. To assure consistent application of screening procedures across staff and settings, a standard operating

procedures manual was created as a reference for Diabetes Project staff. The most current version of this manual is included as Appendix C.

Appendix C

Standard Procedures for Conducting Retinal Screenings IMITS Teleophthalmology Project

Based on multiple issues encountered by Diabetes Project staff working to assemble portable equipment for community healthcare events, a *Camera and LAN Assembly Manual* was developed by members of the Evaluation Team. This manual continues to be referenced during community events. The manual is included as Appendix D.

Appendix D

Camera and LAN Assembly Manual IMITS Teleophthalmology Project

An assessment of low volume recruitment and screenings in clinical areas indicated that patients were not being reliably informed of the option to have their eyes imaged while attending a clinic appointment. To improve recruitment, clinic staff agreed to have information about the research project posted in waiting areas and on intake forms completed by patients at the time of their clinic appointment. The inclusion of information in the clinic environments for purposes of subject recruitment required IRB approval of modifications to the IMITS Diabetes Project protocol; this took considerable time to accomplish since it had to be approved by multiple IRBs. Once approved, recruitment information appeared to significantly increase the volume of retinal screenings conducted in both clinical settings. A sample recruitment flyer is included as Appendix E.

Appendix E

Teleophthalmology Retinal Screening Sample Recruitment Flyer IMITS Teleophthalmology Project

At the onset of the Teleophthalmology Project, project staff from Wilford Hall Medical Center (WHMC) collaborated on the design of the software with intentions of deploying the system in their Diabetes Center. In November 2005, key personnel from UPMC and WHMC met in Pittsburgh to clarify AFMS teleophthalmology requirements and to assess the feasibility of using UPMC's software for WHMC's ophthalmology screenings. Based on WHMC and AFMS requirements for ICDB and CHCS 2 (AHLTA) compatible software and USAF information assurance (AI), it was determined that UPMC's prototype software would not be deployed at WHMC.

DELIVERABLE 2: FEASIBILITY STUDY FOR THE INTEGRATION SOFTWARE WITH PACS

Researchers created the integrated, secure process for packaging and transporting retinal images and patient information from the site of acquisition to storage and incorporation into a central server. Yet, to become fully functional, the images and metadata need to be integrated into the hospital's enterprise archive.

Status

The feasibility of integrating the retinal screening system with PACS was fully analyzed by technical experts. Appendix F documents these requirements for integration and serves to satisfy Deliverable 2.

Research Accomplishments

In order to assess the feasibility of integrating the mobile diabetic retinopathy screening system with a PACS, routine project/discovery meetings were held with domain experts. Experts reviewed functional aspects necessary to accomplish the integration task, given the stand-alone system and the existing PACS. With the functional requirements defined, experts inspected components of existing and developmental systems within the UPMC enterprise to assess technical approach as well as reusability and direct application to the current integration task. PACS requirements and recommendations for system design modifications are presented that would enable the transfer of patient metadata and images to UPMC's enterprise system.

Appendix F

Feasibility Study: Integration of Teleophthalmology Software with PACS IMITS Teleophthalmology Project

DELIVERABLE 3: FINAL REPORT ON DEVELOPMENT OF IMAGE AND METADATA TRANSFER SYSTEM AND OUTCOME OF DATA ANALYSIS

Status

Development of Image and Metadata Transfer System

Deliverable 1 details the research accomplishments for the development of the image and metadata transfer system. Deliverable 2 provides a detailed feasibility study for integrating the image and metadata transfer system into a hospital enterprise (i.e., Stentor PACS). These reports serve to satisfy this portion of Deliverable 3.

Outcome of Data Analysis

An IRB approved research study was conducted to assess the capabilities and effectiveness of the technology and workflow process developed for the teleophthalmology project. The following summary of findings serves to satisfy the outcome of data analysis required for Deliverable 3.

Research Accomplishments

Summary

- 706 subjects with diabetes were successfully consented, registered, imaged, and had their eye images graded. 337 were from community sites and 369 from clinical sites.
- Mean time for subjects to be registered, imaged, and have eye images graded was 00:12:53.
- 51% of the subjects reported that their last eye exam was “Greater than 12 Months” or “Never”
- 76% of our sample were instructed to follow-up with their eye doctor in one year (had no retinopathy or micro aneurysms). Only six (0.8 %) were asked to see their eye doctor within 6 weeks (proliferative retinopathy).

Introduction

There are 20.8 million in the United States, or 7% of the population, who have diabetes. Complications of diabetes result in 12,000 to 24,000 new cases of blindness each year. In the 20 - 74 year age-group, it is the leading cause of blindness. Laser therapy can help prevent blindness from diabetic retinopathy but early detection is essential. The American Diabetes Association recommends annual eye exams for patients with diabetes.

An Evaluation Team from the University of Pittsburgh’s Department of Biomedical Informatics was contracted to assess the capabilities and effectiveness of the technology and workflow process being created to support a teleophthalmology screening program for diabetic retinopathy. The study involved behavioral observations, conducting focus groups, and analyzing screening activity reports and participant surveys. By focusing on assembly/disassembly procedures, workflow

processes, and workflow environments, the Evaluation Team identified potential barriers in order to maximize the project's success.

This study and two subsequent modifications were approved by the University of Pittsburgh's Institutional Review Board (IRB).

Community Sites

History

Diabetic retinal screening began August 27, 2005 at the David L. Lawrence Convention Center in conjunction with the *Healthy 4 Life and American Diabetes Association Expo*. Teleophthalmology software, equipment, and staff were used to consent, register, image, and subsequently grade eye images. This was the first of many visits to community sites. Both urban and rural locations within Pittsburgh and surrounding areas were selected. Depending on availability of an Evaluation Team member the site would be visited to observe and make improvement suggestions. Site reports can be found in Appendix G.

Sites that were visited included:

Temple Emanuel, March 5, 2006 (first use of the dedicated van)
Diabetes Symposium – Quality Inn, Bedford PA, March 16, 2006
McKeesport Palisades, July 18, 2006 and July 19, 2006
Fairchance Health Clinic, August 3, 2006
Yablonski Health Clinic, August 9, 2006
Uniontown Hospital Diabetes Clinic, August 22, 2006
Carmichaels Site, August 23, 2006
Indiana Regional Medical Center, August 25, 2006
Lincoln-Lemington Family Health Care Clinic, November 2, 2006

Appendix G

Site Reports: Observations of Teleophthalmology Retinal Screenings IMITS Teleophthalmology Project

The evaluation team also produced a document that assisted in the screening of prospective patients. The document listed the qualifications required to participate in the diabetic retinopathy screening program.

Appendix H

Research Qualifications for Screening Participation

Community Demographics

	Community n = 337 (%)
Gender	
• Male	132 (39.2)
• Female	205 (60.8)
Mean Age (Years)	61
Race	
• Caucasian	265 (78.6)
• African American	64 (19.0)
• Asian	3 (0.9)
• Hispanic	3 (0.9)
• Multi-Racial	0
• Other/Unknown	2 (0.6)
Diabetes	
• Type 1	21 (6.2)
• Type 2	316 (93.8)
Mean Duration of Diabetes (Years)	7.9
Mean A1C Percentage	7.2
Last Eye Exam	
• Less than 1 Month	15 (4.5)
• 1 – 3 Months	25 (7.4)
• 3 – 6 Months	32 (9.5)
• 6 – 12 Months	71 (21.1)
• Greater than 12 Months	173 (51.3)
• Never	18 (5.3)
• Unknown	3 (0.9)

Table 1

Observations

Each health fair/seminar/symposium seemed to have some sort of challenge. Once overcome, these challenges built for a more efficient and effective program at the next event. Some included:

- Location of camera, was it dark enough, was wiring possible etc.
- Little or no prior advertising
- Need for better and more professional signage
- Moving and storing equipment
- Software/technical problems

Focus Groups

Within a week of the first community event at the *Healthy 4 Life and American Diabetes Association Expo* two focus groups were conducted. Topics included layout, staffing needs, technical issues, images/imaging, and subject's needs. Basically, the discussions set the course on how the community health fairs/seminars/symposiums would continue.

Surveys

In a concern for subject satisfaction, we developed a very short, four question survey to be provided and collected anonymously. A total of 86 were collected and tabulated from six different sites. See Figure 1.

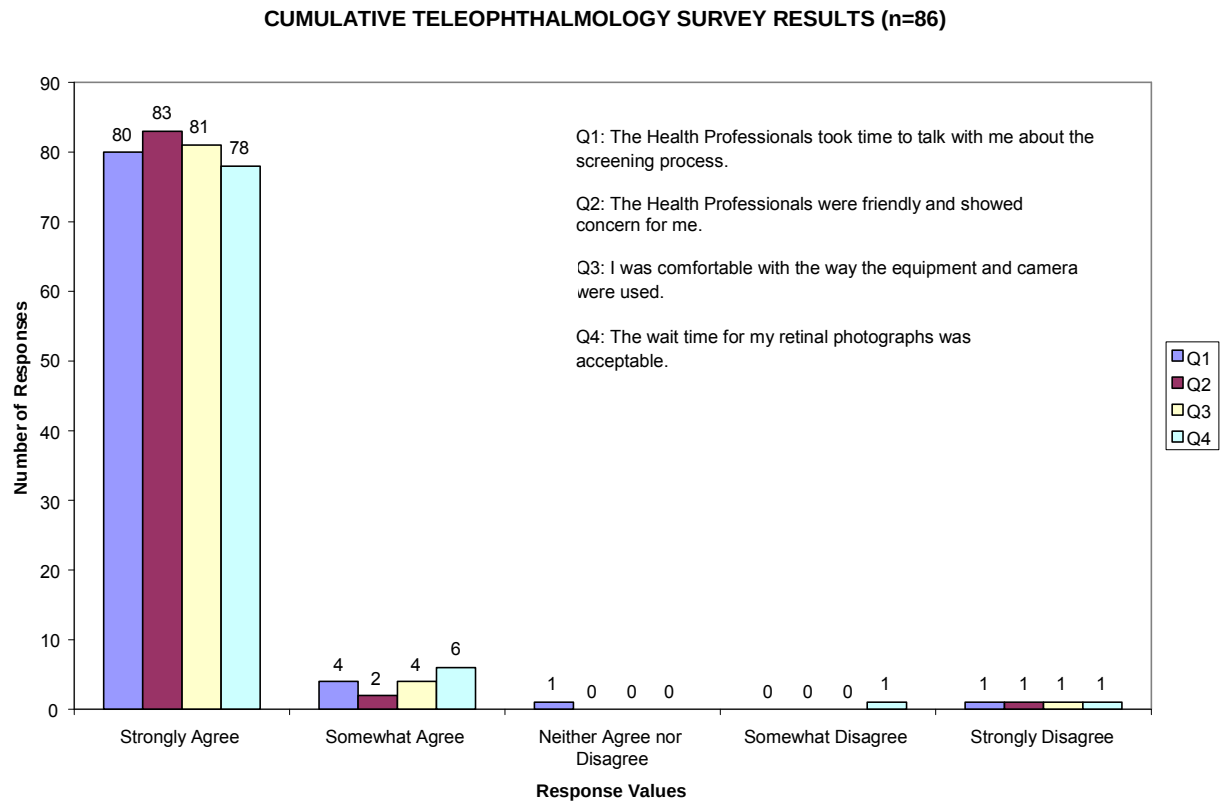
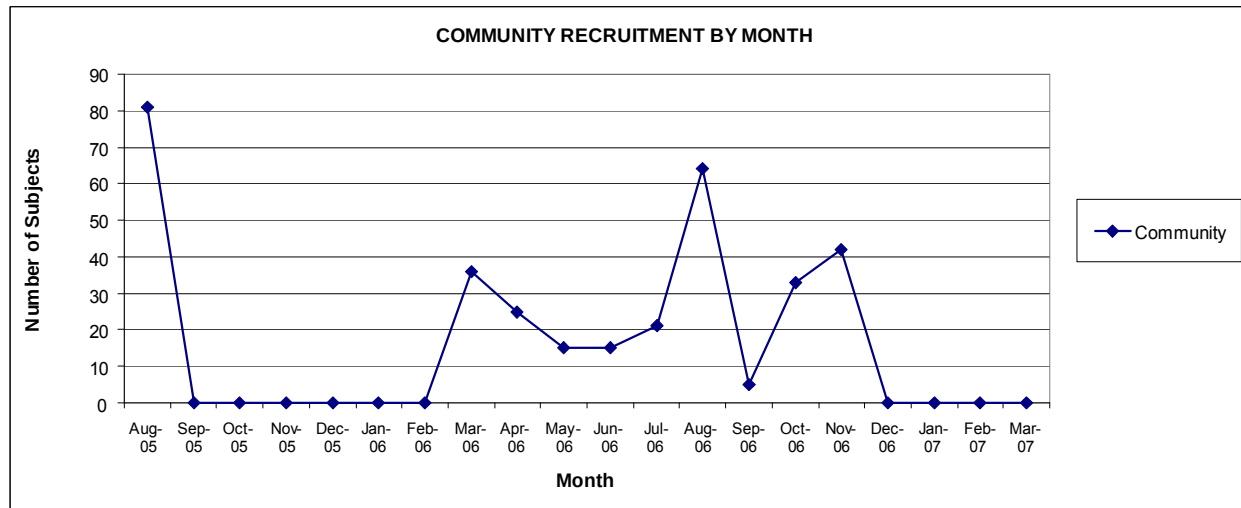


Figure 1

Recruitment Results



Note: No recruitment activities took place from September 2005 through March 2006 pending van preparation. Due to inclement weather, recruiters did not attend community events between December 2006 and March 2007.

Figure 2

Follow-up and Timing Results

	Community n = 337 (%)
Follow-up Recommendation	
• Within 6 Weeks	2 (0.5)
• 3 Months	11 (3.3)
• 6 Months	13 (3.9)
• One Year	263 (78.0)
• Cannot Be Graded*	40 (11.9)
• Process Not Completed	8 (2.4)
Average Process Time (min): (Registration, Imaging, Grading)	11.99

Note: Subjects rated "Cannot Be Graded" may be contacted to schedule another imaging session.

Table 2

Recommendations

- **Set-Up**
 - o During the course of attending these events the Evaluation Team members were able to suggest numerous improvements to the set-up process. Perhaps the most important was the production of the "Camera and LAN Assembly Manual". See Appendix D. This was then used by staff to more efficiently ready the equipment before screening.

- **Trained Staff**
 - o Personnel who are properly trained to take retinal images are a must. That person must also be familiar with the image acquisition software. Ideally, personnel should be well-trained with the mechanisms of the software so that they can overcome technical problems.
 - o Since this is a mobile device, more than one person should attend the events in order to help lift the camera and set-up the system. Improvements to the mobile system could include the permanent attachment of the camera to the camera table. This would prevent injury caused during the lifting of the camera. However, a protective case would have to be designed and built for the camera for this type of application.
- **Equipment**
 - o The equipment van has been imperative to the success of this project. Equipped with an elevator, the van allowed for easy loading/unloading of heavy equipment. Extension cords and duct tape (to secure loose wiring) should always be included. The purchase of a mobile cart was invaluable to this project. The cart contained the computer with most of the equipment already plugged into it. This greatly lessened the set-up and take down times of the mobile system. It also lessened the likelihood of human error during set-up.
 - o One of the problems associated with this project was the acquisition of a dark area so high quality images could be taken. Subjects with smaller pupil sizes have had imaging problems, partly due to the room/space not being dark enough. Solutions could include the purchase of a dark tent that could be set up in any location. The van could also be converted to a permanent, mobile screening location. However, major modifications to the van would have to be made. Subject safety may be compensated as well with this method in regards to boarding and leaving the van via the elevator.
- **Subject Turn-out**
 - o Some of the community events had minimal subject turn-out and study participation. This could be due to the fact that some community events were not solely for diabetics. Another reason included adverse weather conditions that may have discouraged subjects from traveling to the community events. Diabetes focused events were observed to be more successful than non-focused events, and larger events (i.e. community health fairs) were also rather successful. If subjects are properly informed before hand, recruitment may improve. Establishing relationships with key community event personnel may further help advertising and recruitment processes.

Clinical Sites

History

The first clinical site was General Internal Medicine Clinic at UPMC Montefiore Hospital. Imaging began there on November 16, 2005. This was the first site where a dedicated camera was located within the clinic. The second site was the Center for Diabetes and Endocrinology, Falk Clinic at UPMC Presbyterian Hospital and imaging began there February 28, 2006. A camera was also located within the clinic.

Clinical Demographics

	Falk Clinic n = 122 (%)	General Internal Medicine n = 247 (%)
Gender		
• Male	60 (49.2)	122 (49.4)
• Female	62 (50.8)	125 (50.6)
Mean Age (Years)	51	57
Race		
• Caucasian	89 (73.0)	132 (53.4)
• African American	28 (23.0)	102 (41.3)
• Asian	1 (0.8)	2 (0.8)
• Hispanic	3 (2.4)	0
• Multi-Racial	1 (0.8)	1 (0.4)
• Other/Unknown	0	10 (4.1)
Diabetes		
• Type 1	44 (36.1)	18 (7.3)
• Type 2	78 (63.9)	229 (92.7)
Mean Duration of Diabetes (Years)	12.6	9.9
Mean A1C Percentage	7.4	7.3
Last Eye Exam		
• Less than 1 Month	3 (2.5)	4 (1.6)
• 1 – 3 Months	5 (4.1)	24 (9.7)
• 3 – 6 Months	19 (15.6)	28 (11.3)
• 6 – 12 Months	41 (33.6)	73 (29.6)
• Greater than 12 Months	51 (41.8)	111 (45.0)
• Never	3 (2.5)	4 (1.6)
• Unknown	0	3 (1.2)

Table 3

Observations

Once the location of the cameras was established, both in rooms where privacy and darkness was assured, no imaging problems were observed. Occasionally, software/programming errors similar to those in the community setting occurred. The challenge was with recruitment.

Breakfast Meetings

Retinal screening was introduced to the clinical staff at breakfast meetings. General Internal medicine was held on February 3, 2005 and at Falk Clinic on March 3, 2006. Both breakfasts were well attended by nurses and medical assistants. Many questions were asked about procedure and retinopathy. Staff was given the opportunity to visit the camera room and have their image taken.

Interviews

Interviews were conducted with the imagers in both clinics. The pager system in General Internal Medicine seems to be working fine. Sometimes the imager has to wait for a patient to have their blood work completed. The camera room still needs some equipment e.g. lamp. At Falk Clinic the patients are not remembering to stop at the camera room. The staff also needs to remember to phone the imager to come to escort the patient to the camera room.

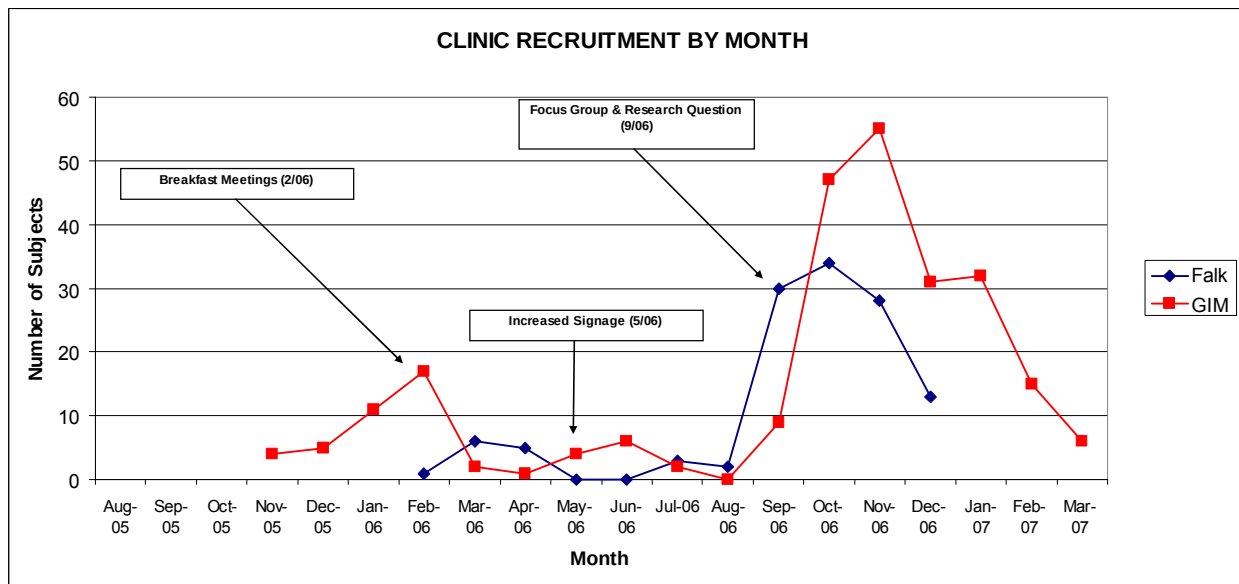
Focus Group Consensus

- Increase signage.
- Question if physician needs to write order?
- Patients often in hurry.
- Staff/physicians forget to offer to patients.
- Question staff handling consent forms?
- Staff willing to help with study.
- Physicians need more information.

Interventions

During the observation period four interventions occurred. The first were the breakfast meetings held in February, 2006. In May of 2006, the clinics began to display a poster advertising fast, easy, and no eye drops (dilation) required eye screening for patients with diabetes. The most dramatic improvements occurred in September, 2006 when focus groups were held at each clinic and the addition of a question asking if they were interested. In General Internal Medicine, it was a question added to their electronic tablet that a patient is asked to complete on each visit. At Falk Clinic, the same question was added to the hard copy of the medical history form that the patient is asked to complete. Their impact on recruitment is displayed in Figure 3.

Recruitment Results



Note: Falk Clinic relocated after December 2006. Imaging is to restart in June 2007.

Figure 3

Follow-up and Timing Results

	Falk Clinic n=122 (%)	General Internal Medicine n=247 (%)
Follow-up Recommendation		
• Within 6 Weeks	2 (1.6)	2 (0.8)
• 3 Months	10 (8.2)	6 (2.4)
• 6 Months	5 (4.1)	10 (4.1)
• One Year	94 (77.1)	181 (73.3)
• Cannot Be Graded*	11 (9.0)	46 (18.6)
• Not Imaged	0	2 (0.8)
Average Process Time (min): (Registration, Imaging, Grading)	18.10	11.39

Note: Subjects rated "Cannot Be Graded" may be contacted to schedule another imaging session.

Table 4

Recommendations

- **Communication With Clinical Staff**
 - o Despite a slow start in the clinical settings participation levels have increased. The Evaluation Team found it important to remind clinical staff periodically of their study participation. This was due primarily to the traffic encountered at each of the clinics and also clinic personnel turnover.
 - o The addition of the electronic research question in General Internal Medicine proved to be effective, because upon clicking yes to the question, a page was

automatically sent to the study coordinator. The coordinator would then meet with the subject to go over the consent form and answer any of the subject's questions. Prior to this, study recruitment depended on clinic staff to inform the patient of the study and then call the coordinator if the patient was interested. A paper copy of this research question is distributed in the Falk Clinic to patients. This too has increased recruitment levels.

- **Increase Patient Interest**

- o One of the major problems encountered in the clinic was that the patient did not have time to participate. They were "in a hurry". Often when patients are at the clinic, they have to wait to check-out, and the study coordinator is not allowed to proceed to the imaging room until the patient is done checking out. Registration and imaging times averaged 11:55 in the clinic setting. If subjects were allowed to be seen by the study coordinator while they were waiting to be checked out, time may be saved and recruitment may also increase.

- **Electronic Health Records**

- o The project could also be absorbed into the current PACS system. Patient's retinal images could be tracked and attached to their electronic health record. This would enable their retinal images to be more accessible to patients' primary care physicians and eye care specialists. The current software for this project would require alteration in order to facilitate interoperability with an electronic health record. This may encourage the medical staff to recommend to their patients having images taken. This may also interest health care insurers in coverage for retinal screening.

Combined Totals

Combined Demographics

	Total n = 706 (%)
Gender	
• Male	314 (44.5)
• Female	392 (55.5)
Mean Age (Years)	58
Race	
• Caucasian	486 (68.8)
• African American	194 (27.5)
• Asian	6 (0.8)
• Hispanic	6 (0.8)
• Multi-Racial	2 (0.3)
• Other/Unknown	12 (1.8)
Diabetes	
• Type 1	83 (11.8)
• Type 2	623 (88.2)
Mean Duration of Diabetes (Years)	9.4
Mean A1C Percentage	7.3
Last Eye Exam	
• Less than 1 Month	22 (3.1)
• 1 – 3 Months	54 (7.7)
• 3 – 6 Months	79 (11.2)
• 6 – 12 Months	185 (26.2)
• Greater than 12 Months	335 (47.5)
• Never	25 (3.5)
• Unknown	6 (0.8)

Table 5

Recruitment Results

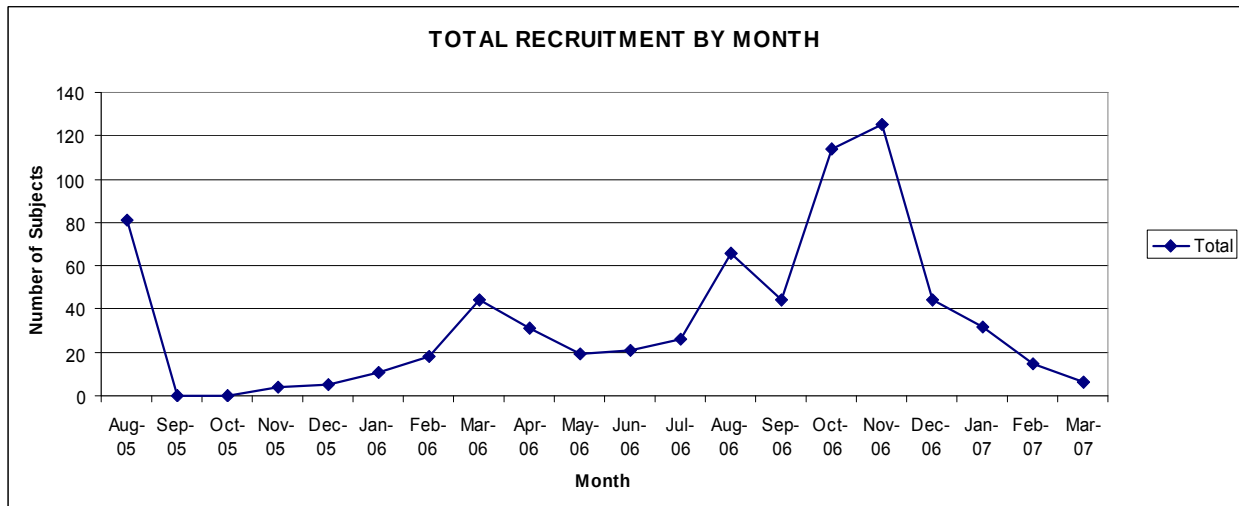


Figure 4

Follow-up and Timing Results

	Total n = 706 (%)
Follow-up Recommendation	
• Within 6 Weeks	6 (0.9)
• 3 Months	27 (3.8)
• 6 Months	28 (4.0)
• One Year	538 (76.2)
• Cannot Be Graded*	97 (13.7)
• Process Not Completed	10 (1.4)
Average Process Time (min): (Registration, Imaging, Grading)	12.88

Note: Subjects rated "Cannot Be Graded" may be contacted to schedule another imaging session.

Table 6

Conclusions

- Eyes do not need to be dilated to produce a gradable retinal image.
- Quality retinal screening can be mobile.
- Mobile screening may reach those who do not have easy access to eye care professionals.
- A limitation of the screening is that we may not be reaching those most in need of eye care
- Quality retinal screening can be done in a clinical setting.

KEY PROJECT ACCOMPLISHMENTS

- Designed, developed, and implemented a prototype image and metadata transfer system.
- Created screens and software components to support registration, imaging, grading, tracking, and reporting processes.
- Purchased equipment to support the technologies associated with acquisition, management and archiving of image sets.
- Design developed with input from Wilford Hall Medical Center (WHMC).
- Supported WHMC assessment of retinal screening options for their Diabetes Center.
- Conducted an IRB approved research study designed to assess the feasibility and functionality of prototype system
- Based in part on results of the research study, adjusted clinical workflow processes and increased monthly patient enrollment figures by over 300%.
- Successfully demonstrated that the retinal screening software and workflow process can be used to overcome challenges of providing adequate screening and diagnostic services for people at risk for diabetic retinopathy.
- Assessed feasibility of integrating system for integration into hospital enterprise (i.e., Stentor PACS).
- Provided recommendations for improvements of software and network configurations.
- Project accomplishments disseminated to audience of professionals through abstracts, presentations, posters, informational brochures, and demonstrations of equipment.

REPORTABLE OUTCOMES

Presentations

This report of research accomplishments serves as a comprehensive summary of the outcomes of design, development, tests, and evaluations for the IMITS Teleophthalmology Retinal Screening System. In addition to this report (and associated appendices), the following presentations, not previously mentioned, were generated as a result of the work that was conducted as part of this deliverable. These documents provide supplemental information about the software, workflow, and evaluation findings with recommendations for advancing the science and integrating the process into the practice of routine care for people with diabetes.

Appendix	Author(s)	Title	Date	Format/Event
I	Wilson, R; Eller, A; Zgibor, J; Ward, J; Petrick, R; & Anthony, L.	<i>Assessing the Capabilities and Effectiveness of a Teleophthalmology Screening Program</i>	May 2006	Oral Presentation 2006 ATA San Diego, CA
J	Uttecht, SD; Eller, A; Smail, J; Ward, J; & Chang, PJ.	<i>Retinal Screening Workflow of the Populace at Health Fairs</i>	May 2006	Oral Presentation 2006 ATA San Diego, CA
K	Waller, S; Lane, G; Flynn, W; Ward, J; Eller, Bursell, SE; & Anthony, L.	<i>Learned from a Teleophthalmology Program in the US Air Force.</i>	May 2006	Poster 2006 ATA San Diego, CA
L	Eller, A; Chang, PJ; & Flynn, W.	<i>Seeing Tomorrow's Vision for the Future, Today</i>	May 2006	Exhibit Area Poster 2006 ATA San Diego, CA
M	Project Team	<i>Teleophthalmology Project Informational Brochure</i>	May 2006	Project Brochure 2006 ATA San Diego, CA
N	Waller, S., Lane, G., Flynn, W., Ward, J.B., Eller, A.W., Bursell, S.E., & Anthony, L.	<i>Lessons Learned from a Teleophthalmology Program in the US Air Force</i>	May 2006	Breakout Session Presentation 2006 ATA San Diego, CA
O	Wilson, R., Eller, A.W., Silowash, R., & Anthony, L.	<i>Implementation and Acceptance of Teleophthalmology Program for Retinal Screening in Clinical Settings</i>	May 2007	Oral Presentation 2007 ATA Nashville, TN
P	UPMC Project Team	<i>Teleophthalmology Project- PowerPoint Loop Presentation</i>	May 2007	Exhibit Area Presentation 2007 ATA Nashville, TN
Q	UPMC Project Team	<i>Retinal Images - PowerPoint Loop Presentation</i>	May 2007	Exhibit Area Presentation 2007 ATA Nashville, TN
R	UPMC Project Team	<i>Teleophthalmology Project Informational Brochure</i>	May 2007	Project Brochure 2006 ATA San Diego, CA
S	UPMC Project Team	<i>Teleophthalmology Project- PowerPoint Informational Presentation</i>	June 2007	Exhibit Area Presentation Showcase for Commerce Johnstown, PA

Conclusions

The primary goal of the Teleophthalmology Project was to develop and implement an image transfer system and enterprise image archive for retinal images. Non-mydriatic cameras captured visible light images of the retina and a customized wrapper integrated patient images with pertinent medical information into a DICOM object. Each object was transferred to a designated central server for subsequent examination.

The project was successfully implemented and the results are encouraging. The system enabled an efficient, non-invasive method for screening individuals at high risk for retinal disease and over 700 people screened for diabetic retinopathy. The design of a distributed architecture supports on-demand access to central repositories for rapid tie-in to other databases (central or otherwise) for healthcare information. Individually customized software components for workflow make the system readily adaptable to applications for other health conditions. For example, in cases of triage of wounded soldier, modifications to the software would enable immediate entry of medical information with digital images of injuries for rapid transfer to remote specialists for real time or delayed review. The software's customizable reporting features facilitate on-demand access to related hospital or battlefield statistics, which can be significant in tracking disease trends and localities.

Despite building this non-invasive, efficient screening procedure, the Diabetes Project initially had difficulty recruiting subject participant. Observations and focus group activities revealed some of the challenges that might be associated with adoption of the system. Of significance, health care staff appeared reluctant in prompting the screenings.

To be successful, a screening program may require:

- o Education of MD's & office staff
- o Education of diabetes associated staff and educators
- o Education of patients
- o Marketing and advertising
- o Ongoing evaluations and interventions to assure optimal usage

In summary, deliverables for the Teleophthalmology Project were completed and the feasibility of the system applications was demonstrated in health clinics using stationary equipment and in communities using portable equipment. Patient recruitment difficulties were not associated with the software, but rather with needs to better educated consumers. Alternative applications of the prototype system are currently under consideration, and UPMC ophthalmologists are meeting with health plan administrators and optical businesses to strategize incorporation of routine screenings into preventative healthcare curriculums.

APPENDICES

page 1



**OPERATIONS MANUAL FOR
TELEOPHTHALMOLOGY
DIABETIC RETINOPATHY
SCREENING SYSTEM**

Introduction

Welcome to the IMITS Teleophthalmology Diabetic Retinopathy screening system. This manual is intended as both an instruction set and a reference.

The system was designed to support retinal screenings for people at high risk for diabetic retinopathy. The Diabetes Project applied this system to a research study into:

1. how well participants having diabetes are being examined and treated for preventable eye malfunctions resulting from diabetic retinopathy
2. how easily participants could be screened at a variety of locations, including clinics and health fairs
3. how easily and efficiently grading and follow up could be done using the internet to allocate scarce resources (a single doctor, one clinical coordinator).

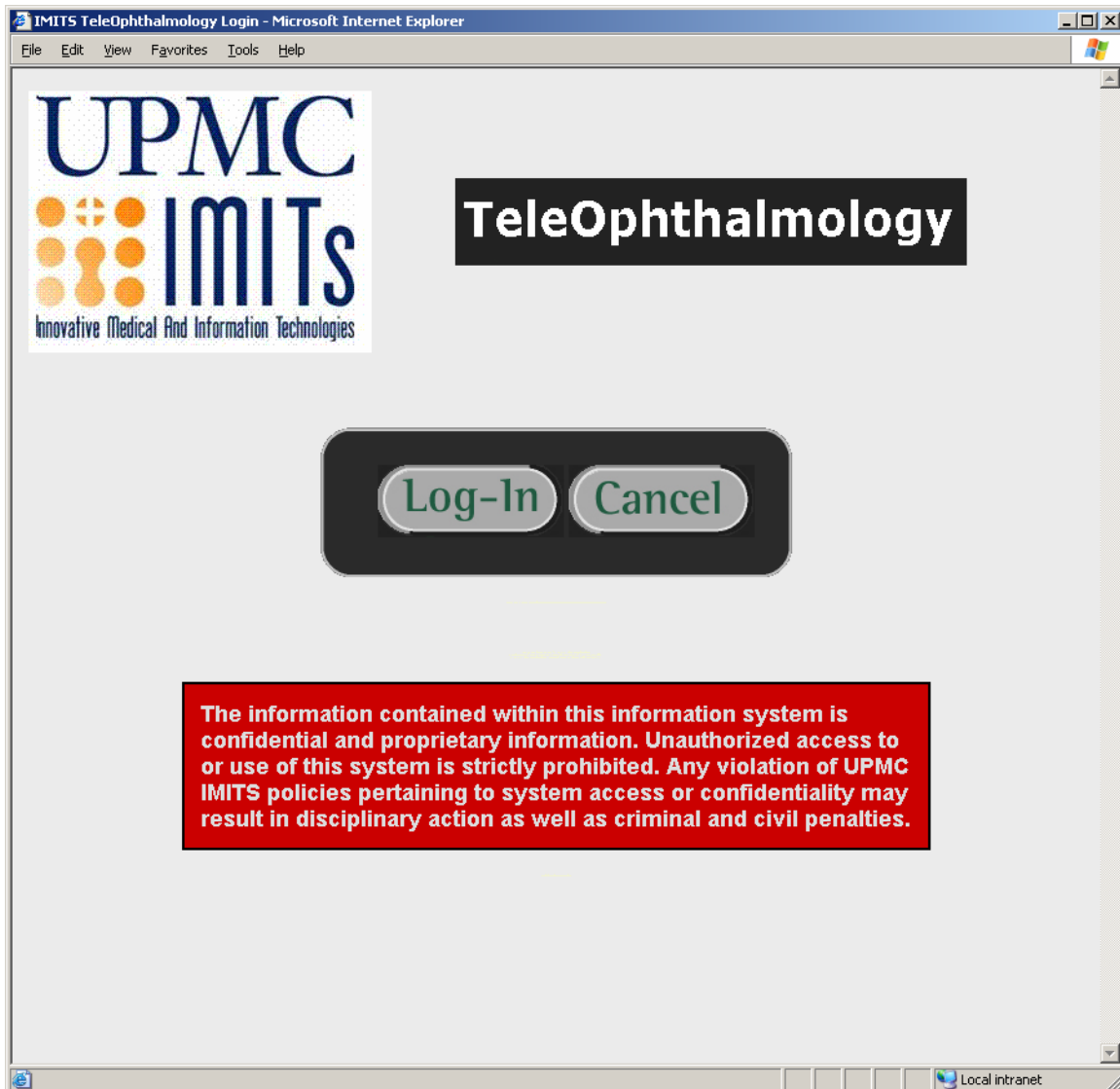
The information collected is minimal, focused on diabetes and eye conditions. This information could be later related to a medical record in a health plan, but the automatic link is not provided today.

The system has four key functions:

- **Registration**
This function allows the user to register a new participant and collect key statistics about the state of the participant's health with reference to his/her diabetes. The function also has an entry allowing editing of the information.
- **Imaging**
This function allows the user to select a participant for imaging and to add comments on any additional or unique attributes of the patient being photographed as well as any technical issues that may have been encountered during imaging process. A non-mydratic camera is used to capture the images and the imaging software then packages the images with registration and imaging data and transfers the images and data to the server.
- **Grading**
This function allows the user to access the server to select participants, either ungraded or graded, and review their results. For ungraded participants, the level of retinopathy, maculopathy, quality of the image, and recommended results can be saved, based on analysis of the images. For graded participants, a QA result can be saved.
- **Tracking and Reporting**
The tracking function allows the user to review and record follow up information about the participant's behavior, based on the recommendation from the grading ophthalmologist.

The reporting function allows the user to quickly collect distribution statistics for the screened population.

Since key personal data is being collected in the system, it is a secure system. The system opens with a Login page; when run on a secure system like UPMC's network, the system uses integrated security and requires a valid username and password.

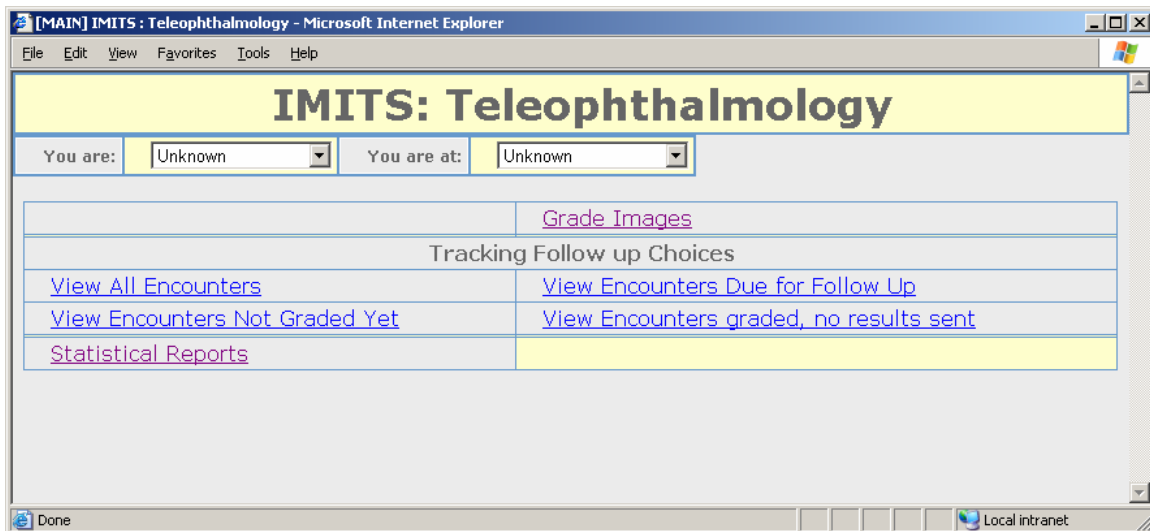


When used outside of a secure network, the user's login must be pre-registered in the database. Only existing users can be selected and use the system. If a user is not selected, further functions will return the user to the main page.

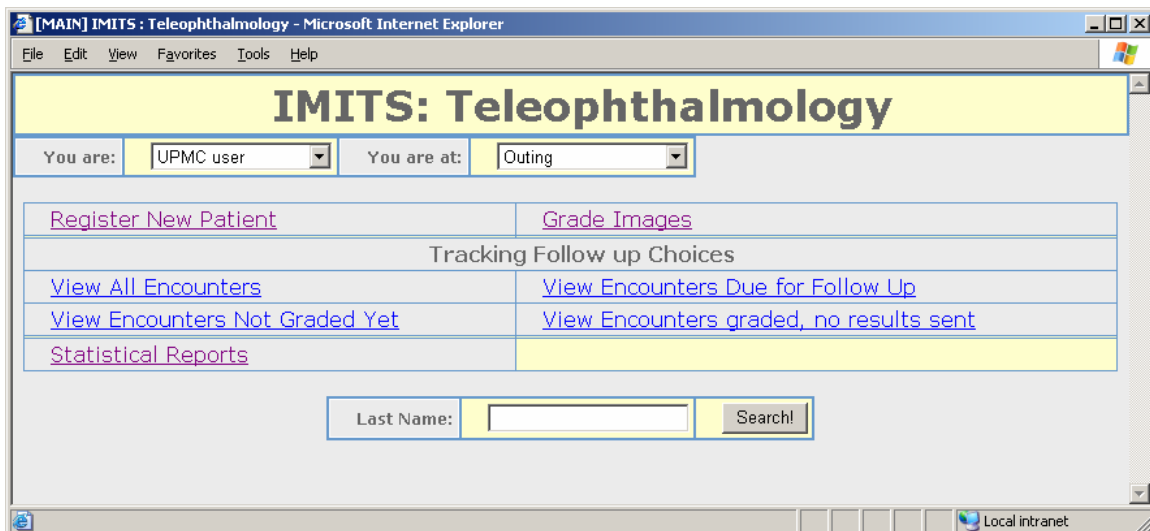
All screens, in all functions, require that login be done first; the user cannot bookmark a page and later bring it up directly. If the user tries to bring up the bookmarked page, an automatic function will redirect the user to the login page.

Administration

The first screen you see after you login is the administration screen.



Once you have selected a user name and location, additional functions appear:



You can search the database for a “repeat” participant and either edit some personal data (if for instance the participant corrects information before the initial encounter is over), or enter a new encounter for a participant who has been imaged before.

Registration

The registration is a series of screens, where the first screen shown establishes basic participant identifying and contact data. On a repeat encounter, this screen will be filled in from database, but can be edited if details (e.g., address, phone) have changed.

IMITS: Teleophthalmology Registration - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites

IMITS: Teleophthalmology

Demographics - Page 1:

First Name:	
Middle Name:	
Last Name:	
Name Suffix:	
Gender:	
Date of Birth:	
Address Line 1:	
Address Line 2:	
City:	
State:	
Zip Code:	
Home Phone:	
Other Phone:	
Race:	
Begin Registration:	5/12/2007 9:46:09 PM

Comments:

Next ->

[Return to Main Page](#)

Done Local intranet

This is followed by screens defining each encounter; the screens are numbered, and the last screen says “Last Page” and the button at the bottom says “Finish.” For any required fields left blank or filled with invalid data (e.g., date of birth this year), the screen refreshes with the fields filled in and an error message next to the field causing the problem. Each time you click on the button, whether Next or Finish, the data entered is saved, if there were no errors. If the Return to Main Page link is used, no data from that page is saved, and the user is returned to the Administration page. The Search could be used to edit and complete the participant’s registration later.

IMITS: Teleophthalmology Registration - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Local intranet

IMITS: Teleophthalmology

Demographics - Page 2:

Type of Diabetes:	Type I
Gestational (Y/N):	No
Year of Diagnosis:	2006
Hbg A1C Level:	Never heard of it

Comments: testing for ATA

Next ->

[Return to Main Page](#)

Done Local intranet

Note that the study is limited to participants with diabetes; the choices are Type 1 or II. If the Hbg A1C level is known, an input slot will appear where the percentage can be entered.

IMITS: Teleophthalmology Registration - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Local intranet

IMITS: Teleophthalmology

Prior Treatments for Diabetic Retinopathy:

Add Another

☒ None		☐ OD	☐ OS
☐ Laser		☐ OD	☐ OS
☐ RD Repair		☐ OD	☐ OS
☐ Vitrectomy		☐ OD	☐ OS
☐ Other		☐ OD	☐ OS

Comments: testing for ATA

Next ->

[Return to Main Page](#)

Done Local intranet

IMITS: Teleophthalmology

Other Medical / Diabetic Problems:

Add Another

☐ None	
☐ CAD - Coronary Artery Disease	
☐ Cholesterol	
☒ Depression	
☐ Foot Disease	
☐ HTN - Hypertension (High Blood Pressure)	
☐ Neuropathy	
☐ Renal	
☐ Other	

Comments:

testing for ATA

Next ->

The comment section is cumulative, so additional comments can be added, or deleted as the registration progresses.

Note that if the user needs to 'go back' to a page, rather than using the back button, the preferred technique is to use the link to Return to the Main Page, do a search on the participant/encounter, and then use the edit link (click on the name) to find the right screen and correct the entry. This ensures that the database is updated correctly.

IMITS: Teleophthalmology Registration - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites

IMITS: Teleophthalmology

Other Eye Problems:

Add Another

☒ None		☐ OD	☐ OS
☐ AMD (Macular Degeneration)		☐ OD	☐ OS
☐ Cataract		☐ OD	☐ OS
☐ Glaucoma		☐ OD	☐ OS
☐ Trauma		☐ OD	☐ OS
☐ Other		☐ OD	☐ OS

Comments:

testing for ATA

Next ->

[Return to Main Page](#)

Done Local intranet

IMITS: Teleophthalmology Registration - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites

IMITS: Teleophthalmology

Other Eye Surgery:

Add Another

☒ None		☐ OD	☐ OS
☐ Cataract Extraction		☐ OD	☐ OS
☐ Glaucoma Surgery		☐ OD	☐ OS
☐ Retinal Detachment Repair		☐ OD	☐ OS
☐ Other		☐ OD	☐ OS

Comments:

testing for ATA

Next ->

[Return to Main Page](#)

Local intranet

IMITS: Teleophthalmology Registration - Microsoft Internet Explorer provided by UPMC

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Go Links

Address <http://localhost:2275/Website/register.aspx?UniqueIdentifierParticipant=11073&UniqueIdentifierEncounter=999857&idRegistrationStage=7&id>

IMITS: Teleophthalmology

Medication Types:

Add Another

☐ None	
☒ Cardiac	
☐ Cholesterol	
☒ Diabetic	
☐ Hypertensive	
☐ Neurological	
☐ Depression	
☐ Renal	
☒ Other	atenolol

Comments:

Next ->

[Return to Main Page](#)

Done Local intranet

The screenshot shows a web browser window titled "IMITS: Teleophthalmology Registration - Microsoft Internet Explorer". The page has a yellow header with the text "IMITS: Teleophthalmology". Below the header, the text "Demographics - Last Page:" is displayed. The form contains several input fields and dropdown menus, all with yellow backgrounds. The fields are: Eye Doctor Name (Dr. Jones), Eye Doctor City (Pittsburgh), Eye Doctor Type (O.D.), Last Dilated Eye Exam (> 12 mos ago), Pupil Size OD (3), Pupil Size OS (3), PCP Name (Dr. Dickinson), PCP City (Carnegie), Share exam results with your Eye Doctor? (No), and Share exam results with your PCP? (No). Below these fields is a large text area labeled "Comments:" containing the text "testing for ATA". At the bottom left of the form is a "Finish" button. Below the "Finish" button is a link "Return to Main Page". The browser's status bar at the bottom shows "Done" and "Local intranet".

Demographics - Last Page:	
Eye Doctor Name:	Dr. Jones
Eye Doctor City:	Pittsburgh
Eye Doctor Type:	O.D.
Last Dilated Eye Exam:	> 12 mos ago
Pupil Size OD:	3
Pupil Size OS:	3
PCP Name:	Dr. Dickinson
PCP City:	Carnegie
Share exam results with your Eye Doctor?	No
Share exam results with your PCP?	No

Comments: testing for ATA

Finish

[Return to Main Page](#)

The last page of registration, when completed and submitted via the Finish button, causes the workflow stage to be set to “ready to image” so that this user will now appear in the list of participants for imaging shown on the Topcon workstation.

Grading

The first screen you see when you have clicked on Grade Images is the Grading List selection screen. Initially this shows only a list of participants with ungraded images. By checking one of the other two boxes and clicking on Get List, the user can see participants with graded images.

Participant ID	Encounter	First Name	Middle Name	Last Name	Suffix Name	Participant Date Of Birth	Participant Gender	Begin Registration	Workflow Stage	Imager	ReaderName	Is a QA Reader	Teaching Case
11097	999883	test	test	test		08-01-1940	F	5/4/2007 10:26:06 AM	Imaging	Bivins, Faith	Eller, Andrew W	True	

This screen only displays a limited number of entries; if there are more entries than can fit on a page, a 'next' page number is displayed at the bottom (scroll down). If more than ten (10) pages worth of entries exist, an underscore is displayed at the end of the list of page numbers; click on that to see the next range of page numbers.

Clicking on the Participant Id link brings up the Grading screen:

IMITS: Teleophthalmology

Registration Data
 Name: test test
 Participant ID: 11078
 Encounter ID: 999862
 Gender: M
 Date of Birth: 03/24/1955
 Ethnicity: Caucasian
 Diabetes Type: Type I
 Diagnosed: 1968
 Hgb A1C Understanding: Known
 Hgb A1C: 5.000%
 Last Eye Exam: 6 - 12 mos ago
 Pupil Size: od 3 - os 3
 Eye Doctor's Name: Dr Scott Portnoy
 Eye Doctor's Type: M.D.
 Eye Doctor's City: Pittsburgh
 PCP's Name:
 PCP's City:

Participant Images
 Right Eye
 Left Eye

Image Quality
☐ Excellent
☐ Adequate
☐ Poor, but barely gradeable
☐ Poor, unable to grade

Recommended Follow-Up
☐ one year-normal
☐ one year - mild
☐ 6 months
☐ 3 months
☐ Within 6 Weeks

☐ Teaching File
☐ External image enhancement software was used to help diagnosis

Reader Comments

Error Messages

Save

Retinal Findings -- Right Eye
 Maculopathy
☐ Yes ☐ No
 Level of Retinopathy
☐ A. None
☐ B. Microaneurysms
☐ C. Intraretinal Hemorrhages
☐ D. Hard Exudates (HE)
☐ E. Cotton Wool Spots

Retinal Findings -- Left Eye
 Maculopathy
☐ Yes ☐ No
 Level of Retinopathy
☐ A. None
☐ B. Microaneurysms
☐ C. Intraretinal Hemorrhages
☐ D. Hard Exudates (HE)
☐ E. Cotton Wool Spots

The left column reflects all of the data entered during Registration for this patient and this encounter. The columns beneath the images and to the right are for grading entries.

Double click on the small image brings up a window with the enlarged image for full viewing, for either eye.

Required grading entries are **Image Quality**, **Recommended Follow-Up**, and under Retinal Findings (by eye), **Maculopathy** and **Level of Retinopathy**.

Scroll down to see the rest of the screen:

IMITS: Teleophthalmology Grading Page - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Search Favorites

Medication Types
None

Screening Location: Outing

Register: UPMC user
Register Login Name: cecilra

Imager: Bivins, Faith
Imager Login Name: bivinsf

Reader: Eller, Andrew W
Reader Login Name: ellowaw
Reader Is a QA Reader: False

QAReader: Unknown
QAReader Login Name: unknown
QAReader Is a QA Reader: False

Logged In Person: IMITS-T43-B\Administrator

Registration Comments
testing for ATA

Imaging Comments
Enter Comments Here

Findings:

☐ B. Microaneurysms	☐ B. Microaneurysms
☐ C. Intraretinal Hemorrhages	☐ C. Intraretinal Hemorrhages
☐ D. Hard Exudates (HE)	☐ D. Hard Exudates (HE)
☐ E. Cotton Wool Spots	☐ E. Cotton Wool Spots
☐ F. Venous Beading	☐ F. Venous Beading
☐ G. Intraretinal Microvascular Abnormalities (IRMA)	☐ G. Intraretinal Microvascular Abnormalities (IRMA)
☐ H. Neovascularization Elsewhere (NVE)	☐ H. Neovascularization Elsewhere (NVE)
☐ I. Neovascularization of the Disc (NVD)	☐ I. Neovascularization of the Disc (NVD)
☐ J. Vitreous Hemorrhage	☐ J. Vitreous Hemorrhage
☐ K. Tractional Retinal Detachment	☐ K. Tractional Retinal Detachment
☐ L. Previous Laser Scars	☐ L. Previous Laser Scars
☐ M. Rhegmatogenous Retinal Detachment	☐ M. Rhegmatogenous Retinal Detachment
☐ N. Retinal Thickening in Macula	☐ N. Retinal Thickening in Macula
☐ O. Soft Exudate (SE)	☐ O. Soft Exudate (SE)
☐ P. Other	☐ P. Other

Maculopathy
☐ Yes ☐ No

Other Findings

☐ A. None	☐ A. None
☐ B. Macular Degeneration	☐ B. Macular Degeneration
☐ C. BRVO	☐ C. BRVO
☐ D. CRVO	☐ D. CRVO
☐ E. Glaucoma	☐ E. Glaucoma

Save

Print

(1 item remaining) Downloading picture http://imits-t43-bc:/Ophthalmology/Images/HealthFairs/1.2.840.10008.114368.223590.1432802

Local intranet

Note that clicking SAVE is required to save the data on this page. If any error messages (in red text) appear, the entries WERE NOT SAVED. They must be made again, the errors corrected, and SAVE clicked once more.

Clicking on print brings up an identical page, but in printer-friendly format.

Tracking

Clicking on any of the Tracking links brings up the same screen, but with slightly different numbers of participants selected, depending on the stated criteria.

Participant's Name	Date Of Study	Sent Copy of Consent Form to Participant	Study Grade (Requested Follow-Up Timeline)	Sent Image Results Letter to Participant	Participant Requests Copy Of Results To Eye Doctor	Completed Giving Copy Of Results To Eye Doctor	Participant Requests Copy Of Results To PCP	Completed Giving Copy Of Results To PCP	Planned Follow-up Date	Reminded Participant of Requested Follow-up	Actual Follow-up Date	Participant Complied with Follow-up	Participant's Comments on Complying with Follow-up
test test	5/4/2007	☐		☐	No		No			☐		Unknown	

The link on the Participant's name pops up a small display with contact information: phone numbers, address, etc.

When the user checks any of the boxes, the database is updated immediately, and the entire screen refreshes. This is also true for the Comments and Actual Follow up Date. Checking the “reminded participant of Requested Follow up” box changes the status of the encounter, such that it no longer will appear in Tracking Requests “View Encounters Due for Follow Up.” If that selection criteria is being used to find participants, it is recommended that the comments and date fields be entered first, and the check be last.

Reporting

IMITS: Teleophthalmology

Counts by Ethnicity and Gender for date span: through

This is a very basic reporting screen; fill in dates and click on the submit button to see the results. The first date cannot be left empty; the ‘through’ date defaults to today, if left empty..

IMITS: Teleophthalmology

Counts by Ethnicity and Gender for date span: 2006-1-1 through

Description	Females	Males
Asian	0	0
Black	0	0
Caucasian	1	0
Hispanic	0	0
Multi-Racial	0	0
Native-American	0	0
Other	0	0

Teleophthalmology Diabetic Retinopathy Screening Image Capture

This supplement to the Teleophthalmology Diabetic Retinopathy Screening System is specific to the operation of the windows program (executable) which is used to take the images, and is run on a workstation that is equipped with the Topcon Imagenet software and connected via hardware cabling to the Topcon camera.

Before the windows program, named SimpleDICOMWrapper.exe, can be run, participants must have been registered through the **Registration** function described in the System manual.

The first **Select Patient** screen is displayed once the program has been started:

Registration Time	Unique Identifier	Participant's Last Name	Participant's First Name	MI	Participant's Birthdate
4/26/2007 8:02:08 AM	999873	Test	Test	tes	1/5/1956

This shows the details for all participants currently registered, for whom imaging is not complete. There may be several lines on this selection screen, if more than one participant has been registered. Select the participant by clicking on the line for the participant who is now physically waiting to be imaged.

Once a participant has been selected, you will see the Acquire Images screen:

If the name shown in the 3rd and 4th blue block does NOT match the name of the person sitting behind the camera, click on the **select patient** tab, and redo the selection on the first screen.

Click on the **Right Eye** icon, and this screen will be replaced with a window into the ImageNet software. Now you can use the camera to take a picture.

Once an acceptable picture is taken, click on the **Save** icon in the upper right-hand corner. This will return you to the Acquire Images screen. A thumbnail photo will appear next to the “Take one” label, and a larger image will appear below the name labels. As you take more pictures (up to 3 for each eye, each time clicking the icon to activate the ImageNet software), more thumbnails will appear, but the larger image will automatically be the last one taken. To see previous images larger, click on the desired and thumbnail, and the larger image will change.

When you have finished imaging for the participant, click on the **Submit Comments and Finish Imaging** button. A pop-up alert will appear to tell you that the submit succeeded.

You can close the program now, or click on the Select Patient tab, to set up another person for imaging, repeating the whole process.

System Installation

[references to VSS mean Visual Source Safe 2005 repository as found on IMITS-oph-DEV01.

1. The server

1. Create the database (using Enterprise Manager, create new database: currently named IMITS_ophthalmology, data file size 6 mb, transaction file size 345 mb. [no idea how these sizes were determined])
2. Create tables using sql table description found in VSS under Teleophthalmology/Database/Scripts: IMITS_ophthalmology-tables.sql
3. Load static data tables using VSS Teleophthalmology/Database/Scripts: idTableLoads.sql
4. Set the starting numbers for the participant and encounter tables by editing and then applying VSS Teleophthalmology/Database/Scripts: LaptopSetup.sql
5. In c:/inetpub/wwwroot/apps, create a folder name Teleophthalmology, and copy in the website code as published from an instance of VSS website code, using Microsoft Visual Studio.
6. Edit the web.config file to use local path names, defaults, usernames and passwords.
7. Under c:/inetpub/wwwroot, create a folder named ws; under that create another folder named TeleophthalmologyWS. Copy in the TeleophthalmologyWS code as published from an instance of VSS TeleophthalmologyWS code, using Microsoft Visual Studio.
8. Edit the web.config file to use local path names, defaults, usernames and passwords, particularly for the final destination for images. Note that a separate directory for images that can be set as a share drive has certain advantages, particularly for backup (easy to find).
9. Under TeleophthalmologyWS, create a folder named Images. Give write access to that folder to the imaging workstation.
10. In IIS, make sure the directory for images is visible, and accessible by the SimpleDICOMWrapper programs coming via the webservice. While there, check the options on the webservice and the website code as well (e.g., is default.aspx in the 'starting' list, are both correctly seen as websites).

2. The imaging workstation

1. Create a folder named SimpleDICOM; under that create a folder named raw images, and a folder named wrapper. Inside wrapper copy in the code compiled from a Visual Studio build of the SimpleDICOMwrapper application.
2. Find the SimpleDICOMWrapper.config file, and edit it to reflect the local pathnames and the server details.
3. Create a folder named scratch under SimpleDICOM as well.

IMITS TELEOPHTHALMOLOGY PROJECT STANDARD OPERATING PROCEDURES FOR RETINAL SCREENINGS

Dr. Andrew W. Eller, Principal Investigator

This document describes standard procedures for recruiting subjects and conducting tele-ophthalmology screening examinations for the IMITS Tele-Ophthalmology Project and the Diabetic Retinopathy Screening Study. Procedures were developed by project team members from the University of Pittsburgh Medical Center, the University of Pittsburgh, and Wilford Hall Medical Center.

1. SCOPE OF PROJECT

Individuals (age ≥ 18 years old) with a known diagnosis of diabetes mellitus will be invited to participate as subjects in this project. Subject information will be recorded and retinal images will be taken and graded by an ophthalmologist. Within a short time, subjects will receive their results and recommendations for follow-up care. Compliance with these recommendations will be tracked over time.

2. SETTINGS

Diabetic retinopathy screenings will be offered at identified UPMC clinics and throughout the greater Pittsburgh area at scheduled community events by means of a mobile unit.

UPMC Clinics

Clinic arrangements are made under the direction of Dr. Andrew Eller, working in collaboration with clinic management and project staff. Specified areas within each clinic are fully equipped and ready for operations as per project protocol requirements. Project staff is assigned to work with specific clinics to provide coverage as required for subject recruitments and screenings. Clinic staff, educated about the project and its potential benefits, work in partnership with project staff to identify and refer eligible participants to the project. Hospital staff may work in collaboration with clinic and project staff to arrange screenings for eligible inpatients.

As pre-arranged by Dr. Eller and in compliance with the IRB, specific strategies may be in place in a given clinic environment to boost subject enrollment (e.g., posters, brochures, questions on clinic questionnaires completed by patients).

Community

Community screenings arrangements are made in advance under the direction of Dr. Andrew Eller and the Project's Clinical Coordinator, working in collaboration with event coordinators or UPMC mobile unit managers. For each community event, the Clinical Coordinator will organize equipment and materials, schedule staff and make arrangements for on-call technical support coverage the day of the event.

3. REGISTRATION AND IMAGING

The following steps outline basic recruitment, enrollment and screening procedures applicable across all settings.

SUBJECT RECRUITMENT AND SCREENING		
Step	Personnel	Task
	ALL	a. Ensure privacy and confidentiality of subject's personal information. b. Ensure comfort and safety of subject.
1.0	Greeter	a. Greet individuals who approach or are directed to the screening area for information about the project and/or the screenings. b. Provide initial information about the screenings and determine eligibility (i.e., volunteer, 18+, known diabetes). c. Provide a consent form to the individual. d. Direct subject to consentor.
2.0	Consenter	a. Check eligibility: ▪ Volunteer ▪ 18 years or older ▪ Known diabetes ▪ Able to comprehend the terms of the consent form b. Review all components of consent form, assure individual understands the terms of the consent form, and address any questions or concerns. c. Request that the individual read and initial the bottom of each page and sign and date document in space provided. d. Witness subject signature and sign and date in space provided. e. Direct subject to registrar. <i>Note: Record any instances in which an eligible individual chose not to participate in the screenings along with the reason, if known (e.g., lack of time, the consenting process, etc.).</i>
3.0	Registrar	a. Check eligibility (volunteer, 18+, known diabetes) and consent form for initials on bottom of pages and signatures/dates. b. Provide a copy of the consent form for the subject or ask subject to address an envelope in order to receive a copy by mail. c. Using project software/equipment, ask subject to provide

SUBJECT RECRUITMENT AND SCREENING		
Step	Personnel	Task
		information needed to complete the Diabetic Retinopathy Screening questionnaire. d. Direct subject to imager.
4.0	Imager	a. Hold back of chair while subject is sitting down and ask subject to remain firmly in seat while images are taken. b. Check eligibility (volunteer, 18+, known diabetes). c. Using project software/equipment, bring up subject's information on monitor and review with subject as needed. d. Review imaging process with subject. e. Measure pupil size and take 1 - 3 photographs per eye based on the quality of the captured images. f. Review timeline for receiving results/recommendations letter from specialist. g. Thank subject for taking time to participate (adds value to the study) and direct him/her on as needed (e.g., to waiting area, facility exit). <i>Note: Be sure to use the text box to enter significant information about the imaging process or subject information that may have been omitted.</i> <i>Note: To enhance image quality:</i> ▪ Take images in a darkened room ▪ Have subjects follow the "green light: in the camera and keep teeth together (This helps keep the optic nerve where the imager needs it and keeps the subject from talking.) ▪ Ask subjects to close eyes for approximately 30 seconds between imaging.

4. IMAGING

RETINAL IMAGING		
Step	Personnel	Task
1.0	Imager	a. Double-click 'SimpleDICOMWrapper' shortcut on the desktop. b. Select or add your name as the imager. c. Select the subject from the list of registered subjects who are waiting to be imaged. Once a subject has been selected, you will see the 'Acquire Images' screen. d. Click on the 'Right Eye' or 'Left Eye' icon. Now you can use the camera to take a picture. e. Using the TopCon camera, focus the retinal image and press the trigger on the joystick to capture the image. f. When the image appears on the monitor, press the 'Save' button. This will return you to the 'Acquire Images' screen. DO NOT TAKE MULTIPLE PICTURES WITHOUT SAVING EACH ONE. g. At this time, you may enter optional comments in the area provided. h. Once an image has been saved, a thumbnail photo will appear next to the 'Take one' label, and a larger image will appear below the name labels. i. Repeat the process until all images have been captured (up to 3 for each eye). More thumbnails will appear, but the larger image will automatically be the last one taken. To see a larger image of a previous photo, click on the desired thumbnail. j. When you have finished imaging the subject, click on the 'Submit Comments and Finish Imaging' button. A pop-up alert will appear to tell you that the images were "Submitted Successfully". k. You can close the program now, or click on the Select Patient tab, to set up another person for imaging, repeating the whole process.

5. GRADING

GRADING AND REPORTING		
Step	Personnel	Task
1.0	Grader	a. Select the subject from the 'Grading List' of participants with ungraded images. b. This brings up the 'Grading' screen. The left column reflects all of the data entered during Registration for this subject and this encounter. The columns beneath the images and to the right are for grading entries. c. Double click on the small image to bring up a window with the enlarged image for full viewing, for either eye. d. Review the images and metadata and complete grading entries. Required grading entries are Image Quality, Recommended Follow-Up, and under Retinal Findings (by eye), Maculopathy and Level of Retinopathy. e. Click 'SAVE' (required) to save the data on this page. If any error messages (in red text) appear, the entries WERE NOT SAVED. They must be made again, the errors corrected, and SAVE clicked once more. f. Clicking on print brings up an identical page, but in printer-friendly format.

6. TRACKING AND REPORTING

TRACKING AND REPORTING		
Step	Personnel	Task
1.0	Coordinator	a. Select a 'Tracking' link to bring up a list of registered patients matching the selected criteria. b. The link on the subject's name pops up a small display with contact information: phone numbers, address, etc. c. Check boxes, add comments and dates in entry boxes to update the subject's record. Data is updated immediately and the entry screen refreshes.

2.0	Coordinator	a. To generate a report, fill in dates and click on the submit button to see the results. The first date cannot be left empty; the 'through' date defaults to today, if left empty.

7. PRIVACY AND CONFIDENTIALITY

All existing policies regarding privacy and confidentiality will be in effect for the teleophthalmology screenings. Every attempt will be made to ensure subject privacy and confidentiality during the screenings.

8. SAFETY AND INFECTION CONTROL

All local policies for infection control and equipment safety will be in effect.

Unanticipated problems involving subject or others will be reported in compliance with all existing policies.

9. DEFINITIONS

Teleophthalmology	Process in which digital photographs of eyes are transmitted telemetrically to a reading center and graded according to the degree of retinopathy found.
Consenter	Project team member trained and approved to consent subjects for participation in this research study (i.e., Principal investigator or an ophthalmic photographer/technician).
Grader	A clinician specializing in retinal disease.
Greeter	The staff member or healthcare provider that initially discusses the project with a potential subject.
Imager	Project staff member trained to photograph retinal images.
Registrar	Project staff member trained to collect required subject information.
Coordinator	Investigator conducting research evaluation of study.
Subject	Individual with <i>known</i> diabetes who agrees to participate in the retinal screening study.
Technical Support	Project staff member with expertise or training needed to assist with technical issues and/or the transfer of data to main server.

TopCon Camera and LAN Assembly Manual



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- **Equipment List.....3**
- **Contact Information.....3**
- **TopCon Camera Set-up.....4**
- **Computer Set-up.....10**
- **Power On Steps.....16**
- **Important Notes.....16**
- **Network and Sign On Information.....16**

Teleophthalmology Equipment

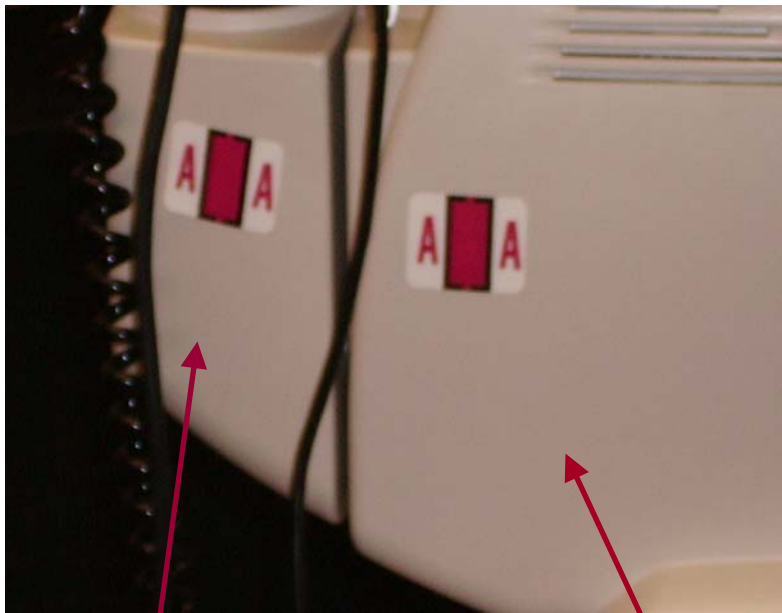
- 1 router with power supply
- 1 TopCon camera table
- 1 TopCon camera
- 1 Nikon camera and interface assembly
- 1 keyboard
- 2 mouse (1 for TopCon computer, 1 for tablet PC)
- 1 IBM T-43 Thinkpad laptop (server) with power cord
- 1 IBM X-41 ThinkPad tablet (registration) with power cord
- UPS device – white power box
- 25' Cat-5e or Cat 6 Ethernet cables
- 1 roll of duct tape
- 2 stools (1 for photographer, 1 for participant)
- cart for moving TopCon camera in case

Important Contact Information

- Steve's Cell: 412-779-9106 (weak signal while in office)
- Work: 412-692-4130
- Pager: 412-958-6501

TopCon Camera Assembly

- Select a good location for the camera. Remember to keep in mind the length of cord and the light requirements (dark) for the camera.
- Place the TopCon camera base onto the Topcon camera's table so that the imager's side of the camera is facing the hole in the table.
- **A: Attach the Nikon camera housing to the TopCon camera base. Once camera housing is correctly attached, LOCK the camera into position using the locking mechanism located at the top of the housing.**



**Nikon Camera
Housing**

**TopCon
Camera Base**

TopCon Camera Assembly (cont'd)

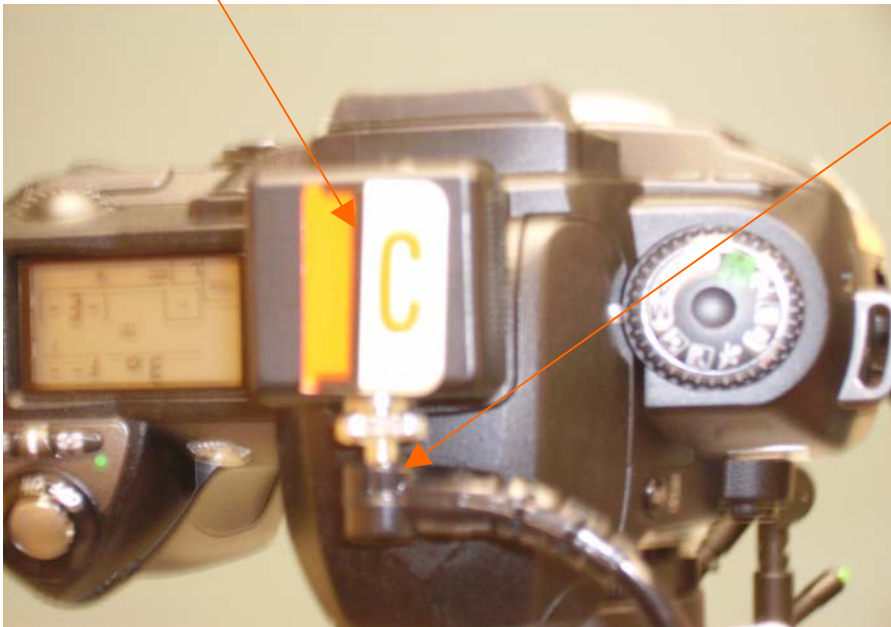
- **B:** On the Nikon camera, place Nikon power cord (cord B) into the DC in hole of the camera.
 - Run the cord through the hole on the table and connect to the EH-5 power supply
 - Run the AC cord from the power supply to the gray chloride power protector (white power box)
 - Place plug into orange labeled socket.



TopCon Camera Assembly (cont'd)

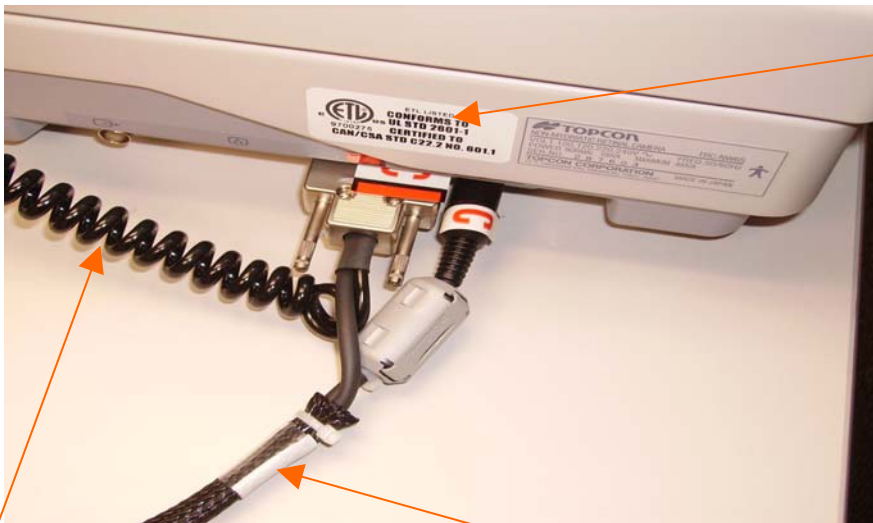
- C: 1. Attach the Nikon flash cord to the Nikon camera.

Side of Camera Facing Imager



Nikon Flash Cord

- C: 2. Attach the other end of the Nikon flash cord to TopCon camera base.



TopCon Base

Flash Cord
from Camera

TopCon Nylon Cord to
Computer

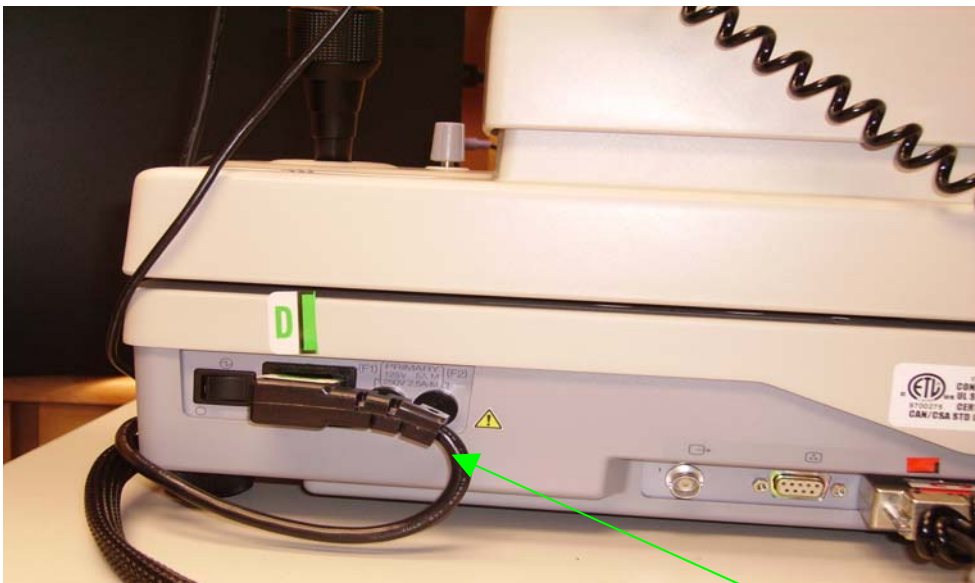
TopCon Camera Assembly (cont'd)

- C: 3. Run the TopCon nylon cord to back of TopCon computer.



TopCon
Nylon
Cord from
TopCon
Camera

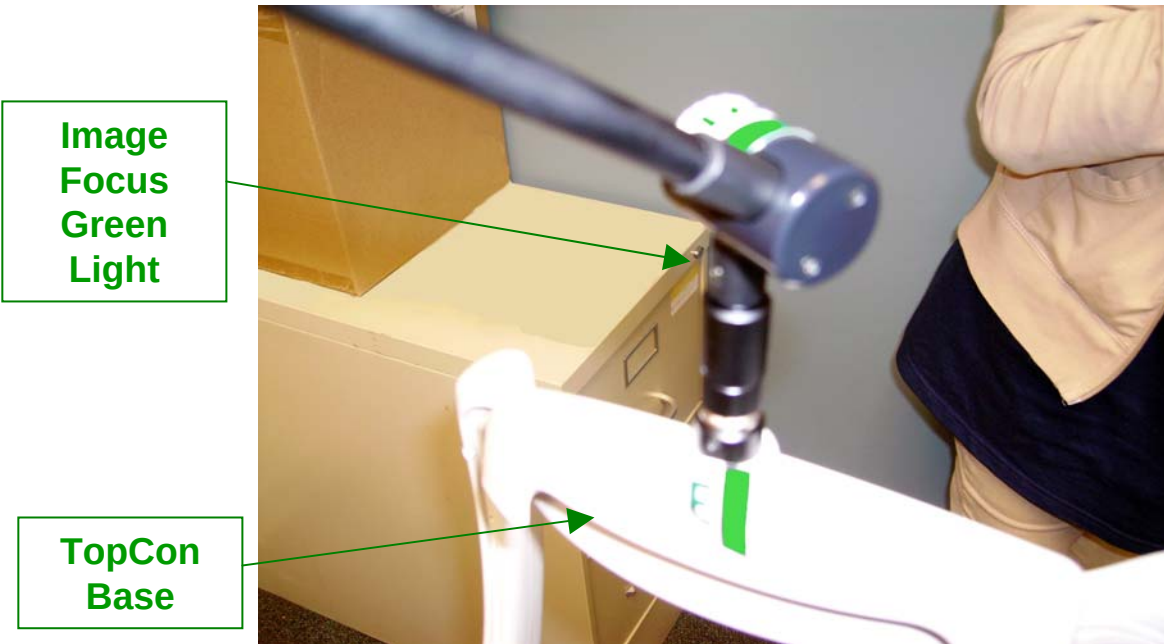
- D: Run the power cord from the TopCon base to the chloride power pack and insert the plug into the green labeled socket.



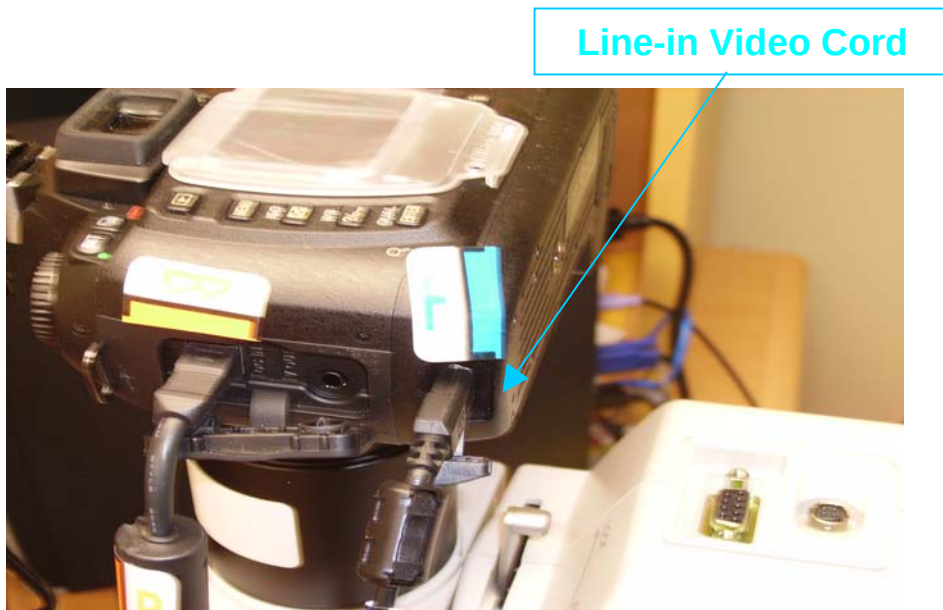
Power Cord

TopCon Camera Assembly (cont'd)

- **E: Attach the image focus green light to the TopCon base.**
 - Be sure to line up the A, B, C holes as well as the notch correctly before screwing the green light onto the base.

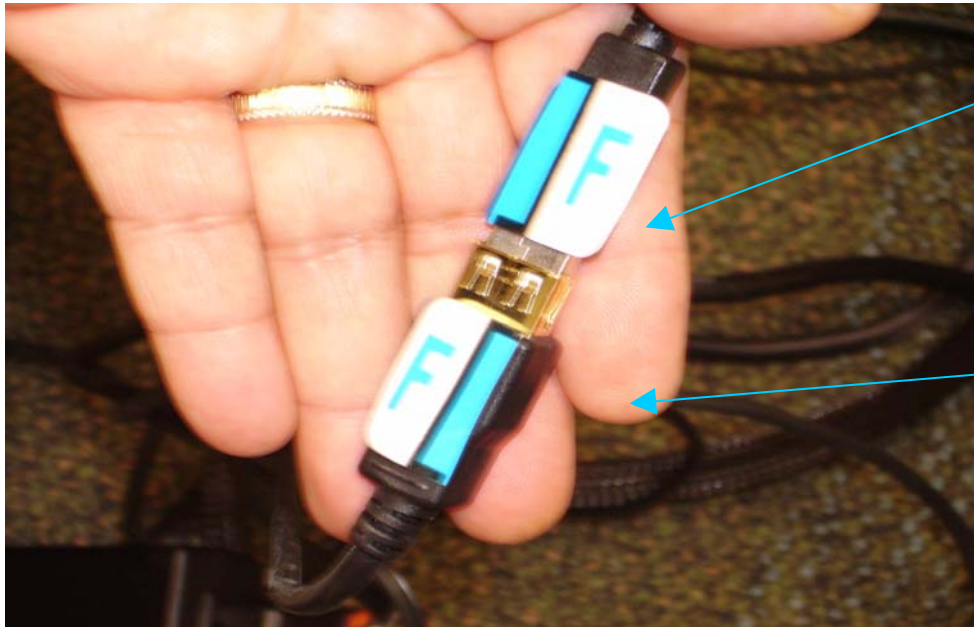


- **F: 1. Attach the line-in video cord to the camera.**



TopCon Camera Assembly (cont'd)

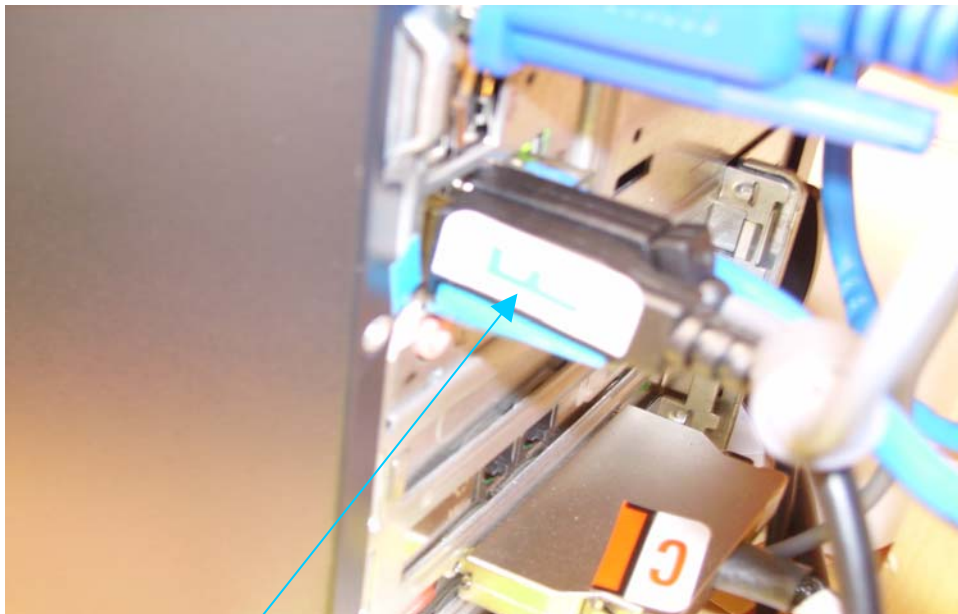
- **F: 2. Attach the line-in cord from the camera to the adapter.**



Adapter
to Free
USB Port

Line-in
Video Cord
from
Camera

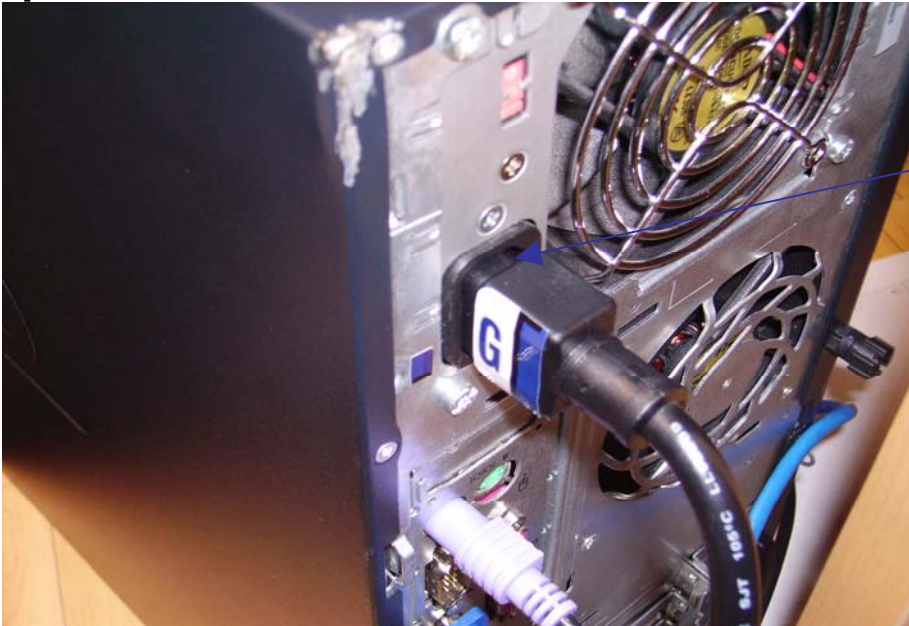
- **Run the adapter cord to a free USB port on the back of the computer.**



Cord from
Adapter

Computer Set-up

- **G: 1. Attach the computer power cord to the back of the computer.**



**Computer
Power
Cord**

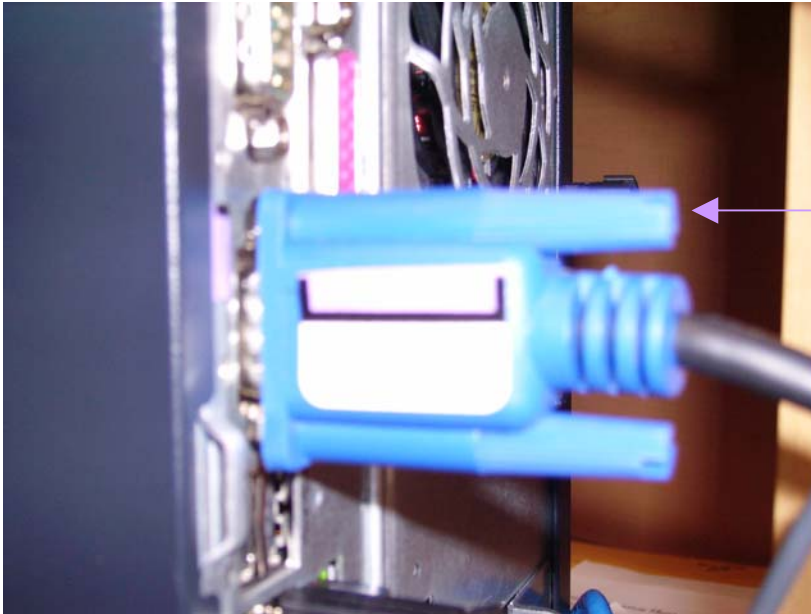
- **G: 2. Connect the power cord from the computer to the gray chloride power box.**



**Power Cord
from Computer**

Computer Set-up (cont'd)

- **H:** Attach the Monitor line from the back of the computer to the back of the monitor.



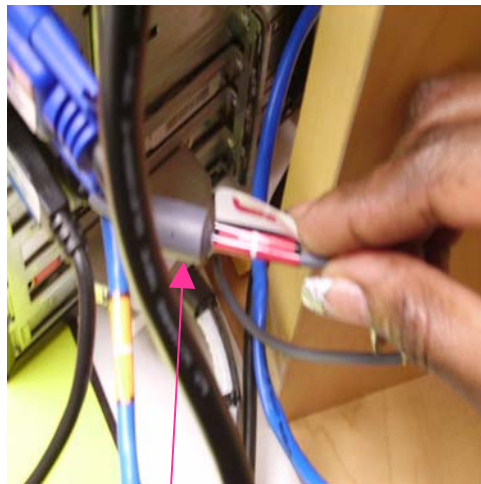
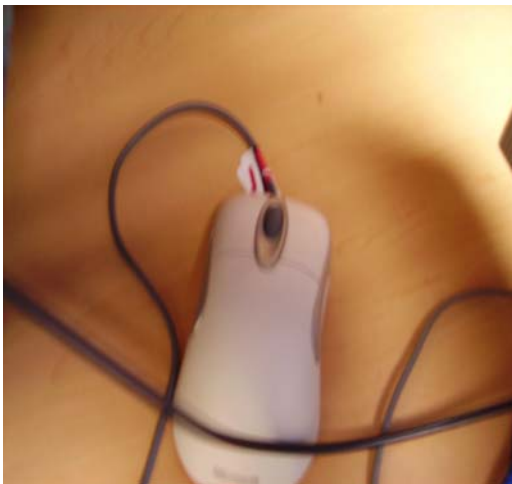
Monitor Line



Monitor Line
in Back of
Monitor

Computer Set-up (cont'd)

- **I:** The keyboard cord (I) connects to the back of the computer and is purple.

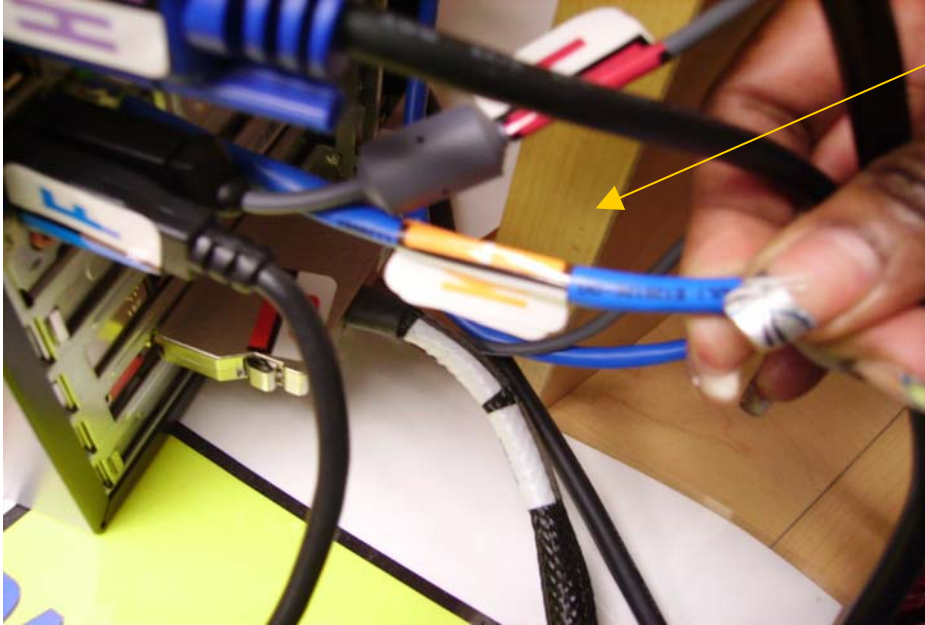


Mouse Prong

- **J:** The mouse has a gray prong and plugs into the back of the computer.

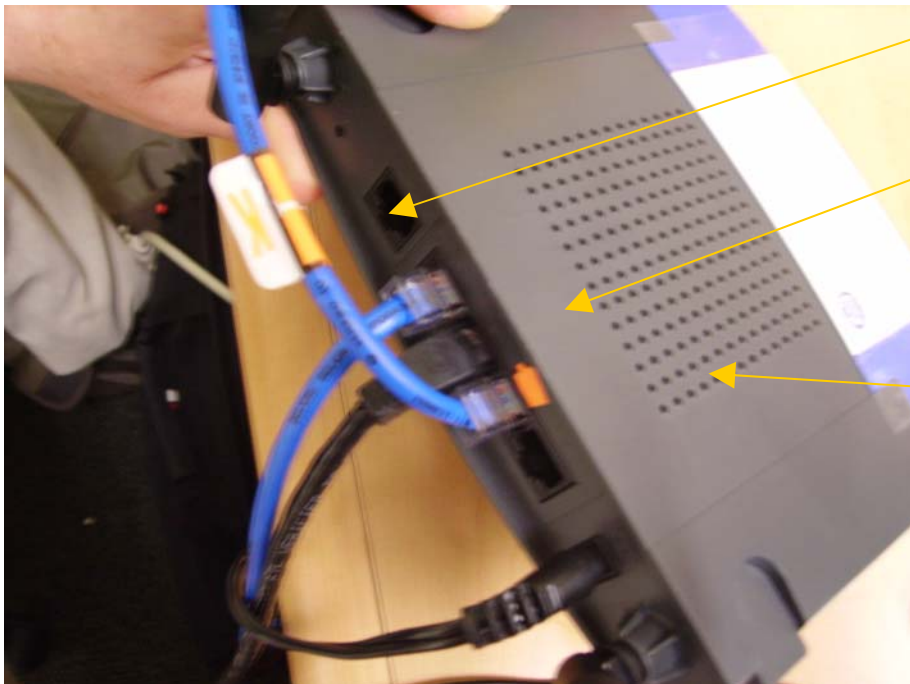
Computer Set-up (cont'd)

- **K: 1. Connect a blue Ethernet cable to an Ethernet port in the back of the computer.**



Ethernet Cable

- **K:2. Run the Ethernet cord from the computer to the router, which should be located in a central position.**



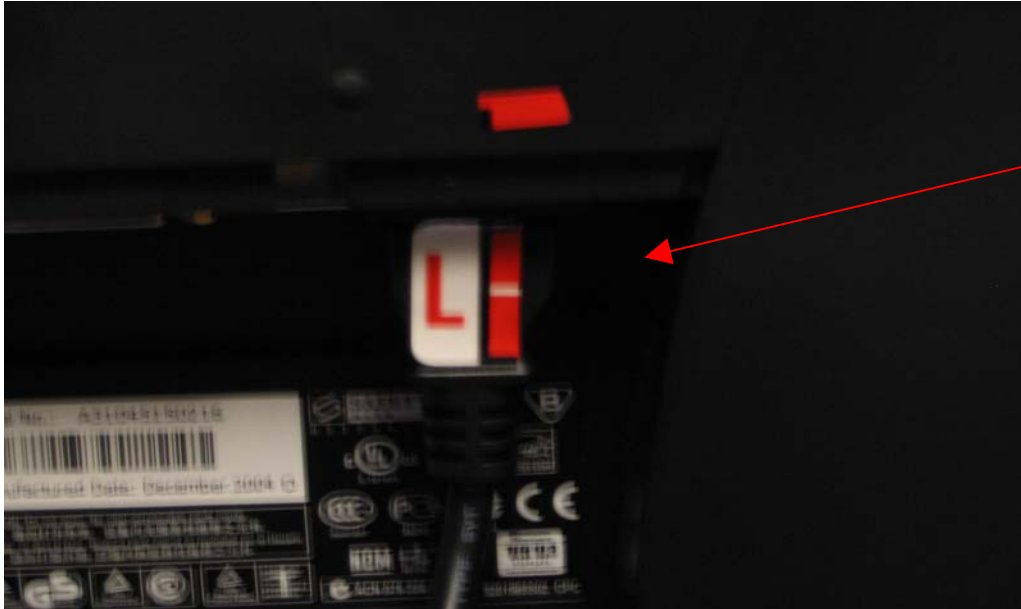
Ethernet Cable

Ethernet Cable Port

Router

Computer Set-up (cont'd)

- **L:** The computer monitor also has a power cord. This power cord connects next to the monitor line (blue prong). Once this cord is plugged into the monitor, plug the opposite end into a chloride power pack.



**Monitor
Power
Cord to
Power
Source**

- **M:** Attach a long Ethernet cable to the Ethernet port of the registration tablet (small laptop).

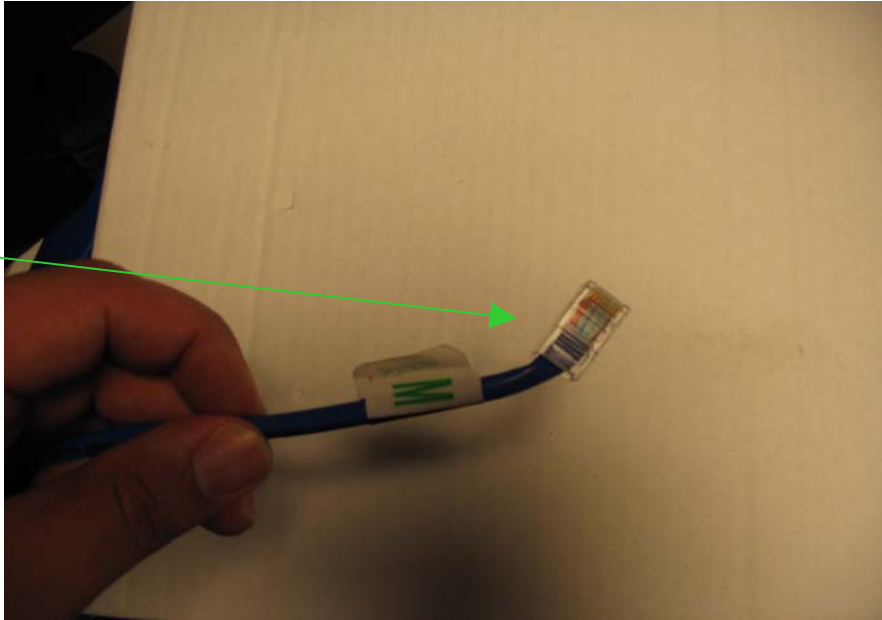


**Ethernet
Cable Port on
Registration
Laptop**

Computer Set-up (cont'd)

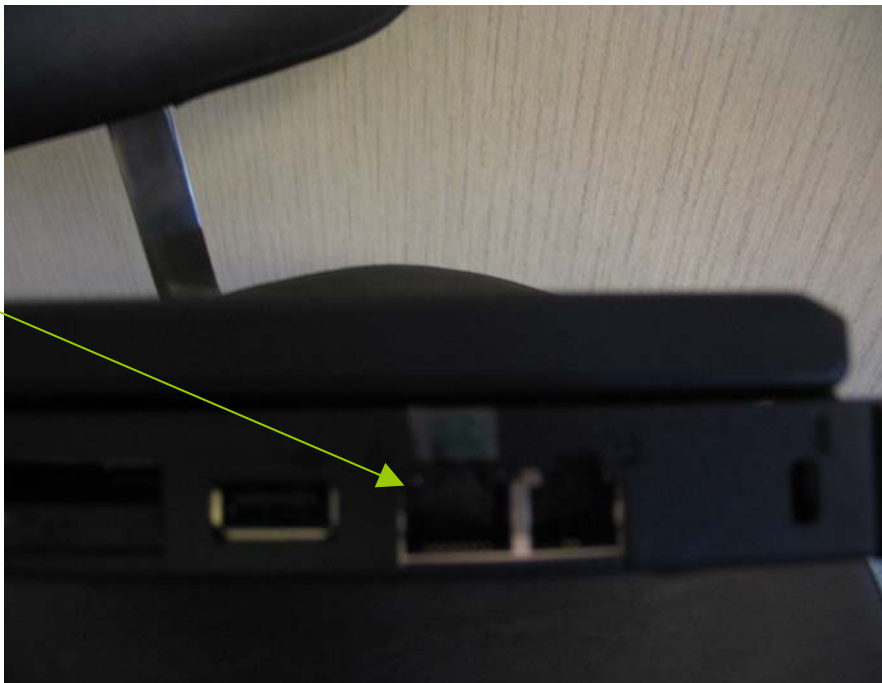
- **M: Run the Ethernet cable from the registration laptop to the back of the router.**

Ethernet
Cable from
Tablet to
Router



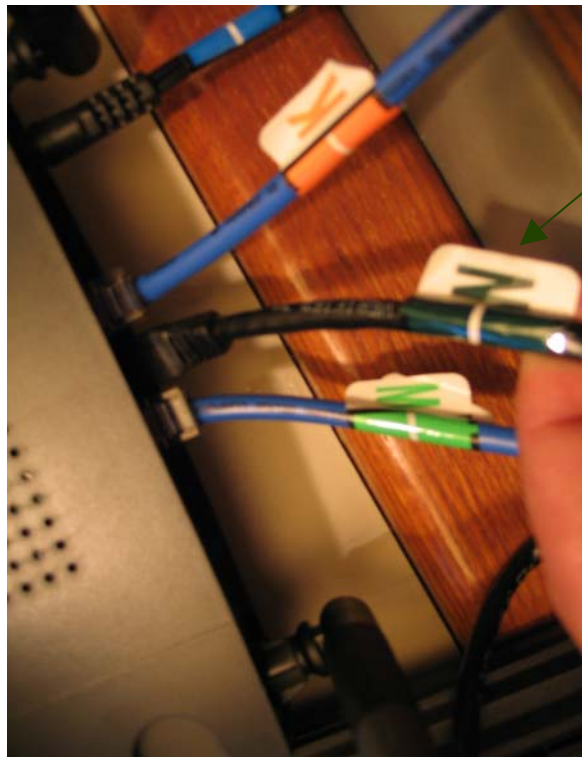
- **N: Connect an Ethernet cable to the back of the server (large laptop).**

Server
Ethernet
Port



Computer Set-up (cont'd)

- **N:** Run the Ethernet cable from the server to the router.



**Ethernet Cable
from Server to
Router**

- **O:** Connect the router power cord to the back of the router.



**Router
Power Cord**

Computer Set-up (cont'd)

- **O:** Run the power cord from the router to an outlet.



**Router
Power Cord**

- **P:** Connect the server power cable to the server (large laptop) and then to the corresponding AC adapter. Once this is done, plug the AC adaptor power cord into a power source.



**Server
Power
Cable from
Server to
Outlet**

Computer Set-up (cont'd)

- **Q: Connect the mouse to the registration tablet (small laptop)**



Mouse
Connects
to Small
Laptop
USB Port

- **R: Connect the registration tablet's power cord to registration tablet and then to a power source.**



Registration
Tablet
(Small
Laptop)

Power On Steps

1. Turn on Digital (Nikon) Camera
2. Turn on TopCon Camera
3. Turn on Server (Large Laptop)
4. Turn on TopCon Computer
5. Turn on Tablet PC (Small Laptop)

Important Notes

- The server (large laptop) should NOT be used for registration. Registration using the server could result in the server freezing and the loss of images/data.
- Do a dry run to make sure everything works as expected

Network & Sign On Information

- Servers IP Address: 192.168.1.2
- Domain: IMITS-T43-A
- Username: Administrator
- Password: remoteis

Diabetes Eye Screening Study

If you have diabetes, or know of someone with diabetes,
a simple research screening is available at this location.

It's fast, it's easy and no eye drops are required.



If you have diabetes, an annual eye exam is essential...

- Retinopathy is the #1 cause of blindness in people with diabetes
- One can have excellent vision, and yet have eye damage
- Early detection and laser treatment can prevent blindness

**Please ask your health care provider to
schedule a screening or call
(412) 647-7109**

AWARD NUMBER:

DAMD17-03-2-0017

TITLE:

Integrated Medical Information Technology System (IMITS) Program: Teleophthalmology Project

CONTRACTING ORGANIZATION:

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REPORT DATE:

12/28/2006

PREPARED BY:

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IMITS Teleophthalmology Project Manager

TYPE OF REPORT:

Feasibility Study

A. INTRODUCTION

Through an appropriation in defense-spending, the University of Pittsburgh Medical Center (UPMC) and the Air Force Medical Service (AFMS) created a strategic partnership called the Integrated Medical Information Technology System (IMITS) Program. The focus of the program is on the implementation and evaluation of telemedicine systems and clinical telemedicine applications. One of the IMITS projects, Teleophthalmology, was established to design a portable, alternative method and workflow for diabetes retinopathy screening.

Diabetic retinopathy, damage to the blood vessels in the retina, is the leading cause blindness in adults 20 – 74 years of age. The longer someone has diabetes, the more likely he/she will get diabetic retinopathy. Nearly 300 million people worldwide have diabetes and nearly half of all people with diabetes will develop some degree of diabetic retinopathy during their lifetime. Many of these people do not receive the care they need. It has been estimated that blindness from diabetic retinopathy is preventable in at least 65% of cases, if detected early. The Teleophthalmology Project aimed to make retinal screenings available to high risk populations at convenient community locations.

Project Accomplishments

Through the Teleophthalmology Project, a flexible, modular and mobile system was designed that effectively integrate medical history with retinal images. The core of this system is a laptop with adequate processing power and memory to act as a server with an SQL database. System functions are designed to be worklist driven, eliminating typing errors and improving productivity. A server-generated unique identifier tracks patient movement through the screening process, possibly non-sequentially depending on the setting and system-configured layout. All patient information is stored in a database on a designated central server.

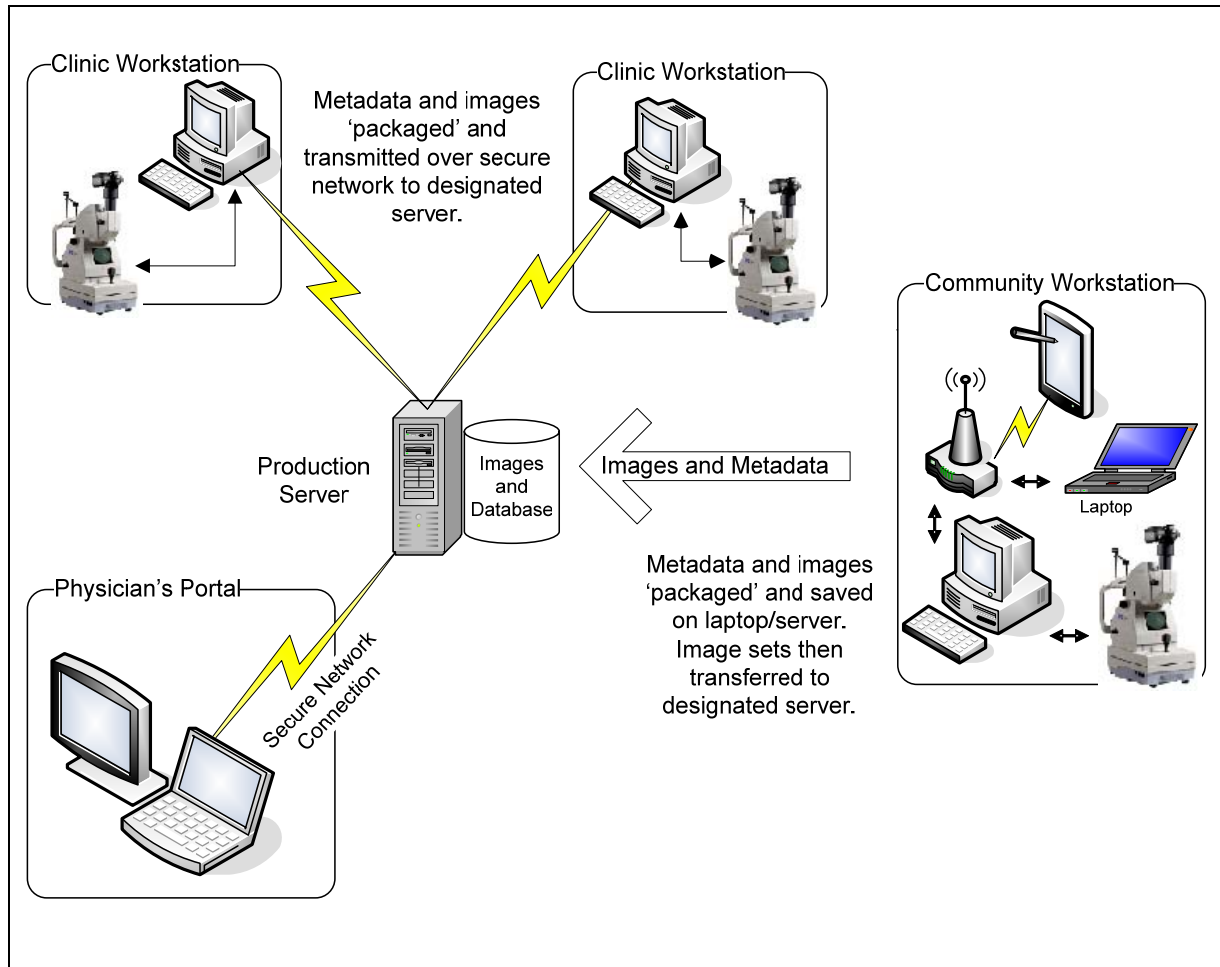
The system is basically comprised of three components: registration, imaging and grading. Each component was designed to be modular and customizable to specific locations and needs. The registration component, a web page that is accessible from the central server, is designed for efficient entry of general patient information (e.g., name, address, etc.) as well as specific health information tailored to diabetes (e.g., medications, diabetic history, etc.).

The imaging component consists of customized software running on a computer attached to the non-mydiatic retinal camera that drives image acquisition. The camera is set up in a darkened area or tent with adequate space and ventilation for the patient, photographer and the computer/server. The initial page displays a worklist of patients, created from the patient registration web page, who are ready to be photographed. A patient is selected from the worklist and a photographer takes up to three images of each eye, in any order. The software includes an area for comments, if the photographer experiences specific issues while capturing the images. Once the images are captured, the entire study (i.e., retinal images and patient data) is submitted to the central server.

The last component is the grading web page. A remotely located grader/specialist uses the internet to access the server to view a worklist of patient with ungraded. The grader views patient specific data, gathered at the time of registration, along with the retinal images. Customized software enables the specialist to efficiently enter exam findings and to indicate

a recommended time-frame for comprehensive follow-up care with the patient's physician. This information is automatically added to the project database.

Figure 1: Teleophthalmology Software Configuration: Capture and transfer of patient metadata (registration component) and retinal images (imaging component) to a designated server for consequent retrieval and examination by a physician (grading component).



The time for each patient to complete each component of the screening process is tracked and permits staff to assess the throughput of the system to determine if more registration stations, cameras, or grading screens are needed to alleviate patient wait times.

A patient tracking component was added to the system to enable easy access and tracking of patient communications and compliance with recommendations given for follow up eye care. The system also supports customized queries of data for statistics and reporting.

Technology developers successfully programmed and tested the functionality of the full prototype system and customizations that support the secure transfer and storage of the visible light images into an enterprise archive (i.e., Stentor PACs). As determined by hospital administration and in compliance with hospital electronic operations, the

teleophthalmology retinal screening software can be modified as needed for integration into an enterprise system.

B. PURPOSE

Researchers created the integrated, secure process for packaging and transporting retinal images and patient information from the site of acquisition to storage and incorporation into a central server. Yet, to become fully functional, the images and patient metadata need to be integrated into the hospital's enterprise archive. The purpose of this document is to identify the requirements for the transfer of patient metadata and images to UPMC's enterprise system.

C. DATA COLLECTION

In order to assess the feasibility of integrating the mobile diabetic retinopathy screening system with a PACS, routine project/discovery meetings were held with domain experts. Experts reviewed functional aspects necessary to accomplish the integration task, given the stand-alone system and the existing PACS. With the functional requirements defined, experts inspected components of existing (or in-development) systems within the UPMC enterprise to assess technical approach as well as reusability and direct application to the current integration task.

D. ANALYSIS

During the review of existing hospital IT components, experts organized an integration approach to coincide with the chronological workflow progression of steps required (as hypothesized) to accomplish integration. For each required step in the integration, experts identified an existing hospital system with the same requirement, and isolated the technology used to meet that requirement. Experts then assessed its applicability to the PACS integration in terms of the data accepted and the data generated and then ascertained if those data input/outputs aligned with the screening project.

E. SUMMARY OF RESULTS

TECHNICAL DEFINITIONS

MS Windows Server 2003 A server-based operating system providing the basic platform on which the application will run. This is a very common technology employed in the industry.

IIS 6.0 Internet Information Server is a component available within, and is tightly integrated into, the Windows Server operating system. The package provides web server and mail server functionality. Version 6.0 is shipped with, and the only version currently available on, Windows Server 2003.

MS SQL Server 2000 A relational database system providing for all database-related functionality including data storage, retrieval, and

reporting purposes. This product is among the leaders in the industry.

***MS .NET
Framework 1.1***

A collection of programming technologies designed to improve application performance, security, and reliability.

ASP.NET 1.1 / C#

Web infrastructure (ASP.NET) and programming language (C#) used to leverage the .NET Framework and create the web pages for data collection and current application functionality.

***Visual Studio .NET
2003***

Development environment used to construct the application.

TopCon

Hardware/software vendor providing the domain-specific camera and software libraries for programmatic interfacing.

REQUIREMENTS FOR UPMC PACS INTEGRATION

1. The PACS system requires an HL7 message to precede the arrival of images for storage.
2. Acquired images must be DICOM-wrapped for storage within the PACS system.
3. Acquired images must be JPEG-formatted for DICOM-wrapping.
4. The PACS system requires a DICOM transfer to receive the acquired images and match them against the previously filed HL7 message.
5. The PACS system requires an HL7 message to update the status of the images if they are not already set to final status on submission.

F. ACTION PLAN

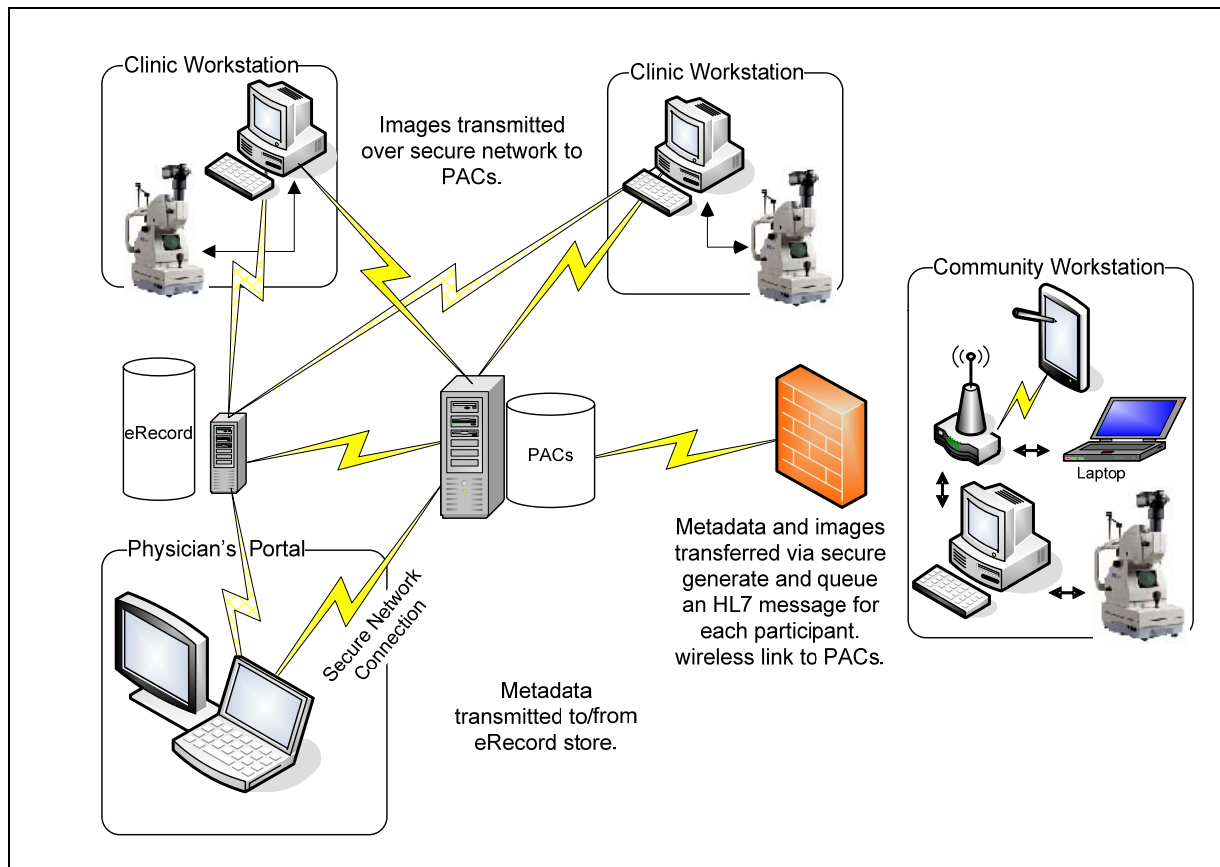
In order to meet the requirements for PACS integration, several existing technical components, both from the screening software as well as hospital systems, would require programming modifications and re-deployment.

The screening registration software can be modified to behave differently according to its environment, i.e. off-network vs. on-hospital-network. When off-network, the registration software can be made to generate and queue an HL7 message for each participant. When the system is brought back and re-attached to the network, the queue of messages could then be processed and sent to the PACS system. When on-network, the registration software could be replaced by an electronic health record (EHR) system supporting online order entry. The placement of an order can generate an HL7 message to both the PACS system as well as the screening system's image-acquisition software. The screening system would require modification to accept this incoming interface and store the data in the same format as though it were provided through the registration component.

Once the image has been captured, if the modality output is other than JPEG-format, the image must be converted to JPEG. Once the image is in JPEG-format, it can be DICOM-wrapped incorporating patient demographic information from the registration component, or from the EHR (depending on network context). If the system is off-network, the images can be stored locally. Once the system is reconnected to the hospital network, the images can be batch-processed and transferred to the PACS after filing of the queued HL7 messages. If the system is used while attached to the network, once the image has been wrapped, it can be immediately transferred to the PACS system.

After the images have been read, and the grading analysis applied, the grading component of the system could be modified to generate an HL7 message to the PACS system to update the status on the images.

Figure 2: Proposed PACs Enterprise Configuration: Patient metadata stored in existing eRecord store. Retinal images transmitted to PACs. Physician retrieves metadata and images for examination via PACs.



G. OTHER OPTIONS

An alternative to the automation described above would be to employ a separate application responsible for manually transferring the images to the PACS. Rather than

making any modifications to the behavior of the screening system and differentiating on-network from off-network behavior, the separate application could be designed to read the screening system's database. It would pull the patient information, generate an HL7 message, DICOM-wrap the screening images, transmit to the PACS, and immediately send an additional HL7 message to update the status. This application could be run manually with the ability to choose independent, discrete patient studies, or in a "batch" mode to process multiple studies at once.

**IMITS Teleophthalmology Project
Observations of Community Screening Events
Evaluation Report**

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Temple Emanuel

March 5, 2006

Site Description:

This diabetic retinopathy screening took place at the Temple Emanuel. It was located in an affluent section south of Pittsburgh. In an attempt to give back to their community the temple held their first health fair. This was also the first health fair which included the retinal screening van. Schedule for the health fair was 9:00-12:30.

Attending Personnel:

Steve Uttecht
Barb Mack
Monica Cassimir
Larry Jefferson
Robb Wilson

Summary

Set-up took from 8:00-9:30 and the location was a coatroom. It was the darkest place to image and still remain relatively close to traffic coming and going through exhibitors. This was their first attempt at a health fair. Large open area was fairly populated with exhibitors but attendance was poor. Many adults that came through were there to pick up children from Sunday School.

Retinal screening was not mentioned on temple flyers but did appear on posters and on their website. Temple posters stated free vision tests for children and adults. Sign(s) were needed to identify retinal screening registration area. The signage used at the Healthy-4-Life Expo would work. Wilson will contact Gerri Weiss UPMC PR) to find out how to obtain.

Need cart to move camera equipment. Mack will check on order. A borrowed dolly worked well for tear down. Thirty minutes for tear down. Because of location the wires were just long enough. Uttecht will determine what extension cords are needed. Coatroom was not dark enough. A tablecloth was taped to entry way to prevent light entering. The positioning of the camera, facing out of the room added to the light problem but because of the coatroom setup could not be better positioned.

Three participants were imaged. The first participant's images were poor due to inefficient dilation and/or cataract problem. Participant will return in April to one of the clinics to try again. The other two participant images were fine.

Needs

1. Cart or dolly to help move equipment safely and quickly.
2. Extension codes both electrical and for the computer.
3. Flexible plastic/nylon tarp to remove light from entering area.
4. Signage to identify area or table e.g. Eye Screening For Diabetic Retinopathy.
5. Uniform shirts for staff to identify them as part of the study.
6. Duct and masking tape.
7. Small portable table(s) or stand(s) for other equipment e.g. camera monitor.

Diabetes Symposium – Quality Inn, Bedford PA

March 16, 2006

Site Description:

The event was a diabetes symposium sponsored by UPMC and located at the Quality Inn in Bedford, Pennsylvania. Participants were pre-registered for this event. There were approximately 200 people present at this event, most of which had diabetes or were “borderline” diabetic. The event started around 9:30am, and the retinal screening equipment van arrived at the same time. Symposium was scheduled from 9:30 to 3:30.

Personnel Attending:

Larry Jefferson
Barb Mack
Russ Silowash
Robb Wilson

Summary:

At the beginning of the symposium, Mack made an announcement about the diabetic retinopathy screening, and that brought a rather positive response from the crowd. Mack was able to hand out consent forms to approximately 30 individuals. .

The retinal screening team was also outfitted with uniformed t-shirts in order to look more professional.

The retinal screening was set up in the “Library Room” of the Quality Inn. This room was rather large, and it had adjustable lighting. Having a large dark space for the imaging to occur was not a problem at this location.

The physical set up of the equipment took approximately one hour to complete. The staff was able to conceal most exposed wires with duct tape. Extension power cords were also implemented to get maximum reach of the equipment. The camera came on a cart with wheels, however, the cart seemed too small for the box, and was still rather clumsy. There were some set-up difficulties concerning the camera, and router. The retinal screening team also experienced server problems that initially inhibited them from properly registering participants. This problem took approximately one hour to fix. The team had to call Steve Uttecht at his office in order to fix these problems. Screening began at 11:45am.

The imaging room was set up for one person to enter the room. The person would then be registered. Once the person was registered, a series of images were taken of the participant’s eyes. Upon finishing the images, the participant was given the option to view their eye images. The participant was then escorted out of the room, and the next participant was brought in. One person entered the room at a time in order to insure patient privacy and HIPAA compliance. Once this process was planned out, the imaging process became more efficient. As participants were waiting to register, Wilson had the participant sit outside of the “Library Room” to read over/initial the consent form. This made the consent process more time efficient, because the participant had already read over the consent form prior to registration. If the participants had any questions concerning the study, they could ask the staff during the registration process.

The retinal screening team was able to image 27 people from the times of 11:30 to approximately 4:00pm. Seven people who originally consented did not show for their imaging. Tear down took approximately 30 minutes.

Needs:

1. **Equipment arrival should be earlier** – In order to help eliminate technical problems the equipment should arrive earlier than the beginning of the individual program. By doing this, setup and technical difficulties can be completed before the start of the individual program. The symposium finished at 3:30pm; however, the imaging team did not get done imaging the participants until around 4:00pm. This could have been avoided if the equipment was set up earlier. Also, 7 participants were not imaged, because they did not show up for imaging. This too may have been avoided by early set-up.
2. **Physical Set-up Descriptions** – The directions for setup should be more precise and detailed. Jefferson came up with a labeling system that would be beneficial to the physical setup. By putting lettered labels on all the equipment and their proper hookups, set-up time could be reduced and problems could be avoided.
3. **Technical difficulties** – Server problems were not easily fixed. A computer specialist could be assigned to the team for such problems. Also, a mach set-up could be performed prior to the event to insure that the equipment and programs will work properly.
4. **Registration** - Registration could have been separate from imaging in order to speed up the entire process. Longer CAT-5 Ethernet cables or barrel connectors could be obtained to enable a longer range of equipment. Another option is having the wireless tablets for registration. This would enable the separation of the registering process from the imaging process. It must be kept in mind that a separate, but private section needs designated for registration in order to insure participant privacy.
5. **Staff Roles** - During a large imaging session such as this one, staff could switch roles or take breaks. When a person does one task for long periods of time, he/she could become tired, stressed, and less efficient. If people switched roles every so often, efficiency could be kept at a high, constant level.

McKeesport Palisades

July 18, 2006 and July 19, 2006

Site Description:

This particular health fair was located on the second floor of the Palisades Building in McKeesport, Pennsylvania at 501 South Water Street. The second floor of the building was approximately sixty feet by one hundred feet in size, resulting in a rather large area that could host a significant amount of people. The retinal screening area was located at the far left corner of the complex. The health fair was scheduled from 9:00 to 7:00 on July 18th and from 9:00 to 2:00 on July 19th.

Attending Personnel:

Barb Mack (both days)
Russell Silowash (both days)
Robb Wilson (1/2 day on July 18th)

Summary:

July 18th: Silowash arrived at the Palisades building at approximately 7:45 am. The retinal screening van was already there at the time of arrival. The van was unloaded at 8:00 am due to parking problems at the facility; the van had to be on a level surface before unloading, and one was not available until the reported unloading time. The van had become easier to unload at this health fair compared to previous health fairs due to the implementation of a storage cart that housed all of the computer equipment needed for the camera apparatus. Once all of the equipment was moved to the second floor of the facility, set-up began. The camera system was set-up in a relatively dark area directly behind the registration table. The camera and the registration table were separated by a dark blue curtain. Opaque screens were borrowed from the facility to surround the camera system in order to block any light from entering the area. The TopCon Camera and LAN Assembly Manual was used when needed. Once the camera and computer systems were set-up properly, the system was powered on in the order provided by the manual. By doing this, there were no problems with the LAN, computer, or camera. Test photos were taken, and registration started promptly at 9:00a.m. Due to the lack of personnel, both Mack and Silowash registered participants. The event was well received by the general population, and the screening area became rather busy. Most of the participants that completed imaging were asked to complete the Diabetic Retinopathy Screening Survey. The survey was well received, and everyone that was asked to complete the survey did so very willingly. Due to the system working properly, there was no long waiting periods for the participants. Once the entire participant's information was entered into the notebook, they could be imaged right away. The only time a participant had to wait was when someone ahead of them was getting their images done. The waiting did not last more than a few minutes. Twenty-eight people completed screening on this day. Once 7:00 pm arrived, the system was shut down, but only the registration equipment and server were disconnected. These items were locked in the storage cart.

July 19th: Silowash arrived promptly at 8:30 am. The retinal screening van arrived shortly after. Only the registration notebook and server had to be set-up on this morning. Once again, the system was powered on in the order according to the assembly manual, and the system worked on the first time again. This day went very similarly to the day before with Mack and Silowash both registering participants. The day started out busy, but there were no problems encountered during the entire health fair. Once again the surveys were completed by

most of the people completing the screening process. If the retinal screening table became busy, people were sometimes missed for the survey. Nineteen people completed screening on this day. The health fair ended at 2:00 pm, and breakdown and loading of the TopCon camera and computer system took about an hour.

Needs:

1. **Black Cart** – The black cart purchased for this program was supposed to be used as a storage center for a working hub; the person in charge of set-up would only have to plug the cart in, and the system would work properly. This was not the case for this health fair. The cart was only used as a storage space for all of the computer equipment. Even though this made unloading and loading the van much easier and efficient, the cart would really be beneficial and more efficient if it was used as it should be.

Solution: Steve Uttecht was appointed in charge of this project. Both carts purchased (one clinic and one for community activities) will be assembled for its proper purpose. Silowash volunteered to help.

2. **Protocol Violation** – It was found that some people completing screenings were not Type 1 or Type 2 diabetic. Some people had family histories of diabetes or were “borderline” diabetic. Registering these people into the study went against IRB protocol.

Solution: Dr. Janice Zgibor was notified of this protocol violation, and the Unintentional Event Form to the IRB will be completed immediately. Dr Zgibor will send an employee to each of the remaining health fairs in order to monitor IRB compliance. Registration participants will each go over the protocol to refresh themselves with the protocol.

3. **Rewards** – As part of the program, eyeball key chains were given to people who completed the screening process. However, during this health fair, the eyeballs were within general public reach; anybody walking past the table would grab a key chain and/or magnifying glass.

Solution: More eyeball key chains may have to be purchased. However, we will only give these rewards to people who have completed the retinal screening. This will be accomplished by having the key chains in a more private location, such as near the camera apparatus

4. **Office Supplies** - Multiple office supplies need to be purchased for this project in order to maximize efficiency and small work environments. Below is a list of items that should be considered.

1. Duct tape – could be used to tape down any wires that may trip participants and staff.
2. Plastic Mail Bins – could be used to separate completed and uncompleted consent forms. The work area often became cluttered with consent forms.
3. Extra Pens
4. Push Pins – could be used to hang additional posters if sites warrant such.

5. **Poster Problems** – The poster designed for the health fairs could not stand up on its own, and had to be propped up against a more permanent fixture i.e. a table. This may have resulted in less publicity for our project because only people approaching our table from one angle could see the poster.

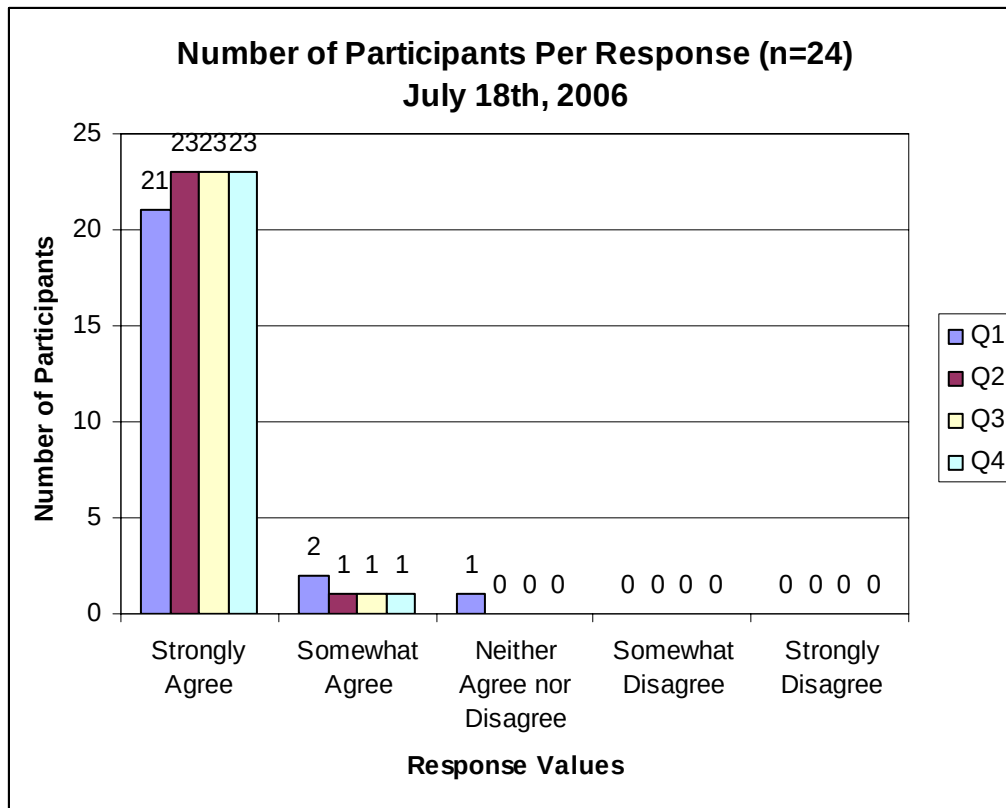
Solution: The poster’s backing could be permanently fixed to the poster (with glue or some other adhesive). Also, we could have multiple posters to cover many viewing angles.

Survey Results:

July 18th: 24 people completed the survey out of 28 screening completers (85.7%). Please note that the following questions refer to Q1, Q2, Q3, and Q4 respectively on each of the graphs.

1. The Health Professionals took time to talk with me about the screening process.

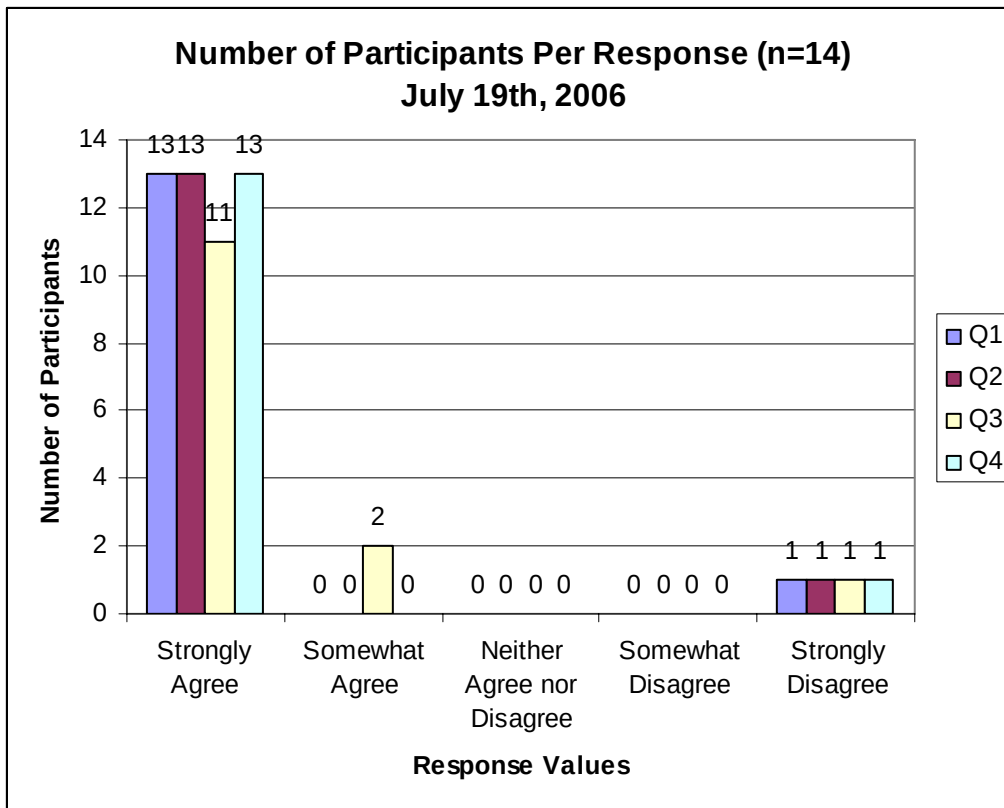
2. The Health Professionals were friendly and showed concerned for me.
3. I was comfortable with the way the equipment and camera were used.
4. The wait time for my retinal photographs was acceptable.



Key Quotes/Comments:

- o “Everyone was professional and friendly.”
- o “It was wonderful; it gave me a sense of wellbeing concerning my vision.”
- o “I have limited insurance coverage – thank you!”

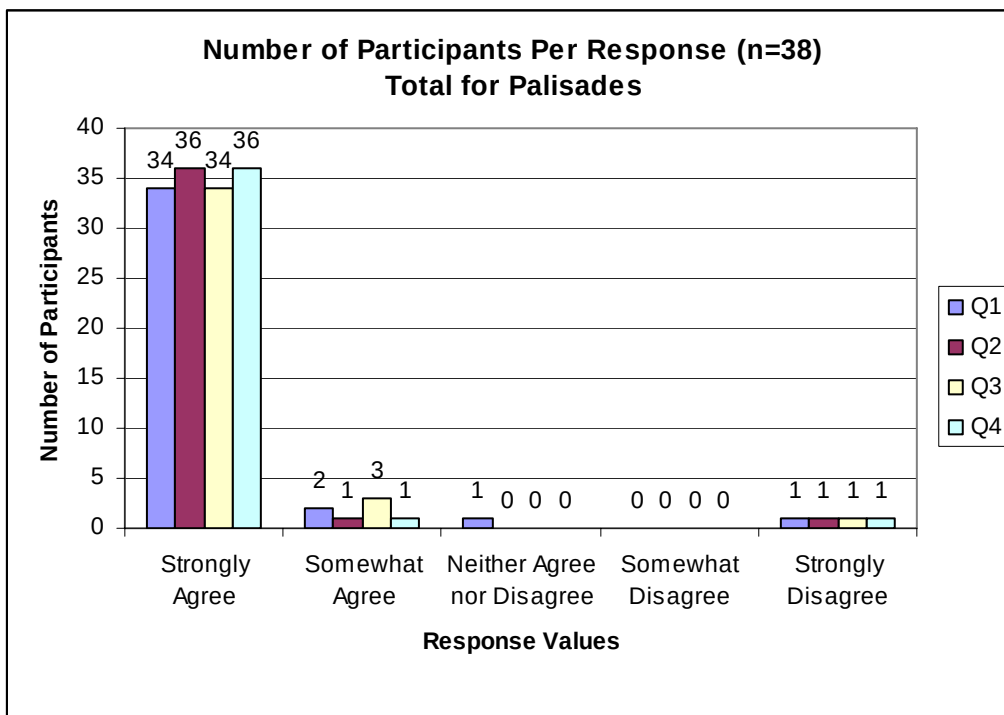
July 19th: 14 people completed the survey out 19 people that completed screening (73.7%)



Key Quotes/Comments:

- o “Thank you for bringing this to the UPMC fair.”

Totals: 38 out of 47 total participants completed the screening survey (80.9%)



Fairchance Health Clinic

August 3, 2006

Site Description:

This event occurred in Fairchance, Pennsylvania. It was a small clinic that served the local community. It was from 10:00 to 2:00.

Attending Personnel:

Barb Mack
Russell Silowash

Summary:

Silowash arrived at 9:20 am. The location was somewhat difficult to find because of the unfamiliarity of the area and the size of the site. The retinal screening van arrived at the site at 9:00 am. Unlike other sites, this site was relatively small and was more of a clinical setting than a community setting; people who had diabetes and were interested in our study were told to come see us by the site's coordinator. The camera, computer, and LAN set-up went very smoothly and with no complications. However, registration of the participants had to occur in the same room as imaging because of the lack of space. The camera and computer were set up in a very small exam room, and the room had a window in it. The window provided too much light for the camera to work properly; shadows were present on many of the images. One participant could not get imaged because they had a very small pupil size, and the room was not dark enough. After many attempts to darken the room with white blankets, Silowash retrieved a thick, dark colored blanket from his car. Once placed over the window, the room was dark enough to obtain better images, and minimal shadows were encountered.

Retinal screenings commenced at 10:00 am. Once the screening of participants started, Mack would carefully go over the consent form with them. Approximately three people were turned down from the study due to not having diabetes. Once the window problem was solved, imaging went very smoothly, and approximately nine people were screened. Retinal screenings ended around 2:30 pm. It took approximately thirty minutes to break down the equipment and put it in the van.

Needs:

- a. **Black Cart** - The black cart purchased for this program was supposed to be used as a storage center for a working hub; the person in charge of set-up would only have to plug the cart in, and the system would work properly. This was not the case. The cart was only used as a storage space for all of the computer equipment. Even though this made unloading and loading the van much easier and efficient, the cart would really be beneficial and more efficient if it was used as it should be.
- b. **Solution:** Steve Uttecht and Russell Silowash plan to finish building all of the carts on August 4, 2006. The cart in the van now has a keyboard drawer, adjustable monitor arm, and a shelf. These components enabled the computer and LAN system to be assembled within the cart and tested. The cart should be fully functional for the next community outing. By setting up the cart appropriately, set-up time and problems will be reduced.
- c. **Office Supplies** - Office supplies could make the teleophthalmology project more organized and prepared for any type of situation. For instance, plastic mail bins could be used to organize the

unsigned consent forms from signed consent forms. Materials could be bought that would allow the retinal screening team to adapt to different lighting situations. The site coordinator at Fairchance stated that many of the sites in Fayette County would not have optimum lighting conditions, so we should be better prepared for the next upcoming events.

- d. **Personnel Shortage** - Two people were at this site. However, an evaluation team member may not be present at all times to help set-up and break down of the retinal screening equipment. This could create future problems, because the equipment is rather heavy, especially the camera. One person assigned to this project should be able to easily lift approximately one hundred pounds. This situation could become problematic. There has been some talk of getting people from the sites that are strong enough to lift the camera. However, this could have legal implications, if the person should hurt themselves while lifting the camera as well as damage the camera.
- e. **Rewards** - The teleophthalmology group did not have any key chains to give away this event. More key chains should be ordered in order to give participants more incentive to have their images done.

Survey Results:

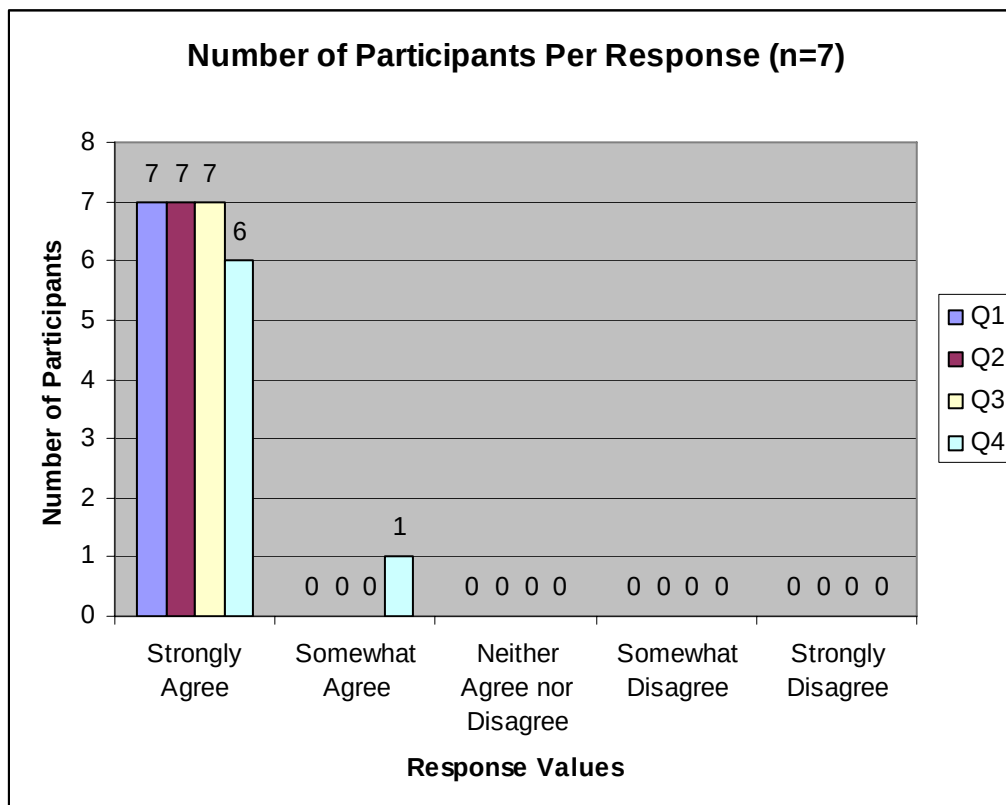
Seven people completed the survey out of nine total people (77.8%). Please note that the following questions refer to Q1, Q2, Q3, and Q4 respectively on the graph.

Q1: The Health Professionals took time to talk with me about the screening process.

Q2: The Health Professionals were friendly and showed concerned for me.

Q3: I was comfortable with the way the equipment and camera were used.

Q4: The wait time for my retinal photographs was acceptable.



Yablonski Health Clinic

August 9, 2006

Site Description:

The Yablonski site was a small, community clinic located in Frederick, Pennsylvania. The event took place from 10:00 am to 12:00 pm.

Attending Personnel:

Barb Mack
Leslie Anthony

Summary:

The location was somewhat difficult to find because of the unfamiliarity of the area and the size of the site. The retinal screening van arrived at about 9:20 am. Like the previous site, this was a small, community clinic. A diabetes educator and a foot specialist were also seeing people at this event. Most of the participants were contacted by clinic staff and encouraged to attend. Modifications made to make the equipment cart to make it more manageable; once it was moved from the van to the imaging room in the clinic, it was quickly assembled and ready for imaging. The camera and computer were set-up in one small exam room that was conducive for imaging; window blinds were drawn and darkened the room adequately. The room across the hall was set-up for participant registrations.

Retinal screenings were conducted from 10:15 am to 12:15 pm. Ten of eleven individuals were confirmed eligible for participation. One participant stated that he was a “borderline diabetic”, but when asked, reported a blood sugar level of 130. He was enrolled in the study. Another participant was clearly unable to comprehend the consent process but his mother, who was accompanying him, stated that she was his legal guardian. Upon further questioning, staff discovered that she was not a “legally” appointed guardian. This person was not enrolled in the study.

In general, Anthony reviewed the consent process and registered participants and Mack assessed pupil size and imaged participants. Both Anthony and Mack confirmed eligibility for all participants. Mack indicated that some duplicate registration records were appearing for people. This issue was likely related to the “learning curve” of the registrar. The equipment remained assembled and ready for screening to be conducted at the same clinic on the following day – no breakdown was required.

Needs:

1. **Camera case** - The camera equipment is heavy and difficult to manage. Currently it requires lifting the equipment (weighing approximately 75 – 100 pounds) from the carrying case to the table top. This could be considered a liability. We should explore alternative options, such as mounting the TopCon equipment on the table.
2. **Black Cart** – This was the first event to follow work that had been done to fully assembled equipment on the cart. Mack needed to run a couple of power cords/cables through the front of the cart, instead of the back, based on the location of the camera table. Otherwise, the set-up was efficient and reduced set-up time dramatically. Once staff becomes a little more familiar with the location of cables/cords this

process will improve even more.

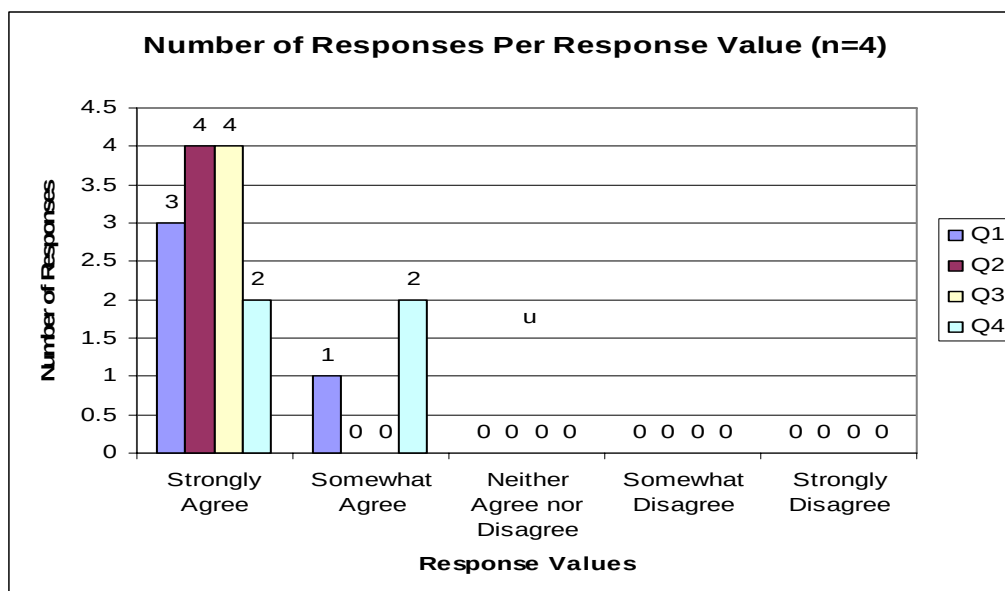
3. **Personnel Shortage** – It is my recommendation that no less than two people should be present at all community events.
4. **Wireless connection** – Staff does not know how to establish a wireless connection from the registration computer to the server. For this event, the cable ran across the hallway into the other exam room. Fortunately, the exam rooms were at the end of the hallway. Staff should be trained and instructions need to be added to the camera assembly manual for wireless operations.

Note: Silowash investigated trying to resolve the wireless network issue. Since we are collecting personal information a wireless network system is strongly discouraged. Unless there is very sophisticated encryption program the risk would be run of having our information available to anyone who really wanted it.

Survey Results:

Four of ten people (40%) completed screening surveys. Please note that the following questions refer to Q1, Q2, Q3, and Q4 respectively on the graph.

- The Health Professionals took time to talk with me about the screening process.
- The Health Professionals were friendly and showed concerned for me.
- I was comfortable with the way the equipment and camera were used.
- The wait time for my retinal photographs was acceptable.



Uniontown Hospital Diabetes Clinic

August 22, 2006

Site Description:

This retinal screening took place at Uniontown Hospital's Diabetes Clinic. It was the grand opening for the newly established diabetes clinic and Congressman Murtha was present to dedicate the clinic. The new diabetes clinic at Uniontown Hospital is part of the Pittsburgh Regional Initiative for Diabetes Education (PRIDE) program.

Attending Personnel:

Barb Mack
Faith Bivins
Robb Wilson
Russell Silowash

Summary:

The evaluation team arrived at 9:20 am; the retinal screening team had arrived before hand and had already unloaded the equipment. The camera system was located in a medium sized exam room, while the registration equipment was located in another exam room. The participants were consented in an office adjacent to the exam rooms or in the registration room. Set-up of the equipment took approximately twenty minutes. Congressman Murtha arrived at 9:40 am, which was 20 minutes earlier than his scheduled time. Because of this, the retinal screening team was unable to demonstrate the camera for Mr. Murtha; however, the team was able to show him example images. Wilson approached Mr. Murtha about the study and spoke with him about the IMITS program in general. Mr. Murtha seemed very interested in the retinal screening project as well as the IMITS program. Mr. Murtha thought that the van was the location for the retinal screening, and appeared confused when he had to go into the clinic to see the camera system. At 10:00 am, Congressman Murtha went outside the clinic to give a speech and to talk about the importance of diabetic treatment in Fayette County.

Once Congressman Murtha's speech and dedication of the newly established clinic was over, the retinal screening team started screening diabetic participants. The main influx of participants did not occur until after 1:00 pm. Announcements were made over the public announcement system of the hospital regarding the project, and handouts were given at the information desk of the hospital. The evaluation team obtained completed surveys from the participants. For this site, the retinal screening team was able to screen 10 participants successfully. However, during the imaging of the sixth participant, the team ran into apparent software problems and was unable to finish imaging of the sixth participant. After restarting the imaging software as well as the computer, the problem persisted, and Steve Uttecht was contacted immediately. Steve helped the team find the problem, which was a wire connection problem, and the screening process was enabled once again. The problem was fixed in approximately 15 minutes.

Bivins was a newly added member to the retinal screening team. Mack and Bivins were able to successfully lift the camera from its case during set-up. Bivins was also being trained on imaging and registration of the participants. Also, Mack was asked how she felt about the new cart that was assembled for the project. She felt that it was very helpful, and it definitely decreased set-up time. The only complaint she had was the need for zip ties to straighten up the wires associated with the system. The diabetic retinopathy team was able to successfully

load and unload the equipment onto the van. The addition of one extra person to the team is definitely helpful and needed.

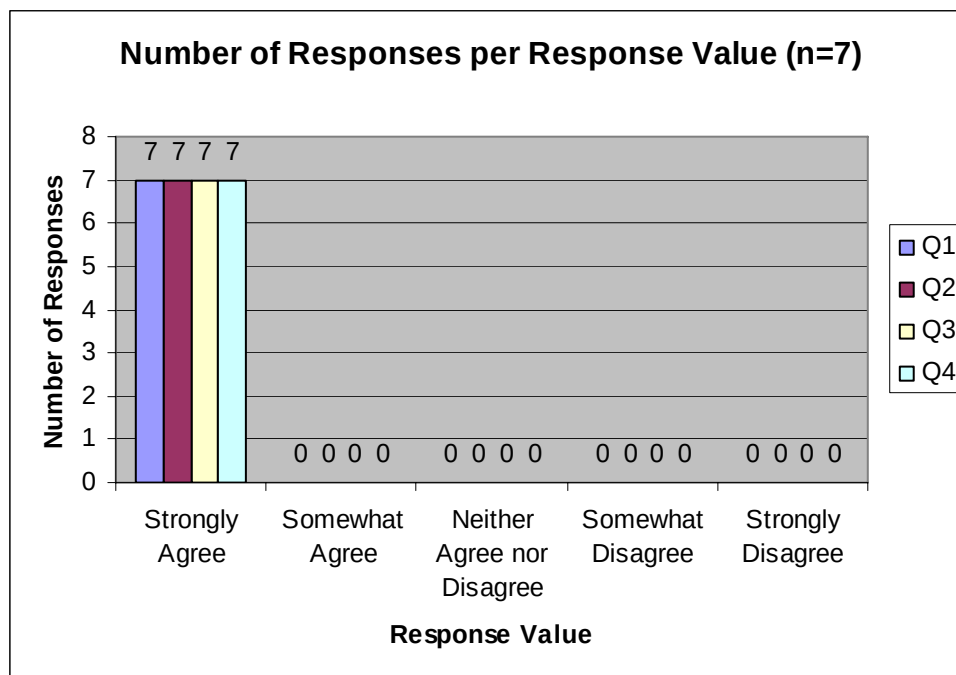
Needs:

1. **Office supplies** - The diabetic retinopathy program still needs to purchase a variety of office supplies. These supplies include but are not limited to: duct tape, push pins, mail bins, zip ties, and business cards for team members.
 - **Solution:** Silowash has volunteered to purchase zip ties, push pins, and duct tape for the project. Leslie Anthony has ordered easels for the posters as well as a file box for the variety of forms involved in the program. Mack reported that her business cards were still being completed.
2. **Van flexibility** - Mack mentioned that the van should be able to function as the screening room. Silowash mentioned that the van would need to have air conditioning capable of cooling the entire van efficiently for both team members and participants. If the van was capable of being the screening room, the project would be completely mobile and could be flexible with any community setting.

Survey Results:

Seven out of ten participants completed screening surveys (70%). Here are the questions from the survey and will be represented graphically below.

1. The Health Professionals took time to talk with me about the screening process.
2. The Health Professionals were friendly and showed concern for me.
3. I was comfortable with the way the equipment and camera were used.
4. The wait time for my retinal photographs was acceptable.



Key Quotes:

1. “The staff was kind and considerate.”

2. "Their explanations were clear and concise."
3. "Thank you for this opportunity."
4. "Very exciting!"

Carmichaels Site

August 23, 2006

Site Description:

This community setting took place at the Carmichaels Volunteer Fire Department Center in Greene County Pennsylvania during the annual Bituminous Coal Festival. The event lasted from 6:00 pm until approximately 9:15 pm, and had a health fair setting. Because of the amount of space available, Silowash was able to assemble the IMITS poster and have additional information available concerning the IMITS program.

Personnel Attending:

Barb Mack
Faith Bivins
Russell Silowash

Summary:

Silowash arrived at the site at 5:25 pm. Upon arrival, the retinal screening equipment had been assembled, and Mack had already taken a test shot. Silowash assembled the IMITS poster and placed the IMITS information as well as the Diabetes Retinopathy Screening posters on the table. The first participant was registered at approximately 5:45 pm. The camera system was assembled in a newly-renovated bathroom of the facility, while the registration equipment was located at a table just outside of the bathroom. The bathroom was capable of complete darkness, so light was not a factor in image quality. Mack reported that the camera and LAN were assembled and tested in no more than twenty minutes. Bivins registered participants while Mack imaged participants and Silowash consented participants. If Bivins came across a problem during registration, either Mack or Silowash helped to solve the problem. Mack was very alert to all of Bivins actions and corrected Bivins if any mistakes were being made. Bivins accidentally started registering participants before properly consenting them a few times. Mack noticed this problem and corrected it; all registered participants were properly consented before imaged.

The event was well attended by the Carmichael's population. The retinal screening team was able to image 18 people successfully. Unlike the last event, there were no equipment problems. Fourteen people completed surveys.

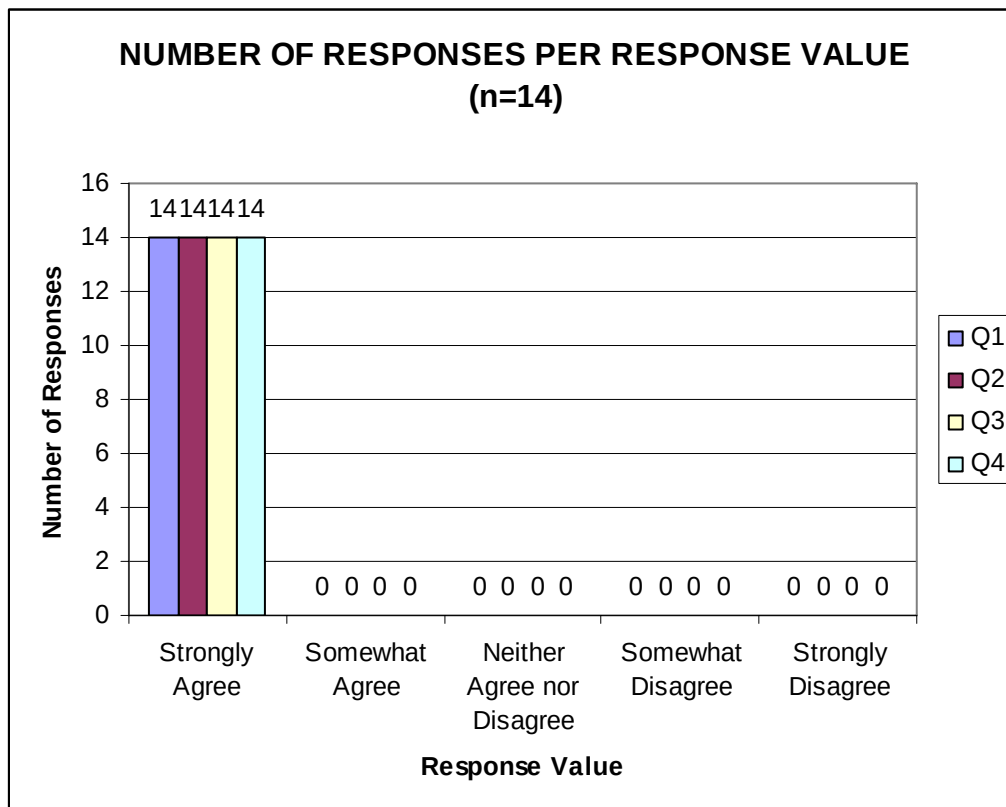
Problems:

1. **Office Supplies** – Silowash purchased zip ties to organize all of the wires associated with the set-up. He also brought duct tape to tape down any wires that may trip participants and/or staff. Thumb tacks were also purchased to hang blankets over windows. Mack reported that her business cards are going to be completed soon, and Leslie Anthony has ordered file organizers for consent forms and easels for posters.
2. **Equipment** – Both Bivins and Silowash have reported that the mouse has been problematic when registering participants. The six button mouse erases information if the wrong button is accidentally pressed. This problem may be solved by implementing a two button mouse. It might be possible to either purchase or trade for a two button mouse for the upcoming events.

Survey Results:

Fourteen participants out of a possible eighteen (77.8%) completed surveys. Please note that the following questions refer to Q1, Q2, Q3, and Q4 respectively on the graph.

5. The Health Professionals took time to talk with me about the screening process.
6. The Health Professionals were friendly and showed concerned for me.
7. I was comfortable with the way the equipment and camera were used.
8. The wait time for my retinal photographs was acceptable.



We now have a total of 80 completed surveys.

Key Quotes:

1. “Everyone was very nice and completely helpful. Thank you.”
2. “Everything went smoothly.”

Indiana Regional Medical Center

August 25, 2006

Site Description:

This retinal screening took place at the Indiana Regional Medical Center. Congressman Murtha was present to speak on the importance of diabetes care. The diabetes clinic at the Indiana Regional Medical Center is part of the Pittsburgh Regional Initiative for Diabetes Education (PRIDE) program.

Attending Personnel:

Barb Mack
Faith Bivins
Robb Wilson
Russell Silowash

Summary:

The event was billed as Diabetes Day. Three large areas of the medical center were devoted to the health fair. None of these areas provided any secluded dark sections. Two other types of vision tests had booths. Retinal screening was not scheduled to be done that day. After explaining the needs to the clinical staff, an office was vacated where both the camera and registration equipment could be set-up. Unfortunately it was a good deal away from the actual health fair. Silowash and Wilson escorted participants to and from the office where Bivins and Mack consented, registered, and imaged.

The health fair was well attended. Congressman Murtha spoke as well as members of the University of Pittsburgh Diabetes Institute. Numerous attendees waited to have their eyes imaged. However, during imaging the team ran into problems. Parts of the equipment shut down and would not allow completion of a participant. This was not a problem seen before and Steve Uttecht was contacted immediately. After some time the equipment was adjusted and began to work again. Five participants were lost due to wait time. The remainder of the day proceeded normally.

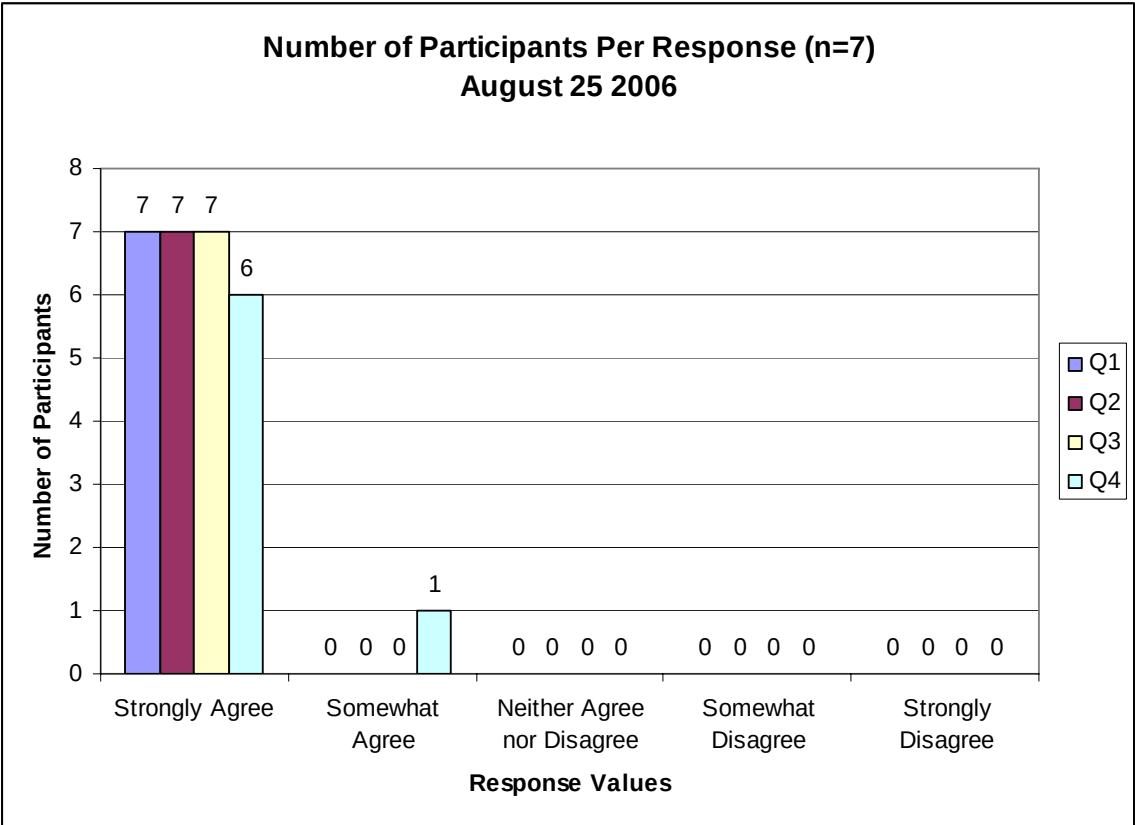
Needs:

Improve communication to assure that those in charge of the clinic or health fair are aware of the special needs of the retinal imaging equipment. Also communication among team members needs to be better.

Survey Results:

Seven people completed the survey. Here are the questions from the survey and will be represented graphically below.

- The Health Professionals took time to talk with me about the screening process.
- The Health Professionals were friendly and showed concern for me.
- I was comfortable with the way the equipment and camera were used.
- The wait time for my retinal photographs was acceptable.



Lincoln-Lemington Family Health Care Clinic

November 2, 2006

Site Description:

This retinal screening took place in a clinic in lower income portion of the city of Pittsburgh. The patient population was older and minority based. Participants were scheduled to report at designated times. Participants were scheduled from 12:30 pm to 4:30 pm.

Attending Personnel:

Barb Mack
Robb Wilson

Summary:

Registration and camera were set up in the same room. The room was not being used for any other purposes that day and it was able to have complete darkness. The room was removed somewhat from the clinic area near the kitchen and conference room. Participants were escorted back to the room by clinical personnel and seemed not to have any problems. Mack reported that she asked a clinic staff person to help her unload the camera. She also reported that she had no problems with the functionality of the equipment. Six participants were imaged.

Needs:

Not every participant that was scheduled to be imaged kept their appointment. There was too much down time for imager. A solution could be to work more with the clinical staff to send some sort of reminders to the participants.

Subject Qualifications for Screening Participation

Internal staff use only. This cannot be given to potential subjects.

Retinal Sceneing Study Inclusion:

All research subjects must have diagnosed diabetes...no one with pre-diabetes can be imaged.

Must Be:

- 18 years old or older
- Diagnosed with Type 1 or Type 2 diabetes
- On Diabetes medication
- Diagnosed with diabetes but glucose levels controlled by diet and/or exercise

Exclusion:

If any of the below criteria apply, then person is ineligible for the screening.

- Younger than 18 years of age
- Pregnant
- No diabetes diagnosis - this includes people who are controlling their condition with diet and exercise
- Anyone failing any one of the probing questions.

Probing Questions

- Are you currently taking medications to control your sugar levels?
Yes - Pass
No - Fail
- Do you know what your last fasting blood sugar level was?
≥ 126 - Pass
<126 - Fail

Assessing the Capabilities and Effectiveness of a Teleophthalmology Screening Program

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Janice Zgibor, RPh, PhD¹

Jane B. Ward, MD³

Robert M Petrick, MSIS²

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Background

- Diabetes
 - Affects 18 million in United States, at least 1 million new cases yearly
 - Leading cause of blindness among adults 20-74 years of age
- Retinopathy
 - Causes 12,000 – 24,000 new cases of blindness yearly
- Prevention
 - Early screening is essential



Background

- Digital Imaging
 - The University of Pittsburgh Medical Center (UPMC) has developed a process for packaging and transporting digital images
- Partnerships
 - Wilford Hall Medical Center at Lackland Air Force Base
- Funding/Disclaimer
 - This work was supported by funding from the U.S. Air Force administered by the U.S. Army Medical Research Acquisition Activity, Fort Detrick, Maryland (Award No. W81XWH-04-2-0030 and Contract No. DAMD 17-0302-0017). We work through the Integrated Medical Information Technology System (IMITS) program.
 - The content of the information does not imply U.S. Air Force or Government endorsement of factual accuracy or opinion.



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Project Evaluation

- Objectives
 - Evaluate innovative approach to diabetic retinopathy screening
 - Assess real-world application of the teleophthalmology technology in a community and clinical setting
 - Apply lessons learned from each phase of implementation to improve the technology and workflow model



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Registration (Part 1)

[Register Patient]IMITS : Tele-Ophthalmology - Microsoft Internet Explorer provided by UPMC

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites

Address  http://localhost/apps/teleophth/PatientRegister.aspx

IMITS : Tele-Ophthalmology

Diabetic Retinopathy Screening

Register Patient/Participant

*

☐ Short Form / ☒ Long Form

First Name: Middle Name: Last Name: Abbrev:

Home Phone: () - Other Phone: () -

Address: Line 1: Eye Doctor Name: Eye Doctor City:
Line 2: Eye Doctor Type: Last Dilated Eye Exam:
City, St Zip: ,

Date Of Birth (mm/dd/yyyy): Gender: ☐ M ☒ F Pregnant? Trimester: Ethnicity:

Type of Diabetes: ☒ Gestational? Year of Diagnosis: Hgb A1C level: %

*



Registration (Part 2)

[Register Patient]IMITS : Tele-Ophthalmology - Microsoft Internet Explorer provided by UPMC

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites

Address http://localhost/apps/teleophth/PatientRegister.aspx

*
Participant Name : John Smail

Prior Treatment for Diabetic Retinopathy:

Add Another ☐ None ☐ OD ☐ OS
☒ Laser ☐ OD ☐ OS
☐ Vitrectomy ☐ OD ☐ OS
☐ RD Repair ☐ OD ☐ OS
☐ Other ☐ OD ☐ OS

Other Medical/Diabetic Problems:

Add Another ☐ None
☐ HTN
☐ CAD
☐ Renal
☐ Neuropathy
☒ Foot Disease
☐ Depression
☐ Cholesterol
☐ Other

Other Eye Problems:

Add Another ☐ None ☐ OD ☐ OS
☒ Cataract ☐ OD ☐ OS
☐ Glaucoma ☐ OD ☐ OS
☐ AMD (Mac Degen) ☐ OD ☐ OS
☐ Trauma ☐ OD ☐ OS
☐ Other ☐ OD ☐ OS

Other Eye Surgery:

Add Another ☐ None ☐ OD ☐ OS
☐ Cataract Extraction ☐ OD ☐ OS
☒ Glaucoma Surgery ☐ OD ☐ OS
☐ Retinal Detachment Repair ☐ OD ☐ OS
☐ Other ☐ OD ☐ OS

Medications:

Add Another ☒ None
☐ Hypertensive
☐ Cardiac
☐ Cholesterol
☐ Diabetic
☐ Other

Vision: Best-Corrected Visual Acuity OD OS
Pupil Size

☒ Participant had Hard-Copy Form
☒ Hard Copy completion improved this patient's Registration process

Submit Form

Done

start teleophth... Cricinfo - ... Inbox - M... [Register... SQL Serv... Camera S... C:\Docum... Help and ... Microsoft ... Local intranet 1:34 PM



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Imaging

SimpleDICOM Wrapper - Version 2.0

File Configuration Help

 **UPMC**
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Medical Center

Select Patient Acquire Images

Refresh 0 Larry Add Photographer

Registration Time	Unique Identifier	Participant's Last Name	Participant's First Name	MI	Participant's Birthdate
9/22/2005 9:28:38 AM	99001	Guy	Sample	1	1/1/1970
9/22/2005 9:39:42 AM	99002	Guy2	Sample		1/1/1970
9/22/2005 9:42:44 AM	99003	Guy2	Sample		1/1/1970
9/26/2005 3:22:56 PM	99007	a	a	a	1/1/1966
8/27/2005 10:37:51 AM	10031				2/16/1942
8/27/2005 11:15:12 AM	10039				12/16/1949
8/27/2005 11:19:58 AM	10040				3/20/1930
8/27/2005 11:23:13 AM	10041				10/16/1942
8/27/2005 12:20:01 PM	10056				6/6/1949
8/27/2005 12:45:29 PM	10059			C.	2/7/1956
8/27/2005 1:21:25 PM	10072			M	10/31/1949
9/14/2005 3:29:42 PM	10094	j	j	j	1/1/2345
9/21/2005 3:47:58 PM	10095	j	jlkj	lj	1/2/3008
9/23/2005 2:23:48 PM	99004	body	some	mi	1/1/2002
9/23/2005 2:26:05 PM	99005	guy	some	ot	1/1/1980
9/23/2005 3:54:09 PM	99006	guy3	some	o	1/1/1889
9/26/2005 3:59:44 PM	99008	c	c	c	1/1/1967



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Grading

SimpleDICOM Wrapper - Version 2.0

File Configuration Help

 **UPMC**
University of Pittsburgh
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Select Patient | Acquire Images

9/22/2005 9:28:38 AM	99001	Guy	Sample	1	1/1/1970


Right Eye
(O.D.)


Left Eye
(O.S.)

Take One



Take Two



Take Three



☐ Patient is not imageable.

Enter Comments Here

Submit Comments
and Finish Imaging



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Grading

- Follow-up Recommendation
 - One Year
 - 6 Months
 - 3 Months
 - ASAP



Healthy 4 Life / Diabetes Expo

- Greeting and Registration



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Healthy 4 Life / Diabetes Expo

- Camera and Registration



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Healthy 4 Life / Diabetes Expo

- Waiting and Grading



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Healthy 4 Life / Diabetes Expo

- Dr. Eller Grading Eye Photos



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Community

- Going Mobile

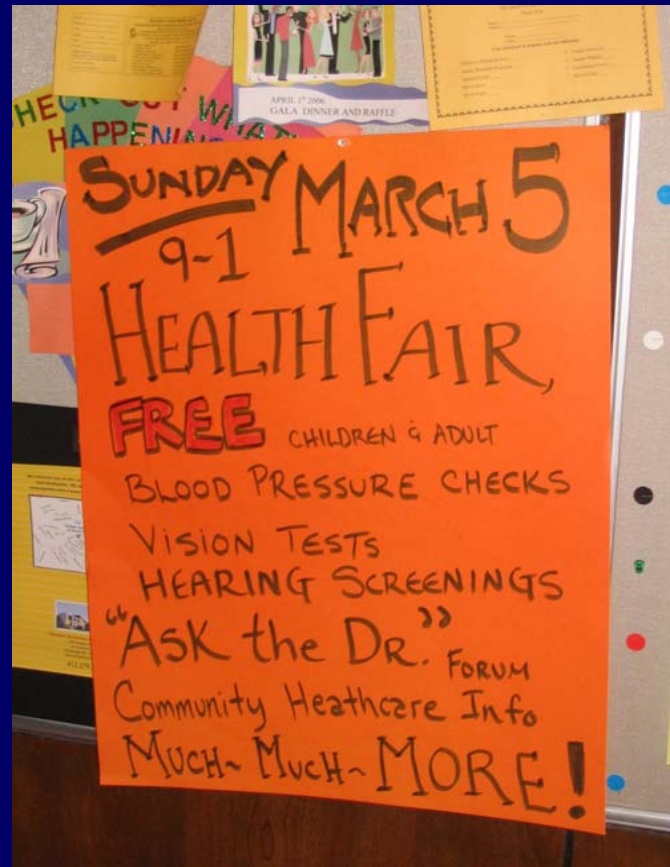


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Community

- Health Fairs



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Community

- Portable



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Community

- Adaptable



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Community

- Adaptable



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Community

- Flexible



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Clinic

- Center for Diabetes and Endocrinology, Falk Clinic at UPMC Presbyterian Hospital
- General Internal Medicine Clinic at UPMC Montefiore Hospital



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Clinic

- Center for Diabetes and Endocrinology, Falk Clinic at UPMC Presbyterian Hospital



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Results

- Timing

	Community (n=98)		Clinic (n=36)		Total (n=134)	
	Mean	S.D.	Mean	S.D.	Mean	S.D.
Registering	7.44	5.10	7.75	9.10	7.53	6.38
Imaging	4.66	2.72	7.87	4.27	5.52	3.50
Grading	2.37	1.36	2.10	2.14	2.29	1.60
Total Time	14.47	6.05	17.71	10.72	15.34	7.68

Due to equipment difficulties three individuals with times over 40 minutes were removed from the timing analysis. Data is as of 3/31/2006.



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Results

- Patient Characteristics (n=134)

Characteristics	Community		Clinic		Total	
	n	(%)	n	(%)	n	(%)
Gender						
Male	39	(39.8)	16	(44.4)	55	(41.0)
Female	59	(60.2)	20	(55.6)	79	(59.0)
Race						
Asian	1	(1.0)	0	(0)	1	(0.7)
Black	17	(17.3)	16	(44.4)	33	(24.6)
Caucasian	78	(79.6)	17	(47.2)	95	(71.0)
Hispanic	2	(2.1)	0	(0)	2	(1.5)
Native American	0	(0)	1	(2.8)	1	(0.7)
Other	0	(0)	2	(5.6)	2	(1.5)
Diabetes						
Type I	4	(4.1)	2	(5.6)	6	(4.5)
Type II	90	(91.8)	32	(88.8)	122	(91.0)
Undiagnosed	4	(4.0)	2	(5.6)	6	(4.5)



Results

- Screening

Follow-Up Recommendation	n (%)
One Year	117 (87.31)
6 Months	7 (5.22)
3 Months	9 (6.72)
ASAP	1 (0.75)



Results

- Site Characteristics

Characteristic	Community (n=98)				Clinic (n=36)			
	n	Mean	Std Dev	Range	n	Mean	Std Dev	Range
Age	96	60.02	12.8	60.3 (27.8 - 88.1)	36	52.3	13.3	64.23 (19.7 - 83.9)
A1C Level	52	7.0	1.1	6.0 (4.0 - 10.0)	19	8.42	2.2	9.0 (6.0 - 15.0)
Duration	93	7.8	8.5	49.0 (0.0 - 49.0)	30	12.9	9.88	44.0 (1.0 - 45.0)



Lessons Learned

- Confidentiality and Accessibility



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Lessons Learned

- Adapting to the Location



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Lessons Learned

- Assembly



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Summary

- 134 subjects were successfully registered, imaged and graded
 - 98 Community; 36 Clinical
- Mean time for registering patients 7.53 min
- Mean time for imaging patients 5.52 min
- Mean time for grading images 2.29 min
- A limitation of the screening is that we may not be reaching those who need screening most (e.g. one subject needed follow-up ASAP)



Conclusions

- Eyes do not need to be dilated to produce a gradable retinal image.
- Quality retinal screening can be mobile.
- Patients can be screened (registered, imaged and graded) on average in 15.34 minutes.
- Mobile screening may reach those who do not have easy access to eye care professionals.



Retinal Screening Workflow of the Populace at Health Fairs



Steve D. Uttecht, MS 1
Andrew Eller, MD 1,2
John Smail, BS 3
Jane Ward, MD 4
Paul J. Chang, MD 1,2



- 1 University of Pittsburgh Medical Center, Pittsburgh, PA
- 2 University of Pittsburgh School of Medicine, Pittsburgh, PA
- 3 University of Pittsburgh, Pittsburgh, PA
- 4 Wilford Hall Medical Center, Lackland Air Force Base, San Antonio, TX

Background

- Digital Imaging
 - The Innovative Medical and Information Technologies Center (IMITS) at the University of Pittsburgh Medical Center (UPMC) has developed a process for digital non-mydriatic diabetic retinopathy photoscreening at local and remote locations.
- Partnerships
 - Wilford Hall Medical Center at Lackland Air Force Base
- Funding
 - This work was supported by funding from the U.S. Air Force administered by the U.S. Army Medical Research Acquisition Activity, Fort Detrick, Maryland (Award No. W81XWH-04-2-0030 and Contract No. DAMD 17-0302-0017). The content of the information does not imply U.S. Air Force or Government endorsement of factual accuracy or opinion.

Purpose

Examine retinas of diabetics using a non-mydriatic fundus imaging system to identify problems that may go undetected due to infrequent ophthalmic care.

Document medical information as it pertains to ocular health to determine effectiveness of the system to best represent the health of each retina from a single image with a limited field of view.

Document workflow of the entire process as well as each component to determine efficiency.

Overview

- Set-up
- Screening Process
- Post-Screening

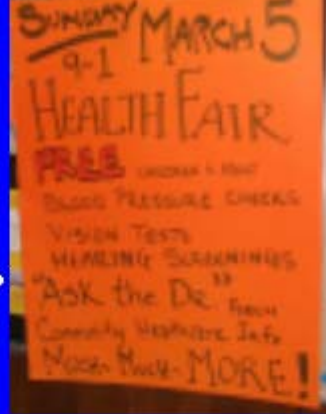
SET-UP



ARRIVE



SET-UP



SIGNS



SCREENING PROCESS



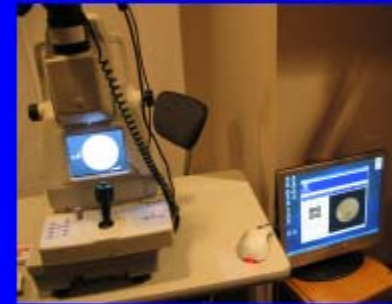
IRB CONSENT



PARTICIPANT
REGISTRATION



PHOTOGRAPHY



POST-SCREENING



IMAGE GRADING & CONSULTATION



FOLLOW-UP

Essential Components

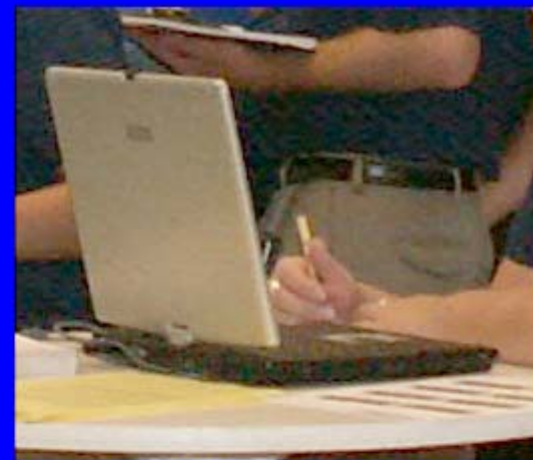
- IRB Consent Forms
- Non-Mydriatic Fundus Digital Camera
- Photographer
- Registration Station
- Router
- Server
- Tent / Curtain / Darkened Area



**Non-Mydriatic Fundus
Digital Camera**



Server & Router



Registration Station



IRB Consent Forms



Photographer



Darkened Area

Optional Components

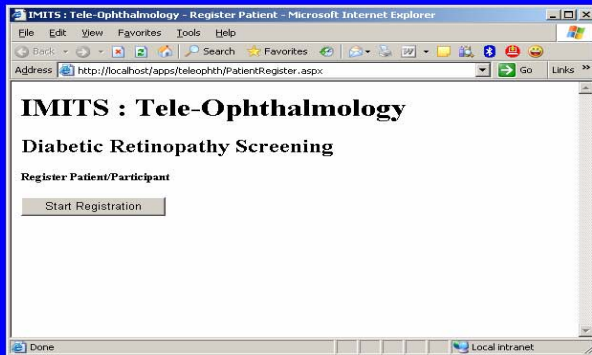
- Image Grading Station
- Vision Tests
- Health Tests
- People to administer the consent forms
- People to register the participants

Hardware

- Server
 - CPU: Pentium M 2.13 GHz
 - Memory: 2 GB
 - OS: Windows Server 2003
 - Hard Drive: 80GB
 - Network: 100 Mb/s
 - Database: Microsoft SQL 2000
- Registration Station
 - CPU: Pentium M 1.5 GHz
 - Memory: 1.5 GB
 - OS: Tablet PC Edition 2005 of Windows XP
 - Hard Drive: 40 GB
 - Network: 802.11 a/b/g (up to 54 Mb/s) or 100 Mb/s

Software

- Registration Page
- Image Acquisition
- Grading Page



IMITS : Tele-Ophthalmology

Diabetic Retinopathy Screening

Register Patient/Participant

Short Form / Long Form

First Name: Mick Middle Name: E Last Name: Mouse Suffix:

Home Phone: (888) 123 - 4567 Other Phone: () - ()

Address: Line 1: 123 Main Street Eye Doctor Name: Dr. Eyes Eye Doctor City: Big City

Line 2: City, St Zip: Anytown, PA 15213 Eye Doctor Type: O.D. Last Dilated Eye Exam: > 12 mos ago

Date Of Birth (mm/dd/yyyy): 01/01/1957 Gender: M C F Pregnant? Trimester: Ethnicity: Multi-Racial

Type of Diabetes: Un-Diagnosed Gestational? Year of Diagnosis: Hgb A1C level: never heard of it %

Next Page



IMITS : Tele-Ophthalmology

Diabetic Retinopathy Screening

Register Patient/Participant

Participant Name : Mick Mouse

Prior Treatment for Diabetic Retinopathy:

Add Another ☒ None ☐ OD ☐ OS

☐ Laser ☐ OD ☐ OS

☐ Vitrectomy ☐ OD ☐ OS

☐ RD Repair ☐ OD ☐ OS

☐ Other ☐ OD ☐ OS

Other Medical/Diabetic Problems:

Add Another ☒ None ☐ HTN ☐ CAD ☐ Renal ☐ Neuropathy ☐ Foot Disease ☐ Depression ☐ Cholesterol ☐ Other

Other Eye Problems:

Add Another ☒ None ☐ Cataract ☐ OD ☐ OS ☐ Glaucoma ☐ OD ☐ OS ☐ AMD (Mac Degen) ☐ OD ☐ OS ☐ Trauma ☐ OD ☐ OS ☐ Other ☐ OD ☐ OS

Other Eye Surgery:

Add Another ☒ None ☐ Cataract Extraction ☐ OD ☐ OS ☐ Glaucoma Surgery ☐ OD ☐ OS ☐ Retinal Detachment Repair ☐ OD ☐ OS ☐ Other ☐ OD ☐ OS

Medications:

Add Another ☒ None ☐ Hypertensive ☐ Cardiac ☐ Cholesterol ☐ Diabetic ☐ Other

Vision: Snellan Visual Acuity: OD 20 OS 20

Pupil Size: 3 3

☒ Participant had Hard-Copy Form

☐ Hard Copy completion improved this patient's Registration process

Submit Form



IMITS : Tele-Ophthalmology

Diabetic Retinopathy Screening

Register Patient/Participant

Mick Mouse has been registered with ID number 10285.

This encounter is ID number 999255.

[Next Participant Registration](#)

SimpleDICOM Wrapper - Version 2.0
File Configuration Help

UPMC
University of Pittsburgh
Medical Center

Select Patient Acquire Images

Refresh 0 uttesd Add Photographer

Registration Time	Unique Identifier	Participant's Last Name	Participant's First Name	MI	Participant's Birthdate
5/6/2006 1:07:00 PM	999255	Mouse	Mick	E	1/1/1957



SimpleDICOM Wrapper - Version 2.0
File Configuration Help

UPMC
University of Pittsburgh
Medical Center

Select Patient Acquire Images

5/6/2006 1:07:00 PM 999255 Mouse Mick E 1/1/1957

Right Eye (O.D.) Left Eye (O.S.)

Take One

Take Two

Take Three

☐ Patient is not imageable.

Enter Comments Here

Submit Comments and Finish Imaging

Diabetes Expo Grading IMITS : Tele-Ophthalmology - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address http://localhost/apps/teleophth/ExpoGrade.aspx

IMITS : Tele-Ophthalmology

Diabetic Retinopathy Screening

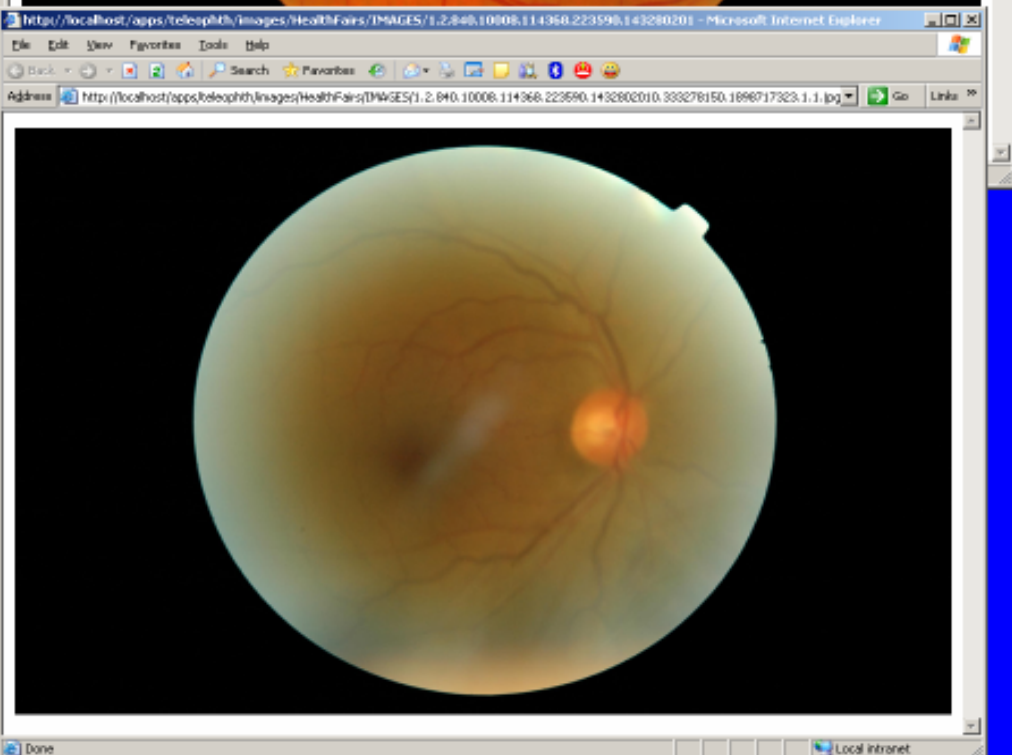
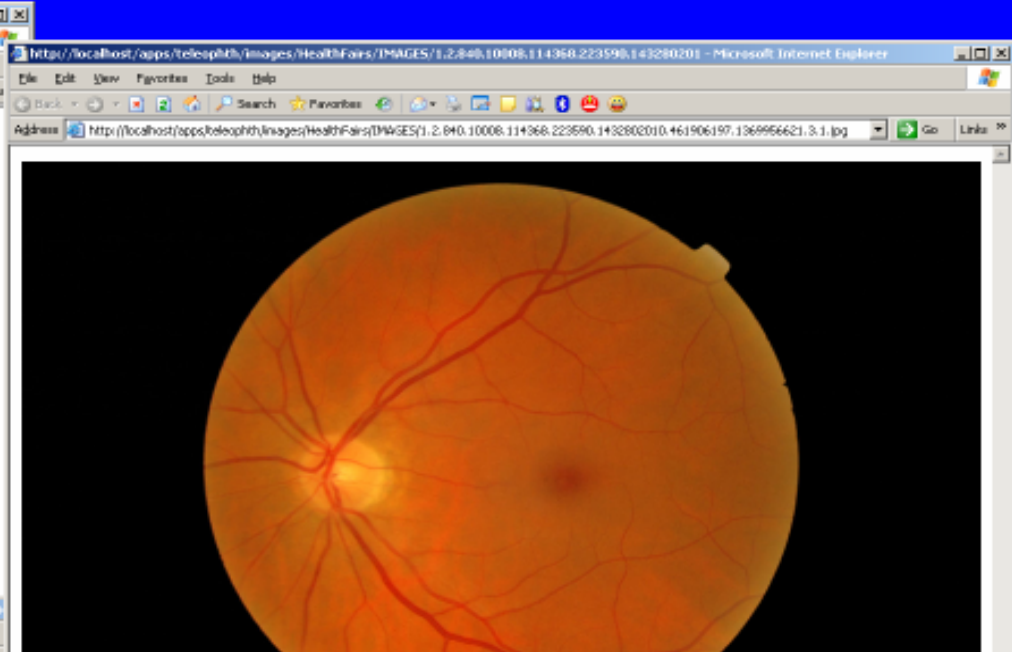
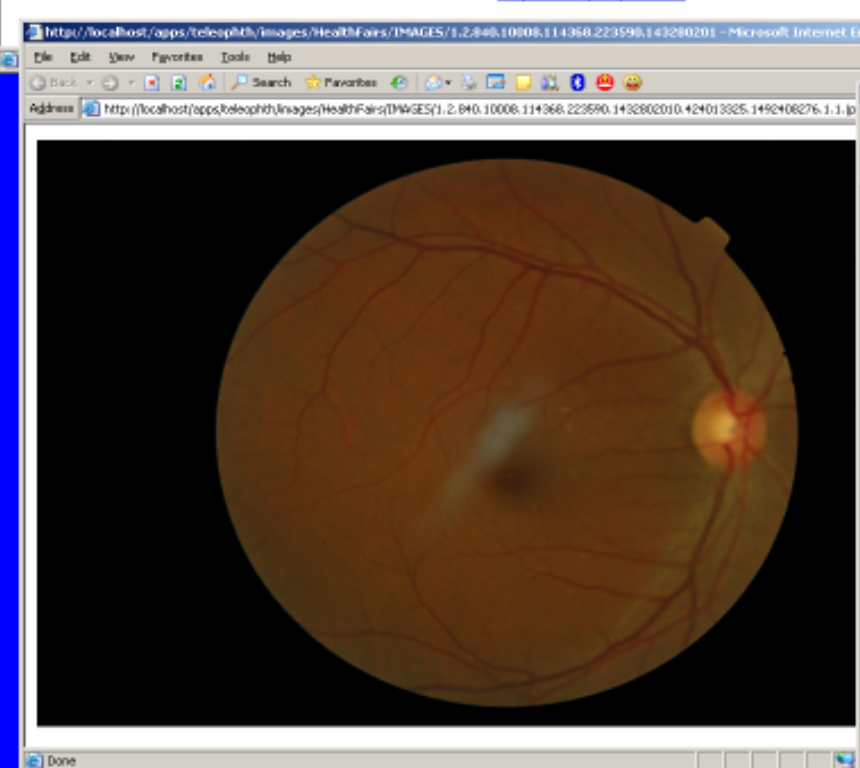
Participant Image Grading

Click on a participant's name to display their list of available images

NOTE: Once a recommended follow-up is selected, the participant will be immediately removed from this list!

Registration Time	Participant Name	Date Of Birth	Recommended Followup	Accession ID
5/4/2006 4:44 PM	Test, My F	1/1/2002		(999254)
5/6/2006 1:07 PM	Morse, Mick E	1/1/1957		(999255)

[OD, Field #0, Sequence #1](#)
[OS, Field #0, Sequence #2](#)
[OD, Field #0, Sequence #3](#)
[OS, Field #0, Sequence #4](#)
[OD, Field #0, Sequence #5](#)
[OS, Field #0, Sequence #6](#)



Discussion

- Electronic Health Record (EHR)
- Automatic timing at each station
- Issues:
 - Camera weight ~27kg (60lbs)
 - Darkened Area
 - Chairs (wheels, backs, armrests)
 - Cables (power, data)
 - Batteries
 - Duct Tape

Conclusion

- Automated method of recording times for each station (registration, imaging, grading)
- Information is easily shared with the EHR.
- Project mobility involves improvisation at each location.

Acknowledgements

- Photographer: Larry Jefferson
- Participant Registration: Barb Mack
- IRB Consent: Monica Cassimir

Contact Information

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- Systems Analyst IV
- UPMC | University of Pittsburgh Medical Center
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OVERVIEW

A non-mydriatic fundus imaging system was used for photo screening of diabetic retinopathy. A flexible, modular and mobile system was designed to efficiently integrate medical history, images and other data. The core of this DOD sponsored system was a laptop with adequate processing power and memory to act as a server with a SQL database, while the rest of the system was comprised of “stations”, such as registration, imaging, and consultation, that can be added, removed or modified as needed to customize the workflow. Each station’s function was worklist driven eliminating typing errors and improving productivity. A server-generated unique identifier tracks participant movement through the stations, possibly non-sequentially depending on the setting and system’s configured layout. Time spent by participants at each station was automatically recorded in the database. The retinal imaging station, configured with custom software, was set up in a darkened area or tent with adequate space and ventilation for the participant, photographer, computer and non-mydriatic retinal camera. The consultation station allowed the participant to discuss their images with a board certified ophthalmologist, who graded the images and made the recommendations for further treatment as was indicated. Methods for developing and customizing the system will be discussed.



Lessons Learned from a Teleophthalmology Program in the US Air Force

Stephen Waller^{1,2}, Gary Lane¹,
William Flynn¹, Jane B. Ward²,
Andrew W. Eller^{2,3}, Sven-Erik Bursell⁴,
and Leslie Anthony³

1. Wilford Hall Medical Center, Lackland AFB, San Antonio, Texas
2. University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania
3. University of Pittsburgh, Pittsburgh, Pennsylvania
4. Joslin Diabetes Center, Boston, Massachusetts

Goals of Study

- To determine the value of undilated retinal photos as a screening tool for retinopathy in the diabetic outreach clinic of a large military hospital
- To validate a system of digital retinal photography with remote reading by teleophthalmology to support screening for diabetic retinopathy
- To serve as phase one of a program to take diabetic retinal photos screening by teleophthalmology to remote military primary care clinics

Methods

- Double-masked clinical trial comparing:
 - dilated retinal exam as 'gold standard'
 - undilated digital retinal photos, read remotely
 - computer reading of digital photos at Texas A&M University (Dept of Computer Sciences and Rural and Community Health Institute, to be reported separately)

IRB approval was obtained from Wilford Hall Medical Center, University of Pittsburgh, and Texas A&M University. Study included intellectual partnership with Joslin Vision Network in Boston.

- Patients from a diabetes outreach clinic gave informed consent for study during annual diabetes exam
- N = 200 selected to obtain adequate statistical power
- Topcon TRC-NWS system with Nikon D-100 camera
- Single posterior pole retinal photo taken by imager with no prior ophthalmologic training
- Photos masked to demographics and clinical outcome, all read later by one ophthalmologist
- Same ophthalmologist performed dilated retinal exam on all subjects, masked to photo results
- Photo data without demographics transmitted to reading center and to Texas A&M University



Approximately 10% of people who have diabetes will develop visual impairment, with 2% becoming blind within 15 years. Blindness from diabetic retinopathy is often preventable with timely treatment. Digital retinal imaging and grading can be used as an important adjunct in identifying patient requiring laser treatment. Patients at risk can be prioritized among large populations of diabetics who do not yet have diabetic retinal disease yet present for annual examination.

American Academy of Ophthalmology Recommendations

- "Not a substitute for comprehensive exam"
- Useful "to identify patients with retinopathy"
- Research on cost-effectiveness and standardized protocols still needed
- Review of literature to date by Ophthalmic Technology Assessment Committee
- Reference: "Single-Field Fundus Photography for Diabetic Retinopathy Screening, A Report by the American Academy of Ophthalmology" Williams GA, et al., *Ophthalmology* 2004; 111:1055-62.

Results

- Sixty-one (15%) of 400 photos read as "unsatisfactory for diagnosis", mostly due to small pupils and cataract.
- Diabetic retinopathy by exam: 14 patients (3.5%)
- Diabetic retinopathy by photo on 14 patients (3.5%)
- Two patients (1%) with need for prompt treatment referred to hospital's retinal specialist on day of exam.
- *If triage of patients had been done on basis of photos alone, none of the 200 study subjects would have been misdirected.*
- *Convenience and avoidance of unpleasant dilation experience led many patients to express enthusiasm for photo screening.*

Challenges

- Lack of access to care may keep some diabetic patients from obtaining their annual eye exam, even in military health system, where care is 'free'.
- It is possible that those patients who have the best social support or the least visual disability are disproportionately present in the group that accesses care successfully.
- Image transfer from the DICOM-compatible proprietary Topcon software, ImageNet, to Microsoft format (.jpg) led to some data overwriting and confusion. By archiving to the Topcon software first, then transferring digital photo data to other media and formats, this error can be avoided.

Opportunities

- Avoidance of unpleasant dilation in up to 85% of patients creates incentive for compliance with recommendations.
- Exam without dilation is faster, leaving time for refraction or additional patients to access care, with emphasis on patients not accessing diabetic eye care now (perhaps due to visual disability or lack of social support).
- Setting up a photo center with lay imager in remote military primary care clinics is our next opportunity!



Summary

- We validated the use of a non-mydratic digital camera to triage diabetic patients for retinopathy.
- Patients were given the same follow-up instructions from the digital photo reading and from the dilated eye exam in 100% of cases.
- When photo quality and patient history are unremarkable, the remote digital photo reading can substitute for annual dilated retinal exam.

Financial Support

This work was supported by funding from Wilford Hall Medical Center, and the U.S. Air Force administered by the U.S. Army Medical Research Acquisition Activity, Fort Detrick, Maryland (Award No. W81XWH-04-2-0030 and Contract No. DAMD 17-0302-0017). The content of the information does not imply U.S. Air Force or Government endorsement of factual accuracy or opinion.

Objective: Develop a flexible, modular and mobile image transfer system and efficient workflow process for non-mydriatic retinal images

UPMC Accomplishments

- Built user interface for importing of data files (JPG or DICOM) and unique identifiers for patients (meta-data)
- Developed process and software to transfer image sets from cameras to server or enterprise network
- Created image reader / grading screens
- Developed a customized TopCon camera assembly manual
- Established SOP and implemented retinal screening process in clinic and community settings
- Collected registration, image and grading data for over 175 subjects

WHMC Accomplishments

- Established ophthalmology service within the Diabetes Outreach Clinic
- Instituted a program of non-mydriatic retinal photos as part of the evaluation for diabetic retinopathy
- Conducted study with 200 subjects for double-masked trial of dilated eye exam vs non-mydriatic photo
- Found 15% of photos not readable by ophthalmologist without access to clinical or demographic information
- Showed that digital photo triage of adult diabetic population was accurate in 100% of study group
- Instituted new clinical standard of care, digital photo reading, in lieu of annual dilated eye exam



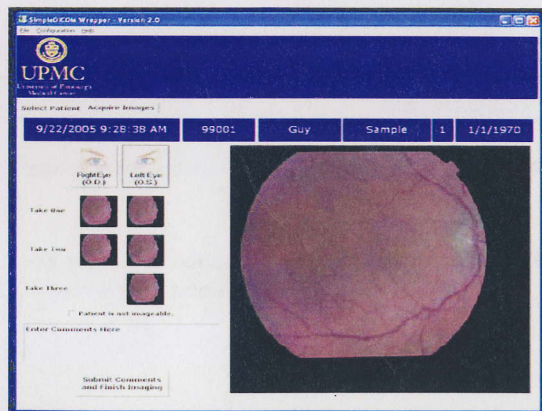
BACKGROUND

Through Congressional funding, the Air Force Medical Service (AFMS) and the University of Pittsburgh Medical Center (UPMC) have created a strategic partnership called the Integrated Medical Information Technology System (IMITS) Program. The focus of the program is on the implementation and evaluation of advanced telemedicine systems and applications. One IMITS project is Teleophthalmology.

Nearly 300 million people have diabetes. Approximately 10% of individuals with diabetes develop severe visual impairments with 2% becoming blind within 15 years. Early screening and diagnosis of diabetic retinopathy before visual loss has occurred is essential. Teleophthalmology offers an alternative method to the traditional office examination; digital images are obtained and sent to specialists at remote locations for diagnosis and tracking.

EVALUATION

Emphasis is placed on the development of sound evaluation methodologies for each project with special attention to areas of user satisfaction and impact on work efficiency and patient care. Findings serve to guide future modifications of the technologies to best meet the needs of UPMC and the military.



UPMC Teleophthalmology Team Members

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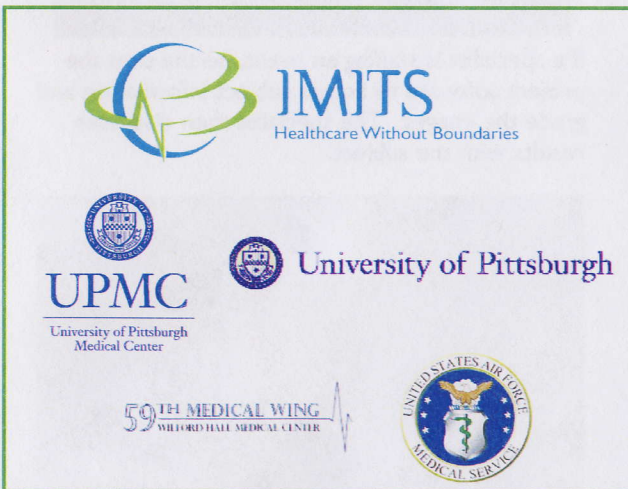
Principle Investigator
Principle Investigator
Project Manager
Systems Programmer
Systems Programmer
Systems Programmer
Software Architect
Clinical Coordinator
Ophthalmic Tech
Ophthalmic Tech
Evaluation Manager
Evaluation Analyst
Diabetes Evaluation
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Ophthalmic Technician
Ophthalmic Technician
SGR Project Manager
Clinical Director

* left UPMC employment March 2006, positions are vacant

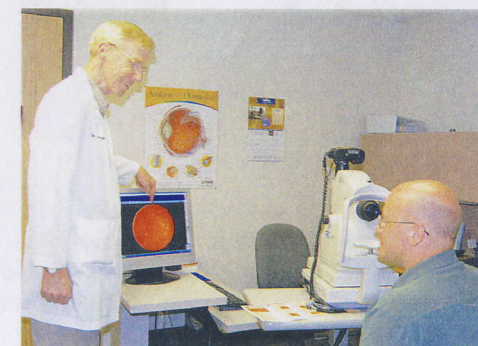


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IMITS TELEOPHTHALMOLOGY PROJECT

Seeing Tomorrow's Vision for the Future, Today



The Screening Process

A flexible, modular and mobile system been developed that can be used efficiently in both clinic and community settings.



Individuals 18 and older with known diabetes are invited to participate as subjects in this project. Subject information is recorded and retinal images are taken by a technologist and graded by a specialist. Subjects receive their results and recommendations for follow-up care. Compliance with

follow-up care is tracked.

Settings

Screenings are offered at two UPMC clinics and at community events held throughout the Pittsburgh area. At Wilford Hall Medical Center, Lackland Air Force Base, screenings were conducted at a base health fair and are routinely offered in a diabetes clinic.



Clinic Settings

Specified areas within each clinic are fully equipped and remain ready for screenings. Project and clinic staff work together to identify and screen eligible subjects. With the ability to store images in a database a specialist can grade the images at a later time. Once grading is complete, a letter is sent to the subject with results.

Community Settings

Upon request, arrangements are made for the project's mobile unit to travel to community events.



If a specialist is staffing an event, he/she uses the project software to access subject information and grade the images. The specialist then discusses results with the subject.



Accomplishments

- Built user interface for packaging images with patient data
- Developed process and software to transfer image sets to server
- Created image reader/grading screens
- Launched screening process in clinic and community settings
- Established SOPs
- Developed customized TopCon camera assembly manuals
- Instituted digital photo screening as the standard of care at WHMC

Evaluation Accomplishments

- University of Pittsburgh collected registration, image and grading data for over 175 subjects
- WHMC completed a study with 200 subjects comparing undilated images to dilated exams
- University of Pittsburgh conducted focus groups with project staff members
- WHMC and UPMC evaluation findings contributed to refinements

Next Steps

- WHMC and UPMC continue to collaborate on this project
- Subject data is being combined to better assess the screening process and outcomes

Lessons Learned from a Teleophthalmology Program in the US Air Force

Stephen Waller^{1,2}, Gary Lane¹,
William Flynn¹, Jane B. Ward²,
Andrew W. Eller^{2,3}, Sven-Erik Bursell⁴,
and Leslie Anthony³

1. Wilford Hall Medical Center, Lackland AFB, San Antonio, Texas
2. University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania
3. University of Pittsburgh, Pittsburgh, Pennsylvania
4. Joslin Diabetes Center, Boston, Massachusetts

- Introduction
- Study Design
- Methods
- Results
- Challenges
- Conclusions

Approximately 10% of people who have diabetes will develop visual impairment, with 2% becoming blind within 15 years.

Blindness from diabetic retinopathy is often preventable with timely treatment.

Digital retinal imaging and grading can be used as an important adjunct in identifying patients requiring laser treatment.

Patients at risk can be prioritized among large populations of diabetics who do not yet have diabetic retinal disease yet present for annual examination.

American Academy of Ophthalmology Recommendations*

- “Not a substitute for comprehensive exam”
- Useful “to identify patients with retinopathy”
- Research on cost-effectiveness and standardized protocols still needed
- Review of literature to date by Ophthalmic Technology Assessment Committee

Reference: “*Single-Field Fundus Photography for Diabetic Retinopathy Screening, A Report by the American Academy of Ophthalmology*” Williams GA, et al., Ophthalmology 2004; 111:1055-62. *

ABSTRACT: In partnership with the University of Pittsburgh Medical Center, Texas A&M University, and the BEetham Eye Institute, Joslin Diabetes Center, ophthalmologists at the US Air Force's Wilford Hall Medical Center have used a non-mydriatic digital camera to capture retinal images of diabetic patients and those at risk for diabetes in a diabetes clinic, primary care clinics, and as a screening modality at a central location within the hospital. The first 4 months of patient outcomes and lessons learned are reported below.

Study Design

- Double-masked clinical trial comparing:
 - Dilated retinal exam as ‘gold standard’
 - One part of complete eye exam by ophthalmologist
 - Undilated digital retinal photos
 - *Specifics of Topcon camera, etc*
 - Computer reading of digital photos at Texas A&M University
 - (Dept of Computer Sciences and Rural and Community Health Institute, to be reported separately)

Methods

- Patients from a Diabetic Outreach Clinic volunteered for study inclusion during annual eye exam
- N = 200 selected by statistician to obtain adequate statistical power from study
- Single macular photo taken by imager with no prior ophthalmic training
- Photos masked to demographics and read later by board-certified ophthalmologist
- Same ophthalmologist performed dilated retinal exam on all subjects masked at the time of exam to photo results for that particular patient

Results

- Sixty-one (15%) of 400 photos read as “unsatisfactory for diagnosis”, mostly due to small pupils and cataract
- Diabetic retinopathy detected by exam on 14 patients (3.5%)
- Diabetic retinopathy detected by photo on 14 patients (3.5%)
- Patients *NUMBER?*(0.5%) with need for prompt laser treatment were referred to Wilford Hall Medical Center retinal specialist on day of examination

More Results

- If triage of patients had been done on basis of photos alone, none of 200 would have been misdirected
- Convenience and avoidance of unpleasant dilation experience led many patients to express enthusiasm for photo screening

Challenges

Administrative

- Referrals/ recruitment/ scheduling

- Workflow

- Reimbursement/ return on investment

Technical

- Camera

- Software

- Imager

Patient/ provider issues

- Patient with other ocular co-morbidity, small pupils

- Education

- Satisfaction

Challenges

- Lack of access to care may keep some diabetic patients from obtaining their annual eye exam, even in the military health system, where care is “free”
- Patients with the best social support or the least visual disability (mildest form of disease) may be disproportionately present in the group who access care successfully

More Challenges

- Data overwriting and confusion
 - Step in the process: Image transfer from the proprietary Topcon software, ImageNet, to Microsoft format (.jpg)
 - Solution: archive to the Topcon software first, then transfer digital photo data to other media and formats

Conclusions

- The use of a non-mydriatic digital camera to triage unscreened type 2 diabetic patients between the ages of 18-62 was validated in a series of 200 patients seen by the Wilford Hall Diabetic Outreach Clinic ophthalmologist
- Patients were given the same follow-up instructions based on either the digital photo reading or from the dilated eye exam in 100% of cases
- When photo quality is good and patient history is unremarkable, the digital photo reading can substitute for annual dilated retinal exam for diabetic retinopathy screening

Additional Comments

- Avoidance of dilation in up to 85% of diabetic patients may create incentives for them to obtain the recommended annual diabetic eye exam
- An eye exam without dilation can be quicker, leaving time for refraction or for additional patients to access care. Particular attention should perhaps be directed towards those who miss appointments or do not access annual eye exams (perhaps due to visual disability or lack of social support or lack of patient/provider education).



Evaluation Team

Implementation and Acceptance of
Teleophthalmology Program for Retinal Screening in
Clinical Settings

Authors

Robb Wilson, MA¹

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Collaborators

- University of Pittsburgh, Department of Biomedical Informatics
- University of Pittsburgh Medical Center (UPMC) Integrated Medical Information Technology System (IMITS)
- University of Pittsburgh, Diabetes Institute
- UPMC Eye Center

Background

- UPMC developed a process for packaging and transporting digital images.
- The IMITS program customized this process for retinal images to overcome challenges of providing adequate screening and diagnostic services for people at risk for diabetic retinopathy.
- The Diabetes Institute used the IMITS customized software to implement an effective/functional telemetric screening program for diabetic retinopathy using single-field non-mydratic digital fundus photography.

Funding/Disclaimer

- This work was supported by funding from the U.S. Air Force administered by the U.S. Army Medical Research Acquisition Activity, Fort Detrick, Maryland (Award No. W81XWH-04-2-0030 and Contract No. DAMD 17-0302-0017).
- The content of the information does not imply U.S. Air Force or Government endorsement of factual accuracy or opinion.

Diabetes

- There are 20.8 million children and adults in the United States, or 7% of the population, who have diabetes.
- Nearly one-third or 6.2 million are unaware that they have the disease.
- It is estimated that if the present trend continues, one in three Americans born in 2000 will develop diabetes in their lifetime.

Diabetic Retinopathy

- Diabetes causes 12,000 to 24,000 new cases of blindness each year and for adults 20 -74 years of age it is the leading cause of blindness.
- We now have tools to help prevent blindness from diabetic retinopathy, i.e. laser therapy.
- Early detection however is essential.

Diabetic Retinopathy



Diabetic Retinopathy is associated with diabetes and results when tiny blood vessels in the retina break causing hemorrhages on or in the retina. Vision may be blurred or distorted or the hemorrhaging can cause a deep reddish veil over the field of vision.

Courtesy National Eye Institute.

Evaluation Objectives

- Evaluate innovative approach to diabetic retinal screening.
- Assess real-world application of the teleophthalmology technology in community and clinical settings.
- Apply lessons learned from each phase of implementation to improve the technology and workflow model.

Observational Settings

- Center for Diabetes and Endocrinology, Falk Clinic at UPMC Presbyterian Hospital
- General Internal Medicine Clinic at UPMC Montefiore Hospital
- Community Health Fairs and Symposiums

Subject Demographics

	Falk Clinic (n=122)	General Internal Medicine (n=247)	Community (n=337)
Gender			
• male	60 (51%)	122 (49%)	132 (39%)
• female	62 (49%)	125 (51%)	205 (61%)
Mean Age In Years	51	57	61
Race			
• Caucasian	89 (73%)	132 (53%)	265 (78%)
• African American	28 (23%)	102 (41%)	64 (19%)
• Asian	1 (1%)	2 (1%)	3 (1%)
• Hispanic	3 (2%)	-	3 (1%)
• Multi-Racial	1 (1%)	1 (1%)	-
• Other/Unknown	-	10 (4%)	2 (1%)

Subject Demographics

	Falk Clinic (n=122)	General Internal Medicine (n=247)	Community (n=337)
Diabetes			
• Type 1	44 (36%)	18 (7%)	21 (6%)
• Type 2	78 (64%)	229 (93%)	316 (94%)
Mean Duration In Years	13	10	8
Mean A1c Percentage	7.4	7.3	7.2
Last Eye Exam			
• Less than 1 Month	3 (2%)	4 (2%)	15 (5%)
• 1 – 3 Months	5 (4%)	24 (10%)	25 (7%)
• 3 – 6 Months	19 (16%)	28 (11%)	32 (10%)
• 6 – 12 Months	41 (34%)	73 (29%)	71 (21%)
• Greater Than 12 Months	51 (42%)	111 (45%)	173 (51%)
• Never	3 (2%)	4 (2%)	18 (5%)
• Unknown	-	3 (1%)	3 (1%)

IMITS: Teleophthalmology

Registration Data

Name: Test
Participant ID:
Encounter ID:
Gender: F
Date of Birth: 2/10/1918
Ethnicity: Caucasian

Diabetes Type: Un-Diagnosed
Diagnosed:

Hgb A1C Understanding: Not Known
Hgb A1C: %

Last Eye Exam: 6 - 12 mos ago

Eye Doctor's Name: Dr.
Eye Doctor's Type: M.D.
Eye Doctor's City: Bedford

PCP's Name:
PCP's City:

Prior Treatment for Diabetic Retinopathy

Treatment	OS	OD
None		

Other Eye Problems

Eye Problem	OS	OD
None		

Other Eye Surgery

Eye Surgery	OS	OD
Cataract Extraction	X	X

Medical / Diabetic Problems

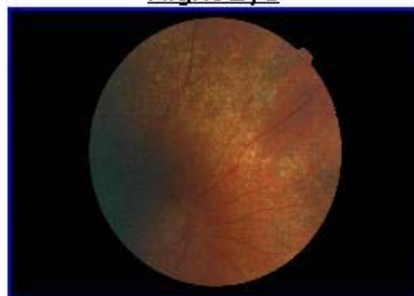
Cholesterol
HTN -
Hypertension
(High Blood
Pressure)

Medication Types

Hypertensive

Participant Images

Right Eye



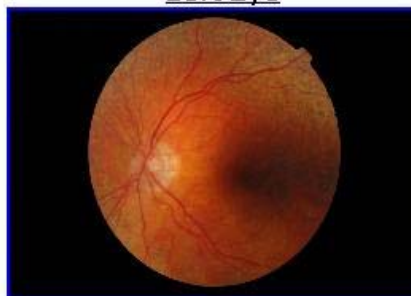
**This Photograph
Was Not Taken**

Retinal Findings -- Right Eye

Level of Retinopathy

- ☐ A. Microaneurysms
- ☐ B. Intraretinal Hemorrhages
- ☐ C. Hard Exudates (HE)
- ☐ D. Cotton Wool Spots
- ☐ E. Venous Beading
- ☐ F. Intraretinal Microvascular

Left Eye



**This Photograph
Was Not Taken**

Retinal Findings -- Left Eye

Level of Retinopathy

- ☐ A. Microaneurysms
- ☐ B. Intraretinal Hemorrhages
- ☐ C. Hard Exudates (HE)
- ☐ D. Cotton Wool Spots
- ☐ E. Venous Beading
- ☐ F. Intraretinal Microvascular

Image Quality

- ☐ Excellent
- ☐ Adequate
- ☐ Poor, but barely gradeable
- ☐ Poor, unable to grade

Recommended Follow-Up

- ☒ One Year
- ☐ 6 Months
- ☐ 3 Months
- ☐ Within 6 Weeks

☐ Teaching File

☐ External image enhancement
software was used to help
diagnosis

Reader Comments

Error Messages

Save

Print

Eye Category: ☐ ☒ ☐
Cataract Extraction ☒ ☒

Medical / Diabetic Problems
Cholesterol
HTN - Hypertension (High Blood Pressure)

Medication Types
Hypertensive

Screening Location: Outing

Register: Unknown
Register Login Name: unknown

Imager: Jefferson, Larry M
Imager Login Name: jefflm

Reader: Eller, Andrew W
Reader Login Name: elleraw
Reader Is a QA Reader: True

QAReader: Unknown
QAReader Login Name: unknown
QAReader Is a QA Reader: False

Logged In Person: 1UPMC-ACCT\cecilra
*** True *** Negotiate

Registration Comments

Imaging Comments

Retinal Findings -- Right Eye

Level of Retinopathy

☐ A. Microaneurysms
☐ B. Intraretinal Hemorrhages
☐ C. Hard Exudates (HE)
☐ D. Cotton Wool Spots
☐ E. Venous Beading
☐ F. Intraretinal Microvascular Abnormalities (IRMA)
☐ G. Neovascularization Elsewhere (NVE)
☐ H. Neovascularization of the Disc (NVD)
☐ I. Vitreous Hemorrhage
☐ J. Tractional Retinal Detachment
☐ K. Previous Laser Scars
☐ L. Rhemaogenous Retinal Detachment
☐ M. Retinal Thickening in Macula
☐ N. Soft Exudate (SE)
☐ O. Other
☐ P. None

Maculopathy
☐ Yes ☐ No

Other Findings

☐ A. Macular Degeneration
☐ B. BRVO
☐ C. CRVO
☐ D. Glaucoma
☐ E. None

Retinal Findings -- Left Eye

Level of Retinopathy

☐ A. Microaneurysms
☐ B. Intraretinal Hemorrhages
☐ C. Hard Exudates (HE)
☐ D. Cotton Wool Spots
☐ E. Venous Beading
☐ F. Intraretinal Microvascular Abnormalities (IRMA)
☐ G. Neovascularization Elsewhere (NVE)
☐ H. Neovascularization of the Disc (NVD)
☐ I. Vitreous Hemorrhage
☐ J. Tractional Retinal Detachment
☐ K. Previous Laser Scars
☐ L. Rhemaogenous Retinal Detachment
☐ M. Retinal Thickening in Macula
☐ N. Soft Exudate (SE)
☐ O. Other
☐ P. None

Maculopathy
☐ Yes ☐ No

Other Findings

☐ A. Macular Degeneration
☐ B. BRVO
☐ C. CRVO
☐ D. Glaucoma
☐ E. None

Error Messages

Save

Print

Copy Screen To Clipboard

Grading Follow-up Recommendations

- Within six weeks – proliferative retinopathy
- Three months – severe non-proliferative retinopathy
- Six months – moderate non-proliferative retinopathy
- One year – no retinopathy or microaneurysms

Imaging Results

	Falk Clinic (n=122)	General Internal Medicine (n=247)	Community (n=337)
Follow-up Recommendation			
• Within 6 Weeks	2 (2%)	2 (1%)	2 (1%)
• 3 Months	10 (8%)	6 (2%)	11 (3%)
• 6 Months	5 (4%)	10 (4%)	13 (4%)
• One Year	94 (77%)	181 (73%)	263 (78%)
• Cannot Be Graded	11 (9%)	46 (19%)	40 (12%)
• Not Imaged	-	2 (1%)	8 (2%)

Result Letter

Appendix 6.3

 **UPMC** | University of Pittsburgh
Medical Center

Patient Name: _____

Thank you for participating in the Diabetic Retinopathy Screening program, through the UPMC Eye Center and University of Pittsburgh Diabetes Institute. Please be advised that this was done for screening purposes only, and it does not take the place of a complete eye exam with an ophthalmologist.

It is recommended that everyone with diabetes have a dilated eye exam on a yearly basis. In some cases, more frequent eye exams are recommended. If you have not had an eye exam in the past year, we recommend that you schedule an appointment for a dilated eye exam.

Your diabetic retinopathy screening was performed on _____.

Based on your screening we recommend:

☐ Continued yearly, dilated eye exams (normal or mild Diabetic Retinopathy)

☐ Dilated eye exam within the next:

☐ Six months (moderate Diabetic Retinopathy)

☐ Three months (risk of progression needing treatment)

☐ Six weeks (disease requiring immediate evaluation)

☐ Other: _____

☐ No recommendation can be made because of problems with the camera.

If you have any questions, please give us a call at 412-647-7109.

Screeners Initials: _____

Clinics

- Falk Clinic
 - Imaging began February, 2006
 - Imaging temporarily stopped
January, 2007
- General Internal Medicine
 - Imaging began November, 2005

Clinic Camera

- Falk Clinic



General Internal Medicine

- 100-150 patients attend clinic on a typical day, 75-100 are given an electronic tablet.
- 4924 patients with any type of diabetes.
- 247 patients imaged from Nov/05 - Mar/07.
 - 5% of the patients with diabetes.

Methods of Interventions In Clinics

- Breakfast meetings
- Signage
- Focus groups
- Research question

Signage

Diabetes Eye Screening Study

If you have diabetes, or know of someone with diabetes,
a simple research screening is available at this location.

It's fast, it's easy and NO EYE DROPS are required.



If you have diabetes, an annual eye exam is essential...

- Retinopathy is the number one cause of blindness in people with diabetes
- One can have excellent vision, and yet have eye damage
- Early detection and laser treatment can prevent blindness

Please ask your health care provider to
schedule your screening TODAY.

Schedule at another time by calling (412) 647-7109.

Focus Groups

- Increase signage.
- Physician need/not need to write order/recommendation?
- Patients often in hurry.
- Staff/physicians forget to offer to patients.
- Staff handle/not handle consent forms?
- Staff willing to help with study.
- Physicians need more information.



University of Pittsburgh
Division of General Internal Medicine

[<--Back](#)

You are logged in as: PunkRock Girl

[Print Comprehensive](#)

This office is participating in a research study using retinal photography (a picture of the blood vessels in your eyes) to check for damage to your eyes from diabetes. This can help detect eye disease while it is still treatable and help prevent loss of vision. This study does not involve eye drops and it does not substitute for your usual eye exams. Would you be interested in learning more about this study?

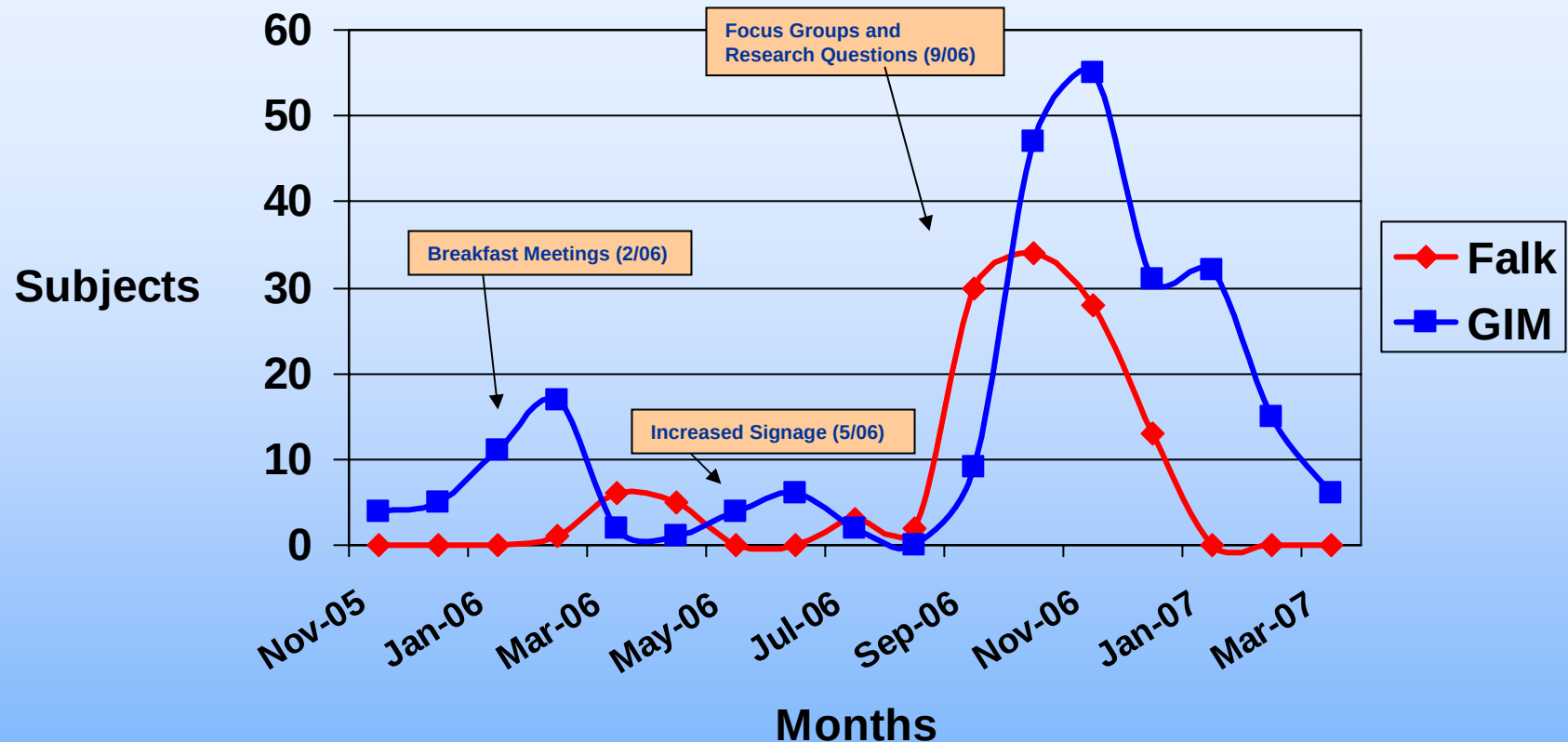
☐ Yes ☐ No ☐ Not Sure, I'd like more information

Next Page

Response to Question

- 635 patients with diabetes given the electronic question from Sep/06 through Mar/07.
 - 196 responded YES to question.
 - 97 responded MAYBE to question.
 - 46% positive response to question.
- 195 patients imaged since electronic question was turned on.

Interventions Over Time



Summary

- 653 subjects with diabetes were successfully consented, registered, imaged and had their eye photos graded.
 - 337 community sites
 - 316 clinical sites.
- Mean time for subjects to be registered, imaged and have eye photos graded was 00:13:13.
- 52% of the subjects reported that their last eye exam was “Greater than 12 Months” or “Never”
- 89% of our sample were instructed to follow-up with their eye doctor within one year. Six (1.08 %) were asked to see their eye doctor within 6 weeks.

Conclusions

- Eyes do not need to be dilated to produce a gradable retinal image.
- Quality retinal screening can be done in a clinical setting.
- Communication with clinical staff is essential.
- Providing patient results to the clinical staff is a plus.
- We can supply a valuable service to the patient with diabetes.

Website

<http://www.dbmi.pitt.edu/news.html#archive>

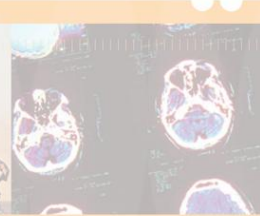
UPMC



Innovative Medical And Information Technologies

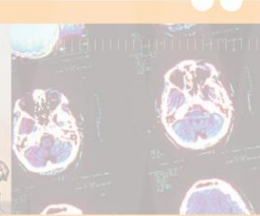
Teleophthalmology

Diabetic Retinopathy Screening Study



Background

- **Purpose**
 - Develop a flexible, modular, and mobile image transfer system and efficient workflow process for non-mydratic, retinal images
- **Collaborators**
 - UPMC IMITs Center
 - University of Pittsburgh Diabetes Institute
 - UPMC Eye Center
 - University of Pittsburgh Department of Biomedical Informatics
 - Wilford Hall Medical Center



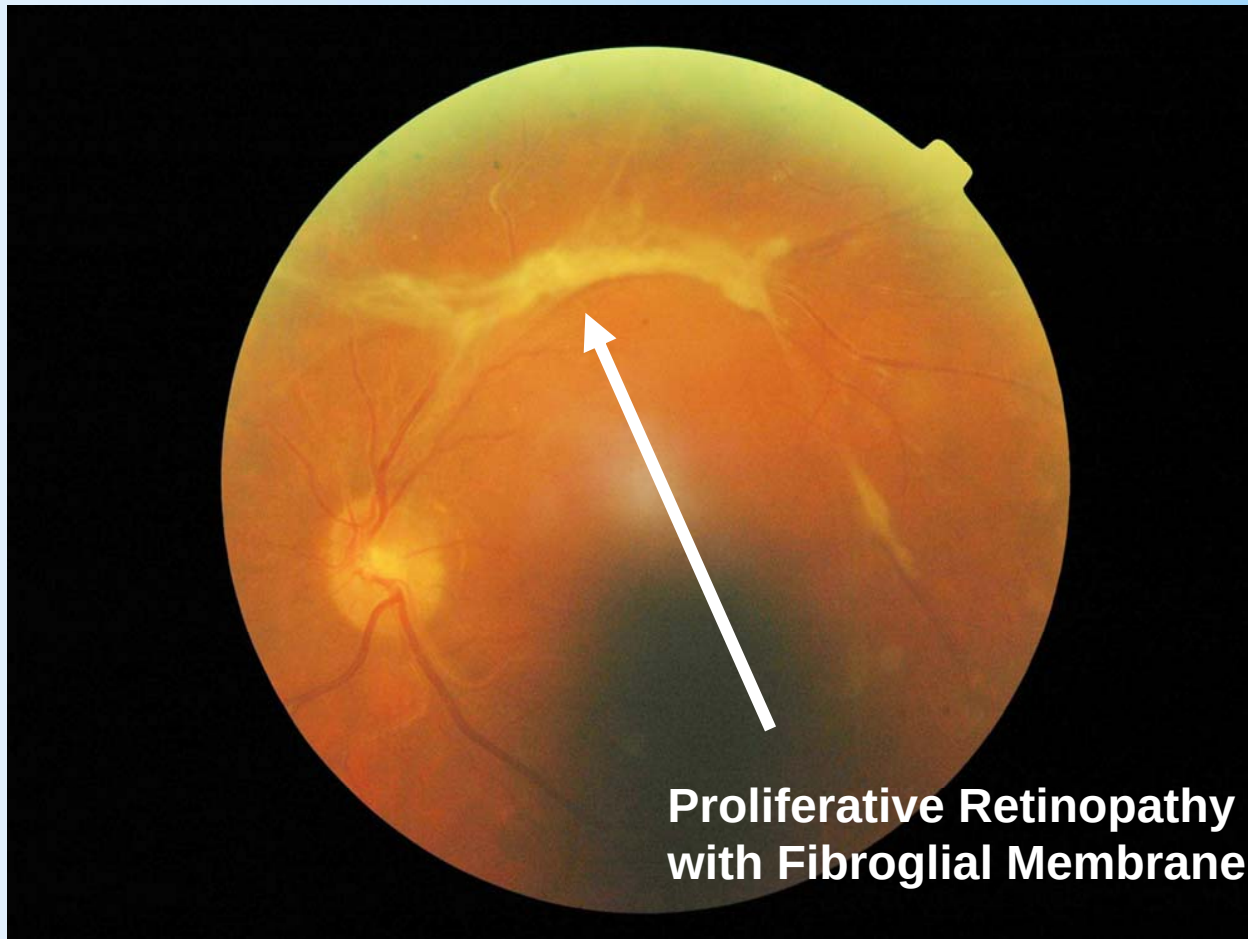
Background



- **Funding**
 - 2004 congressional appropriations were awarded to the IMITS initiative with support from Congressman Murtha
 - The Teleophthalmology Project was created to help detect and treat diabetic retinopathy

Fact

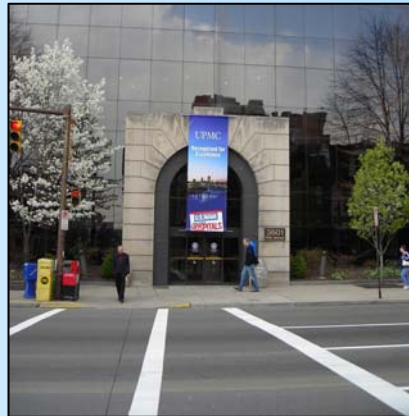
- **Complications of diabetes result in 12,000 to 24,000 new cases of blindness each year**



Significance



- **Stationary equipment located in a clinical setting can promote retinal screenings for people at high risk for diabetic retinopathy**



Significance

- Portable equipment transported to community events can enable retinal screenings for people in areas with poor access to eye care



- No dilation required; retinal images are rapidly captured with non-mydriatic fundus cameras



Process

- Medical history is linked with images and transmitted to a remote specialist



- A specialist uses the internet to access and grades the images

IMITS: Teleophthalmology

Participant Images

Registration Data

Name: Test
 Participant ID:
 Encounter ID:
 Gender: F
 Date of Birth: 2/10/1918
 Ethnicity: Caucasian

Diabetes Type: Un-Diagnosed
 Diagnosed:

Hgb A1C Understanding: Not Known
 Hgb A1C: %

Last Eye Exam: 6 - 12 mos ago

Eye Doctor's Name: Dr.
 Eye Doctor's Type: M.D.
 Eye Doctor's City: Bedford

PCP's Name:
 PCP's City:

Prior Treatment for Diabetic Retinopathy		
Treatment	OS	OD
None		

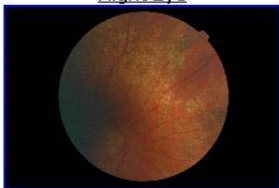
Other Eye Problems		
Eye Problem	OS	OD
None		

Other Eye Surgery		
Eye Surgery	OS	OD
Cataract Extraction	X	X

Medical / Diabetic Problems	
Cholesterol	
HTN - Hypertension (High Blood Pressure)	

Medication Types	
Hypertensive	

Right Eye




This Photograph Was Not Taken

Left Eye




This Photograph Was Not Taken

Retinal Findings -- Right Eye

Level of Retinopathy

☐ A. Microaneurysms

☐ B. Intraretinal Hemorrhages

☐ C. Hard Exudates (HE)

☐ D. Cotton Wool Spots

☐ E. Venous Beading

☐ F. Intraretinal Microvascular

Retinal Findings -- Left Eye

Level of Retinopathy

☐ A. Microaneurysms

☐ B. Intraretinal Hemorrhages

☐ C. Hard Exudates (HE)

☐ D. Cotton Wool Spots

☐ E. Venous Beading

☐ F. Intraretinal Microvascular

Image Quality

☐ Excellent

☐ Adequate

☐ Poor, but barely gradeable

☐ Poor, unable to grade

Recommended Follow-Up

☒ One Year

☐ 6 Months

☐ 3 Months

☐ Within 6 Weeks

☐ Teaching File

☐ External image enhancement software was used to help diagnosis

Reader Comments

Error Messages

Save

Print

- Treatment recommendations are sent to the subject and compliance is monitored with project software

Appendix 6.3

 **UPMC** | University of Pittsburgh Medical Center

Patient Name: _____

Thank you for participating in the Diabetic Retinopathy Screening program, through the UPMC Eye Center and University of Pittsburgh Diabetes Institute. Please be advised that this was done for screening purposes only, and it does not take the place of a complete eye exam with an ophthalmologist.

It is recommended that everyone with diabetes have a dilated eye exam on a yearly basis. In some cases, more frequent eye exams are recommended. If you have not had an eye exam in the past year, we recommend that you schedule an appointment for a dilated eye exam.

Your diabetic retinopathy screening was performed on _____.

Based on your screening we recommend:

☐ Continued yearly, dilated eye exams (normal or mild Diabetic Retinopathy)

☐ Dilated eye exam within the next:

☐ Six months (moderate Diabetic Retinopathy)

☐ Three months (risk of progression needing treatment)

☐ Six weeks (disease requiring immediate evaluation)

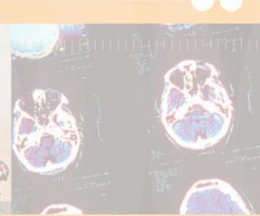
☐ Other: _____

☐ No recommendation can be made because of problems with the camera.

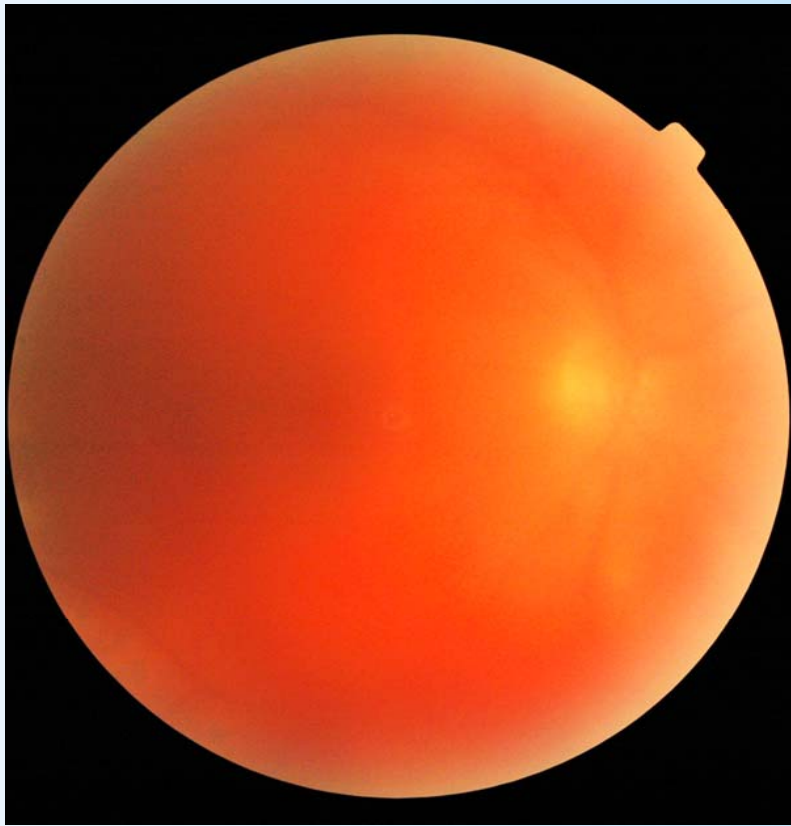
If you have any questions, please give us a call at 412-647-7109.

Screener's Initials: _____

IMITS: Teleophthalmology												
Participant Tracking												
Participant's Name	Date Of Study	Sent Copy of Consent Form to Participant	Study Grade (Requested Follow-Up Timeline)	Sent Image Results Letter to Participant	Participant Requests Copy Of Results To Eye Doctor	Completed Giving Copy Of Results To Eye Doctor	Participant Requests Copy Of Results To PCP	Completed Giving Copy Of Results To PCP	Planned Follow-up Date	Reminded Participant of Requested Follow-up	Actual Follow-up Date	Participant Complied with Follow-up
	8/27/2005	☒		☒	No		No			☒		Unknown
	8/27/2005	☒		☒	No		No			☒		Unknown
	8/27/2005	☒		☒	No		No			☒		Unknown
	8/27/2005	☒		☒	No		No			☒		Unknown
	8/27/2005	☒		☒	No		No			☒		Unknown
	8/27/2005	☒		☒	No		No			☒		Unknown



- Timely laser therapy can help prevent blindness from diabetic retinopathy



Vitreous Hemorrhage



PRP Laser



- Over 700 high-risk subjects were screened for diabetic retinopathy

	Endocrinology Clinic (n = 122)	General Internal Medicine Clinic (n=247)	Community Events (n=337)
Race			
• Caucasian	89	132	265
• African American	28	102	64
• Asian	1	2	3
• Hispanic	3	0	3
• Multi-Racial	1	1	0
• Other	0	10	1
• Unknown	0	0	1
Gender			
• Male	60	122	132
• Female	62	125	205
Last Eye Exam			
• < 1 Month	3	4	15
• 1 – 3 Months Ago	5	24	25
• 3 – 6 Months Ago	19	28	32
• 6 – 12 Months Ago	41	73	71
• > 12 Months	51	111	173
• Never	3	4	18
• Unknown	0	3	3



Results

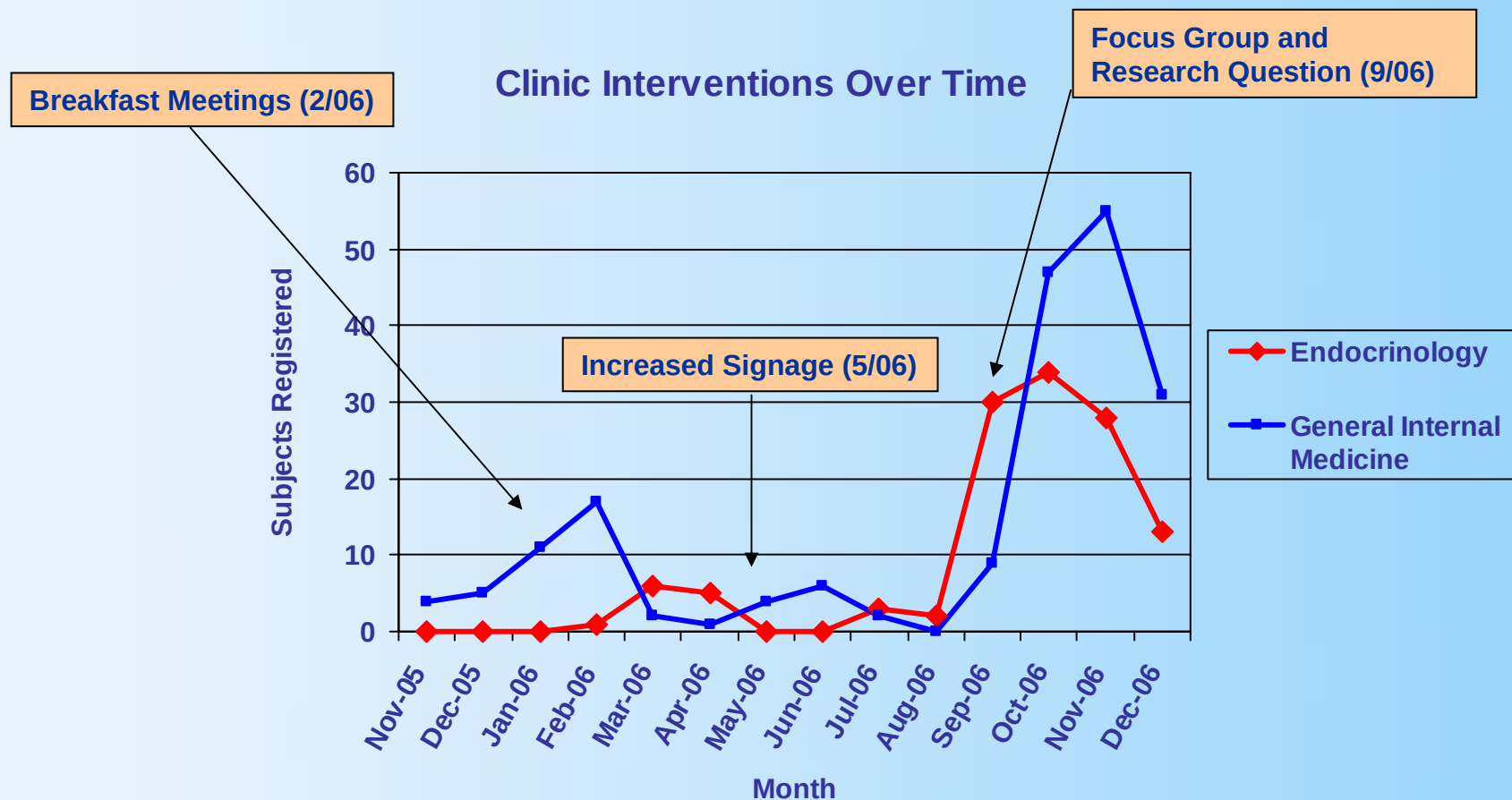
- Subjects received reliable, accurate information in a timely manner from dedicated personnel

	Endocrinology Clinic (n=122)	General Internal Medicine Clinic (n=247)	Community Events (n=337)
Type of Diabetes			
• Type 1	44	18	21
• Type 2	78	229	316
Follow-up Recommendation			
• Within 6 Weeks	2	2	2
• 3 Months	10	6	11
• 6 Months	5	10	13
• One Year	94	181	263
• Cannot Be Graded*	11	46	40
• Not Imaged	0	2	8
Average Process Time (Registration, Imaging, Grading)	18.10 min	11.39 min	11.99 min

* Subjects who had a “Cannot Be Graded” rating will be contacted in order to schedule another imaging session

Evaluation Results

- A number of interventions were conducted with clinic staff in order to identify workflow and recruitment problem areas

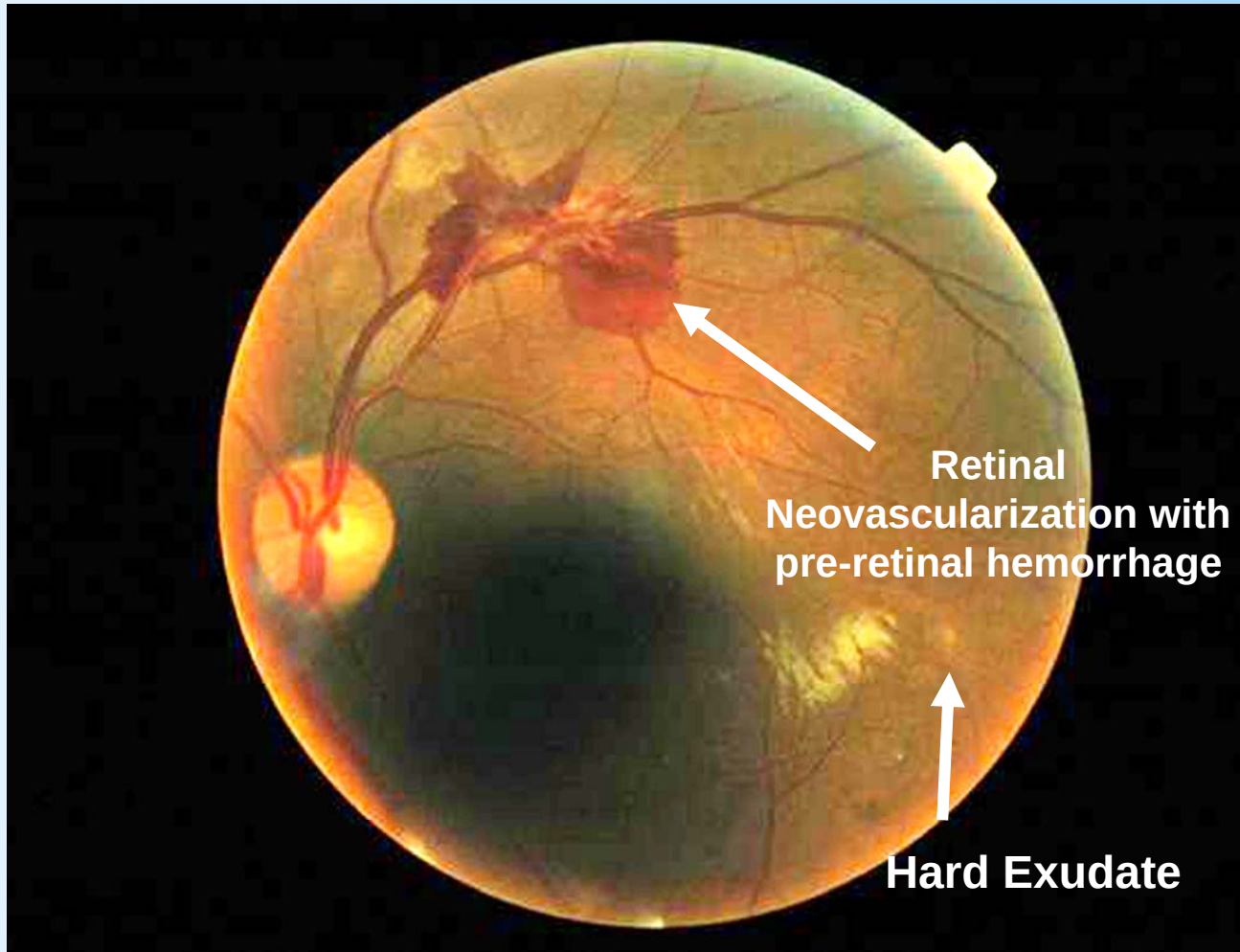


Evaluation Results

- **88% of the population had Type 2 diabetes**
- **51% of the population had their last eye examination over a year ago**

With the prevalence of diabetes increasing, it is imperative for diabetics to receive yearly eye exams that screen for diabetic retinopathy as well as other eye diseases

- Early detection is essential.



Q: If you build it, will they come?



- Despite building this non-invasive, easy and free screening procedure, the project initially had difficulty recruiting participants



Conclusion

- A: YES, diabetics will come for screenings, but we cannot assume that this will be automatic**
- Some health care workers may see the screenings as interfering with their work**
 - A successful screening program will require:**
 - Education of MD's & office staff**
 - Education of patients**
 - Marketing / Advertising**
 - Ongoing evaluations and interventions to assure optimal usage**



Next Steps

- **Train diabetic educators as imagers and link educational sessions with retinal screenings**
- **Recruit health plans to target people with diabetes who are not receiving proper eye care**
- **Promote retinal screenings in the consumer market place (e.g., Pearl Vision, Walmart) to maximize outreach**



Acknowledgement

- This work was supported by funding from the U.S. Air Force administered by the U.S. Army Medical Research Acquisition Activity, Fort Detrick, Maryland (Award No. W81XWH-04-2-0030 and Contract No. DAMD 17-0302-0017). We work through the Integrated Medical Information Technology System (IMITS) program.
- The content of the information does not imply U.S. Air Force or Government endorsement of factual accuracy or opinion

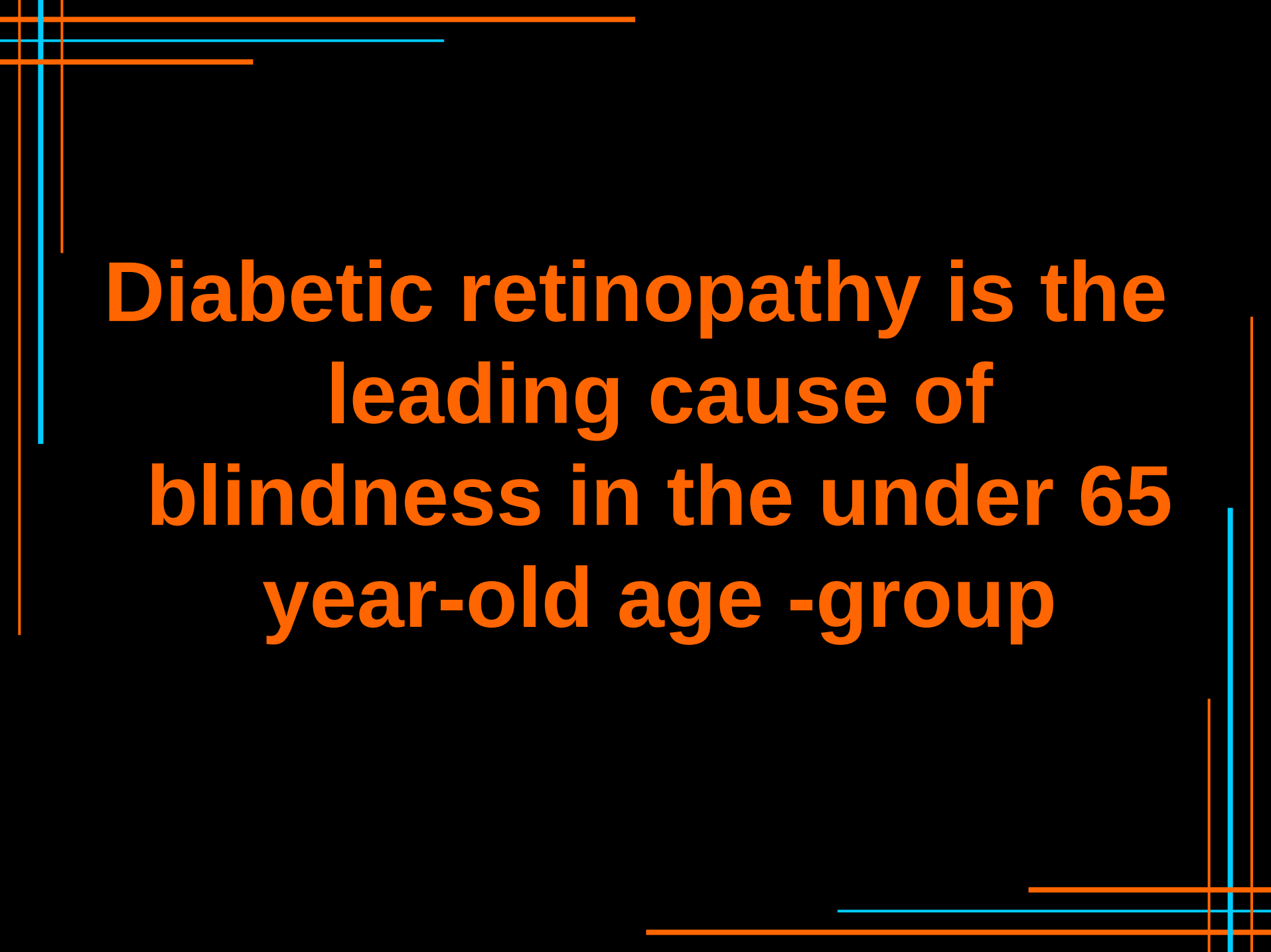
Diabetic Retinopathy Screening



Teleophthalmology Project

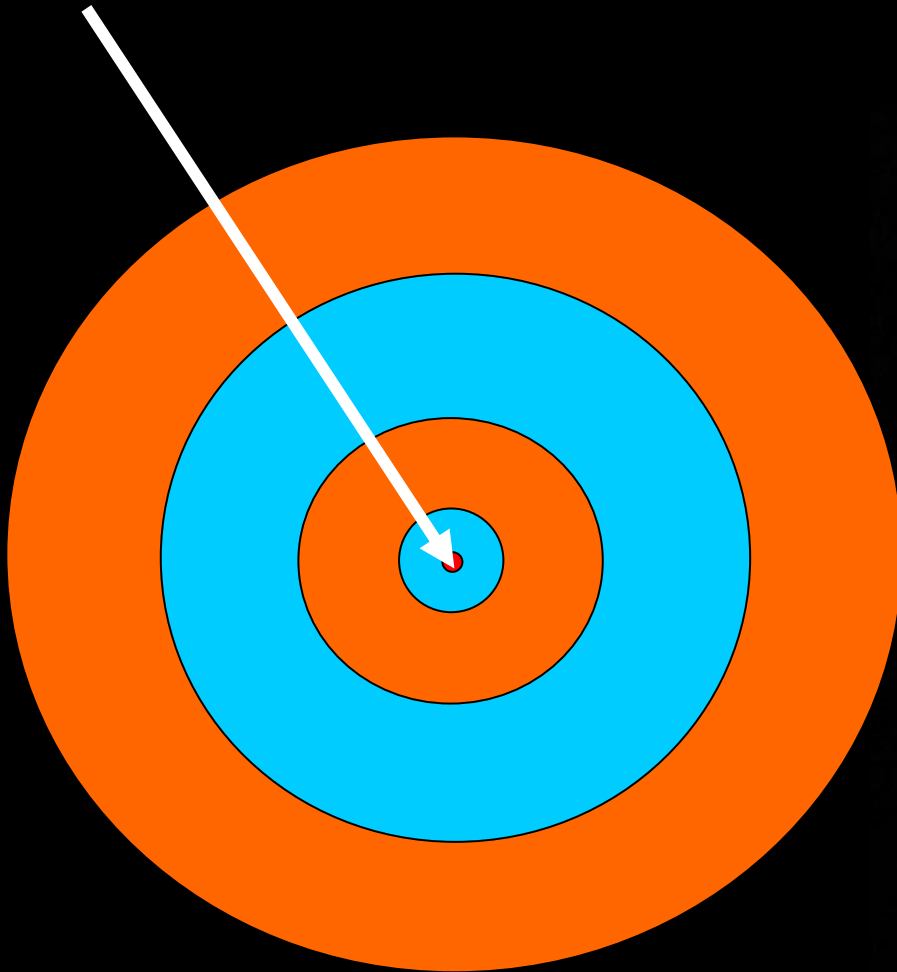


**The foremost mission of all
ophthalmologists is the
prevention or treatment of
blindness**

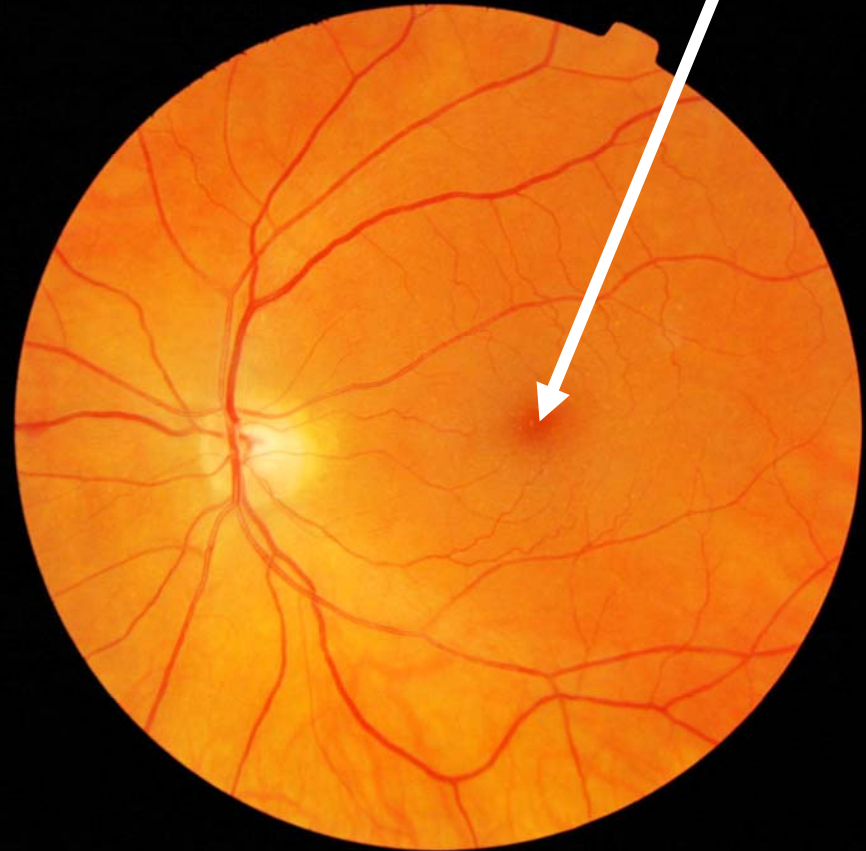


**Diabetic retinopathy is the
leading cause of
blindness in the under 65
year-old age -group**

Highest points = best vision



Bulls eye = 100 points



Center of Macula (Fovea)

= 20/20 vision

Macula

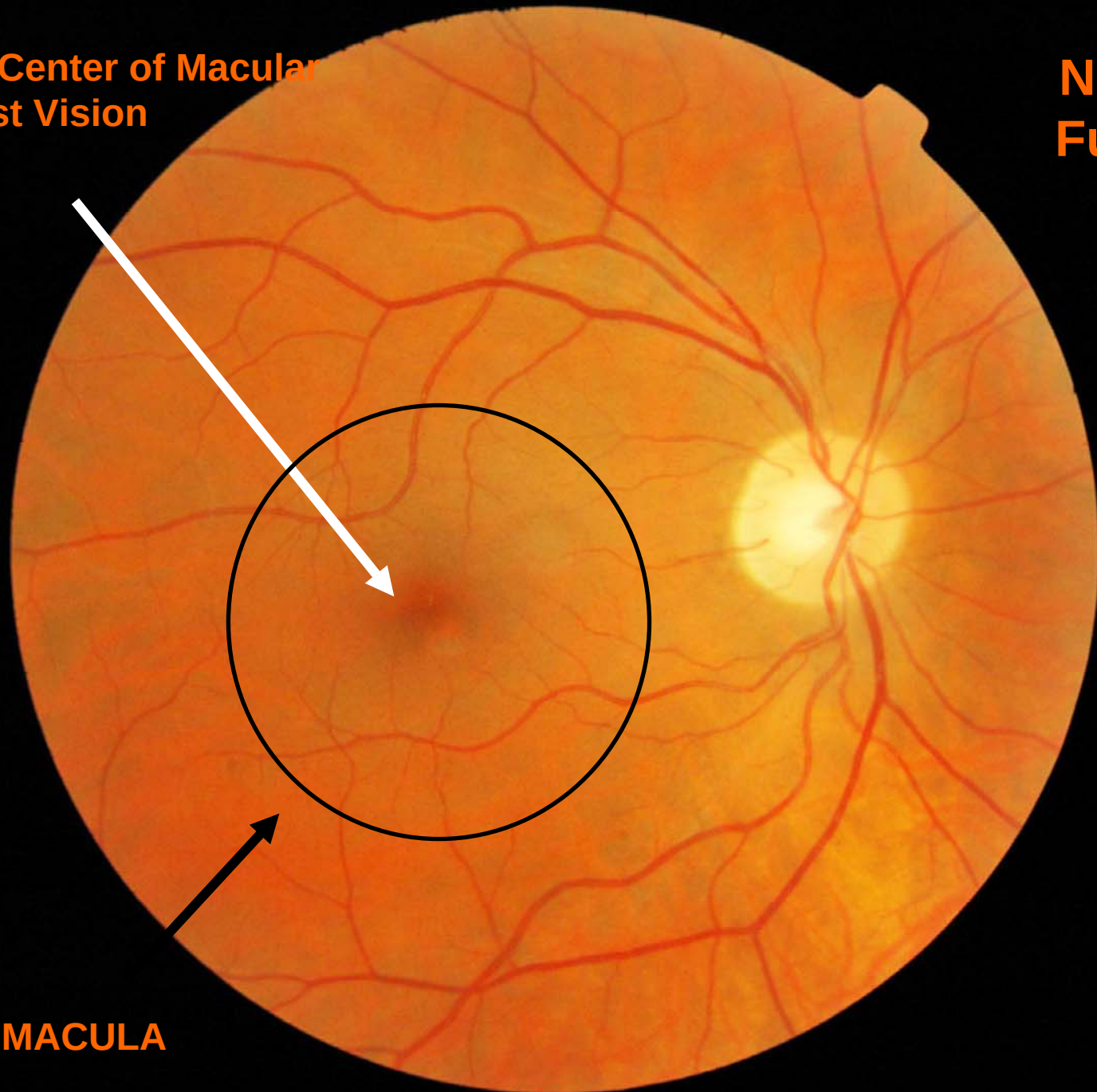
**Central area of the retina,
surrounding the fovea;
area of acute central
vision. Used for reading
and discriminating fine
detail and color**

Fovea

Central depression in the center of the macula that is responsible for the sharpest vision

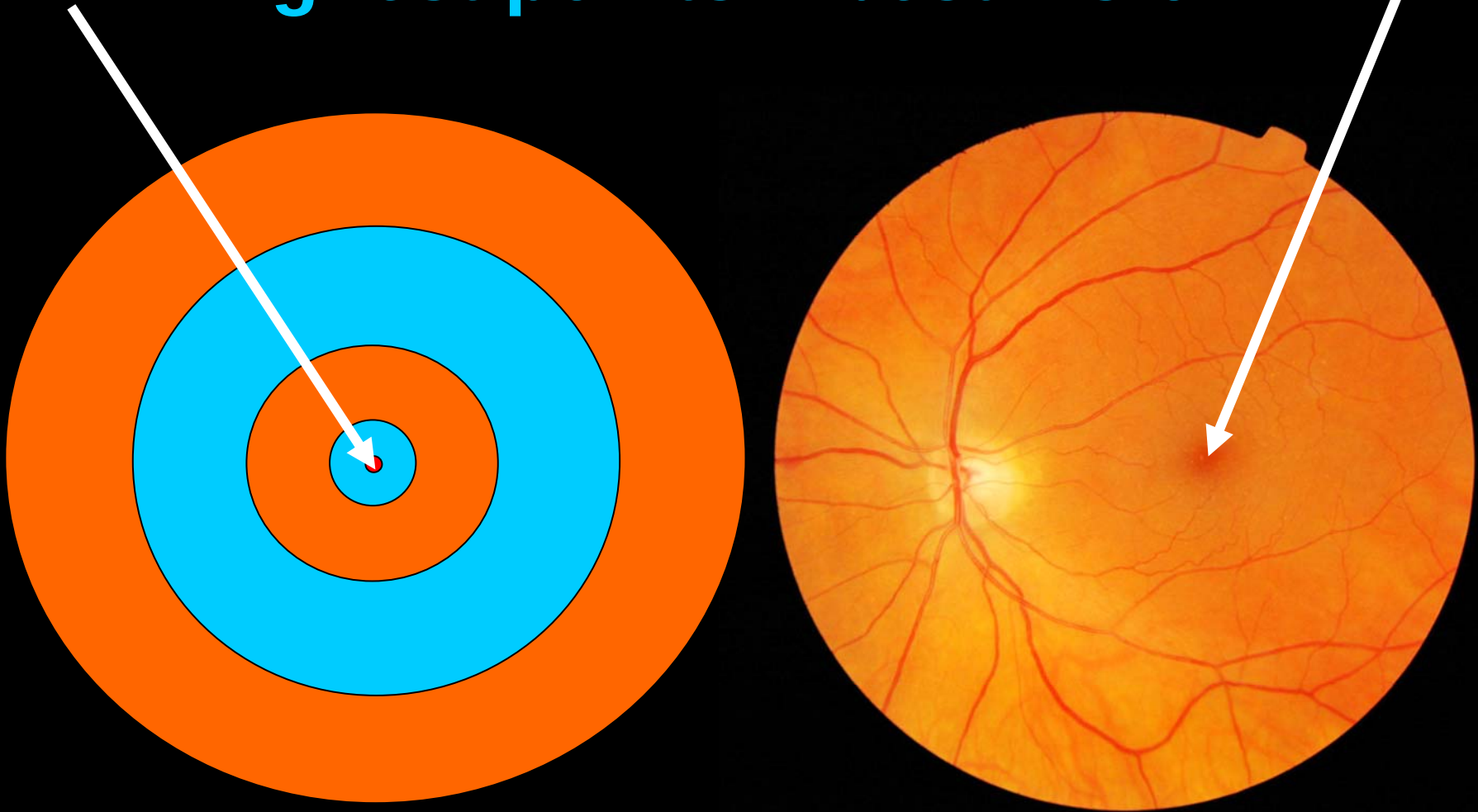
**FOVEA – Center of Macular
– Best Vision**

**Normal
Fundus**



MACULA

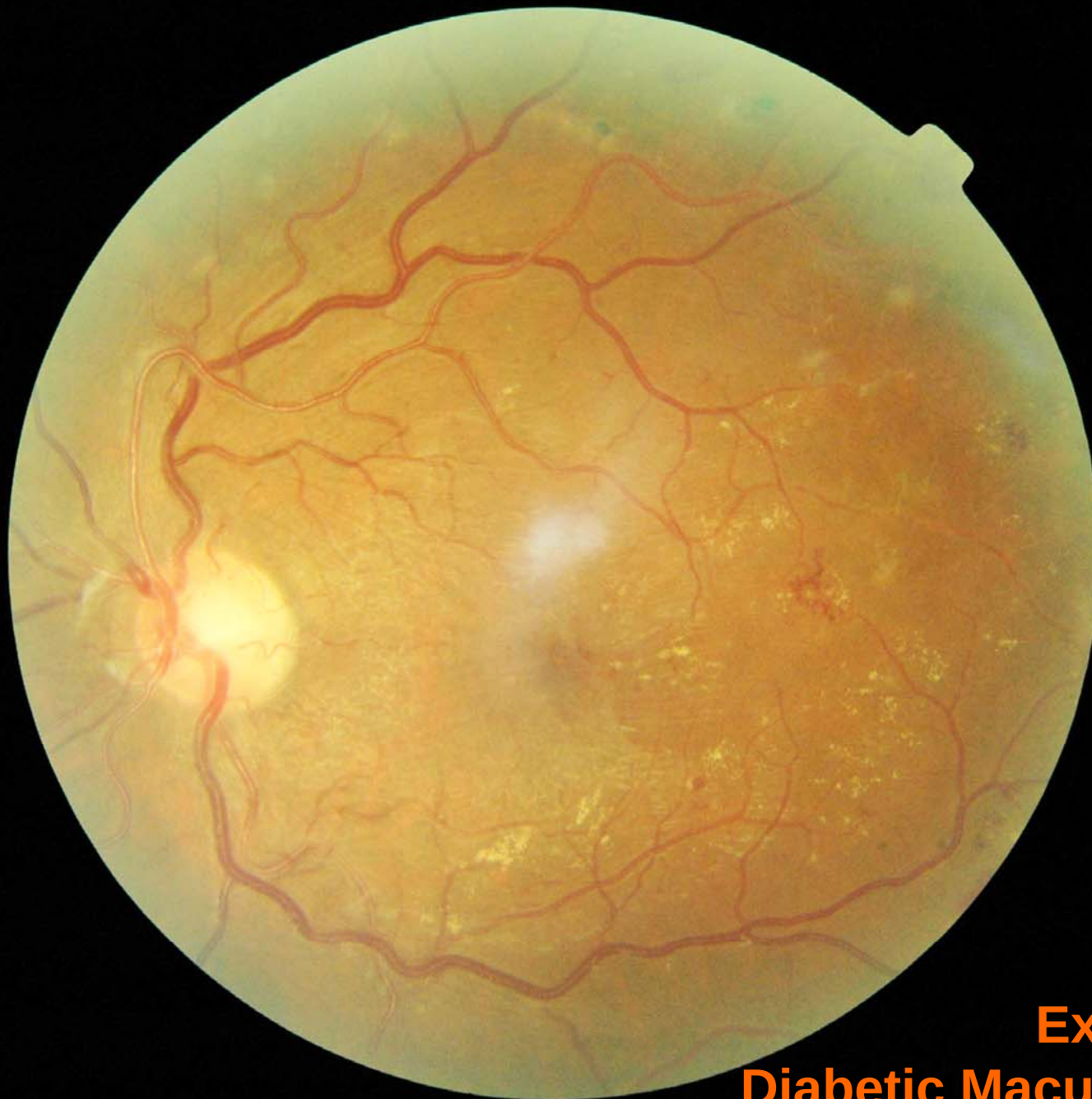
Highest points = best vision



Damage to the Macula = less points
Vision is compromised

Diabetic Maculopathy

Any diabetic lesions – hemorrhages, hard exudates, or microaneurysms that are located in the macula. These lesions are a result of damaged blood vessels from diabetes. When disease extends to the fovea, vision is compromised

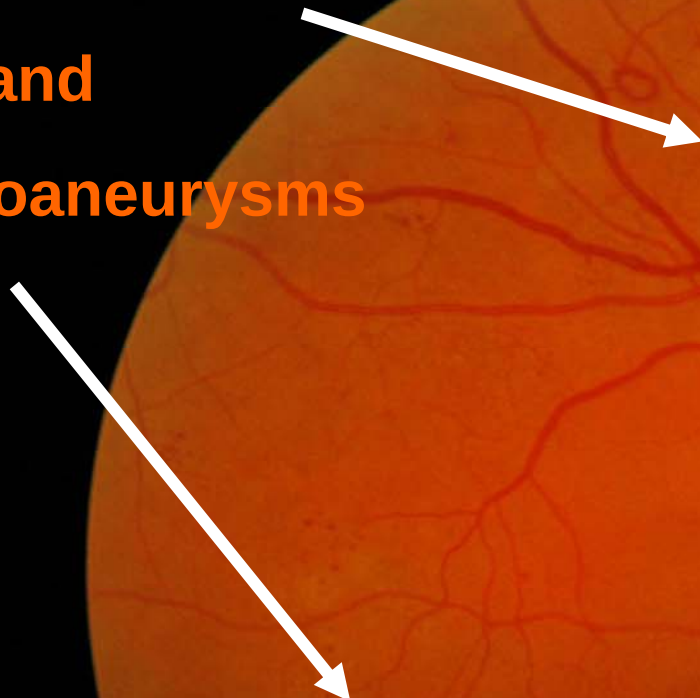


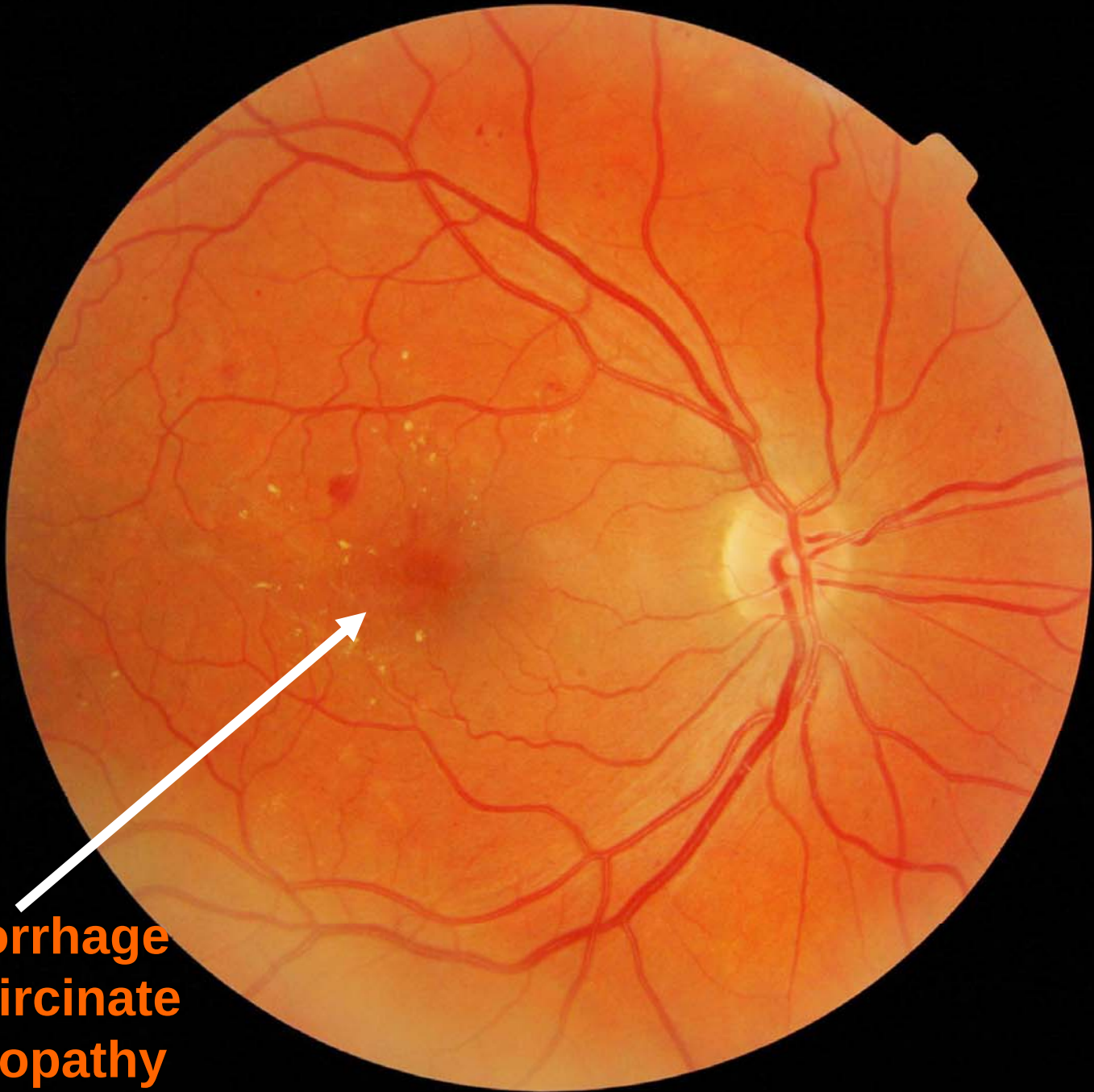
**Extensive
Diabetic Maculopathy**

Microaneurysm

Minute bubble or defect in the wall of a small blood vessel. Fluid (serum) leaks through these defects into the retina, and leads to swelling or edema.

**Hemorrhages
and
Microaneurysms**





**Hemorrhage
and Circinate
Retinopathy**

Hard Exudate

Deposits in the retina that usually contain fat and protein; caused by excessive vascular leakage into the retinal tissue

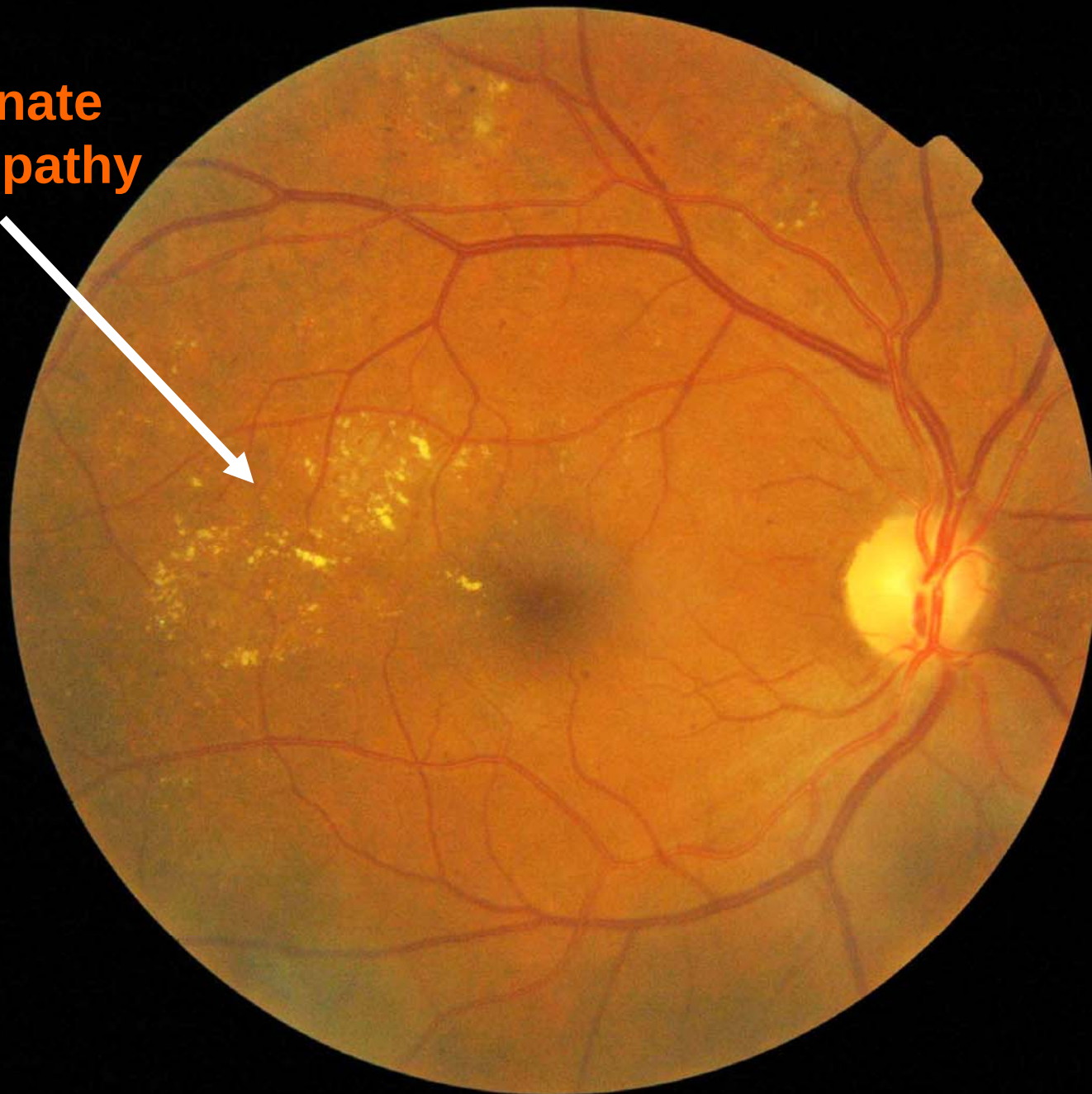
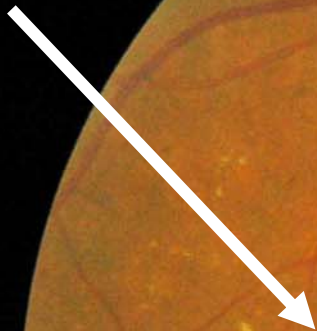


**Extensive
Hard
Exudates**

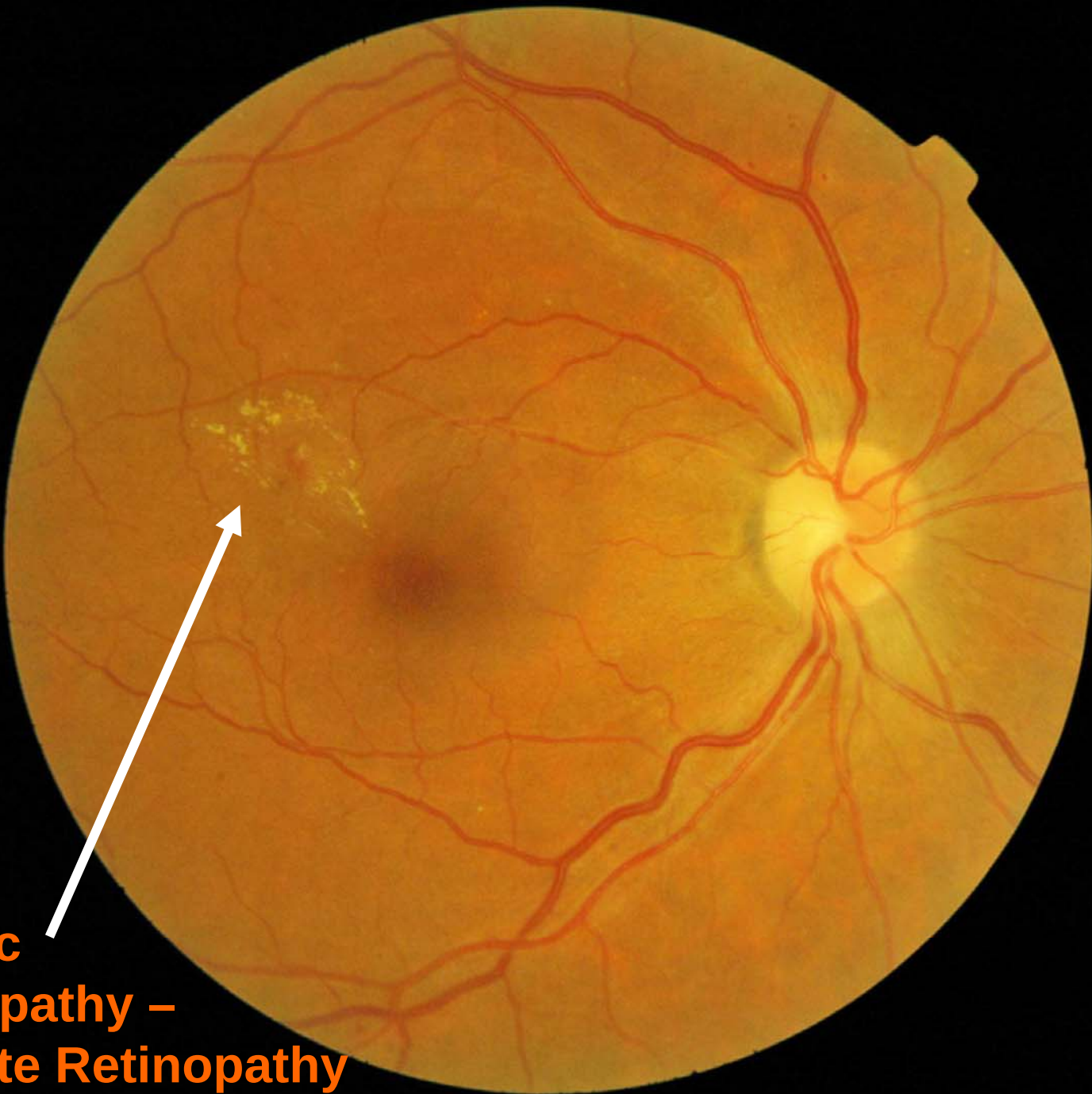
Circinate Retinopathy

Ring shaped deposits of exudates within the retina from retinal vascular leakage caused by diabetic damaged blood vessels. When leakage extends to the fovea, vision is compromised

**Circinate
Retinopathy**



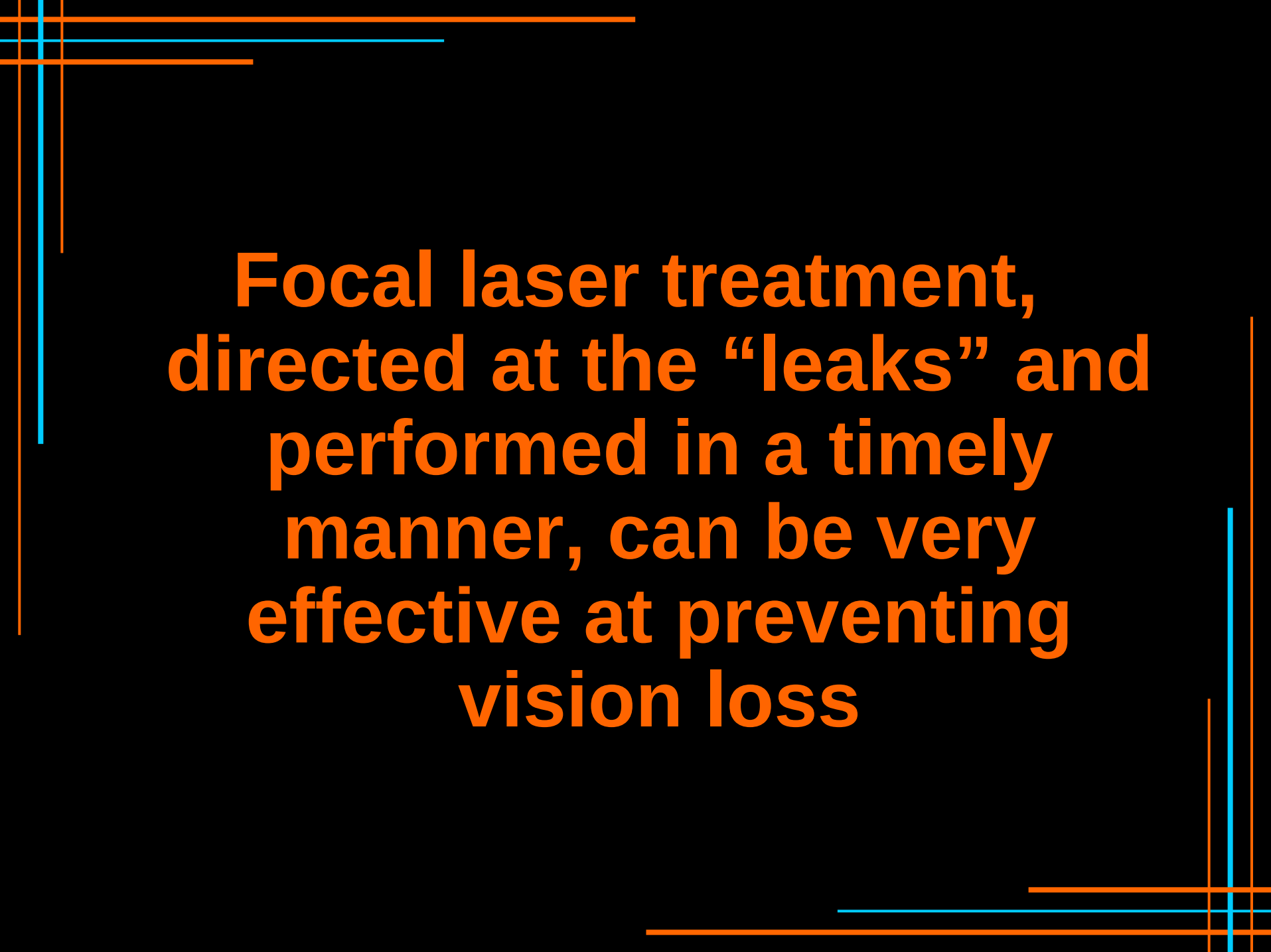
**In many cases, a patient
may have advanced
diabetic retinopathy, and
yet retain good vision. By
the time they begin to
experience vision loss, it
may be permanent**



**Diabetic
Maculopathy –
Circinate Retinopathy**

**Extensive
Diabetic
Maculopathy**



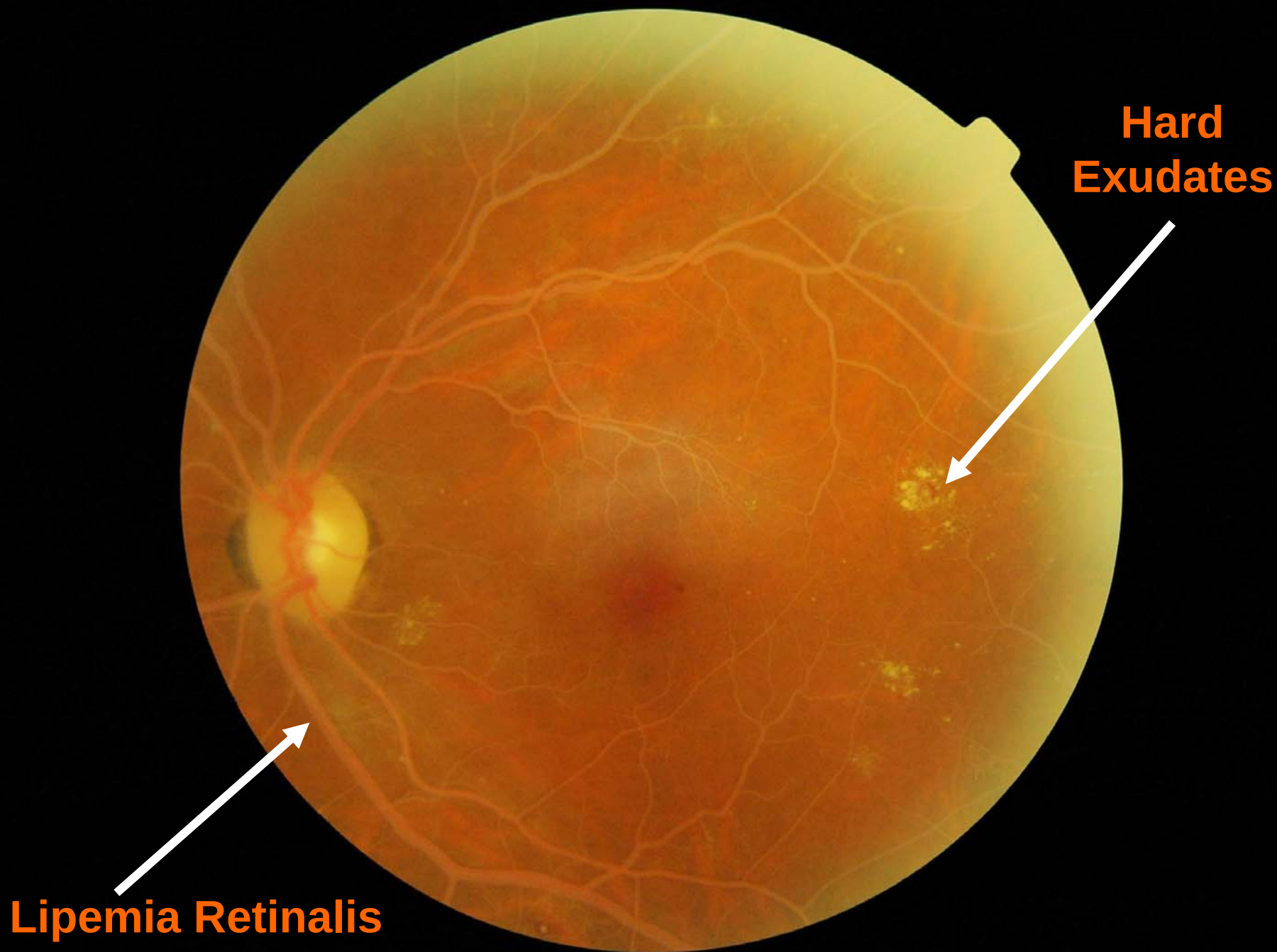


**Focal laser treatment,
directed at the “leaks” and
performed in a timely
manner, can be very
effective at preventing
vision loss**

Lipemia Retinalis

**Creamy coloring of retinal
blood vessels due to high
blood fat (lipid) level**

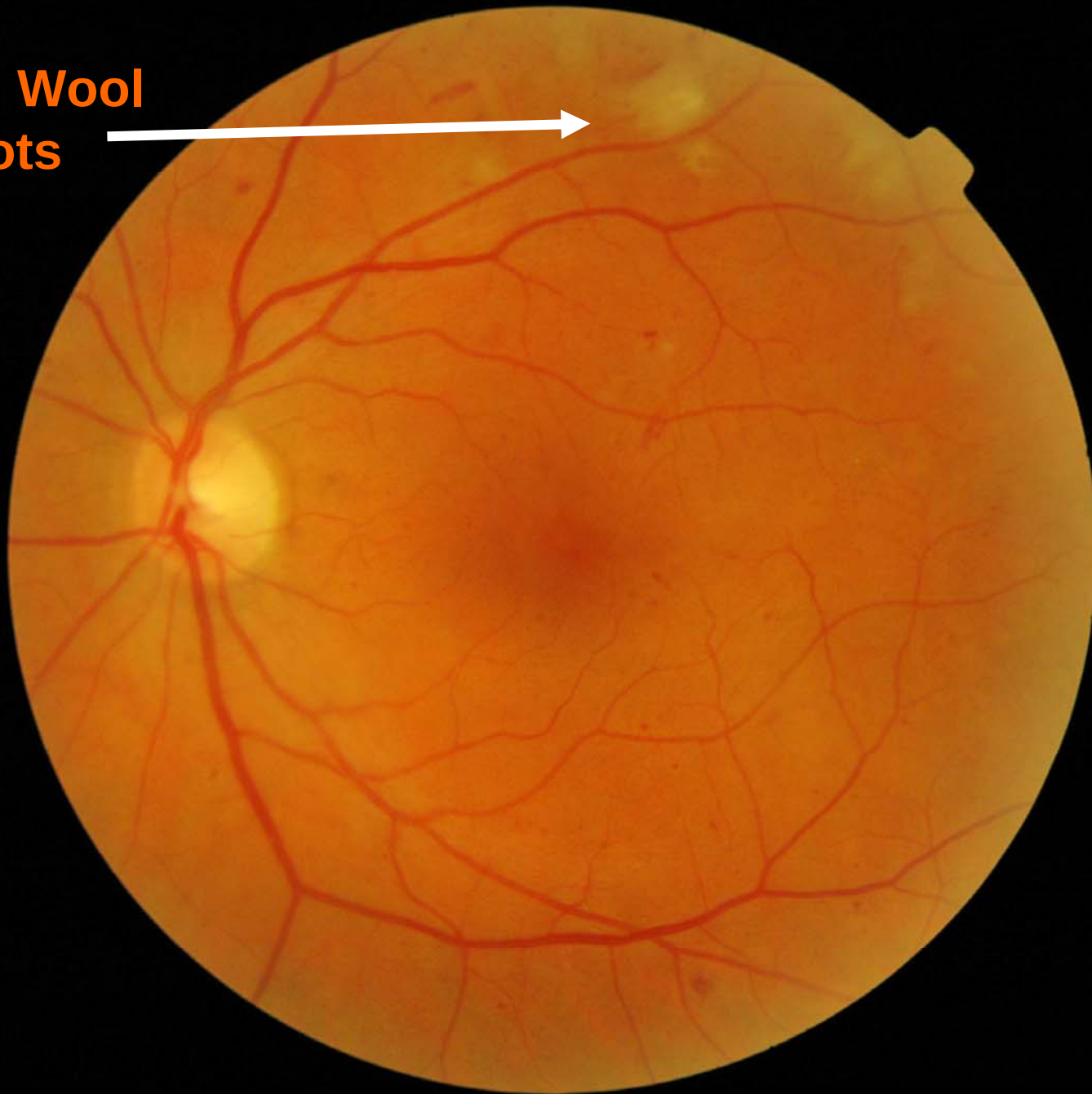
**Blood vessels often appear
to be pink**



Cotton Wool Spots

“Fluffy-looking” white deposits (resembling tufts of cotton) within the retinal nerve fiber layer that represents small patches of retina that have lost their blood supply due to vessel obstruction

**Cotton Wool
Spots**



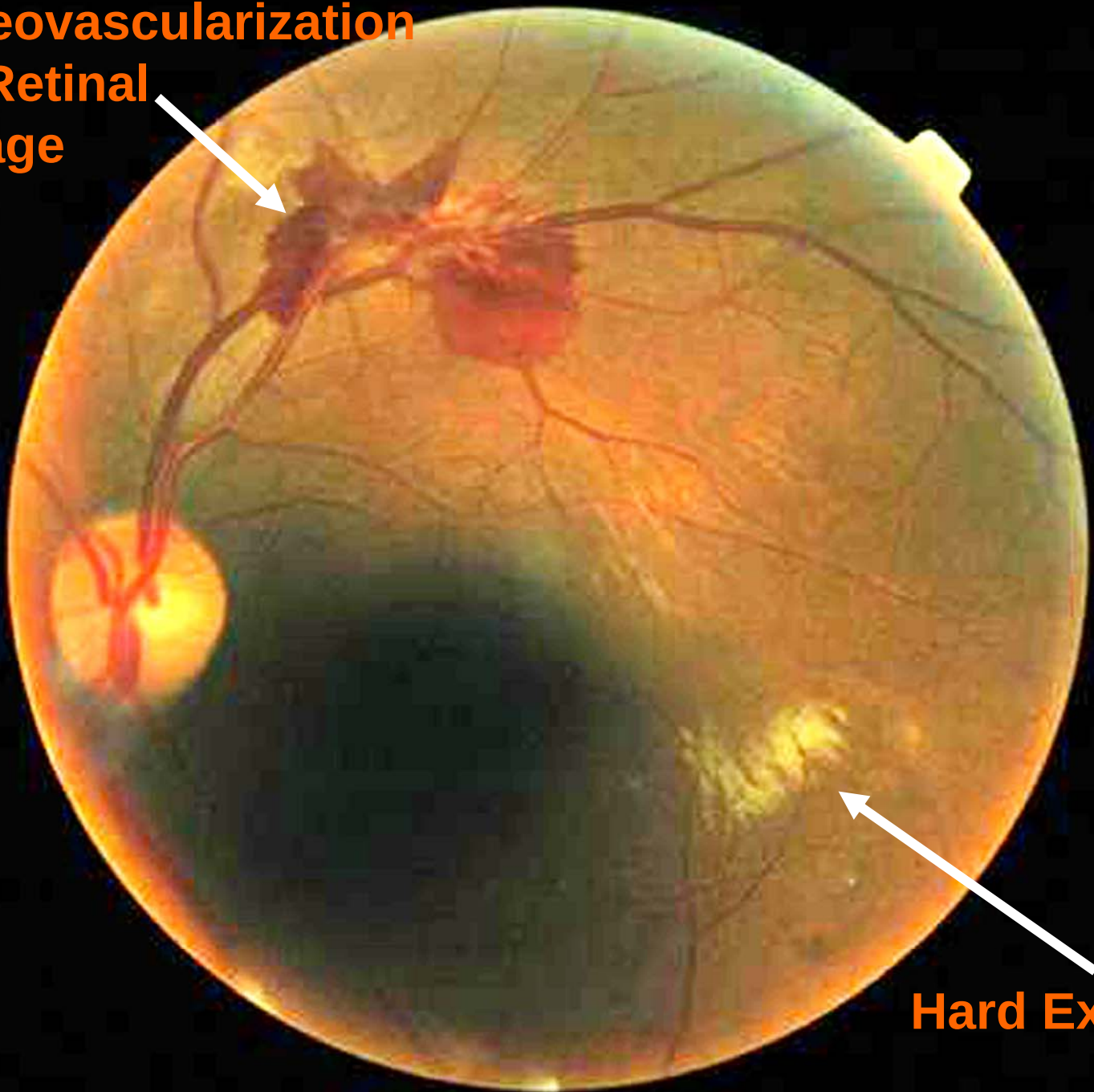
Proliferative Retinopathy

Retinal disease that includes abnormal growth of new blood vessels (neovascularization) and fibrous tissue. Develops as diabetic damaged blood vessels result in poor oxygenation to retinal tissues

Neovascularization

**Formation of new, abnormal
blood vessels on the surface
of the retina**

**Retinal Neovascularization
with Pre-Retinal
Hemorrhage**



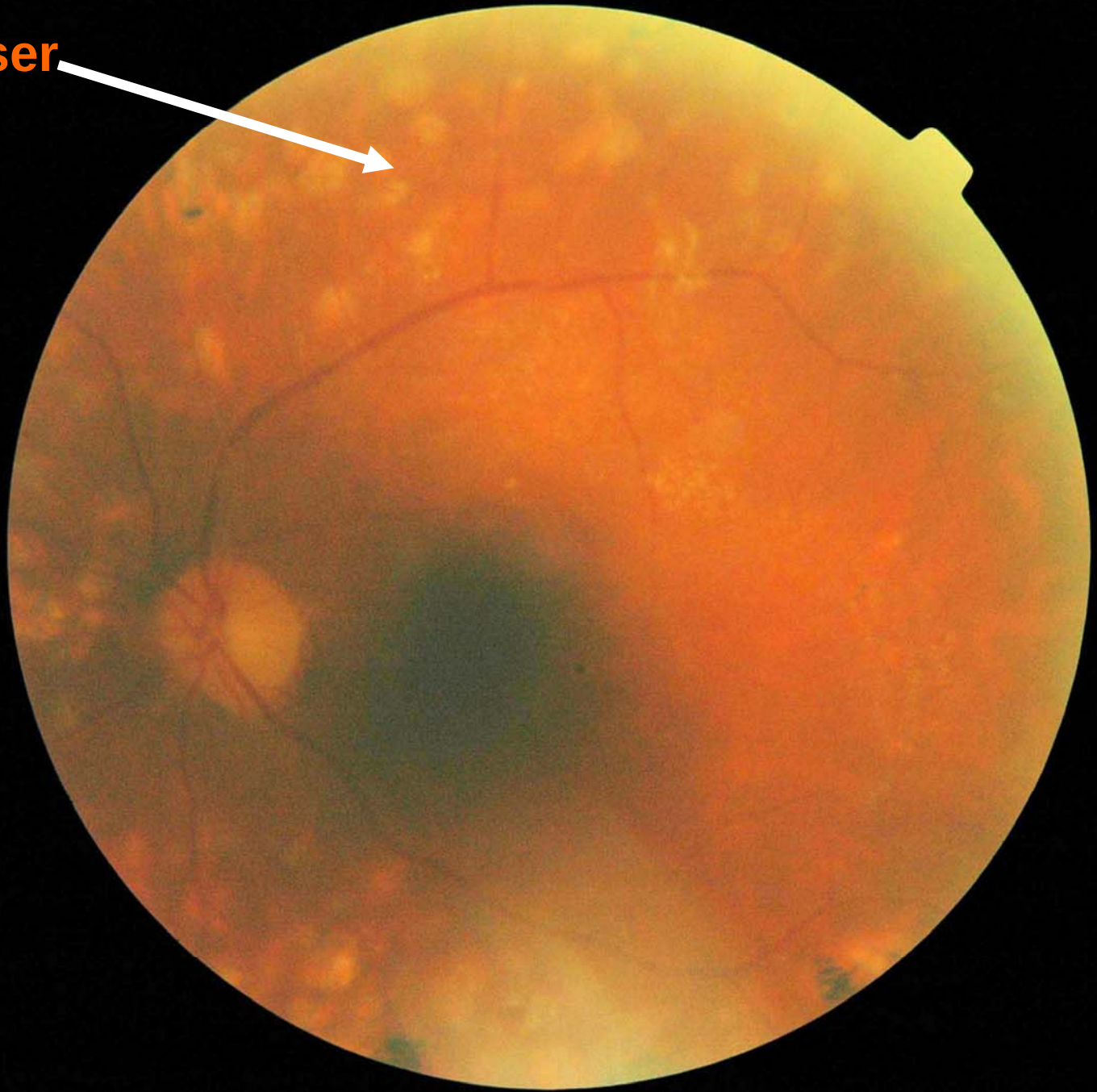
Hard Exudate

PRP Laser

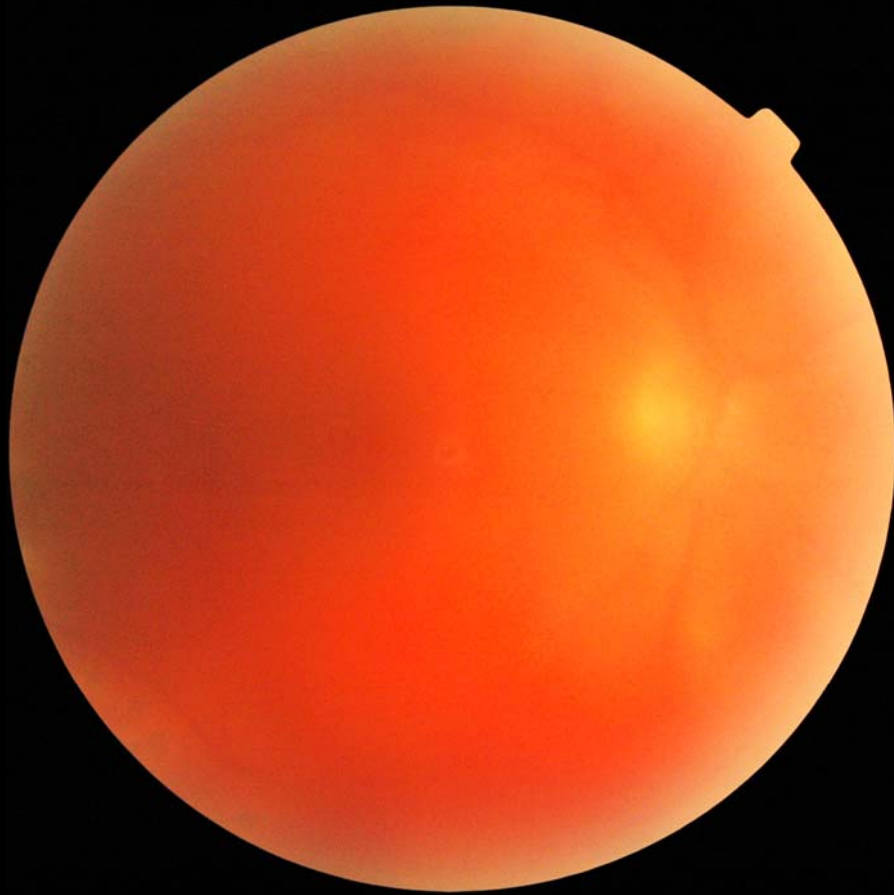
Panretinal Photocoagulation

Use of a laser beam to create hundreds of retinal burns to reduce the tendency of bleeding in abnormal retinal blood vessels.

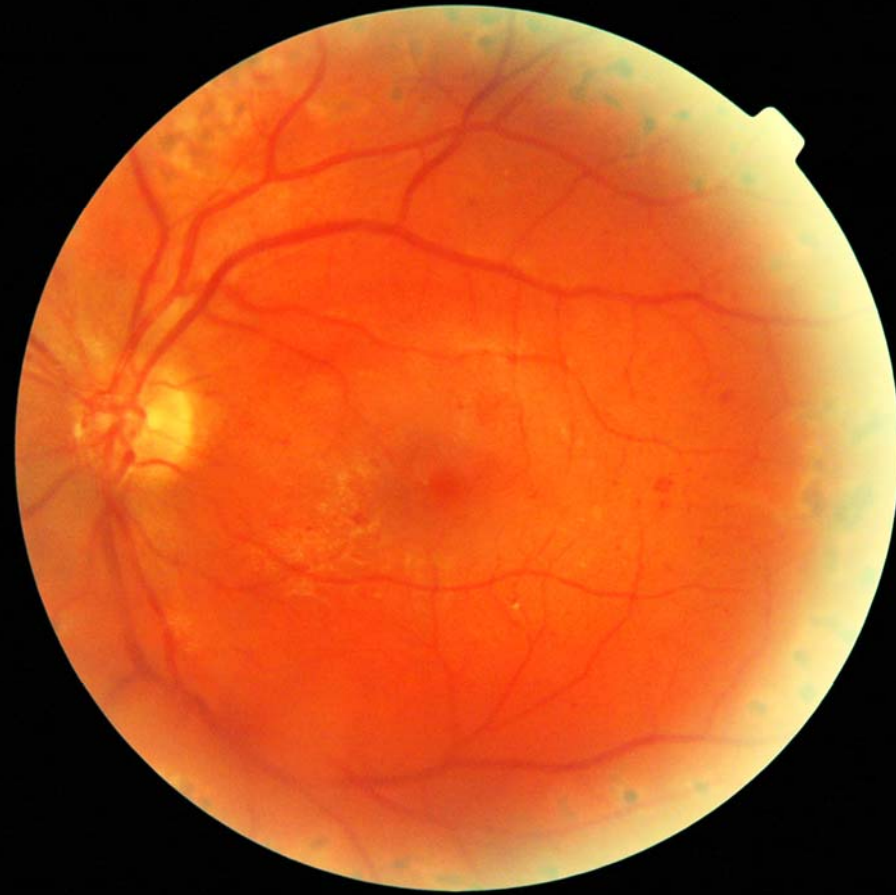
PRP Laser



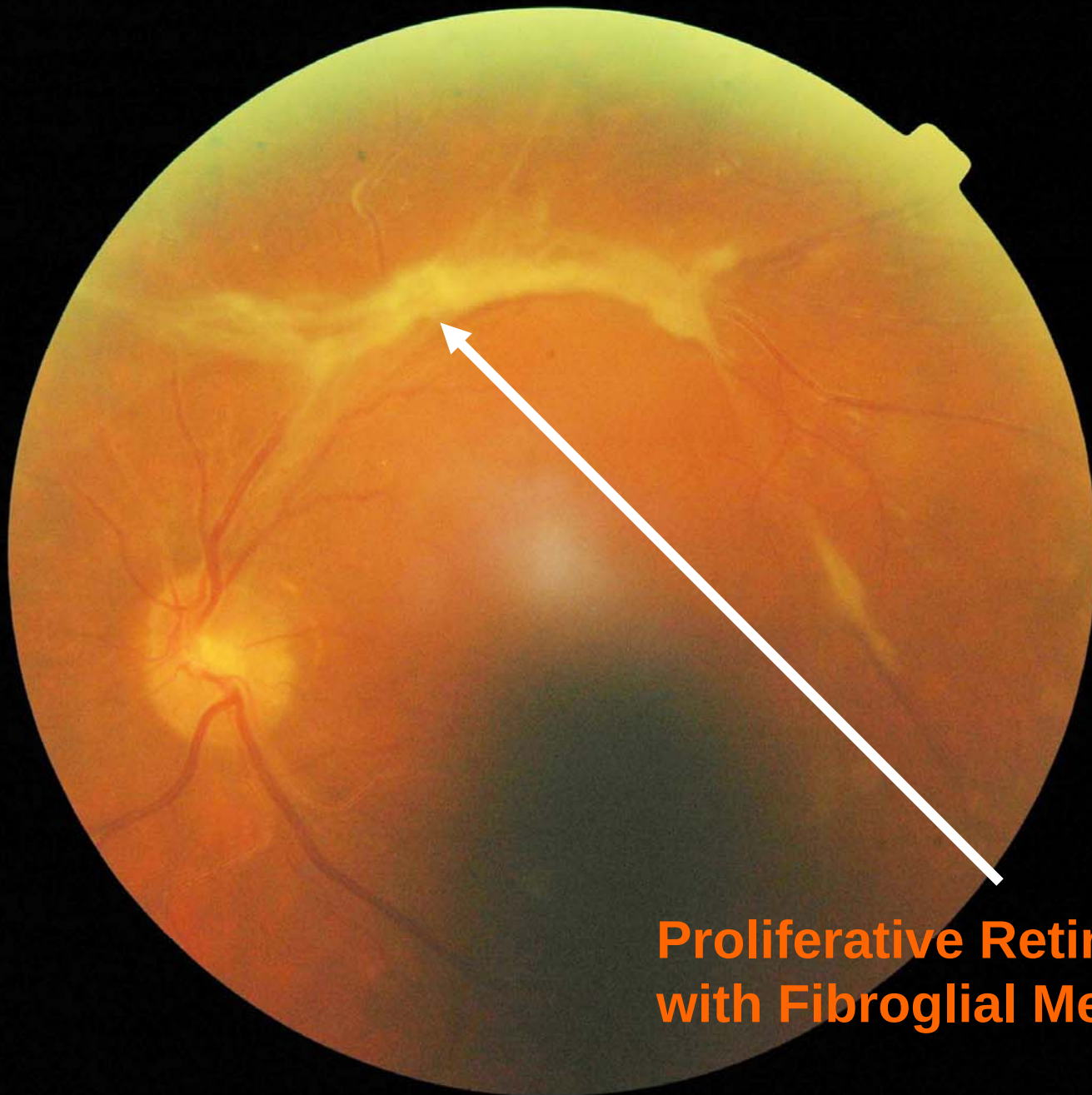
Proliferative Diabetic Retinopathy



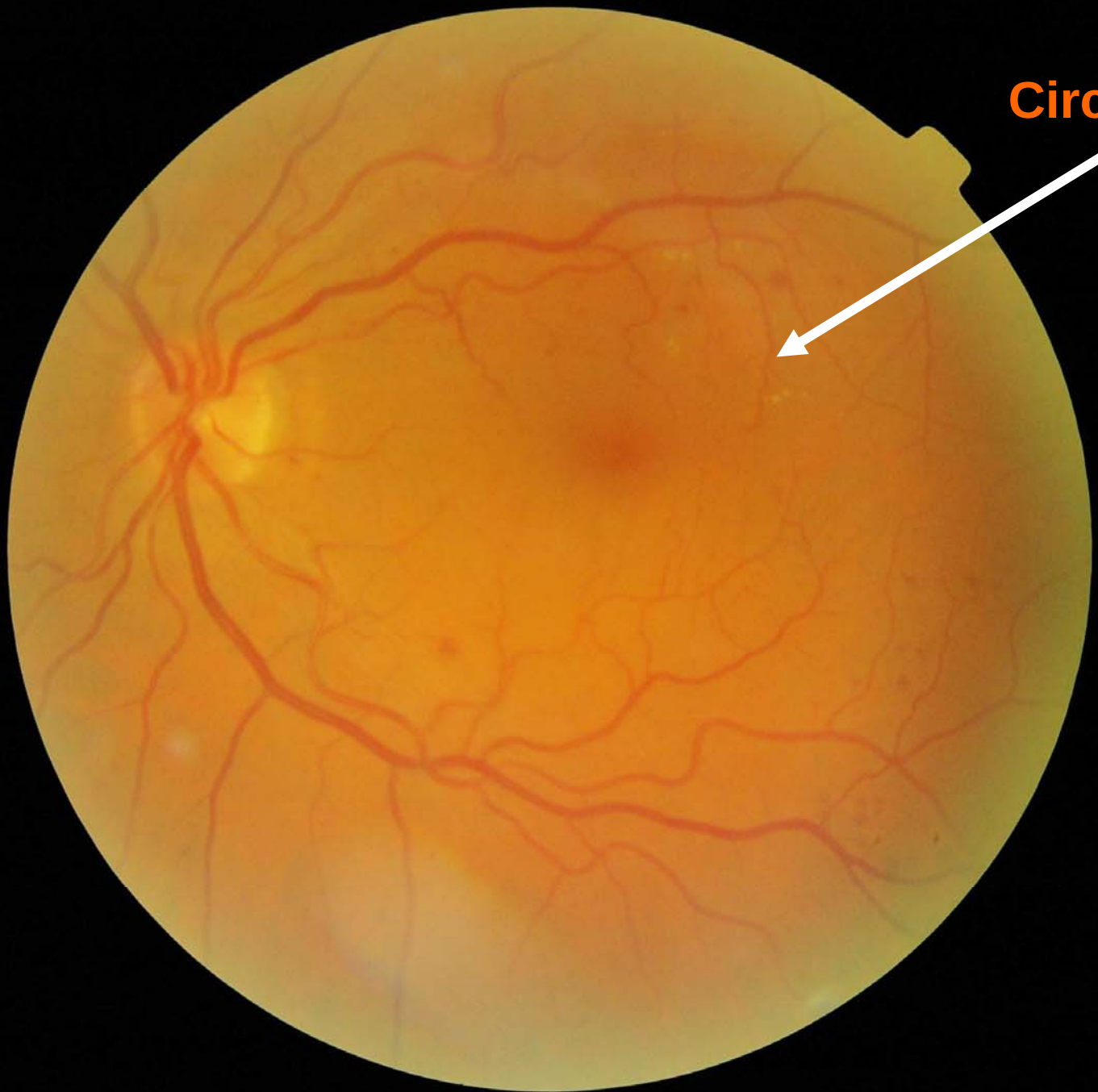
Vitreous Hemorrhage



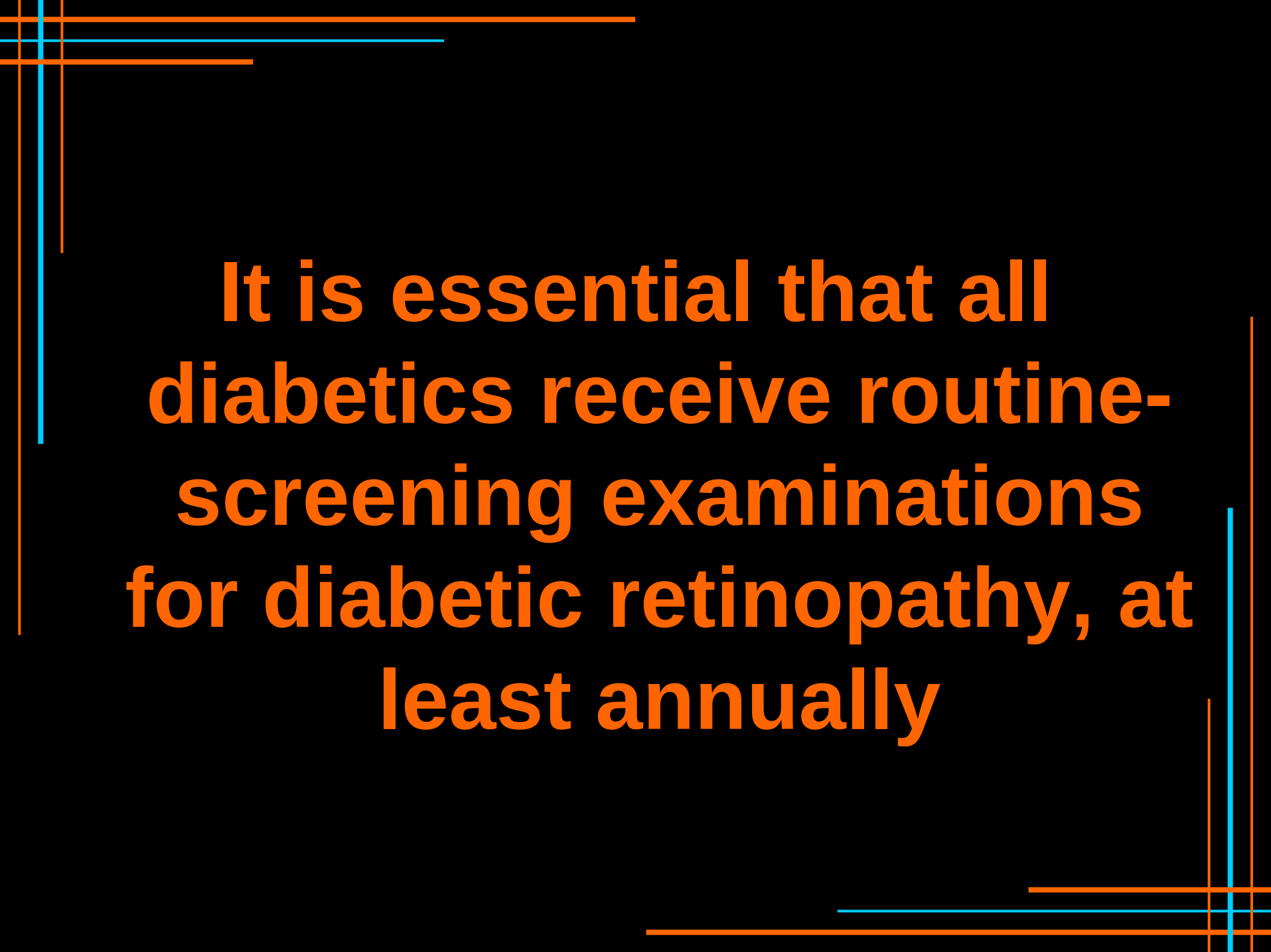
PRP Laser



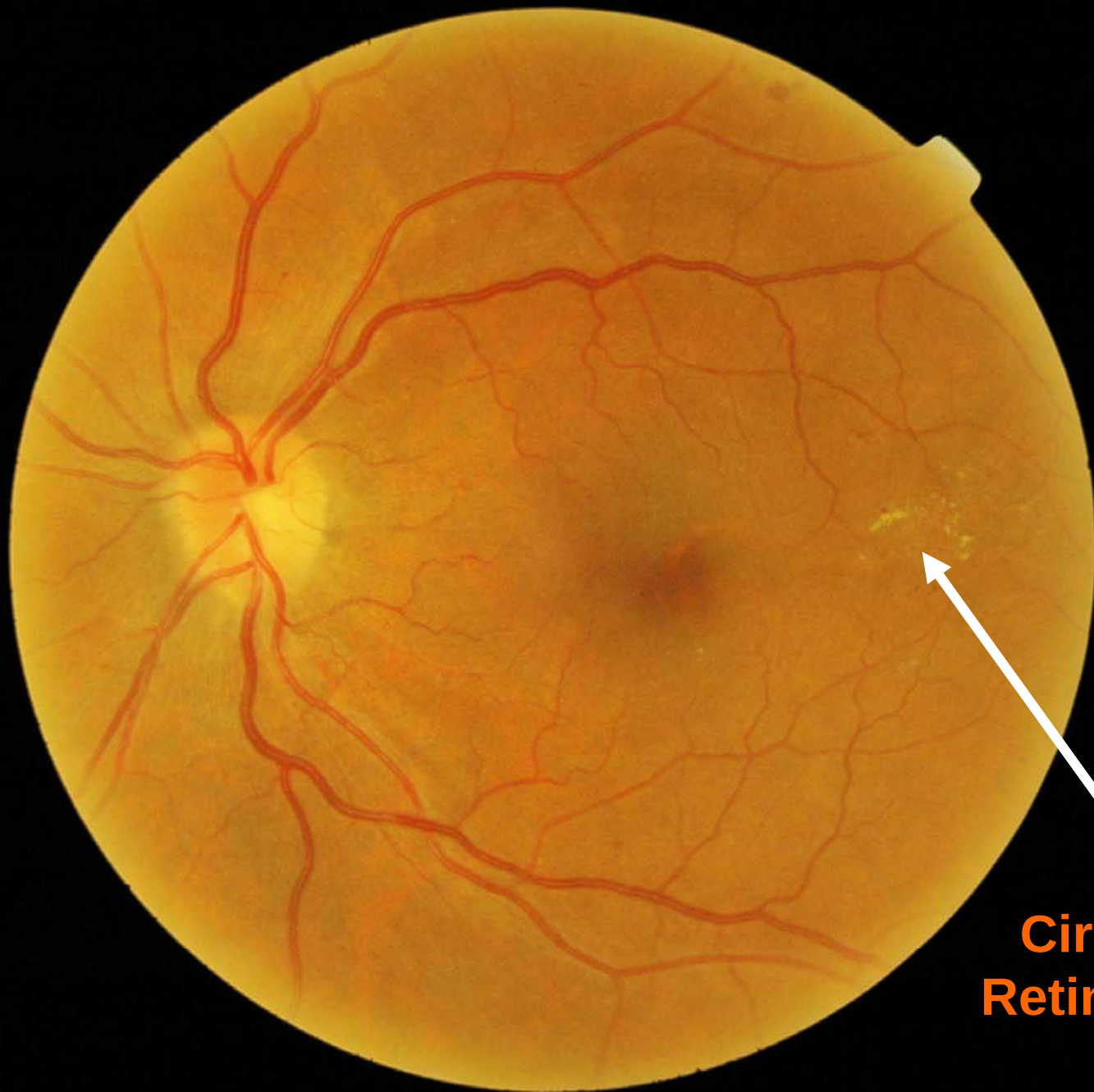
**Proliferative Retinopathy
with Fibroglial Membrane**



Circinate



**It is essential that all
diabetics receive routine-
screening examinations
for diabetic retinopathy, at
least annually**



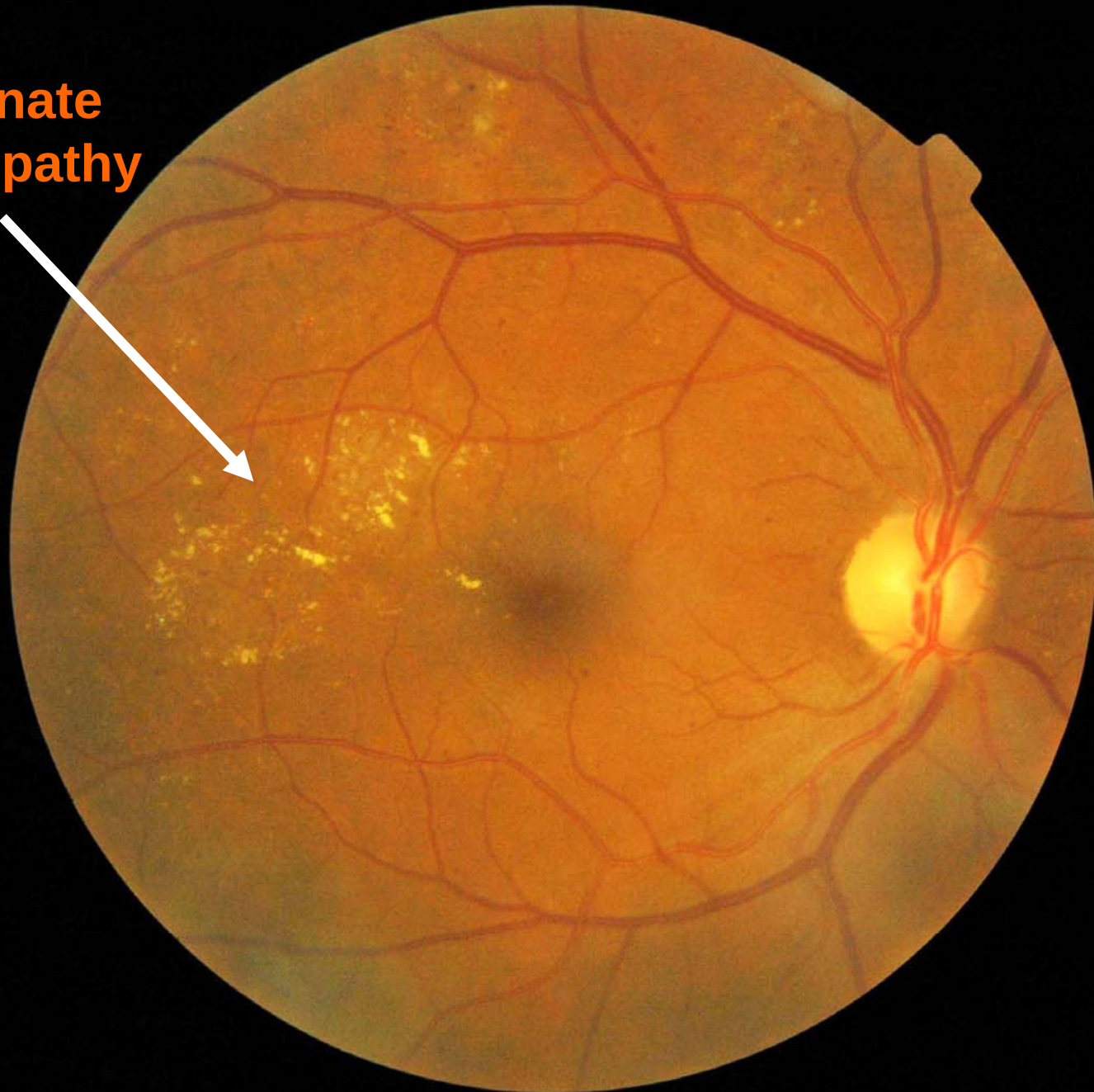
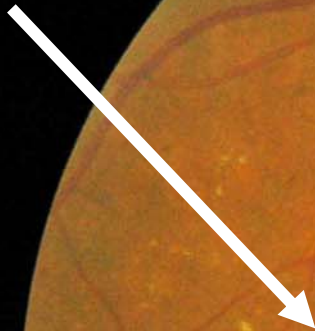
**Circinate
Retinopathy**

**It has been well documented
that only 50 to 70% of
diabetics are undergoing
regular eye examinations on
an annual basis to screen
for diabetic retinopathy.
This places a large number
of patients at risk for
blindness**



**Normal
Fundus**

**Circinate
Retinopathy**



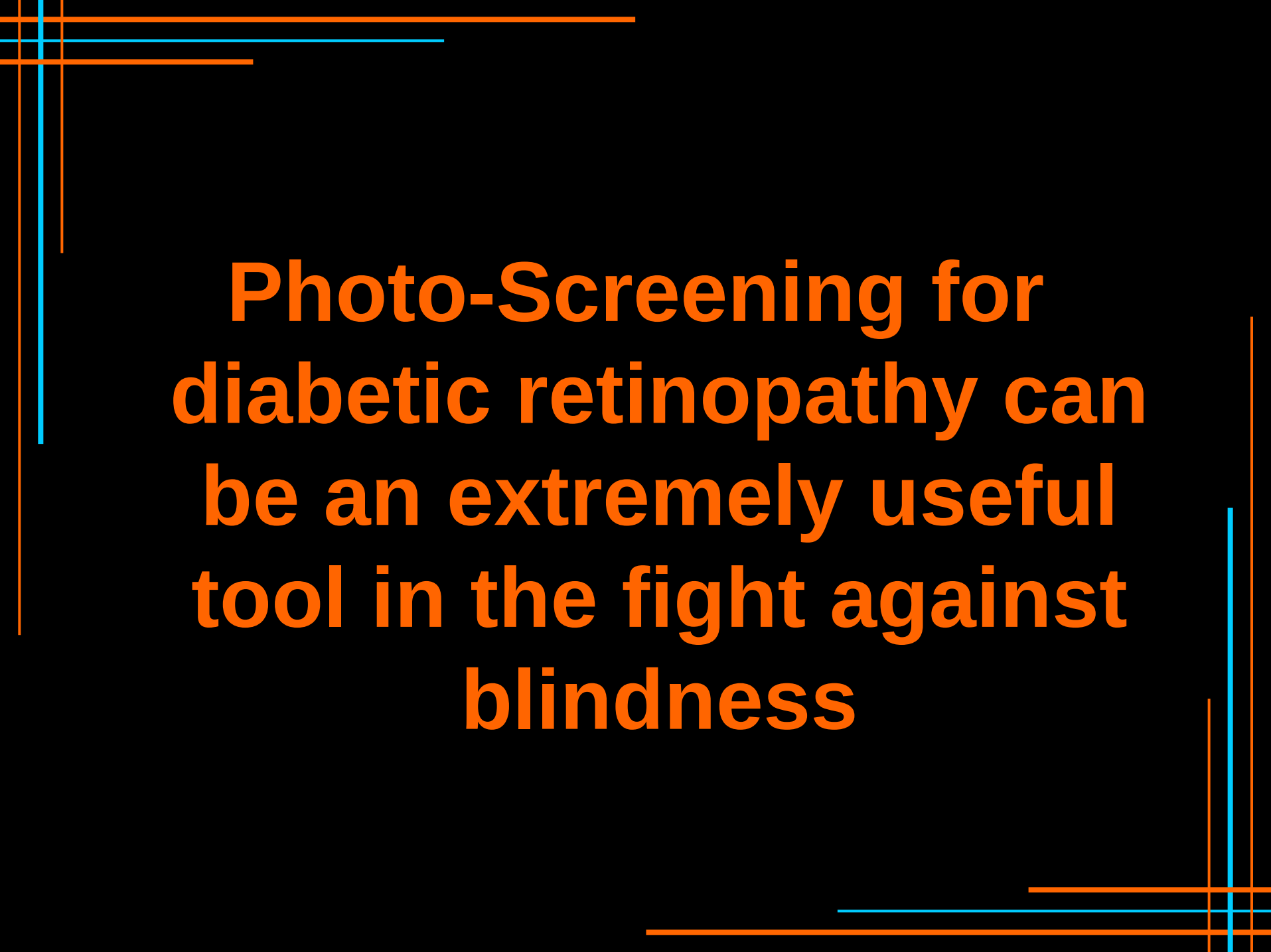


**Photo-Screening for
diabetic retinopathy can
be an extremely useful
tool in the fight against
blindness**

**Extensive
Diabetic
Maculopathy**



**A Photo-Screening session
can also be used as another
opportunity to reinforce the
importance of optimal
diabetic control in
preventing blindness as well
as all of the other
complications of diabetes
mellitus**

ACCOMPLISHMENTS

- Created user interface for collecting subject medical history and imaging data
- Built software and process for 'packaging' medical history with retinal images
- Developed software for transferring image sets from cameras to server or enterprise network
- Customized grading software for rapid examination of retinal images
- Prepared community event assembly manual for retinal screening process
- Established standard operating procedures for clinic and community-based screenings
- Imaged over 700 people with diabetes at high-risk for Diabetic Retinopathy

CONCLUSION



With the support of dedicated personnel, people can be efficiently screened for diabetic retinopathy with recommendations for care provided in a timely manner.

IMITS TEAM

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Diabetes Evaluation
Project Director
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SGR Project Manager



This work was supported by funding from the US Army Medical Research Acquisition Activity, Fort Detrick, MD (Award No. W81XWH-04-0030 and Contract No. DAMD 17-0302-0017). This information does not imply US Air Force or government endorsement of factual accuracy or opinion.



Teleophthalmology Project

Vision for the Future



IMITS: Teleophthalmology

Participant Images

Right Eye

Left Eye



Retinal Findings -- Right Eye

Level of Retinopathy

- ☐ A. Microaneurysms
- ☐ B. Intraretinal Hemorrhages
- ☐ C. Hard Exudates (HE)
- ☐ D. Cotton Wool Spots
- ☐ E. Venous Beading

Retinal Findings -- Left Eye

Level of Retinopathy

- ☐ A. Microaneurysms
- ☐ B. Intraretinal Hemorrhages
- ☐ C. Hard Exudates (HE)
- ☐ D. Cotton Wool Spots
- ☐ E. Venous Beading

BACKGROUND

Through a defense-spending appropriation, the University of Pittsburgh Medical Center (UPMC) and the Air Force Medical Service (AFMS) created a strategic partnership known as the Integrated Medical Information Technology System (IMITS). IMITS focuses on the implementation and evaluation of advanced medical technologies.

Twenty million people in the US have diabetes and many will develop visual impairments over the course of their disease. One of the IMITS initiatives, the Teleophthalmology Project, developed a simple, effective retinal screening process for people with diabetes. Portable equipment and customized software enables rapid acquisition of patient images.

IMITS: Teleophthalmology											
Participant Tracking											
Participant's Name	Date of Study	Send Copy of Consent Form to Participant	Study Grade Requested Follow-Up Timeline	Send Image Results Letter to Participant	Participant Requests Copy Of Results To Eye Doctor	Completed Giving Copy Of Results To Eye Doctor	Participant Requests Copy Of Results To PCP	Completed Giving Copy Of Results To PCP	Planned Participant Follow-up Date Requested	Reminded Participant of Follow-up	Actual Follow-up Date
	8/27/2005	☐		☐	No		No			☐	
	8/27/2005	☐		☐	No		No			☐	

SCREENING PROCESS

A flexible, modular and mobile system is used efficiently in clinic and community settings.

A retinal imaging station, configured with custom software, is set up in a darkened area with adequate ventilation and space for the participant, photographer, computer and non-mydratic retinal camera. Personal and medical information is collected and retinal images are captured. Medical history and retinal images are 'packaged' and transferred to a designated server.

In a timely manner, an ophthalmologist is able to use a computer to access the images and medical history and provide recommendations for further treatment as indicated.

SETTINGS



Clinics

Screenings are offered at UPMC's Endocrinology and Internal Medicine Clinics. Specified areas within each clinic are fully equipped and remain ready for screenings. Project and clinic staff work together to identify and screen subjects. Screenings add less than ½ hour to a clinic visit.

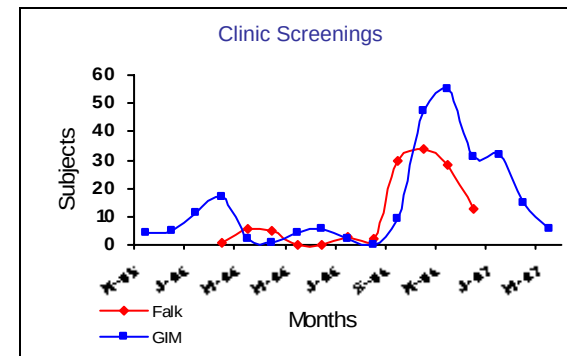


Community

Arrangements are made upon request for the project's mobile unit to travel to community events. When the ophthalmologist attends the event, he uses project software to grade the images and discuss the results with each subject.

EVALUATION

Emphasis is placed on the development of sound evaluation methodologies for each project with special attention to areas of user satisfaction and impact on work efficiency and patient care. Findings serve to guide future modifications of the technologies to best meet the needs of UPMC and the military.



Some Findings

- Over 87% of the study population had type two diabetes
- Age was significantly higher for subjects screened in community settings
- Comorbidities such as hypertension, neuropathy, renal disease and depression were significantly higher in clinic settings
- Almost half of the population had their last eye exam more than a year ago
- The majority of subjects received a recommendation to see an eye doctor in one year
- A small percentage of subjects received a recommendation to see a doctor as soon as possible for immediate evaluation or treatment

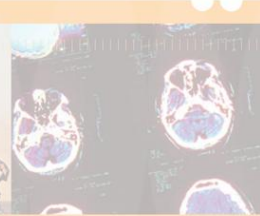
UPMC



Innovative Medical And Information Technologies

Teleophthalmology Project

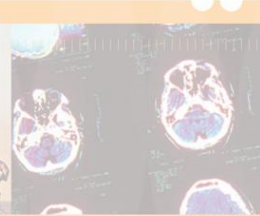
Diabetic Retinopathy Screenings



Background

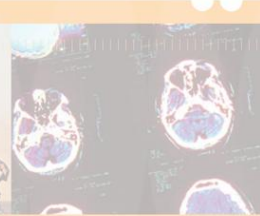


- **Funding**
 - Congressional appropriations were awarded to the IMITS initiative in 2004 with support from Congressman Murtha
 - The Teleophthalmology Project was funded to help detect and treat diabetic retinopathy



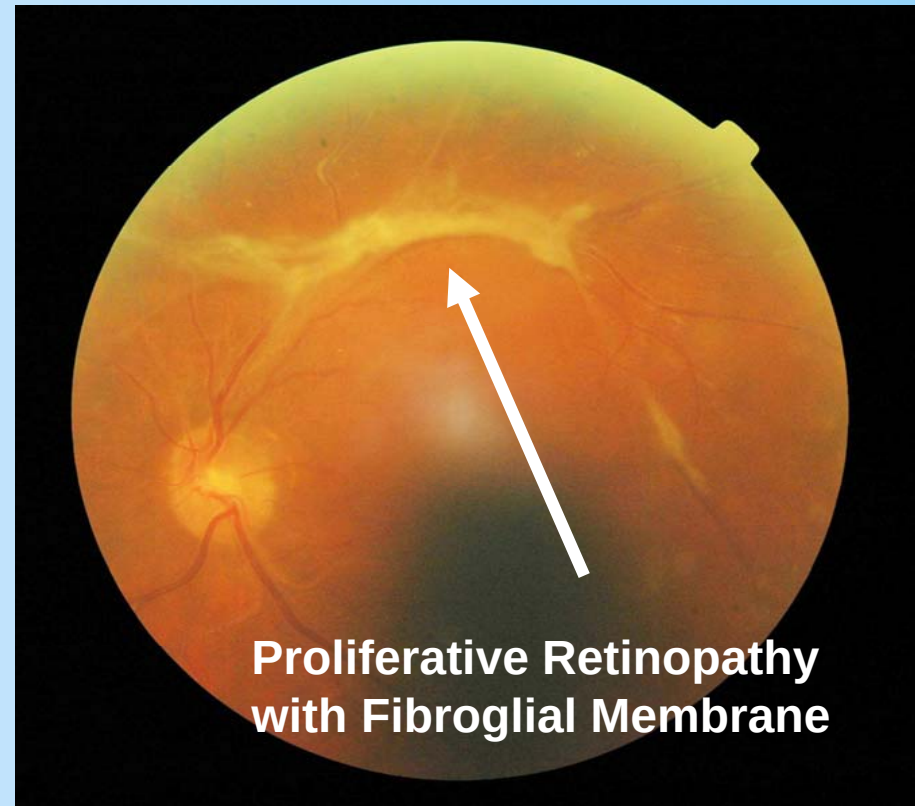
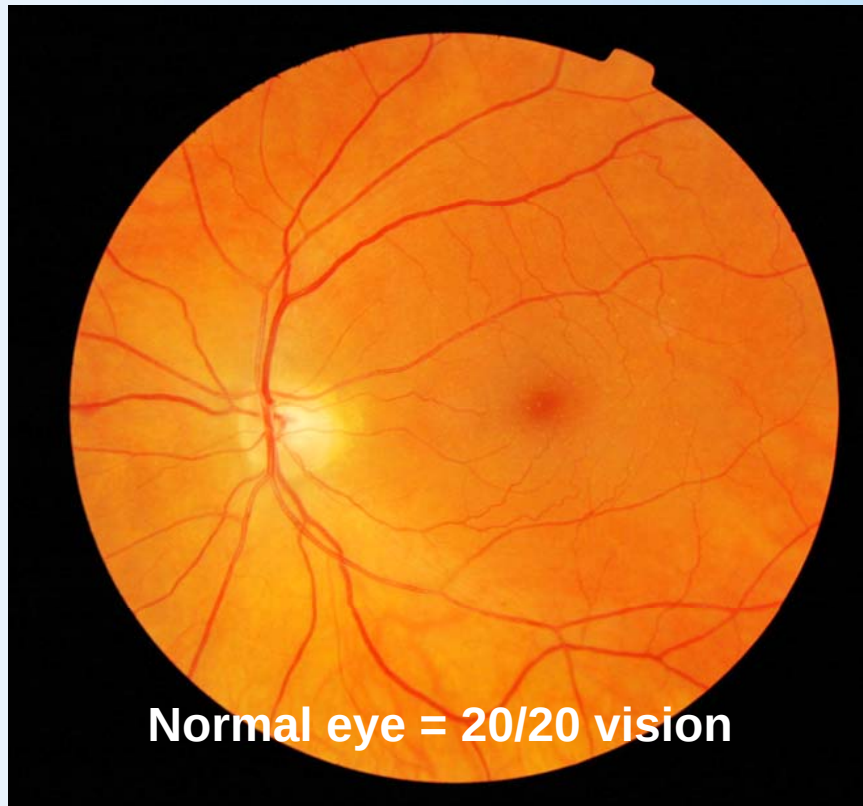
Background

- **Purpose**
 - To develop a modular, mobile image capture and transfer system with an efficient workflow process for screening for diabetic retinopathy
- **Collaborators**
 - UPMC IMITs Center
 - University of Pittsburgh Diabetes Institute
 - University of Pittsburgh Department of Biomedical Informatics
 - Wilford Hall Medical Center



Fact

- Complications from diabetes result in 12,000 to 24,000 new cases of blindness each year



Photos of images captured during course of this project.

Premise



- Stationary equipment located in healthcare clinics will promote retinal screenings for people at highest risk for diabetic retinopathy



- Portable equipment transported to community events will enable retinal screenings for people in areas with poor access to eye care



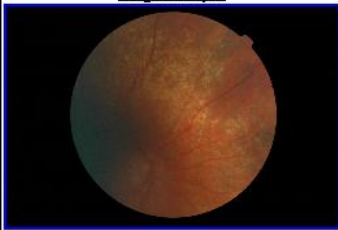
Process

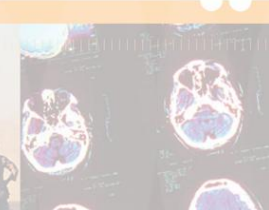
1. Digital images of the retina are captured with a non-mydriatic fundus camera - no dilation is required.



2. Medical information and retinal images are 'packaged' and transferred to a designated server.

3. The specialist uses customized software to grade the images.

Registration Data			IMITS: Teleophthalmology																																				
Name: Test Participant ID: Encounter ID: Gender: F Date of Birth: 2/10/1918 Ethnicity: Caucasian Diabetes Type: Un-Diagnosed Diagnosed: Hgb A1C Understanding: Not Known Hgb A1C: % Last Eye Exam: 6 - 12 mos ago Eye Doctor's Name: Dr. Eye Doctor's Type: M.D. Eye Doctor's City: Bedford PCP's Name: PCP's City:			Participant Images Right Eye  Left Eye    This Photograph Was Not Taken This Photograph Was Not Taken Retinal Findings -- Right Eye Level of Retinopathy ☐ A. Microaneurysms ☐ B. Intraretinal Hemorrhages ☐ C. Hard Exudates (HE) ☐ D. Cotton Wool Spots Retinal Findings -- Left Eye Level of Retinopathy ☐ A. Microaneurysms ☐ B. Intraretinal Hemorrhages ☐ C. Hard Exudates (HE) ☐ D. Cotton Wool Spots		Image Quality ☐ Excellent ☐ Adequate ☐ Poor, but barely gradeable ☐ Poor, unable to grade Recommended Follow-Up ☒ One Year ☐ 6 Months ☐ 3 Months ☐ Within 6 Weeks ☐ Teaching File ☐ External image enhancement software was used to help diagnosis																																		
<table border="1"> <thead> <tr> <th colspan="3">Prior Treatment for Diabetic Retinopathy</th> </tr> <tr> <th>Treatment</th> <th>OS</th> <th>OD</th> </tr> </thead> <tbody> <tr> <td>None</td> <td></td> <td></td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th colspan="3">Other Eye Problems</th> </tr> <tr> <th>Eye Problem</th> <th>OS</th> <th>OD</th> </tr> </thead> <tbody> <tr> <td>None</td> <td></td> <td></td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th colspan="3">Other Eye Surgery</th> </tr> <tr> <th>Eye Surgery</th> <th>OS</th> <th>OD</th> </tr> </thead> <tbody> <tr> <td>Cataract Extraction</td> <td>X</td> <td>X</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th colspan="3">Medical / Diabetic Problems</th> </tr> </thead> <tbody> <tr> <td>Cholesterol</td> <td></td> <td></td> </tr> <tr> <td>HTN - Hypertension</td> <td></td> <td></td> </tr> </tbody> </table>			Prior Treatment for Diabetic Retinopathy			Treatment	OS	OD	None			Other Eye Problems			Eye Problem	OS	OD	None			Other Eye Surgery			Eye Surgery	OS	OD	Cataract Extraction	X	X	Medical / Diabetic Problems			Cholesterol			HTN - Hypertension			Reader Comments Error Messages
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Medical / Diabetic Problems																																							
Cholesterol																																							
HTN - Hypertension																																							
			Save																																				



4. Results and recommendations for care are sent to the patient.

Name: _____

Thank you for participating in the Diabetic Retinopathy Screening program, through the UPMC Eye Center and University of Pittsburgh Diabetes Institute. Please be advised that this was done for screening purposes only, and it does not take the place of a complete eye exam with an ophthalmologist.

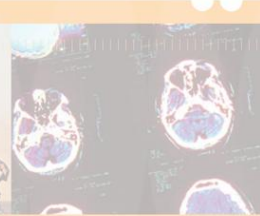
It is recommended that everyone with diabetes have a dilated eye exam on a yearly basis. In some cases, more frequent eye exams are recommended. If you have not had an eye exam in the past year, we recommend that you schedule an appointment for a dilated eye exam.

Your diabetic retinopathy screening was performed on _____.

Based on your screening we recommend:

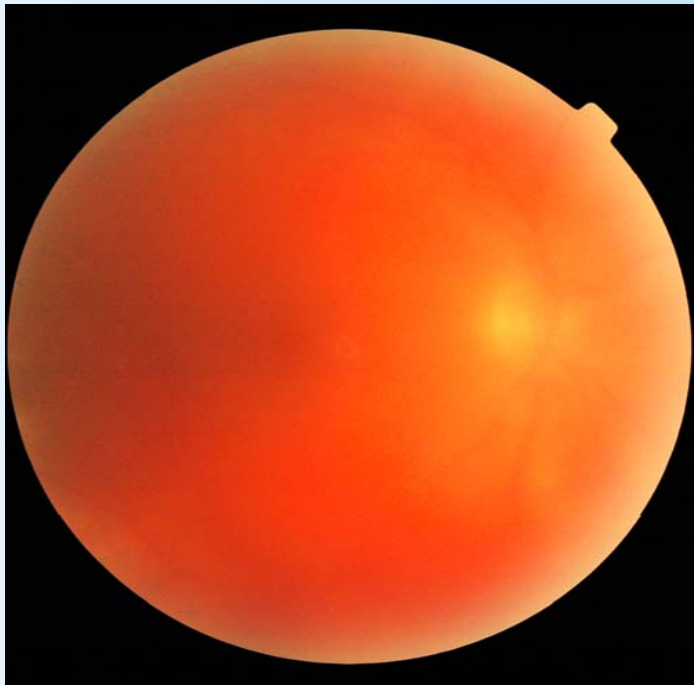
- ☐ Continued yearly, dilated eye exams
- ☐ Dilated eye exam within the next:
- ☐ Six months (mild to moderate Diabetic Retinopathy)
- ☐ Three months (risk of progression needing treatment)
- ☐ As soon as possible (disease requiring immediate treatment)

Other: _____



Fact

- Timely laser therapy can help prevent blindness from diabetic retinopathy



**Vitreous
Hemorrhage**

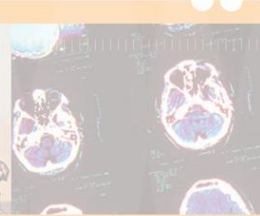


PRP Laser

Photos of images captured during course of this project.

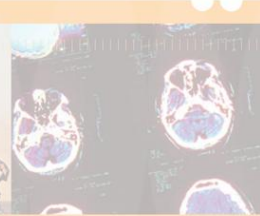


Results



- Over 700 people with diabetes were screened for diabetic retinopathy
- 88% had Type 2 diabetes
- 2% had serious eye disease
- 51% had their last eye examination over a year ago

Given the prevalence of diabetes, it is imperative for people with diabetes to receive yearly eye exams that screen for diabetic retinopathy as well as other eye diseases.



Fact

- Early detection is essential.

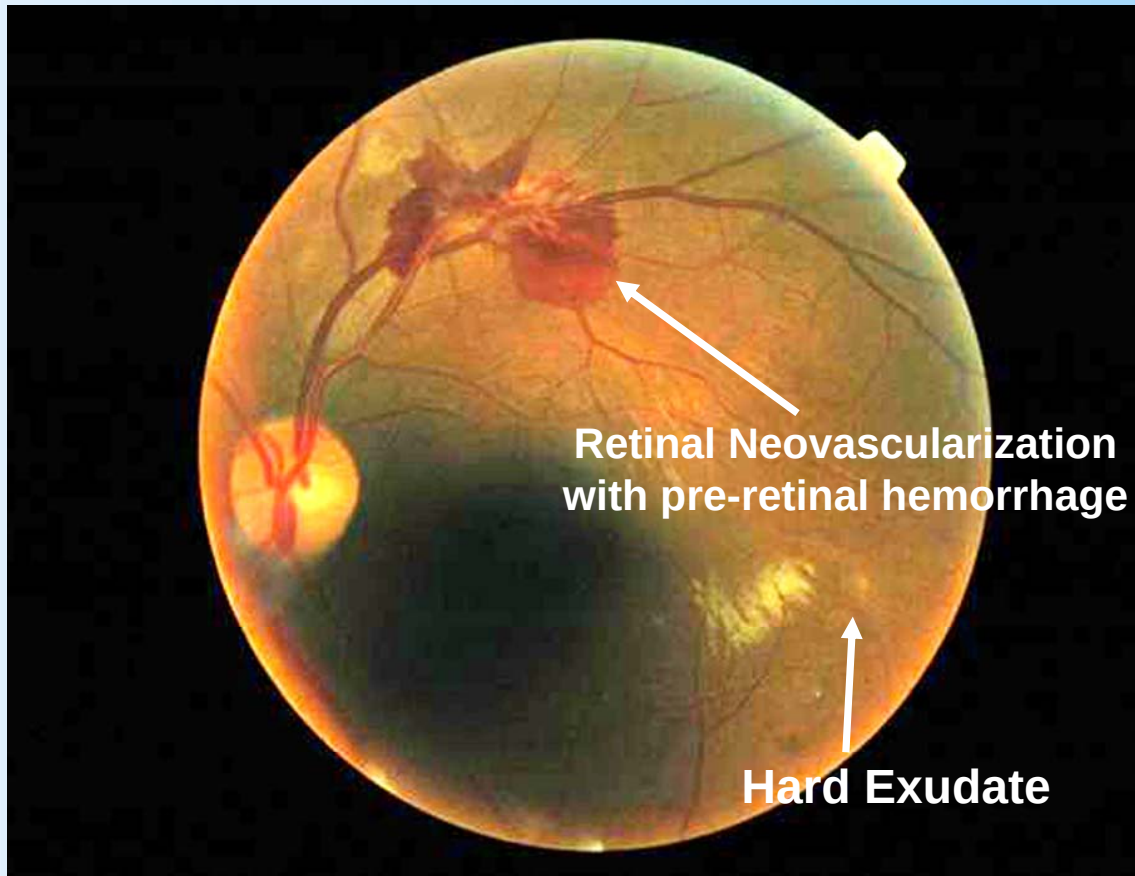
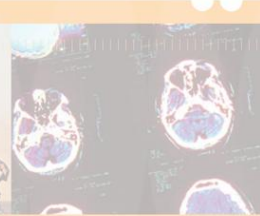


Photo of image captured during course of this project.

Q: If you build it, will they come?



- Despite building this non-invasive, easy and free screening procedure, the project initially had difficulty recruiting participants.



Conclusion

Q: If you build it, will they come?

A: YES, diabetics will come for screenings, but we cannot assume that this will be automatic

- Health care workers may see the screenings as interfering with their work
- A successful screening program will require:
 - Education of MD's & office staff
 - Education of patients
 - Marketing / Advertising
 - Ongoing evaluations and interventions to assure optimal usage

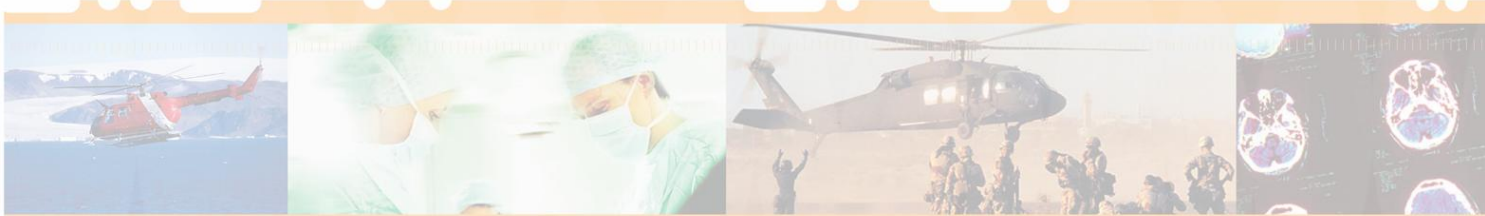


Next Steps

- **Train diabetic educators as imagers and link educational sessions with retinal screenings**
- **Recruit health plans to target people with diabetes who are not receiving proper eye care**
- **Promote retinal screenings in the consumer market place (e.g., Pearl Vision, Walmart) to maximize outreach**

Acknowledgement

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- The content of the information does not imply U.S. Air Force or government endorsement of factual accuracy or opinion.



Healthy in war and peace...mission ready
Resource efficient Preparing for the future

