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13. Abstract (Maximum 200 Words) (abstract should contain no proprietary or confidential information)

The Assistive Technology Research Center, ATRC, is comprised of a set of interrelated research and development projects which apply modern technologies, in particular those which have been exploited in the military, to the practice of medical rehabilitation and technological support for independent living for individuals with disabilities. The Center seeks to work collaboratively to meet the particular mandates of the U.S. Army Medical Research and Materiel Command. Projects are physically conducted and administratively located in the departments of rehabilitation engineering and neuroscience at the National Rehabilitation Hospital. Individual researchers from several other hospital services and clinical professions are also involved.

The ATRC takes advantage of a unusual combination of skills, facilities and interests; specifically a strong community of r&d specialists in biomedical engineering and neuropsychology is positioned to undertake collaborative projects unlike those under way at more conventionally staffed laboratories.

The projects whose progress is detailed in this report target the needs of individuals with head injury, stroke, spinal cord injury and developmental disabilities. These activities address the clinical techniques of psychologists, occupational and physical therapist, physicians and speech pathologists. They make use of technologies based particularly in software development but also in man-machine systems, human factors, biomechanics, telehealth, virtual reality methods, and instrumentation. Assessment and enhancement of motor and cognitive function; and support and measurement of functional performance are the prevailing research themes.

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Introduction: Highlights, Changes, Proposed Changes, and Justifications

Highlights

- ANAM found its way into programs at Stanford University Sports Medicine Program, Lucas MRS Imaging Center, the Uniformed Services University of Health Sciences (USUHS), NIH/NIAMS SLE Clinics and Albert Einstein College of Medicine. Dr. Bleiberg advised Stanford staff on adding ANAM, fMRI, and DTI to specifically examine neuropsychologic and neurologic consequences of concussion.

- At USUHS, ANAM will be used at baseline and at three month follow-up to document cognitive performance as part of an NIH study to identify brain regions functionally associated with acute stress and post traumatic stress disorder following motor vehicle accidents.

- Magnetic resonance spectroscopy (MRS) will be performed in order to correlate measures of brain functioning with cognitive testing and ANAM in the NIH/NIAMS SLE/Albert Einstein collaboration. The primary objective of this study is to evaluate the association between cognitive dysfunction and serum anti-pentapeptide Ab in patients with SLE.

- The Virtual Mall, developed by Drs. Ramesh Ramloll and Cheryl Trepagnier, is an operational video/audio/haptic environment with aesthetically pleasing virtual inhabitants. 3D graphics modeling tools have been used to model the inanimate contents and the gestures and gait of the virtual humans. A commercial force joystick provides force feedback to the subject using it to control her/his avatar, in particular to enhance the perception of collisions with other (virtual) people. This testbed provides a highly controllable instrumented infrastructure for numerous studies which include recording – and perhaps modifying – some social behaviors of people with autism.

- Leveraging ancillary funding from both NIDRR and NSF, Anthrotronix is three quarters of the way through a year-long study on gestural interfaces used in therapy at Mount Washington Pediatric Facility. Supporting this research is the ATRC-developed sensor test bed developed in year three. The wearable sensors allow subjects to control toys and games while performing strength and range of motion enhancement exercises.

- With joint funding from the NIDRR-funded RERC on Telerehabilitation, an application known as RESPECT (REmote SPEech-language and Cognitive Therapy) has been reduced to practice as a beta prototype by engineers Dave Brennan and Linsey Barker. This is a powerful and flexible tool for a broad range of on-site and tele treatment and assessment activities. It allows video, audio, GUI-based and touchscreen interaction between patient and computer and patient and practitioner. In-house use at in SLP at NRH reflects demand from clinicians who find that it has

numerous practical advantages independent of telerehabilitation application. Their use of the system in face-to-face treatment should facilitate acceptance of telepractice using the same system.

- Work on the Visual Feedback system (for capture and instant replay of patient performance video and audio, along with various other stored static and animated therapy-related materials) has caught the attention of occupational therapists and other clinicians at NRH. A clinical co-design team, working with engineers Barker and Justin Carter, has substantially broadened the design goals for this system. Application of a Pugh Chart analysis to alternative conceptual designs has narrowed the field of probable system configurations. Commercial potential of this system – likely to be comprised of off-the-shelf subsystems under the control of custom interface software – is considerable with possible civilian and military training applications running way beyond the practice of rehabilitation.

- Work funded by the ATRC and the RERC has spawned a grant to Dr. Trepagnier from NSF as well as pending grant applications to NIDRR (two Field-Initiated Research proposals from Dr's Rosen and Trepagnier); to NIH for an SBIR (from Rosen and Donal Lauderdale with Russ Holt and other principals at AccessInformation; and to NIH for an R21 grant (from Trepagnier).

Changes During Year 3 and Rationale

Staffing

- ATRC activity in Virtual Reality r&d has gathered a powerful team of four doctoral students from the Psychology Department at the Catholic University of American to play central roles in conduct of experiments and data analysis. Willie Stewart, Andreas Finkelmeyer, Maisely Jones-Paxton and Maya Coleman report to Dr. Trepagnier and contribute to both components of her VR project detailed in the narrative below.
- On the Neuroscience side of the ATRC, Allison Cernich, PhD, has joined the ANAM effort to serve as coordinator for the Fairfax County High School Sports Concussion Project.

Projects
<u>Rehabilitation Engineering-based Activities</u>
   (Note: This section deals with rescheduled and new projects in the same order that they appear in Table 1 below and in the Research Narrative. **Asterisks relate these paragraphs to line items in the Table.**)
   *The *composite brace project* had been underway again when issues related to skin breakdown were resolved. MRI IRB approval of a four-subject evaluation study of pre-production prototype composite braces was obtained and MRMC IRB approval was pending. This activity has now been permanently halted, however. The rationale for discontinuation concerns the *de facto* completion of our proposed study in the marketplace. Becker Orthopedics and other manufacturer/vendors of leg orthoses have brought to market close-fitting shell-type braces – KAFO's and others – and many such units have been fitted to consumers and are in use. While this is, in a sense, vindication of the material selection central to our project, it means that the industry doesn't feel that an experimental study of effectiveness and safety is needed
   ** In the *Boing! Ani-Mate project*, a decision was at the start of year three to devote more effort than originally planned to a clinician-friendly animation authoring system and to a larger menu of customizable games than originally planned. That effort will continue into the fourth and final year of the ATRC grant., mechanical revisions to Boing! and replication for clinical trials will be completed. Evaluation by users and clinicians and investigation of commercialization prospects will also be part of the year four agenda.. Clinical users – patients and professionals – will be more easily recruited now that NRH has formed a contractual relationship with Children's National Medical Center and has opened a pediatric rehab unit here at NRH.
   ***The *Magic Walker project* progressed during year three as detailed below in the project narrative below. A halt was called when the budget for that year would not support the extensive professional market study required at this point to continue the project in a rational way. The initial conceptual design work for this potential product began several years ago at the University of Tennessee, Memphis. At that time, the field was populated by different products than today. Clinical attitudes about gait trainers and walking aids may also have changed – along with reimbursement policies for such equipment. The evaluation phase of this project will be a sensible expenditure of MRMC funds only if it is clear that there is a market for the Magic Walker.

****The *Harness Walking project* has been deferred once again for two reasons. The first is the substantially greater effort level required from Dr. Lauro Halstead, the PI, to advance the wound assessment study through all the barriers to its start (see the narrative on that project below). The second factor is that the Lokomat protocol (funded under the Neuroscience Center grant from MRMC) is demanding enough of that facility that adding another protocol has been problematic in year 3. Dr's Halstead and Hidler (PI of the Lokomat project) will define a one-year study for ATRC year 4 using the Lokomat to a practicable extent; or determine that the budget for that project should best be folded into another ATRC project. Should that recommendation be made, approval will be sought from our MRMC project officer.

Neuroscience-based Activities
Neuroscience-based activities are on course as detailed in the original scope of work.

Proposed Changes for Year 4 and Rationale

Staffing
Dr. Allison Cernich as joined the neuroscience team to coordinate the ANAM concussion study under way in the Fairfax County, Virginia, High School system.

Projects
Rehabilitation Engineering-based Activities
    No changes planned.,

Neuroscience-based Activities
    No changes planned.

Table 1
Projects Based in the Rehabilitation Engineering Service

Continuing beyond original timeline

Project	Completion Date Proposed in Previous Annual Report	Completion Date Proposed Here	Cause of Change
Composite brace	End of year 3	**Discontinued**	*Commercial braces undermine rationale for study
Boing! & Ani-Mate	End of year 3	End of year 4	**Continued effort devoted to Ani-Mate
Magic Walker	End of year 3	End of year 4	***Need for market study

Delayed start

Project	Start Date Proposed in Previous Annual Report	Start and Finish Proposed Here	Cause of Delay
Harness walking	Mid-year 3 to end of year 4	Year 4	****

Ongoing as projected

Project	Completion Date
"Wired Independence Square" and Visual Feedback	End of year 4
VR and Gaze	End of year 4
Home Evaluation Kit	End of year 4
VR R&D under Contract to Anthrotronix	End of year 4
Technology-assisted Wound Assessment	End of year 4
IRIS videophone (Part if "videoconferencing enhancements" project)	End of year 4

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Research Narrative

Projects based in the Rehabilitation Engineering Service

BOING! & Ani-Mate – A Home Exercise Arcade & Video Game Authoring System for Children with Disabilities

Status: continuing

Principal Investigators: Dave Brennan, John Noiseux
Co-investigators: Mike Rosen
Person-months committed:

Project abstract:
Ani-Mate is an easy-to-use video game authoring package that will allow therapists and parents to create custom games for each user in a variety of game metaphors (collision, avoidance, tracking, etc.). Options in the games such as characters, activities, light and sound levels, and number of repetitions can be adjusted to the specific needs and interests of the child through an easy to use menu-driven interface. This design will result in games that are within the child's cognitive capacities, and avoid puzzling or startling stimuli; engage her/his sense of humor by including favorite objects and situations; and offer on-screen rewards for successful completion of the desired number of repetitions.

Year 3 Progress and outcomes:
Delays in introduction of the National Center for Children's Rehabilitation opening at NRH have led to delays in implementation of Boing! and Ani-Mate with end users. It is anticipated that the center will begin more formal operation in Spring 2003. This will provide an opportunity for the system to be used in an actual clinical environment with input from potential users on additional modifications to the system.

In the past year meetings have been held with multiple therapists regarding their impressions of the Ani-Mate software and additional modifications that can be made to improve it. Additional input will be sought on new games that are being developed. New game development had been postponed until additional input could be gathered on improvements to the current games.

Continuation plan:
- Convening additional formal focus group of therapists to solicit additional design input
- Modifying of existing games and system based on additional therapist input
- Construction of additional games
- Integration of additional game options
- Initial clinical placement of Ani-Mate with Boing! or another interface for evaluation.

Magic Walker w/ Brakes

Status: Continuing

Principal Investigator: John Noiseux
Co-investigators: Richard Keller, Michael Rosen

Project abstract:

The Magic Walker was designed at the University of Tennessee. It is a gait trainer / walker device that provides a child with support in the upright standing position. The child's weight is partially born on the walker seat and partially supported by the child's legs. The amount of support received can be customized based on the needs of the child. Steering of the walker is achieved by flexion of the trunk laterally. The mechanical coupling of steering to lateral trunk flexion leaves the upper limbs free for other tasks or for the child to stabilize himself / herself. The utilization of lateral trunk flexion, in contrast to rotation, is what most clearly distinguishes this design from other gait trainers / walkers. The main objective of the Magic Walker Brake Development project is to incorporate a brake system into the present design of the walker. This will enhance safety and may increase the marketability of the design. In particular, it will permit the Magic Walker to be used (with supervision) in an outdoor setting where inadvertent access to down slopes requires automatic activation of the brakes.

Year 3 Progress and outcomes:

The split-caliper braking system identified in Year 1 has been successfully integrated into the Magic Walker design. Upon identifying the actual braking technique, various approaches to control the activation of the brakes were explored. These approaches included direct application of the brakes via a hand grip technique (i.e. traditional bicycle caliper brakes), some type of automatic application of the brakes when a certain pitch of the walker (fore-aft tipping of the walker) or speed was achieved; and mechanical linkage to the walker seat. A mechanical linkage to the seat was selected for several reasons.

The walker's seat mounting was successfully redesigned such that the seat is connected to the walker by a pivot at the front and by springs at the rear. The spring force supporting the rear of the seat is adjustable. When the seat is depressed (i.e. the child sits down on the seat) this motion operates the Magic Walker brakes through a mechanical linkage and brake cable. Because the spring stiffness is adjustable, the amount of support that the seat can provide *without* activating the brakes is adjustable. This will allow a parent or therapist to provide more support to children that can bear very little weight through their legs, while also allowing the brakes to be adjusted to encourage children with greater ability to support their own weight, to do so. Children who can support more of their own weight can be discouraged from sitting down and propelling the walker like a ride-on toy by having the brakes become activated with less force applied to the seat.

The rationale for the seat/linkage system was that, in a situation where the walker was gaining too much speed (or the child was trying to ride it down a hill) the child would tend to either deliberately (as in riding scenario) pick his/her feet up off the ground or stumble (uncontrolled scenario) – either way placing his/her weight on the seat and activating the brakes. It was

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decided that this was a good balance between the complexity, maintenance, and reliability issues of a more sophisticated electro/mechanical system and the risks of an system that relied solely on the deliberate activation of the brakes by the user. Also, it avoids the need for batteries and battery replacement implied by braking designs based on sensors.

Addition progress was made in Year 1 with respect to planning for product dissemination. We continue to plan to include the use of the Magic Walker with brakes at the new National Children's Center for Rehabilitation at NRH (previously referred to as the Pediatric Rehabilitation inpatient and outpatient unit at NRH) for patients with whom it is deemed appropriate. However, the delay in the opening of the center has prevented progress along this specific path. We have, however, been in touch with several companies/organizations that facilitate product evaluation and connections to potential business partners. At this time a company has been selected to assist in determining additional potential modifications and facilitate industry contacts. A detailed proposal for market research has been submitted to the ATRC for consideration which is underway at this time.

Continuation plan: We will continue developing final plans with respect to placement for clinical evaluation and working with a marking analysis expert to bring the walker to the commercial market. It is still our intention to utilize the stronger connections that are developing between the National Children's Medical Center and the National Rehabilitation Hospital with the joint development of the National Children's Center for Rehabilitation at NRH. We look to recruitment appropriate children to evaluate the Magic Walker when the facility is opened in the second or third quarter of this year. The NRH Rehabilitation Engineering Service anticipates numerous contacts with children with disabilities through clinical assertive technology service delivery activities.

Unobtrusive Functional Assessment ("Wired Independence Square")

Status: ongoing

Principal Investigator: J. Carter
Co-investigators: M. Rosen

This project now incorporates the main Wired Independence Square project (WISq), as well as a formalized Digital Visual Feedback (DVF) project (see Year 2 Report). This report will present each of these projects independently. Since submission of the WISq project protocol (see below) to the MRMC IRB, our time has been primarily dedicated to the DVF project.

WIRED INDEPENDENCE SQUARE
Project abstract:
Assessment of patients' functional status in a rehabilitation setting is typically done by an observing therapist using a subjective rating scale such as the FIM, Functional Independence Measure. As a method to introduce objectivity and "ecological validity" into the assessment process, ATRC engineers at NRH installed sensors into the Independence Square (a real-life home and community setting) which was constructed in the hospital in March 1998. The aim of the project is to add objective data to a patient's chart without requiring additional time or effort from the physical, occupational, or speech therapist. With the acquisition of the Rehabilitation Engineering Research Center (RERC) on Telerehabilitation (funded by the National Institute on Disability and Rehabilitation Research, NIDRR, of the U.S. Department of Education), the project was expanded (under the new funding) to further develop the system for use *outside the hospital in clients' homes*.

Year 3 Progress and outcomes:
The main accomplishments of Year 3 follow:
- finalized the protocol details for pilot study
- wrote and submitted proposal to NRH Research Review Committee, 09-04-02
- received MedStar IRB approval, 10-02-02
- submitted proposal to Army IRB, 10-17-02 (approval pending at this writing)

The majority of effort in Year 3 went toward designing the initial study for this project. The research team (engineers and an occupational therapist) in consultation with a statistician decided on the subject population and number of subjects; selected the clinical/functional tasks subjects will perform; and designed the overall protocol. The results of these discussions, i.e. a summary of the proposal, is excerpted below from the submitted proposal.

This is a pilot for a full study. The goal of the full study will be to identify objective performance measures which can predict functional performance. While a subject is performing an activity of daily living (ADL) in the therapy area kitchen, objective timing-based information will be collected. These data will be transformed into several Performance Metrics which will be

tested to determine how well they predict functional performance as measured by a standard clinical assessment method, the Assessment of Motor and Process Skills (AMPS).

Subjects in the study will do nothing different than they would do if they were selected for an AMPS assessment. For the assessment, subjects will perform two ADL tasks with which they are familiar. The first task will be chosen with an occupational therapist, and the second task will be to make a bowl of cold cereal and a beverage. While subjects are performing this second task, simple sensors in the kitchen will record when subjects open and close items such as cabinets, drawers, or the refrigerator. This is the information we will use to try to predict their functional performance, as scored by the AMPS.

This pilot study is intended to provide initial data on potential Performance Metrics to be used to predict functional performance. We will use these initial data to help choose predictor variables, to identify necessary changes in the protocol, and to form the basis of a power analysis to determine the number of subjects necessary for a future full-scale study.

Continuation plan:
Pending approval from the MRMC IRB, we will run our 5-subject Pilot Study. Data collection will be completed in at most two months and the next four months will be spent reducing and analyzing the results. Analysis will include examining the data collected from the sensors to identify trends across subjects. Any frequently observed characteristics (e.g. sequences of sensor "activations" [defined as an event such as opening or closing a cabinet that causes an on-off or off-on change of switch state], excessive gaps between activations, skipped activations, etc.) will be viewed as prospective basis for Performance Metrics which will be compared with the results from the AMPS assessments. From these results and comparisons, we will perform a Power Analysis to determine the number of subjects needed for a full study. A proposal for the full study will be written and submitted to the NRH Research Review Committee, to the MedStar IRB on NRH approval, and to the MRMC IRB after MedStar approval. Assuming Army IRB approval of our pilot-study proposal within the next 2 months, these goals should be accomplished by the end of Year 4.

DIGITAL VISUAL FEEDBACK
Project abstract:
The purpose of the Digital Visual Feedback project (DVF) is to design a clinical tool to record and play back video and audio information in a simple, convenient, and intuitive way. This information can be edited to highlight certain aspects and can be saved for future use. The tool will be used in any environment (e.g. patient rooms and bathrooms, treatment areas, cars, homes, outdoors) *by* clinicians *with* patients, family members, and other clinicians. It will be used for education and training purposes such as patient treatment, family training, and clinical in-service education.

Year 3 Background, status and outcomes:
The main accomplishments of Year 3 follow:
* convened a clinical panel of eight physical, occupational, and speech therapists to brainstorm functional ideas for the new system

- identified an occupational therapist (Neepa Shah, OTR/L) to be a member of the design team, and worked with her to prioritize the brainstorming results based on clinical need and technical feasibility
- constructed a Pugh chart to identify the most promising system designs
- reconvened the clinical panel to get feedback on our top design choices
- began investigating software choices to meet our design needs

We expect the initial system to consist of a computer (desktop, laptop, or tablet), large flatscreen monitor (minimum 15"), and wireless camera and microphone all mounted and adjustable on a single pole on wheels. There will also be a simple remote control which will allow a clinician to remotely position the camera (pan-tilt) and capture video segments. The system can be rolled to any environment where the clinician wants to record activities, and in restricted spaces (e.g. patient bathrooms) the system can be kept nearby with only the wireless camera moved to the location. Future systems could be housed in a briefcase for easier transport outside the hospital.

During a treatment session (for the scenario where a clinician is using the system with a patient), the clinician will roll the system to the treatment area and position the camera in the appropriate location by viewing a preview of the camera image on the monitor. Using the start and stop buttons on the remote control, she will control the camera's activity and record as many video segments as necessary. At any time she can stop and review the video(s) with the patient. She can review videos from the current treatment session or retrieve videos from previous sessions by clinician or patient name, date, or keyword. She can also compare two videos, including a "correct" version from a database of videos. While reviewing video(s) with the patient, she can utilize any of the following features:

- standard media player control buttons (e.g. start, stop, pause)
- clickable/dragable horizontal timeline for immediate access to any part of the video
- button to pause the video for single-frame analysis
- stylus to draw and/or annotate on the videos
- slow motion replay

At the conclusion of a session, the videos can be saved on the computer, or output to various media including CDs, DVDs, VHS tapes, and printouts. In addition to the standard features mentioned above, future versions will allow for incorporating vital signs and other physiologic information (e.g. heart rate, blood pressure) to be collected and presented along with the videos.

Continuation plan:
Currently, we have divided the system's operations into several categories (e.g. collect video, display video, annotate video, save information in a database, etc.) and are investigating existing components to accomplish these tasks. Once these components are identified (or we decide we will create them) we will begin the software development phase of the project. Functionality will be assessed continually by Neepa, the occupational therapist on the team, to ensure clinical acceptability. Once we are comfortable with an alpha design, we will construct a prototype which will then be tested extensively by the members of our clinical panel. Based on their feedback, we will continue software and hardware design iterations until we are satisfied, at which point we will produce a beta system and make it available for general use at NRH.

Virtual Reality Display and Gaze Monitoring to Investigate Impairments of Visual Processing of Social Stimuli

Principal Investigator: C. Trepagnier
Co-investigators: M. M. Sebrechts, R. Ramloll, L. Baker, M. Jones Paxton, M. Coleman, A. Finkelmeyer, W. Stewart

Part A: Virtual Environment for Assessment and Training of Social Skills
- the Virtual Mall

Status: Continuing

Project abstract:

Social perceptual deficits are a significant barrier to independence for many individuals with traumatic brain injury, stroke, and autism. This project will develop virtual environments, using the metaphor of a shopping mall, presenting social contexts in which persons with impaired social judgment can be observed as they make behavioral choices. The long-term goal is the development and evaluation of a clinically practical and ecologically valid assessment of social cognitive function and a rehabilitation modality to improve the ability of individuals with acquired or congenital social cognitive impairment to function in everyday environments.

Year 3 Progress & Outcomes

In order to create commercial grade 3d environments with aesthetically pleasing virtual inhabitants, a graduate student has been assigned exclusively to the task of creating the artwork. A set of 3D graphics modeling tools including Discreet's Studio3D Max, Qtip are being used to model the contents of our virtual environments. Currently, the gestures and gait of the virtual humans are being modeled manually in Studio 3D Max. While we are satisfied with the current gestures of our virtual humans, we believe there is room for improvement.

We have purchased a WingMan Force 3D joystick which provides throw in the x and y directions and a handle that twists around the z-axis. The joystick also provides force feedback. In-house software was developed to allow the joystick to control the subject's avatar in the virtual environment and to provide appropriate force feedback to indicate events that happens in the environment. For example, if the avatar of the subject collides with objects in the environment, the joystick will respond with some preselected level of force fed back to the subject. Mild force feedback accompanied by auditory indication of collision is expected to enhance the perception that actual contact has taken place.

We currently can project a large 3d anaglyph view of the virtual world on a white wall. When the 3d anaglyph is viewed through simple red-cyan filter glasses, the virtual world appears in three dimensions.

We have created a minimal world for the purpose of training navigation skills, in order to avoid confounds between effects of lack of expertise in operating the environment and perceptions of presence. This minimal environment is a fenced serpentine path with obstacles placed along the way. Subjects will have to navigate from one end of the path to the other while avoiding obstacles. In addition to providing a training environment this will also allow us to identify difficulties posed by use of the controller we have selected. The virtual environment has been instrumented so that the time and location of the avatar representing the user are captured. The user's navigation pattern can then be readily visualized in order to evaluate progress of learning and success in collision avoidance.

Continuation Plan

In order to create more realistic physical behaviors, we will assess the benefits of motion capture of gesture data of real subjects using the Motion Lab Systems at The Catholic University of America. We will use this captured data to drive the physical behavior of our virtual humans.

We will also review display options at this time. We have available to us a Virtual Reality head-mounted display, and a Flock of Birds head tracker. We are looking into the possibility of accessing a no-contact 3D display from Dynamic Digital Depth Inc, and exploring potential collaboration with this innovative company.

The Virtual Mall will be tried by members of the research group and the lab, and further modified as needed. We have been informed that IRB approval is imminent. Once it is obtained, trials will be carried out with patients and controls, who will be asked to complete a small number of tasks in the environment (e.g., locate a lost parcel; get to the candy store before it closes). We are particularly interested in the user's perception of the experience and feeling of presence. As described in the protocol, we will use qualitative methods to gain a picture of users' impressions, and feed these results back into the design. Once the design is stabilized, we will compile quantitative scores of individuals with and without disability in order to compute a power estimate for formal evaluation of sensitivity and specificity of the Virtual Mall as an assessment of social impairment. Analysis of these data will provide an indication of whether and how to modify or develop the assessment further. We will use off the shelf spatio-temporal data analysis software to study our data.

We are exploring collaborations with individuals on the forefront of technology development in the domains of animation, natural-language interface and 3-dimensional representation without contact between equipment and viewer. If the study results are promising we envisage seeking outside funding to develop a natural language interface that will allow users to interact verbally with virtual humans. This would enlarge the applicability of the mall from assessment and training of social ambulation and proxemics to include assessment and training of judgment and fundamental aspects of social interaction. These are very important aspects of the autistic deficit. At the same time, this also has potential for other kinds of training, including training in second language and culture.

Status: Continuing

Project abstract:
This arm of the Virtual Reality project looks at social aspects of the visual perceptual deficits associated with right hemisphere stroke. A remote eye-tracking system is used in a face- and object-recognition paradigm to ascertain whether learning and recognition of novel faces and objects is impaired in persons with a clinical diagnosis of left visuospatial neglect; whether these individuals display reduced gaze toward the left side of the images, and finally whether social stimuli (faces) are more resistant to neglect gaze deficits than non-social stimuli (objects).

Year 1 Progress and outcomes:
Despite improvements accomplished in the comfort and usability of the 'VR-Eye' system, the head-mounted display with an earlier ISCAN eye-tracking camera installed in it, the system, which was used in a study under other funding, proved to be fragile, and malfunctions entailed long periods of unavailability while it was out for repair. It was finally decided to terminate use of this device, and pursue eye-tracking and virtual reality display as separate instrumentation for the current project, pending availability of reasonably priced immersive 3-D display that does not entail wearing of a headset or goggles. We have begun negotiations with a developer of 3-D representation that does not entail wearing of any equipment with a view to collaboration. For the purposes of this study, however, we are committed to the technology we proposed in the IRB application material: A remote (desk-top) eye tracking camera and display using a video monitor. Since Dr. Ramloll's arrival, progress has been made in systematizing the data reduction procedures we use for this study, and facilitating verification of data integrity. The fixation analysis and display application, originally developed for use with an Onyx, has been extended so that it correctly handles data captured on the Intergraph platform. A labeled grid can be displayed in place of target pictures in order to facilitate review of identified fixations with the visual (video) record. This grid is used by the investigator acquiring the data to make on-the-spot judgments of the acceptability of calibration. Thanks to this technique, the likelihood of acquiring data that will later have to be rejected because of inaccuracy is greatly reduced.

Testing and analysis have been carried out to determine the optimal configuration of the remote (not head-worn) ISCAN eye-tracker, the monitor on which stimuli are displayed, and the subject. In addition to an Obus support, a Versa Form foam-filled cushion is positioned around the subject's shoulders, neck and head for stability during eye-tracking. A height-adjustable table can be crank-adjusted to achieve constant visual angle between subject's eyes and monitor center, and between eyes and eye-tracker lens, regardless of subject's height whether seated in the chair or in a transport wheelchair

Continuation plan:
Additional software has been developed to ready the protocol for data acquisition. Software has been produced to provide targets that can be made to flash, and whose position and display duration can be controlled by the investigator. This allows

acquisition of calibration points and verification of calibration for patients who require cuing (flashing) to detect the target, and gradual moving of the target from the area of the monitor they are looking at to the area for which we wish to calibrate.

Stimuli were adapted to be presented either centrally on the monitor, displaced to the right, or displaced to the left. Regions of interest were identified and mapped on the pictures to make it possible to carry out data analyses.

Patients clinically identified as having neglect associated with single, right-hemisphere stroke will be enrolled, and their neurological status verified by a neurologist (M. Yaseen, M.D.), who will conduct a bedside neurological examination and review the visualization studies, and by a member of the research group, who will carry out parts of the Behavioral Inattention Test.

Four graduate students from the Department of Psychology of The Catholic University of America have joined the eye tracking and virtual reality research group. All four have trained and become proficient in eye tracking and conducting the data acquisition procedure, and maintain their expertise by regular practice.

Outreach has begun with hospital staff to alert clinicians regarding the characteristics of patients we would like to enroll.

This study is awaiting IRB approval. It was submitted and successfully processed through all levels and approved. Almost immediately afterwards, an administrative change initiated by MedStar Research Institute necessitated its resubmission, and it is still awaiting DAMRMC approval.

Home Evaluation Kit

Status: Ongoing

Principal Investigator: J. Noiseux
Co-investigators: M. Rosen , C. Ellis
Person-months committed: 2

Project abstract:

The outcome of this project will be a practical durable portable home evaluation kit, HEK, which can be carried into a client's home to evaluate the site for its compatibility with special needs and assistive technology. Its purpose will be to allow a home evaluation to be conducted by a trained technician, health aid or family member objectively and efficiently so that it becomes financially feasible under current restricted reimbursement. Thoroughness and objectivity will be essential to determine essential modifications, determine family training needs, select assistive devices for/with the patient, and plan define discharge criteria.

Year 3 Progress and outcomes:

The Home Evaluation Kit has undergone several permutations over the previous year. Additional consultation has taken place with occupational therapists, and physical therapists with the focus continuing to be on 'what can the Home Evaluation Kit bring to a home evaluation that currently is not done, that is of value". The main related issues are:
1) Time and expense. Is a home evaluation is possible at all, do to severe funding and time constraints? These constraints include reimbursability of clinician's time, specifically:
    a. travel time is not reimbursable
    b. clinician can't bill if not accompanied by the patient
    c. costs increase with distance from the hospital)
2) Transportation. Transportation issues with respect to the patient who's home is being evaluated, include: scheduling, availability of the transport van, medical stability of the patient being transported (as hospital stays have shortened the window of time that the patient is in the hospital and able to tolerate road trips has gotten continuously shorter)
3) Technology. What additional technology is needed? Current home evals can involve the use of digital cameras, video cameras, and questionnaires.

In order to provide a homesite evaluation, reduce the transportation difficulties, and maintain direct patient contact between the therapist and the patient, a family member, or OT or PT aid could be utilized to perform the evaluation. In the past this has been done by sending the family member home with a camera and a questionnaire. In some instances video cameras have been used so that a video tape "tour" of the home can be used to analyze potential trouble spots in the home. The problem with this approach is that it provides only a static record of the home visit. When reviewing the videotape if a question arises as to the width of

a door, the height of a surface, the size of a staircase landing, or the distance to the property line, the question or problem cannot be addressed immediately.

By utilizing a live virtual presence the patient and therapist can participate in the homevisit, have efficient and billable contact time, and eliminate the transportation difficulties related to the patient and the therapist.

Currently the Home Evaluation Kit is focusing on developing a lightweight portable unit (building on experience gained from the IRIS project) that will provide an interactive two way audio with live video connection from the patient home. The current prototype in development utilizes a rollable suitcase design with one removable component (a combined videotelephone coder-decoder and a wireless video sender/receiver) that will plug into the standard phone line in the patient home. The rest of the system will be highly transportable and will be rolled/carried to the various points of interest around the patient home. Simultaneous with the live connection back to the hospital, a questionnaire will be utilized to record details of the home (how many levels, number of entrances, width of entrances, number of bathrooms, etc.). This questionnaire may operate off of a palm top computer so that specific answers to question will cause the automated questionnaire to jump to appropriate follow-up questions. For example, answering "yes" to the question "Is there a second bathroom?" would lead to questions about dimensions, etc. Answering "No" would cause the questionnaire to move onto other topics. The advantage to this is that the information gathered could be quickly and automatically formatted and used to generate the homesite report.

Continuation plan:

In the coming year the prototype will be completed and the questionnaire will be finalized. In order to make refinements and deploy the systems within the hospital, and pilot demonstration project will be instituted.

Whereas, a deployable system will be developed in this project, programmatic support (to support a staff member performing actual pilot homevisits using this technology) will be pursued through foundation grants.

Multi-Modal Interfaces and Transfer of Training from Virtual to Real Environments

Status: Ongoing under contract with Anthrotronix

Principal Investigator: Corinna Lathan (formerly Associate Professor of Biomedical Engineering at the Catholic University of America)
Co-investigator: J. M. Vice

Project abstract:
This project has two principal objectives: 1) To provide children with disabilities opportunities to navigate and manipulate their environment using advanced interfaces; and 2) To explore the use of virtual environments to learn developmental tasks.

Year 3 Progress and Outcomes:

Objective 1: We are engaged in a year-long study on gestural interfaces used in therapy at Mount Washington Pediatric Facility. This is work in conjunction with the RERC on Telerehabilitation. This past year we created a sensor test bed for subjects to control a Nintendo game and a remote-control car with our wearable sensors while performing wrist extension exercises in order to increase wrist strength and range of motion. Using a single-subject, multiple baseline design, we investigated the child's motivation and the technology's data collection and activity correction capabilities. Preliminary analysis shows increased self-initiation on tasks and less corrective intervention required by the therapists, compared to baseline activities.
Objective 2: We will continue to pursue the second objective through support of the "VR Buddy" project, which was initiated this past year by developing a system to use virtual environments for learning social and cognitive skills. We developed the mechanical interface and system to integrate VR environments with eye tracking and a mechanical "ride" to motivate and reward the child for appropriate behaviors such a looking at faces. We will continue to support this work in the upcoming year.

Continuation plan:
We intend to seek Congressional funding to continue our work as described above. We will also explore other avenues of funding with MRMC.

Timeline and Deliverables:
Quarter 1: February 1-April 30
    ⇒ Finish analyzing data from the gestural interface test bed and write final report.
    ⇒ Continue modifications to the VR Buddy.
    ⇒ Attend CSUN conference
Quarter 2: May 1 - July 30
    ⇒ Support data collection with the VR Buddy.
    ⇒ Year 4 report
(note: All work on this subcontract is deliverable within the first 6 months of grant year 4.)

Teleassessment of Pressure Ulcers and other Wounds

Status: Continuation during year 3

Principal investigator: L. Halstead
Co-investigator: M. Rosen

Project Abstract:

This project is Phase II of a two-part study that involves the use of telemedicine (TM) to treat people with wounds living at home. Wounds represent a significant and costly health-care problem for many home care individuals. At the present time, these individuals are managed by visiting nurses who generally do not have special expertise in the evaluation and treatment of wounds. The purpose of this project is to address this health care need by investigating three methods of treating persons with wounds at home by nurses and consulting wound care specialists (WCSs) employed by MedStar VNA. 180 patients will be divided into three groups with the assignment of 60 participants and their visiting nurses to each group made by chance. One group (Group A: telemedicine) will have visiting nurses who take digital photos of the patients' wounds to supplement weekly consults with the WCS. The second group of patients (Group B: non-telemedicine) will have visiting nurses who consult with a WCS each week but without the use of digital images. The third group of patients (Group C: control) will have visiting nurses who provide usual and customary care and obtain consults with a WCS as needed. To determine which of the three groups receives the most effective wound care, we will collect and analyze a number of types of data including wound healing time, complications, cost, number of nursing visits, and satisfaction of the participants, visiting nurses and WCSs. The collection of data is scheduled to begin by the end of February 2003. A variety of factors including the MRMC IRB process have delayed the start of this protocol.

Year 3 progress and outcomes:

The initial goal of Phase II was to complete all preliminary activities in time to begin enrolling subjects by late May or early June 2002. However, many of the tasks that had to be completed before data collection could begin took longer than anticipated. One unanticipated lengthy process we encountered was the need to seek IRB approval from the Department of Defense (DOD). The initial funding for Phase I of this project was through a Rehabilitation Engineering Research Center (RERC) grant awarded by the National Institute for Disability Rehabilitation and Research (NIDRR). This federal agency accepts the IRB process created by NRH and MRI. When the funding source for this project was transferred in the spring of 2002 from NIDRR to the DOD, it was necessary to go through a number of steps to secure DOD IRB approval. These included re-writing the consent form, submitting the protocol and revised consent form for review, revising and re-submitting the protocol and consent form in response to requested

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changes and then returning the protocol for a second review by the DOD IRB Committee. This process is now complete and final approval by the DOD IRB has been obtained.

The other sources of delay included the following: 1) completing the design and testing of the Telehealth Kit. The primary users of the Telehealth Kit will be the nurses in Group A who will be taking digital images of the subjects' wounds in their homes. To ensure that the Telehealth Kit will be easy to use and experienced as user-friendly by the Group A nurses, it was important to go through several iterative design cycles using feedback from these nurses and the Wound Care Specialists (WCS) before final decisions were made and appropriate equipment purchased; 2) completing the "wound expertise" evaluation of *all* the VNA nurses who were potential candidates to be randomly selected to participate in the study in Groups A, B and C. This was a much larger task than had been anticipated, primarily because the evaluation could only be performed by two individuals (the 2 WCS in the study) and because part of the assessment required a one-on-one critique of each nurse's wound care skills in a wound care patient's home. To accomplish this, it was necessary to schedule and often re-schedule the evaluation sessions to accommodate the busy work day of the VNA nurses--who are spread out across Northern Virginia, DC, and Southern Maryland--as well as holidays, sick leave, delays due to weather and traffic, etc.; and 3) completing the orientation, "buy-in" (willingness of each nurse to participate in the study), and training sessions. Each of these sessions was mandatory for the nurses in all 3 groups, while special orientation and buy-in sessions were necessary for the nursing supervisors (Operation Directors) and the schedulers. Planning, scheduling, and completing all these sessions simply took longer than expected. The activities associated with participating in this study are "add-ons" to the regular work schedule for most of the VNA personnel. Getting the nurses and others together, even in small groups, to complete the sessions described above was complicated by unexpected changes in work schedules, illness, holidays, travel delays, etc. These delays were further compounded by some nurses in groups A, B, and C leaving the VNA. These individuals then had to be replaced with randomly selected backup nurses who had to go through all the standard orientation and training sessions. All of these obstacles typify the difficulties of superimposing a substantive controlled study on the daily practice of clinicians.

Continuation Plan:

Our goal for the coming year is to implement Phase II with data collection to begin by the end of February 2003 and be completed over the ensuing 8-10 months. Data collection will be followed by a period of data analysis that will include a nonlinear, hierarchical, mixed model that will test the main hypothesis of a difference between healing time between groups. A mixed model contains both random and fixed effects. An effect is fixed if the study contains all levels of interest. An effect is random if the levels are a sampling of levels. In this study, treatment group is a fixed effect, while Geographical Units (GU) and VNIs are random effects. The model is hierarchical because VNIs are nested within GUs and GUs are nested within treatment group. The unit of analysis is the wound. The correlation matrix will be corrected for the correlation

of multiple wounds within one patient. Wound type (surgical, pressure ulcer, and stasis ulcer) will be treated as a fixed effect. The interaction between wound type and treatment group will be assessed. Patient satisfaction data will be analyzed using simple descriptive statistics. Responses to the open-ended questions will be analyzed for trends and specific comments/suggestions to improve wound care and the use of telemedicine. Finally, we will begin preparations for disseminating results of the project. This will include presentations at local and national conferences and writing articles for submission to peer reviewed journals. Most importantly, if the data warrant it, we will prepare a Phase III project to take the next step. This involves a direct comparison of digital images supplemented by consultations with a WCS with live interactive videophone consultations between the home care nurse and WCS.

Technology for Enhanced Telerehabilitation Interaction

Status: Continuing*
*This activity includes and extends the work related to the IRIS project (new project in Year 2)

Principal Investigator: David Brennan
Co-investigators: John Noiseux, Linsey Barker

Project abstract

Videoconferencing (VC) equipment allows people to interact across long distances. However, existing commercially-available systems are somewhat limited in that they typically only transmit voice and video signals and also require VC participants to remain in the same physical location throughout the call. These limitations constrain the types of interaction that can take place during VC-based rehabilitation sessions. This project seeks to extend the utility of existing technologies by developing systems and processes to address their limitations. The work is centered on two distinct goals:

- **Goal 1**: Create a wireless audio-video terminal that uses standard analog phone service and allows for fully mobile videoconferencing.
- **Goal 2**: Develop methods for delivering treatment and assessment materials during a videoconference-based encounter with a patient. The target population includes patients living with disabilities resulting from stroke, traumatic brain injuries, and other neurologic conditions.

Year 3 Progress and outcomes

- **Goal 1:**

The design and fabrication of a new IRIS base station was completed. The final design consisted of a simplified self-contained unit that allows flexibility for a multitude of audio/video connections to be used with IRIS (see Figure below for diagram of base station connection panel). The base station houses both a 2.4GHz wireless audio/video transmitter and receiver, operating at slightly different frequencies so as to minimize cross-talk. RCA jacks are provided so that connections can be made for audio/video signals to be transmitted both to and from the IRIS mobile unit. The flexibility this base station affords allows the mobile IRIS unit to serve as a wireless audio-video terminal for any VC system with external audio/video input and output.

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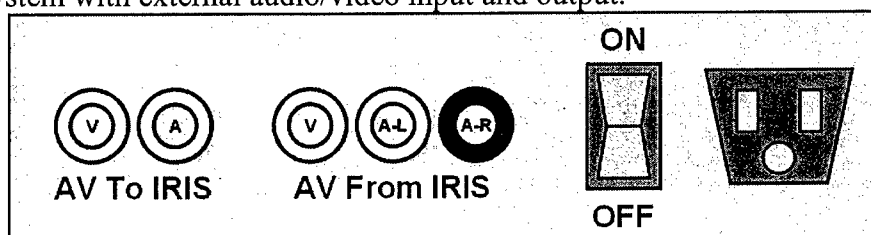
A next generation mobile IRIS unit has been designed and is currently being fabricated. While it is scaled down in size relative to the original IRIS prototype (10" Monitor versus 15" monitor) for the purpose of portability, it sacrifices none of the performance characteristics of the original, most importantly its wireless range of up to 100 feet indoors, through and around walls (with considerably better performance in large open spaces) and a battery life of more than three hours between recharges. It is designed to have a "roll-about" form factor, much like a small wheeled suitcase that can be carried and setup by one person. All components can be stored inside during transport, then removed and quickly affixed in their proper locations to conduct a videoconference session. The necessary components have been purchased and the mounting hardware is currently being constructed.

- **Goal 2:**

This work extends previous R&D efforts conducted under the NIDRR-funded RERC on Telerehabilitation, hosted in the Rehab Engineering Labs at NRH, which have involved investigating Internet-based VC as a means for providing speech-language and cognitive rehabilitation to adult clients with neurologic impairments. The work stream presented here involves, more specifically, the development of digitized versions of existing paper-based therapeutic treatment and assessment materials. These materials are currently being used in (1) traditional face-to-face treatment sessions and (2) as part of VC-based telerehabilitation interactions.

1) Based on suggestions and feedback from a focus group of clinicians, a library of therapy and assessment tasks across a broad range of skill areas (e.g., reading comprehension, deductive reasoning, functional math) was created. Graphical user interfaces (GUIs) for each task were developed in Visual Basic 6. The GUIs are populated with information (e.g. prompts and correct answers to questions) from a back-end database that is also responsible for recording responses to the tasks. A main menu screen provides easy access to and navigation between tasks. The program was compiled as a stand-alone software package and installed on tablet computers, which are being used by SLP clinicians at NRH. This approach allows them to take the software to the patient rather than move the patient to a computer, and also allows them to carry a large quantity of their treatment material with them, rather than needing to photocopy pages from workbooks.

2) The RESPECT (REmote SPEech-language and Cognitive Therapy) system allows for a wide range of treatment interventions to be incorporated in a computer-based VC session. RESPECT allows a clinician to administer the therapy and assessment tasks described above to a remote client during a telerehab session. The clinician controls which tasks are presented on the patient's computer, with the patient's responses transmitted in real-time to the clinician's screen. Another capacity of RESPECT permits clinician and client to utilize drawing "whiteboards" and shared applications such as Microsoft Word or Internet Explorer. Strict attention was given to usability and human factors guidelines when designing RESPECT so as to simplify access to all controls.

Continuation plan

- **Goal 1:**

The identification of potential placements for IRIS will continue. Several projects both within the RERC on Telerehabilitation as well as in the new NRH Telehealth Center are likely to make use of IRIS. In addition, NRH's clinical ROHP (Regional Occupational Health Program) initiative has recognized IRIS as a potential tool for providing remote evaluation of workplace ergonomics. Once it is determined in which settings IRIS will be used, duplicates of the system will be fabricated as necessary with needed customizations being made on a case-by-case basis.

- **Goal 2:**

With the new breed of Tablet PCs, it is anticipated that the software will be updated to incorporate some of the features of "digital ink." This will allow users to interact more naturally (i.e. via direct writing or drawing) with the treatment and assessment material in addition to the current point-and-click interface. RESPECT will look to take advantage of "digital ink" to improve the interaction between clinician and a client. An NIH-R21 application is currently being considered to gain additional funding to conduct more extensive investigation for the development and usability testing of the RESPECT concept with the eventual goal being technology transfer of an open-ended platform for providing a wide variety of remote rehabilitation interventions for clients with neurologic impairments.

Projects Based in Neuroscience

Automated Neuropsychological Assessment Metrics (ANAM): Psychometric Development and Integration into Military and Civilian Studies of Cerebral Concussion and Psychopharmacologic Treatment of Brain Injuries and Diseases

Status: Ongoing
Principal Investigator: J. Bleiberg (NRH)
Co-Investigators: D. Reeves (U.S. Navy), R. Kane (Veterans Administration and NASA), T. Elsmore (Private Consultant), and K. Winter (U.S. Naval Computer and Telecommunications Station, Pensacola)

Products:

1. Behavioral Medicine ANAM. This is a software program consisting of ANAM subtests developed for use with medical populations and for pharmaceutical trials. Manual development, evaluation of psychometrics, and reference group norms are in progress.

2. Sports Medicine ANAM. This is a software program consisting of ANAM subtests used for concussion surveillance and management programs. Subtests were chosen based on sensitivity to concussion in previous research and in response to feedback from current ANAM users. Manual development, evaluation of psychometrics, and reference group norms are in progress.

3. NRHReview. This is a software program for displaying ANAM data in a fashion useful for clinical interpretation. NRHReview provides a turnkey, single-step solution for aggregating serial testing data from a single subject, extracting the data from raw ANAM data files, automatically creating tabular and graphical data displays, and generating printed reports suitable for inclusion in medical records. The software has gone through three major revisions this past year to accommodate user-friendliness issues as well as several of the psychometric issues described below. NRHReview was developed by Drs. Elsmore, Reeves, and Bleiberg, and is scheduled for multiple enhancements this coming year. Specifically, the current version only compares a subject's current data with his/her previous data. The planned enhancements will include comparison with normative databases and the use of Reliable Change Index (RCI) statistics to identify and flag clinically meaningful changes in performance. As described below, we currently are using multiple data sets acquired this past year to explore and compare the five different published methods for calculating RCI's in order to determine the most clinically useful RCI procedure to incorporate into NRHReview. Clinical usefulness, in this context, is determined by analysis of Receiver Operating Curves and clinical "hit rates" (false positives and false negatives).

4. ANAM ClinicView. This is the current iteration of NRHReview, as distributed on the ANAM FTP site. NRHReview became the "chassis" for an expanded set of ANAM data utilities that distributed by Kathy Winter through SPAWAR Pensacola. Many of the data inference upgrades described above have been completed and have been incorporated

into the ANAM SBIR to Tim Elsmore in San Diego. The name change was designed to parallel the companion ANAM utility, ANAM DataView, the development of which is directly supported by MRMC.

5. <u>NRH ANAM/Access Database</u>. This is a Microsoft Access database designed to extract and manage extremely large ANAM data sets. The software package also is been incorporated into the ANAM SBIR, and is being widely distributed to the ANAM user community. Dr. Reeves currently is working with Kathy Winter on the translation of this Access database to an Oracle platform.

6. <u>ANAMOnline.com</u>. This is the product of last year's subcontract from NRH to Kathy Winter at the U.S. Navy Computer and Telecommunications Station, Pensacola. It is a Web site designed to provide several functions for integrating and facilitating work within the ANAM user community. The Web site has the capacity to support chat groups and discussions, to allow users to download and upload data files, to serve as a central repository for all of the existing ANAM technical and scientific literature, and for distributing ANAM software. The Web site has been completed but has not gone "live" because of the current MRMC patent application for ANAM and the prohibition on distributing ANAM software pending completion of the patent application. Discussions on February 21, 2002 with Kathy Winter indicate an estimate of May 1, 2002 for the Web site going online. The FTP site went online in December of 2002 and the first project to use the site for support is the Stanford University concussion project.

Funded Research Incorporating ANAM:

(One of the primary objectives stated in last year's progress report was to expand the ANAM user base. Described below are extramural and intramural federally-funded research projects, and pending grant applications, in which NRH has assisted other agencies to incorporate ANAM into their research programs, and in which NRH staff have become co investigators.)

1. <u>Stanford University Sports Medicine Program, Lucas MRS Imaging Center.</u>
   Kirschen, M., Chen, A., Desmond, J., Moseley, M., Glover, G., Bleiberg, J., Johnson, J., Reeves, D. Cognitive effects after concussion injury in football players: A fMRI and DTI study. This group had an ongoing sideline concussion assessment and management program. This year they proposed adding ANAM, fMRI, and DTI to specifically examine neuropsychologic and neurologic consequences of concussion. Specifically, this group is interested in exploring cerebro-cerebellar circuitry as it relates to concussion symptomology. This year, Dr. Bleiberg visited Stanford, advised them on their protocol, provided ANAM software and training, and presented ANAM concussion research to their Sports Medicine and Neuroimaging Departments. Data collect began in February, 2003 and is ongoing.

2. <u>Uniformed Services University of Health Sciences</u> – Elizabeth A. Osuch, Wayne C. Drevets, Robert J. Ursano, Christian Grillon, Carol S. Fullerton, Frank Schraml, Brian Crowley, Richard Epstein. Functional Neuroimaging in Acute Stress Disorder & PTSD. This group has

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a study funded by NIH to identify brain regions functionally associated with acute stress and post traumatic stress disorder following motor vehicle accidents. ANAM will be used at baseline and at three month follow-up to document cognitive performance. This year, Dr. Bleiberg met with Dr. Osuch and her research team and provided ANAM software and training. Data collection began in January, 2003 and is ongoing.

3. NIH/NIAMS SLE Clinics & Albert Einstein College of Medicine - Role of the Antibody Against NR2 Glutamate Receptor in Cognitive Dysfunction in Patients with Systemic Lupus Erythematosus. The primary objective of this study is to evaluate the association between cognitive dysfunction and serum anti-pentapeptide Ab in patients with SLE. In this cross-sectional study, up to 60 patients with SLE will be enrolled through Rheumatology clinics at NIAMS. Participants will undergo neuropsychological testing, neuroimaging studies, and blood tests for antibody with the reactivity to the pentapeptide consensus sequence of the human NMDA receptor NR2a and NR2b subunits. Magnetic resonance imaging (MRI) will be performed for evaluation of potentially confounding central nervous system (CNS) disease. Magnetic resonance spectroscopy (MRS) will be performed in order to correlate measures of brain functioning with cognitive testing and ANAM. Data collection began in December of 2002 and is ongoing. An additional proposal has been submitted to the DANA foundation to follow these patients longitudinally and use change in ANAM performance to signal follow-up MRS scans. ANAM performance and MRS data will be correlated. Dr. Bleiberg met with all participating centers and provided ANAM software and training.

Data Analysis:

1. Reanalysis of Data Sets from Other ANAM Users. As the result of collaborations described in previous progress reports, we now are beginning to receive ANAM data sets for reanalysis. This includes: crossover clinical trials for pharmacologic treatment of migraine (Imitrex study, N=27; Maxalt vs. Fiorinal study, N=24), three years (N = 100) of geriatric chronobiology data from Phyllis Zee, M.D. Ph.D., Northwestern University Medical School; a placebo-crossover clinical trial (N = 54) of a heat shock protein inducer (TEX-OE) as a treatment for ETOH hangover, performed by Jeff Wiese, M.D., Department of Psychiatry, Tulane University School of Medicine; and, also from Dr. Wiese at Tulane, a dose-escalation pilot-study (N = 12) of ANAM performance at baseline and three increasing dose levels of ETOH. Combined existing concussion databases for development of reference group norms and calculation of psychometrics and reliable change indices.

2. Analysis of Year 2000 West Point Concussion Data. The Year 2000 West Point data is ongoing and multiple manuscripts are in preparation. Specifically, we have documented recovery from concussion using ANAM as an outcome measure, demonstrated residual effects of previous concussion on baseline performance, and demonstrated the impact of concussion history on acute concussion presentation. The latter has been accepted for presentation at the American Academy of Neurology meetings in April of 2003. Current analyses continue to center on the issue of clinical inference procedures and developing ways for clinical interpretation of ANAM data at the single subject level. The systems are based on Reliable Change Index (RCI) procedures and regression-based methods and permit the analysis of the contribution of ANAM scores to correct classification both for individual and

combined ANAM subtests. Database preparation of the West Point 2001 data is underway. We plan to replicate previous findings and prospectively validate classification methods developed from the 2000 West Point data.

3. Fort Bragg Concussion Study. ANAM data from over 5,000 82nd Airborne baselines have been analyzed and summarized, and constitute an extensive normative database. These data supplied to Kathy Winter SPAWAR Pensacola and to Tim Elsmore to serve as basic normative data for ongoing projects to automate ANAM interpretation.

Ongoing and Continuation Projects:

1. Sports Medicine Department, University of North Carolina Chapel Hill. This group has had an ongoing sports concussion surveillance grant funded by the Centers for Disease Control. Their existing grant used conventional neuropsychological tests as primary outcome measures and made no use of computerized tests. The UNC sports concussion surveillance program covers the contact sports teams (male and female) at 20 NCAA universities and 26 high schools from all regions of the United States. One very important feature of the supplemental application is that it supports repeated ANAM administrations in healthy control subjects. This is essential information for calculation of increasingly precise RCI's for use with injured subjects. The terms of the collaboration between NRH and UNC will make this normative data available for incorporation into the clinical interpretation modules of NRHReview. Moreover, the UNC project will be available as a testbed for an Internet-enabled ANAM. A paper based on the initial data set has been submitted for presentation at the annual meeting of the National Athletic Training Association (NATA), June 2003.

2. Sports Medicine Department, State University of New York at Buffalo. This project involves concussion surveillance at a number of universities and high schools in the Buffalo area. However, it has the unique feature of incorporating a detailed comparison of the efficacy of two computerized neuropsychological test batteries, ANAM and ImPACT. ImPACT is the product of the University of Pittsburgh's long relationship with the National Football League. ImPACT is similar to ANAM, but it is Internet-enabled and has been field-tested and validated with approximately half of the NFL teams. This "head to head" comparison of two computerized batteries will generate important information regarding what is effective and what is not effective, both in terms of psychometric properties as well as the user-software interface and other practical usability issues. This project also includes a brief battery of traditional clinical neuropsychological tests (the original pencil and paper "NFL battery" from the University of Pittsburgh), such that the psychometric properties of both ANAM and Impact can be analyzed.

3. NIH-National Institute of Drug Abuse. Dr. Bleiberg is a coinvestigator on two NIDA projects which have been approved for intramural funding. The first study uses ANAM in a dose escalation study of lofexidine for relapse prevention in methadone maintenance patients. The purpose of the study is to determine the cost/benefits of various doses of lofexidine in terms of reduction of cravings versus onset of sedation and cognitive impairment. The second study examines the effectiveness of adding bupropion to a cocaine-abuse treatment program consisting of buprenorphine and cognitive-behavioral therapy. In this study, ANAM is used

to explore the treatment's effects on attention and concentration in patients with dual diagnosis of cocaine abuse and attention deficit hyperactivity disorder.

4. <u>University Of Texas at San Antonio Medical School -- Systemic Lupus Erythematosus</u>. UTSA currently has a major NIH grant for an SLE research and training center, which includes an inception-cohort SLE monitoring project. Steven Holliday, Ph.D., the senior neuropsychologist on this project, has been using a DOS version of ANAM for the past three years (acquired at one of the ANAM courses taught by Drs. Reeves, Kane, and Bleiberg at the American Psychological Association in 1995). The basic design of the study is for all 300 patients to receive the American Academy of Rheumatology recommended traditional neuropsychological test battery at annual intervals and receive ANAM at each quarterly clinic visit. Similar procedures will be applied to an equal number of matched controls. This project monitors extensive serological and other disease activity markers of SLE, such that the relation between disease activity and cognitive function can be explored in this design. Moreover, this will provide a very solid foundation for clinical use of ANAM with SLE and similar populations. A paper based on the initial data set currently is in preparation.

5. <u>NIH Clinical Center SLE Clinic</u>. The preparations for the UTSA SLE project provided the foundation for approaching NIH regarding incorporation of ANAM within the NIH SLE Clinic. This clinic serves as the central hub for SLE at NIH and supports numerous SLE research projects. The director of the clinic, Gabor Illie, M.D., following a presentation from Dr. Bleiberg on the UTSA ANAM project, requested that Dr. Bleiberg install ANAM on the NIH SLE clinic's computer system. Work started on December 20, 2001 and continues to the present. The version of ANAM used at NIH is identical to that at the UTSA project and the intention is to maintain common methods across both projects, upgrading and enhancing the NIH version based on results of the UTSA project. We consider this project important because it represents the incorporation of cognitive testing as a routine feature of clinic-based medical services -- essentially embodying the primary objective of NRH's efforts to develop ANAM as an instrument for assessment of cognitive function as a routine and efficient element of primary care medicine and public health surveillance. The prime obstacle is that the NIH Clinical Center database uses Macintosh computers in each exam room. Dr. Illie currently is acquiring IBM PC notebooks for several of the exam rooms, but this is not a satisfactory long-term solution. Removal of hardware compatibility problems such as this is one of the primary objectives of an Internet-enabled, platform-independent, ANAM. Data collection has started and is ongoing.

6. <u>American Fibromyalgia Syndrome Association (AFSA) Proposal</u>. Arthur Weinstein, M.D., of the Department of Medicine at the Washington Hospital Center has submitted a proposal examination of cognitive symptoms related to fibromyalgia and other regional pain disorders. Included in this study, is a small aggressive treatment protocol for previously untreated fibromyalgia patients. ANAM is the primary cognitive outcome variable. PET scanning will be used to track neurological functioning and will be correlated with ANAM performance. This proposal was recently accepted and data collection will begin in March, 2003.

7. <u>Fairfax County High School Concussion Project</u>. This is a demonstration project that will integrate ANAM software into a public high school concussion surveillance and management program. Additional sideline measures of concussion severity include: Virginia Neurological Index (VNI), and the Standardized Assessment of Concussion (SAC). Further the project will provide data regarding the natural history of recovery from sports concussion in male and female adolescents, with special emphasis on the female athletes who heretofore have not been well covered by previous research. The protocol has undergone revisions at the request of the DoD IRB in the past year. The protocol has been recently approved by the DoD IRB and data collection will begin in the summer of 2003 pending resubmission to the MedStar IRB.

8. <u>ANAM Dissemination, Support, and Technical Assistance Core</u>. Many of the richest sources for ANAM development consist of collaborations in which NRH directs and manages the ANAM component of studies sponsored by other institutions. The major advantage of engaging in these collaborations is that they are an extraordinarily powerful way of leveraging NRH's and DOD's research dollars, rapidly and efficiently expanding the ANAM user-base and facilitating the creation of a vibrant ANAM user community. Moreover, each of the collaborative projects contains a scientifically important neuroscience research problem. We propose to aggregate these types of projects into a program core of "ANAM Dissemination, Support, and Technical Assistance," with a single budget that has provisions for support of the above described projects, as well as for stimulation and support of new projects.

   The specific activities included in the ANAM Dissemination, Support, and Technical Assistance core are:

   1. Consultation between NRH personnel (Drs. Bleiberg, Kane, or Reeves) and outside investigators to determine if ANAM is an appropriate tool for a proposed study, and to determine whether the proposed study is of sufficient quality to justify investment of NRH-DOD resources
   2. Provision of an ANAM "workshop" to the investigator's laboratory or institution, including installation of ANAM and training in its use
   3. ANAM software modifications and enhancements to address specific needs of the proposed study, typically performed under subcontract from NRH to Navy Computer Telecommunication Station (NCTS) and/or Tim Elsmore, Ph.D.
   4. Provision of assistance to outside investigators for writing ANAM-related sections of research proposals, IRB submissions, and study procedure manuals
   5. Data extraction, data management, and data analysis for ANAM and related data
   6. Participation in delivering scientific papers and posters, and preparation of papers for publication
   7. Integration and facilitation of the above via ANAMOnline.com, with emphasis on automating as many of the above support functions as possible

Key R&D Accomplishments

- A second-generation IRIS (Interactive Rollabout Imaging Station) has been fabricated consisting of a mobile unit (with a 15" flat panel video monitor, an electronic Pan-Tilt-Zoom camera, and a rechargeable power supply with over hours of run-time) and a base-station. IRIS utilizes 2.4 GHz receivers and transmitters for wireless transmission of audio and video signals. StarView 400 Pro videophones are used to code and decode the signals and transmit them over standard analog POTS phone lines.
- As part of the VR work, real-time gaze-fixation detection software has been further refined and accelerated so that changes occur in the display contingent on the direction of the participant's gaze. This will be utilized in a future project to train individuals with social cognition deficits to direct their gaze at face-borne communication.
- A preliminary design of the Wound Telehealth Kit was completed based on recommendations from the MedStar VNA nurses, who will be involved in the phase II study. The kit will consist of a digital camera, tripod, laptop computer, portable lighting and a rolling hard case. The nurse will use the laptop for gathering patient information and capturing and storing the digital images of wounds. The computer will also provide a contingent guide to use of the remainder of the equipment. The images will be forwarded to a wound specialist at a later time. A final design will be completed by mid-Spring for use in the phase II study.
- Significant progress was made developing clinical inference procedures for ANAM, the results of which have been accepted for presentation at the April 2002 American Academy of Neurology annual meeting

Reportable Outcomes

Publications:

Appel, P.R., Bleiberg, J. & Noiseux, J. 2002. "Behavioral Telehealth for Pain Management: Efficacy and Consumer Satisfaction." [Abstract]. In: *Telemedicine Journal and e-Health*, 8(2),:224.

Brennan, D.M., Georgeadis, A., & Barron, C. 2002. "Telerehabilitation Tools for the Provision of Remote Speech-Language Treatment." *Topics in Stroke Rehabilitation*, 8(4):71-78.

Halstead, L.S., Balch, D., Clark, P., Vesmarovich, S. Synopsis of Instructional Course presented at the ASIA Annual Meeting on "The Future of Telerehabilitation and Spinal Cord Injury Care". (In press in Spinal Cord).

Halstead, LS, Dang, T, Elrod, M, Convit RJ, Rosen MJ. "Teleassessment compared with Live Assessment in a Wound Clinic: A Pilot Study." *Advances in Skin and Wound Care*. (In press 2002).

Halstead, L.S., Dang, T.D., Elrod, M.W., Convit, R., Rosen, M.J., Woods, S. (b 2002). "Distance Evaluation of Skin Health: Teleassessment of Individuals in Remote Settings with Spinal Cord Injury and Pressure Ulcers" In (M.J. Rosen & D.E. Lauderdale, Eds.) *Proceedings of the State of the Science Conference on Telerehabilitation and Applications of Virtual Reality*. Washington, DC, NRH Press.

Lathan, C.E., M.R. Tracey, M.M., Sebrechts, D.M. Clawson, and G. Higgins "Using Virtual Environments as Training Simulators: Measuring Transfer" in *Handbook of Virtual Environments: Design, Implementation, and Applications,* Ed. K. Stanney, Mahwah, NJ: Lawrence Erlbaum Associates, 2002.

Lathan, C.E., and M.R. Tracey, "The Interaction of Spatial Ability and Motor Learning in the Transfer of Training From a Simulator to a Real Task." Invited to resubmit *to Presence: Teleoperators and Virtual Environments*, MIT Press.

Rosen, M.J., Winters, J.M. & Lauderdale, D.E. 2002. "Telerehabilitation." In J. Winters, C. Robinson, R. Simpson, & G. Vanderheiden (Eds.), *Emerging and Accessible Telecommunications, Information and Healthcare Technologies,* Chapter 18, 220-245. Arlington, RESNA Press.

Tran, B.Q., Krainak, D.M., Lauderdale, D.E., & Winters, J.M. 2002. "Video telephony in tele-health care: Accessible and emerging technologies." In J. Winters, C. Robinson, R. Simpson, & G. Vanderheiden (Eds.), *Emerging and Accessible Telecommunications, Information and Healthcare Technologies,* Chapter 13, 119-27. Arlington, RESNA Press.

Tran, B.Q., Walz, L.L., Buckley, K.M, & Rosen, M.J., 2002. "Digital images: Guidelines for optimal image acquisition and transfer for health care." In J. Winters, C. Robinson, R. Simpson, & G. Vanderheiden (Eds.), *Emerging and Accessible Telecommunications, Information and Healthcare Technologies*, Chapter 14, 128-135. Arlington, RESNA Press.

Trepagnier, C. (2002) "Tracking Gaze of Patients with Visuospatial Neglect." *Topics in Stroke Rehabilitation - Technology for Clinical Stroke Applications* 8(4), 79-88.

Trepagnier, C., Sebrechts, M.M., & Peterson, R. (2002). "Atypical Face Gaze in Autism." *CyberPsychology & Behavior*. 5(3), 213-217.

Woodard, J., Marker, C., Tabanico, F., Miller, S., Dorsett, E., Cox, L., Gould, F., and Bleiberg, J. (2002). "A Validation Study of the Automated Neuropsychological Assessment Metrics (ANAM) in Non-Concussed High School Football Players." *Journal of the International Neuropsychological Society*. 8 (2): 175.

Conference Presentations (with Proceedings):

Appel, P.R., Bleiberg, J. & Noiseux, J. 2002. "Behavioral Telehealth for Pain Management: Efficacy and Consumer Satisfaction." [Abstract]. In: *Telemedicine Journal and e-Health*, 8(2),:224. Dr. Appel made a poster presentation of this paper at the 21st Annual Scientific Meeting of the American Pain Society. March 14 - 17, 2002, Baltimore, MD

Bleiberg, J., Warden, D., Sun, A., Reeves, D. (2002, April). Computerized Neuropsychological Concussion Surveillance Instruments: Using the Reliable Change Index (RCI) As a Basis for Clinical Decision-Making. Accepted for presentation at the 54th American Academy of Neurology Annual Meeting. Denver, Colorado.

Bleiberg, J., Warden, D., Sun, A., Reeves, D. (2002, April). Computerized Neuropsychological Concussion Surveillance Instruments: Using the Reliable Change Index (RCI) As a Basis for Clinical Decision-Making. Presentation at the 54th American Academy of Neurology Annual Meeting. Denver, Colorado.

Bleiberg, J. (2003, January). Neuropsychological Assessment: DoD Methods. Presentation at the International Conference on Closed Head Trauma: Traumatic Brain Injury (TBI) Mechanisms and Design Criteria for Effective Protections Strategies. San Juan, Puerto Rico

Bleiberg, J. (2003, January). Session Chair on Effects of Mild Traumatic Brain Injury (MTBI) on Human Performance: Symptoms and State-of-the-Art Assessment Methods. The International Conference on Closed Head Trauma: Traumatic Brain Injury (TBI) Mechanisms and Design Criteria for Effective Protections Strategies. San Juan, Puerto Rico

Bleiberg, J., Reeves, D.L., Kane, R.L., Cernich, A.N., Roebuck-Spencer, T. M. (2003, August). Neuropsychology as a Public Health Intervention. Symposium accepted for American Psychological Association Meeting, Toronto, Ontario.

Brennan, D., Georgeadis, A., Barker, L. 2002. "Comparison between
face-to- face and remote telerehabilitation with brain injured subjects."
[Abstract]. In: *Telemedicine Journal and e-Health*, 8(2):224.

Brown, L., Brewster, S.A., Ramloll, R., Reidel, B., and Yu, W. 2000. "Browsing Modes for
Exploring Sonified Line Graphs." In *Proceedings of British HCI*, 2. London, UK.

Puskin, D.S., Lauderdale, D.E., & Savard, L. 2002. "Telerehabilitation payment policy:
lessons learned and to be learned." [Abstract]. In: *Telemedicine Journal and e-Health*,
8(2):224.

Rosen, M.J., Palsbo, S.E., Lauderdale, D.E., & Cole, A. 2002. "Medicaid reimbursement
opportunities for rehabilitation services provided at a distance."
[Abstract]. In: *Telemedicine Journal and e-Health*, 8(2):205.

Trepagnier, C. (2002) Atypical Gaze in Autism & Implications for Remote Assessment. To be
presented at American Telemedicine Association, June 2-5, Los Angeles, CA. Abstract to appear
in *Telemedicine Journal and e-Health*.

Warden, D.L., Bleiberg, J., Cameron, K.L., Sun, W., Sparling, M.B., Cernich, A.N., Peck, K.,
Reeves, D.L., Walter, J., Uhorchak, J., Ecklund, J. (2003, April). The Effect of Concussion
History on Cognitive Performance Following Acute Concussion. To be presented at the 55th
American Academy of Neurology Annual Meeting. Honolulu, Hawaii.

Other Invited Presentations, Demonstrations, Theses and Talks without Proceedings:

Georgeadis, A., Brennan, D. 2002. "Telerehabilitation for Remote Speech-Language
Treatment." Presentation at the *National Aphasia Association - Speaking Out! 2002*,
Washington, DC. June.

Rosen, M.J. "Applications of Distance Rehabilitation Technologies in Service Delivery
to Aging Americans" & Lauderdale, D.E., "Demand for and Barriers to Rapid
Implementation of Distance Health Care Services" 2002. In a concurrent session,
Emerging Role of Telemedicine in Home Healthcare for the Elderly, RESNA 25th
International Conference on Technology & Disability: Research, Design, and Practice,
Los Angeles, CA, June.

Rosen, M.J., & Lauderdale, D.E. 2002. "The Role of Assistive Technology and
Telerehabilitation in Community Living," a workshop offered as part of *Fulfilling the
Promise of Community Living, Second Annual Systems Change Conference*. Center for
Medicare and Medicaid Services, Baltimore, MD, March.

Rosen, M., Savard, L., Tran, B., & Trepagnier, C. 2002. Pre-Conference Invited Course on "Tools and Techniques for Telerehabilitation in 2002," *California State University at Northridge Conference on Technology and Persons with Disabilities*. March.

Trepagnier, C., Lathan, C., Sebrechts, M.M., Ramloll, R., Vice, M., Pettersen, M., & Rosen, M., Design and Evaluation of a Virtual Environment for Teaching Nonverbal Communication. (2003). Refereed platform presentation at CyberTherapy, San Diego, CA, January 20.

Woodard, J., Marker, C., Tabanico, F., Miller, S., Dorsett, E., Cox, L., Gould, F., and Bleiberg, J. (2002, February). A Validation Study of the Automated Neuropsychological Assessment Metrics (ANAM) in Non-Concussed High School Football Players. Poster presented at the International Neuropsychological Society Annual Meeting. Toronto, Canada.

Proposals Submitted and Awarded Based on ATRC Accomplishments

Dr. Bleiberg participated in the preparation of supplementary funding requests to insert ANAM into existing studies, with funding successfully achieved for: development of ANAM to be used in an operational environment (DoD SBIR); development of data consolidation and extraction software to be used in conjunction with ANAM (DoD SBIR); use of ANAM as cognitive marker for correlation with biological markers in Lupus (NIH/NIAMS & Albert Einstein College of Medicine); use of ANAM to track elderly retired athletes at risk for neurodegenerative disease (University of North Carolina, Chapel Hill); and use of ANAM to monitor cognition in individuals with acute stress and PTSD following motor vehicle accidents (USUHS).

Doctoral Dissertation

Stephanie Johnson has completed and presented her doctoral dissertation, <u>Global vs. local perceptual bias in autism</u> under the supervision of M. M. Sebrechts, Ph.D., with C. Trepagnier as a committee member. *Abstract:* Ms. Johnson found confirmation of expected impairments in configurational face processing and expected advantage in the Embedded Figures test. This profile did not translate into the predicted local-over-global advantage, however. Her results are consistent with the hypothesis of a developmental impairment related to failure to acquire configurational face processing in the early months of life. They are not fully consistent with the "Weak central coherence" model of autism, which predicts an advantage for local over global processing.

Proposals Submitted and Awarded Based on ATRC Accomplishments

NSF Small Grant for Exploratory Research (SGER), C. Trepagnier and C. Lathan *"Development of an interactive virtual environment for delivery of rehabilitative intervention to children with social cognitive deficits."* No cost extension into 2003.

Conclusions

PLEASE NOTE:

All conclusions have been incorporated into each project's narratives in the previous sections.